Dossier zur Nutzenbewertung gemäß § 35a SGB V

Sacituzumab govitecan (Trodelvy®)

Gilead Sciences GmbH

Anhang 4-G

Monotherapie zur Behandlung von erwachsenen Patienten mit nicht resezierbarem, lokal fortgeschrittenem oder metastasiertem triple-negativem Mammakarzinom (TNBC), die zuvor keine systemische Therapie zur Behandlung der metastasierten Erkrankung erhalten haben und für eine PD-1- oder eine PD-L1-Inhibitor-Therapie nicht geeignet sind

Analysen für das Nutzendossier

Stand: 20.07.2026

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   Datenschnitt: 22. April 2026

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   - Inhaltsverzeichnis: Patientenberichtete Endpunkte

   Datenschnitt: 27. Oktober 2025

   - Inhaltsverzeichnis: Baseline-Charakteristika, Wirksamkeits- und Sicherheitsendpunkte
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Hinweis: **Das Dokument ist vollständig über die Lesezeichen und die darin verknüpften Inhaltsverzeichnisse navigierbar.**

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2. TFLs

Population: Triple-negative breast cancer (mTNBC)

Sub-Populations:
— Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin
Data Cut Date: 22 APR 2026
Report Date: 11 June 2026

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4. Disposition And Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

4.1. Table 1.1.1: Participant Disposition — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Screened			97
mITT	52	45	97
Randomized but not Treated	1	1	2
Safety Analysis Set	51	44	95
Study Treatment Completion Status (Randomized Phase)			

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Continuing Study Treatment	7 (13.5%)	0	7 (7.2%)
Discontinued Study Treatment	45 (86.5%)	45 (100.0%)	90 (92.8%)
Adverse Event	4 (7.7%)	6 (13.3%)	10 (10.3%)
Pregnancy	0	0	0
Investigator's Discretion	2 (3.8%)	1 (2.2%)	3 (3.1%)
Non-Compliance with Study Drug	0	0	0
Subject Decision	3 (5.8%)	3 (6.7%)	6 (6.2%)
Study Terminated by Sponsor	0	0	0
Progressive Disease	35 (67.3%)	34 (75.6%)	69 (71.1%)
Lost to Follow-Up	0	0	0
Death	1 (1.9%)	1 (2.2%)	2 (2.1%)
Received Study Treatment in Crossover Phase		23 (51.1%)	
Study Completion Status			
Continuing Study	24 (46.2%)	9 (20.0%)	33 (34.0%)
Discontinued Study	28 (53.8%)	36 (80.0%)	64 (66.0%)
Death	24 (46.2%)	36 (80.0%)	60 (61.9%)
Withdrew Consent	4 (7.7%)	0	4 (4.1%)
Lost to Follow-Up	0	0	0
Study Terminated by Sponsor	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Screened Population: Participants who have signed an informed consent and participated in the screening procedures at site to assess eligibility.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug.
Denominator of percentages is the number of participants in each treatment group.
Randomized Phase excludes crossover phase when participants in TPC arm started to receive SG.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table1.Disposition of participants.R

4.2. Table 1.1.2: Demographic and Baseline Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Age (years)			
N	52	45	97
Mean (Sd)	60.1 (12.4)	54.9 (12.6)	57.7 (12.7)
Median	59.0	55.0	58.0
Q1, Q3	52.0, 71.0	45.0, 63.0	49.0, 66.0
Min, Max	29.0, 84.0	32.0, 86.0	29.0, 86.0
Age Group			
< 65	35 (67.3%)	35 (77.8%)	70 (72.2%)
>= 65	17 (32.7%)	10 (22.2%)	27 (27.8%)
Sex at Birth			
F	52 (100.0%)	45 (100.0%)	97 (100.0%)
Race			
ASIAN	12 (23.1%)	12 (26.7%)	24 (24.7%)
BLACK OR AFRICAN AMERICAN	1 (1.9%)	1 (2.2%)	2 (2.1%)
NOT REPORTED	3 (5.8%)	3 (6.7%)	6 (6.2%)
OTHER	2 (3.8%)	1 (2.2%)	3 (3.1%)
WHITE	34 (65.4%)	27 (60.0%)	61 (62.9%)
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (2.2%)	1 (1.0%)
Ethnicity			
HISPANIC OR LATINO	9 (17.3%)	7 (15.6%)	16 (16.5%)
NOT HISPANIC OR LATINO	41 (78.8%)	36 (80.0%)	77 (79.4%)
NOT REPORTED	2 (3.8%)	2 (4.4%)	4 (4.1%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Region			
Rest of the World	26 (50.0%)	28 (62.2%)	54 (55.7%)
US/Canada/Western Europe	26 (50.0%)	17 (37.8%)	43 (44.3%)
Country			
Argentina	2 (3.8%)	2 (4.4%)	4 (4.1%)
Belgium	1 (1.9%)	0	1 (1.0%)
Brazil	1 (1.9%)	1 (2.2%)	2 (2.1%)
Canada	2 (3.8%)	0	2 (2.1%)
Chile	3 (5.8%)	1 (2.2%)	4 (4.1%)
Czech Republic	2 (3.8%)	0	2 (2.1%)
France	7 (13.5%)	5 (11.1%)	12 (12.4%)
Germany	4 (7.7%)	2 (4.4%)	6 (6.2%)
Hungary	1 (1.9%)	2 (4.4%)	3 (3.1%)
Israel	2 (3.8%)	4 (8.9%)	6 (6.2%)
Italy	2 (3.8%)	2 (4.4%)	4 (4.1%)
Japan	10 (19.2%)	8 (17.8%)	18 (18.6%)
Korea, Republic of	2 (3.8%)	3 (6.7%)	5 (5.2%)
Mexico	2 (3.8%)	2 (4.4%)	4 (4.1%)
Netherlands	2 (3.8%)	1 (2.2%)	3 (3.1%)
Spain	4 (7.7%)	3 (6.7%)	7 (7.2%)
Turkey	1 (1.9%)	4 (8.9%)	5 (5.2%)
United States	4 (7.7%)	1 (2.2%)	5 (5.2%)
Austria	0	2 (4.4%)	2 (2.1%)
Malaysia	0	1 (1.0%)	1 (1.0%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
United Kingdom	0	1 (2.2%)	1 (1.0%)
Weight (kg)			
N	52	45	97
Mean (Sd)	70.1 (16.4)	63.5 (11.3)	67.0 (14.6)
Median	70.5	61.0	65.0
Q1, Q3	58.0, 79.0	55.2, 71.0	57.0, 78.0
Min, Max	46.4, 130.0	42.0, 88.0	42.0, 130.0
Height (cm)			
N	52	45	97
Mean (Sd)	161.4 (7.2)	161.3 (6.3)	161.4 (6.8)
Median	161.0	162.0	161.9
Q1, Q3	158.0, 165.0	156.0, 166.0	157.0, 165.3
Min, Max	140.0, 180.0	149.4, 172.0	140.0, 180.0
BMI (kg/m2)			
N	52	45	97
Mean (Sd)	26.9 (6.3)	24.4 (4.2)	25.8 (5.5)
Median	26.0	23.6	24.3
Q1, Q3	22.7, 30.9	21.7, 27.1	22.3, 29.3
Min, Max	17.7, 50.8	16.8, 36.2	16.8, 50.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Age (in years) was collected on the date of first study drug administration (Day 1) if dosed, or randomization if not dosed.
Not Permitted = local regulators did not allow collection of race or ethnicity information or participant refused to provide information.
*Body Mass Index (BMI) (kg/m^2) = [Weight (kg) / Height (cm)^2]*10,000*
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table2.Demographic and Baseline Characteristics.R

4.3. Table 1.1.3: Other Baseline Disease Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Baseline ECOG Score			
0	35 (67.3%)	26 (57.8%)	61 (62.9%)
1	17 (32.7%)	19 (42.2%)	36 (37.1%)
UGT1A1 Genotype			
*1/*1	25 (48.1%)	23 (51.1%)	48 (49.5%)
*1/*28	19 (36.5%)	16 (35.6%)	35 (36.1%)
*1/*6	3 (5.8%)	0 (0.0%)	3 (3.1%)
*28/*28	3 (5.8%)	4 (8.9%)	7 (7.2%)
*6/*6	1 (1.9%)	1 (2.2%)	2 (2.1%)
Missing/Not Done	1 (1.9%)	0 (0.0%)	1 (1.0%)
*6/*28	0 (0.0%)	1 (2.2%)	1 (1.0%)
Menopausal Status (Females Only)			
Post-menopausal	44 (84.6%)	31 (68.9%)	75 (77.3%)
Pre-menopausal	8 (15.4%)	14 (31.1%)	22 (22.7%)
BRCA1 Mutation Status			
Mutant	3 (5.8%)	2 (4.4%)	5 (5.2%)
Unknown	25 (48.1%)	24 (53.3%)	49 (50.5%)
Wild Type	24 (46.2%)	19 (42.2%)	43 (44.3%)
BRCA2 Mutation Status			
Mutant	1 (1.9%)	1 (2.2%)	2 (2.1%)
Unknown	25 (48.1%)	24 (53.3%)	49 (50.5%)
Wild Type	26 (50.0%)	20 (44.4%)	46 (47.4%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
BRCA1/2 Mutation Status			
Mutant	3 (5.8%)	3 (6.7%)	6 (6.2%)
Unknown	25 (48.1%)	23 (51.1%)	48 (49.5%)
Wild Type	24 (46.2%)	19 (42.2%)	43 (44.3%)
PD-L1 CPS			
1 to <10	28 (53.8%)	38 (84.4%)	66 (68.0%)
<1	23 (44.2%)	7 (15.6%)	30 (30.9%)
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Estrogen Receptor Status			
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Negative (< 1%)	51 (98.1%)	45 (100.0%)	96 (99.0%)
Progesterone Receptor Status			
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Negative (< 1%)	51 (98.1%)	45 (100.0%)	96 (99.0%)
HER2 Status			
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Negative	51 (98.1%)	45 (100.0%)	96 (99.0%)
Disease Stratification			
De novo	26 (50.0%)	23 (51.1%)	49 (50.5%)
Recurrent disease occurring > 12 months	23 (44.2%)	19 (42.2%)	42 (43.3%)
Recurrent disease within 6 to 12 months	3 (5.8%)	3 (6.7%)	6 (6.2%)
Pre-selected TPC Prior to Randomization			
Taxane	52 (100.0%)	45 (100.0%)	97 (100.0%)
Breast Cancer Stage at Initial Diagnosis			

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
STAGE 1	9 (17.3%)	4 (8.9%)	13 (13.4%)
STAGE 2	11 (21.2%)	13 (28.9%)	24 (24.7%)
STAGE 3	9 (17.3%)	5 (11.1%)	14 (14.4%)
STAGE 4	23 (44.2%)	23 (51.1%)	46 (47.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subtype of Cancer at Initial Diagnosis			
HR+/HER2+	2 (3.8%)	0 (0.0%)	2 (2.1%)
HR+/HER2-	5 (9.6%)	8 (17.8%)	13 (13.4%)
HR-/HER2+	1 (1.9%)	0 (0.0%)	1 (1.0%)
HR-/HER2- (TNBC)	43 (82.7%)	36 (80.0%)	79 (81.4%)
Missing	1 (1.9%)	1 (2.2%)	2 (2.1%)
Disease Status at Screening			
Locally advanced and Inoperable	1 (1.9%)		1 (1.0%)
Metastatic	51 (98.1%)	45 (100.0%)	96 (99.0%)
Site of Metastasis at Screening			
Bone	17 (32.7%)	19 (42.2%)	36 (37.1%)
Brain	2 (3.8%)	2 (4.4%)	4 (4.1%)
Liver	11 (21.2%)	13 (28.9%)	24 (24.7%)
Lung	28 (53.8%)	22 (48.9%)	50 (51.5%)
Lymph Node	33 (63.5%)	30 (66.7%)	63 (64.9%)
Other	15 (28.8%)	15 (33.3%)	30 (30.9%)
Time from Locally Advanced and Inoperable or Metastatic Disease to Randomization (months) [a]			
N	52	45	97
Mean (StD)	2.1 (1.40)	2.5 (2.20)	2.3 (1.81)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Median	1.7	2.0	1.9
Q1, Q3	1.2, 2.5	1.4, 2.8	1.3, 2.8
Min, Max	0.6, 8.3	0.8, 13.2	0.6, 13.2

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages for other baseline characteristics is the number of participants in each treatment group.
[a] Mutant denotes participant is either BRCA1 or BRCA2 mutant, or both mutant. Wild type denotes participant is both BRCA1 and BRCA2 wild type. Unknown denotes participant is BRCA1 unknown and BRCA2 wild type or unknown, or participant is BRCA1 wild type or unknown and BRCA2 unknown.
PD-L1 CPS (combined positive score) and TNBC status were collected centrally.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table3.Other Baseline Disease Characteristics.R

4.4. Table 1.1.4: Medical History by System Organ Class and Preferred Term — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Number (%) of Participants with Any Medical History	47 (90.4%)	39 (86.7%)	86 (88.7%)
Blood and lymphatic system disorders	3 (5.8%)	4 (8.9%)	7 (7.2%)
Anaemia	2 (3.8%)	4 (8.9%)	6 (6.2%)
Lymphadenopathy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Thrombocytopenia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Cardiac disorders	3 (5.8%)	4 (8.9%)	7 (7.2%)
Sinus tachycardia	1 (1.9%)	1 (2.2%)	2 (6.2%)
Arrhythmia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Atrial fibrillation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cardiac failure chronic	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cardiac failure congestive	1 (1.9%)	0 (0.0%)	1 (6.2%)
Carditis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Myocardial infarction	0 (0.0%)	1 (2.2%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Congenital, familial and genetic disorders	2 (3.8%)	4 (8.9%)	6 (7.2%)
Adenomatous polyposis coli	0 (0.0%)	1 (2.2%)	1 (6.2%)
Congenital neuropathy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Developmental hip dysplasia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Factor V Leiden mutation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Renal fusion anomaly	1 (1.9%)	0 (0.0%)	1 (6.2%)
Thalassaemia sickle cell	0 (0.0%)	1 (2.2%)	1 (6.2%)
Ear and labyrinth disorders	5 (9.6%)	0 (0.0%)	5 (7.2%)
Vertigo	2 (3.8%)	0 (0.0%)	2 (6.2%)
Cholesteatoma	1 (1.9%)	0 (0.0%)	1 (6.2%)
Deafness	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hypoacusis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Vertigo positional	1 (1.9%)	0 (0.0%)	1 (6.2%)
Endocrine disorders	10 (19.2%)	7 (15.6%)	17 (7.2%)
Hypothyroidism	6 (11.5%)	5 (11.1%)	11 (6.2%)
Hyperparathyroidism	1 (1.9%)	1 (2.2%)	2 (6.2%)
Thyroid disorder	2 (3.8%)	0 (0.0%)	2 (6.2%)
Autoimmune thyroiditis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hyperthyroidism	0 (0.0%)	1 (2.2%)	1 (6.2%)
Eye disorders	5 (9.6%)	5 (11.1%)	10 (7.2%)
Cataract	2 (3.8%)	3 (6.7%)	5 (6.2%)
Dry eye	2 (3.8%)	3 (6.7%)	5 (6.2%)
Glaucoma	1 (1.9%)	0 (0.0%)	1 (6.2%)
Myopia	0 (0.0%)	1 (2.2%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Retinal haemorrhage	1 (1.9%)	0 (0.0%)	1 (6.2%)
Strabismus	0 (0.0%)	1 (2.2%)	1 (6.2%)
Gastrointestinal disorders	12 (23.1%)	7 (15.6%)	19 (7.2%)
Gastrooesophageal reflux disease	5 (9.6%)	1 (2.2%)	6 (6.2%)
Constipation	3 (5.8%)	2 (4.4%)	5 (6.2%)
Nausea	0 (0.0%)	2 (4.4%)	2 (6.2%)
Abdominal distension	1 (1.9%)	0 (0.0%)	1 (6.2%)
Anal incontinence	1 (1.9%)	0 (0.0%)	1 (6.2%)
Anal sphincter atony	1 (1.9%)	0 (0.0%)	1 (6.2%)
Coeliac disease	0 (0.0%)	1 (2.2%)	1 (6.2%)
Colitis ulcerative	0 (0.0%)	1 (2.2%)	1 (6.2%)
Crohn's disease	0 (0.0%)	1 (2.2%)	1 (6.2%)
Dyspepsia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Gastric ulcer	1 (1.9%)	0 (0.0%)	1 (6.2%)
Gastrointestinal pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Haemorrhoids	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hiatus hernia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Large intestine polyp	1 (1.9%)	0 (0.0%)	1 (6.2%)
Mucosal prolapse syndrome	1 (1.9%)	0 (0.0%)	1 (6.2%)
Obstructive pancreatitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Oral pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Periodontal disease	1 (1.9%)	0 (0.0%)	1 (6.2%)
Stomatitis	1 (1.9%)	0 (0.0%)	1 (6.2%)
General disorders and administration site conditions	3 (5.8%)	5 (11.1%)	8 (7.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Fatigue	2 (3.8%)	3 (6.7%)	5 (6.2%)
Asthenia	0 (0.0%)	2 (4.4%)	2 (6.2%)
Oedema peripheral	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hepatobiliary disorders	4 (7.7%)	2 (4.4%)	6 (7.2%)
Cholelithiasis	1 (1.9%)	1 (2.2%)	2 (6.2%)
Biliary fistula	1 (1.9%)	0 (0.0%)	1 (6.2%)
Cholangitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cholecystitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hepatic function abnormal	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hypertransaminasaemia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Liver disorder	1 (1.9%)	0 (0.0%)	1 (6.2%)
Metabolic dysfunction-associated steatohepatitis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Immune system disorders	7 (13.5%)	3 (6.7%)	10 (7.2%)
Seasonal allergy	6 (11.5%)	0 (0.0%)	6 (6.2%)
Drug hypersensitivity	2 (3.8%)	3 (6.7%)	5 (6.2%)
Iodine allergy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rubber sensitivity	0 (0.0%)	1 (2.2%)	1 (6.2%)
Infections and infestations	8 (15.4%)	6 (13.3%)	14 (7.2%)
Appendicitis	3 (5.8%)	0 (0.0%)	3 (6.2%)
Herpes zoster	2 (3.8%)	1 (2.2%)	3 (6.2%)
Pneumonia	1 (1.9%)	2 (4.4%)	3 (6.2%)
Breast abscess	0 (0.0%)	1 (2.2%)	1 (6.2%)
Helicobacter infection	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hepatitis viral	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Lung abscess	1 (1.9%)	0 (0.0%)	1 (6.2%)
Peritonitis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rhinitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Viral pericarditis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Injury, poisoning and procedural complications	4 (7.7%)	0 (0.0%)	4 (7.2%)
Contusion	1 (1.9%)	0 (0.0%)	1 (6.2%)
Femur fracture	1 (1.9%)	0 (0.0%)	1 (6.2%)
Neck injury	1 (1.9%)	0 (0.0%)	1 (6.2%)
Radiation skin injury	1 (1.9%)	0 (0.0%)	1 (6.2%)
Investigations	10 (19.2%)	3 (6.7%)	13 (7.2%)
Aspartate aminotransferase increased	5 (9.6%)	0 (0.0%)	5 (6.2%)
Blood alkaline phosphatase increased	4 (7.7%)	0 (0.0%)	4 (6.2%)
Hepatic enzyme increased	2 (3.8%)	0 (0.0%)	2 (6.2%)
Alanine aminotransferase increased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Alpha 1 foetoprotein abnormal	1 (1.9%)	0 (0.0%)	1 (6.2%)
Biopsy skin	0 (0.0%)	1 (2.2%)	1 (6.2%)
Blood albumin decreased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Blood bilirubin increased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Blood glucose increased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Blood triglycerides increased	0 (0.0%)	1 (2.2%)	1 (6.2%)
Electrocardiogram QT shortened	0 (0.0%)	1 (2.2%)	1 (6.2%)
Liver function test abnormal	1 (1.9%)	0 (0.0%)	1 (6.2%)
Metabolism and nutrition disorders	15 (28.8%)	8 (17.8%)	23 (7.2%)
Dyslipidaemia	3 (5.8%)	2 (4.4%)	5 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Diabetes mellitus	2 (3.8%)	2 (4.4%)	4 (6.2%)
Type 2 diabetes mellitus	2 (3.8%)	2 (4.4%)	4 (6.2%)
Glucose tolerance impaired	2 (3.8%)	1 (2.2%)	3 (6.2%)
Hypercholesterolaemia	3 (5.8%)	0 (0.0%)	3 (6.2%)
Hypoalbuminaemia	1 (1.9%)	1 (2.2%)	2 (6.2%)
Vitamin D deficiency	1 (1.9%)	1 (2.2%)	2 (6.2%)
Decreased appetite	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hypercalcaemia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hyperlipidaemia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hyperuricaemia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hypomagnesaemia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Lactose intolerance	1 (1.9%)	0 (0.0%)	1 (6.2%)
Sarcopenic obesity	1 (1.9%)	0 (0.0%)	1 (6.2%)
Musculoskeletal and connective tissue disorders	19 (36.5%)	10 (22.2%)	29 (7.2%)
Arthralgia	6 (11.5%)	2 (4.4%)	8 (6.2%)
Back pain	5 (9.6%)	2 (4.4%)	7 (6.2%)
Bone pain	2 (3.8%)	2 (4.4%)	4 (6.2%)
Osteoarthritis	2 (3.8%)	2 (4.4%)	4 (6.2%)
Intervertebral disc protrusion	3 (5.8%)	0 (0.0%)	3 (6.2%)
Osteoporosis	1 (1.9%)	2 (4.4%)	3 (6.2%)
Arthritis	1 (1.9%)	1 (2.2%)	2 (6.2%)
Fibromyalgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Groin pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Jaw cyst	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Muscular weakness	1 (1.9%)	0 (0.0%)	1 (6.2%)
Musculoskeletal pain	0 (0.0%)	1 (2.2%)	1 (6.2%)
Myalgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Neck pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Osteopenia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pain in extremity	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rheumatoid arthritis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Scoliosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Vertebral foraminal stenosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (9.6%)	12 (26.7%)	17 (7.2%)
Cancer pain	1 (1.9%)	4 (8.9%)	5 (6.2%)
Tumour pain	2 (3.8%)	2 (4.4%)	4 (6.2%)
Uterine leiomyoma	0 (0.0%)	3 (6.7%)	3 (6.2%)
Basal cell carcinoma	1 (1.9%)	1 (2.2%)	2 (6.2%)
Breast cancer	0 (0.0%)	2 (4.4%)	2 (6.2%)
Colorectal adenoma	0 (0.0%)	1 (2.2%)	1 (6.2%)
Follicular lymphoma	0 (0.0%)	1 (2.2%)	1 (6.2%)
Metastases to bone	0 (0.0%)	1 (2.2%)	1 (6.2%)
Prolactin-producing pituitary tumour	1 (1.9%)	0 (0.0%)	1 (6.2%)
Nervous system disorders	10 (19.2%)	4 (8.9%)	14 (7.2%)
Headache	3 (5.8%)	3 (6.7%)	6 (6.2%)
Migraine	2 (3.8%)	0 (0.0%)	2 (6.2%)
Neuropathy peripheral	2 (3.8%)	0 (0.0%)	2 (6.2%)
Presyncope	2 (3.8%)	0 (0.0%)	2 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Carotid arteriosclerosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Epilepsy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Essential tremor	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hydromyelia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Intercostal neuralgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Peripheral sensory neuropathy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Syncope	1 (1.9%)	0 (0.0%)	1 (6.2%)
Trigeminal neuralgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Psychiatric disorders	10 (19.2%)	10 (22.2%)	20 (7.2%)
Insomnia	6 (11.5%)	4 (8.9%)	10 (6.2%)
Anxiety	2 (3.8%)	5 (11.1%)	7 (6.2%)
Depression	4 (7.7%)	1 (2.2%)	5 (6.2%)
Bipolar disorder	0 (0.0%)	1 (2.2%)	1 (6.2%)
Claustrophobia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Nightmare	1 (1.9%)	0 (0.0%)	1 (6.2%)
Post-traumatic stress disorder	1 (1.9%)	0 (0.0%)	1 (6.2%)
Schizophrenia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Renal and urinary disorders	5 (9.6%)	0 (0.0%)	5 (7.2%)
Nephrolithiasis	2 (3.8%)	0 (0.0%)	2 (6.2%)
Urinary incontinence	2 (3.8%)	0 (0.0%)	2 (6.2%)
Chronic kidney disease	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pollakiuria	1 (1.9%)	0 (0.0%)	1 (6.2%)
Proteinuria	1 (1.9%)	0 (0.0%)	1 (6.2%)
Reproductive system and breast disorders	7 (13.5%)	3 (6.7%)	10 (7.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Breast pain	3 (5.8%)	2 (4.4%)	5 (6.2%)
Ovarian cyst	2 (3.8%)	1 (2.2%)	3 (6.2%)
Menopausal symptoms	2 (3.8%)	0 (0.0%)	2 (6.2%)
Rectocele	1 (1.9%)	0 (0.0%)	1 (6.2%)
Uterovaginal prolapse	1 (1.9%)	0 (0.0%)	1 (6.2%)
Respiratory, thoracic and mediastinal disorders	9 (17.3%)	10 (22.2%)	19 (7.2%)
Cough	3 (5.8%)	4 (8.9%)	7 (6.2%)
Asthma	1 (1.9%)	3 (6.7%)	4 (6.2%)
Rhinitis allergic	2 (3.8%)	2 (4.4%)	4 (6.2%)
Chronic obstructive pulmonary disease	1 (1.9%)	0 (0.0%)	1 (6.2%)
Dysphonia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Dyspnoea	0 (0.0%)	1 (2.2%)	1 (6.2%)
Productive cough	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pulmonary artery thrombosis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Pulmonary toxicity	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pulmonary venous thrombosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Sinus congestion	0 (0.0%)	1 (2.2%)	1 (6.2%)
Tracheal mass	1 (1.9%)	0 (0.0%)	1 (6.2%)
Skin and subcutaneous tissue disorders	8 (15.4%)	2 (4.4%)	10 (7.2%)
Dermatitis contact	2 (3.8%)	0 (0.0%)	2 (6.2%)
Actinic keratosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Alopecia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Erythema	1 (1.9%)	0 (0.0%)	1 (6.2%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.0%)	1 (2.2%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Pruritus	1 (1.9%)	0 (0.0%)	1 (6.2%)
Psoriasis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rash	0 (0.0%)	1 (2.2%)	1 (6.2%)
Skin mass	1 (1.9%)	0 (0.0%)	1 (6.2%)
Social circumstances	3 (5.8%)	0 (0.0%)	3 (7.2%)
Ex-tobacco user	1 (1.9%)	0 (0.0%)	1 (6.2%)
Joint prosthesis user	1 (1.9%)	0 (0.0%)	1 (6.2%)
Menopause	1 (1.9%)	0 (0.0%)	1 (6.2%)
Surgical and medical procedures	13 (25.0%)	11 (24.4%)	24 (7.2%)
Hysterectomy	4 (7.7%)	2 (4.4%)	6 (6.2%)
Cholecystectomy	2 (3.8%)	2 (4.4%)	4 (6.2%)
Cardiac pacemaker insertion	2 (3.8%)	0 (0.0%)	2 (6.2%)
Hip arthroplasty	0 (0.0%)	2 (4.4%)	2 (6.2%)
Knee arthroplasty	2 (3.8%)	0 (0.0%)	2 (6.2%)
Ovarian cystectomy	0 (0.0%)	2 (4.4%)	2 (6.2%)
Salpingo-oophorectomy bilateral	1 (1.9%)	1 (2.2%)	2 (6.2%)
Aortic valve replacement	1 (1.9%)	0 (0.0%)	1 (6.2%)
Appendicectomy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Cartilage operation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cataract operation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Constipation prophylaxis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Corneal transplant	1 (1.9%)	0 (0.0%)	1 (6.2%)
Eye excision	0 (0.0%)	1 (2.2%)	1 (6.2%)
Eye prosthesis insertion	0 (0.0%)	1 (2.2%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Gastrointestinal disorder prophylaxis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Implantable cardiac monitor insertion	1 (1.9%)	0 (0.0%)	1 (6.2%)
Joint arthroplasty	0 (0.0%)	1 (2.2%)	1 (6.2%)
Lymphadenectomy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Oophorectomy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Oophorectomy bilateral	1 (1.9%)	0 (0.0%)	1 (6.2%)
Radical mastectomy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Retinal operation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Spinal operation	1 (1.9%)	0 (0.0%)	1 (6.2%)
Thrombectomy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Thyroidectomy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Vascular disorders	23 (44.2%)	16 (35.6%)	39 (7.2%)
Hypertension	21 (40.4%)	16 (35.6%)	37 (6.2%)
Peripheral venous disease	2 (3.8%)	0 (0.0%)	2 (6.2%)
Deep vein thrombosis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hot flush	0 (0.0%)	1 (2.2%)	1 (6.2%)
Lymphoedema	1 (1.9%)	0 (0.0%)	1 (6.2%)
Orthostatic hypotension	1 (1.9%)	0 (0.0%)	1 (6.2%)
Varicose vein	0 (0.0%)	1 (2.2%)	1 (6.2%)
White coat hypertension	0 (0.0%)	1 (2.2%)	1 (6.2%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Medical history was coded according to MedDRA Version 27.1.
Participants may report >=1 medical history per system organ class or preferred term. At each level of summarization, a participant was counted once if the participant reported 1 or more medical history.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table4.Summary of Medical History.R

4.5. Table 1.1.5: Summary of Prior Systemic Therapy — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Patients with Prior Systemic Therapy	25 (48.1%)	19 (42.2%)	44 (45.4%)
Number of Prior Regimens			
1	17 (32.7%)	12 (26.7%)	29 (29.9%)
2	3 (5.8%)	6 (13.3%)	9 (9.3%)
3	5 (9.6%)	1 (2.2%)	6 (6.2%)
Regimen Setting			
ADJUVANT	20 (38.5%)	15 (33.3%)	35 (36.1%)
NEO-ADJUVANT	5 (9.6%)	4 (8.9%)	9 (9.3%)
Best Response to Prior Therapy			
Complete Remission	4 (7.7%)	4 (8.9%)	8 (8.2%)
Partial Remission	3 (5.8%)	0 (0.0%)	3 (3.1%)
Stable Disease	2 (3.8%)	0 (0.0%)	2 (2.1%)
Progressive Disease	1 (1.9%)	3 (6.7%)	4 (4.1%)
Not Available	11 (21.2%)	6 (13.3%)	17 (17.5%)
Unknown	4 (7.7%)	6 (13.3%)	10 (10.3%)
Progression After Prior Therapy			
Yes	22 (42.3%)	15 (33.3%)	37 (38.1%)
No	3 (5.8%)	4 (8.9%)	7 (7.2%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table5.Summary of Prior Systemic Therapy.R

4.6. Table 1.1.6: Prior Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Participants with Any Prior Anti-Cancer Therapy, n (%)	25 (48.1%)	19 (42.2%)	44 (45.4%)
Prior Neoadjuvant or Adjuvant Anti-cancer Therapy [a]			
Yes	25 (48.1%)	19 (42.2%)	44 (45.4%)
Taxanes	18 (34.6%)	14 (31.1%)	32 (33.0%)
Anthracyclines	18 (34.6%)	13 (28.9%)	31 (32.0%)
Platinum	6 (11.5%)	4 (8.9%)	10 (10.3%)
Anti-PD-1/PD-L1 agents	2 (3.8%)	0	2 (2.1%)
Capecitabine	6 (11.5%)	3 (6.7%)	9 (9.3%)
PARP inhibitors	0	0	0
Other	21 (40.4%)	17 (37.8%)	38 (39.2%)
No	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
[a] Participants can receive multiple categories of prior neoadjuvant or adjuvant anti-cancer therapy.
Participants who received any prior neoadjuvant or adjuvant anti-cancer therapy will be summarized as "Yes".
Participants who received prior anti-cancer therapy but did not receive any prior neoadjuvant/adjuvant anti-cancer therapy will be summarized as "No".
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table6.Prior Anti-Cancer Therapy.R

4.7. Table 1.1.7: Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Participants with Any Subsequent Anti Cancer Therapy, n (%)	31 (59.6%)	33 (73.3%)	64 (66.0%)
Taxanes	17 (32.7%)	4 (8.9%)	21 (21.6%)
DOCETAXEL	1 (1.9%)	1 (2.2%)	2 (2.1%)

Category	SG (N=52)	TPC (N=45)	Total (N=97)
PACLITAXEL	15 (28.8%)	2 (4.4%)	17 (17.5%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	2 (3.8%)	2 (4.4%)	4 (4.1%)
Anthracyclines	7 (13.5%)	9 (20.0%)	16 (16.5%)
DOXORUBICIN	1 (1.9%)	5 (11.1%)	6 (6.2%)
DOXORUBICIN HYDROCHLORIDE	0	1 (2.2%)	1 (1.0%)
EPIRUBICIN	4 (7.7%)	1 (2.2%)	5 (5.2%)
EPIRUBICIN HYDROCHLORIDE	2 (3.8%)	0	2 (2.1%)
LIPOSOMAL DOXORUBICIN	0	1 (2.2%)	1 (1.0%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	0	1 (2.2%)	1 (1.0%)
Platinum	9 (17.3%)	16 (35.6%)	25 (25.8%)
CARBOPLATIN	9 (17.3%)	13 (28.9%)	22 (22.7%)
CISPLATIN	0	3 (6.7%)	3 (3.1%)
Anti-PD-1/PD-L1 agents	3 (5.8%)	4 (8.9%)	7 (7.2%)
ATEZOLIZUMAB	1 (1.9%)	1 (2.2%)	2 (2.1%)
PEMBROLIZUMAB	2 (3.8%)	3 (6.7%)	5 (5.2%)
PARP inhibitors	1 (1.9%)	1 (2.2%)	2 (2.1%)
OLAPARIB	1 (1.9%)	1 (2.2%)	2 (2.1%)
ADC	9 (17.3%)	30 (66.7%)	39 (40.2%)
SACITUZUMAB GOVITECAN	1 (1.9%)	30 (66.7%)	31 (32.0%)
TRASTUZUMAB DERUXTECAN	7 (13.5%)	6 (13.3%)	13 (13.4%)
TRASTUZUMAB DERUXTECAN NXKI	1 (1.9%)	0	1 (1.0%)
Other	23 (44.2%)	21 (46.7%)	44 (45.4%)
BEVACIZUMAB	2 (3.8%)	0	2 (2.1%)
CAPECITABINE	10 (19.2%)	10 (22.2%)	20 (20.6%)

Category	SG (N=52)	TPC (N=45)	Total (N=97)
CYCLOPHOSPHAMIDE	5 (9.6%)	3 (6.7%)	8 (8.2%)
ERIBULIN	10 (19.2%)	8 (17.8%)	18 (18.6%)
ERIBULIN MESILATE	2 (3.8%)	3 (6.7%)	5 (5.2%)
GEMCITABINE	2 (3.8%)	12 (26.7%)	14 (14.4%)
GEMCITABINE HYDROCHLORIDE	3 (5.8%)	4 (8.9%)	7 (7.2%)
GEN 1047	0	1 (2.2%)	1 (1.0%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	2 (3.8%)	1 (2.2%)	3 (3.1%)
IMC 002	0	1 (2.2%)	1 (1.0%)
INVESTIGATIONAL DRUG	0	2 (4.4%)	2 (2.1%)
METHOTREXATE	0	1 (2.2%)	1 (1.0%)
NIVOLUMAB	0	1 (2.2%)	1 (1.0%)
PERTUZUMAB	1 (1.9%)	0	1 (1.0%)
RUCAPARIB	0	1 (2.2%)	1 (1.0%)
TRASTUZUMAB	1 (1.9%)	0	1 (1.0%)
TUCATINIB	1 (1.9%)	0	1 (1.0%)
VINORELBINE	0	1 (2.2%)	1 (1.0%)
VINORELBINE TARTRATE	1 (1.9%)	0	1 (1.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table10.Subsequent Anti cancer by preferred drug name.R

4.8. Table 1.1.8: First Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Participants with First Subsequent Anti Cancer Therapy, n (%)	31 (59.6%)	33 (73.3%)	64 (66.0%)
Taxanes	14 (26.9%)	1 (2.2%)	15 (15.5%)
DOCETAXEL	1 (1.9%)	0	1 (1.0%)
PACLITAXEL	12 (23.1%)	0	12 (12.4%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	1 (1.9%)	1 (2.2%)	2 (2.1%)
Anthracyclines	2 (3.8%)	1 (2.2%)	3 (3.1%)
EPIRUBICIN	1 (1.9%)	1 (2.2%)	2 (2.1%)
EPIRUBICIN HYDROCHLORIDE	1 (1.9%)	0	1 (1.0%)
Platinum	4 (7.7%)	0	4 (4.1%)
CARBOPLATIN	4 (7.7%)	0	4 (4.1%)
Anti-PD-1/PD-L1 agents	2 (3.8%)	0	2 (2.1%)
ATEZOLIZUMAB	1 (1.9%)	0	1 (1.0%)
PEMBROLIZUMAB	1 (1.9%)	0	1 (1.0%)
PARP inhibitors	1 (1.9%)	0	1 (1.0%)
OLAPARIB	1 (1.9%)	0	1 (1.0%)
ADC	3 (5.8%)	28 (62.2%)	31 (32.0%)
SACITUZUMAB GOVITECAN	1 (1.9%)	28 (62.2%)	29 (29.9%)
TRASTUZUMAB DERUXTECAN	1 (1.9%)	0	1 (1.0%)
TRASTUZUMAB DERUXTECAN NXKI	1 (1.9%)	0	1 (1.0%)
Other	14 (26.9%)	3 (6.7%)	17 (17.5%)
CAPECITABINE	4 (7.7%)	3 (6.7%)	7 (7.2%)
CYCLOPHOSPHAMIDE	2 (3.8%)	0	2 (2.1%)

Category	SG (N=52)	TPC (N=45)	Total (N=97)
ERIBULIN	4 (7.7%)	0	4 (4.1%)
ERIBULIN MESILATE	1 (1.9%)	0	1 (1.0%)
GEMCITABINE HYDROCHLORIDE	1 (1.9%)	0	1 (1.0%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (1.9%)	0	1 (1.0%)
PERTUZUMAB	1 (1.9%)	0	1 (1.0%)
TRASTUZUMAB	1 (1.9%)	0	1 (1.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table11.First Subsequent Anti cancer therapy by Preferred drug name.R

5. Efficacy - mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

5.1. Table 1.1.1: Observation Period (Months) for Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	SG (N=52)	TPC (N=45)	Total (N=97)
Observation Period (months)			
N	52	45	97
Mean (SD)	21.9 (8.8)	18.4 (8.8)	20.3 (8.9)
Median	24.1	18.3	21.8
Q1, Q3	16, 28.1	12.5, 24.7	13.5, 26.9
Min, Max	0.5, 38.6	0.2, 35.1	0.2, 38.6

Statistic	SG (N=52)	TPC (N=45)	Total (N=97)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Observation period is defined as time from randomisation to death date or the last date known alive.
Data Cut Date: 22 APR 2026.

5.2. Table 1.1.2: Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events (Death)	26 (50.0%)	36 (80.0%)
Number (%) of Participants Censored	26 (50.0%)	9 (20.0%)
Ongoing [a]	24 (46.2%)	9 (20.0%)
Discontinued Study	2 (3.8%)	0
Kaplan-Meier Estimate of OS (Months) (95% CI) [b]		
Q1	16.00 (12.06, 20.86)	12.48 (7.69, 14.06)
Median	28.68 (20.86, NR)	18.33 (14.03, 24.38)
Q3	NR (32.95, NR)	28.65 (23.23, NR)
Absolute Difference in Median OS, SG vs TPC (Months)	10.35	
Kaplan-Meier Estimate of OS Rate (95% CI) [b]		
At 12 Months	0.885 (0.761, 0.946)	0.778 (0.626, 0.874)
At 18 Months	0.688 (0.542, 0.796)	0.511 (0.358, 0.645)
At 24 Months	0.585 (0.437, 0.707)	0.371 (0.232, 0.511)
At 30 Months	0.456 (0.292, 0.606)	0.161 (0.063, 0.298)
At 36 Months	0.380 (0.197, 0.562)	NR (NR, NR)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.0034	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.476 (0.284, 0.799)	

Parameter	SG (N=52)	TPC (N=45)
Duration of OS Follow-up (Months) [e]		
N	52	45
Mean (StD)	21.91 (8.812)	18.42 (8.758)
Median	24.15	18.33
Q1, Q3	15.97, 28.14	12.48, 24.74
Min, Max	0.53, 38.64	0.16, 35.09
>=12 Months	45 (86.5%)	35 (77.8%)
>=18 Months	34 (65.4%)	23 (51.1%)
>=24 Months	27 (51.9%)	13 (28.9%)
>=30 Months	9 (17.3%)	4 (8.9%)
>=36 Months	2 (3.8%)	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice; NR = Not Reached; IWRS = Interactive Web Response System.
[a] Ongoing participants are those who have not discontinued participation in the study by the data cutoff date.
[b] OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Based on Kaplan-Meier estimates with 95% CI using the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test, adjusted for randomization stratification factors (IWRS).
[d] Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
[e] Duration of OS follow-up (months) = (date of death or censoring - date of randomization + 1) / 30.4375.
Data Cut Date: 22 APR 2026.

5.3. Table 1.1.3: Subgroup Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Disease stratification [a]			
De novo	26	23	0.3338
Number (%) of Participants with Events (Death)	15 (57.7%)	20 (87.0%)	
Number (%) of Participants Censored	11 (42.3%)	3 (13.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	24.18 (15.87, NR)	17.38 (12.48, 24.74)	
Log-Rank Test p-value (unstratified)	0.2033		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.648 (0.331, 1.271)		
Recurrent disease	26	22	
Number (%) of Participants with Events (Death)	11 (42.3%)	16 (72.7%)	
Number (%) of Participants Censored	15 (57.7%)	6 (27.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	32.95 (20.86, NR)	19.29 (13.50, 26.91)	
Log-Rank Test p-value (unstratified)	0.0158		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.388 (0.175, 0.860)		
Geographic region			
US/Canada/Western Europe	26	17	0.3110
Number (%) of Participants with Events (Death)	17 (65.4%)	13 (76.5%)	
Number (%) of Participants Censored	9 (34.6%)	4 (23.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	24.82 (16.03, 32.95)	15.93 (11.17, 24.74)	
Log-Rank Test p-value (unstratified)	0.1639		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.596 (0.285, 1.245)		
Rest of the world	26	28	
Number (%) of Participants with Events (Death)	9 (34.6%)	23 (82.1%)	
Number (%) of Participants Censored	17 (65.4%)	5 (17.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (20.90, NR)	20.75 (14.03, 25.53)	
Log-Rank Test p-value (unstratified)	0.0059		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.354 (0.163, 0.766)		
Age group			
< 65	35	35	0.2869
Number (%) of Participants with Events (Death)	19 (54.3%)	28 (80.0%)	
Number (%) of Participants Censored	16 (45.7%)	7 (20.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	25.46 (18.40, NR)	19.75 (14.03, 25.53)	
Log-Rank Test p-value (unstratified)	0.0605		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.574 (0.319, 1.032)		
>= 65	17	10	
Number (%) of Participants with Events (Death)	7 (41.2%)	8 (80.0%)	
Number (%) of Participants Censored	10 (58.8%)	2 (20.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	28.68 (12.71, NR)	16.66 (2.17, NR)	
Log-Rank Test p-value (unstratified)	0.0405		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.340 (0.116, 1.001)		
Race [a]			
White	34	27	0.3255
Number (%) of Participants with Events (Death)	19 (55.9%)	22 (81.5%)	
Number (%) of Participants Censored	15 (44.1%)	5 (18.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	25.49 (17.48, NR)	16.23 (12.81, 28.65)	
Log-Rank Test p-value (unstratified)	0.0596		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.557 (0.301, 1.032)		

	SG (N=52)	TPC (N=45)	Interaction
Other	15	15	
Number (%) of Participants with Events (Death)	5 (33.3%)	12 (80.0%)	
Number (%) of Participants Censored	10 (66.7%)	3 (20.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (12.71, NR)	21.78 (10.45, 25.53)	
Log-Rank Test p-value (unstratified)	0.0270		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.323 (0.113, 0.925)		
Baseline ECOG status			
0	35	26	0.5600
Number (%) of Participants with Events (Death)	16 (45.7%)	18 (69.2%)	
Number (%) of Participants Censored	19 (54.3%)	8 (30.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	28.68 (18.76, NR)	21.01 (13.50, 28.75)	
Log-Rank Test p-value (unstratified)	0.0990		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.569 (0.289, 1.120)		
1	17	19	
Number (%) of Participants with Events (Death)	10 (58.8%)	18 (94.7%)	
Number (%) of Participants Censored	7 (41.2%)	1 (5.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	25.46 (12.06, NR)	16.00 (6.11, 24.38)	
Log-Rank Test p-value (unstratified)	0.0226		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.401 (0.178, 0.902)		
History of liver metastasis			
Yes	11	13	0.4863

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Death)	8 (72.7%)	12 (92.3%)	
Number (%) of Participants Censored	3 (27.3%)	1 (7.7%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	23.52 (8.87, NR)	14.03 (3.91, 21.78)	
Log-Rank Test p-value (unstratified)	0.4777		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.718 (0.286, 1.800)		
No	41	32	
Number (%) of Participants with Events (Death)	18 (43.9%)	24 (75.0%)	
Number (%) of Participants Censored	23 (56.1%)	8 (25.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	28.68 (20.86, NR)	20.75 (15.31, 25.53)	
Log-Rank Test p-value (unstratified)	0.0157		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.477 (0.258, 0.881)		
PD-L1 Status			
CPS < 1	23	7	0.6883
Number (%) of Participants with Events (Death)	9 (39.1%)	6 (85.7%)	
Number (%) of Participants Censored	14 (60.9%)	1 (14.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (13.24, NR)	24.74 (11.73, NR)	
Log-Rank Test p-value (unstratified)	0.1287		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.457 (0.162, 1.288)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Death)	16 (57.1%)	30 (78.9%)	
Number (%) of Participants Censored	12 (42.9%)	8 (21.1%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	25.49 (17.54, NR)	17.86 (14.03, 23.23)	
Log-Rank Test p-value (unstratified)	0.0423		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.536 (0.291, 0.987)		
Menopausal status			
Pre-menopausal	8	14	0.7659
Number (%) of Participants with Events (Death)	4 (50.0%)	12 (85.7%)	
Number (%) of Participants Censored	4 (50.0%)	2 (14.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	23.52 (12.22, NR)	20.76 (12.81, 28.75)	
Log-Rank Test p-value (unstratified)	0.4189		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.629 (0.202, 1.956)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Death)	22 (50.0%)	24 (77.4%)	
Number (%) of Participants Censored	22 (50.0%)	7 (22.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	28.68 (18.40, NR)	16.23 (12.48, 25.53)	
Log-Rank Test p-value (unstratified)	0.0135		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.488 (0.273, 0.873)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Median OS from Kaplan-Meier estimate. 95% CI based on log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
Log-rank test is unstratified.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Participants with unknown BRCA 1/2 status were excluded from that subgroup.
Disease stratification and geographic region are collected from IWRS.
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
[a] Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').
Data Cut Date: 22 APR 2026.

5.4. Table 1.1.4: Follow-up Duration (Months) for PFS and Tumor Response by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	SG (N=52)	TPC (N=45)	Total (N=97)
Follow-up duration (months) for Progression-Free Survival by Blinded Independent Central Review (BICR) [a]			
N	52	45	97
Mean (SD)	9.8 (8.3)	5.1 (4.4)	7.6 (7.2)
Median	7.4	4	5.4
Q1, Q3	3.2, 15.3	2.2, 8.1	2.7, 10.8
Min, Max	0, 31.8	0, 18	0, 31.8
Tumor Response by Blinded Independent Central Review (BICR), n (%)			
CR	2 (3.8%)	2 (4.4%)	4 (4.1%)
PR	25 (48.1%)	21 (46.7%)	46 (47.4%)
SD	14 (26.9%)	11 (24.4%)	25 (25.8%)
PD	5 (9.6%)	5 (11.1%)	10 (10.3%)
NE	1 (1.9%)	1 (2.2%)	2 (2.1%)
NON-CR/NON-PD	1 (1.9%)	0 (0.0%)	1 (1.0%)
Missing/NE	4 (7.7%)	5 (11.1%)	9 (9.3%)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; BICR = blinded independent central review; IWRS = Interactive Web Response System; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE = not evaluable; NON-CR/NON-PD = non-complete response/non-progressive disease (applicable to non-measurable disease).
[a] Observation period for PFS is defined as time from randomisation to the event or censoring date of progression-free survival.
Tumour response assessed by BICR per RECIST v1.1; confirmed responses only.
Data Cut Date: 22 APR 2026.

5.5. Table 1.1.5: Analysis of PFS by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events	31 (59.6%)	36 (80.0%)
Disease Progression (PD)	29 (55.8%)	34 (75.6%)
Death	2 (3.8%)	2 (4.4%)
Number (%) of Participants Censored	21 (40.4%)	9 (20.0%)
PD after Starting New Anti-Cancer Therapy	1 (1.9%)	0
PD right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	1 (1.9%)	0
Death after Starting New Anti-Cancer Therapy	3 (5.8%)	4 (8.9%)
Death right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	3 (5.8%)	3 (6.7%)
No PD and No Death without New Anti-Cancer Therapy	6 (11.5%)	0
No PD and No Death with New Anti-Cancer Therapy	6 (11.5%)	0
No Baseline or Postbaseline Evaluable Assessment [a]	1 (1.9%)	2 (4.4%)
Kaplan-Meier Estimate of PFS (Months) (95% CI) [b]		
Q1	4.30 (3.29, 8.15)	2.86 (1.45, 3.98)
Median	12.71 (7.13, 15.34)	5.39 (3.06, 7.29)
Q3	19.32 (15.31, NR)	8.28 (6.93, 12.32)
Absolute Difference in Median PFS, SG vs TPC (Months)	7.33	
Kaplan-Meier Estimate of PFS Rate (95% CI) [c]		
At 3 Months	0.890 (0.756, 0.953)	0.691 (0.519, 0.811)
At 6 Months	0.708 (0.550, 0.819)	0.425 (0.267, 0.574)
At 9 Months	0.582 (0.420, 0.713)	0.187 (0.079, 0.331)
At 12 Months	0.505 (0.345, 0.644)	0.125 (0.041, 0.259)
At 18 Months	0.328 (0.185, 0.478)	0.031 (0.002, 0.136)

Parameter	SG (N=52)	TPC (N=45)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [d]	<0.0001	
Stratified Hazard Ratio of SG vs TPC (95% CI) [e]	0.325 (0.185, 0.570)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
[a] Censoring due to no baseline or no postbaseline evaluable assessment does not include death events before the second scheduled postbaseline visit.
[b] PFS (months) = (date of event or censoring − date of randomisation + 1) / 30.4375. The 95% CI is based on the log-log transformation.
[c] PFS rate is the proportion of participants alive without progressive disease (PD). The 95% CI is based on the log-log transformation.
[d] The two-sided p-value is from stratified log-rank test.
[e] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.6. Table 1.1.6: Analysis of PFS by BICR – Subgroup — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Disease stratification [a]			
De novo	26	23	0.7889
Number (%) of Participants with Events	16 (61.5%)	19 (82.6%)	
Disease Progression (PD)	15 (57.7%)	19 (82.6%)	
Death	1 (3.8%)	0	
Number (%) of Participants Censored	10 (38.5%)	4 (17.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.17, 15.31)	4.21 (2.86, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.375 (0.185, 0.759)		
p-value (Log-Rank Test, Unstratified)	0.0048		
Recurrent disease	26	22	
Number (%) of Participants with Events	15 (57.7%)	17 (77.3%)	
Disease Progression (PD)	14 (53.8%)	15 (68.2%)	

	SG (N=52)	TPC (N=45)	Interaction
Death	1 (3.8%)	2 (9.1%)	
Number (%) of Participants Censored	11 (42.3%)	5 (22.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.21 (7.13, 19.32)	8.28 (2.89, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.287 (0.132, 0.625)		
p-value (Log-Rank Test, Unstratified)	0.0010		
Geographic region			
US/Canada/Western Europe	26	17	0.8066
Number (%) of Participants with Events	14 (53.8%)	12 (70.6%)	
Disease Progression (PD)	13 (50.0%)	12 (70.6%)	
Death	1 (3.8%)	0	
Number (%) of Participants Censored	12 (46.2%)	5 (29.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.27, 15.21)	5.55 (1.77, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.377 (0.167, 0.852)		
p-value (Log-Rank Test, Unstratified)	0.0152		
Rest of the world	26	28	
Number (%) of Participants with Events	17 (65.4%)	24 (85.7%)	
Disease Progression (PD)	16 (61.5%)	22 (78.6%)	
Death	1 (3.8%)	2 (7.1%)	
Number (%) of Participants Censored	9 (34.6%)	4 (14.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.31 (6.93, 18.27)	4.21 (3.06, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.301 (0.149, 0.609)		

	SG (N=52)	TPC (N=45)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0004		
Age group			
< 65	35	35	0.8780
Number (%) of Participants with Events	23 (65.7%)	29 (82.9%)	
Disease Progression (PD)	23 (65.7%)	28 (80.0%)	
Death	0	1 (2.9%)	
Number (%) of Participants Censored	12 (34.3%)	6 (17.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	11.10 (4.53, 15.34)	4.21 (2.89, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.348 (0.191, 0.634)		
p-value (Log-Rank Test, Unstratified)	0.0003		
>= 65	17	10	
Number (%) of Participants with Events	8 (47.1%)	7 (70.0%)	
Disease Progression (PD)	6 (35.3%)	6 (60.0%)	
Death	2 (11.8%)	1 (10.0%)	
Number (%) of Participants Censored	9 (52.9%)	3 (30.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (4.30, NR)	5.39 (1.41, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.337 (0.115, 0.985)		
p-value (Log-Rank Test, Unstratified)	0.0378		
Race [a]			
White	34	27	0.8940
Number (%) of Participants with Events	21 (61.8%)	20 (74.1%)	
Disease Progression (PD)	20 (58.8%)	18 (66.7%)	

	SG (N=52)	TPC (N=45)	Interaction
Death	1 (2.9%)	2 (7.4%)	
Number (%) of Participants Censored	13 (38.2%)	7 (25.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.76 (4.53, 15.34)	5.55 (2.92, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.382 (0.198, 0.739)		
p-value (Log-Rank Test, Unstratified)	0.0030		
Other	15	15	
Number (%) of Participants with Events	9 (60.0%)	13 (86.7%)	
Disease Progression (PD)	8 (53.3%)	13 (86.7%)	
Death	1 (6.7%)	0	
Number (%) of Participants Censored	6 (40.0%)	2 (13.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (2.92, 18.27)	4.04 (2.86, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.317 (0.123, 0.818)		
p-value (Log-Rank Test, Unstratified)	0.0127		
Baseline ECOG status			
0	35	26	0.0108
Number (%) of Participants with Events	16 (45.7%)	22 (84.6%)	
Disease Progression (PD)	15 (42.9%)	22 (84.6%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	19 (54.3%)	4 (15.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.31 (11.10, NR)	5.55 (3.98, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.193 (0.094, 0.394)		

		SG (N=52)	TPC (N=45)	Interaction
	p-value (Log-Rank Test, Unstratified)	<0.0001		
1		17	19	
	Number (%) of Participants with Events	15 (88.2%)	14 (73.7%)	
	Disease Progression (PD)	14 (82.4%)	12 (63.2%)	
	Death	1 (5.9%)	2 (10.5%)	
	Number (%) of Participants Censored	2 (11.8%)	5 (26.3%)	
	Kaplan-Meier Estimate of PFS (Months) (95% CI)			
	Median	4.27 (2.92, 7.13)	3.81 (2.73, 8.80)	
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.826 (0.386, 1.766)		
	p-value (Log-Rank Test, Unstratified)	0.6134		
History of liver metastasis				
Yes		11	13	0.4867
	Number (%) of Participants with Events	9 (81.8%)	11 (84.6%)	
	Disease Progression (PD)	8 (72.7%)	9 (69.2%)	
	Death	1 (9.1%)	2 (15.4%)	
	Number (%) of Participants Censored	2 (18.2%)	2 (15.4%)	
	Kaplan-Meier Estimate of PFS (Months) (95% CI)			
	Median	6.42 (1.51, NR)	2.76 (0.59, 4.21)	
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.243 (0.082, 0.719)		
	p-value (Log-Rank Test, Unstratified)	0.0062		
No		41	32	
	Number (%) of Participants with Events	22 (53.7%)	25 (78.1%)	
	Disease Progression (PD)	21 (51.2%)	25 (78.1%)	
	Death	1 (2.4%)	0	

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants Censored	19 (46.3%)	7 (21.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.21 (7.66, 19.32)	7.29 (4.04, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.336 (0.179, 0.630)		
p-value (Log-Rank Test, Unstratified)	0.0004		
PD-L1 Status			
CPS < 1	23	7	0.3677
Number (%) of Participants with Events	14 (60.9%)	5 (71.4%)	
Disease Progression (PD)	13 (56.5%)	5 (71.4%)	
Death	1 (4.3%)	0	
Number (%) of Participants Censored	9 (39.1%)	2 (28.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.41 (3.98, 18.07)	4.04 (0.59, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.268 (0.086, 0.836)		
p-value (Log-Rank Test, Unstratified)	0.0162		
CPS ≥ 1	28	38	
Number (%) of Participants with Events	17 (60.7%)	31 (81.6%)	
Disease Progression (PD)	16 (57.1%)	29 (76.3%)	
Death	1 (3.6%)	2 (5.3%)	
Number (%) of Participants Censored	11 (39.3%)	7 (18.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.21 (4.53, 18.27)	5.39 (3.06, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.331 (0.172, 0.636)		
p-value (Log-Rank Test, Unstratified)	0.0005		

	SG (N=52)	TPC (N=45)	Interaction
Menopausal status			
Pre-menopausal	8	14	0.9906
Number (%) of Participants with Events	6 (75.0%)	12 (85.7%)	
Disease Progression (PD)	6 (75.0%)	12 (85.7%)	
Death	0	0	
Number (%) of Participants Censored	2 (25.0%)	2 (14.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	11.81 (2.92, NR)	4.88 (1.41, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.254 (0.079, 0.823)		
p-value (Log-Rank Test, Unstratified)	0.0143		
Post-menopausal	44	31	
Number (%) of Participants with Events	25 (56.8%)	24 (77.4%)	
Disease Progression (PD)	23 (52.3%)	22 (71.0%)	
Death	2 (4.5%)	2 (6.5%)	
Number (%) of Participants Censored	19 (43.2%)	7 (22.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (7.13, 18.27)	5.39 (2.89, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.365 (0.201, 0.665)		
p-value (Log-Rank Test, Unstratified)	0.0006		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Intent-to-treat (ITT) Analysis Set includes all participants who were randomised in the study.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS (months) = (date of events or censoring − date of randomisation + 1) / 30.4375. 95% CI based on log-log transformation. Median PFS from Kaplan-Meier estimate.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
[a] Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring

	SG (N=52)	TPC (N=45)	Interaction

> 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').

Data Cut Date: 22 APR 2026.

5.7. Table 1.1.7: Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events	35 (67.3%)	37 (82.2%)
Disease Progression (PD)	18 (34.6%)	23 (51.1%)
Death	17 (32.7%)	14 (31.1%)
Number (%) of Participants Censored	17 (32.7%)	8 (17.8%)
Alive Without PFS2 Event and Without Second Next-Line Therapy	4 (7.7%)	3 (6.7%)
Alive Without PFS2 Event and With Second Next-Line Therapy	1 (1.9%)	3 (6.7%)
Discontinued Study	0	0
No Baseline or Postbaseline Evaluable Assessment	0	0
Kaplan-Meier Estimate of PFS2 (Months) (95% CI) [a]		
Q1	13.14 (6.70, 16.00)	9.53 (7.59, 9.95)
Median	23.49 (15.87, 25.49)	12.48 (9.69, 15.84)
Q3	28.68 (25.46, NR)	20.24 (14.32, 27.93)
Absolute Difference in Median PFS2, SG vs TPC (Months)	11.01	
Kaplan-Meier Estimate of PFS2 Rate (95% CI) [b]		
At 3 Months	0.981 (0.871, 0.997)	0.955 (0.832, 0.989)
At 6 Months	0.885 (0.761, 0.946)	0.910 (0.777, 0.965)
At 9 Months	0.827 (0.694, 0.906)	0.773 (0.619, 0.871)
At 12 Months	0.788 (0.651, 0.877)	0.500 (0.346, 0.636)

Parameter	SG (N=52)	TPC (N=45)
At 18 Months	0.566 (0.419, 0.690)	0.286 (0.160, 0.425)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [c]	0.0008	
Stratified Hazard Ratio of SG vs TPC (95% CI) [d]	0.417 (0.247, 0.705)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first. Next line therapy is defined as the first new systemic anti-cancer therapy (including crossover treatment) initiated after discontinuation of study treatment regardless of end of treatment reason.
[a] Quantile of PFS2 is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.8. Table 1.1.8: Subgroup Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Disease stratification [a]			
De novo	26	23	0.4912
Number (%) of Participants with Events	20 (76.9%)	22 (95.7%)	
Disease Progression (PD)	19 (73.1%)	22 (95.7%)	
Death	1 (3.8%)	0	
Number (%) of Participants Censored	6 (23.1%)	1 (4.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.66 (4.17, 13.63)	4.01 (2.76, 5.55)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.410 (0.216, 0.779)		
p-value (Log-Rank Test, Unstratified)	0.0052		
Recurrent disease	26	22	
Number (%) of Participants with Events	21 (80.8%)	18 (81.8%)	

	SG (N=52)	TPC (N=45)	Interaction
Disease Progression (PD)	20 (76.9%)	16 (72.7%)	
Death	1 (3.8%)	2 (9.1%)	
Number (%) of Participants Censored	5 (19.2%)	4 (18.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	10.15 (4.30, 15.34)	8.15 (2.20, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.391 (0.192, 0.793)		
p-value (Log-Rank Test, Unstratified)	0.0075		
Geographic region			
US/Canada/Western Europe	26	17	0.9620
Number (%) of Participants with Events	21 (80.8%)	14 (82.4%)	
Disease Progression (PD)	20 (76.9%)	14 (82.4%)	
Death	1 (3.8%)	0	
Number (%) of Participants Censored	5 (19.2%)	3 (17.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.66 (4.14, 11.10)	4.16 (1.45, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.470 (0.228, 0.968)		
p-value (Log-Rank Test, Unstratified)	0.0365		
Rest of the world	26	28	
Number (%) of Participants with Events	20 (76.9%)	26 (92.9%)	
Disease Progression (PD)	19 (73.1%)	24 (85.7%)	
Death	1 (3.8%)	2 (7.1%)	
Number (%) of Participants Censored	6 (23.1%)	2 (7.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (5.55, 15.34)	4.21 (2.89, 8.08)	

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.352 (0.183, 0.675)		
p-value (Log-Rank Test, Unstratified)	0.0011		
Age group			
< 65	35	35	0.7306
Number (%) of Participants with Events	31 (88.6%)	32 (91.4%)	
Disease Progression (PD)	31 (88.6%)	31 (88.6%)	
Death	0	1 (2.9%)	
Number (%) of Participants Censored	4 (11.4%)	3 (8.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.23 (4.17, 15.21)	4.21 (2.86, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.418 (0.242, 0.722)		
p-value (Log-Rank Test, Unstratified)	0.0013		
>= 65	17	10	
Number (%) of Participants with Events	10 (58.8%)	8 (80.0%)	
Disease Progression (PD)	8 (47.1%)	7 (70.0%)	
Death	2 (11.8%)	1 (10.0%)	
Number (%) of Participants Censored	7 (41.2%)	2 (20.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.76 (4.17, 20.01)	4.60 (1.41, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.405 (0.153, 1.072)		
p-value (Log-Rank Test, Unstratified)	0.0606		
Race [a]			
White	34	27	0.6127
Number (%) of Participants with Events	27 (79.4%)	23 (85.2%)	

	SG (N=52)	TPC (N=45)	Interaction
Disease Progression (PD)	26 (76.5%)	21 (77.8%)	
Death	1 (2.9%)	2 (7.4%)	
Number (%) of Participants Censored	7 (20.6%)	4 (14.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.66 (4.30, 15.21)	4.80 (2.73, 8.08)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.406 (0.221, 0.745)		
p-value (Log-Rank Test, Unstratified)	0.0026		
Other	15	15	
Number (%) of Participants with Events	12 (80.0%)	14 (93.3%)	
Disease Progression (PD)	11 (73.3%)	14 (93.3%)	
Death	1 (6.7%)	0	
Number (%) of Participants Censored	3 (20.0%)	1 (6.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.07 (2.92, 15.31)	4.01 (2.83, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.446 (0.192, 1.035)		
p-value (Log-Rank Test, Unstratified)	0.0533		
Baseline ECOG status			
0	35	26	0.1361
Number (%) of Participants with Events	25 (71.4%)	22 (84.6%)	
Disease Progression (PD)	24 (68.6%)	22 (84.6%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	10 (28.6%)	4 (15.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	13.63 (7.66, 18.07)	5.55 (3.98, 8.15)	

		SG (N=52)	TPC (N=45)	Interaction
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.312 (0.165, 0.589)		
	p-value (Log-Rank Test, Unstratified)	0.0002		
1		17	19	
	Number (%) of Participants with Events	16 (94.1%)	18 (94.7%)	
	Disease Progression (PD)	15 (88.2%)	16 (84.2%)	
	Death	1 (5.9%)	2 (10.5%)	
	Number (%) of Participants Censored	1 (5.9%)	1 (5.3%)	
	Kaplan-Meier Estimate of PFS (Months) (95% CI)			
	Median	4.22 (1.54, 7.13)	2.97 (1.64, 5.62)	
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.714 (0.353, 1.441)		
	p-value (Log-Rank Test, Unstratified)	0.3390		
History of liver metastasis				
Yes		11	13	0.1581
	Number (%) of Participants with Events	10 (90.9%)	12 (92.3%)	
	Disease Progression (PD)	9 (81.8%)	10 (76.9%)	
	Death	1 (9.1%)	2 (15.4%)	
	Number (%) of Participants Censored	1 (9.1%)	1 (7.7%)	
	Kaplan-Meier Estimate of PFS (Months) (95% CI)			
	Median	6.42 (1.51, 15.31)	2.74 (0.59, 4.21)	
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.228 (0.078, 0.665)		
	p-value (Log-Rank Test, Unstratified)	0.0035		
No		41	32	
	Number (%) of Participants with Events	31 (75.6%)	28 (87.5%)	
	Disease Progression (PD)	30 (73.2%)	28 (87.5%)	

	SG (N=52)	TPC (N=45)	Interaction
Death	1 (2.4%)	0	
Number (%) of Participants Censored	10 (24.4%)	4 (12.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.07 (5.55, 15.21)	6.93 (3.98, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.460 (0.264, 0.799)		
p-value (Log-Rank Test, Unstratified)	0.0048		
PD-L1 Status			
CPS < 1	23	7	0.1071
Number (%) of Participants with Events	15 (65.2%)	6 (85.7%)	
Disease Progression (PD)	14 (60.9%)	6 (85.7%)	
Death	1 (4.3%)	0	
Number (%) of Participants Censored	8 (34.8%)	1 (14.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.41 (3.98, 18.07)	3.47 (0.59, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.231 (0.078, 0.678)		
p-value (Log-Rank Test, Unstratified)	0.0041		
CPS ≥ 1	28	38	
Number (%) of Participants with Events	26 (92.9%)	34 (89.5%)	
Disease Progression (PD)	25 (89.3%)	32 (84.2%)	
Death	1 (3.6%)	2 (5.3%)	
Number (%) of Participants Censored	2 (7.1%)	4 (10.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (4.17, 15.21)	4.21 (2.92, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.484 (0.275, 0.850)		

	SG (N=52)	TPC (N=45)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0098		
Menopausal status			
Pre-menopausal	8	14	0.8417
Number (%) of Participants with Events	8 (100.0%)	13 (92.9%)	
Disease Progression (PD)	8 (100.0%)	13 (92.9%)	
Death	0	0	
Number (%) of Participants Censored	0	1 (7.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.23 (2.92, 15.31)	4.21 (1.41, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.284 (0.097, 0.837)		
p-value (Log-Rank Test, Unstratified)	0.0157		
Post-menopausal	44	31	
Number (%) of Participants with Events	33 (75.0%)	27 (87.1%)	
Disease Progression (PD)	31 (70.5%)	25 (80.6%)	
Death	2 (4.5%)	2 (6.5%)	
Number (%) of Participants Censored	11 (25.0%)	4 (12.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.15 (4.27, 15.21)	4.01 (2.86, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.441 (0.256, 0.762)		
p-value (Log-Rank Test, Unstratified)	0.0026		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from an unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
[a] Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring

	SG (N=52)	TPC (N=45)	Interaction

> 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').

Data Cut Date: 22 APR 2026.

5.9. Table 1.1.9: Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events	40 (76.9%)	43 (95.6%)
First Subsequent Therapy	31 (59.6%)	33 (73.3%)
Death	9 (17.3%)	10 (22.2%)
Number (%) of Participants Censored	12 (23.1%)	2 (4.4%)
Kaplan-Meier Estimate of TFST (Months) (95% CI) [a]		
Q1	7.64 (4.80, 11.66)	4.40 (2.43, 5.75)
Median	15.87 (11.66, 18.96)	7.59 (5.59, 9.53)
Q3	25.07 (18.76, NR)	11.53 (9.46, 15.44)
Absolute Difference in Median TFST, SG vs TPC (Months)	8.28	
Kaplan-Meier Estimate of TFST Rate (95% CI) [b]		
At 3 Months	0.923 (0.808, 0.970)	0.867 (0.727, 0.938)
At 6 Months	0.788 (0.651, 0.877)	0.622 (0.465, 0.746)
At 9 Months	0.712 (0.568, 0.815)	0.422 (0.278, 0.560)
At 12 Months	0.615 (0.470, 0.732)	0.178 (0.083, 0.301)
At 18 Months	0.397 (0.264, 0.527)	0.133 (0.054, 0.249)
At 24 Months	0.258 (0.148, 0.383)	NR (NR, NR)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	<0.0001	

Parameter	SG (N=52)	TPC (N=45)
Hazard Ratio of SG vs TPC (95% CI) [d]	0.349 (0.219, 0.557)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomization to the start date of the first subsequent anti-cancer therapy after discontinuation of randomized treatment, or death due to any cause.
[a] Quantile of TFST is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] TFST rate is the proportion of participants alive without any subsequent therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d]Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.10. Table 1.1.10: Subgroup Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Disease stratification [a]			
De novo	26	23	0.1848
Number (%) of Participants with Events	20 (76.9%)	23 (100.0%)	
First Subsequent Therapy	16 (61.5%)	19 (82.6%)	
Death	4 (15.4%)	4 (17.4%)	
Number (%) of Participants Censored	6 (23.1%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	13.86 (8.15, 18.96)	5.59 (3.94, 7.59)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.275 (0.141, 0.537)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
Recurrent disease	26	22	
Number (%) of Participants with Events	20 (76.9%)	20 (90.9%)	
First Subsequent Therapy	15 (57.7%)	14 (63.6%)	
Death	5 (19.2%)	6 (27.3%)	
Number (%) of Participants Censored	6 (23.1%)	2 (9.1%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.92 (11.60, 20.67)	9.59 (6.77, 11.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.482 (0.253, 0.916)		
p-value (Log-Rank Test, Unstratified)	0.0231		
Geographic region			
US/Canada/Western Europe	26	17	0.1114
Number (%) of Participants with Events	23 (88.5%)	15 (88.2%)	
First Subsequent Therapy	17 (65.4%)	12 (70.6%)	
Death	6 (23.1%)	3 (17.6%)	
Number (%) of Participants Censored	3 (11.5%)	2 (11.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.87 (8.15, 18.76)	7.69 (3.02, 11.66)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.546 (0.277, 1.076)		
p-value (Log-Rank Test, Unstratified)	0.0771		
Rest of the world	26	28	
Number (%) of Participants with Events	17 (65.4%)	28 (100.0%)	
First Subsequent Therapy	14 (53.8%)	21 (75.0%)	
Death	3 (11.5%)	7 (25.0%)	
Number (%) of Participants Censored	9 (34.6%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.79 (11.60, NR)	7.28 (5.13, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.283 (0.149, 0.538)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
Age group			

	SG (N=52)	TPC (N=45)	Interaction
< 65	35	35	0.7242
Number (%) of Participants with Events	29 (82.9%)	34 (97.1%)	
First Subsequent Therapy	26 (74.3%)	27 (77.1%)	
Death	3 (8.6%)	7 (20.0%)	
Number (%) of Participants Censored	6 (17.1%)	1 (2.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.00 (11.66, 18.96)	7.59 (5.75, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.386 (0.229, 0.653)		
p-value (Log-Rank Test, Unstratified)	0.0003		
>= 65	17	10	
Number (%) of Participants with Events	11 (64.7%)	9 (90.0%)	
First Subsequent Therapy	5 (29.4%)	6 (60.0%)	
Death	6 (35.3%)	3 (30.0%)	
Number (%) of Participants Censored	6 (35.3%)	1 (10.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	15.87 (7.13, NR)	7.56 (2.17, 11.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.405 (0.162, 1.010)		
p-value (Log-Rank Test, Unstratified)	0.0455		
Race [a]			
White	34	27	0.7503
Number (%) of Participants with Events	27 (79.4%)	25 (92.6%)	
First Subsequent Therapy	21 (61.8%)	19 (70.4%)	
Death	6 (17.6%)	6 (22.2%)	
Number (%) of Participants Censored	7 (20.6%)	2 (7.4%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.00 (11.47, 19.84)	7.59 (4.47, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.404 (0.229, 0.713)		
p-value (Log-Rank Test, Unstratified)	0.0013		
Other	15	15	
Number (%) of Participants with Events	11 (73.3%)	15 (100.0%)	
First Subsequent Therapy	8 (53.3%)	12 (80.0%)	
Death	3 (20.0%)	3 (20.0%)	
Number (%) of Participants Censored	4 (26.7%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	13.86 (4.86, 18.96)	6.97 (3.52, 9.66)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.382 (0.168, 0.866)		
p-value (Log-Rank Test, Unstratified)	0.0191		
Baseline ECOG status			
0	35	26	0.7187
Number (%) of Participants with Events	25 (71.4%)	24 (92.3%)	
First Subsequent Therapy	17 (48.6%)	20 (76.9%)	
Death	8 (22.9%)	4 (15.4%)	
Number (%) of Participants Censored	10 (28.6%)	2 (7.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	18.96 (15.01, 21.59)	8.26 (5.75, 11.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.353 (0.196, 0.636)		
p-value (Log-Rank Test, Unstratified)	0.0003		
1	17	19	

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events	15 (88.2%)	19 (100.0%)	
First Subsequent Therapy	14 (82.4%)	13 (68.4%)	
Death	1 (5.9%)	6 (31.6%)	
Number (%) of Participants Censored	2 (11.8%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.47 (3.25, 13.86)	6.77 (3.02, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.524 (0.260, 1.056)		
p-value (Log-Rank Test, Unstratified)	0.0667		
Physician's choice of chemotherapy			
Taxane	52	45	NE
Number (%) of Participants with Events	40 (76.9%)	43 (95.6%)	
First Subsequent Therapy	31 (59.6%)	33 (73.3%)	
Death	9 (17.3%)	10 (22.2%)	
Number (%) of Participants Censored	12 (23.1%)	2 (4.4%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	15.87 (11.66, 18.96)	7.59 (5.59, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.387 (0.246, 0.609)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
History of liver metastasis			
Yes	11	13	0.5294
Number (%) of Participants with Events	10 (90.9%)	13 (100.0%)	
First Subsequent Therapy	7 (63.6%)	9 (69.2%)	
Death	3 (27.3%)	4 (30.8%)	
Number (%) of Participants Censored	1 (9.1%)	0	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.03 (4.80, 19.58)	5.13 (2.43, 7.69)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.291 (0.111, 0.764)		
p-value (Log-Rank Test, Unstratified)	0.0085		
No	41	32	
Number (%) of Participants with Events	30 (73.2%)	30 (93.8%)	
First Subsequent Therapy	24 (58.5%)	24 (75.0%)	
Death	6 (14.6%)	6 (18.8%)	
Number (%) of Participants Censored	11 (26.8%)	2 (6.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.79 (12.65, 19.84)	9.49 (5.75, 11.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.410 (0.242, 0.693)		
p-value (Log-Rank Test, Unstratified)	0.0006		
PD-L1 Status			
CPS < 1	23	7	0.3755
Number (%) of Participants with Events	15 (65.2%)	7 (100.0%)	
First Subsequent Therapy	12 (52.2%)	5 (71.4%)	
Death	3 (13.0%)	2 (28.6%)	
Number (%) of Participants Censored	8 (34.8%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	13.86 (11.60, NR)	7.59 (2.43, 11.73)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.236 (0.086, 0.648)		
p-value (Log-Rank Test, Unstratified)	0.0025		
CPS ≥ 1	28	38	

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events	24 (85.7%)	36 (94.7%)	
First Subsequent Therapy	19 (67.9%)	28 (73.7%)	
Death	5 (17.9%)	8 (21.1%)	
Number (%) of Participants Censored	4 (14.3%)	2 (5.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.39 (6.01, 19.84)	7.33 (5.13, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.469 (0.271, 0.813)		
p-value (Log-Rank Test, Unstratified)	0.0060		
Menopausal status			
Pre-menopausal	8	14	0.5011
Number (%) of Participants with Events	7 (87.5%)	13 (92.9%)	
First Subsequent Therapy	7 (87.5%)	11 (78.6%)	
Death	0	2 (14.3%)	
Number (%) of Participants Censored	1 (12.5%)	1 (7.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	12.65 (3.25, 18.96)	6.03 (2.43, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.549 (0.215, 1.399)		
p-value (Log-Rank Test, Unstratified)	0.2028		
Post-menopausal	44	31	
Number (%) of Participants with Events	33 (75.0%)	30 (96.8%)	
First Subsequent Therapy	24 (54.5%)	22 (71.0%)	
Death	9 (20.5%)	8 (25.8%)	
Number (%) of Participants Censored	11 (25.0%)	1 (3.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	16.02 (11.60, 20.30)	8.84 (5.59, 10.84)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.367 (0.217, 0.621)		
p-value (Log-Rank Test, Unstratified)	0.0001		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomisation to the start date of the first subsequent anti-cancer therapy after discontinuation of randomised treatment, or death due to any cause.
TFST rate is the proportion of participants alive without any subsequent therapy.
Hazard ratio and 95% CIs calculated using unstratified Cox proportional hazards model. Efron method used to handle ties. Reference arm = TPC.
Log-rank p-value is from an unstratified log-rank test.
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.

[a] Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').
Data Cut Date: 22 APR 2026.

6. Safety - mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

6.1. Table 1.1.1: Summary of Treatment Exposure - Treatment Duration (months) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	Taxane (N=44)	Any TPC (N=44)
Total Duration of Exposure to Study Drug			
Duration (months)			
N	51	44	44
Mean (StD)	11.43 (9.063)	5.44 (4.341)	5.44 (4.341)
Median	9.23	4.76	4.76
Q1, Q3	4.06, 17.84	2.17, 7.68	2.17, 7.68
Min, Max	0.26, 33.45	0.03, 17.91	0.03, 17.91
Cumulative Number (%) of Participants			
Exposed to Study Drug			

	SG (N=51)	Taxane (N=44)	Any TPC (N=44)
>= 3 months, n, (%)	42 (82.4%)	28 (63.6%)	28 (63.6%)
>= 6 months, n, (%)	32 (62.7%)	16 (36.4%)	16 (36.4%)
>= 12 months, n, (%)	21 (41.2%)	3 (6.8%)	3 (6.8%)
>= 24 months, n, (%)	5 (9.8%)	0 (0.0%)	0 (0.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, Gem = gemcitabine, Carbo = carboplatin.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug. Taxane includes participants who have received Paclitaxel. TPC column includes participants who have received any of Gem, Carbo or Paclitaxel.
Duration of exposure to study drug (months) = (last dosing date − first dosing date + 1)/30.4375.
Data Cut Date: 22 APR 2026.

6.2. Table 1.1.2: Observation Period (Months) for Safety — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Total (N=95)
Observation Period (months) for Safety [a]			
N	51	44	95
Mean (StD)	12.30 (8.892)	6.40 (4.375)	9.57 (7.718)
Median	10.22	5.75	7.49
Q1, Q3	5.04, 18.83	3.15, 8.67	3.79, 13.13
Min, Max	0.49, 33.61	0.10, 18.89	0.10, 33.61

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
[a] Observation period is defined as the time from first dose until Data cutoff date, study treatment discontinuation +30 days for any AE and any serious AE, or death, whichever comes first and stops the collection of endpoint data.
Data Cut Date: 22 APR 2026.

6.3. Table 1.1.3: Analysis of Time to First Treatment-Emergent Adverse Event (TEAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Total Patients	51	44

	SG (N=51)	TPC (N=44)
Patients (%) With Events	51 (100.0%)	42 (95.5%)
Patients (%) Without Events (Censored)	0 (0.0%)	2 (4.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.10 (0.07, 0.26)	0.13 (0.07, 0.23)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.267 (0.826, 1.944)
p-value		0.2754

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.4. Table 1.1.4: Subgroup Analysis of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.8594
De novo			
Total Patients	26	22	
Patients (%) With Events	26 (100.0%)	21 (95.5%)	
Patients (%) Without Events (Censored)	0	1 (4.5%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.26)	0.11 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.113 (0.619, 2.003)	
p-value		0.6845	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	25 (100.0%)	21 (95.5%)	
Patients (%) Without Events (Censored)	0	1 (4.5%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.26)	0.16 (0.03, 0.26)	
Hazard Ratio (95% CI)		1.392 (0.748, 2.589)	
p-value		0.3236	
Geographic region			0.3568
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	25 (100.0%)	15 (93.8%)	
Patients (%) Without Events (Censored)	0	1 (6.2%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.33)	0.16 (0.03, 0.26)	
Hazard Ratio (95% CI)		1.108 (0.571, 2.151)	
p-value		0.7387	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	26 (100.0%)	27 (96.4%)	
Patients (%) Without Events (Censored)	0	1 (3.6%)	
Median Time to First TEAE, months (95% CI)	0.08 (0.07, 0.20)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.452 (0.824, 2.557)	
p-value		0.1927	
Age group			0.7631
< 65			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	34	34	
Patients (%) With Events	34 (100.0%)	32 (94.1%)	
Patients (%) Without Events (Censored)	0	2 (5.9%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.07, 0.26)	0.16 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.264 (0.758, 2.108)	
p-value		0.3924	
>= 65			
Total Patients	17	10	
Patients (%) With Events	17 (100.0%)	10 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.03, 0.16)	0.11 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.233 (0.547, 2.782)	
p-value		0.5836	
Race *			0.9264
White			
Total Patients	34	26	
Patients (%) With Events	34 (100.0%)	24 (92.3%)	
Patients (%) Without Events (Censored)	0	2 (7.7%)	
Median Time to First TEAE, months (95% CI)	0.15 (0.07, 0.26)	0.20 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.249 (0.721, 2.166)	
p-value		0.4096	
Other			
Total Patients	14	15	
Patients (%) With Events	14 (100.0%)	15 (100.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.26)	0.10 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.292 (0.604, 2.764)	
p-value		0.4860	
Baseline ECOG status			0.3545
0			
Total Patients	34	25	
Patients (%) With Events	34 (100.0%)	23 (92.0%)	
Patients (%) Without Events (Censored)	0	2 (8.0%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.33)	0.20 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.191 (0.689, 2.059)	
p-value		0.5639	
1			
Total Patients	17	19	
Patients (%) With Events	17 (100.0%)	19 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.03, 0.10)	0.13 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.512 (0.757, 3.020)	
p-value		0.2478	
History of liver metastasis			0.4518
Yes			
Total Patients	11	12	
Patients (%) With Events	11 (100.0%)	10 (83.3%)	
Patients (%) Without Events (Censored)	0	2 (16.7%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.49)	0.13 (0.03, 1.41)	
Hazard Ratio (95% CI)		1.465 (0.601, 3.569)	
p-value		0.3947	
No			
Total Patients	40	32	
Patients (%) With Events	40 (100.0%)	32 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.07, 0.26)	0.16 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.153 (0.709, 1.875)	
p-value		0.5473	
PD-L1 Status			0.4697
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	23 (100.0%)	6 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.20 (0.03, NR)	
Hazard Ratio (95% CI)		2.257 (0.760, 6.704)	
p-value		0.1151	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	28 (100.0%)	36 (94.7%)	
Patients (%) Without Events (Censored)	0	2 (5.3%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.26)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.083 (0.652, 1.798)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.7399	
Menopausal status			0.1982
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	8 (100.0%)	14 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.31 (0.07, NR)	0.13 (0.03, 0.26)	
Hazard Ratio (95% CI)		0.835 (0.338, 2.061)	
p-value		0.6562	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	43 (100.0%)	28 (93.3%)	
Patients (%) Without Events (Censored)	0	2 (6.7%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.16 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.386 (0.842, 2.282)	
p-value		0.1749	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.5. Table 1.1.5: Analysis of Time to First Serious Treatment-Emergent Adverse Event (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	12 (23.5%)	8 (18.2%)
Patients (%) Without Events (Censored)	39 (76.5%)	36 (81.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.234 (0.504, 3.024)
p-value		0.6547

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.6. Table 1.1.6: Subgroup Analysis of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.4588
De novo			
Total Patients	26	22	
Patients (%) With Events	8 (30.8%)	4 (18.2%)	
Patients (%) Without Events (Censored)	18 (69.2%)	18 (81.8%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.659 (0.498, 5.530)	
p-value		0.4071	
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	4 (16.0%)	4 (18.2%)	
Patients (%) Without Events (Censored)	21 (84.0%)	18 (81.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.823 (0.205, 3.298)	
p-value		0.7639	
Geographic region			0.4018
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	8 (32.0%)	3 (18.8%)	
Patients (%) Without Events (Censored)	17 (68.0%)	13 (81.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (4.76, NR)	
Hazard Ratio (95% CI)		1.761 (0.465, 6.669)	
p-value		0.4057	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	4 (15.4%)	5 (17.9%)	
Patients (%) Without Events (Censored)	22 (84.6%)	23 (82.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.769 (0.206, 2.874)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.6951	
Age group			0.2178
< 65			
Total Patients	34	34	
Patients (%) With Events	3 (8.8%)	5 (14.7%)	
Patients (%) Without Events (Censored)	31 (91.2%)	29 (85.3%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.537 (0.128, 2.258)	
p-value		0.3844	
>= 65			
Total Patients	17	10	
Patients (%) With Events	9 (52.9%)	3 (30.0%)	
Patients (%) Without Events (Censored)	8 (47.1%)	7 (70.0%)	
Median Time to First Serious TEAE, months (95% CI)	6.57 (0.53, NR)	NR (0.26, NR)	
Hazard Ratio (95% CI)		1.775 (0.479, 6.570)	
p-value		0.3902	
Race *			0.8812
White			
Total Patients	34	26	
Patients (%) With Events	10 (29.4%)	6 (23.1%)	
Patients (%) Without Events (Censored)	24 (70.6%)	20 (76.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (4.76, NR)	
Hazard Ratio (95% CI)		1.216 (0.441, 3.352)	
p-value		0.7157	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Other			
Total Patients	14	15	
Patients (%) With Events	2 (14.3%)	2 (13.3%)	
Patients (%) Without Events (Censored)	12 (85.7%)	13 (86.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.905 (0.126, 6.500)	
p-value		0.9213	
Baseline ECOG status			0.0024
0			
Total Patients	34	25	
Patients (%) With Events	11 (32.4%)	2 (8.0%)	
Patients (%) Without Events (Censored)	23 (67.6%)	23 (92.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.399 (0.974, 19.860)	
p-value		0.0359	
1			
Total Patients	17	19	
Patients (%) With Events	1 (5.9%)	6 (31.6%)	
Patients (%) Without Events (Censored)	16 (94.1%)	13 (68.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (2.76, NR)	
Hazard Ratio (95% CI)		0.146 (0.017, 1.223)	
p-value		0.0402	
History of liver metastasis			0.7548
Yes			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	11	12	
Patients (%) With Events	3 (27.3%)	3 (25.0%)	
Patients (%) Without Events (Censored)	8 (72.7%)	9 (75.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (0.43, NR)	NR (2.27, NR)	
Hazard Ratio (95% CI)		1.094 (0.220, 5.428)	
p-value		0.9274	
No			
Total Patients	40	32	
Patients (%) With Events	9 (22.5%)	5 (15.6%)	
Patients (%) Without Events (Censored)	31 (77.5%)	27 (84.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.381 (0.462, 4.123)	
p-value		0.5656	
PD-L1 Status			0.2496
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	5 (21.7%)	2 (33.3%)	
Patients (%) Without Events (Censored)	18 (78.3%)	4 (66.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (0.30, NR)	
Hazard Ratio (95% CI)		0.533 (0.102, 2.769)	
p-value		0.4386	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	7 (25.0%)	6 (15.8%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	21 (75.0%)	32 (84.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.597 (0.536, 4.754)	
p-value		0.4034	
Menopausal status			0.7546
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	1 (12.5%)	1 (7.1%)	
Patients (%) Without Events (Censored)	7 (87.5%)	13 (92.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (3.58, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		1.254 (0.077, 20.400)	
p-value		0.8736	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	11 (25.6%)	7 (23.3%)	
Patients (%) Without Events (Censored)	32 (74.4%)	23 (76.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.045 (0.405, 2.698)	
p-value		0.9430	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
NC = Not Calculable: the hazard ratio and 95% CI are not estimable by the Cox model.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.7. Table 1.1.7: Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	33 (64.7%)	18 (40.9%)
Patients (%) Without Events (Censored)	18 (35.3%)	26 (59.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.04 (0.79, 6.41)	7.79 (2.27, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.789 (1.003, 3.191)
p-value		0.0459

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.8. Table 1.1.8: Subgroup Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.9716
De novo			
Total Patients	26	22	
Patients (%) With Events	16 (61.5%)	8 (36.4%)	
Patients (%) Without Events (Censored)	10 (38.5%)	14 (63.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, NR)	NR (1.71, NR)	
Hazard Ratio (95% CI)		1.950 (0.832, 4.571)	
p-value		0.1143	
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	17 (68.0%)	10 (45.5%)	
Patients (%) Without Events (Censored)	8 (32.0%)	12 (54.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.43, NR)	7.36 (1.35, NR)	
Hazard Ratio (95% CI)		1.789 (0.807, 3.964)	
p-value		0.1538	
Geographic region			0.8921
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	15 (60.0%)	6 (37.5%)	
Patients (%) Without Events (Censored)	10 (40.0%)	10 (62.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, NR)	7.79 (2.27, NR)	
Hazard Ratio (95% CI)		2.022 (0.782, 5.227)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.1395	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	18 (69.2%)	12 (42.9%)	
Patients (%) Without Events (Censored)	8 (30.8%)	16 (57.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.89 (0.56, 22.34)	NR (1.35, NR)	
Hazard Ratio (95% CI)		1.705 (0.814, 3.574)	
p-value		0.1550	
Age group			0.7682
< 65			
Total Patients	34	34	
Patients (%) With Events	20 (58.8%)	13 (38.2%)	
Patients (%) Without Events (Censored)	14 (41.2%)	21 (61.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.58 (0.95, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		1.839 (0.912, 3.706)	
p-value		0.0862	
>= 65			
Total Patients	17	10	
Patients (%) With Events	13 (76.5%)	5 (50.0%)	
Patients (%) Without Events (Censored)	4 (23.5%)	5 (50.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.56 (0.43, 22.34)	1.97 (0.26, NR)	
Hazard Ratio (95% CI)		1.495 (0.526, 4.246)	
p-value		0.4312	
Race *			0.4049

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
White			
Total Patients	34	26	
Patients (%) With Events	21 (61.8%)	11 (42.3%)	
Patients (%) Without Events (Censored)	13 (38.2%)	15 (57.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.20 (0.92, NR)	NR (1.41, NR)	
Hazard Ratio (95% CI)		1.614 (0.777, 3.352)	
p-value		0.1943	
Other			
Total Patients	14	15	
Patients (%) With Events	11 (78.6%)	6 (40.0%)	
Patients (%) Without Events (Censored)	3 (21.4%)	9 (60.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.72 (0.26, NR)	7.36 (0.46, NR)	
Hazard Ratio (95% CI)		2.384 (0.862, 6.589)	
p-value		0.0911	
Baseline ECOG status			0.0181
0			
Total Patients	34	25	
Patients (%) With Events	24 (70.6%)	7 (28.0%)	
Patients (%) Without Events (Censored)	10 (29.4%)	18 (72.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.53, 4.14)	NR (6.90, NR)	
Hazard Ratio (95% CI)		3.513 (1.510, 8.170)	
p-value		0.0020	
1			
Total Patients	17	19	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	9 (52.9%)	11 (57.9%)	
Patients (%) Without Events (Censored)	8 (47.1%)	8 (42.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.41 (0.92, NR)	2.27 (0.30, NR)	
Hazard Ratio (95% CI)		0.766 (0.308, 1.907)	
p-value		0.5746	
History of liver metastasis			0.9011
Yes			
Total Patients	11	12	
Patients (%) With Events	7 (63.6%)	5 (41.7%)	
Patients (%) Without Events (Censored)	4 (36.4%)	7 (58.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.43, NR)	NR (0.53, NR)	
Hazard Ratio (95% CI)		1.746 (0.553, 5.516)	
p-value		0.3327	
No			
Total Patients	40	32	
Patients (%) With Events	26 (65.0%)	13 (40.6%)	
Patients (%) Without Events (Censored)	14 (35.0%)	19 (59.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, 22.34)	NR (1.97, NR)	
Hazard Ratio (95% CI)		1.844 (0.942, 3.611)	
p-value		0.0692	
PD-L1 Status			0.5593
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	16 (69.6%)	4 (66.7%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	7 (30.4%)	2 (33.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.92 (0.53, 3.58)	1.69 (0.30, NR)	
Hazard Ratio (95% CI)		1.290 (0.430, 3.865)	
p-value		0.6552	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	17 (60.7%)	14 (36.8%)	
Patients (%) Without Events (Censored)	11 (39.3%)	24 (63.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	4.48 (0.95, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		1.721 (0.838, 3.533)	
p-value		0.1350	
Menopausal status			0.8832
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	5 (62.5%)	5 (35.7%)	
Patients (%) Without Events (Censored)	3 (37.5%)	9 (64.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.58 (0.72, NR)	NR (1.41, NR)	
Hazard Ratio (95% CI)		2.027 (0.576, 7.132)	
p-value		0.2620	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	28 (65.1%)	13 (43.3%)	
Patients (%) Without Events (Censored)	15 (34.9%)	17 (56.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.56, 22.34)	7.79 (1.97, NR)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.651 (0.851, 3.202)	
p-value		0.1360	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.9. Table 1.1.9: Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Number of patients at risk	51 (100.0%)	44 (100.0%)
Number of patients with events	4 (7.8%)	6 (13.6%)
Sacituzumab Govitecan	4 (7.8%)	0
Paclitaxel	0	6 (13.6%)
Number of patients censored	47 (92.2%)	38 (86.4%)
Probability of being event-free [a] [95% CI] [b] at:		
Month 3	96.0 [85.1, 99.0]	95.2 [82.0, 98.8]
Month 6	91.5 [78.9, 96.7]	91.8 [76.2, 97.3]
Month 9	91.5 [78.9, 96.7]	75.2 [50.8, 88.7]
Month 12	91.5 [78.9, 96.7]	75.2 [50.8, 88.7]
Kaplan-Meier Quartiles of Time to Event (months)		

	SG (N=51)	TPC (N=44)
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.450 (0.126, 1.611)
p-value		0.2086

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[a] Estimated from the Kaplan-Meier method.
[b] Calculated using the log-log transformation (Brookmeyer-Crowley method).
[c] Median 95% CI based on Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties. p-value is from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm in the Safety Analysis Set.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.10. Table 1.1.10: Subgroup Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.6418
De novo			
Total Patients	26	22	
Patients (%) With Events	2 (7.7%)	2 (9.1%)	
Patients (%) Without Events (Censored)	24 (92.3%)	20 (90.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.830 (0.117, 5.911)	
p-value		0.8524	
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	2 (8.0%)	4 (18.2%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	23 (92.0%)	18 (81.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.74, NR)	
Hazard Ratio (95% CI)		0.328 (0.060, 1.801)	
p-value		0.1774	
Geographic region			0.9215
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	3 (12.0%)	4 (25.0%)	
Patients (%) Without Events (Censored)	22 (88.0%)	12 (75.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.74, NR)	
Hazard Ratio (95% CI)		0.386 (0.085, 1.746)	
p-value		0.2000	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	1 (3.8%)	2 (7.1%)	
Patients (%) Without Events (Censored)	25 (96.2%)	26 (92.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.414 (0.037, 4.631)	
p-value		0.4605	
Age group			0.3959
< 65			
Total Patients	34	34	
Patients (%) With Events	1 (2.9%)	4 (11.8%)	
Patients (%) Without Events (Censored)	33 (97.1%)	30 (88.2%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.186 (0.021, 1.689)	
p-value		0.0953	
>= 65			
Total Patients	17	10	
Patients (%) With Events	3 (17.6%)	2 (20.0%)	
Patients (%) Without Events (Censored)	14 (82.4%)	8 (80.0%)	
Median Time to Discontinuation, months (95% CI)	NR (4.11, NR)	NR (1.97, NR)	
Hazard Ratio (95% CI)		0.676 (0.111, 4.126)	
p-value		0.6697	
Race *			0.4131
White			
Total Patients	34	26	
Patients (%) With Events	2 (5.9%)	4 (15.4%)	
Patients (%) Without Events (Censored)	32 (94.1%)	22 (84.6%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.74, NR)	
Hazard Ratio (95% CI)		0.272 (0.049, 1.505)	
p-value		0.1110	
Other			
Total Patients	14	15	
Patients (%) With Events	2 (14.3%)	2 (13.3%)	
Patients (%) Without Events (Censored)	12 (85.7%)	13 (86.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.67, NR)	
Hazard Ratio (95% CI)		0.912 (0.126, 6.609)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.9276	
Baseline ECOG status			0.0643
0			
Total Patients	34	25	
Patients (%) With Events	4 (11.8%)	3 (12.0%)	
Patients (%) Without Events (Censored)	30 (88.2%)	22 (88.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.845 (0.188, 3.806)	
p-value		0.8264	
1			
Total Patients	17	19	
Patients (%) With Events	0	3 (15.8%)	
Patients (%) Without Events (Censored)	17 (100.0%)	16 (84.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.67, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0627	
History of liver metastasis			1.0000
Yes			
Total Patients	11	12	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	11 (100.0%)	12 (100.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		1.0000	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
No			
Total Patients	40	32	
Patients (%) With Events	4 (10.0%)	6 (18.8%)	
Patients (%) Without Events (Censored)	36 (90.0%)	26 (81.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.465 (0.131, 1.659)	
p-value		0.2271	
PD-L1 Status			0.4478
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	1 (4.3%)	1 (16.7%)	
Patients (%) Without Events (Censored)	22 (95.7%)	5 (83.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (1.97, NR)	
Hazard Ratio (95% CI)		0.280 (0.017, 4.480)	
p-value		0.3360	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	3 (10.7%)	5 (13.2%)	
Patients (%) Without Events (Censored)	25 (89.3%)	33 (86.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.633 (0.150, 2.662)	
p-value		0.5288	
Menopausal status			0.2643
Pre-menopausal			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	8	14	
Patients (%) With Events	0	2 (14.3%)	
Patients (%) Without Events (Censored)	8 (100.0%)	12 (85.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.67, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.2132	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	4 (9.3%)	4 (13.3%)	
Patients (%) Without Events (Censored)	39 (90.7%)	26 (86.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.548 (0.136, 2.210)	
p-value		0.3911	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. NC = Not Calculable (HR is NC when one treatment arm has zero events; log-rank p-value remains valid).
Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.11. Table 1.1.11: Analysis of Time to First TEAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Blood and lymphatic system disorders		
Total Patients	51	44
Patients (%) With Events	38 (74.5%)	20 (45.5%)
Patients (%) Without Events (Censored)	13 (25.5%)	24 (54.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.72 (0.49, 1.02)	5.55 (2.30, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.441 (1.407, 4.233)
p-value		0.0013
Anaemia		
Total Patients	51	44
Patients (%) With Events	22 (43.1%)	12 (27.3%)
Patients (%) Without Events (Censored)	29 (56.9%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (2.76, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.600 (0.789, 3.247)
p-value		0.1912
Leukopenia		
Total Patients	51	44
Patients (%) With Events	10 (19.6%)	2 (4.5%)
Patients (%) Without Events (Censored)	41 (80.4%)	42 (95.5%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.379 (0.958, 20.014)
p-value		0.0375
Lymphopenia		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	47 (92.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (9.20, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.562 (0.148, 2.128)
p-value		0.3866
Neutropenia		
Total Patients	51	44
Patients (%) With Events	33 (64.7%)	11 (25.0%)
Patients (%) Without Events (Censored)	18 (35.3%)	33 (75.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 3.02)	13.34 (13.34, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.398 (1.708, 6.759)
p-value		0.0003
Cardiac disorders		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	3 (6.8%)
Patients (%) Without Events (Censored)	42 (82.4%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.562 (0.693, 9.468)
p-value		0.1434
Eye disorders		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	45 (88.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.743 (0.221, 2.499)
p-value		0.6305
Gastrointestinal disorders		
Total Patients	51	44
Patients (%) With Events	49 (96.1%)	24 (54.5%)
Patients (%) Without Events (Censored)	2 (3.9%)	20 (45.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.26 (0.10, 0.43)	2.89 (0.26, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		2.663 (1.614, 4.392)
p-value		0.0001
Abdominal pain		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	4 (9.1%)
Patients (%) Without Events (Censored)	43 (84.3%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.255 (0.365, 4.311)
p-value		0.7235
Constipation		
Total Patients	51	44
Patients (%) With Events	23 (45.1%)	9 (20.5%)
Patients (%) Without Events (Censored)	28 (54.9%)	35 (79.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (0.82, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.550 (1.179, 5.513)
p-value		0.0141
Diarrhoea		
Total Patients	51	44
Patients (%) With Events	31 (60.8%)	10 (22.7%)
Patients (%) Without Events (Censored)	20 (39.2%)	34 (77.3%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.74 (0.72, 17.35)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.005 (1.466, 6.163)
p-value		0.0017
Nausea		
Total Patients	51	44
Patients (%) With Events	31 (60.8%)	12 (27.3%)
Patients (%) Without Events (Censored)	20 (39.2%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.83 (0.95, 5.09)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.586 (1.327, 5.039)
p-value		0.0036
Stomatitis		
Total Patients	51	44
Patients (%) With Events	15 (29.4%)	2 (4.5%)
Patients (%) Without Events (Censored)	36 (70.6%)	42 (95.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (11.76, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		6.585 (1.499, 28.925)
p-value		0.0040
Vomiting		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	15 (29.4%)	5 (11.4%)
Patients (%) Without Events (Censored)	36 (70.6%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (21.13, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.469 (0.889, 6.857)
p-value		0.0725
General disorders and administration site conditions		
Total Patients	51	44
Patients (%) With Events	36 (70.6%)	22 (50.0%)
Patients (%) Without Events (Censored)	15 (29.4%)	22 (50.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.41 (0.59, 3.91)	3.98 (0.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.497 (0.880, 2.547)
p-value		0.1341
Fatigue		
Total Patients	51	44
Patients (%) With Events	30 (58.8%)	19 (43.2%)
Patients (%) Without Events (Censored)	21 (41.2%)	25 (56.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.79 (1.18, NR)	7.26 (3.78, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		1.472 (0.828, 2.616)
p-value		0.1860
Oedema peripheral		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	5 (11.4%)
Patients (%) Without Events (Censored)	48 (94.1%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.302 (0.066, 1.374)
p-value		0.1033
Pyrexia		
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	4 (9.1%)
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (21.13, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.210 (0.355, 4.119)
p-value		0.7603
Infections and infestations		
Total Patients	51	44
Patients (%) With Events	35 (68.6%)	21 (47.7%)
Patients (%) Without Events (Censored)	16 (31.4%)	23 (52.3%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	4.76 (2.04, 7.46)	5.75 (2.27, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.220 (0.704, 2.113)
p-value		0.4778
Nasopharyngitis		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	3 (6.8%)
Patients (%) Without Events (Censored)	44 (86.3%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.411 (0.359, 5.552)
p-value		0.6204
Upper respiratory tract infection		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	45 (88.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.629 (0.187, 2.119)
p-value		0.4506
Urinary tract infection		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	7 (15.9%)
Patients (%) Without Events (Censored)	46 (90.2%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.430 (0.125, 1.477)
p-value		0.1672
Injury, poisoning and procedural complications		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	8 (18.2%)
Patients (%) Without Events (Censored)	45 (88.2%)	36 (81.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.498 (0.168, 1.473)
p-value		0.2016
Infusion related reaction		
Total Patients	51	44
Patients (%) With Events	1 (2.0%)	5 (11.4%)
Patients (%) Without Events (Censored)	50 (98.0%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		0.161 (0.019, 1.377)
p-value		0.0569
Investigations		
Total Patients	51	44
Patients (%) With Events	25 (49.0%)	13 (29.5%)
Patients (%) Without Events (Censored)	26 (51.0%)	31 (70.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	19.35 (3.45, NR)	NR (6.60, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.413 (0.712, 2.804)
p-value		0.3203
Alanine aminotransferase increased		
Total Patients	51	44
Patients (%) With Events	11 (21.6%)	5 (11.4%)
Patients (%) Without Events (Censored)	40 (78.4%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.389 (0.469, 4.114)
p-value		0.5474
Aspartate aminotransferase increased		
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	5 (11.4%)
Patients (%) Without Events (Censored)	42 (82.4%)	39 (88.6%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.187 (0.387, 3.644)
p-value		0.7628
Blood alkaline phosphatase increased		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	1 (2.3%)
Patients (%) Without Events (Censored)	44 (86.3%)	43 (97.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.481 (0.530, 37.886)
p-value		0.1322
Metabolism and nutrition disorders		
Total Patients	51	44
Patients (%) With Events	22 (43.1%)	15 (34.1%)
Patients (%) Without Events (Censored)	29 (56.9%)	29 (65.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	18.96 (3.45, NR)	NR (3.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.147 (0.589, 2.233)
p-value		0.6843
Decreased appetite		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	10 (19.6%)	11 (25.0%)
Patients (%) Without Events (Censored)	41 (80.4%)	33 (75.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (6.90, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.647 (0.271, 1.546)
p-value		0.3231
Hyperglycaemia		
Total Patients	51	44
Patients (%) With Events	2 (3.9%)	5 (11.4%)
Patients (%) Without Events (Censored)	49 (96.1%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.296 (0.057, 1.545)
p-value		0.1258
Hypokalaemia		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	0 (0.0%)
Patients (%) Without Events (Censored)	43 (84.3%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		NC
p-value		0.0127
Musculoskeletal and connective tissue disorders		
Total Patients	51	44
Patients (%) With Events	22 (43.1%)	19 (43.2%)
Patients (%) Without Events (Censored)	29 (56.9%)	25 (56.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	12.78 (6.08, NR)	5.16 (3.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.673 (0.355, 1.274)
p-value		0.2209
Arthralgia		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	46 (90.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.403 (0.103, 1.577)
p-value		0.1787
Back pain		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	5 (11.4%)
Patients (%) Without Events (Censored)	43 (84.3%)	39 (88.6%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (24.51, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.984 (0.310, 3.126)
p-value		0.9778
Myalgia		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	7 (15.9%)
Patients (%) Without Events (Censored)	47 (92.2%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.383 (0.108, 1.356)
p-value		0.1233
Nervous system disorders		
Total Patients	51	44
Patients (%) With Events	21 (41.2%)	27 (61.4%)
Patients (%) Without Events (Censored)	30 (58.8%)	17 (38.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (4.47, NR)	3.12 (1.97, 6.24)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.411 (0.222, 0.762)
p-value		0.0035
Headache		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	5 (11.4%)
Patients (%) Without Events (Censored)	44 (86.3%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.972 (0.303, 3.121)
p-value		0.9623
Neuropathy peripheral		
Total Patients	51	44
Patients (%) With Events	1 (2.0%)	10 (22.7%)
Patients (%) Without Events (Censored)	50 (98.0%)	34 (77.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (6.90, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.057 (0.007, 0.453)
p-value		0.0003
Peripheral sensory neuropathy		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	9 (20.5%)
Patients (%) Without Events (Censored)	48 (94.1%)	35 (79.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (9.46, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		0.176 (0.045, 0.681)
p-value		0.0053
Psychiatric disorders		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	6 (13.6%)
Patients (%) Without Events (Censored)	43 (84.3%)	38 (86.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (21.42, NR)	16.53 (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.718 (0.226, 2.281)
p-value		0.5724
Renal and urinary disorders		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	7 (15.9%)
Patients (%) Without Events (Censored)	45 (88.2%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (8.74, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.562 (0.185, 1.703)
p-value		0.3017
Reproductive system and breast disorders		
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	4 (9.1%)
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (10.61, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.121 (0.335, 3.749)
p-value		0.8528
Respiratory, thoracic and mediastinal disorders		
Total Patients	51	44
Patients (%) With Events	19 (37.3%)	12 (27.3%)
Patients (%) Without Events (Censored)	32 (62.7%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (6.51, NR)	NR (6.44, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.043 (0.501, 2.173)
p-value		0.9059
Cough		
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	4 (9.1%)
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.406 (0.423, 4.673)
p-value		0.5761
Dyspnoea		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	45 (88.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.869 (0.264, 2.859)
p-value		0.8175
Skin and subcutaneous tissue disorders		
Total Patients	51	44
Patients (%) With Events	35 (68.6%)	22 (50.0%)
Patients (%) Without Events (Censored)	16 (31.4%)	22 (50.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 2.20)	3.29 (0.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.539 (0.901, 2.628)
p-value		0.1101
Alopecia		
Total Patients	51	44
Patients (%) With Events	29 (56.9%)	16 (36.4%)
Patients (%) Without Events (Censored)	22 (43.1%)	28 (63.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.41 (0.72, NR)	NR (1.84, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		1.717 (0.931, 3.164)
p-value		0.0788
Nail disorder		
Total Patients	51	44
Patients (%) With Events	0 (0.0%)	5 (11.4%)
Patients (%) Without Events (Censored)	51 (100.0%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0048
Vascular disorders		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	8 (18.2%)
Patients (%) Without Events (Censored)	44 (86.3%)	36 (81.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (11.20, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.486 (0.169, 1.399)
p-value		0.1732

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=51)	TPC (N=44)

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.12. Table 1.1.12.1: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.9723
De novo			
Total Patients	26	22	
Patients (%) With Events	18 (69.2%)	9 (40.9%)	
Patients (%) Without Events (Censored)	8 (30.8%)	13 (59.1%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.69, 2.33)	5.55 (0.95, NR)	
Hazard Ratio (95% CI)		2.581 (1.143, 5.828)	
p-value		0.0199	
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	20 (80.0%)	11 (50.0%)	
Patients (%) Without Events (Censored)	5 (20.0%)	11 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 0.95)	4.30 (0.43, NR)	
Hazard Ratio (95% CI)		2.380 (1.119, 5.060)	
p-value		0.0221	
Geographic region			0.3462
US/Canada/Western Europe			
Total Patients	25	16	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	14 (56.0%)	6 (37.5%)	
Patients (%) Without Events (Censored)	11 (44.0%)	10 (62.5%)	
Median Time to First TEAE, months (95% CI)	1.68 (0.69, NR)	5.55 (2.30, NR)	
Hazard Ratio (95% CI)		2.011 (0.768, 5.263)	
p-value		0.1518	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	24 (92.3%)	14 (50.0%)	
Patients (%) Without Events (Censored)	2 (7.7%)	14 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.71 (0.26, 0.72)	4.34 (0.49, NR)	
Hazard Ratio (95% CI)		3.348 (1.667, 6.726)	
p-value		0.0005	
Age group			0.4650
< 65			
Total Patients	34	34	
Patients (%) With Events	27 (79.4%)	15 (44.1%)	
Patients (%) Without Events (Censored)	7 (20.6%)	19 (55.9%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.49, 1.02)	5.55 (3.29, NR)	
Hazard Ratio (95% CI)		2.869 (1.505, 5.470)	
p-value		0.0011	
>= 65			
Total Patients	17	10	
Patients (%) With Events	11 (64.7%)	5 (50.0%)	
Patients (%) Without Events (Censored)	6 (35.3%)	5 (50.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.92 (0.26, NR)	4.90 (0.23, NR)	
Hazard Ratio (95% CI)		1.536 (0.532, 4.432)	
p-value		0.4352	
Race *			0.0046
White			
Total Patients	34	26	
Patients (%) With Events	24 (70.6%)	13 (50.0%)	
Patients (%) Without Events (Censored)	10 (29.4%)	13 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 2.30)	4.30 (0.95, NR)	
Hazard Ratio (95% CI)		1.738 (0.879, 3.439)	
p-value		0.1048	
Other			
Total Patients	14	15	
Patients (%) With Events	13 (92.9%)	5 (33.3%)	
Patients (%) Without Events (Censored)	1 (7.1%)	10 (66.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.26, 0.72)	NR (0.49, NR)	
Hazard Ratio (95% CI)		6.671 (2.129, 20.906)	
p-value		0.0006	
Baseline ECOG status			0.8597
0			
Total Patients	34	25	
Patients (%) With Events	26 (76.5%)	12 (48.0%)	
Patients (%) Without Events (Censored)	8 (23.5%)	13 (52.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.43, 1.25)	5.49 (2.30, NR)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.616 (1.301, 5.261)	
p-value		0.0061	
1			
Total Patients	17	19	
Patients (%) With Events	12 (70.6%)	8 (42.1%)	
Patients (%) Without Events (Censored)	5 (29.4%)	11 (57.9%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 3.02)	NR (0.66, NR)	
Hazard Ratio (95% CI)		2.110 (0.852, 5.226)	
p-value		0.1059	
History of liver metastasis			0.8106
Yes			
Total Patients	11	12	
Patients (%) With Events	10 (90.9%)	5 (41.7%)	
Patients (%) Without Events (Censored)	1 (9.1%)	7 (58.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 2.30)	NR (0.26, NR)	
Hazard Ratio (95% CI)		2.611 (0.884, 7.712)	
p-value		0.0683	
No			
Total Patients	40	32	
Patients (%) With Events	28 (70.0%)	15 (46.9%)	
Patients (%) Without Events (Censored)	12 (30.0%)	17 (53.1%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.30, 1.68)	5.55 (2.30, NR)	
Hazard Ratio (95% CI)		2.332 (1.231, 4.418)	
p-value		0.0095	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
PD-L1 Status			0.1655
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	16 (69.6%)	5 (83.3%)	
Patients (%) Without Events (Censored)	7 (30.4%)	1 (16.7%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.43, 3.02)	3.79 (0.66, NR)	
Hazard Ratio (95% CI)		1.415 (0.511, 3.921)	
p-value		0.5407	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	22 (78.6%)	15 (39.5%)	
Patients (%) Without Events (Censored)	6 (21.4%)	23 (60.5%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 1.25)	NR (2.30, NR)	
Hazard Ratio (95% CI)		3.001 (1.531, 5.882)	
p-value		0.0009	
Menopausal status			0.3702
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	8 (100.0%)	6 (42.9%)	
Patients (%) Without Events (Censored)	0 (0.0%)	8 (57.1%)	
Median Time to First TEAE, months (95% CI)	0.87 (0.26, 2.30)	5.55 (1.41, NR)	
Hazard Ratio (95% CI)		6.314 (1.828, 21.816)	
p-value		0.0013	
Post-menopausal			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	43	30	
Patients (%) With Events	30 (69.8%)	14 (46.7%)	
Patients (%) Without Events (Censored)	13 (30.2%)	16 (53.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.30, 1.25)	5.49 (0.66, NR)	
Hazard Ratio (95% CI)		1.941 (1.023, 3.685)	
p-value		0.0426	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.13. Table 1.1.12.2: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.0466
De novo			
Total Patients	26	22	
Patients (%) With Events	26 (100.0%)	10 (45.5%)	
Patients (%) Without Events (Censored)	0 (0.0%)	12 (54.5%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.28 (0.10, 0.49)	5.98 (0.30, NR)	
Hazard Ratio (95% CI)		5.499 (2.448, 12.353)	
p-value		<0.0001	
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	23 (92.0%)	14 (63.6%)	
Patients (%) Without Events (Censored)	2 (8.0%)	8 (36.4%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.07, 0.72)	0.64 (0.13, NR)	
Hazard Ratio (95% CI)		1.554 (0.793, 3.046)	
p-value		0.1920	
Geographic region			0.6288
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	24 (96.0%)	10 (62.5%)	
Patients (%) Without Events (Censored)	1 (4.0%)	6 (37.5%)	
Median Time to First TEAE, months (95% CI)	0.36 (0.16, 0.53)	1.61 (0.26, NR)	
Hazard Ratio (95% CI)		2.943 (1.366, 6.337)	
p-value		0.0043	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	25 (96.2%)	14 (50.0%)	
Patients (%) Without Events (Censored)	1 (3.8%)	14 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.07, 0.53)	5.98 (0.13, NR)	
Hazard Ratio (95% CI)		2.596 (1.330, 5.066)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.0036	
Age group			0.8271
< 65			
Total Patients	34	34	
Patients (%) With Events	32 (94.1%)	18 (52.9%)	
Patients (%) Without Events (Censored)	2 (5.9%)	16 (47.1%)	
Median Time to First TEAE, months (95% CI)	0.38 (0.10, 0.59)	3.94 (0.26, NR)	
Hazard Ratio (95% CI)		2.432 (1.346, 4.393)	
p-value		0.0021	
>= 65			
Total Patients	17	10	
Patients (%) With Events	17 (100.0%)	6 (60.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	4 (40.0%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.36)	1.61 (0.03, NR)	
Hazard Ratio (95% CI)		2.687 (1.025, 7.045)	
p-value		0.0386	
Race *			0.1674
White			
Total Patients	34	26	
Patients (%) With Events	32 (94.1%)	15 (57.7%)	
Patients (%) Without Events (Censored)	2 (5.9%)	11 (42.3%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.49)	1.91 (0.13, NR)	
Hazard Ratio (95% CI)		2.176 (1.164, 4.071)	
p-value		0.0117	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Other			
Total Patients	14	15	
Patients (%) With Events	14 (100.0%)	6 (40.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	9 (60.0%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.07, 0.59)	NR (0.10, NR)	
Hazard Ratio (95% CI)		4.322 (1.619, 11.537)	
p-value		0.0016	
Baseline ECOG status			0.7432
0			
Total Patients	34	25	
Patients (%) With Events	32 (94.1%)	14 (56.0%)	
Patients (%) Without Events (Censored)	2 (5.9%)	11 (44.0%)	
Median Time to First TEAE, months (95% CI)	0.36 (0.10, 0.53)	3.94 (0.43, NR)	
Hazard Ratio (95% CI)		2.644 (1.396, 5.009)	
p-value		0.0021	
1			
Total Patients	17	19	
Patients (%) With Events	17 (100.0%)	10 (52.6%)	
Patients (%) Without Events (Censored)	0 (0.0%)	9 (47.4%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.07, 0.59)	1.91 (0.03, NR)	
Hazard Ratio (95% CI)		2.735 (1.181, 6.334)	
p-value		0.0123	
History of liver metastasis			0.7989
Yes			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	11	12	
Patients (%) With Events	11 (100.0%)	6 (50.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	6 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.49)	4.75 (0.03, NR)	
Hazard Ratio (95% CI)		2.488 (0.909, 6.807)	
p-value		0.0585	
No			
Total Patients	40	32	
Patients (%) With Events	38 (95.0%)	18 (56.2%)	
Patients (%) Without Events (Censored)	2 (5.0%)	14 (43.8%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.13, 0.53)	2.89 (0.30, NR)	
Hazard Ratio (95% CI)		2.696 (1.516, 4.794)	
p-value		0.0005	
PD-L1 Status			0.8758
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	23 (100.0%)	3 (50.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	3 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.36 (0.10, 0.59)	5.98 (0.03, NR)	
Hazard Ratio (95% CI)		3.233 (0.938, 11.142)	
p-value		0.0467	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	26 (92.9%)	21 (55.3%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	2 (7.1%)	17 (44.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.07, 0.39)	1.91 (0.26, NR)	
Hazard Ratio (95% CI)		2.551 (1.419, 4.585)	
p-value		0.0012	
Menopausal status			0.9068
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	7 (87.5%)	7 (50.0%)	
Patients (%) Without Events (Censored)	1 (12.5%)	7 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.43 (0.07, 4.07)	5.98 (0.13, NR)	
Hazard Ratio (95% CI)		2.180 (0.760, 6.254)	
p-value		0.1439	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	42 (97.7%)	17 (56.7%)	
Patients (%) Without Events (Censored)	1 (2.3%)	13 (43.3%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.10, 0.43)	1.61 (0.26, NR)	
Hazard Ratio (95% CI)		2.605 (1.463, 4.638)	
p-value		0.0007	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.14. Table 1.1.12.3: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Disease stratification *			0.7137
De novo			
Total Patients	26	22	
Patients (%) With Events	11 (42.3%)	13 (59.1%)	
Patients (%) Without Events (Censored)	15 (57.7%)	9 (40.9%)	
Median Time to First TEAE, months (95% CI)	NR (2.07, NR)	3.12 (0.46, NR)	
Hazard Ratio (95% CI)		0.628 (0.280, 1.407)	
p-value		0.2479	
Recurrent disease			
Total Patients	25	22	
Patients (%) With Events	10 (40.0%)	14 (63.6%)	
Patients (%) Without Events (Censored)	15 (60.0%)	8 (36.4%)	
Median Time to First TEAE, months (95% CI)	12.78 (6.44, NR)	5.09 (2.07, 6.90)	
Hazard Ratio (95% CI)		0.255 (0.099, 0.662)	
p-value		0.0027	
Geographic region			0.6881
US/Canada/Western Europe			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	25	16	
Patients (%) With Events	11 (44.0%)	10 (62.5%)	
Patients (%) Without Events (Censored)	14 (56.0%)	6 (37.5%)	
Median Time to First TEAE, months (95% CI)	NR (2.07, NR)	2.27 (1.41, NR)	
Hazard Ratio (95% CI)		0.519 (0.216, 1.248)	
p-value		0.1363	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	10 (38.5%)	17 (60.7%)	
Patients (%) Without Events (Censored)	16 (61.5%)	11 (39.3%)	
Median Time to First TEAE, months (95% CI)	NR (4.47, NR)	3.52 (1.97, 6.24)	
Hazard Ratio (95% CI)		0.334 (0.137, 0.816)	
p-value		0.0115	
Age group			0.3102
< 65			
Total Patients	34	34	
Patients (%) With Events	11 (32.4%)	21 (61.8%)	
Patients (%) Without Events (Censored)	23 (67.6%)	13 (38.2%)	
Median Time to First TEAE, months (95% CI)	NR (11.33, NR)	4.47 (1.94, 6.90)	
Hazard Ratio (95% CI)		0.233 (0.099, 0.549)	
p-value		0.0003	
>= 65			
Total Patients	17	10	
Patients (%) With Events	10 (58.8%)	6 (60.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	7 (41.2%)	4 (40.0%)	
Median Time to First TEAE, months (95% CI)	2.10 (0.36, NR)	2.27 (0.03, NR)	
Hazard Ratio (95% CI)		0.686 (0.236, 1.997)	
p-value		0.4899	
Race *			0.7805
White			
Total Patients	34	26	
Patients (%) With Events	12 (35.3%)	15 (57.7%)	
Patients (%) Without Events (Censored)	22 (64.7%)	11 (42.3%)	
Median Time to First TEAE, months (95% CI)	NR (4.47, NR)	5.09 (2.07, NR)	
Hazard Ratio (95% CI)		0.397 (0.178, 0.886)	
p-value		0.0200	
Other			
Total Patients	14	15	
Patients (%) With Events	7 (50.0%)	9 (60.0%)	
Patients (%) Without Events (Censored)	7 (50.0%)	6 (40.0%)	
Median Time to First TEAE, months (95% CI)	11.89 (0.26, NR)	2.20 (0.36, NR)	
Hazard Ratio (95% CI)		0.503 (0.166, 1.528)	
p-value		0.2102	
Baseline ECOG status			0.2933
0			
Total Patients	34	25	
Patients (%) With Events	13 (38.2%)	17 (68.0%)	
Patients (%) Without Events (Censored)	21 (61.8%)	8 (32.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (6.44, NR)	3.12 (1.41, 6.90)	
Hazard Ratio (95% CI)		0.286 (0.127, 0.644)	
p-value		0.0013	
1			
Total Patients	17	19	
Patients (%) With Events	8 (47.1%)	10 (52.6%)	
Patients (%) Without Events (Censored)	9 (52.9%)	9 (47.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.30, NR)	2.92 (1.97, NR)	
Hazard Ratio (95% CI)		0.733 (0.286, 1.884)	
p-value		0.5122	
History of liver metastasis			0.4133
Yes			
Total Patients	11	12	
Patients (%) With Events	3 (27.3%)	7 (58.3%)	
Patients (%) Without Events (Censored)	8 (72.7%)	5 (41.7%)	
Median Time to First TEAE, months (95% CI)	NR (0.99, NR)	2.07 (0.39, NR)	
Hazard Ratio (95% CI)		0.344 (0.087, 1.357)	
p-value		0.1114	
No			
Total Patients	40	32	
Patients (%) With Events	18 (45.0%)	20 (62.5%)	
Patients (%) Without Events (Censored)	22 (55.0%)	12 (37.5%)	
Median Time to First TEAE, months (95% CI)	12.78 (3.91, NR)	4.47 (1.97, 6.24)	
Hazard Ratio (95% CI)		0.451 (0.226, 0.898)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.0197	
PD-L1 Status			0.7781
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	6 (26.1%)	3 (50.0%)	
Patients (%) Without Events (Censored)	17 (73.9%)	3 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (11.89, NR)	9.13 (2.20, NR)	
Hazard Ratio (95% CI)		0.393 (0.092, 1.677)	
p-value		0.1914	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	15 (53.6%)	24 (63.2%)	
Patients (%) Without Events (Censored)	13 (46.4%)	14 (36.8%)	
Median Time to First TEAE, months (95% CI)	11.33 (2.10, NR)	2.92 (1.84, 5.75)	
Hazard Ratio (95% CI)		0.530 (0.266, 1.055)	
p-value		0.0668	
Menopausal status			0.6033
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	2 (25.0%)	8 (57.1%)	
Patients (%) Without Events (Censored)	6 (75.0%)	6 (42.9%)	
Median Time to First TEAE, months (95% CI)	NR (0.26, NR)	5.09 (0.39, NR)	
Hazard Ratio (95% CI)		0.304 (0.062, 1.483)	
p-value		0.1213	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	19 (44.2%)	19 (63.3%)	
Patients (%) Without Events (Censored)	24 (55.8%)	11 (36.7%)	
Median Time to First TEAE, months (95% CI)	12.78 (4.40, NR)	2.27 (1.84, 6.90)	
Hazard Ratio (95% CI)		0.417 (0.210, 0.826)	
p-value		0.0098	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
** Categories were merged for the following subgroup(s): Disease stratification: 'Recurrent disease within 6 to 12 months from completion of treatment in the curative setting' and 'Recurrent disease occurring > 12 months from completion of treatment in the curative setting' were combined into 'Recurrent disease' ('De novo' vs 'Recurrent disease'). Race: 'Asian' and 'Other' were combined into 'Other' ('White' vs 'Other').*
Data Cut Date: 22 APR 2026.

6.15. Table 1.1.12.4: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Age group			0.6771
< 65			
Total Patients	34	34	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	25 (73.5%)	10 (29.4%)	
Patients (%) Without Events (Censored)	9 (26.5%)	24 (70.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 2.33)	13.34 (13.34, NR)	
Hazard Ratio (95% CI)		3.472 (1.651, 7.304)	
p-value		0.0006	
>= 65			
Total Patients	17	10	
Patients (%) With Events	8 (47.1%)	1 (10.0%)	
Patients (%) Without Events (Censored)	9 (52.9%)	9 (90.0%)	
Median Time to First TEAE, months (95% CI)	9.00 (0.72, NR)	NR (0.46, NR)	
Hazard Ratio (95% CI)		5.090 (0.624, 41.517)	
p-value		0.0911	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.16. Table 1.1.12.5: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Diarrhoea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
History of liver metastasis			0.0109
Yes			
Total Patients	11	12	
Patients (%) With Events	7 (63.6%)	0 (0.0%)	
Patients (%) Without Events (Censored)	4 (36.4%)	12 (100.0%)	
Median Time to First TEAE, months (95% CI)	0.79 (0.26, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0017	
No			
Total Patients	40	32	
Patients (%) With Events	24 (60.0%)	10 (31.2%)	
Patients (%) Without Events (Censored)	16 (40.0%)	22 (68.8%)	
Median Time to First TEAE, months (95% CI)	2.27 (0.72, 17.35)	NR (3.94, NR)	
Hazard Ratio (95% CI)		2.040 (0.970, 4.289)	
p-value		0.0555	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.17. Table 1.1.12.6: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Nausea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
PD-L1 Status			0.0671
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	13 (56.5%)	0 (0.0%)	
Patients (%) Without Events (Censored)	10 (43.5%)	6 (100.0%)	
Median Time to First TEAE, months (95% CI)	3.58 (0.53, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0305	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	18 (64.3%)	12 (31.6%)	
Patients (%) Without Events (Censored)	10 (35.7%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	2.33 (0.36, NR)	NR (3.09, NR)	
Hazard Ratio (95% CI)		2.297 (1.105, 4.773)	
p-value		0.0208	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased →

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.18. Table 1.1.13: Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Blood and lymphatic system disorders		
Total Patients	51	44
Patients (%) With Events	24 (47.1%)	7 (15.9%)
Patients (%) Without Events (Censored)	27 (52.9%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	22.34 (2.04, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.369 (1.445, 7.858)
p-value		0.0029
Febrile neutropenia		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.1161
Lymphopenia		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	2 (3.9%)	3 (6.8%)
Patients (%) Without Events (Censored)	49 (96.1%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.456 (0.075, 2.772)
p-value		0.3824
Neutropenia		
Total Patients	51	44
Patients (%) With Events	20 (39.2%)	3 (6.8%)
Patients (%) Without Events (Censored)	31 (60.8%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	22.34 (3.48, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		6.331 (1.872, 21.410)
p-value		0.0007
Gastrointestinal disorders		
Total Patients	51	44
Patients (%) With Events	10 (19.6%)	1 (2.3%)
Patients (%) Without Events (Censored)	41 (80.4%)	43 (97.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.71, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		6.915 (0.869, 55.004)
p-value		0.0342
Diarrhoea		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	0 (0.0%)
Patients (%) Without Events (Censored)	47 (92.2%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0630
Stomatitis		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.1714
General disorders and administration site conditions		
Total Patients	51	44
Patients (%) With Events	2 (3.9%)	3 (6.8%)
Patients (%) Without Events (Censored)	49 (96.1%)	41 (93.2%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (20.11, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.222 (0.023, 2.157)
p-value		0.1559
Infections and infestations		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	4 (9.1%)
Patients (%) Without Events (Censored)	46 (90.2%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.920 (0.245, 3.446)
p-value		0.9011
Investigations		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	3 (6.8%)
Patients (%) Without Events (Censored)	45 (88.2%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.158 (0.269, 4.989)
p-value		0.8439
Alanine aminotransferase increased		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	2 (4.5%)
Patients (%) Without Events (Censored)	46 (90.2%)	42 (95.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.338 (0.235, 7.608)
p-value		0.7422
Metabolism and nutrition disorders		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	1 (2.3%)
Patients (%) Without Events (Censored)	47 (92.2%)	43 (97.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.407 (0.381, 30.481)
p-value		0.2436
Respiratory, thoracic and mediastinal disorders		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	3 (6.8%)
Patients (%) Without Events (Censored)	47 (92.2%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		1.030 (0.230, 4.617)
p-value		0.9697

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.19. Table 1.1.14: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

No Eligible Subgroups

6.20. Table 1.1.15: Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Blood and lymphatic system disorders		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC

	SG (N=51)	TPC (N=44)
p-value		0.1242
Gastrointestinal disorders		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	0 (0.0%)
Patients (%) Without Events (Censored)	45 (88.2%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0211
Diarrhoea		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.1068
Infections and infestations		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	46 (90.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		

	SG (N=51)	TPC (N=44)
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.727 (0.209, 2.525)
p-value		0.6142

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.21. Table 1.1.16: Subgroup Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

No Eligible Subgroups

6.22. Table 1.1.17: Incidence of TEAE leading to Study Drug Discontinuation by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Number (%) of Participants with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	4 (7.8%)	6 (13.6%)
Gastrointestinal disorders	1 (2.0%)	0
Diarrhoea	1 (2.0%)	0
General disorders and administration site conditions	0	1 (2.3%)
Fatigue	0	1 (2.3%)
Infections and infestations	1 (2.0%)	1 (2.3%)

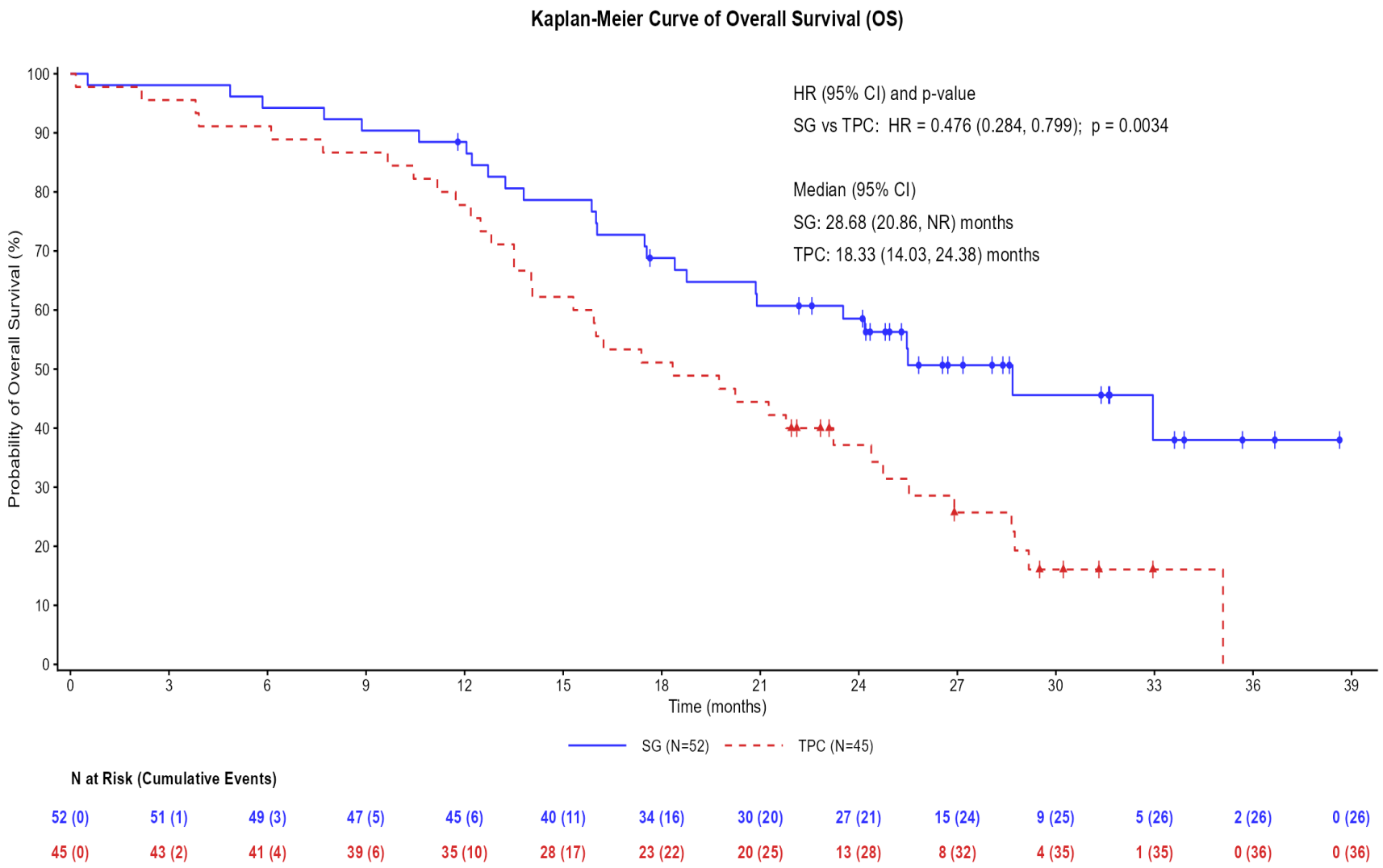
	SG (N=51)	TPC (N=44)
Nail bed infection	0	1 (2.3%)
Urosepsis	1 (2.0%)	0
Injury, poisoning and procedural complications	0	1 (2.3%)
Infusion related reaction	0	1 (2.3%)
Musculoskeletal and connective tissue disorders	0	1 (2.3%)
Musculoskeletal pain	0	1 (2.3%)
Nervous system disorders	0	1 (2.3%)
Neuropathy peripheral	0	1 (2.3%)
Psychiatric disorders	1 (2.0%)	0
Restlessness	1 (2.0%)	0
Respiratory, thoracic and mediastinal disorders	1 (2.0%)	0
Interstitial lung disease	1 (2.0%)	0
Skin and subcutaneous tissue disorders	0	1 (2.3%)
Skin oedema	0	1 (2.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Adverse events were coded according to MedDRA Version 27.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

7. KM FIGURES — Efficacy

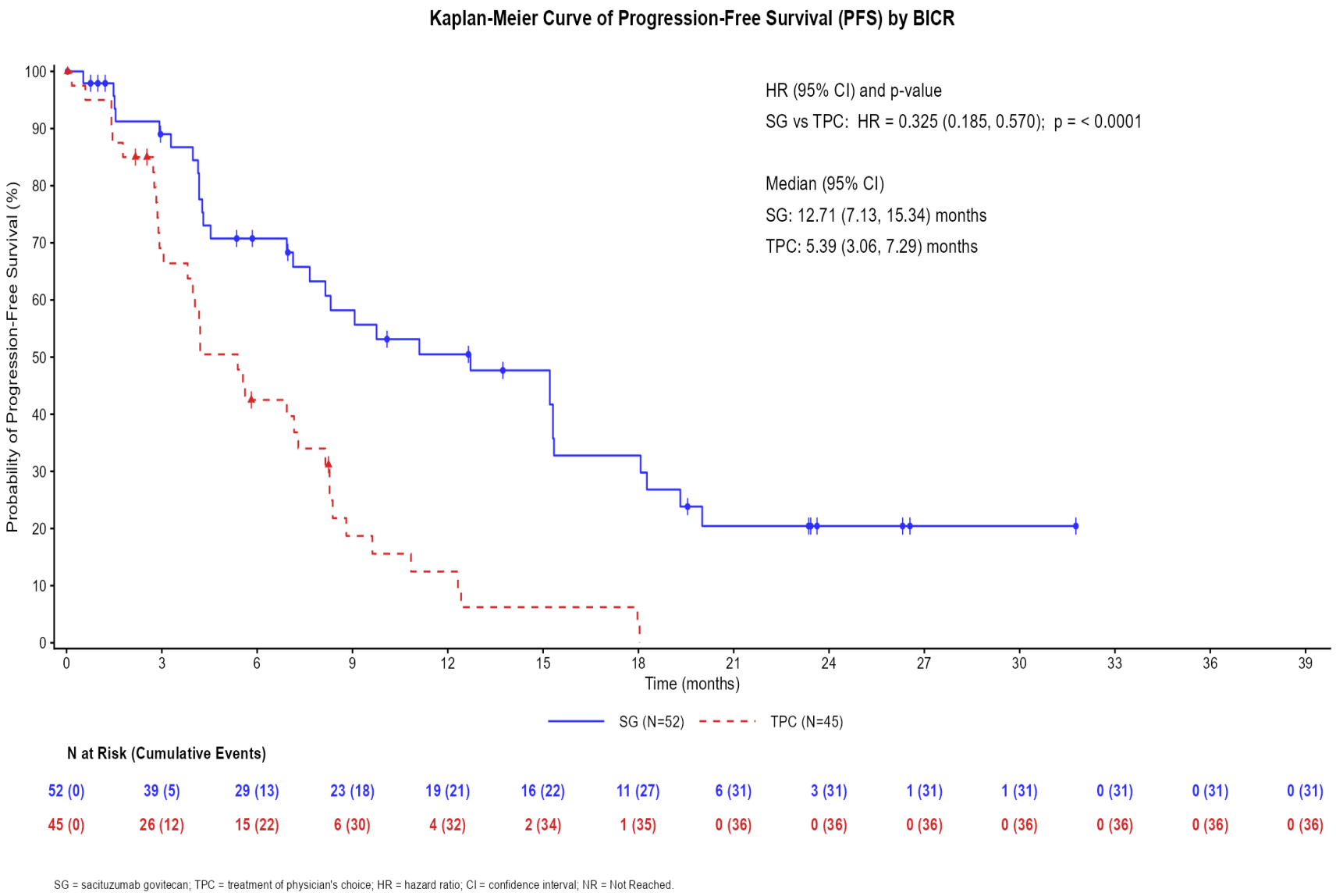
7.1. mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

7.2. Figure 1.1.1: Kaplan-Meier Curve of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



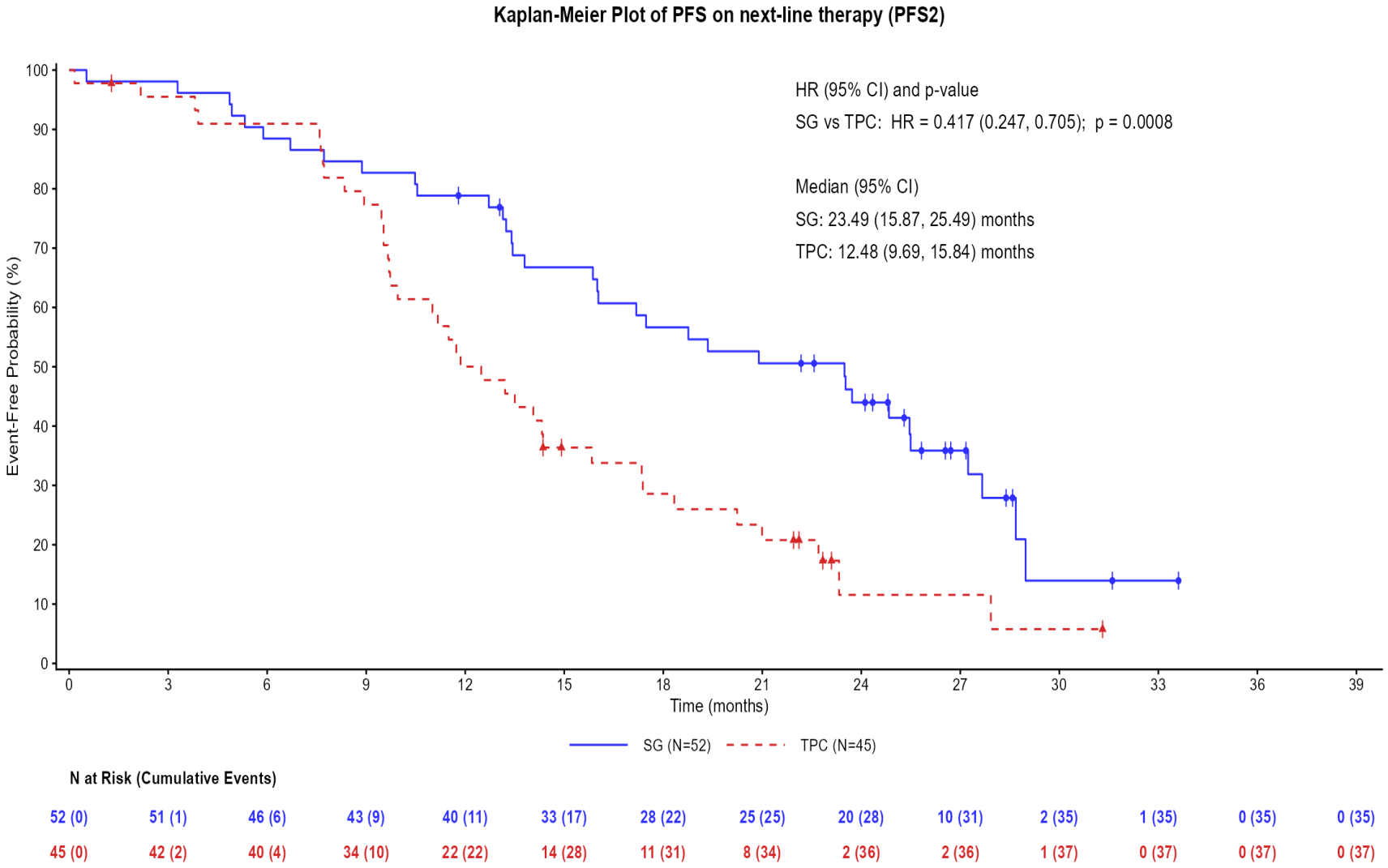
Two-sided p-value from the log-rank test stratified by the randomization stratification factors (STRAT1, STRAT2) from IWRS; hazard ratio from a Cox model adjusted for the same factors as covariates. SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.3. Figure 1.1.2: Kaplan-Meier Curve of Progression-Free Survival (PFS) by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



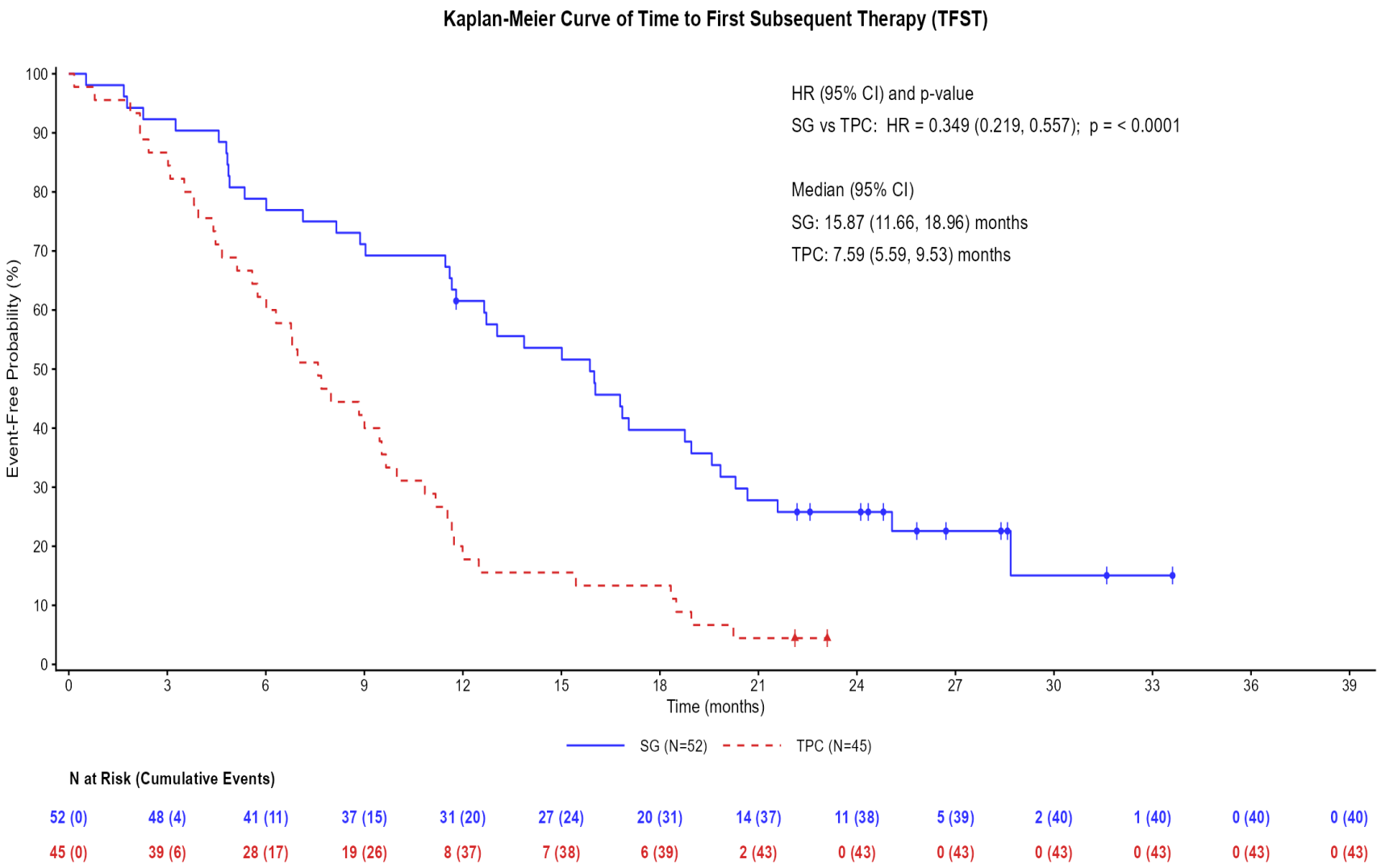
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.4. Figure 1.1.3: Kaplan-Meier Plot of PFS on next-line therapy (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



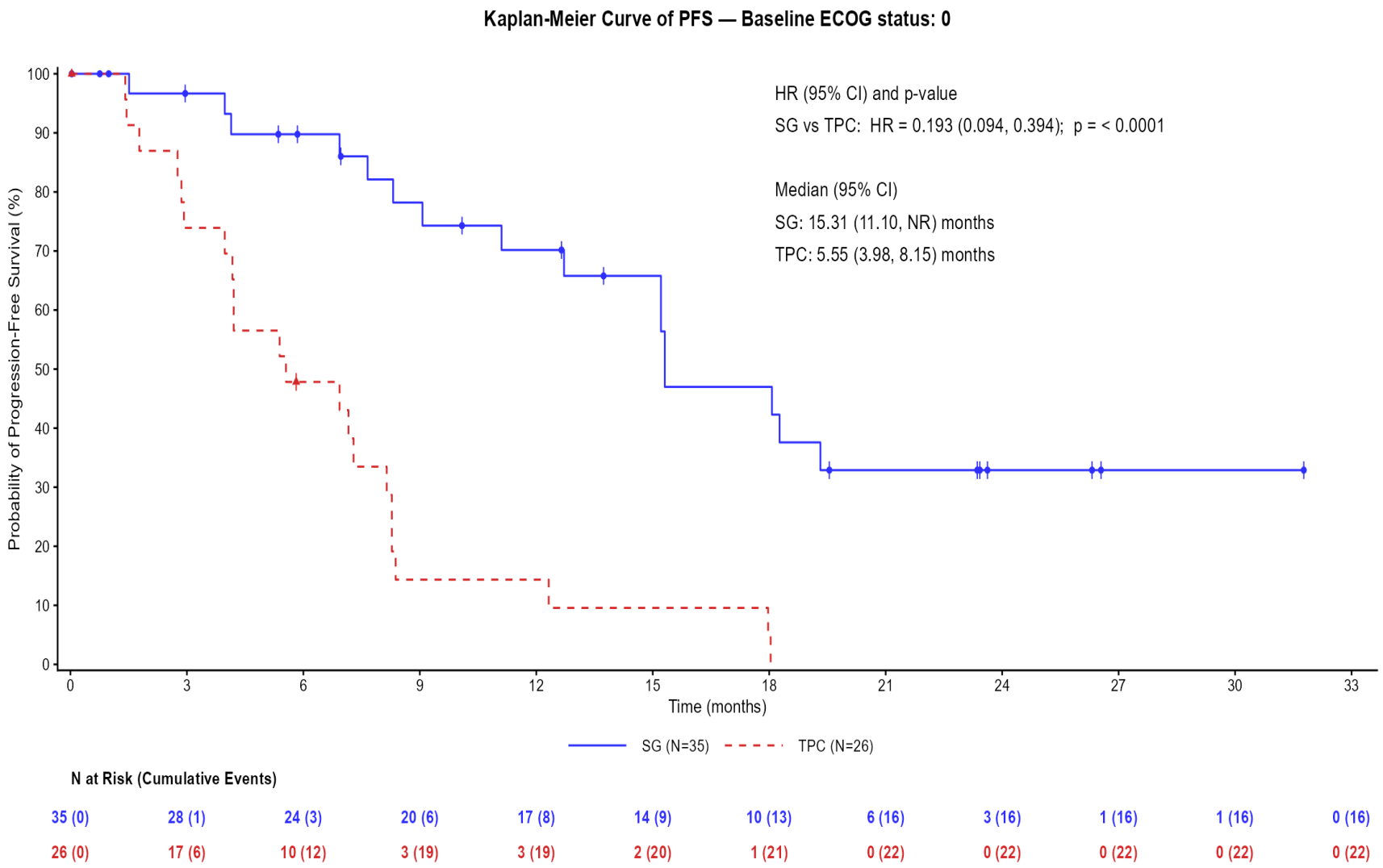
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.5. Figure 1.1.4: Kaplan-Meier Curve of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



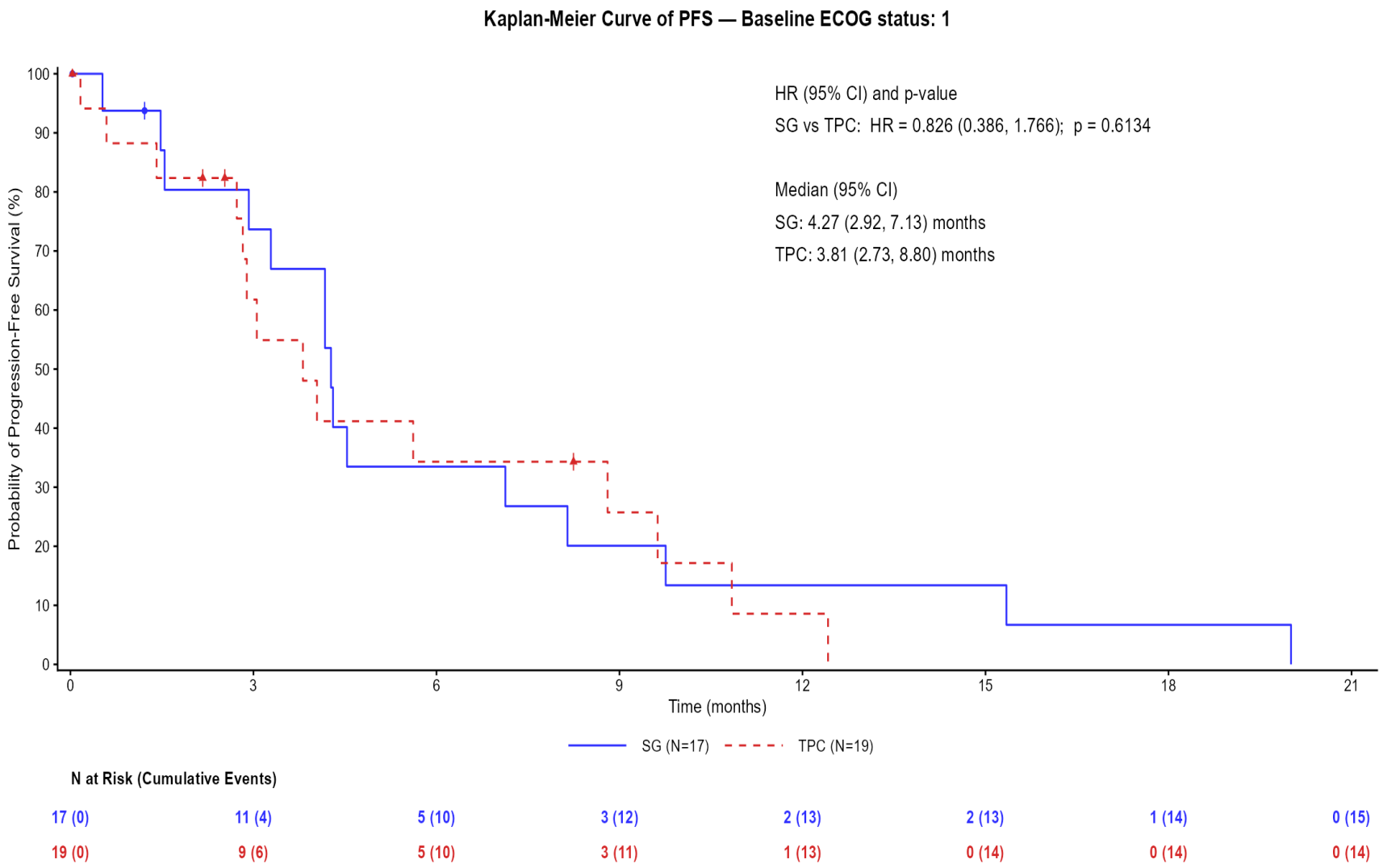
Two-sided p-value from the log-rank test stratified by the randomization stratification factors (STRAT1, STRAT2) from IWRS; hazard ratio from a Cox model adjusted for the same factors as covariates. SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.6. Figure 1.1.5: Kaplan-Meier Curve of PFS — Baseline ECOG status: 0 — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.7. Figure 1.1.6: Kaplan-Meier Curve of PFS — Baseline ECOG status: 1 — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

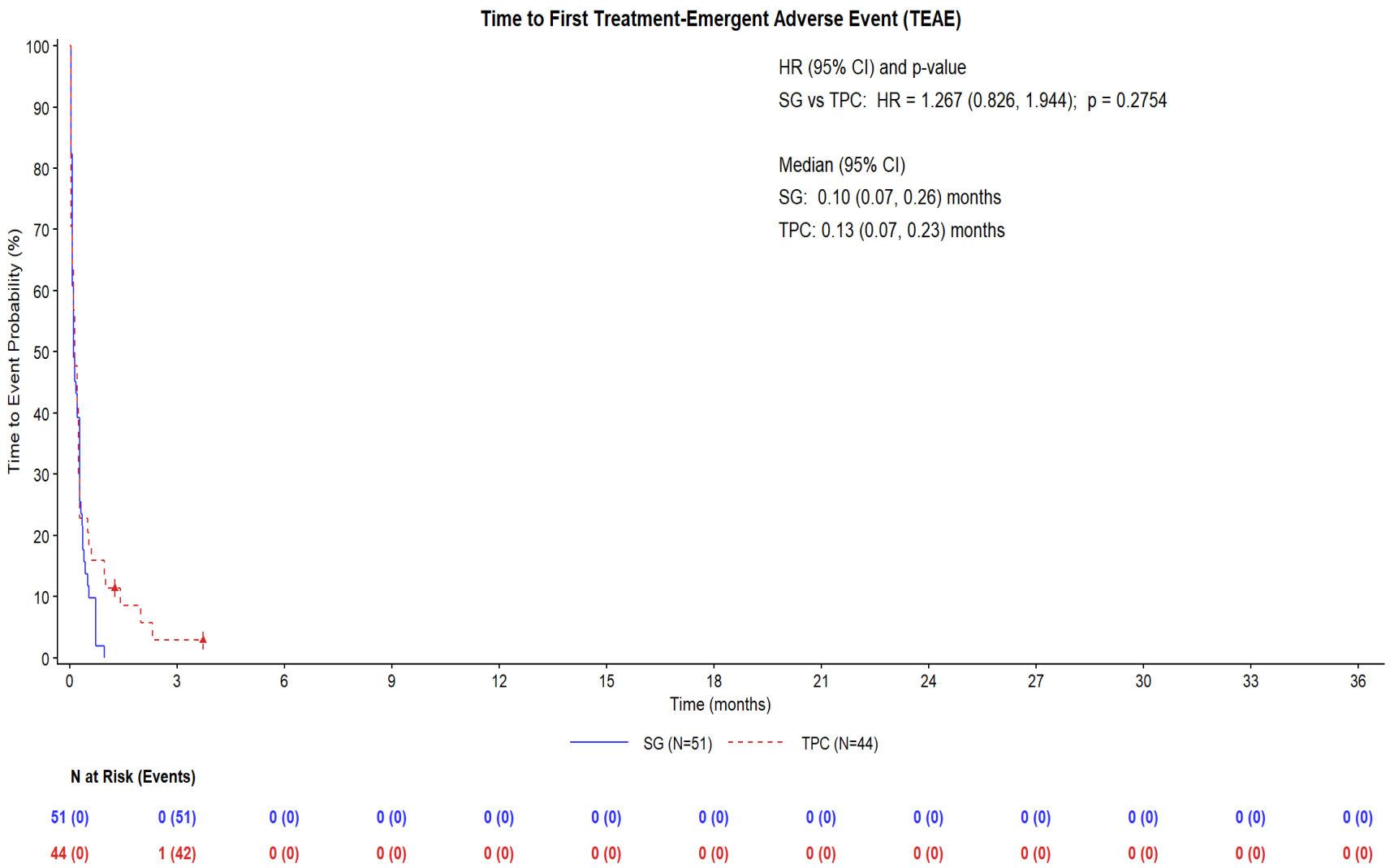


SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

8. KM FIGURES — Safety

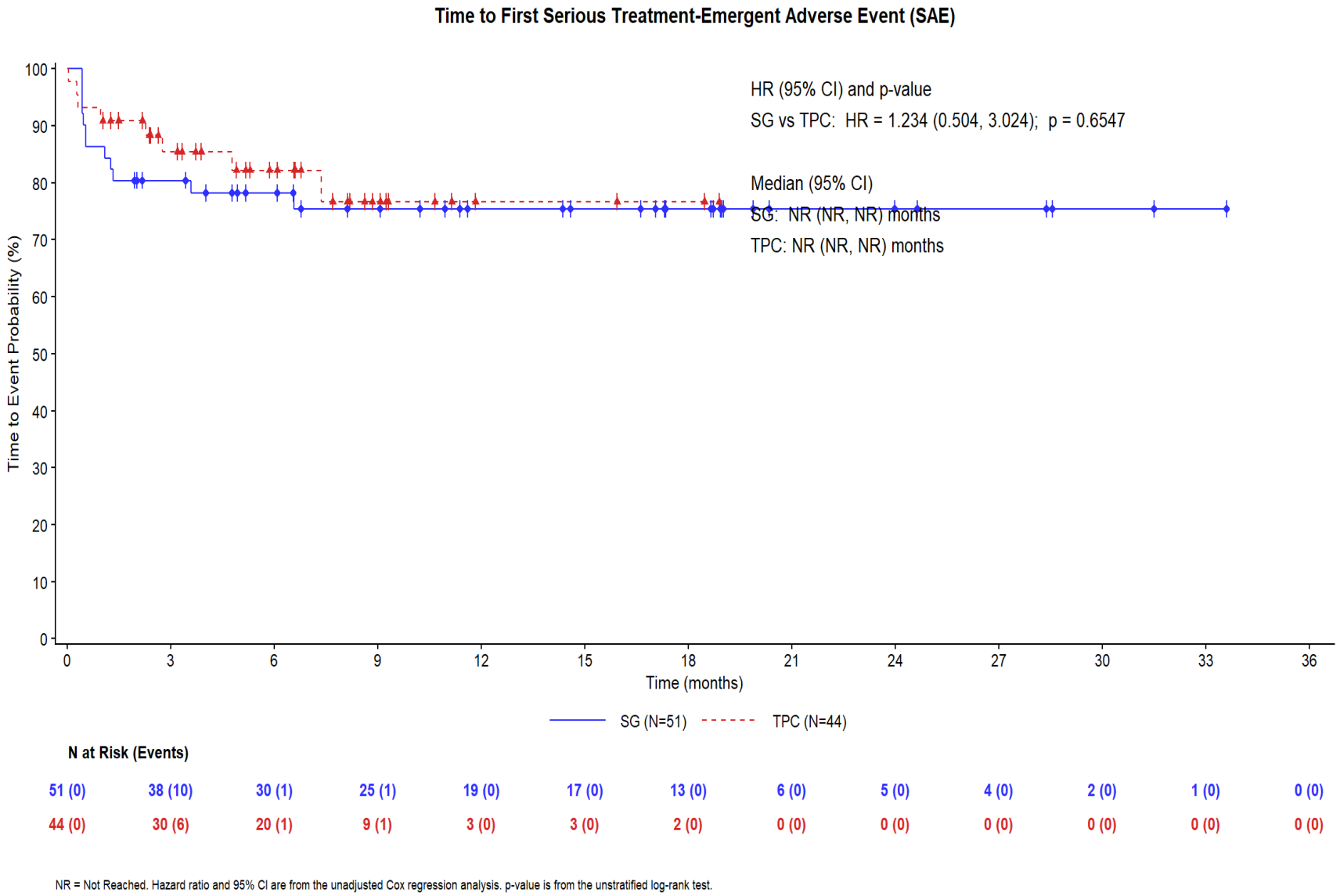
8.1. mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

8.2. Figure 1.1.1: Kaplan Meier Plot of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



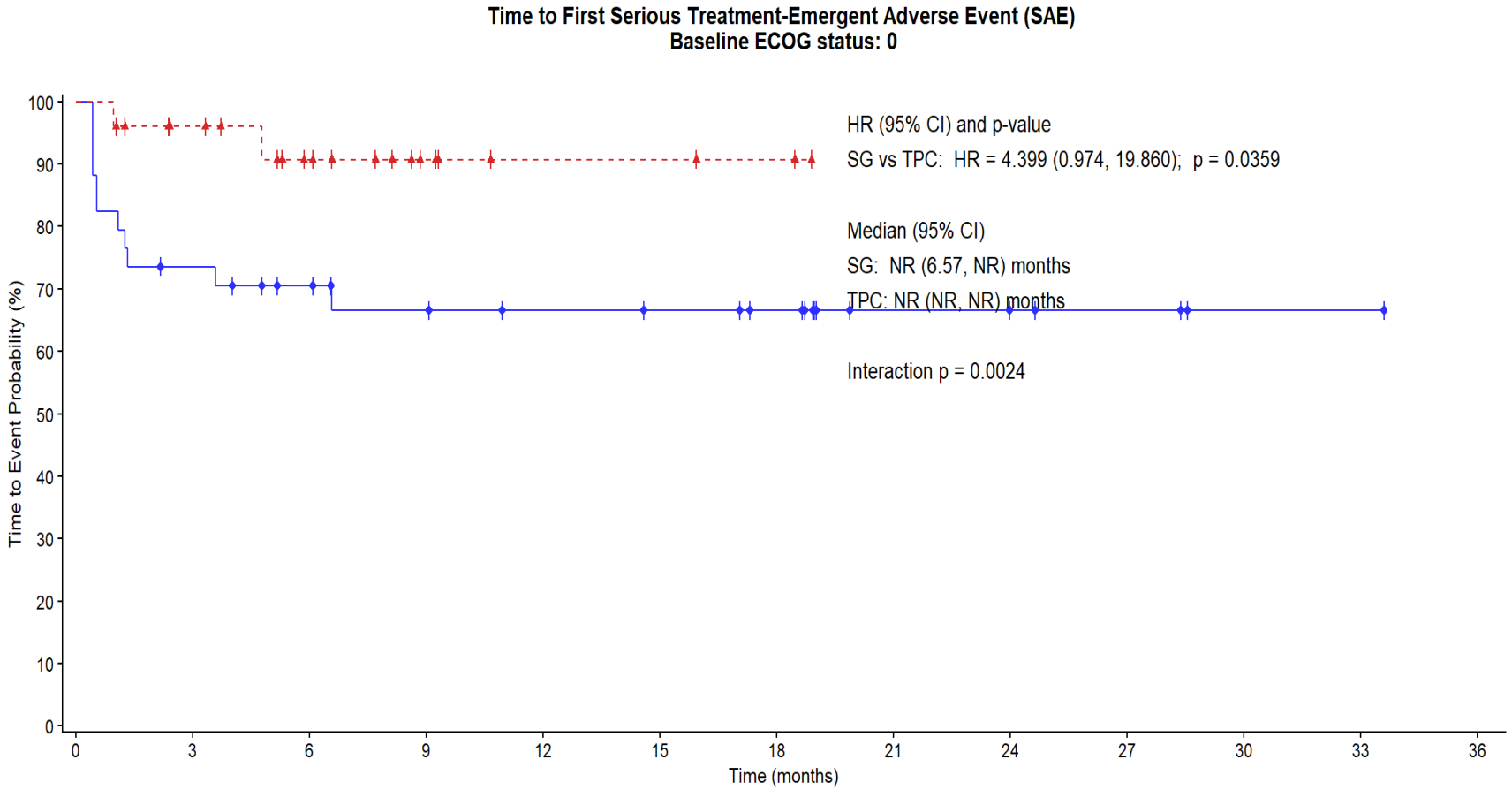
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.3. Figure 1.1.2: Kaplan Meier Plot of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



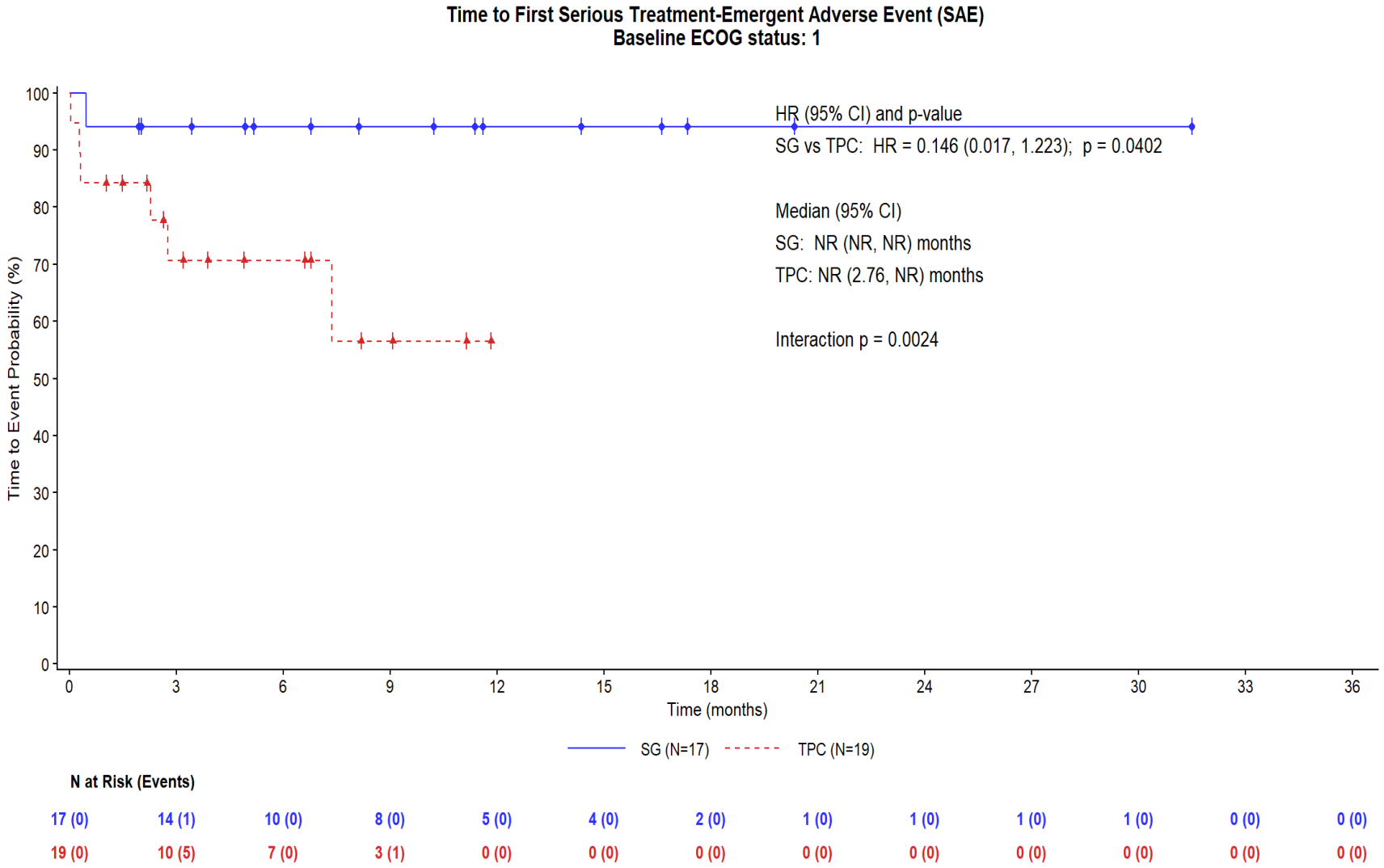
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.4. Figure 1.1.3: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Baseline ECOG status 0 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



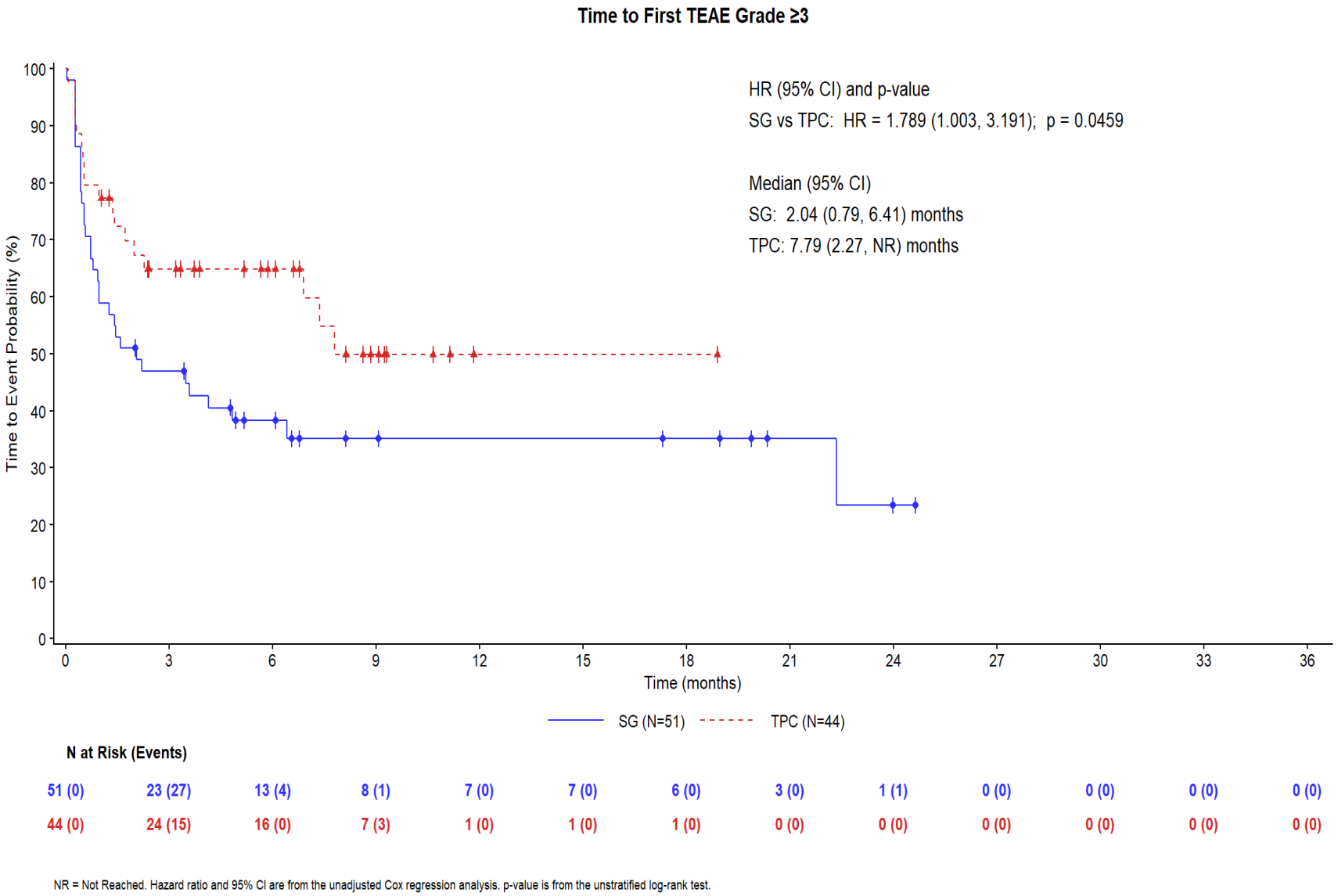
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.5. Figure 1.1.4: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Baseline ECOG status 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



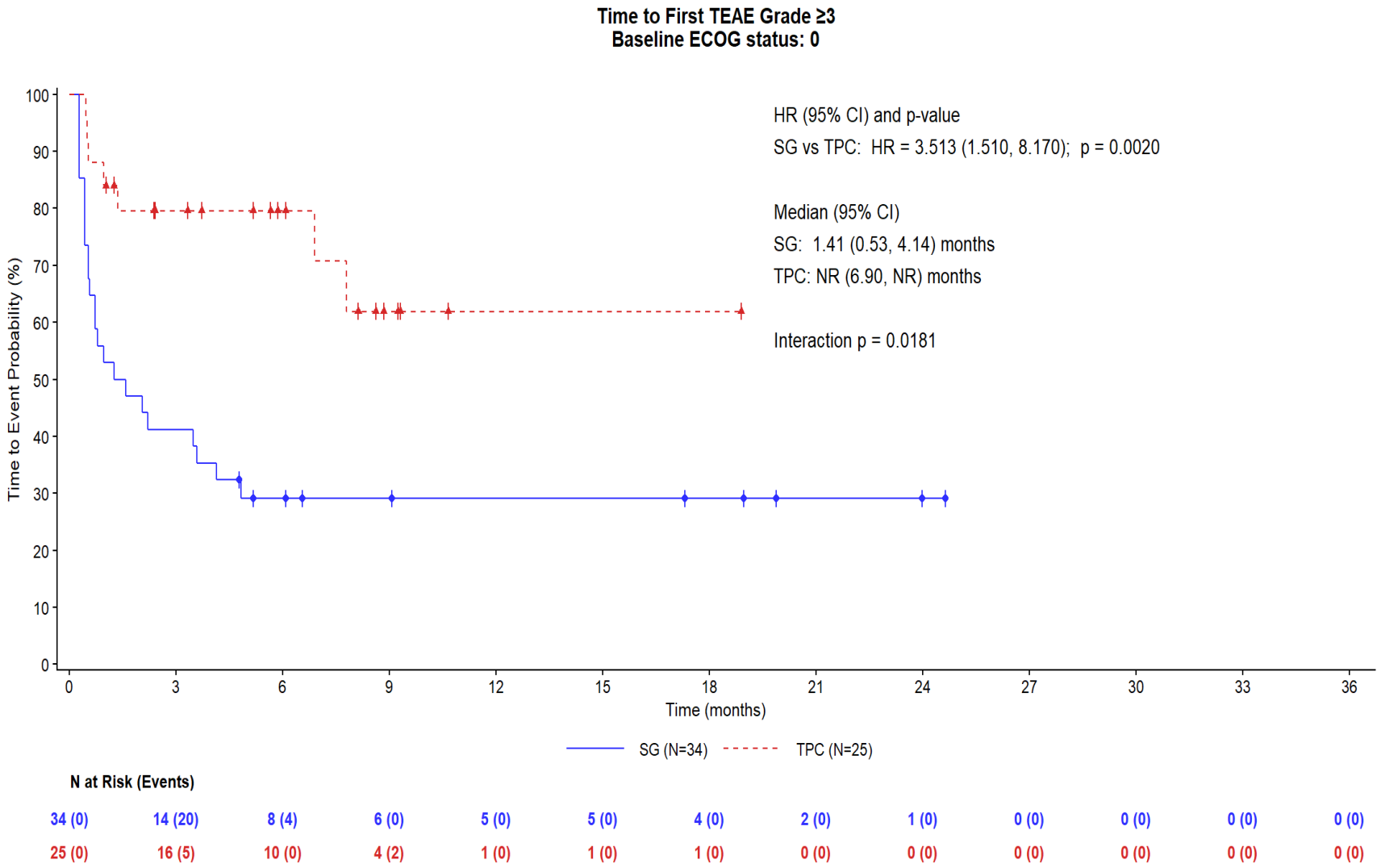
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.6. Figure 1.1.5: Kaplan Meier Plot of Time to First TEAE Grade 3 or higher — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



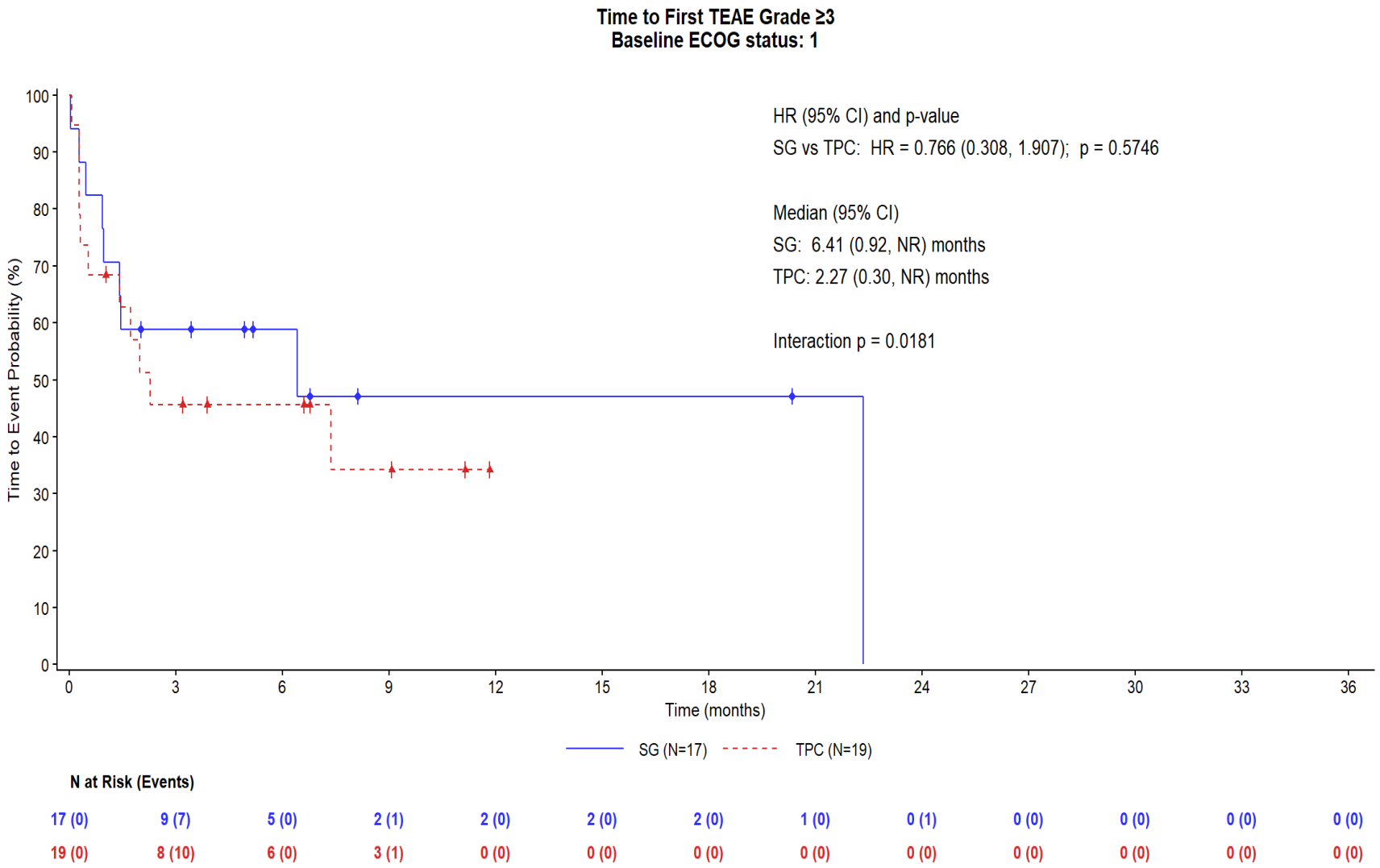
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.7. Figure 1.1.6: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Baseline ECOG status 0 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



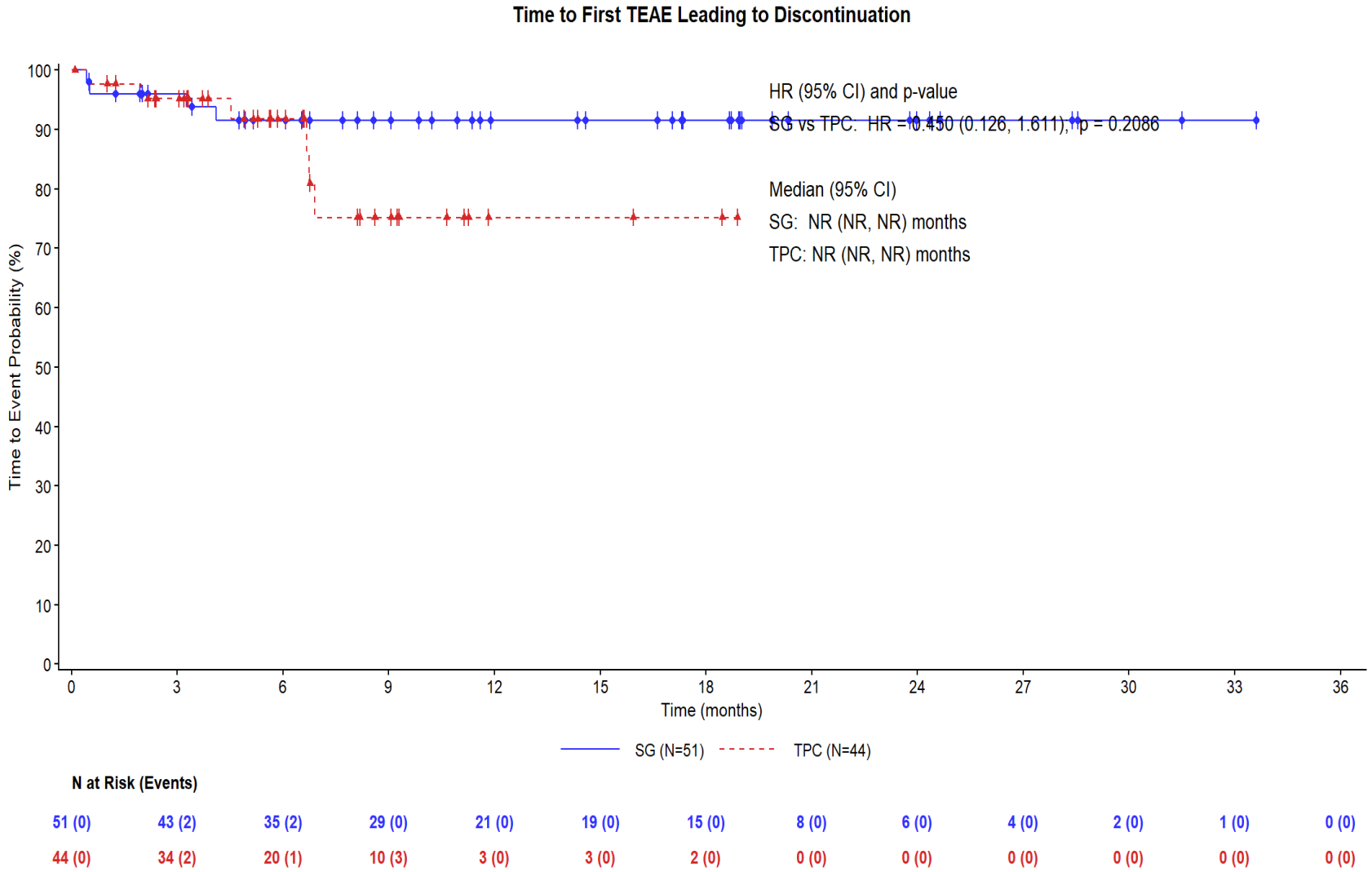
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.8. Figure 1.1.7: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Baseline ECOG status 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



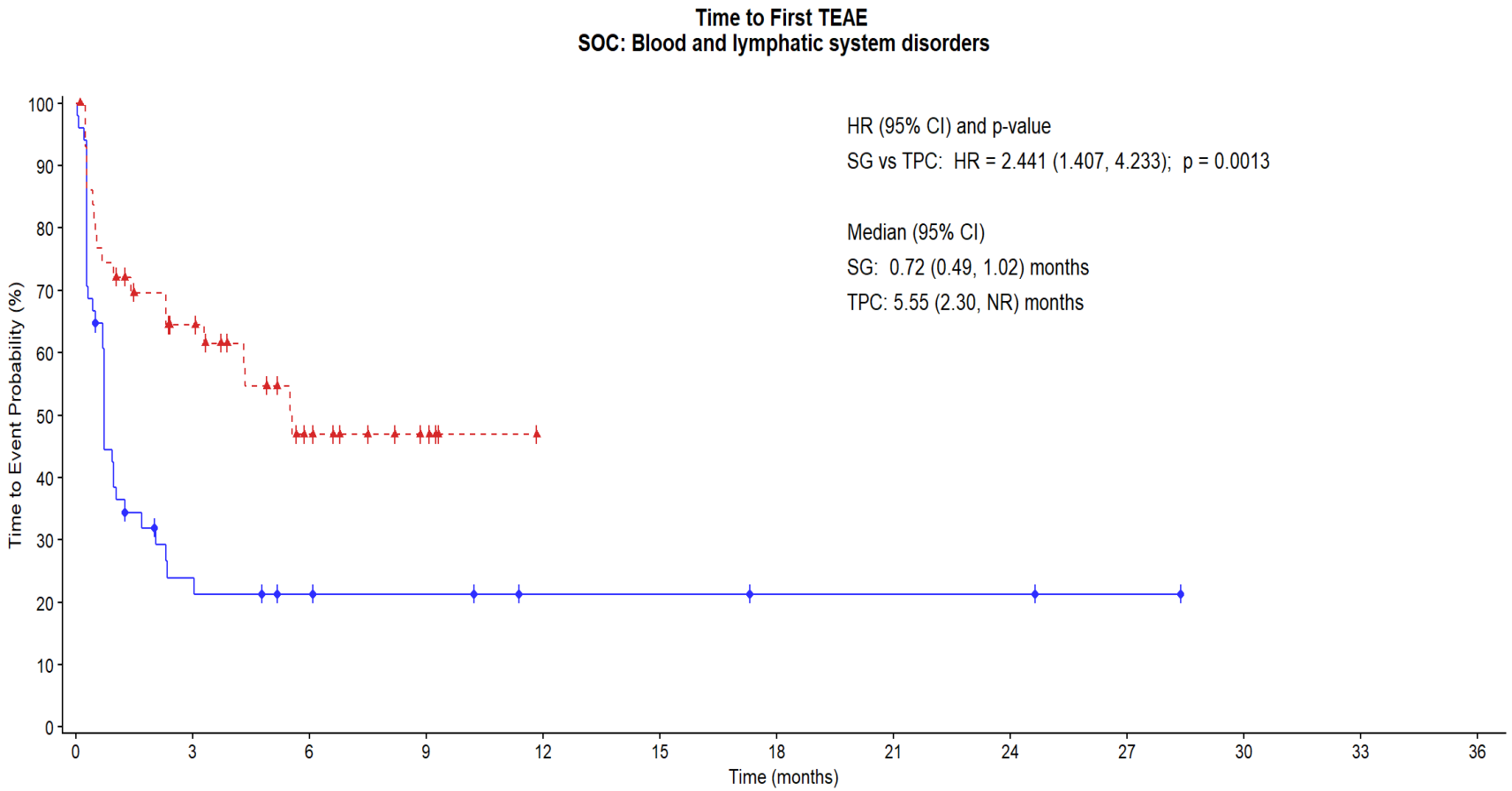
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.9. Figure 1.1.8: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



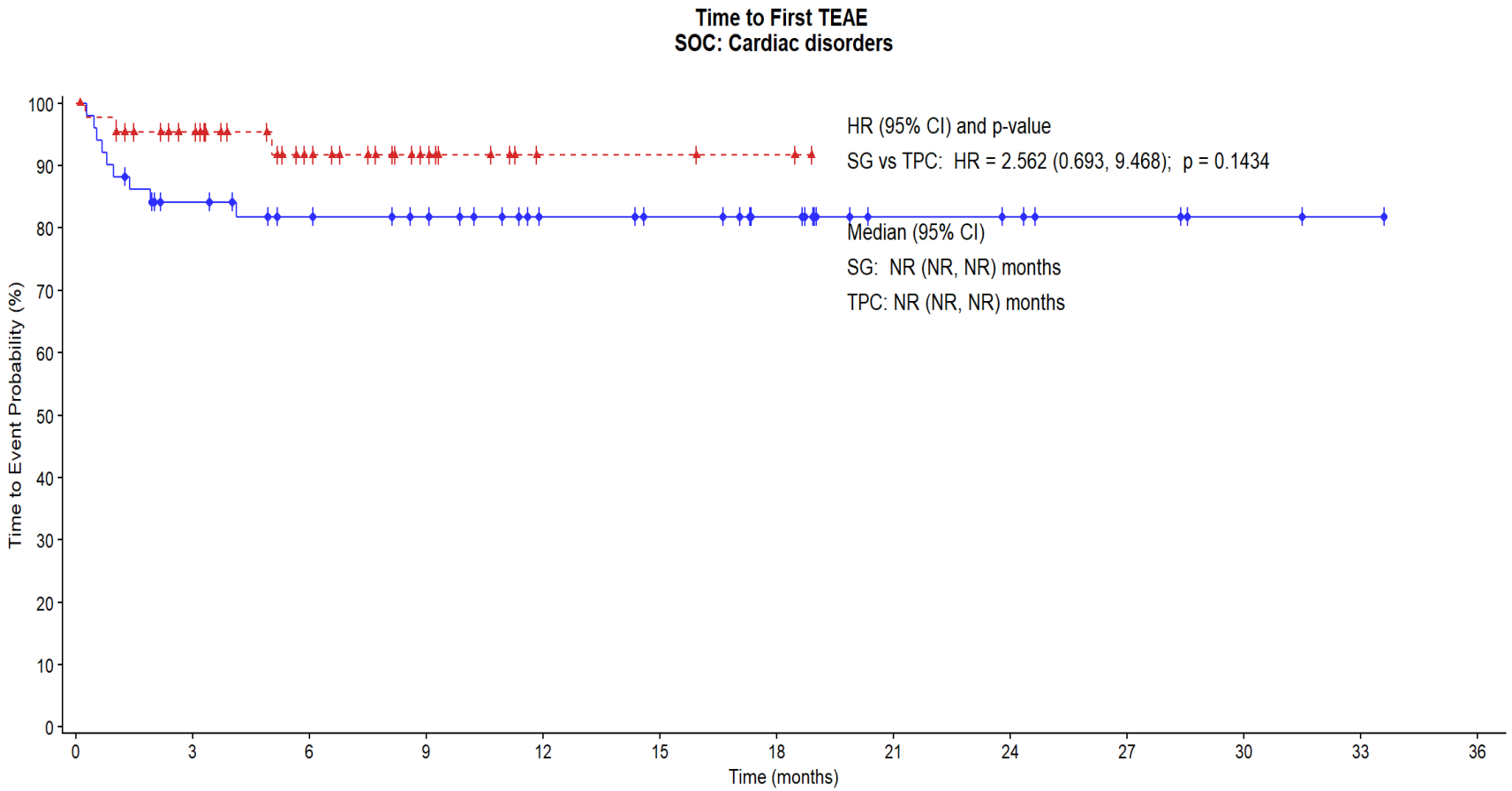
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.10. Figure 1.1.9: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



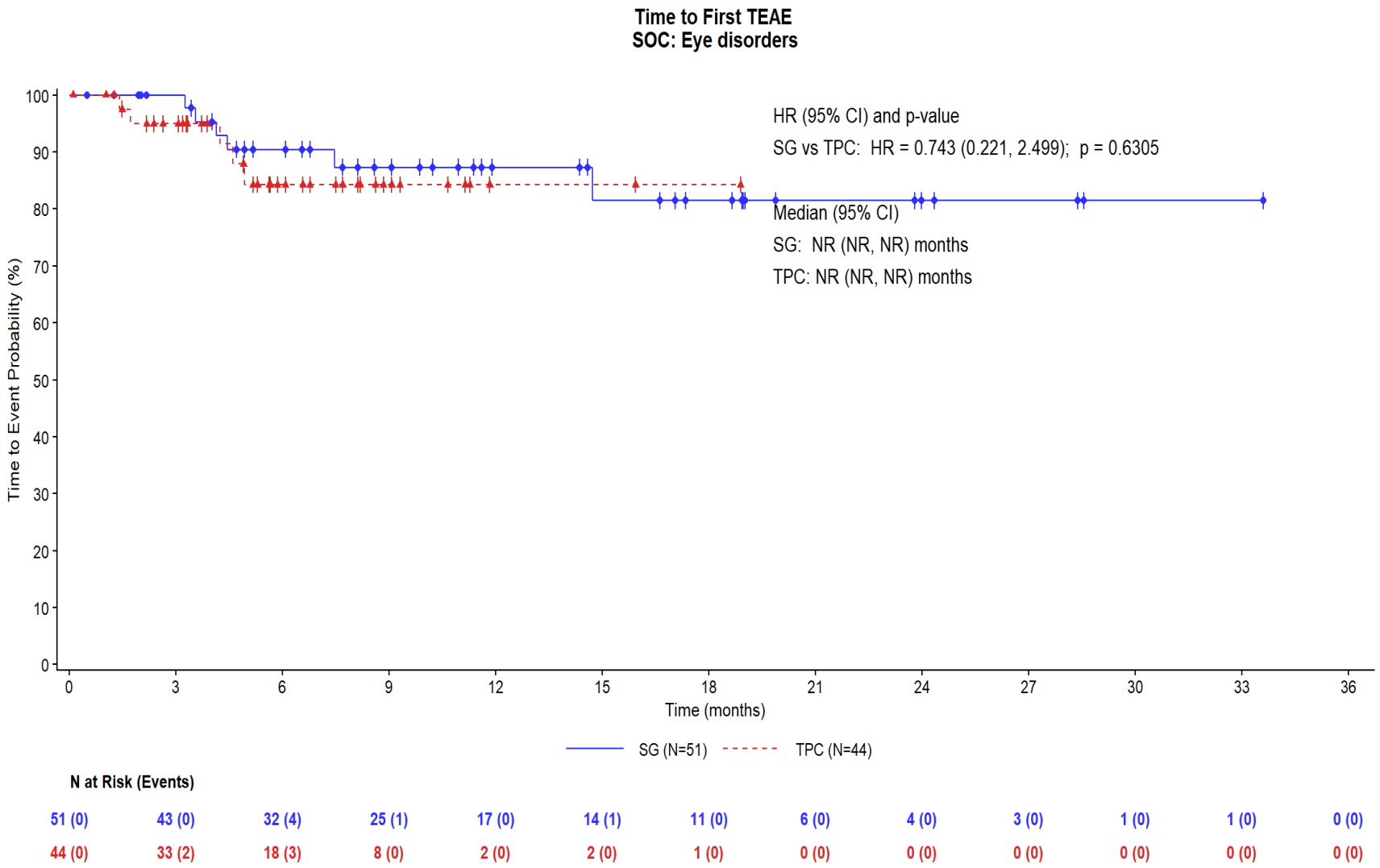
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.11. Figure 1.1.10: Kaplan Meier Plot of Time to First TEAE by SOC Cardiac disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



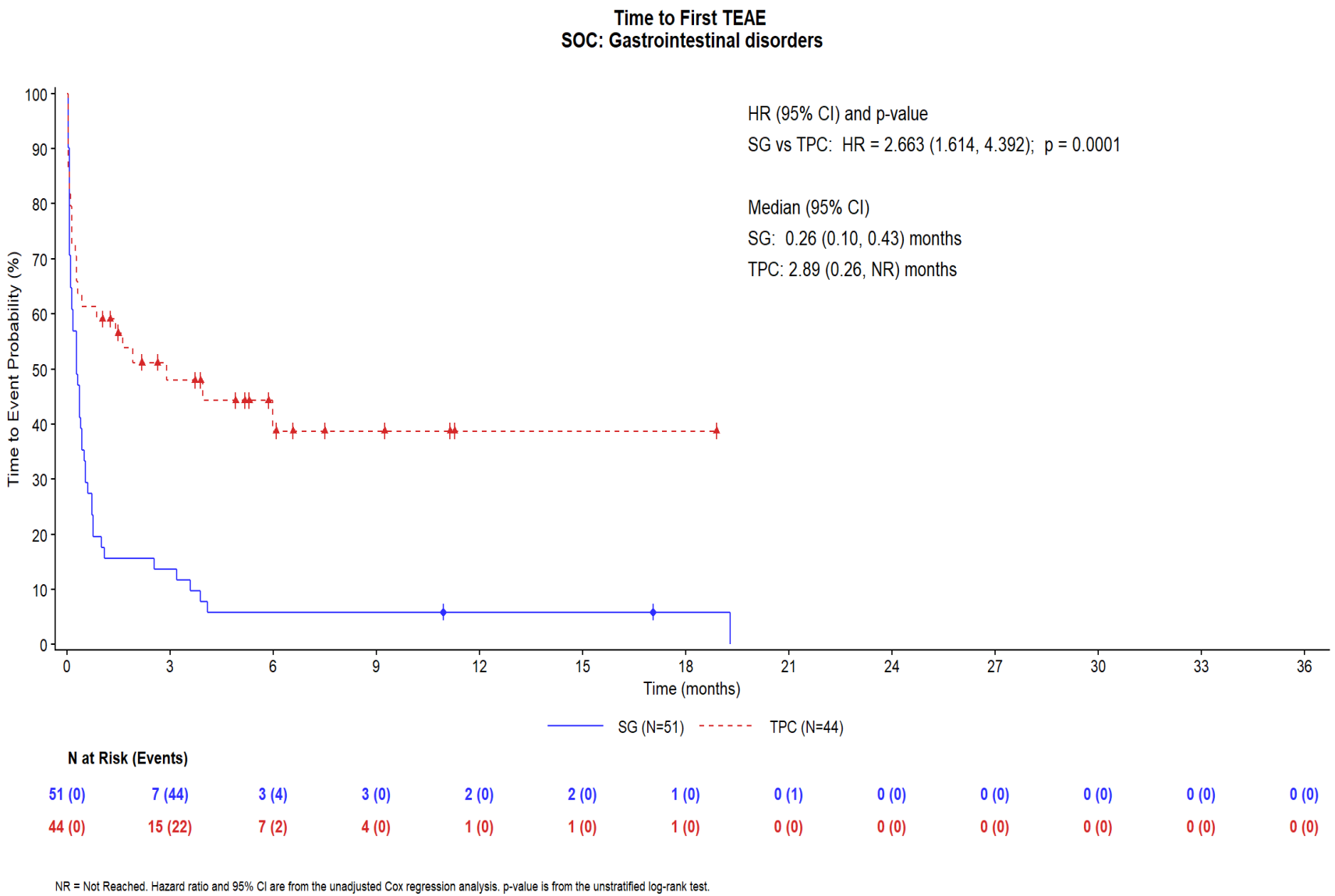
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.12. Figure 1.1.11: Kaplan Meier Plot of Time to First TEAE by SOC Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



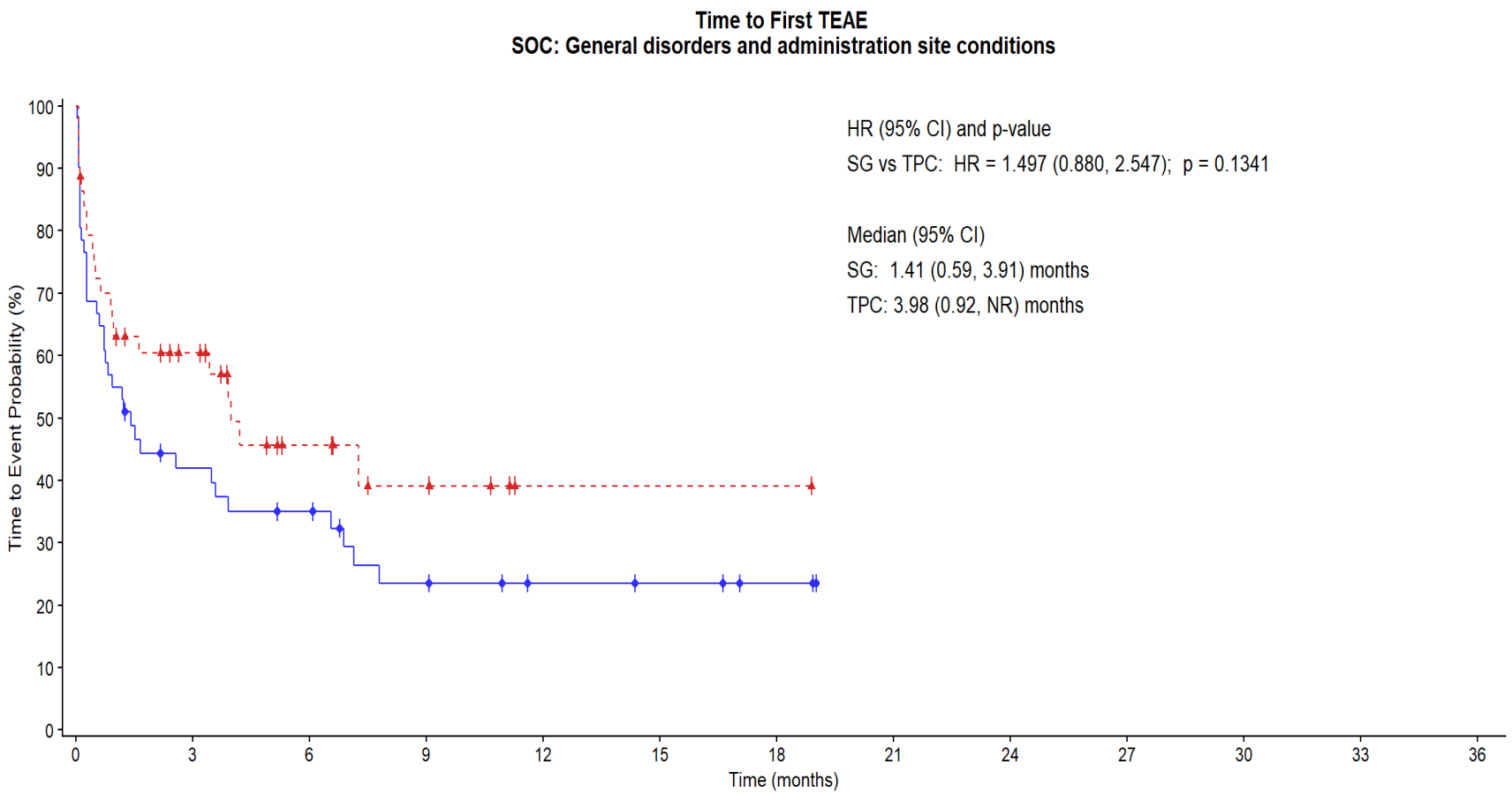
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.13. Figure 1.1.12: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



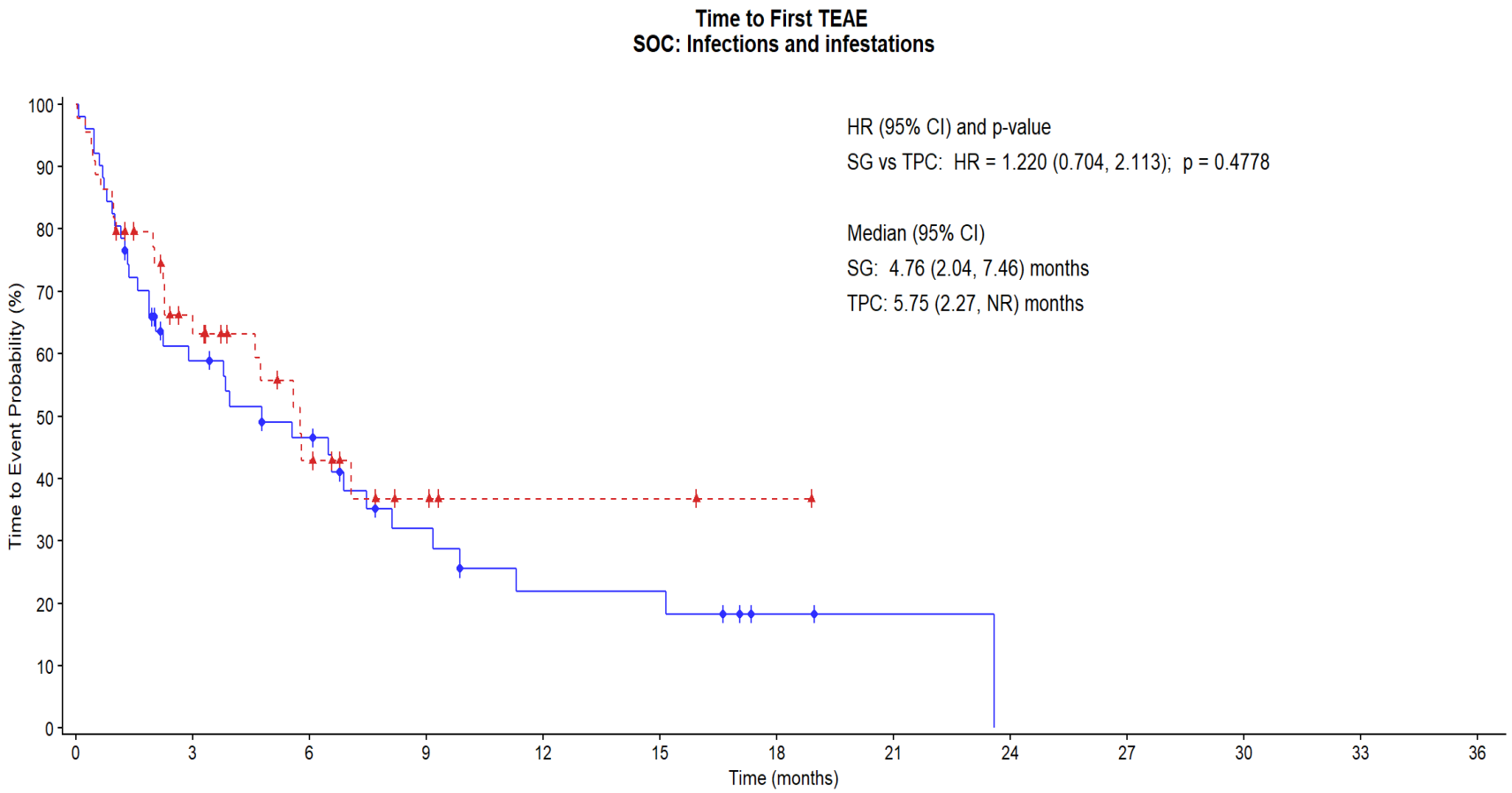
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.14. Figure 1.1.13: Kaplan Meier Plot of Time to First TEAE by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



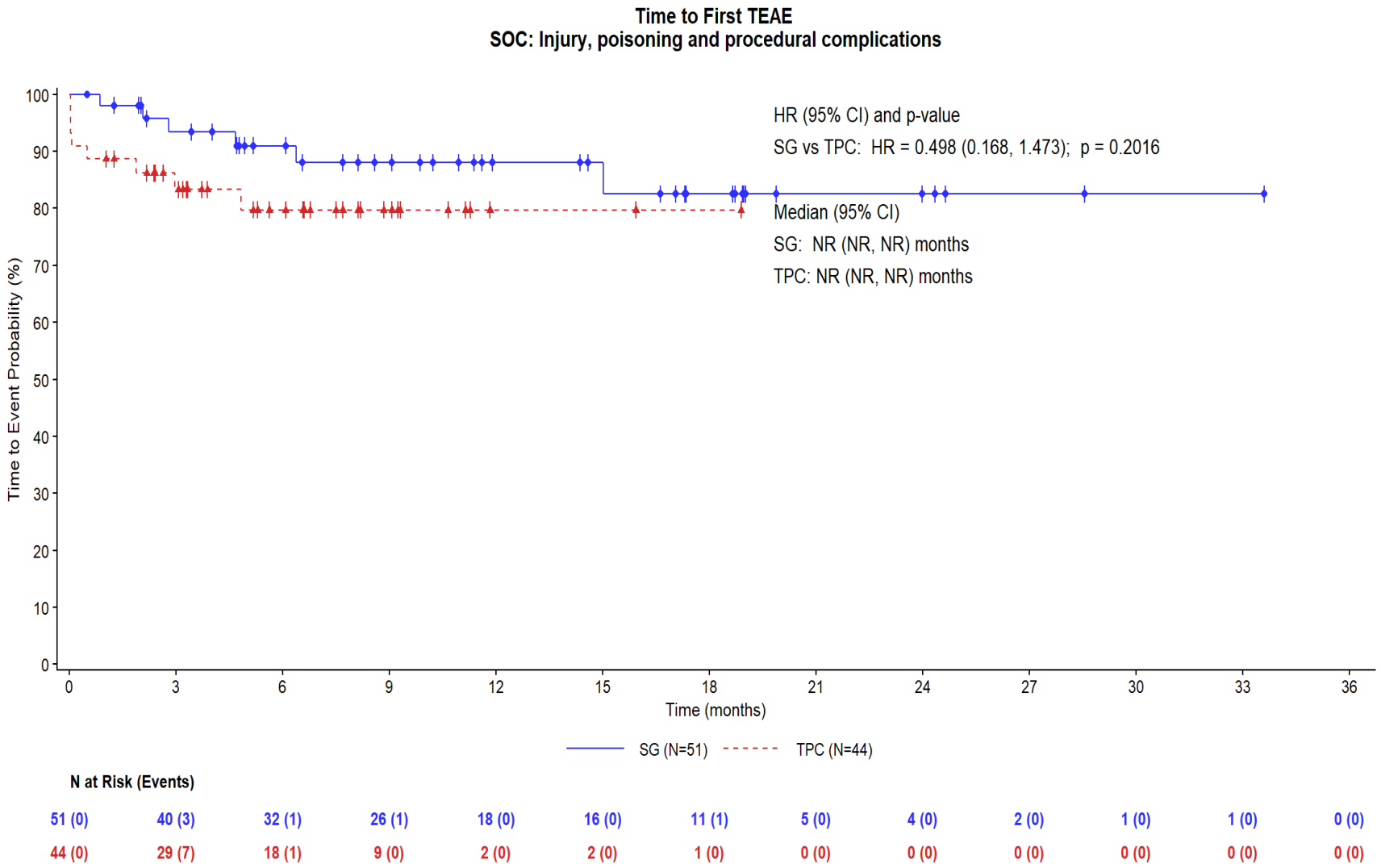
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.15. Figure 1.1.14: Kaplan Meier Plot of Time to First TEAE by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



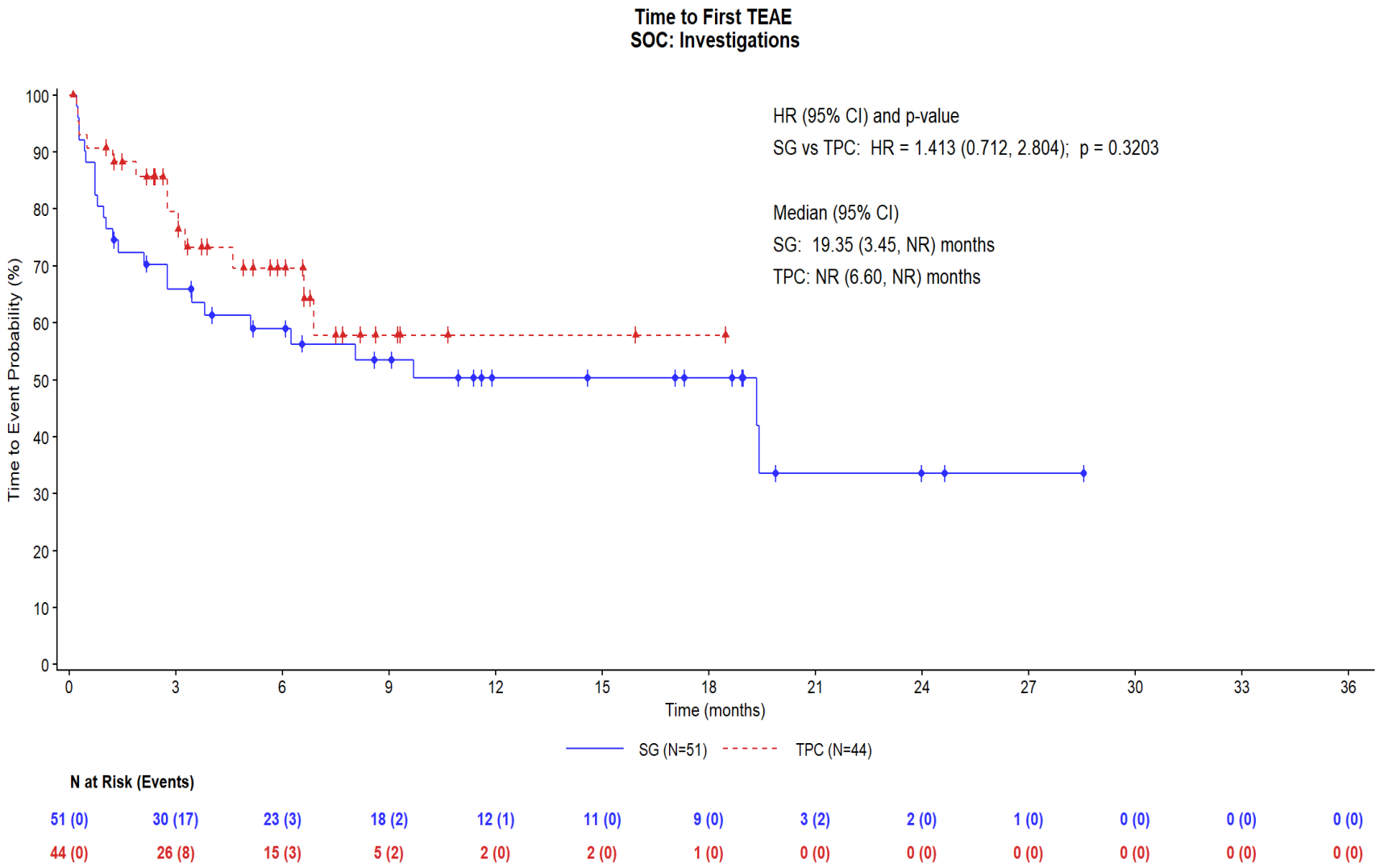
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.16. Figure 1.1.15: Kaplan Meier Plot of Time to First TEAE by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



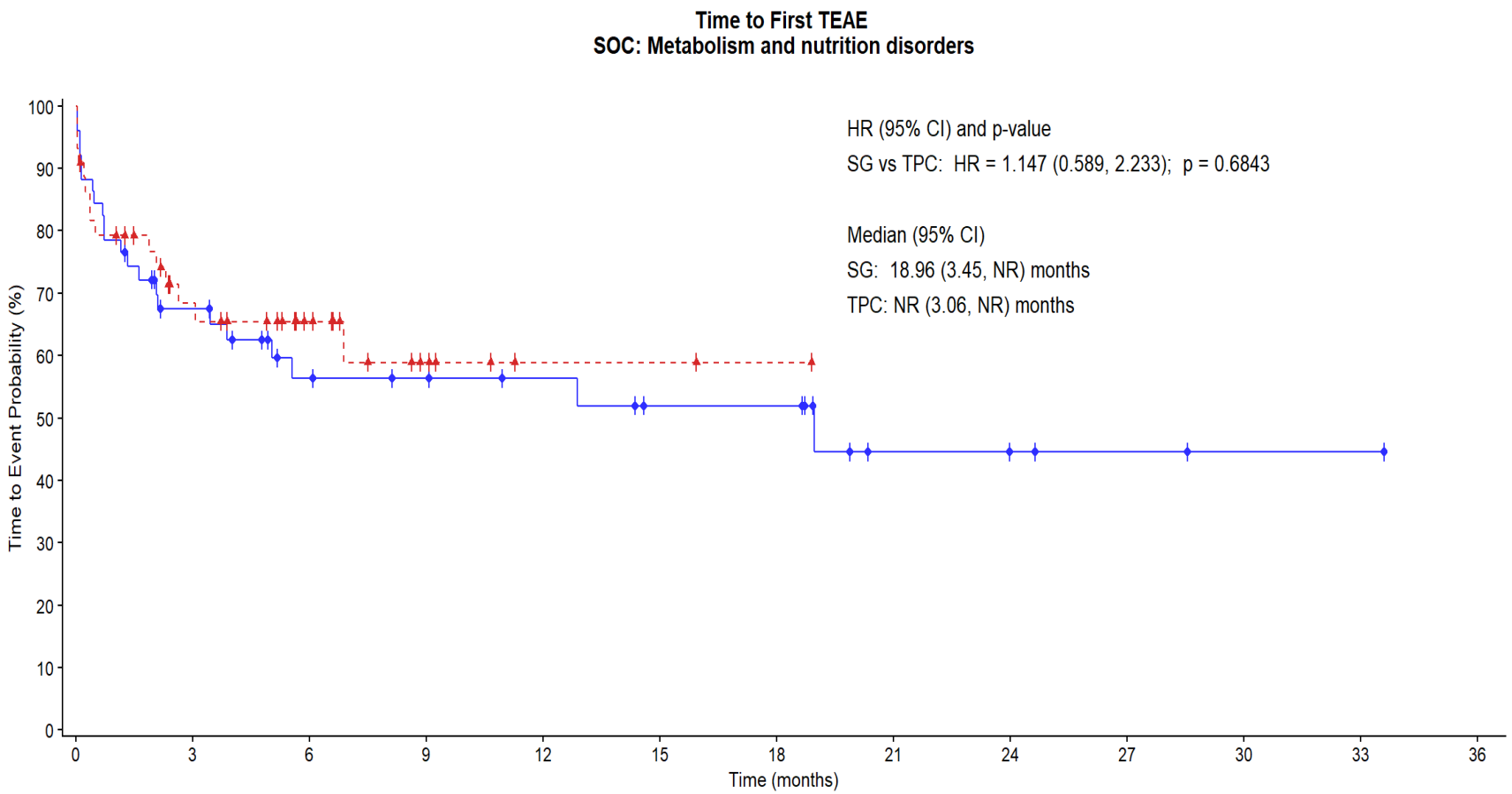
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.17. Figure 1.1.16: Kaplan Meier Plot of Time to First TEAE by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



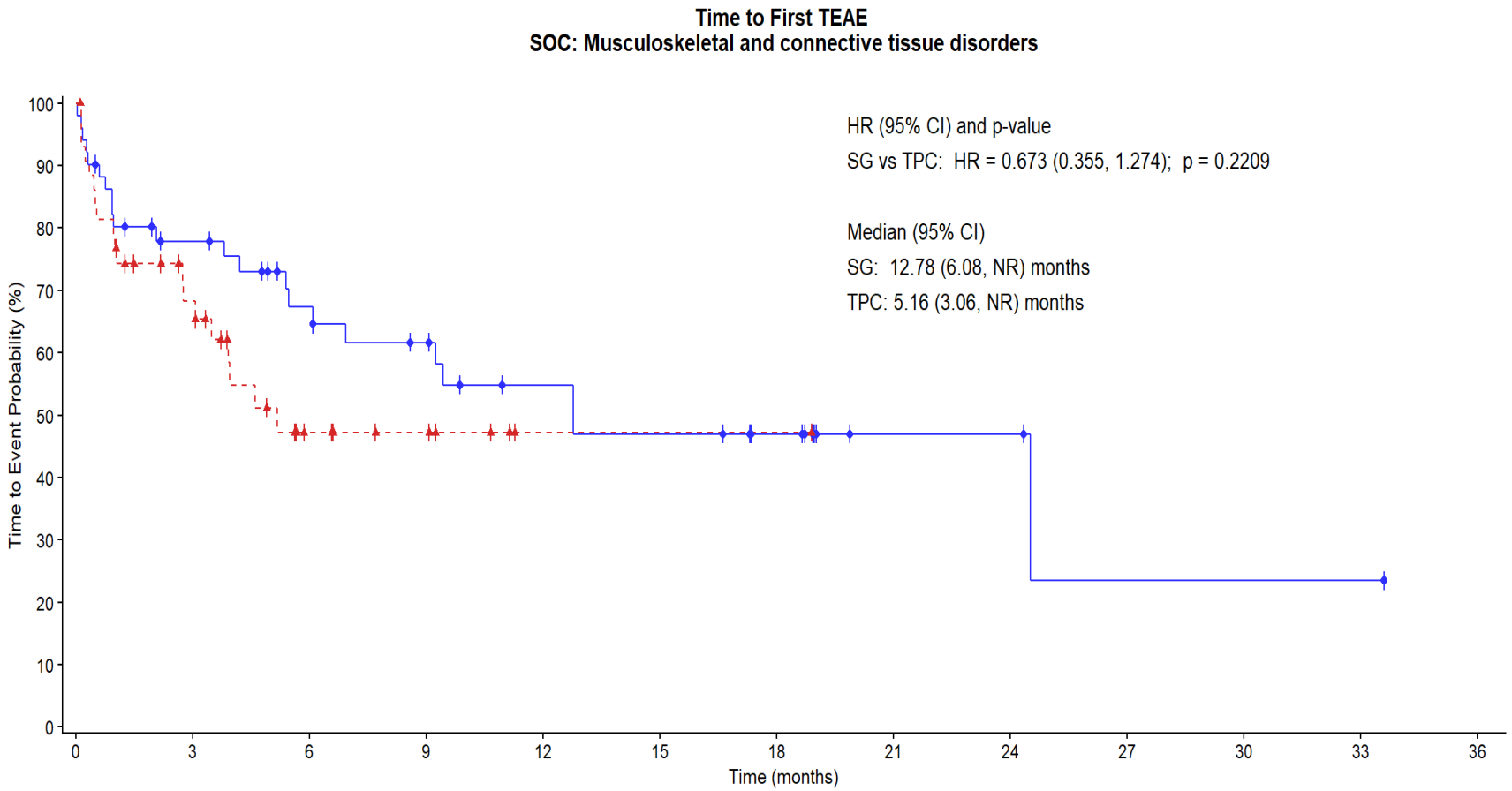
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.18. Figure 1.1.17: Kaplan Meier Plot of Time to First TEAE by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



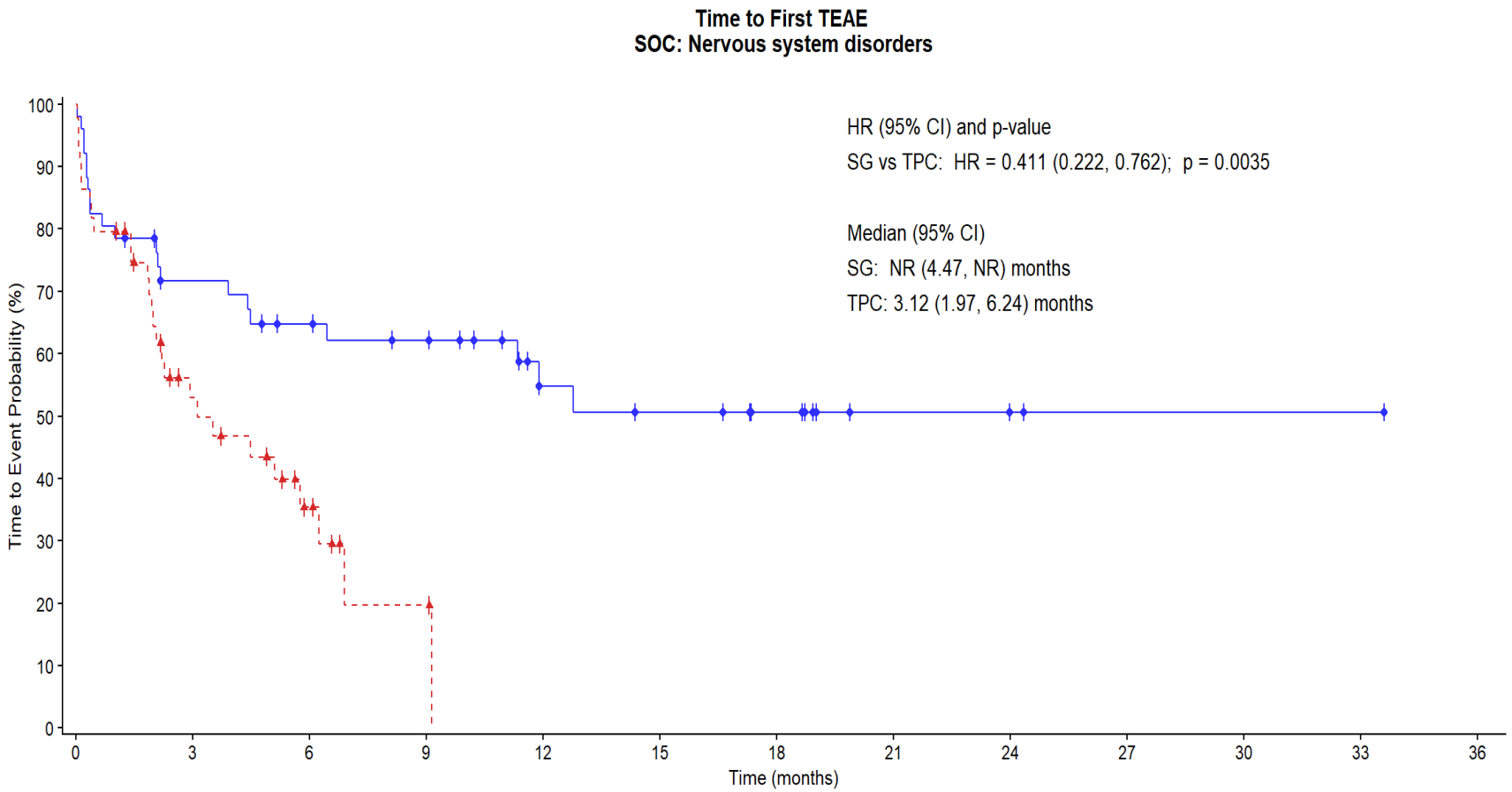
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.19. Figure 1.1.18: Kaplan Meier Plot of Time to First TEAE by SOC Musculoskeletal and connective tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



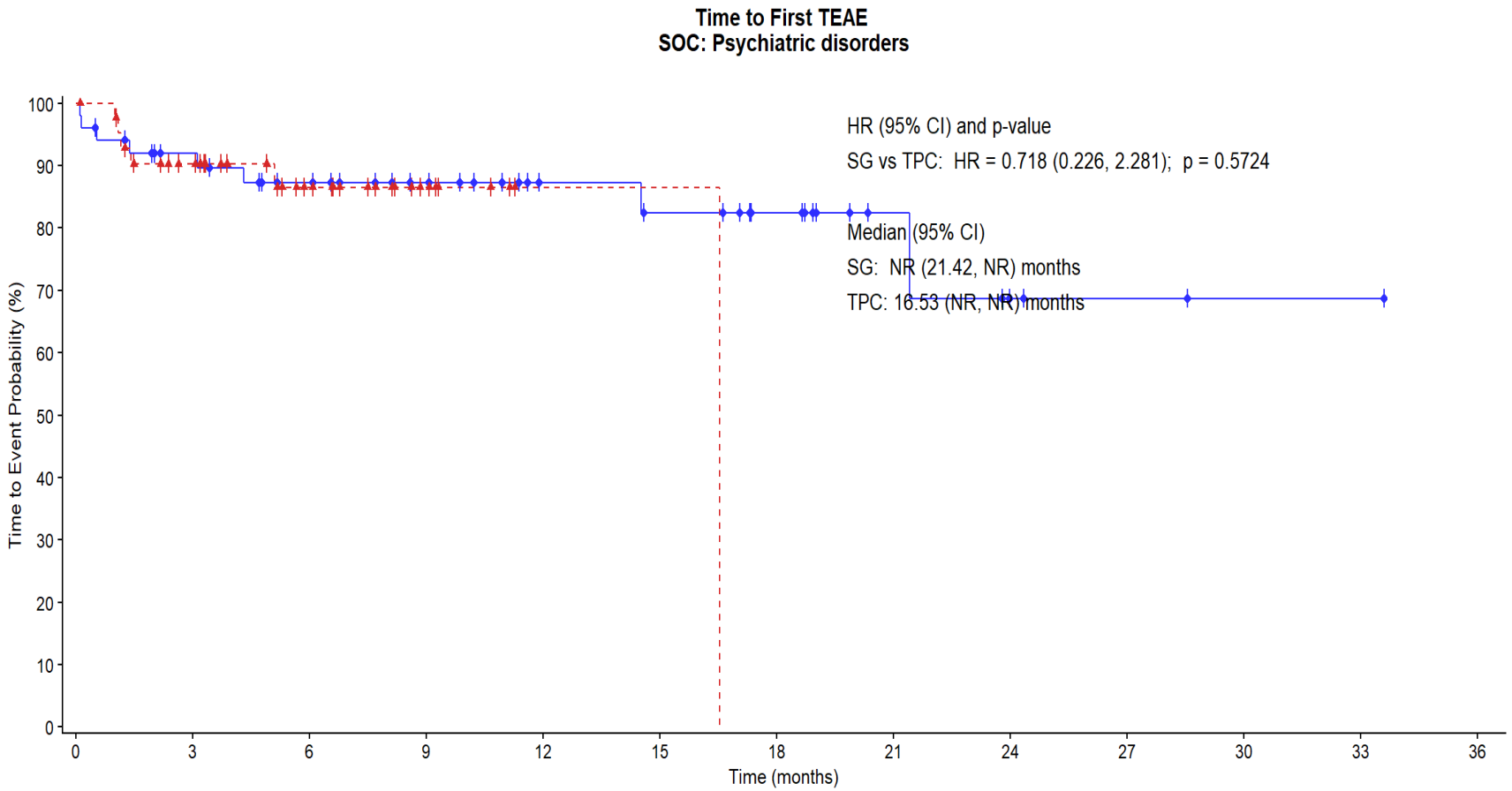
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.20. Figure 1.1.19: Kaplan Meier Plot of Time to First TEAE by SOC Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



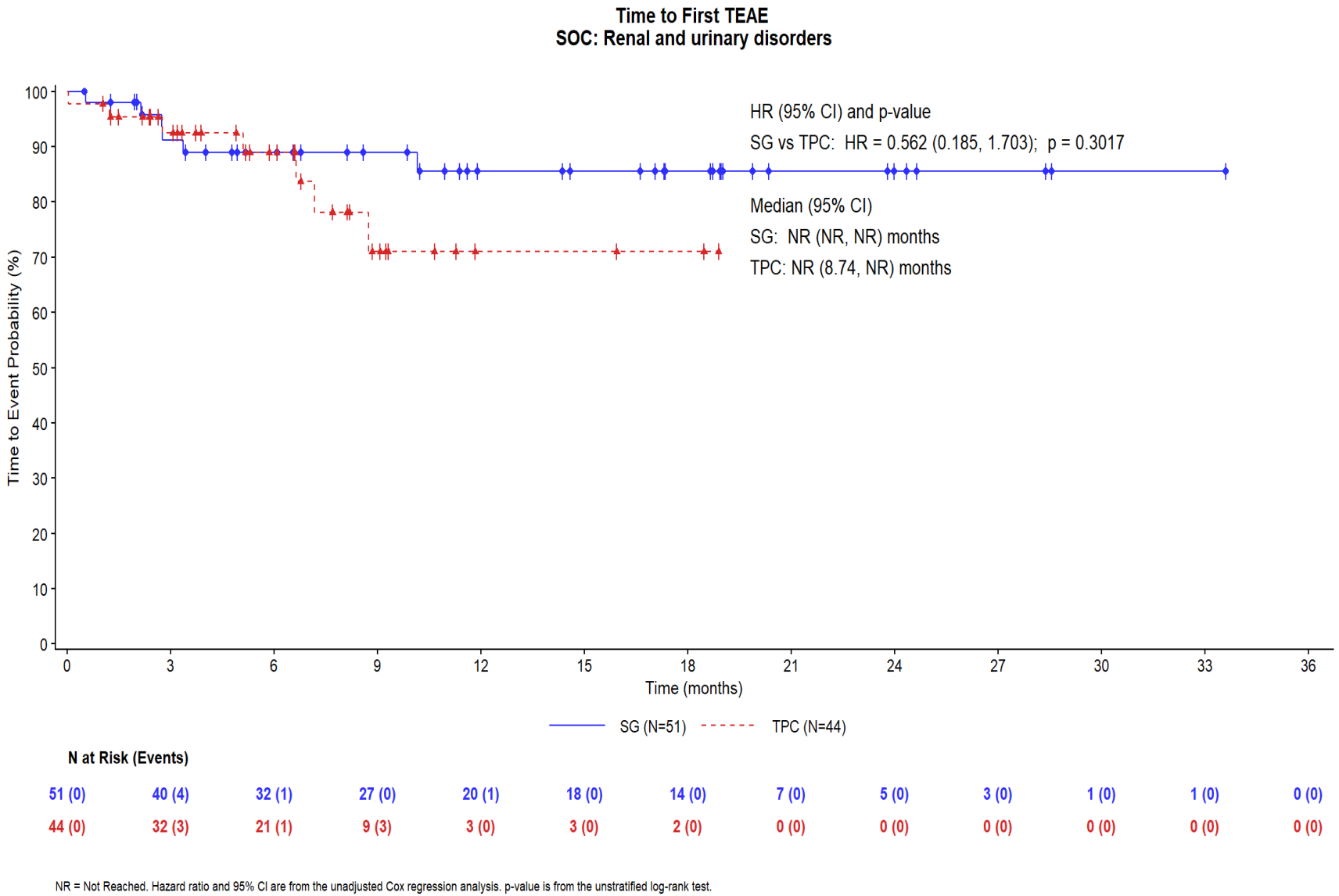
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.21. Figure 1.1.20: Kaplan Meier Plot of Time to First TEAE by SOC Psychiatric disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



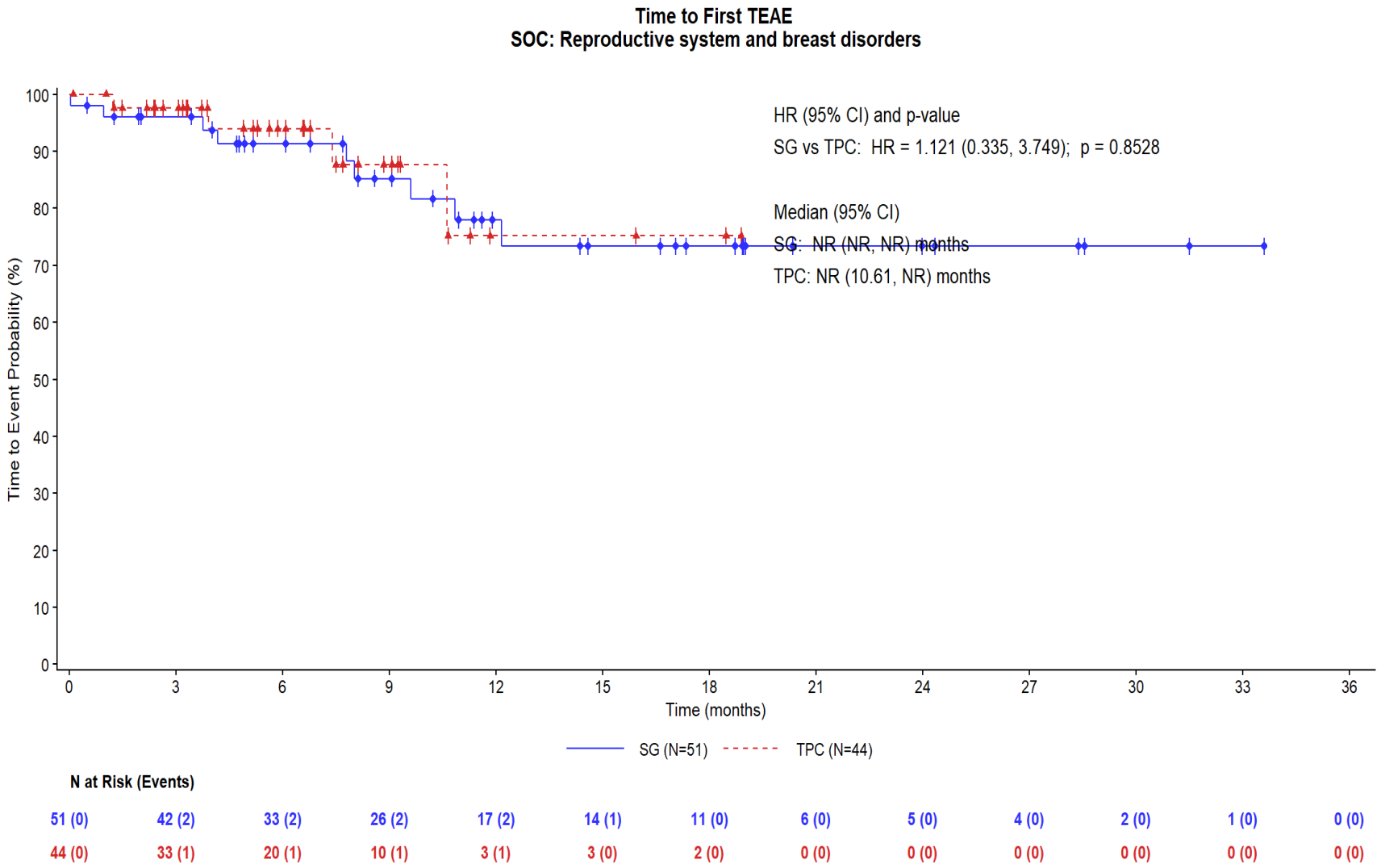
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.22. Figure 1.1.21: Kaplan Meier Plot of Time to First TEAE by SOC Renal and urinary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



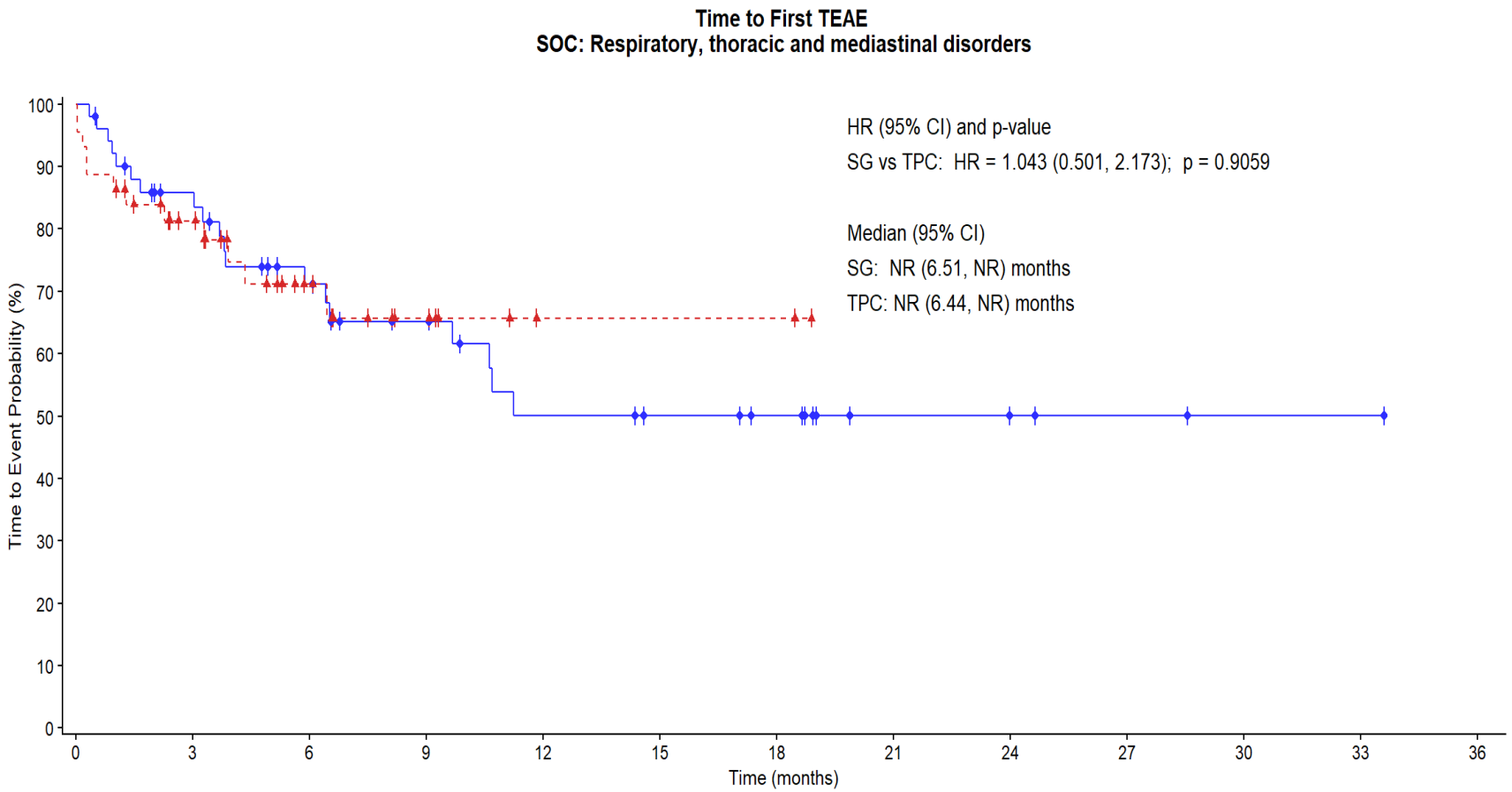
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.23. Figure 1.1.22: Kaplan Meier Plot of Time to First TEAE by SOC Reproductive system and breast disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



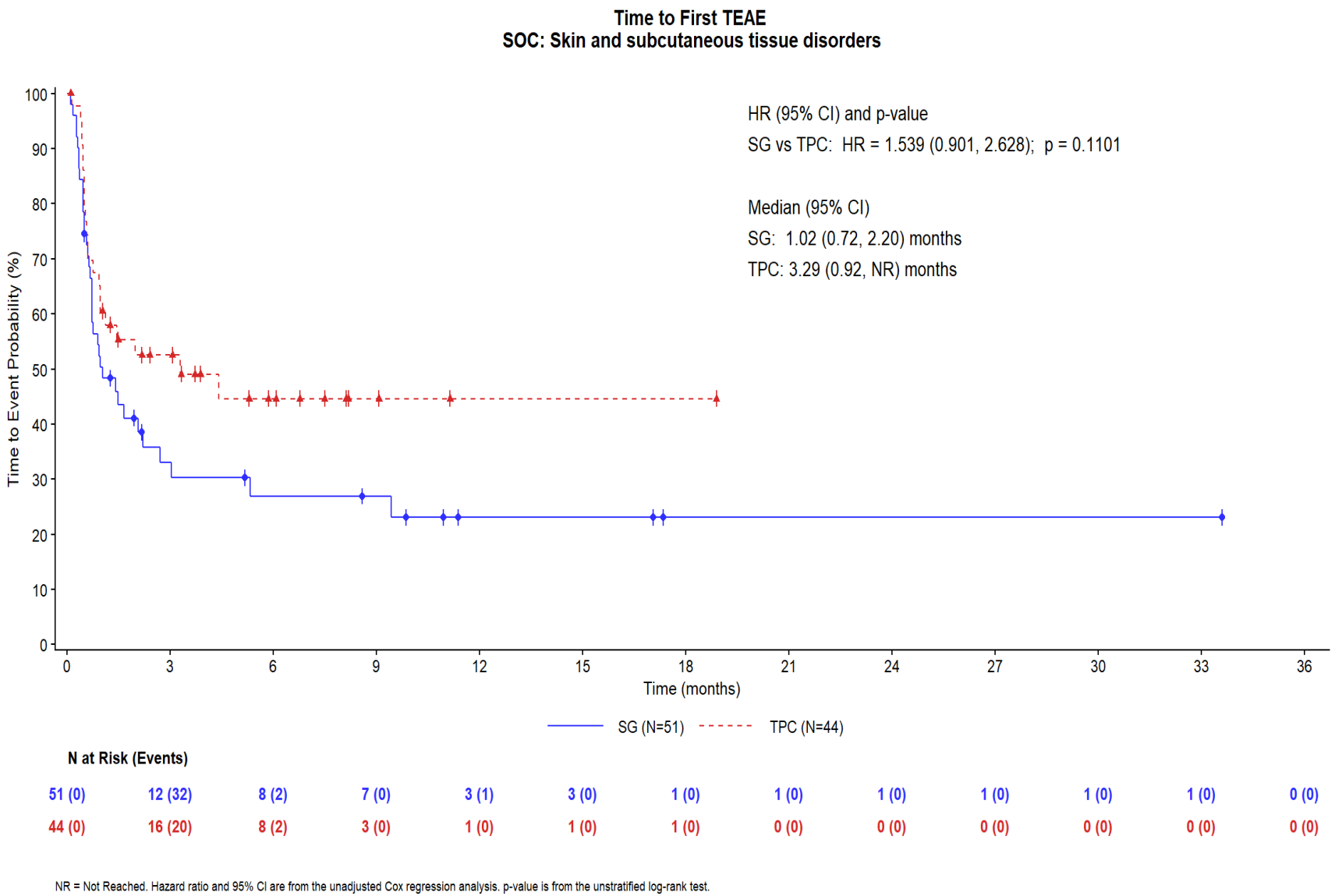
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.24. Figure 1.1.23: Kaplan Meier Plot of Time to First TEAE by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



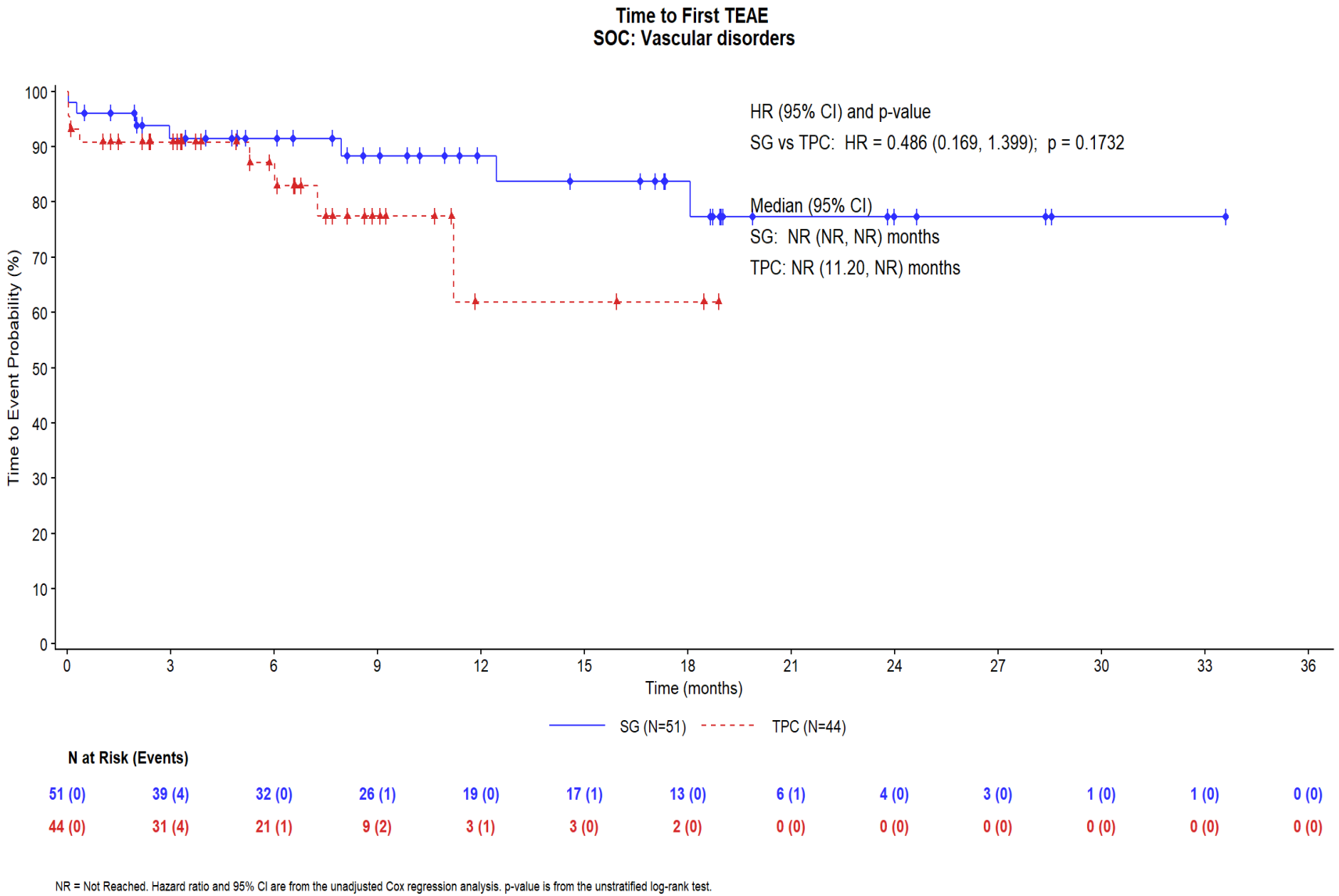
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.25. Figure 1.1.24: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



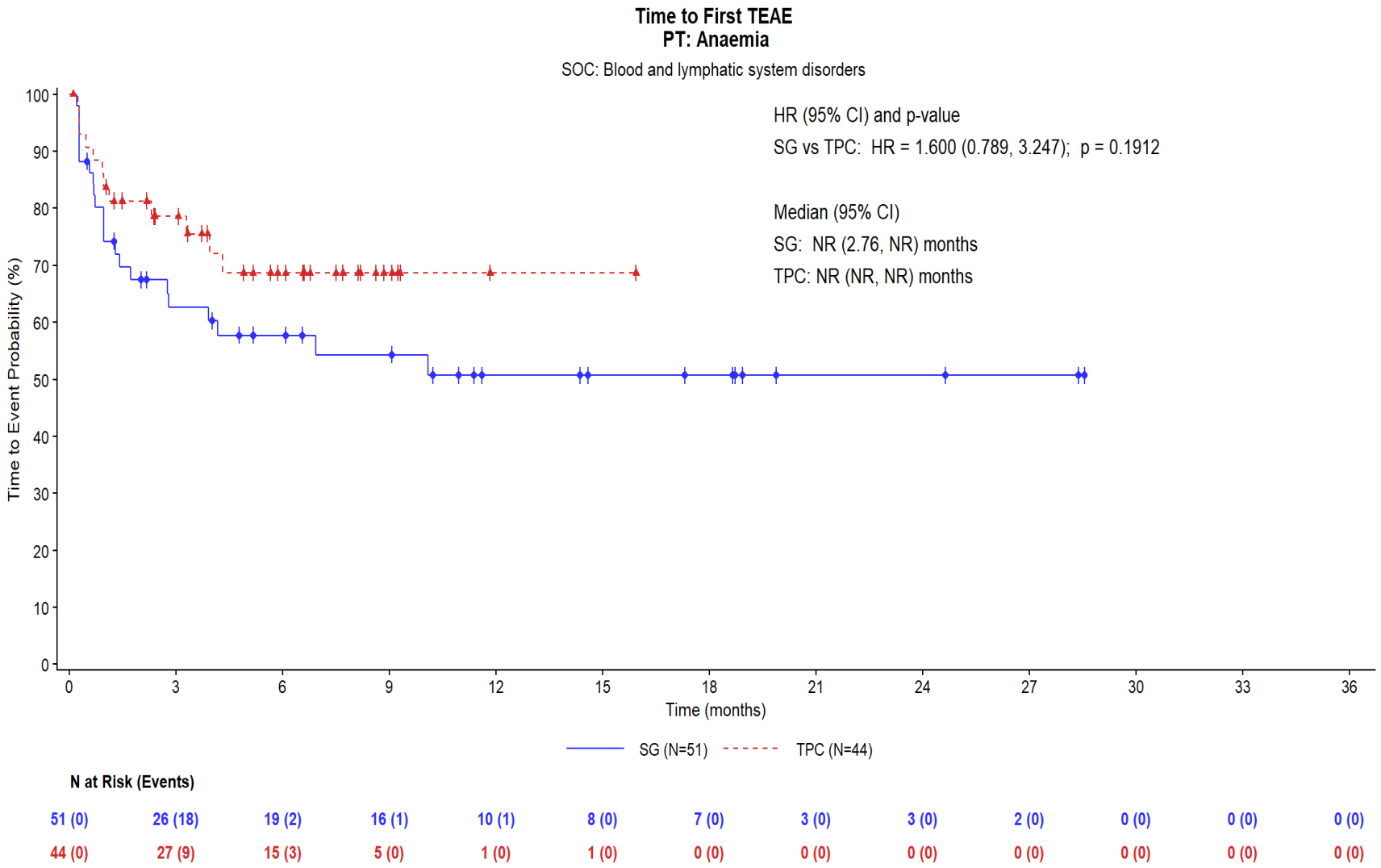
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.26. Figure 1.1.25: Kaplan Meier Plot of Time to First TEAE by SOC Vascular disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



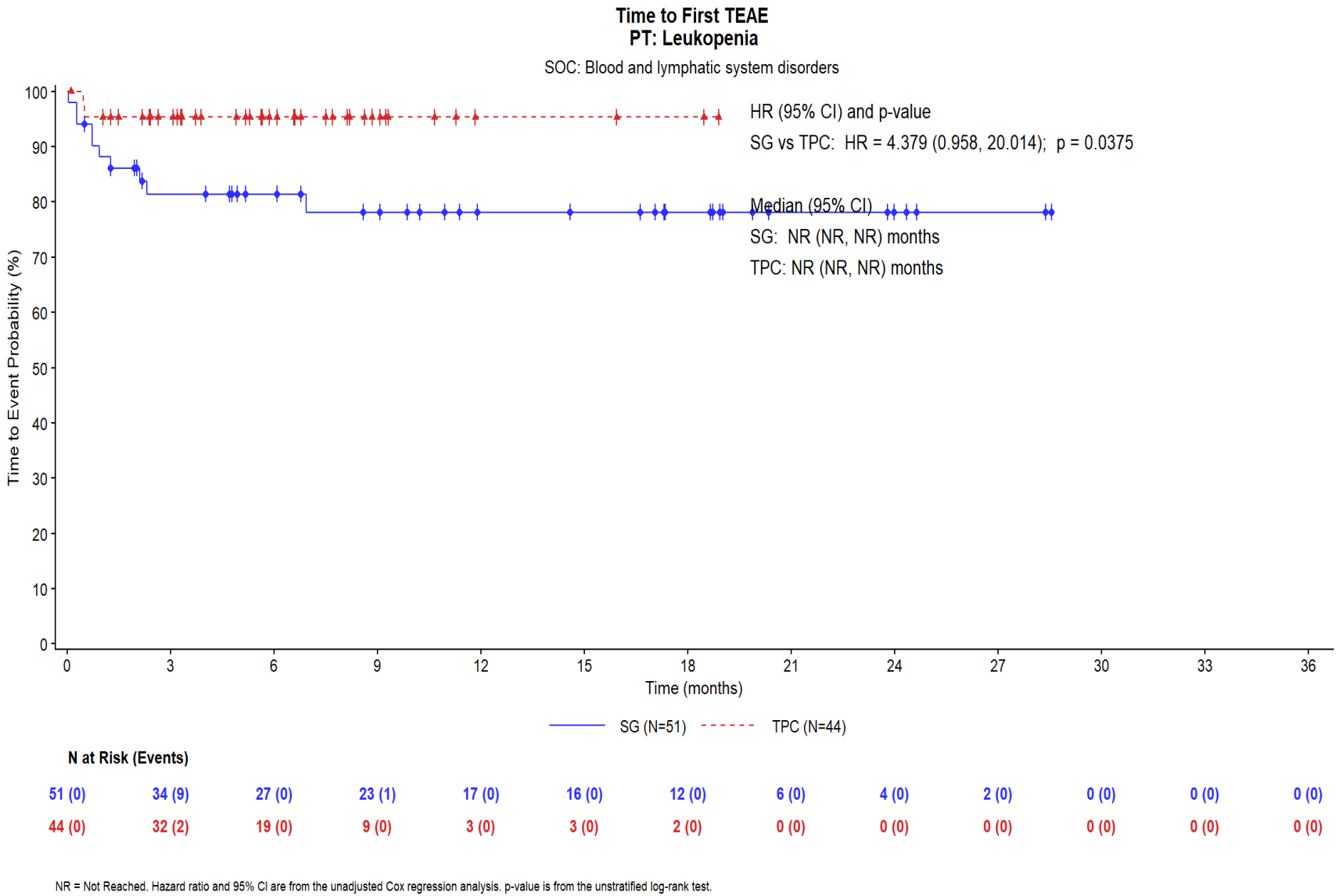
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.27. Figure 1.1.26: Kaplan Meier Plot of Time to First TEAE by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



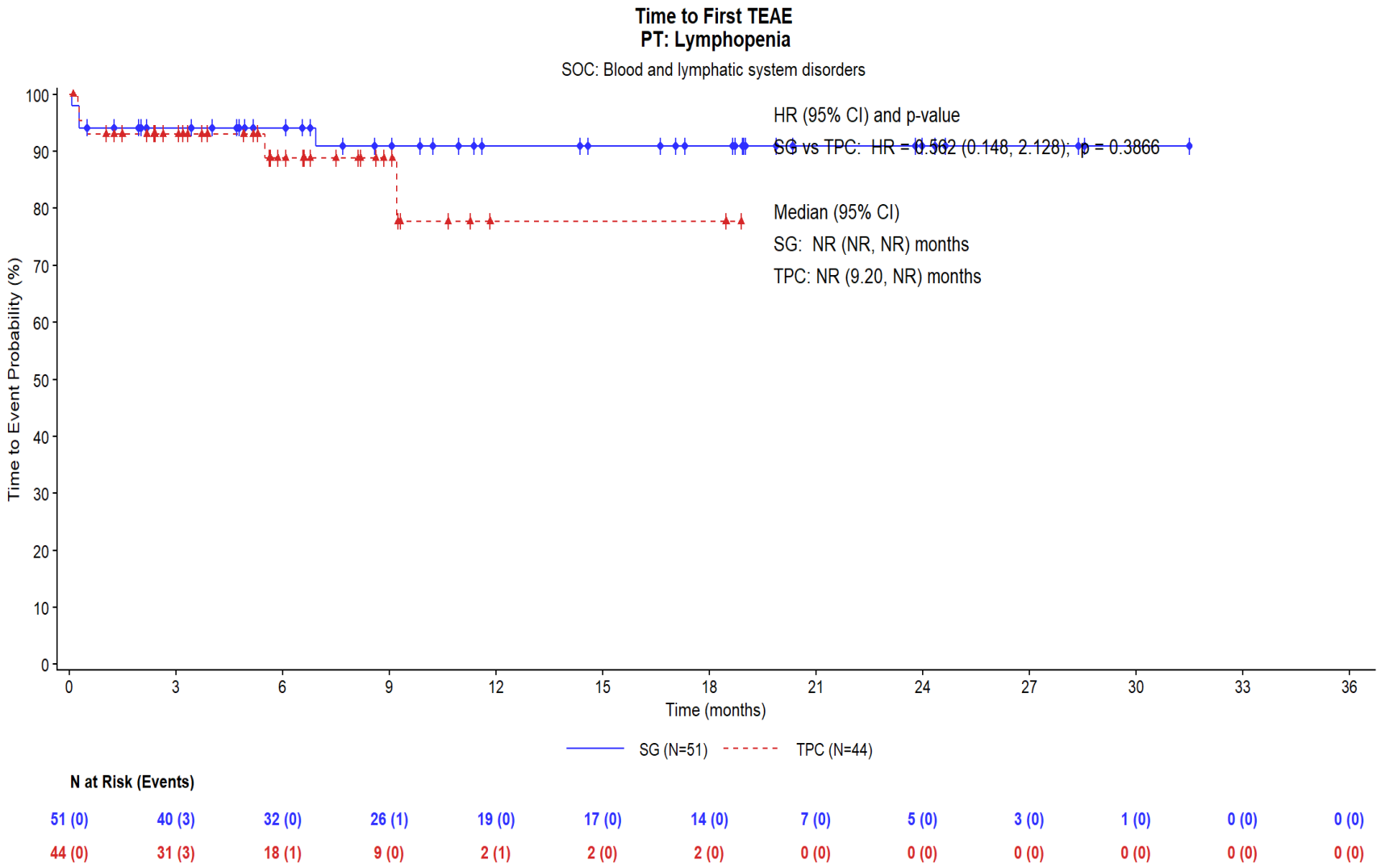
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.28. Figure 1.1.27: Kaplan Meier Plot of Time to First TEAE by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



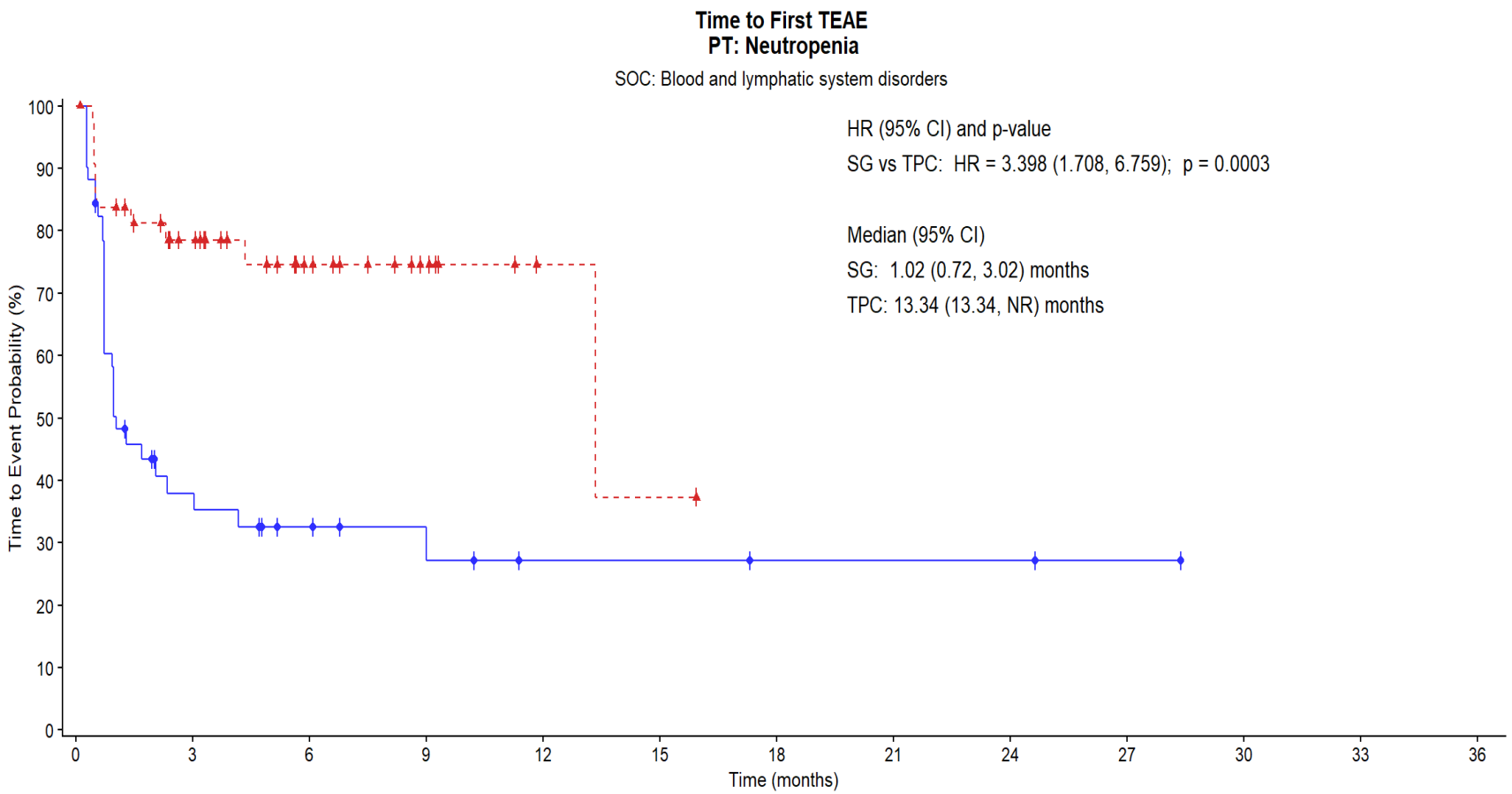
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.29. Figure 1.1.28: Kaplan Meier Plot of Time to First TEAE by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



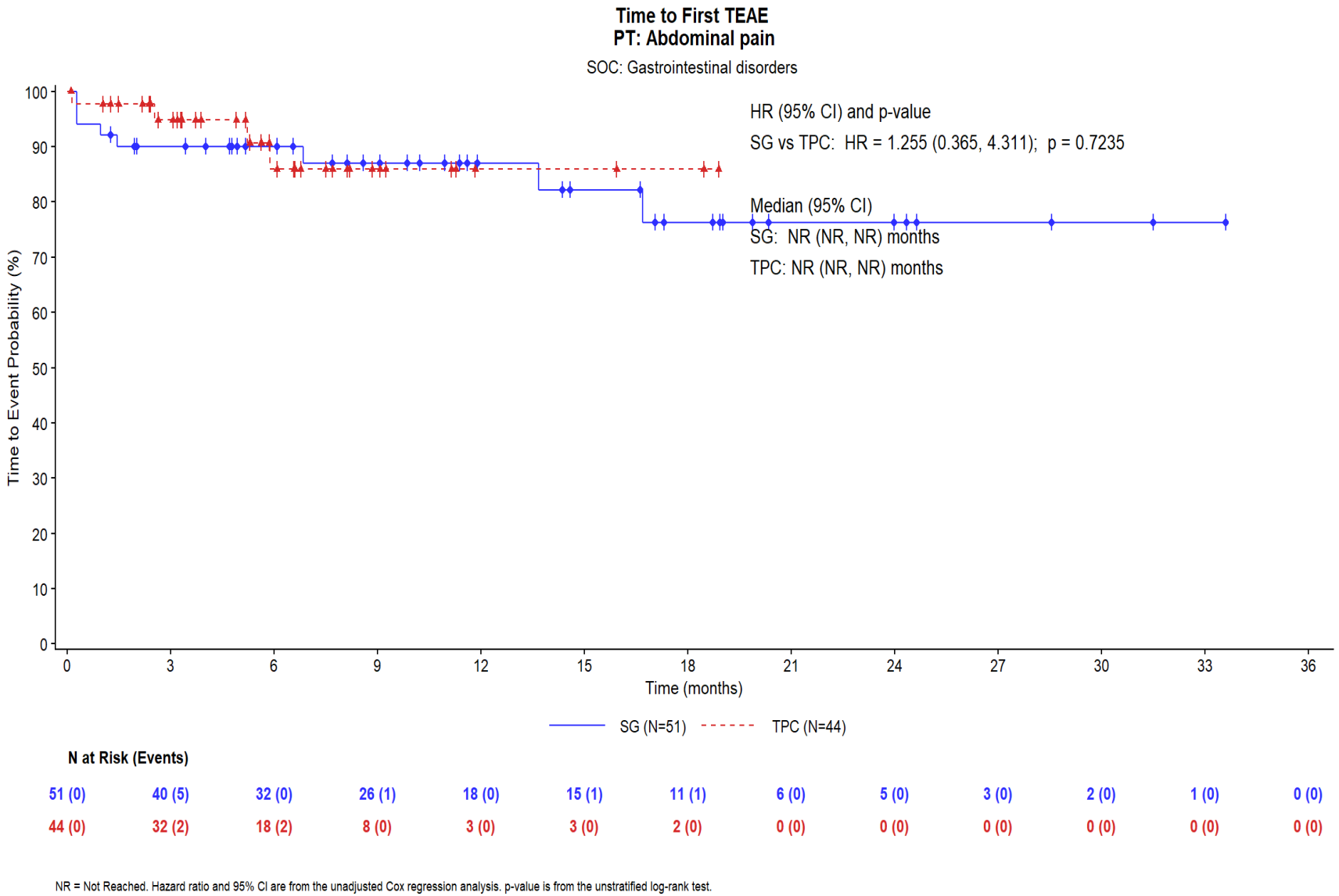
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.30. Figure 1.1.29: Kaplan Meier Plot of Time to First TEAE by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



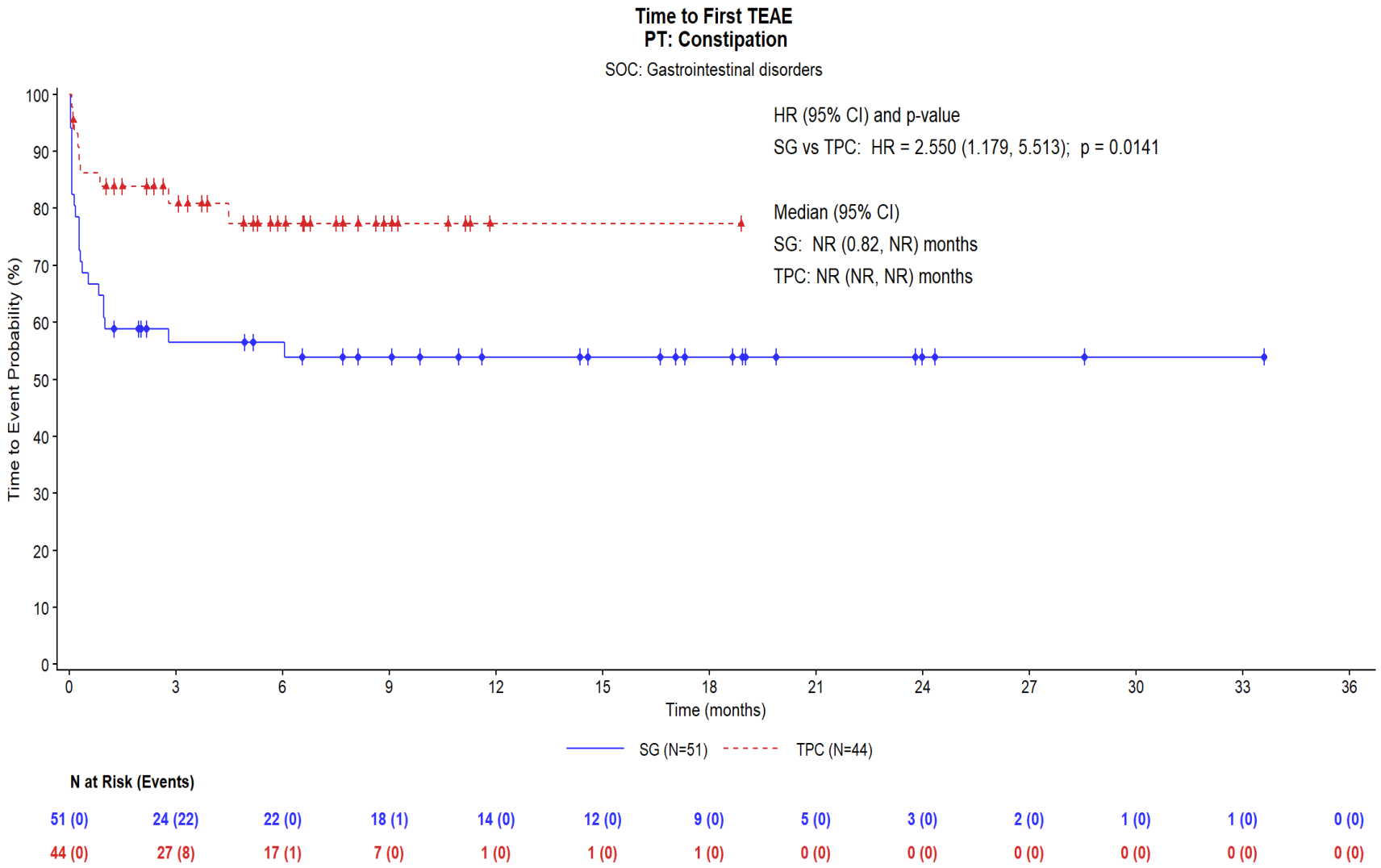
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.31. Figure 1.1.30: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



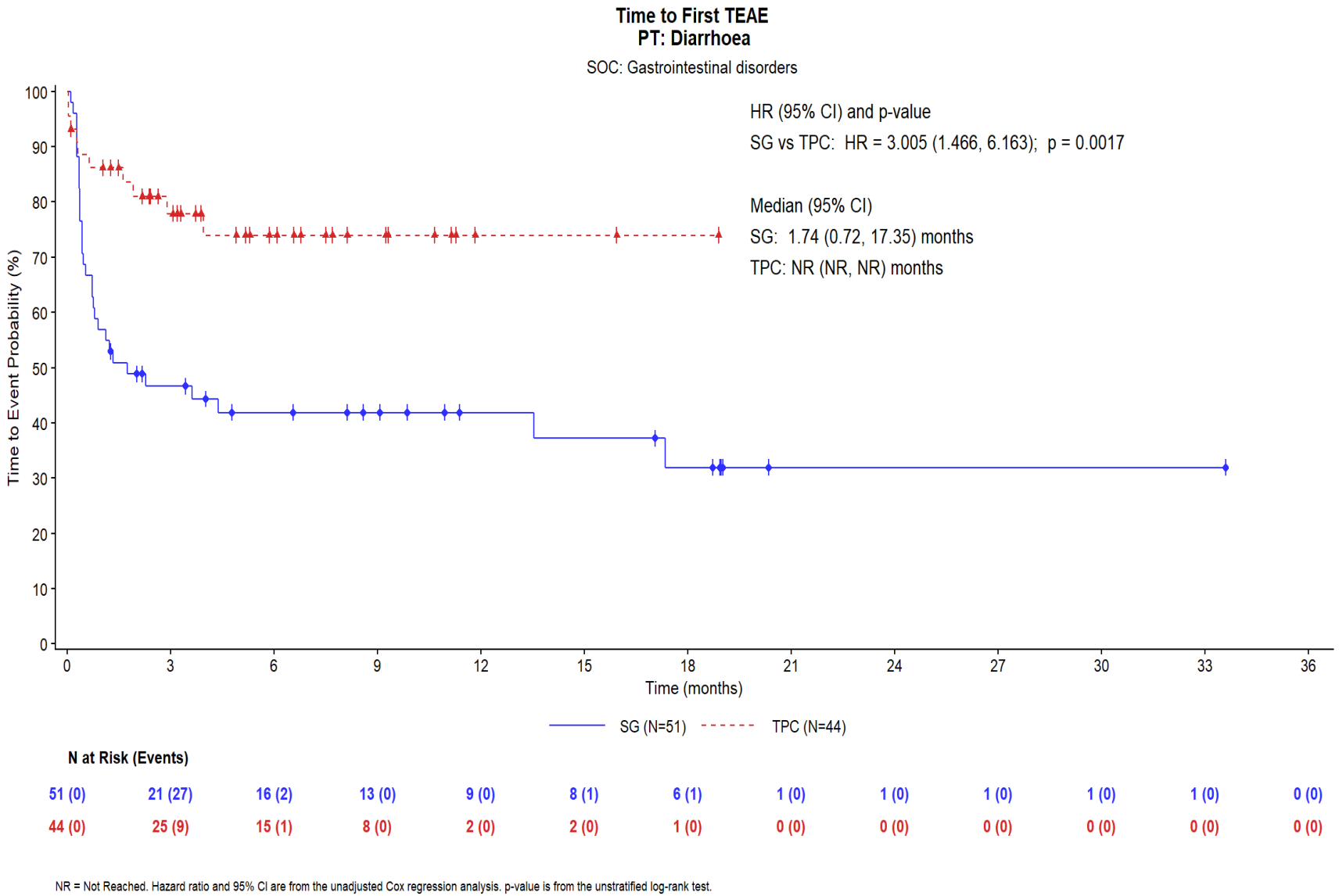
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.32. Figure 1.1.31: Kaplan Meier Plot of Time to First TEAE by PT Constipation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



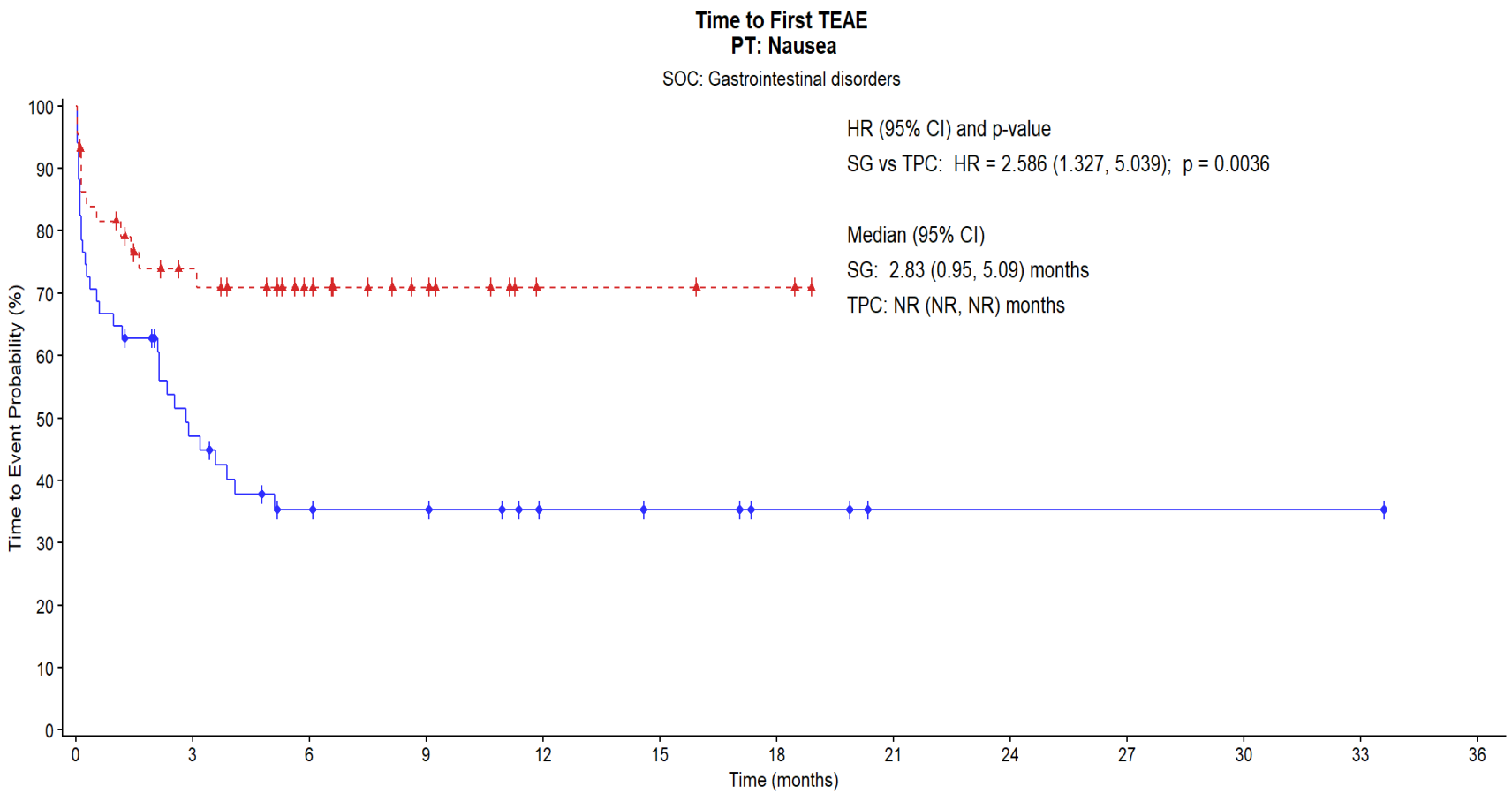
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.33. Figure 1.1.32: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



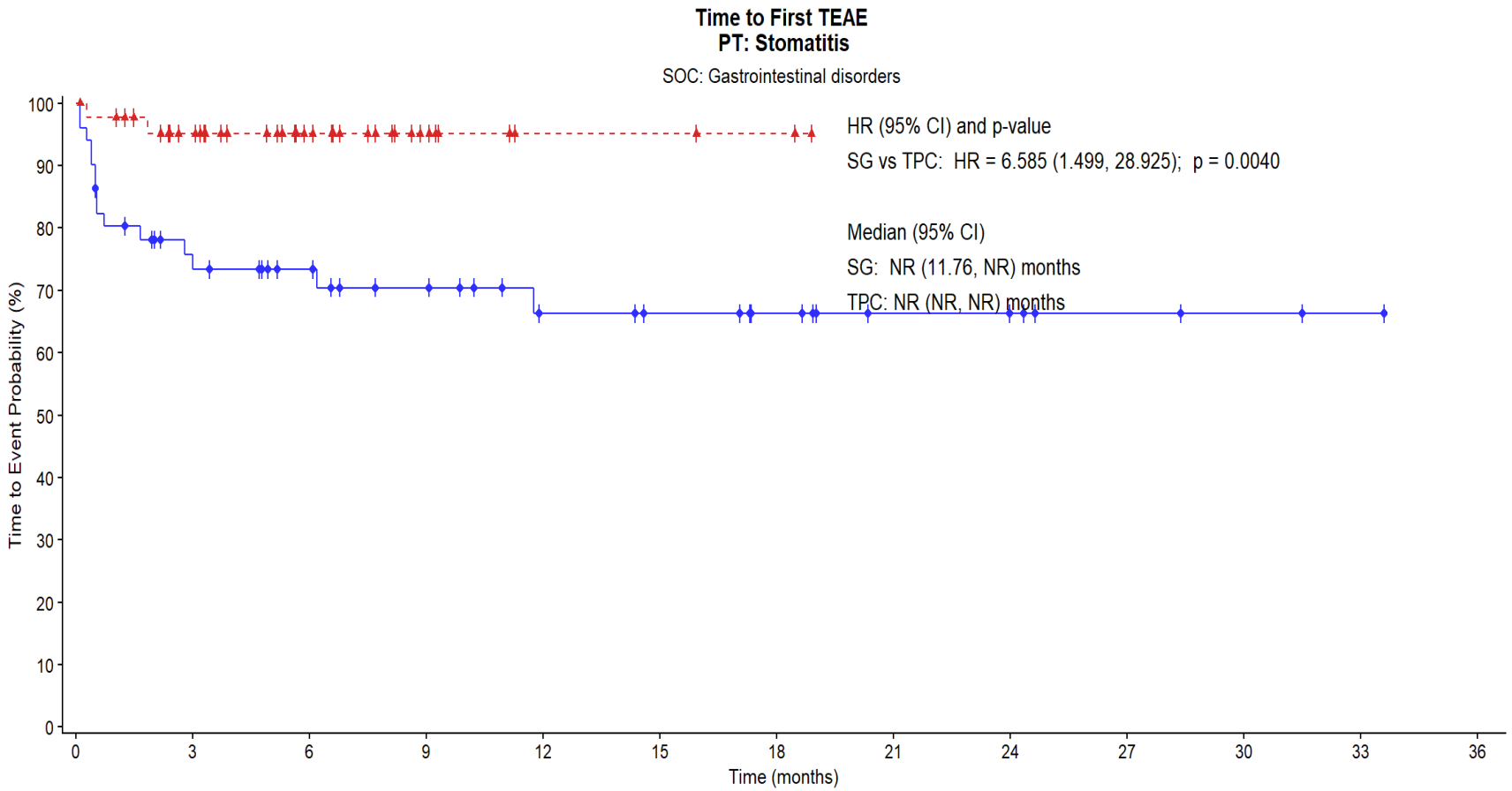
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.34. Figure 1.1.33: Kaplan Meier Plot of Time to First TEAE by PT Nausea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



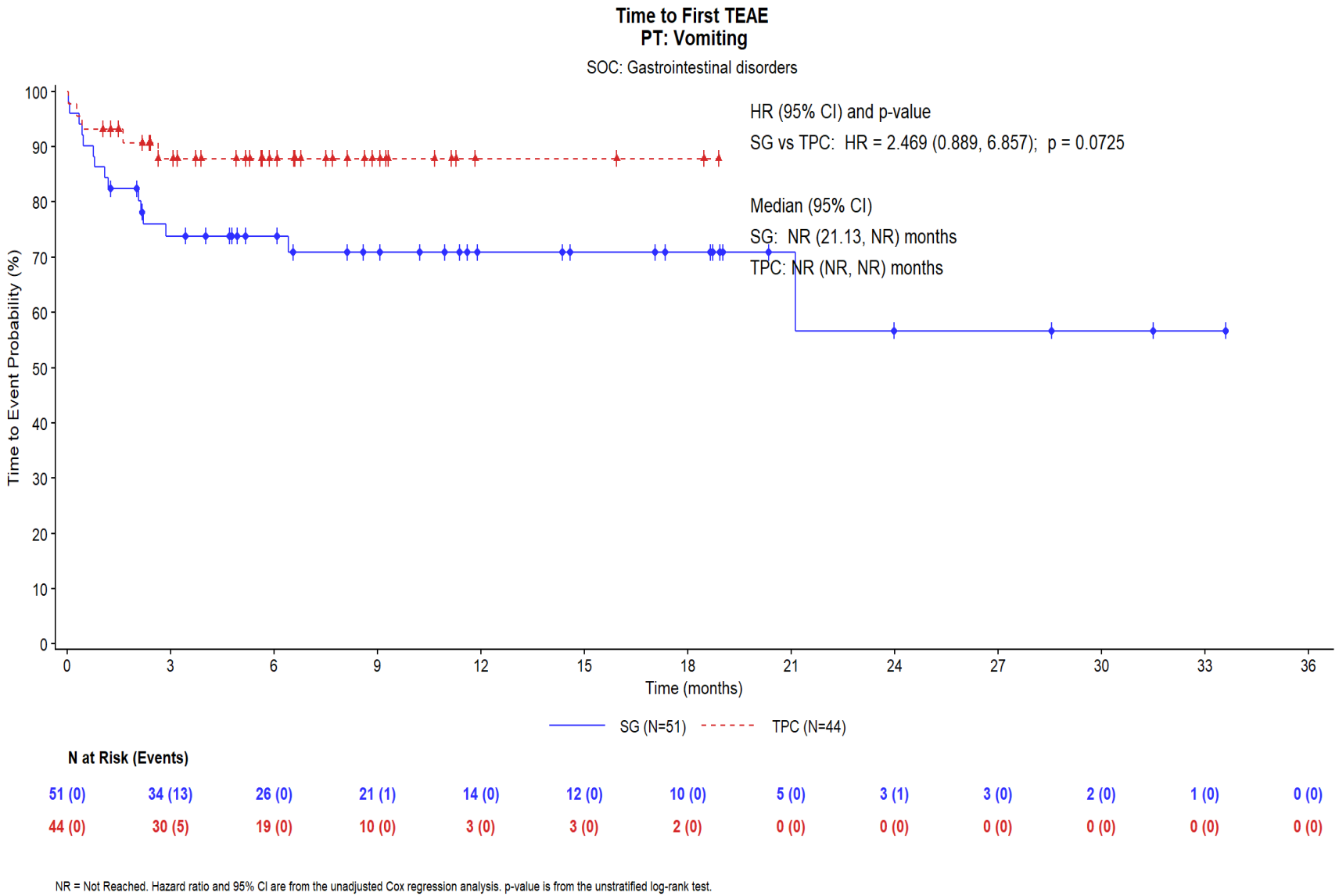
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.35. Figure 1.1.34: Kaplan Meier Plot of Time to First TEAE by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



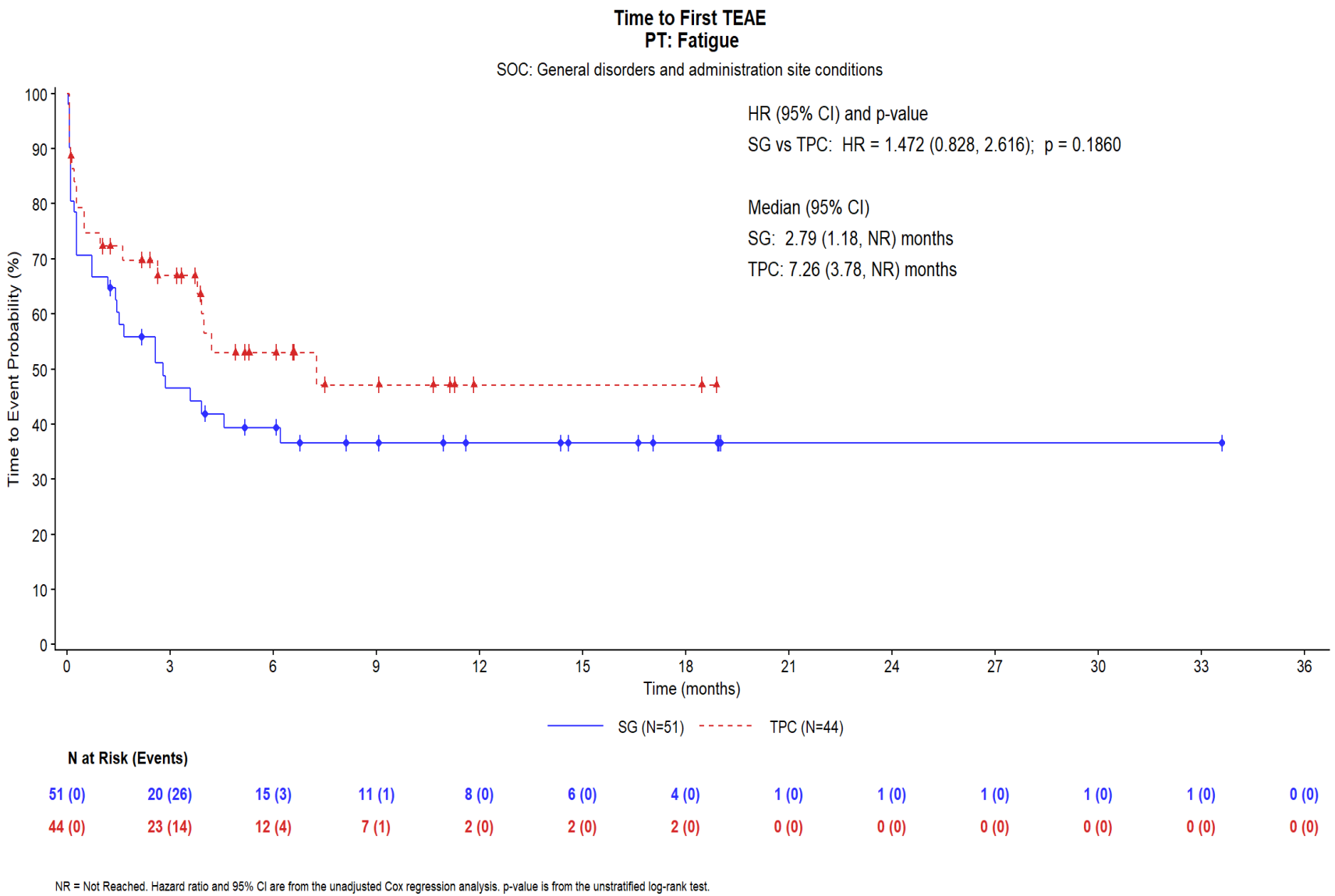
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.36. Figure 1.1.35: Kaplan Meier Plot of Time to First TEAE by PT Vomiting — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



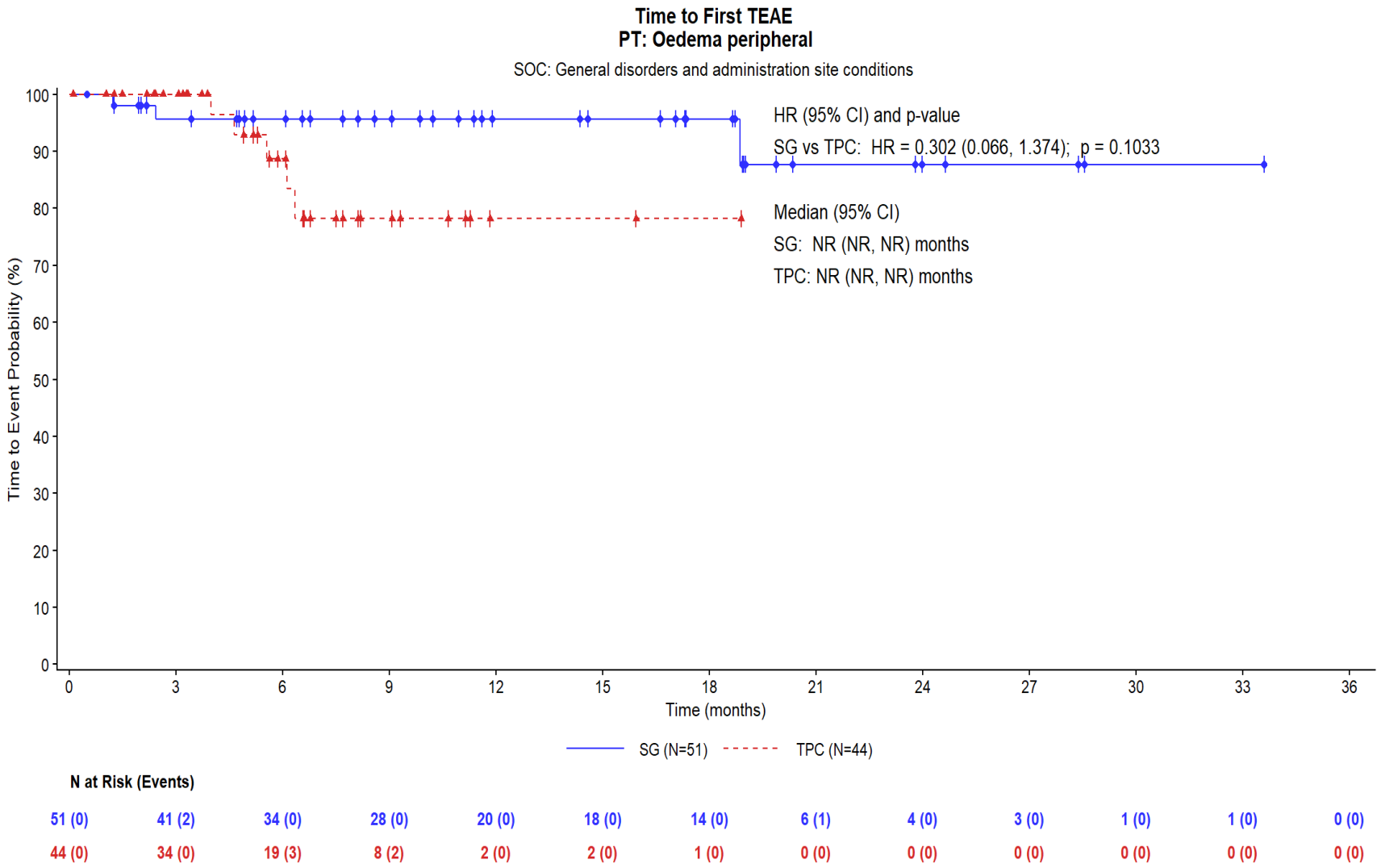
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.37. Figure 1.1.36: Kaplan Meier Plot of Time to First TEAE by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



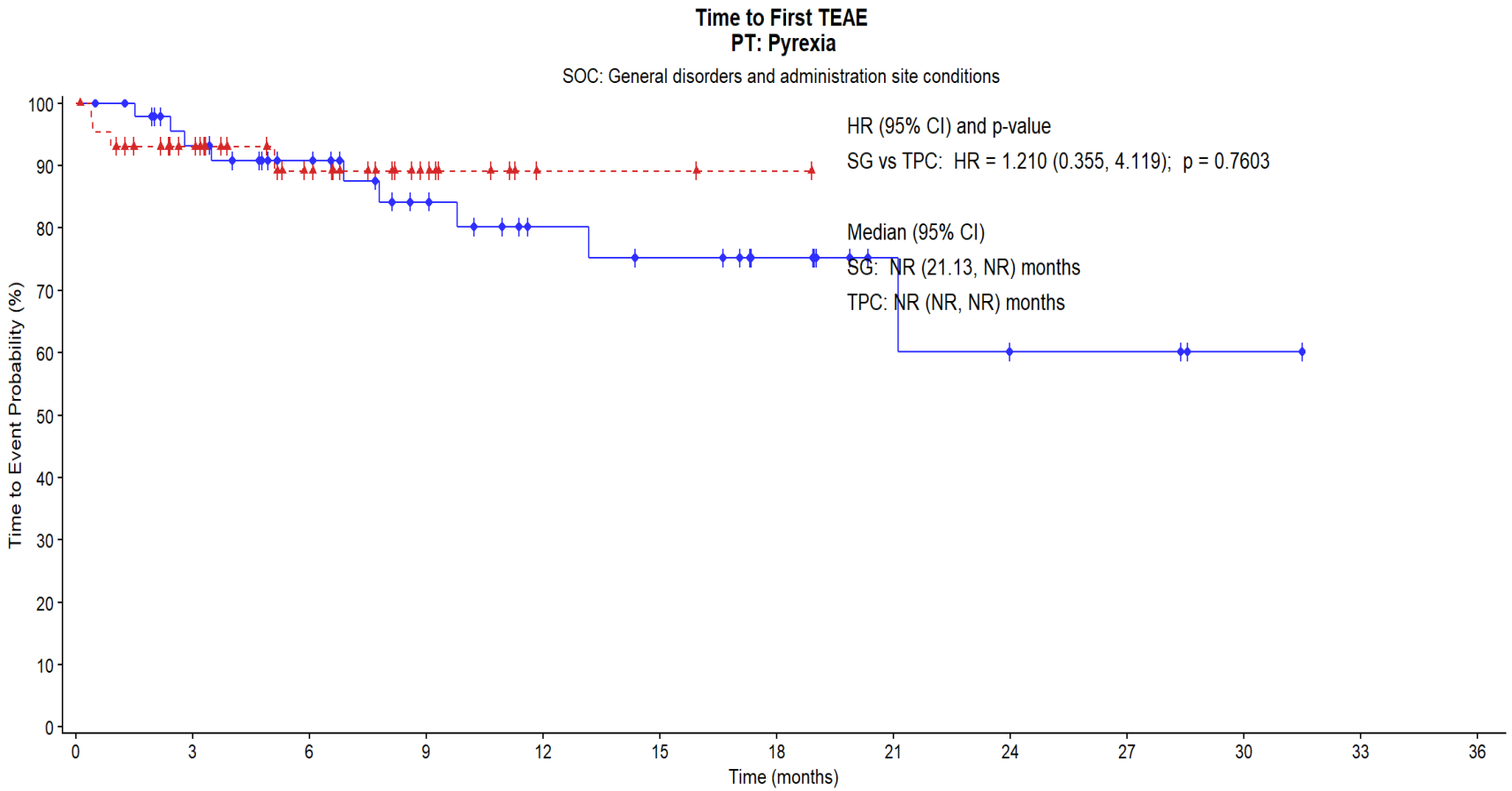
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.38. Figure 1.1.37: Kaplan Meier Plot of Time to First TEAE by PT Oedema peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



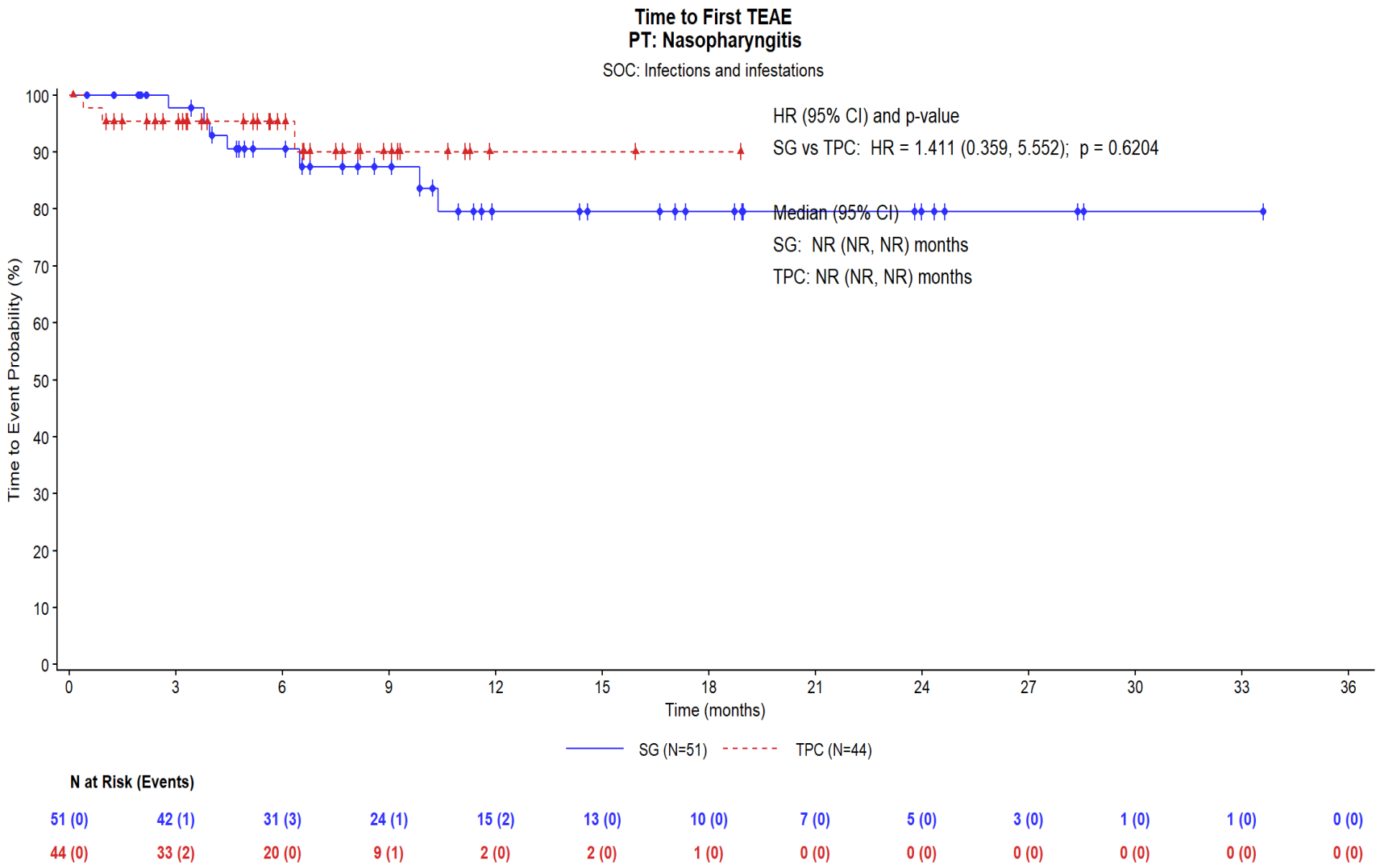
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.39. Figure 1.1.38: Kaplan Meier Plot of Time to First TEAE by PT Pyrexia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



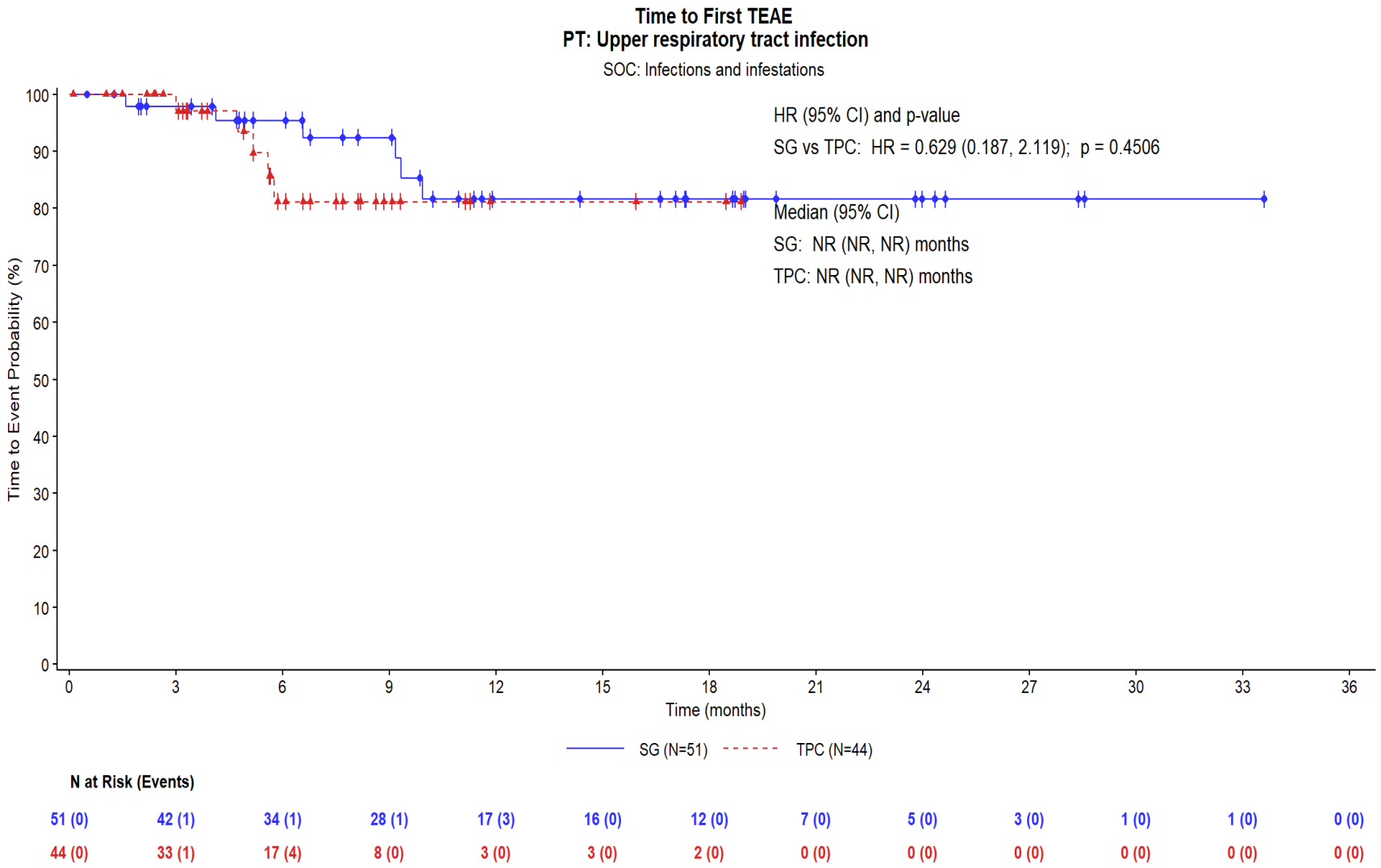
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.40. Figure 1.1.39: Kaplan Meier Plot of Time to First TEAE by PT Nasopharyngitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



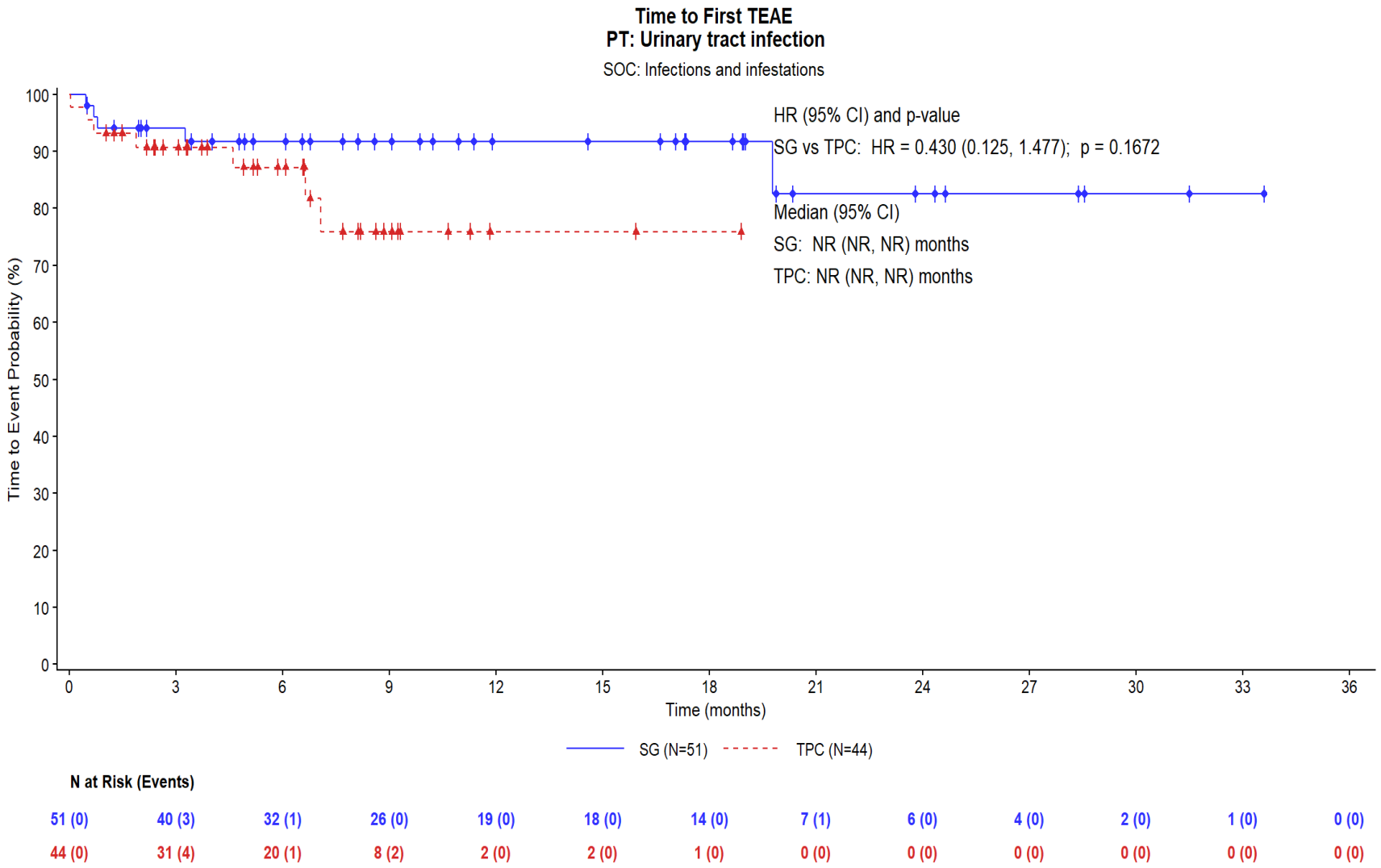
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.41. Figure 1.1.40: Kaplan Meier Plot of Time to First TEAE by PT Upper respiratory tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



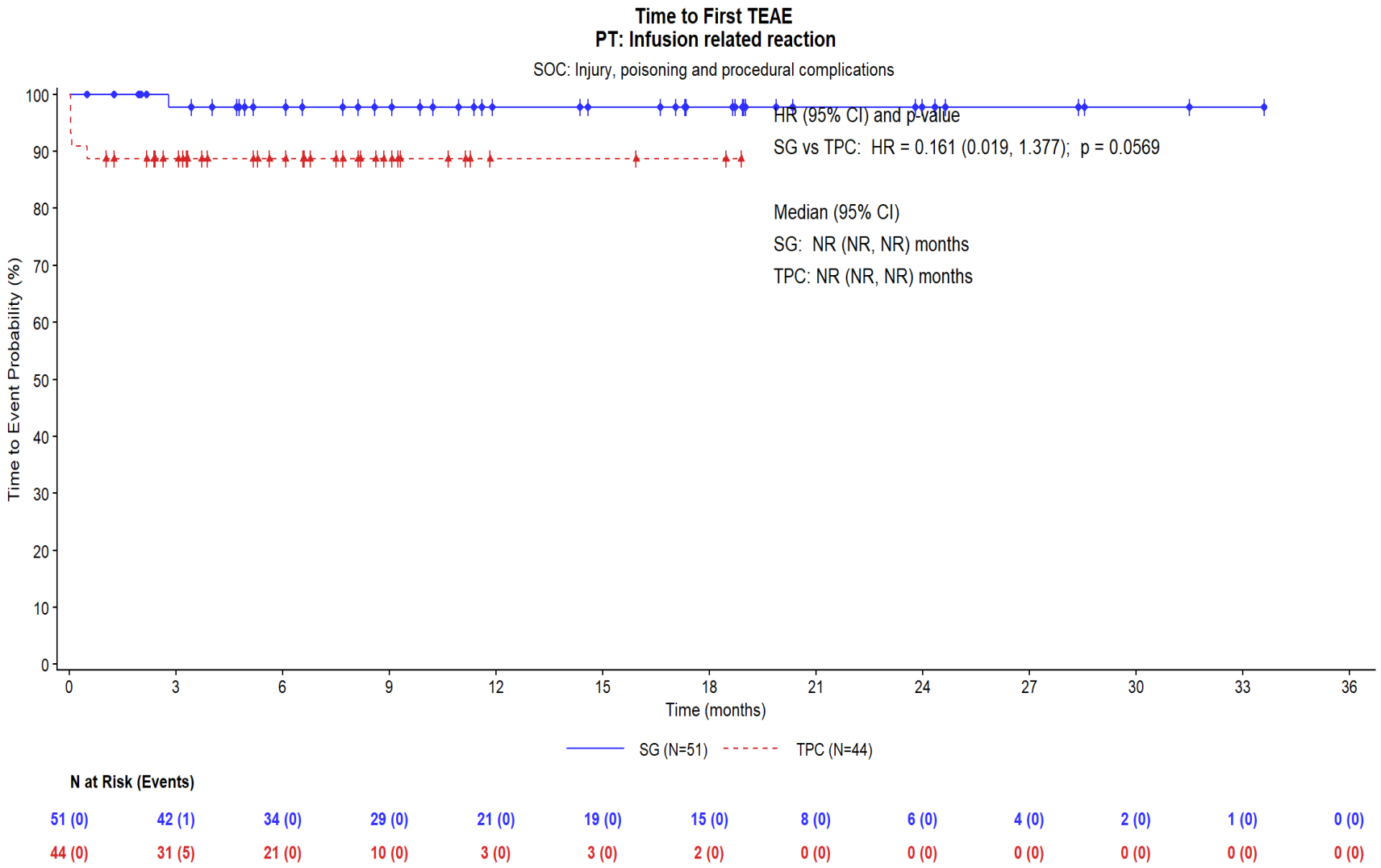
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.42. Figure 1.1.41: Kaplan Meier Plot of Time to First TEAE by PT Urinary tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



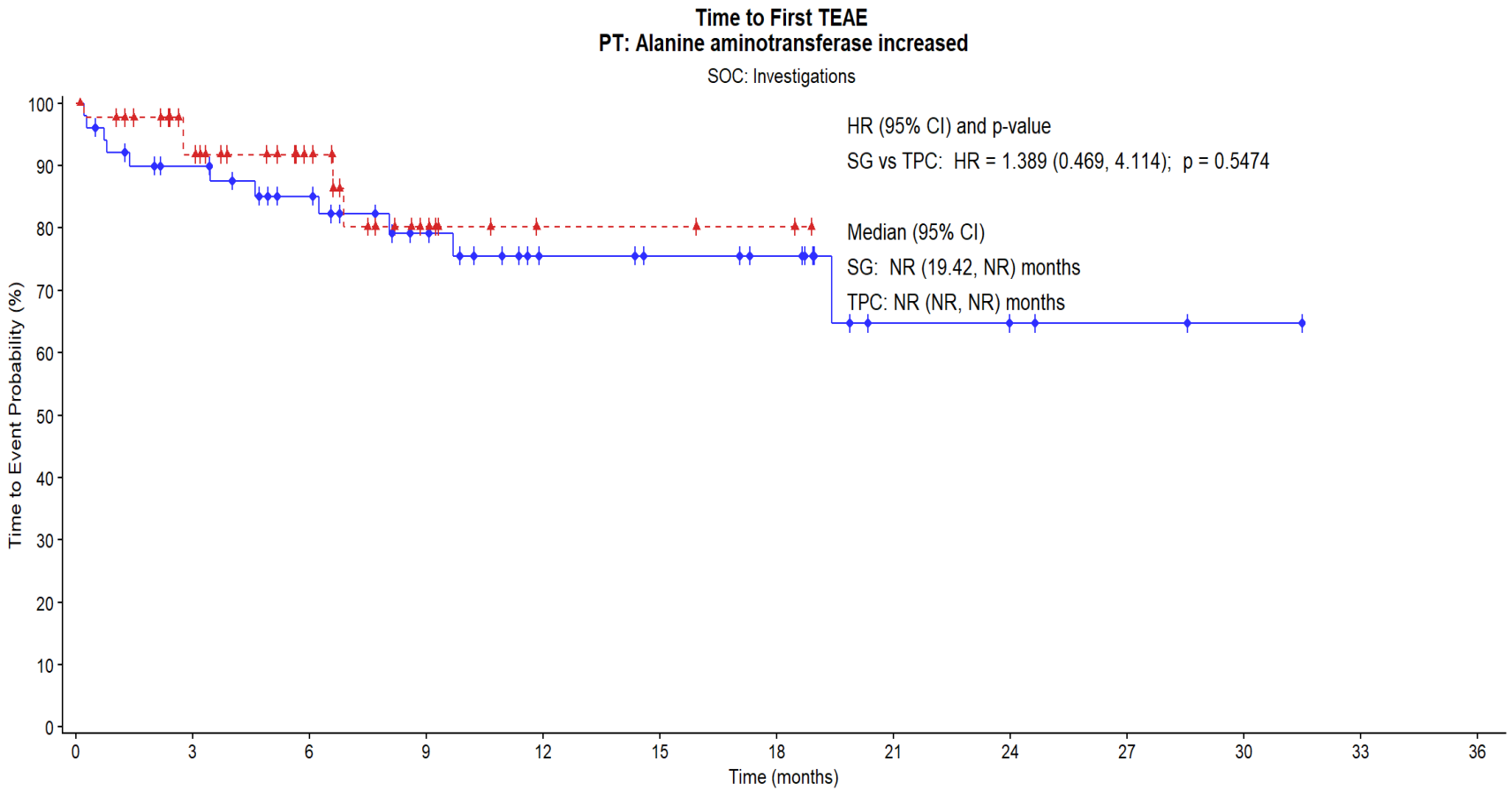
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.43. Figure 1.1.42: Kaplan Meier Plot of Time to First TEAE by PT Infusion related reaction — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



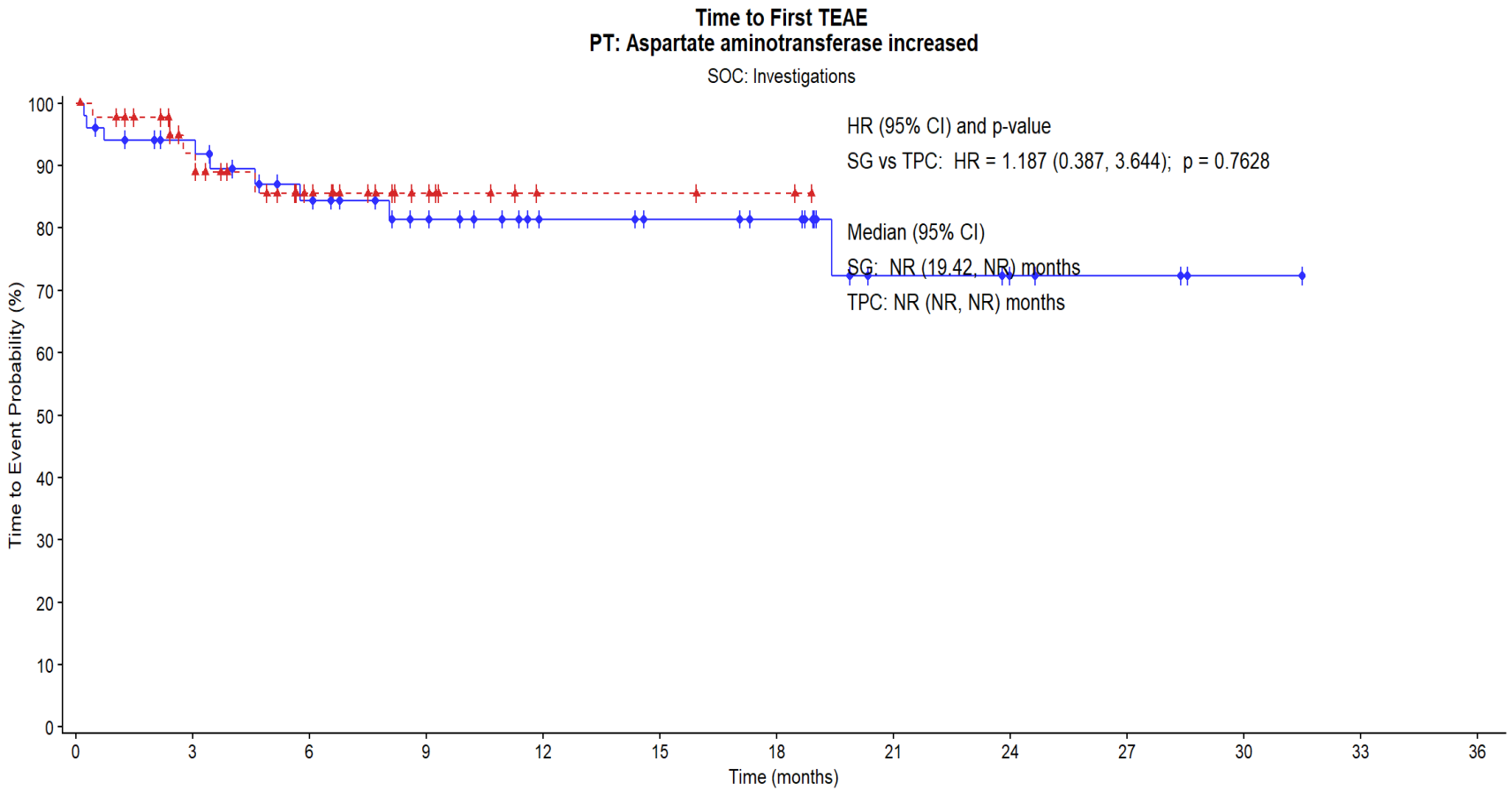
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.44. Figure 1.1.43: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



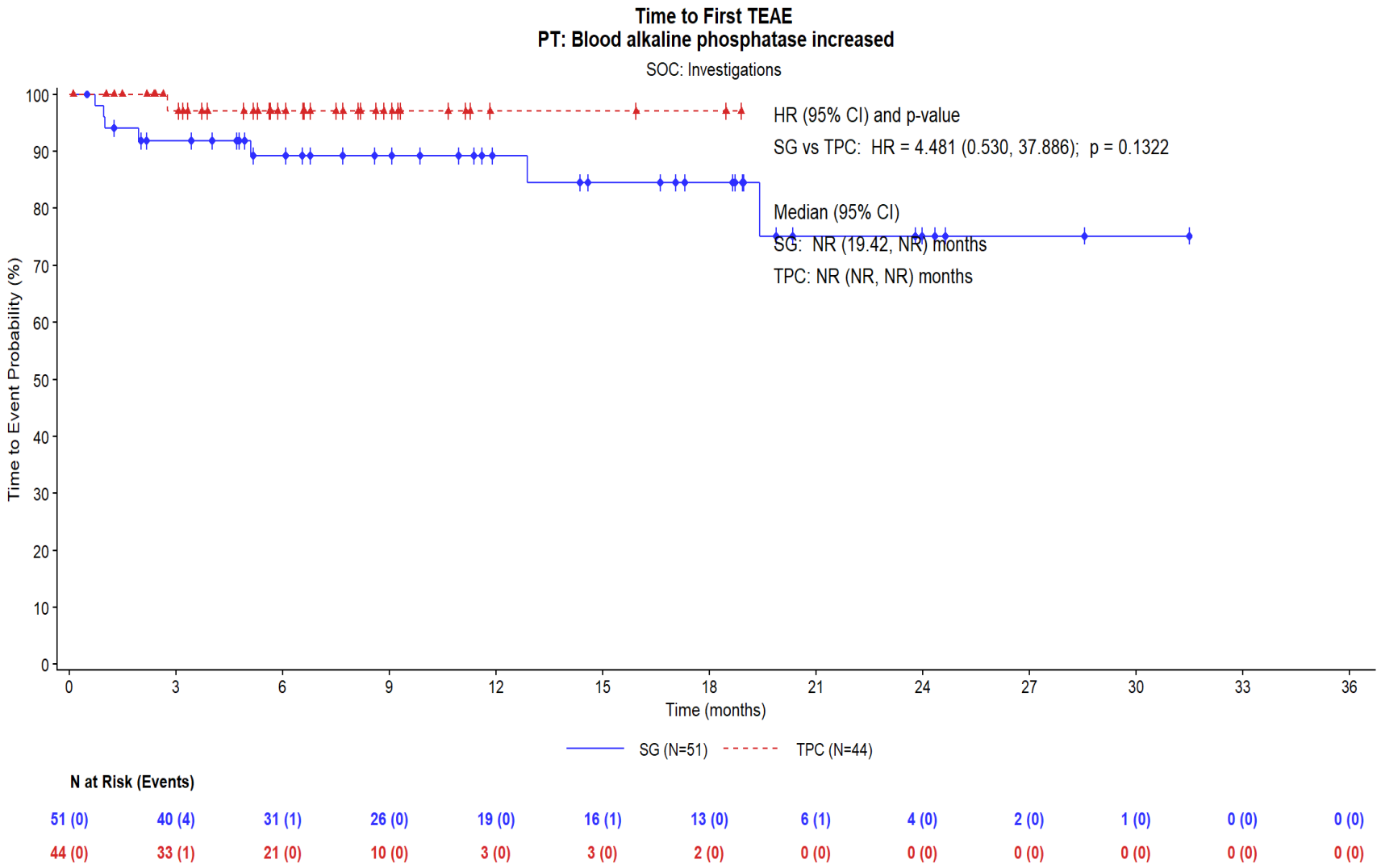
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.45. Figure 1.1.44: Kaplan Meier Plot of Time to First TEAE by PT Aspartate aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



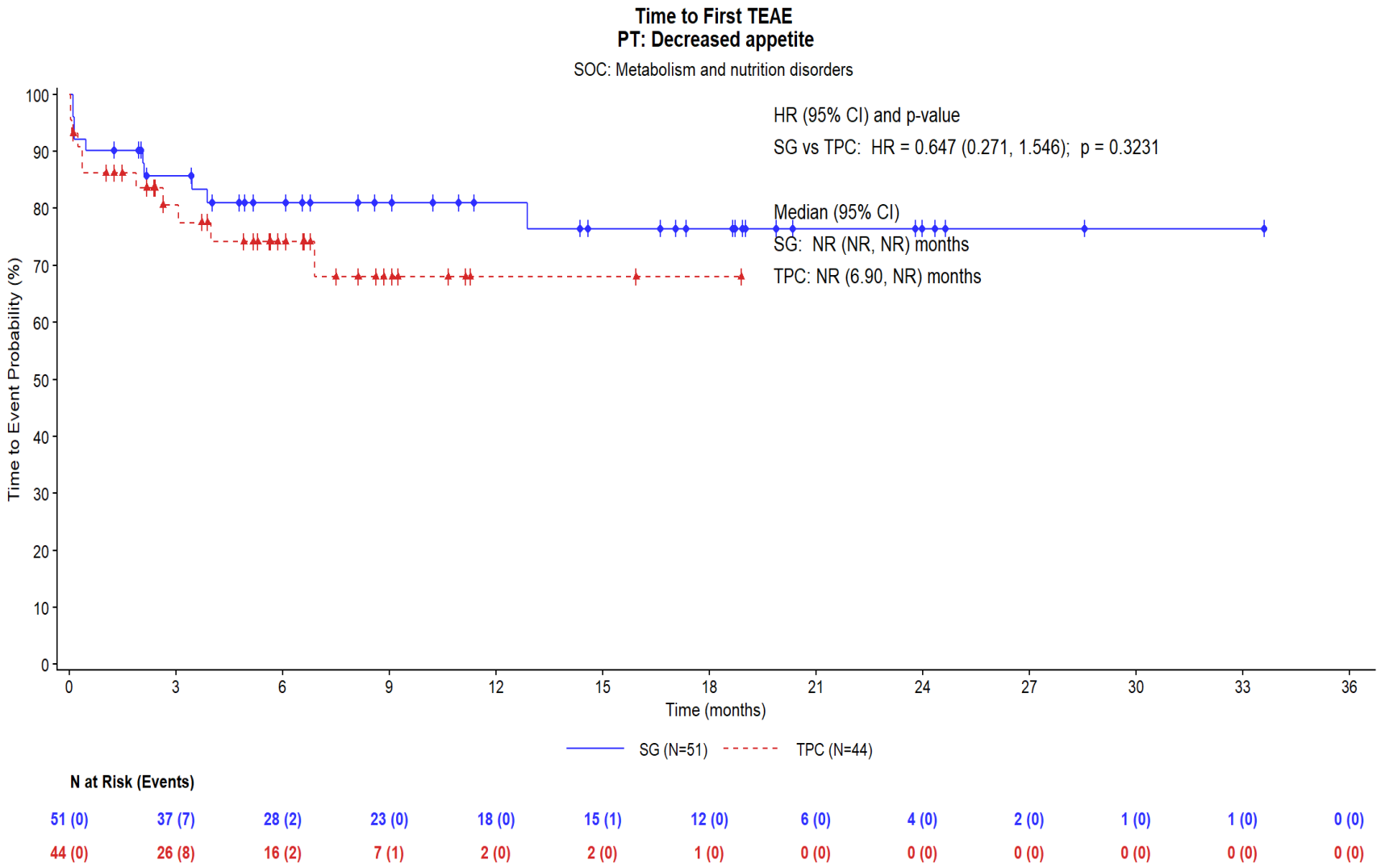
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.46. Figure 1.1.45: Kaplan Meier Plot of Time to First TEAE by PT Blood alkaline phosphatase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



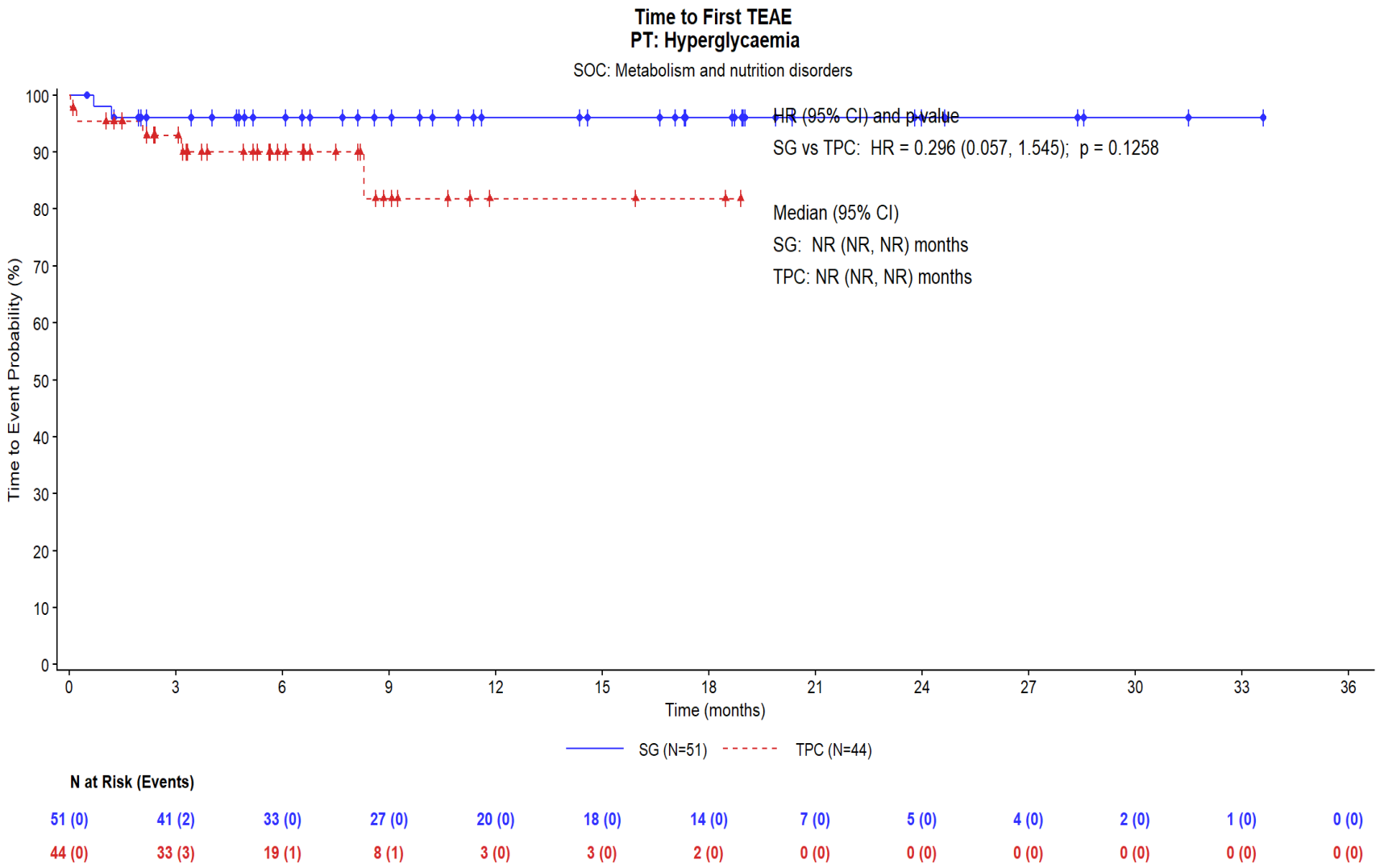
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.47. Figure 1.1.46: Kaplan Meier Plot of Time to First TEAE by PT Decreased appetite — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



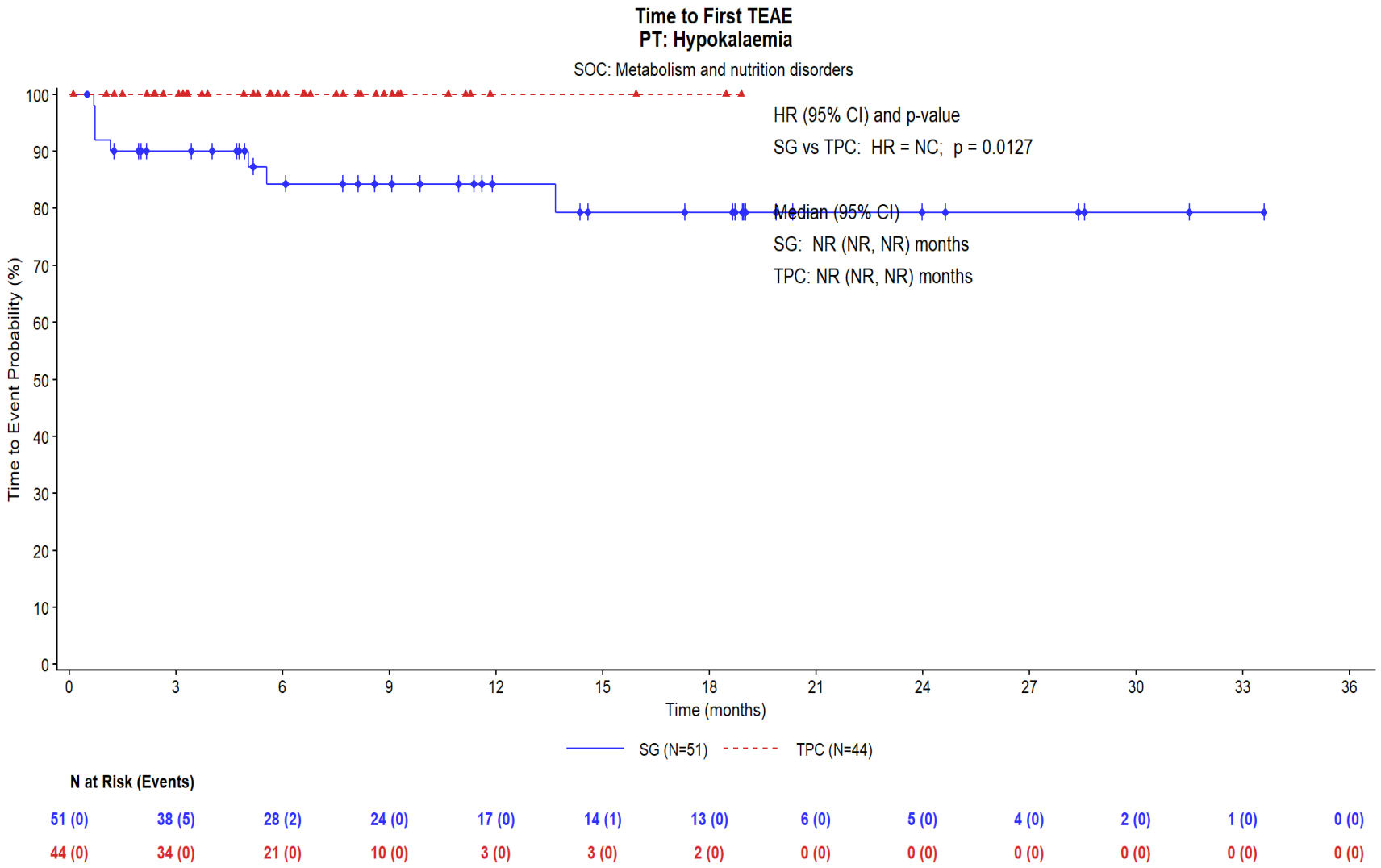
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.48. Figure 1.1.47: Kaplan Meier Plot of Time to First TEAE by PT Hyperglycaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



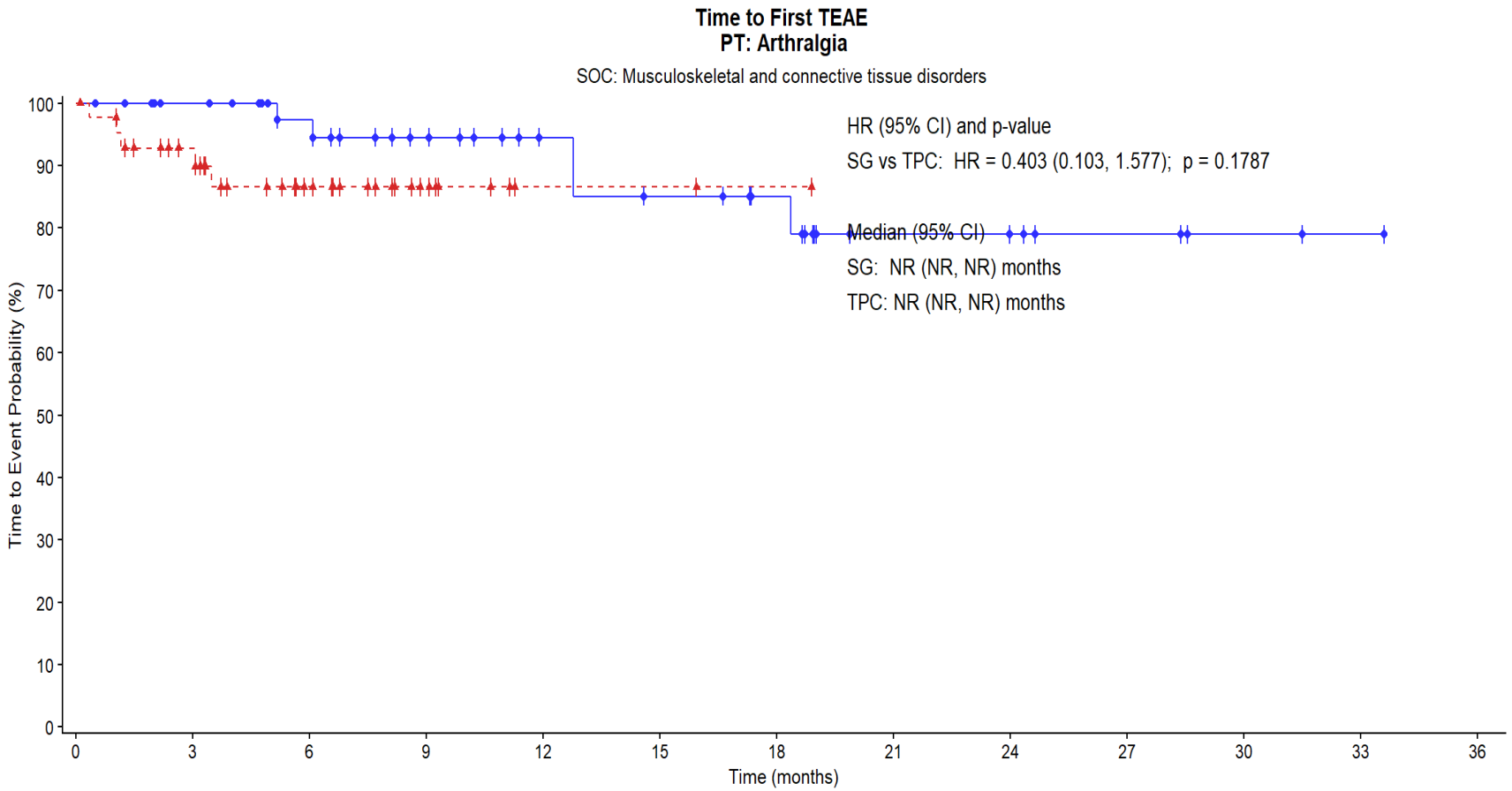
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.49. Figure 1.1.48: Kaplan Meier Plot of Time to First TEAE by PT Hypokalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



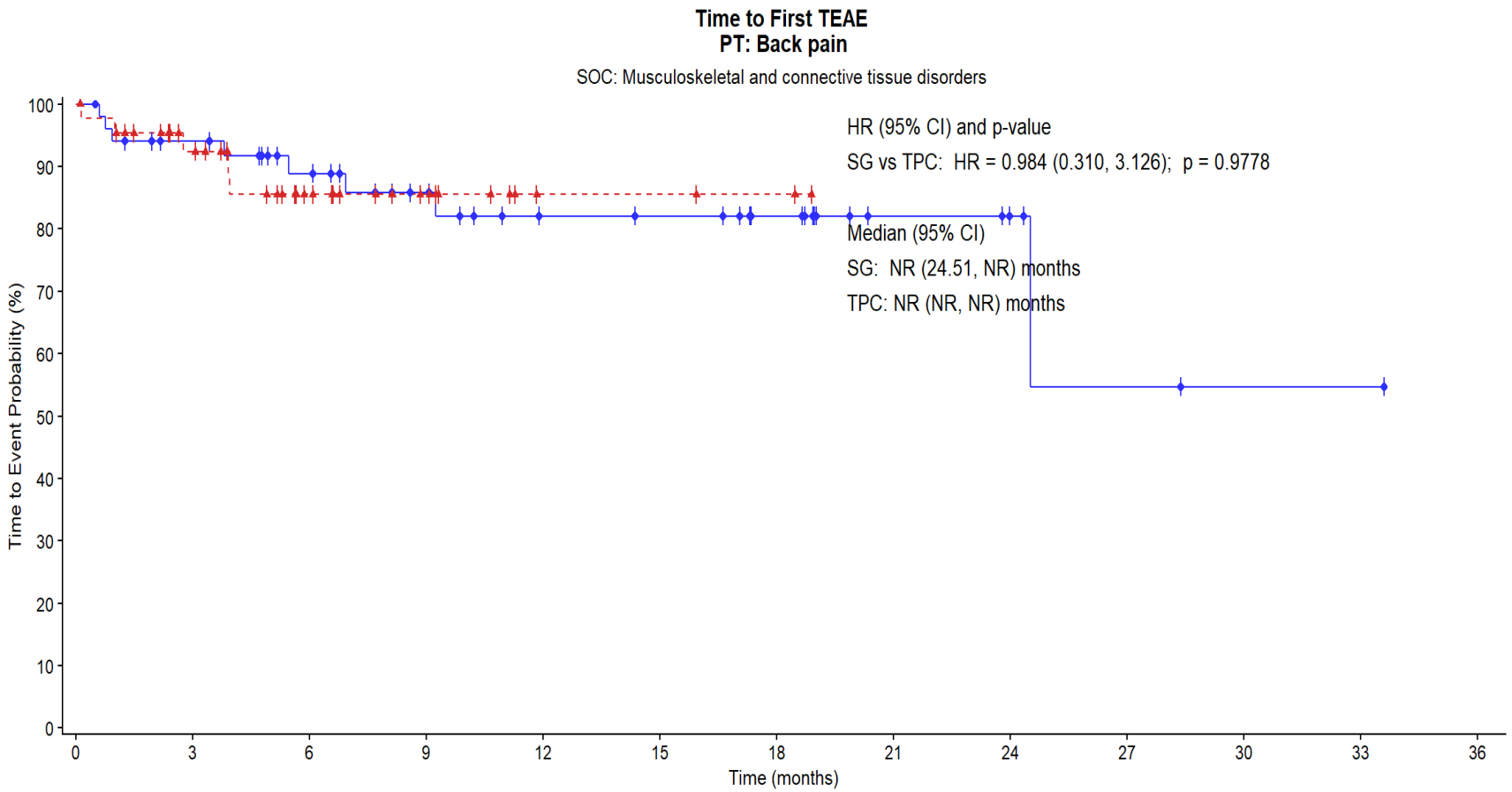
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.50. Figure 1.1.49: Kaplan Meier Plot of Time to First TEAE by PT Arthralgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



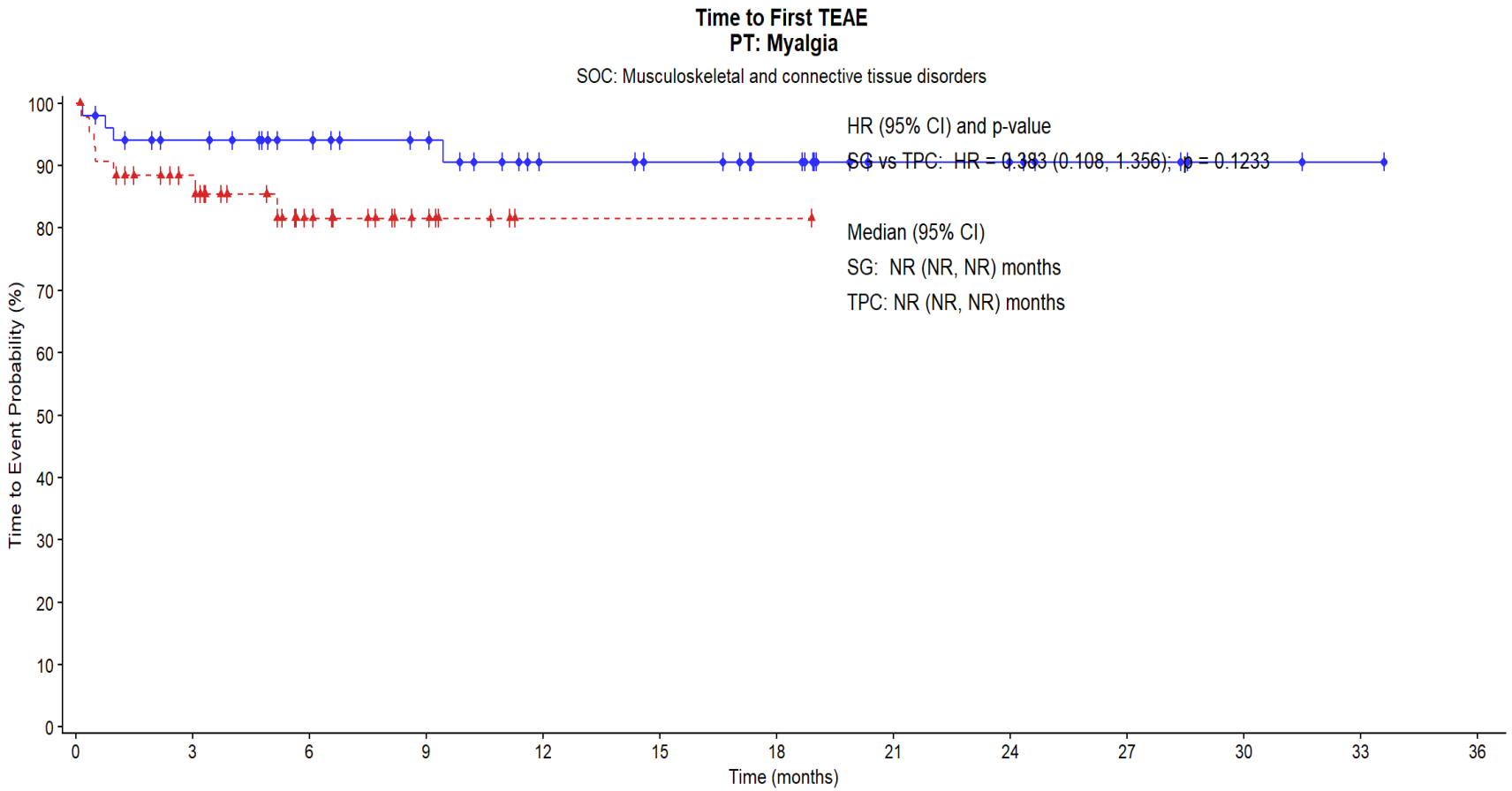
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.51. Figure 1.1.50: Kaplan Meier Plot of Time to First TEAE by PT Back pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



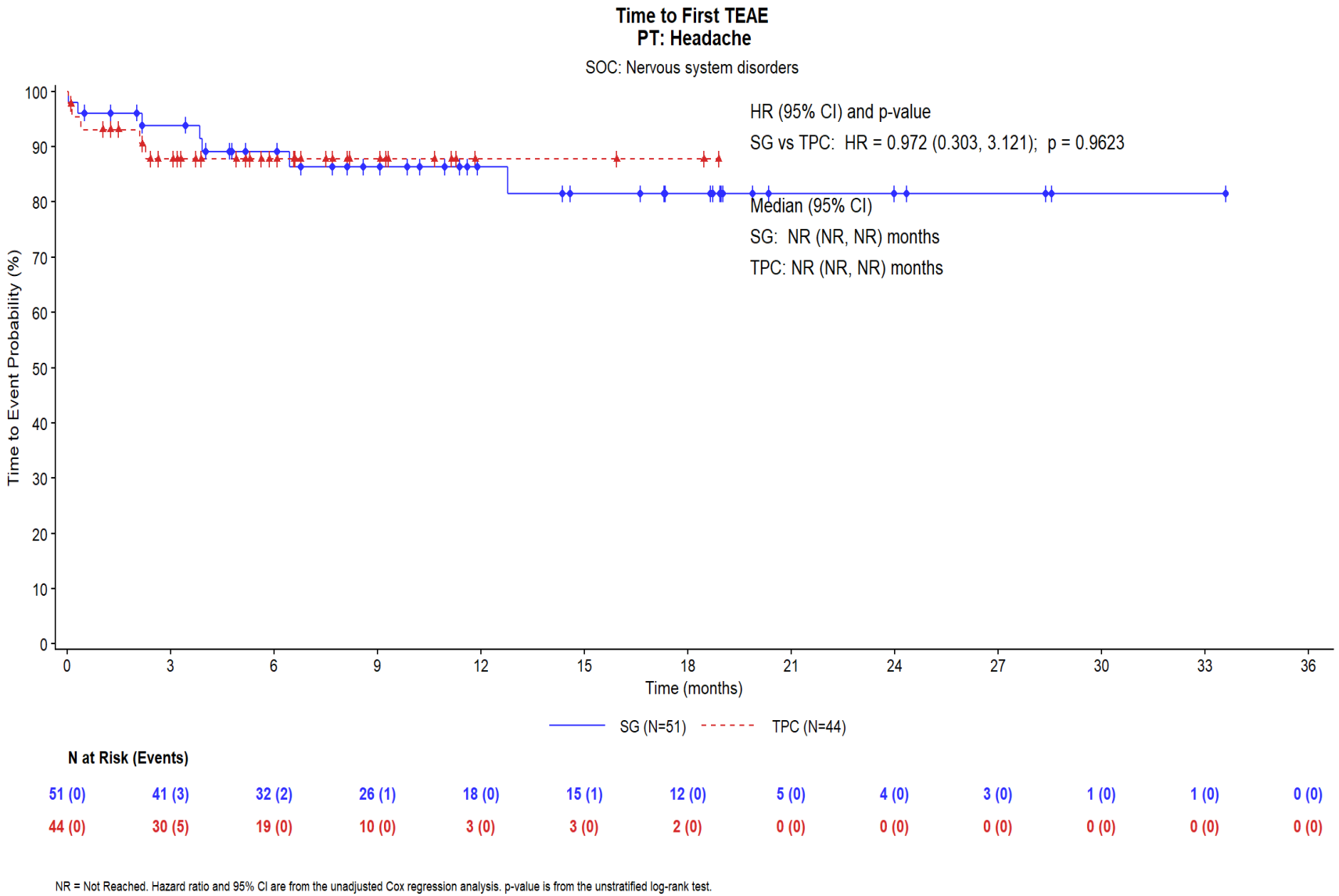
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.52. Figure 1.1.51: Kaplan Meier Plot of Time to First TEAE by PT Myalgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



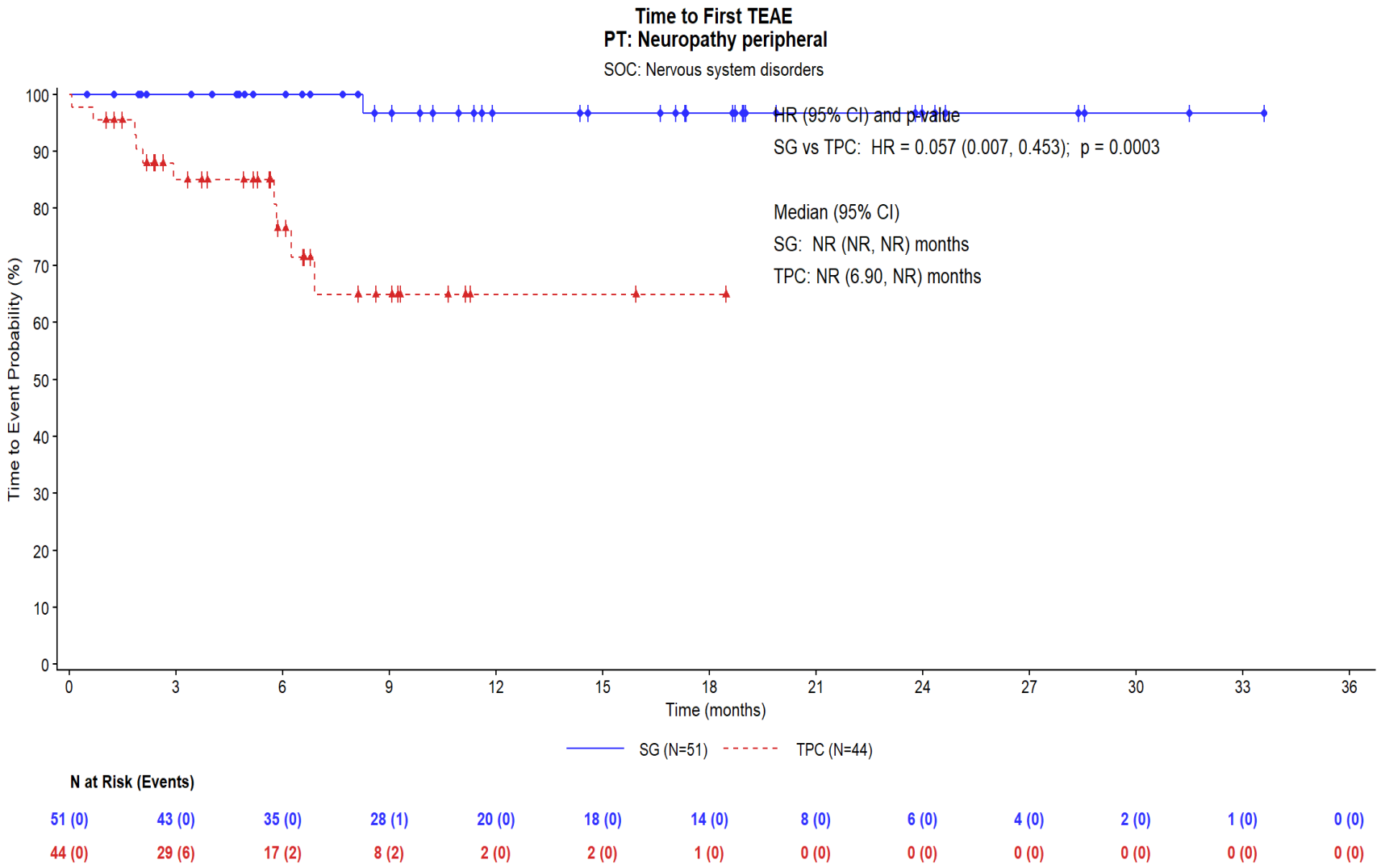
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.53. Figure 1.1.52: Kaplan Meier Plot of Time to First TEAE by PT Headache — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



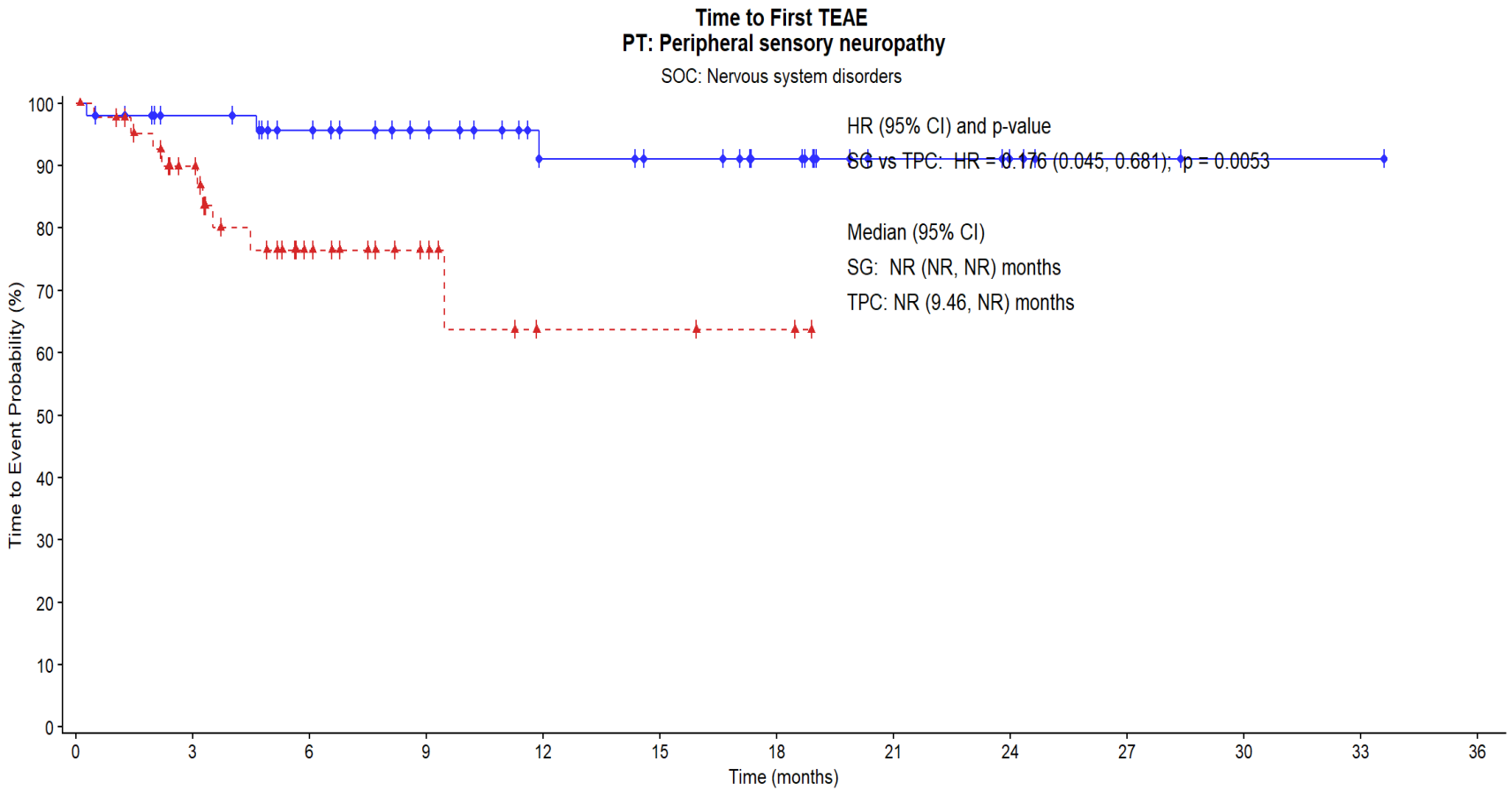
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.54. Figure 1.1.53: Kaplan Meier Plot of Time to First TEAE by PT Neuropathy peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



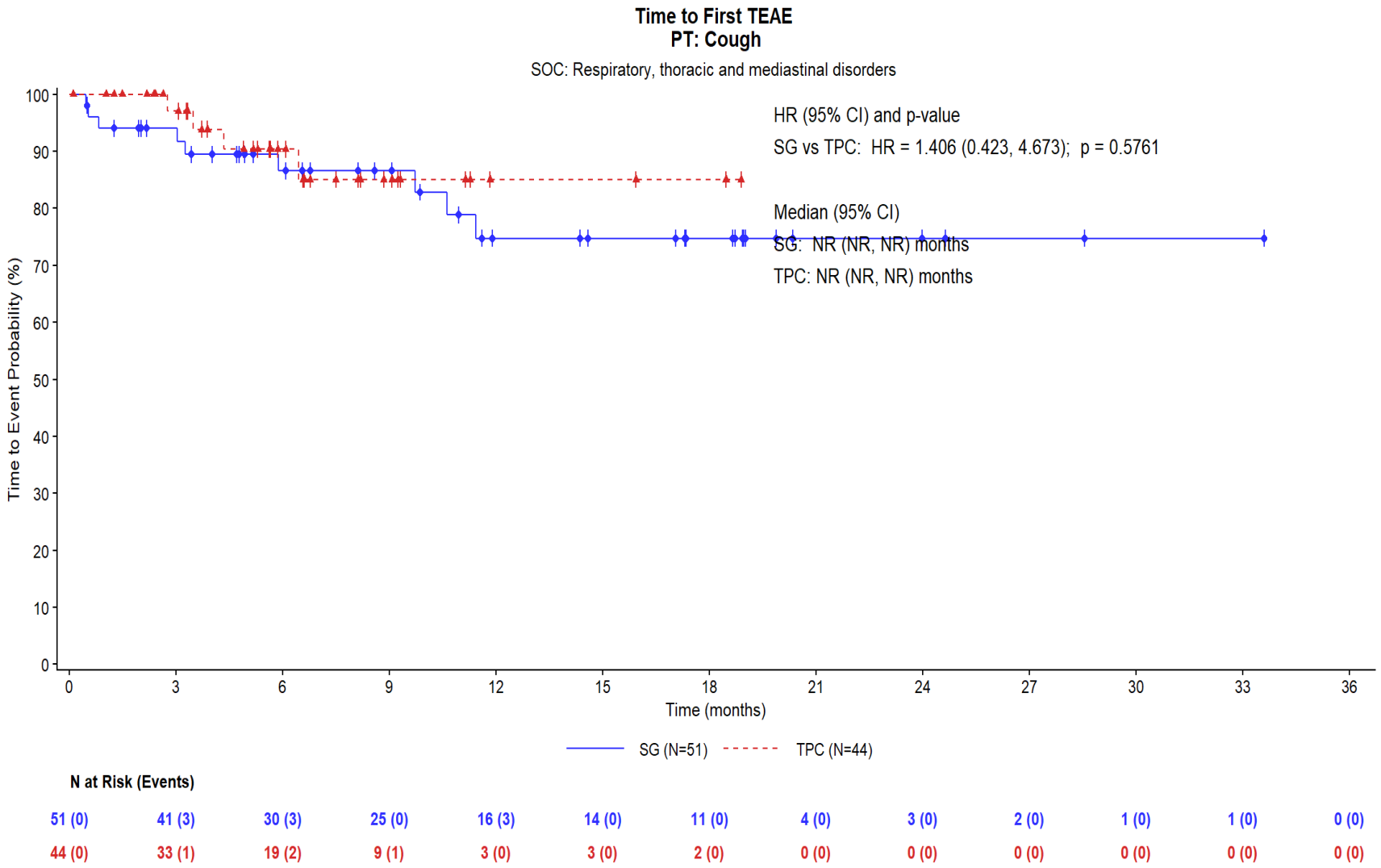
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8.55. Figure 1.1.54: Kaplan Meier Plot of Time to First TEAE by PT Peripheral sensory neuropathy — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



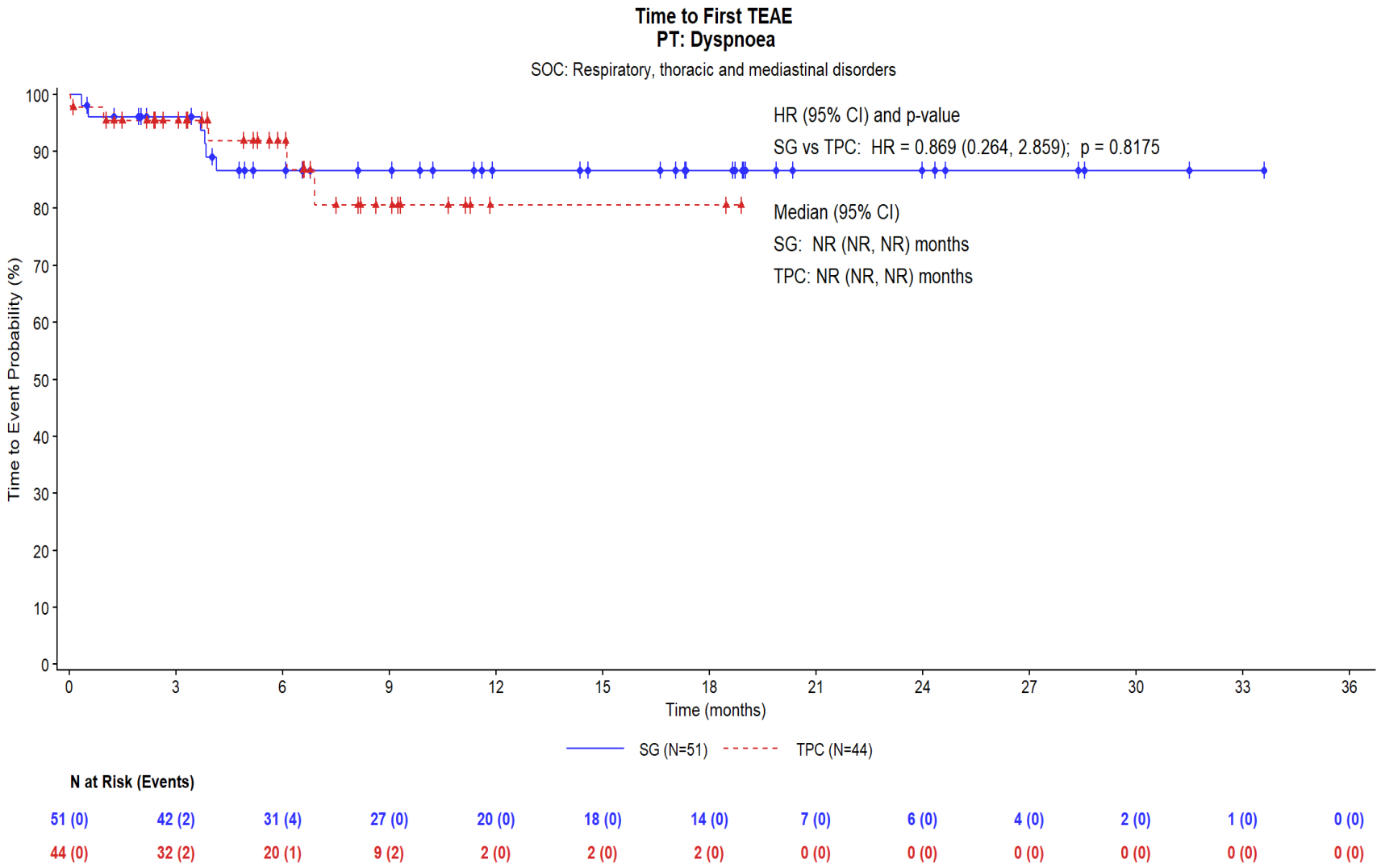
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.56. Figure 1.1.55: Kaplan Meier Plot of Time to First TEAE by PT Cough — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



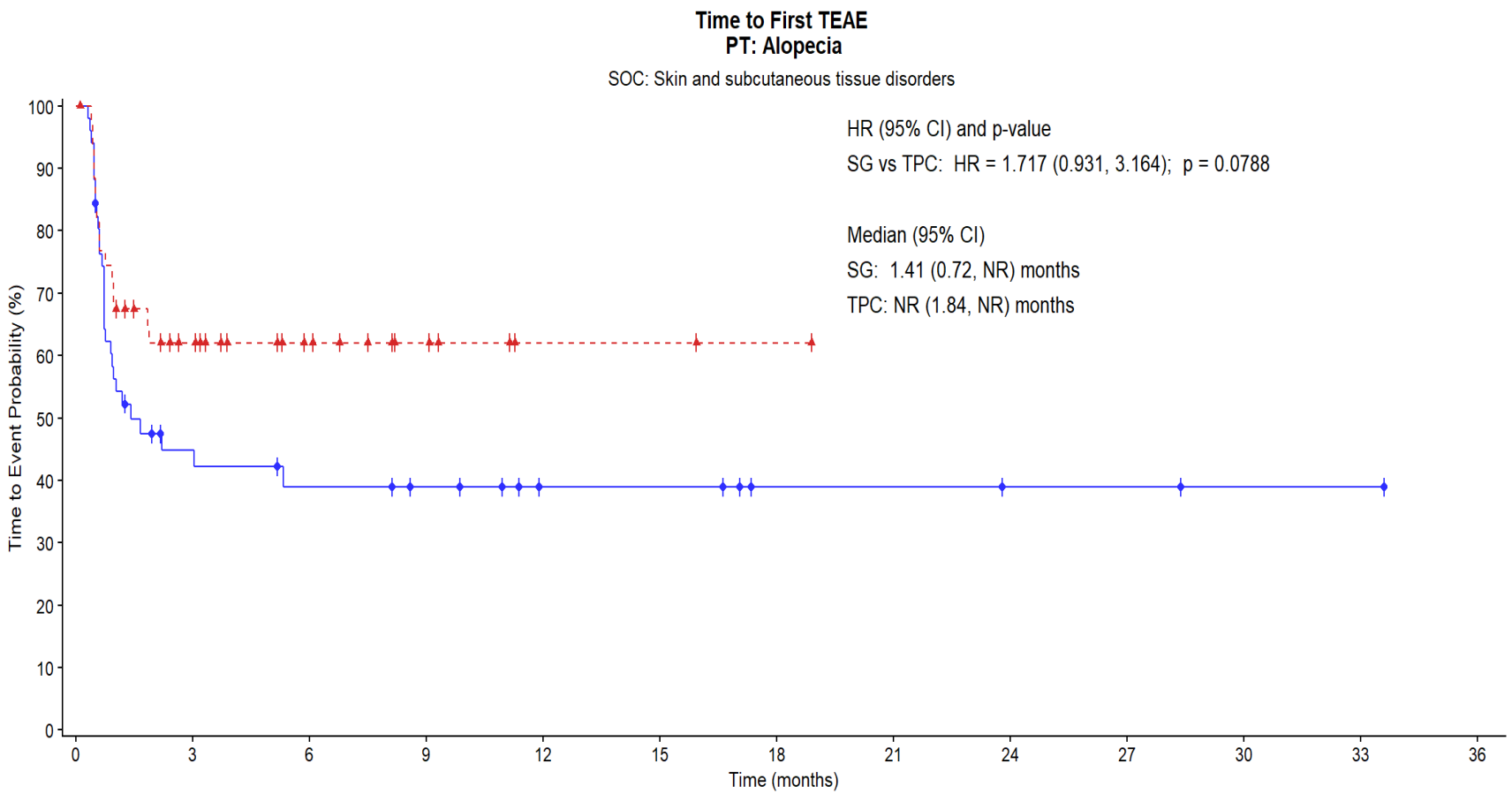
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.57. Figure 1.1.56: Kaplan Meier Plot of Time to First TEAE by PT Dyspnoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



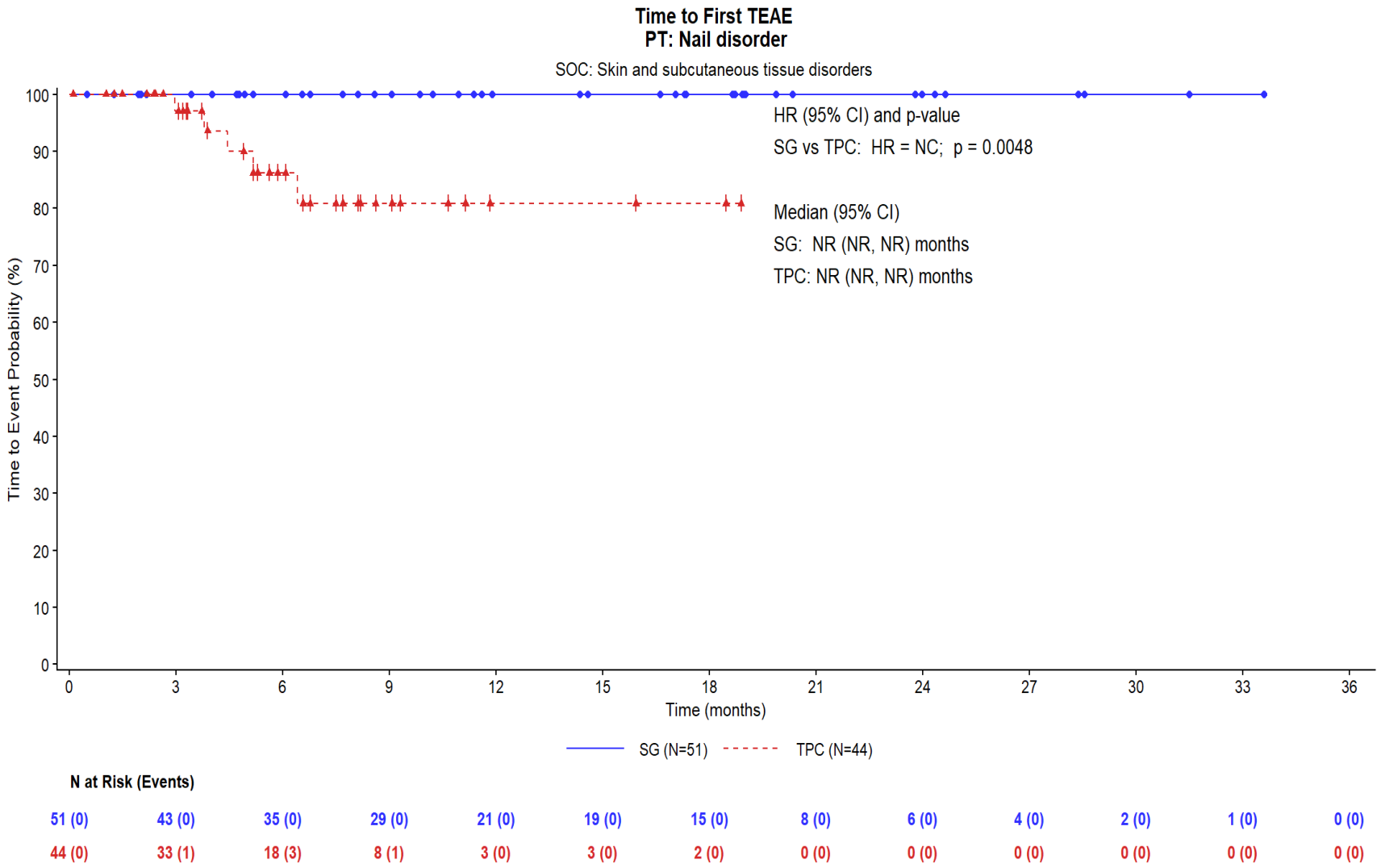
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.58. Figure 1.1.57: Kaplan Meier Plot of Time to First TEAE by PT Alopecia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



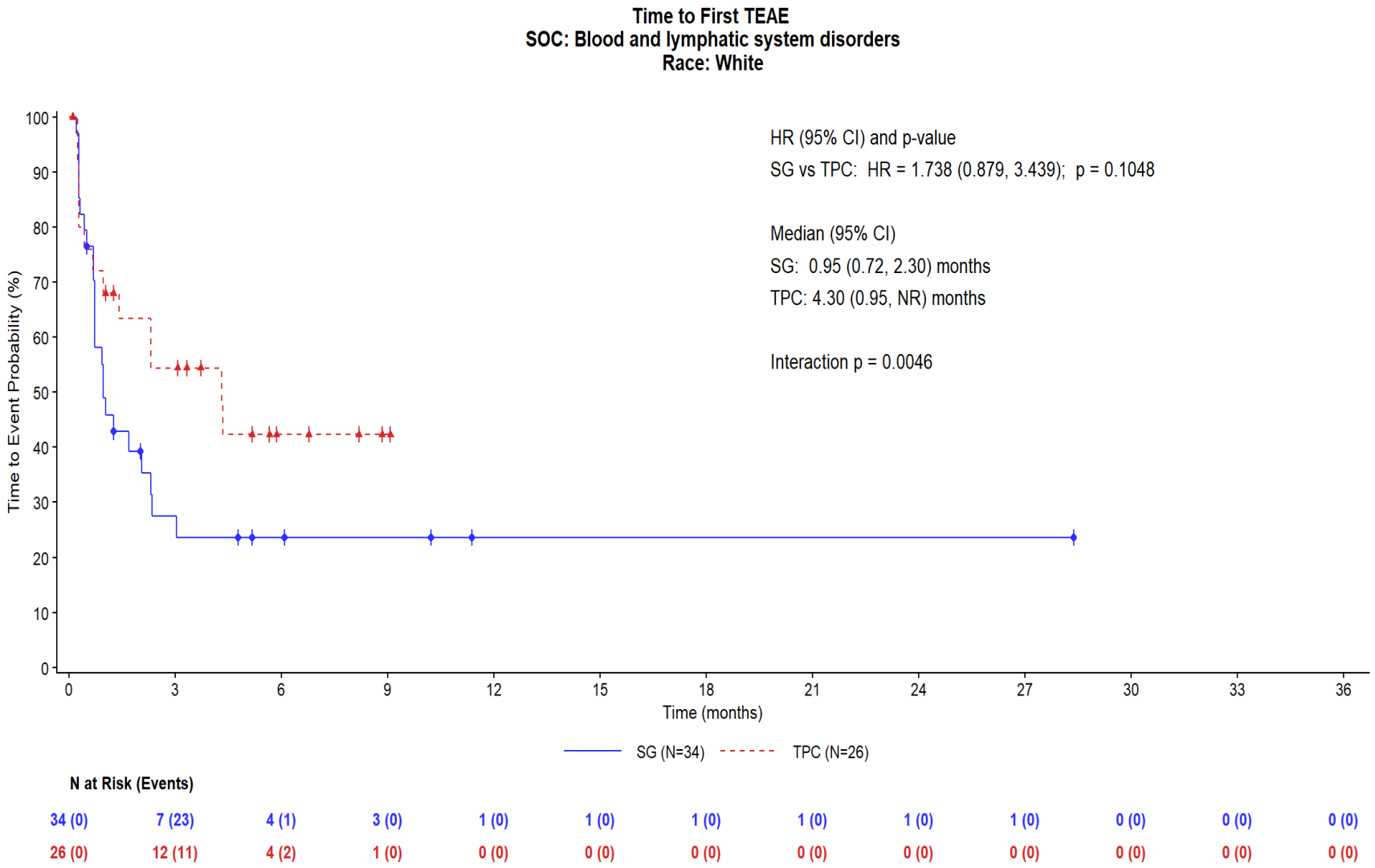
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.59. Figure 1.1.58: Kaplan Meier Plot of Time to First TEAE by PT Nail disorder — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



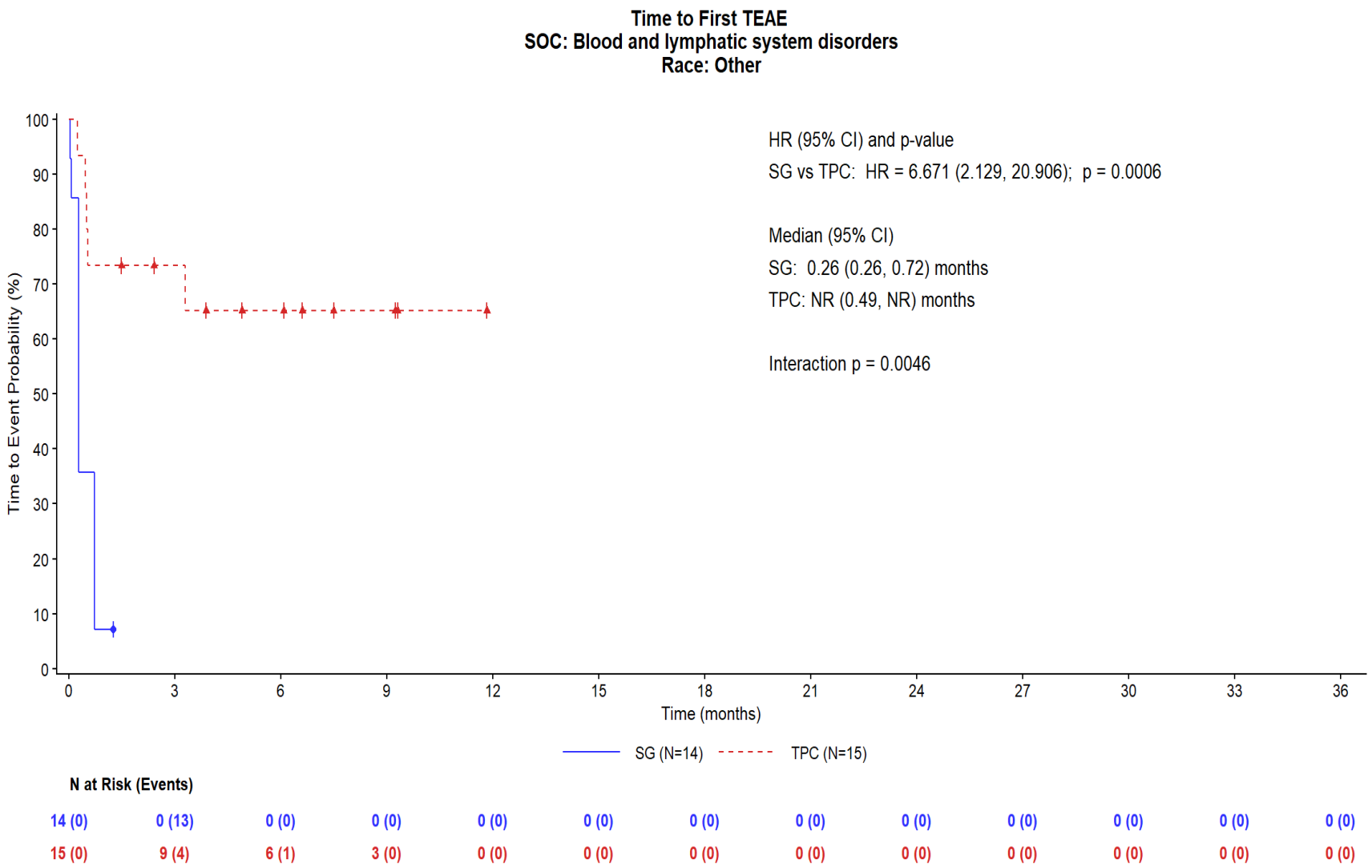
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.60. Figure 1.1.59: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



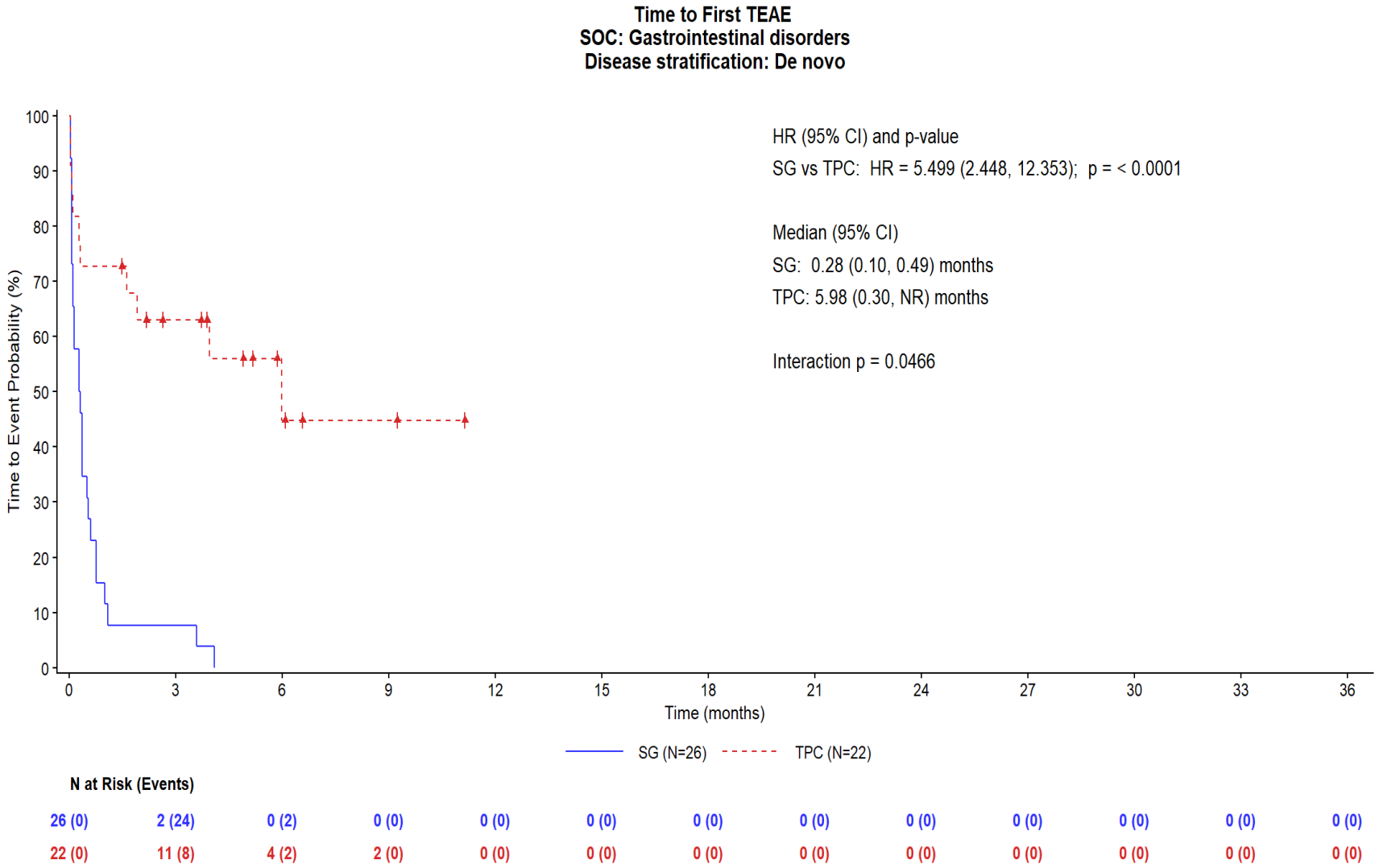
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.61. Figure 1.1.60: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



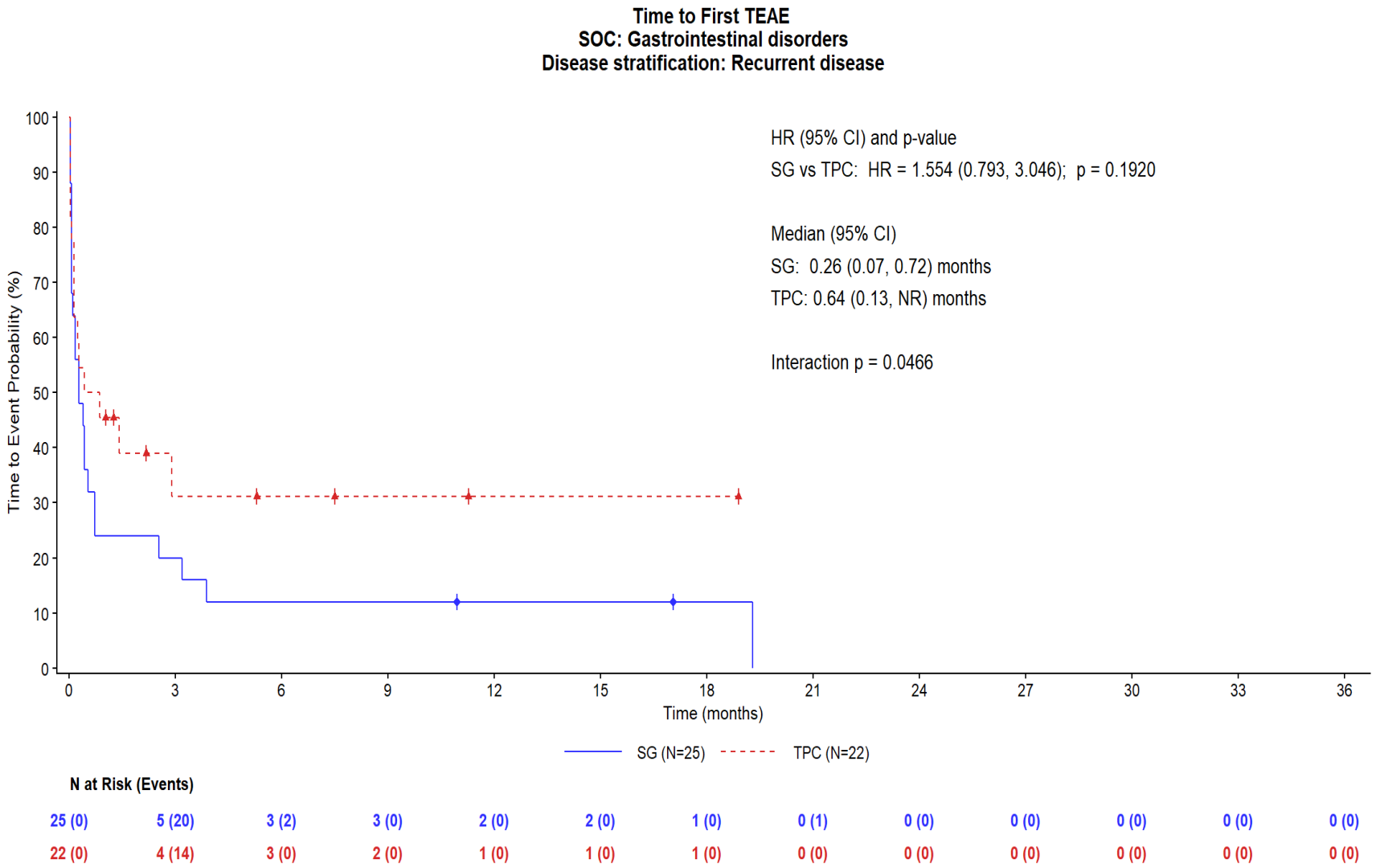
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.62. Figure 1.1.61: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders Disease stratification De novo — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



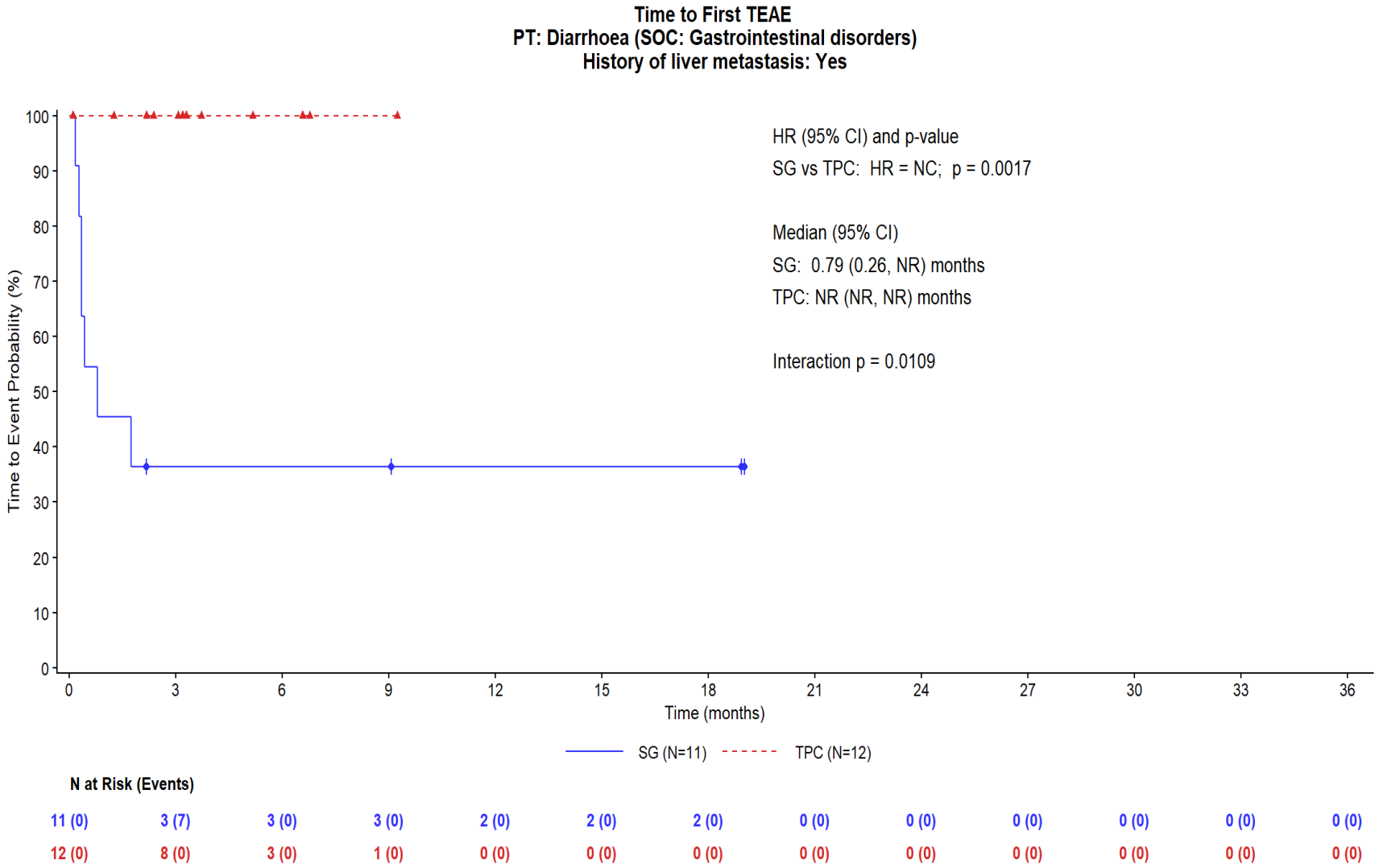
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.63. Figure 1.1.62: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders Disease stratification Recurrent disease — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



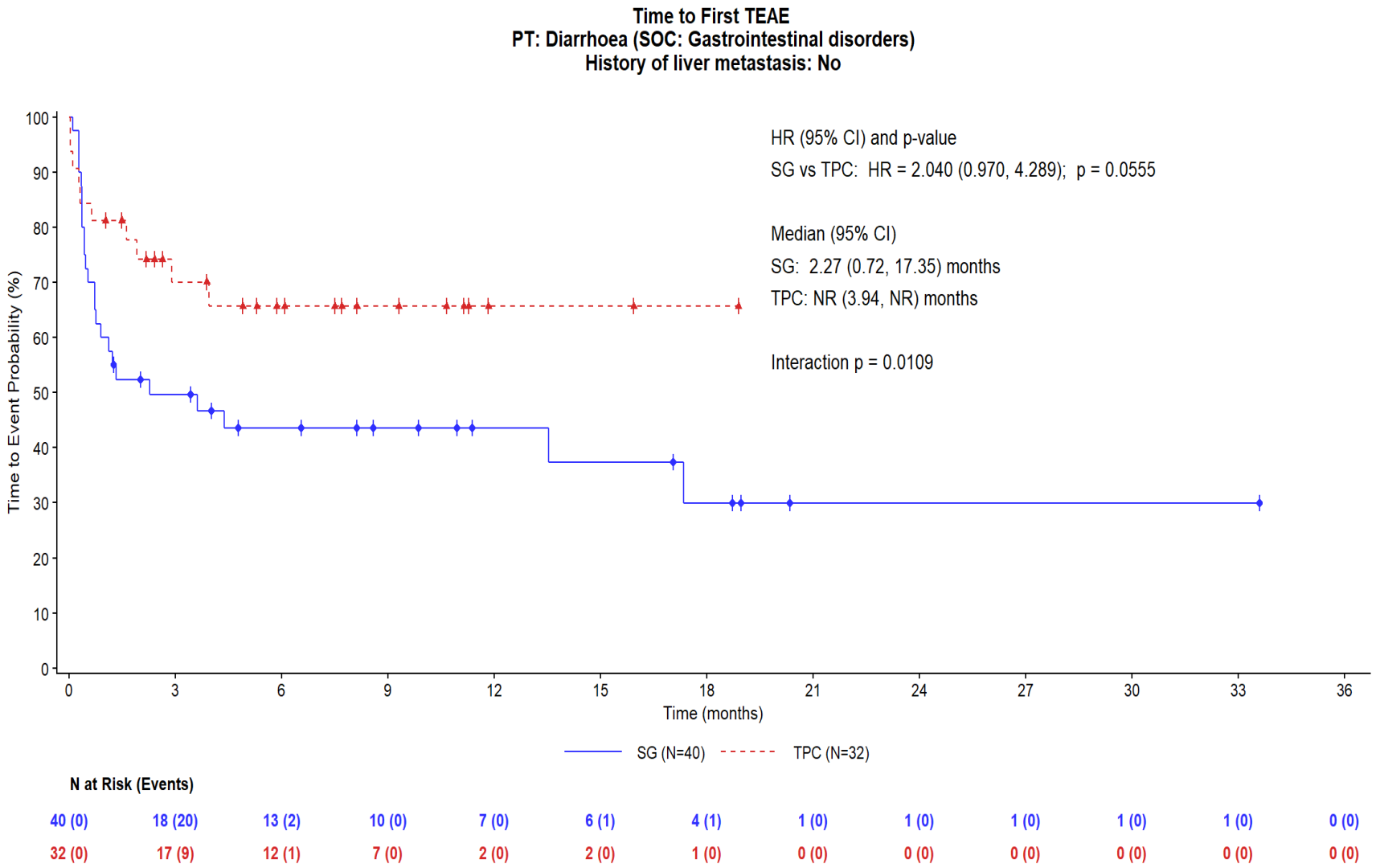
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.64. Figure 1.1.63: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) History of liver metastasis Yes — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



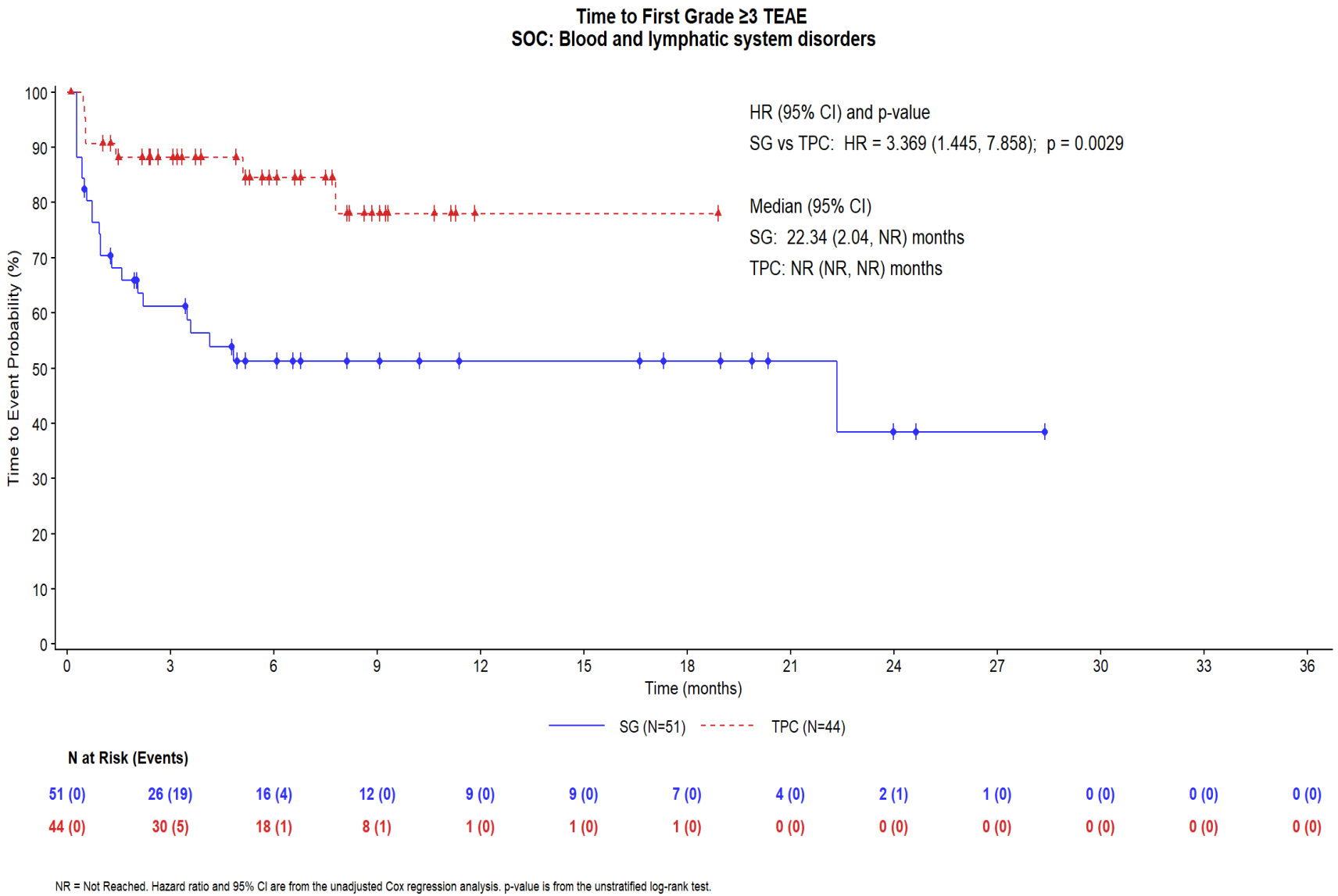
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.65. Figure 1.1.64: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) History of liver metastasis No — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



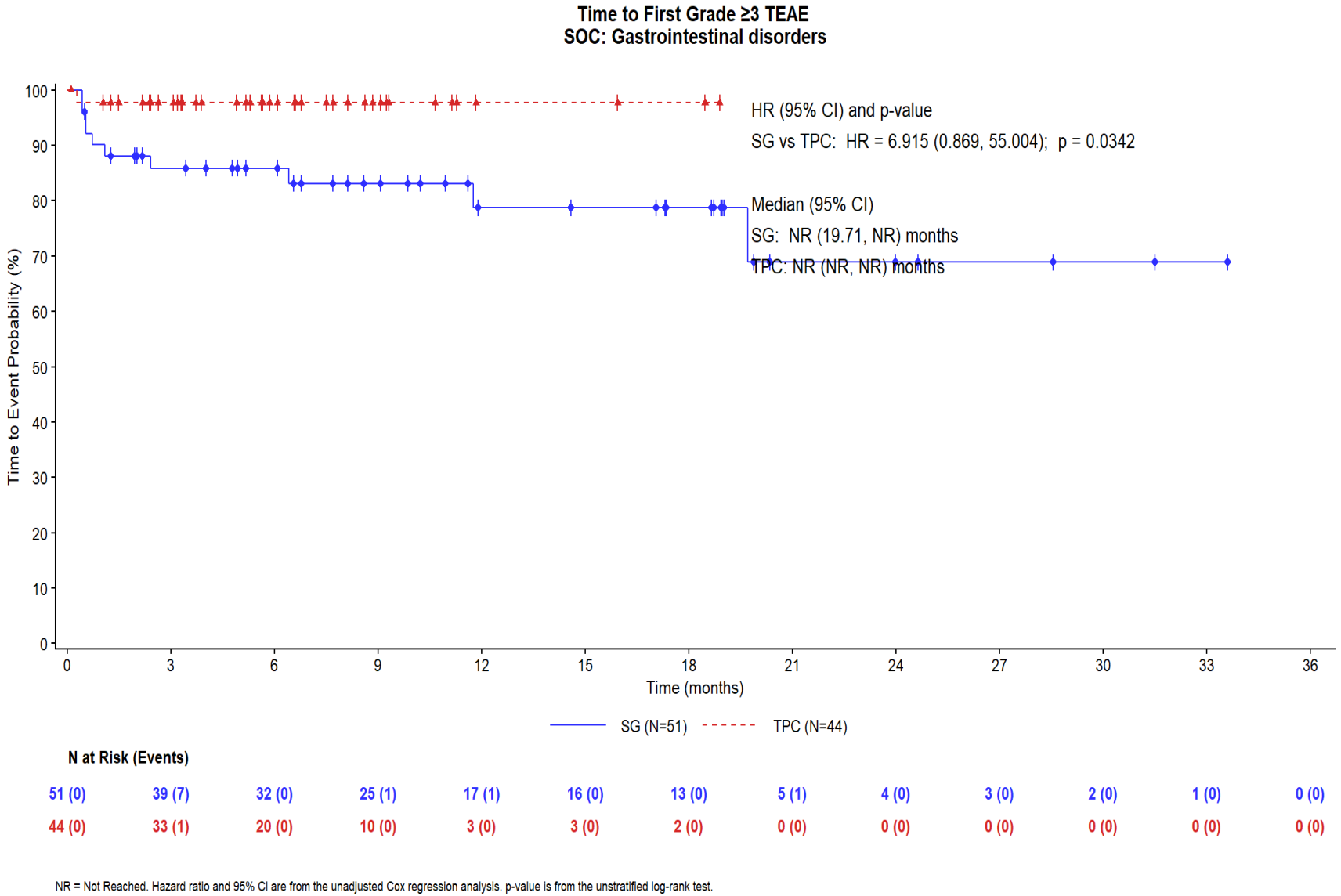
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

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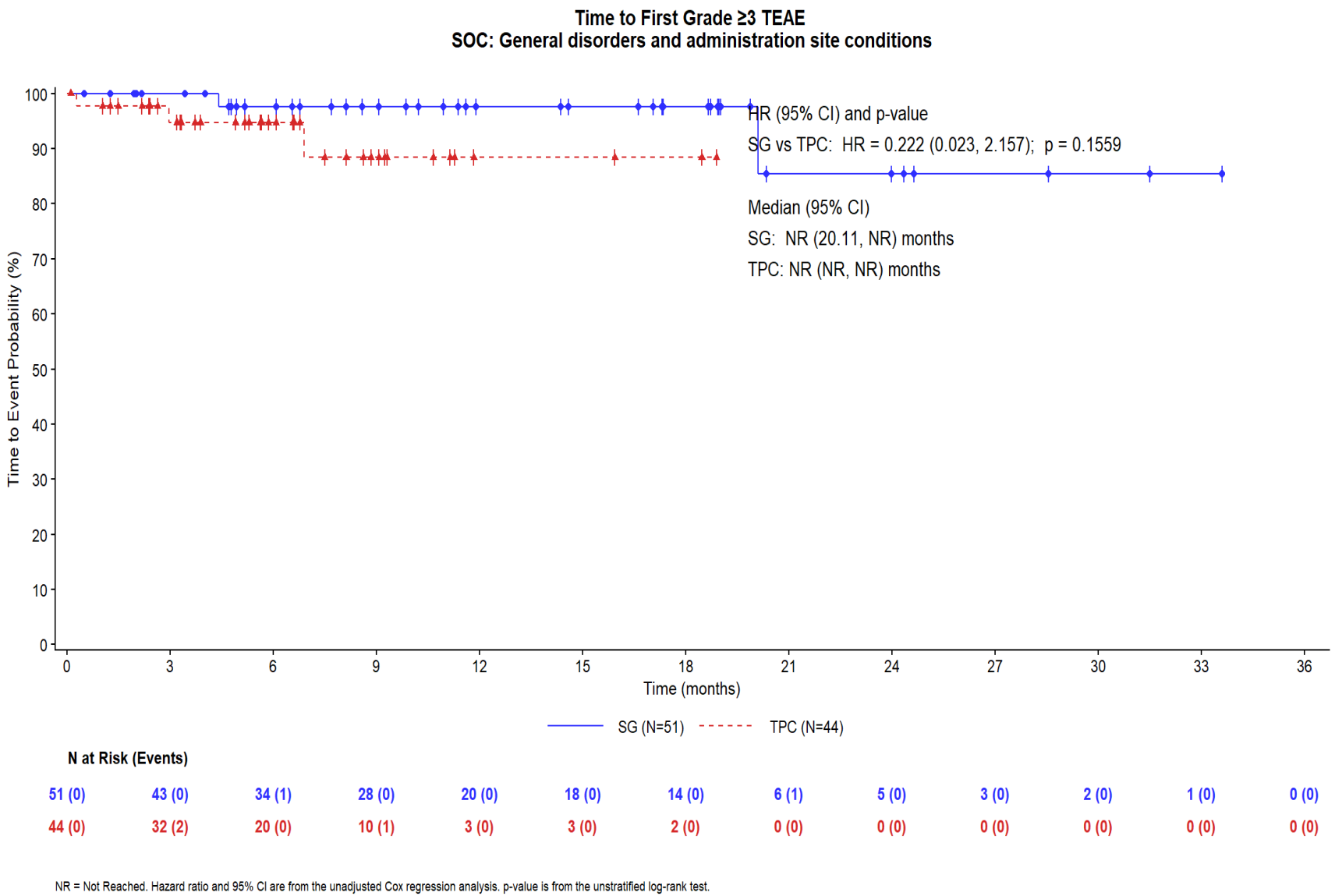
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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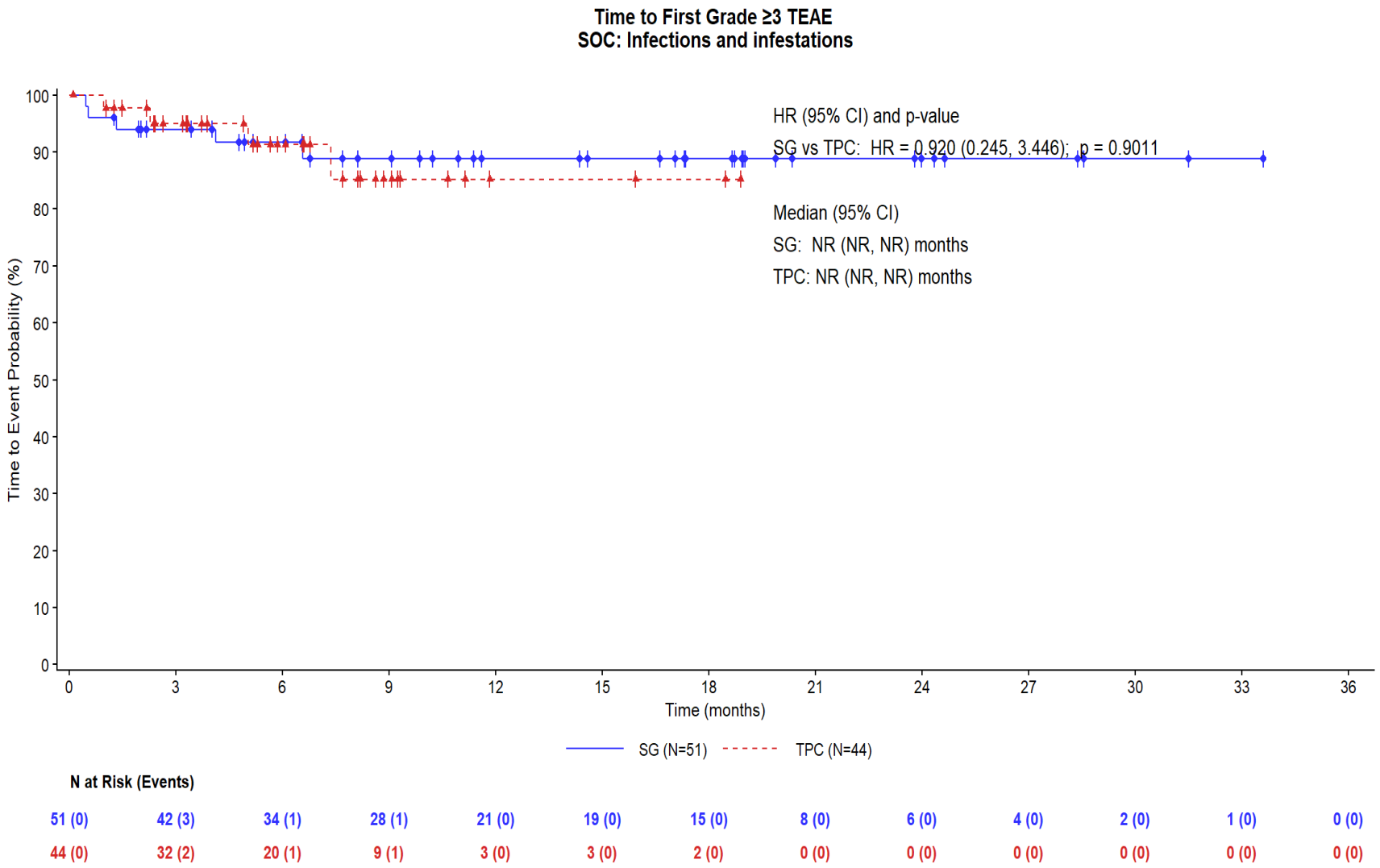
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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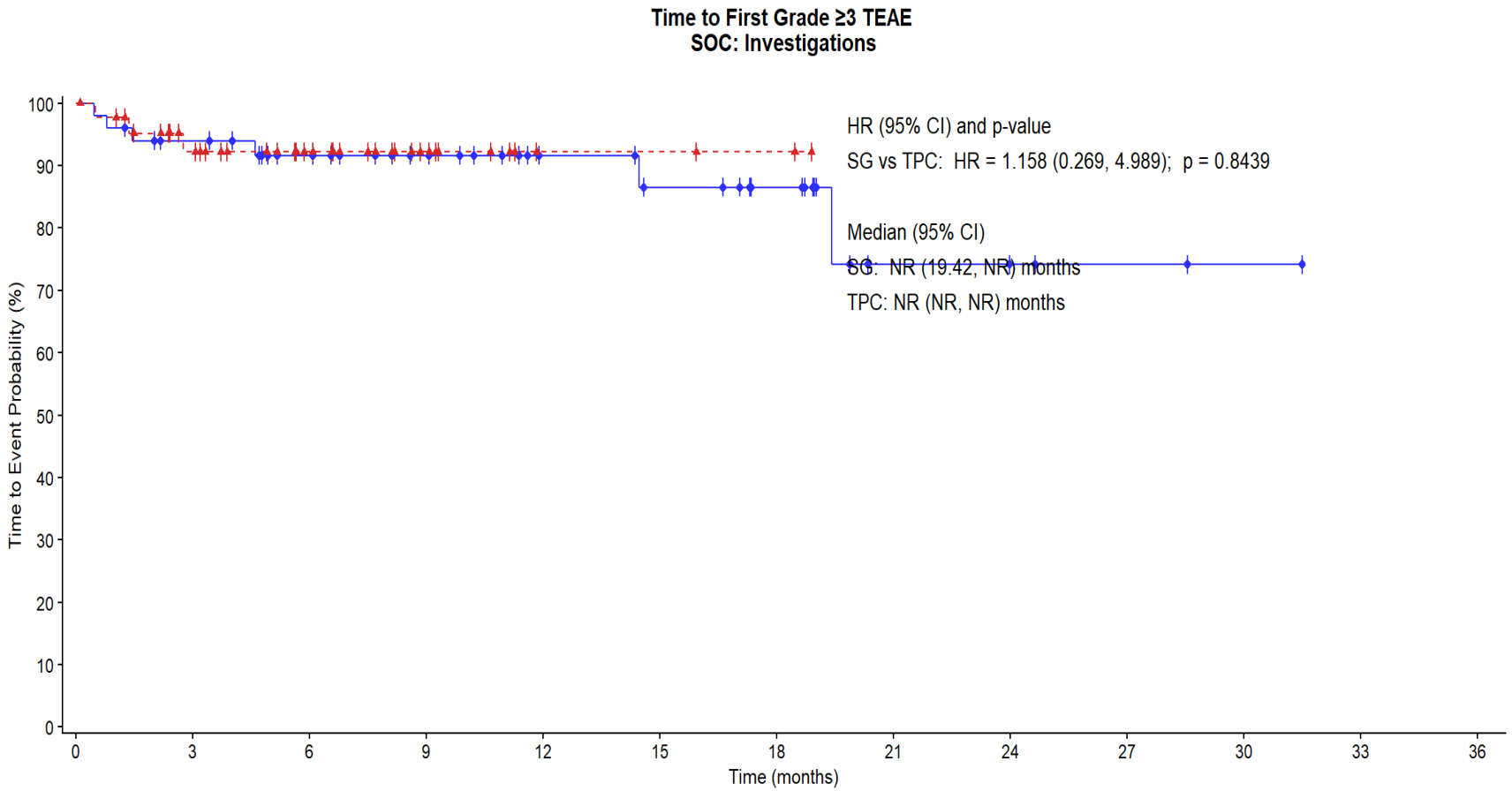
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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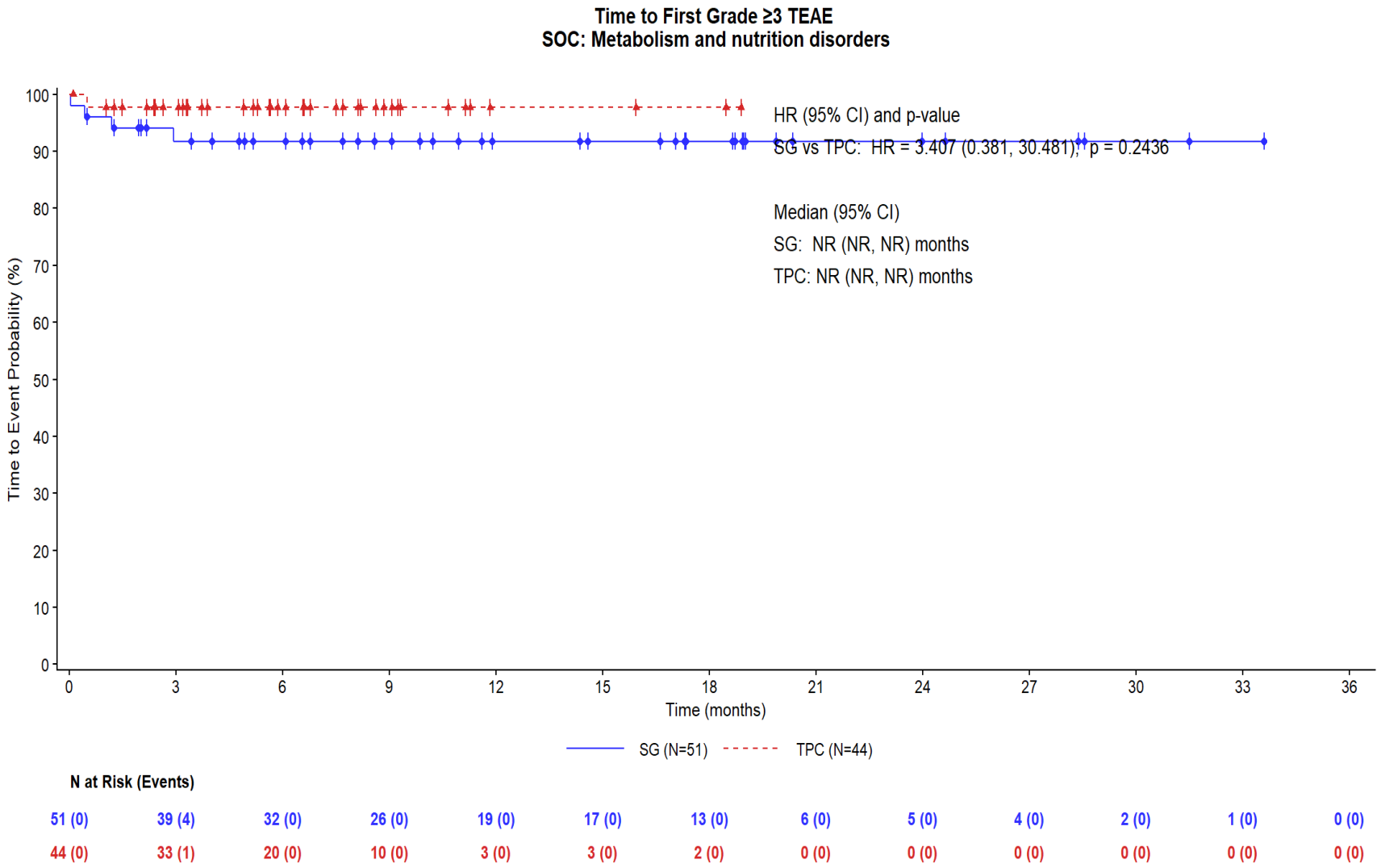
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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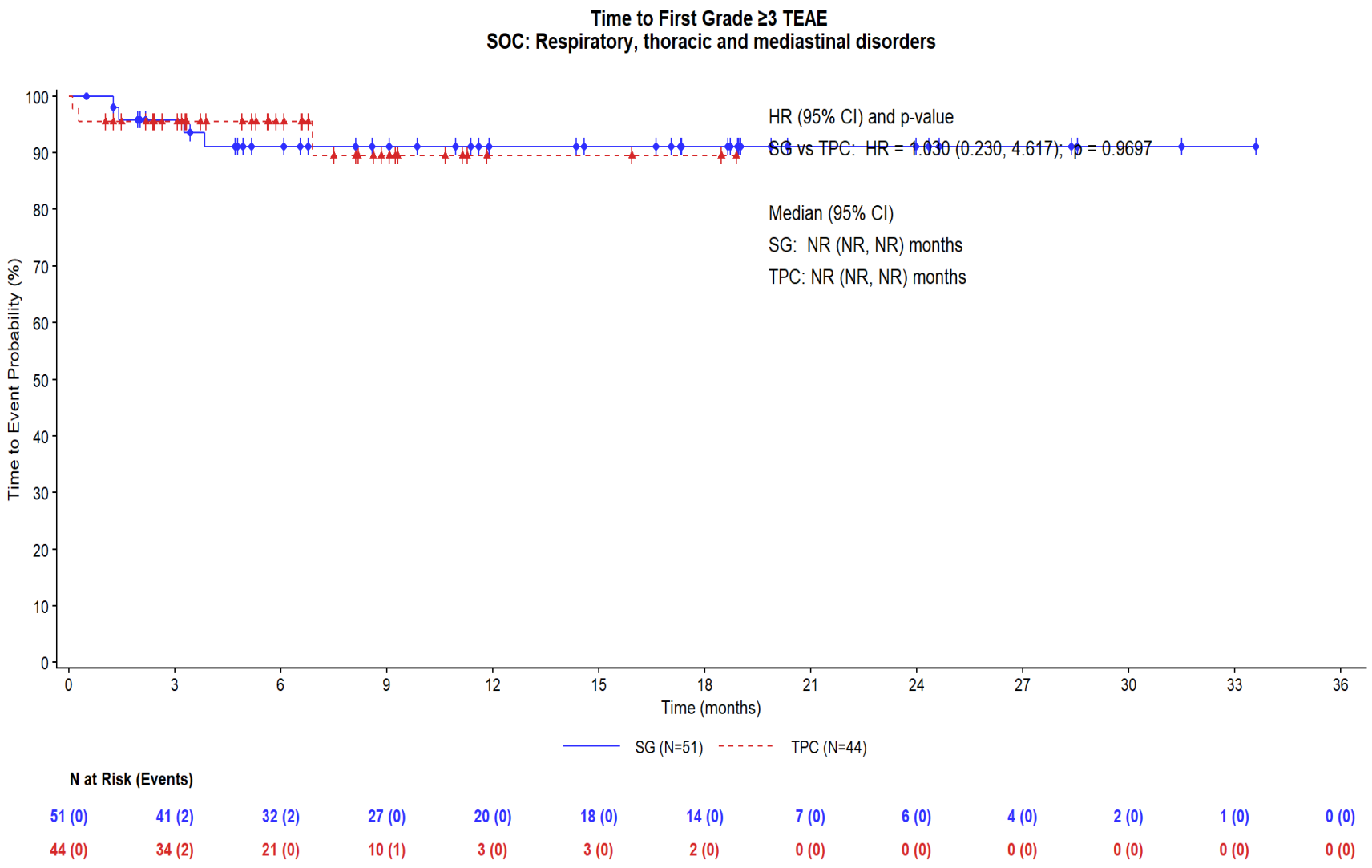
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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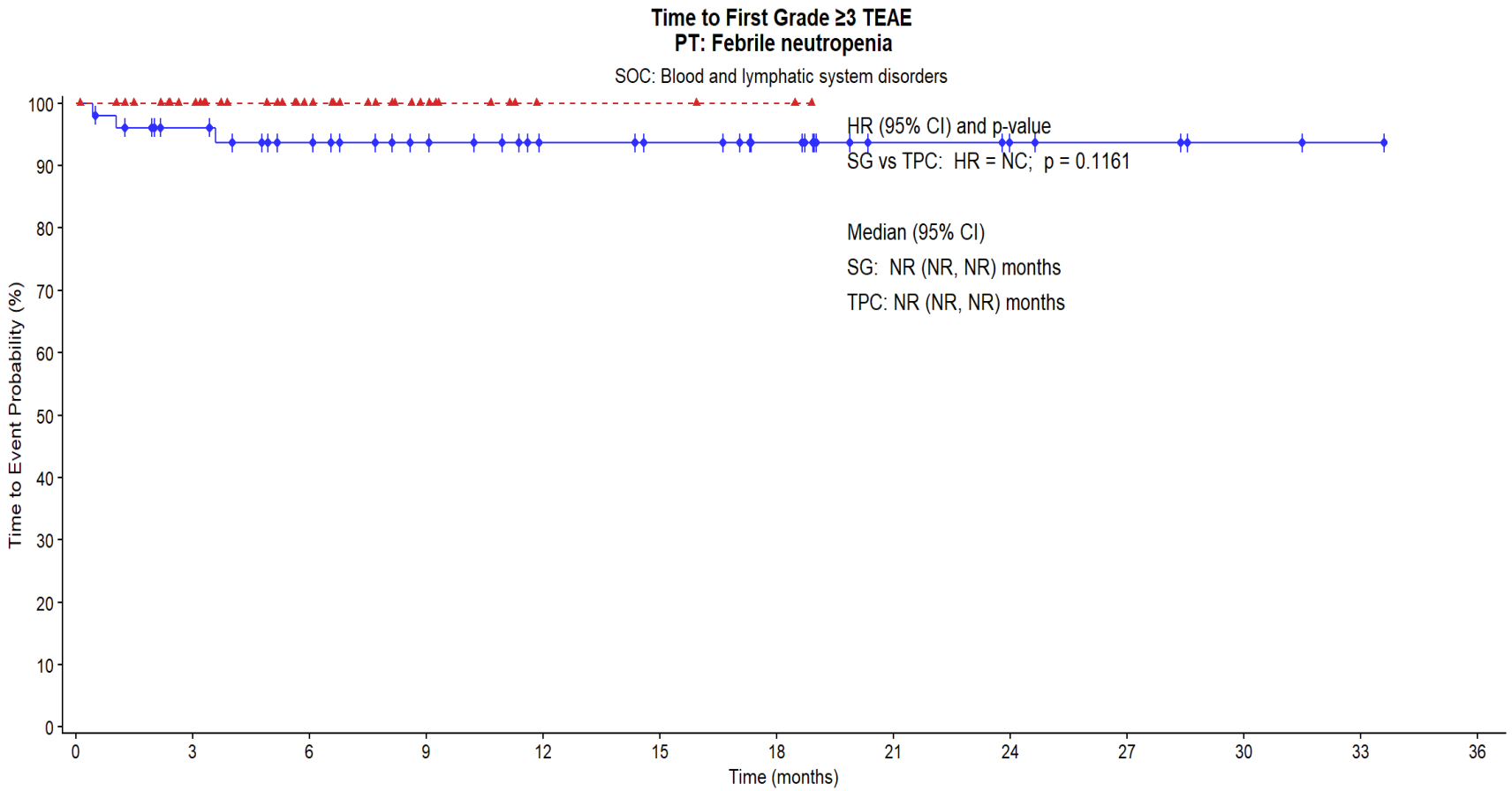
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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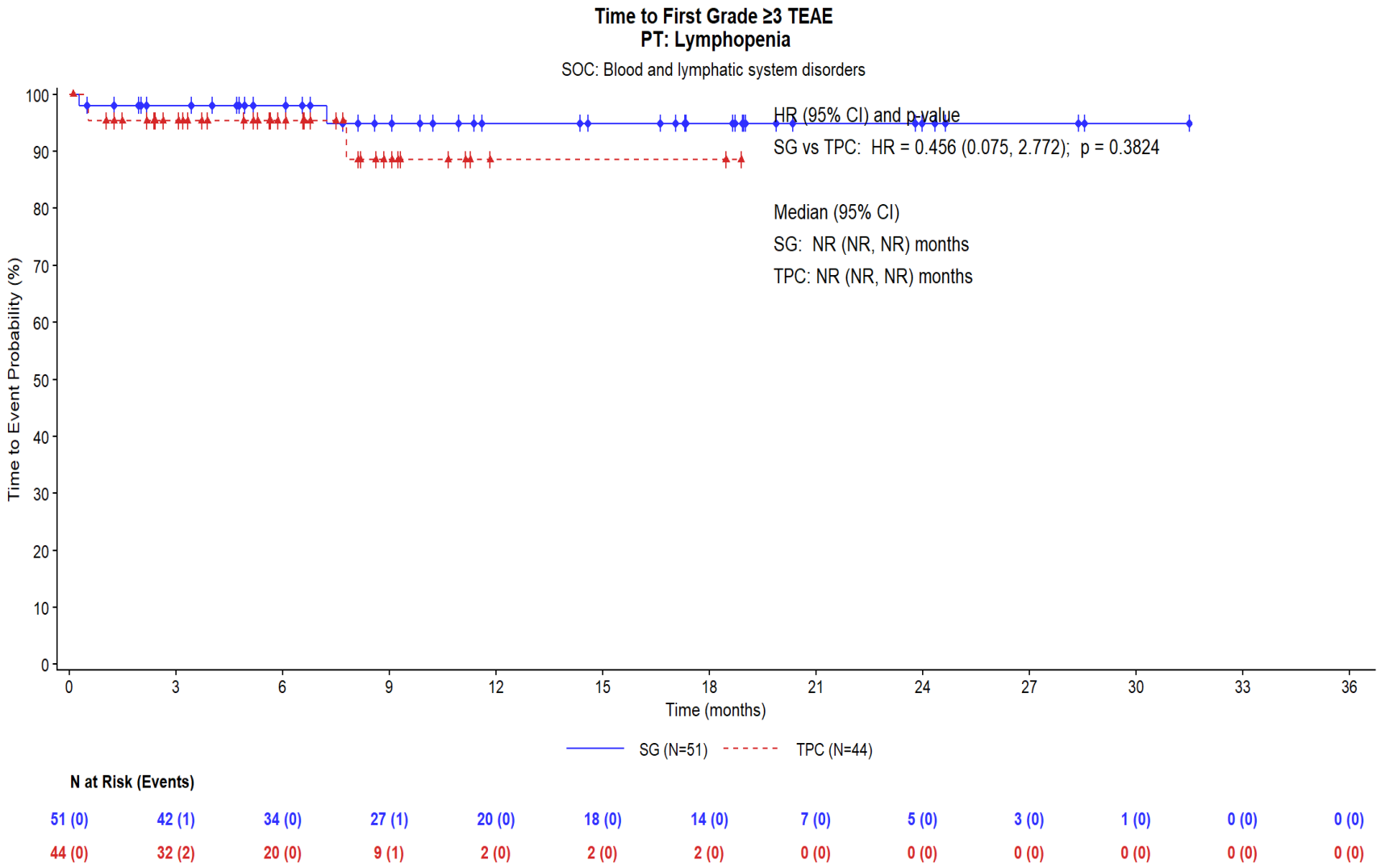
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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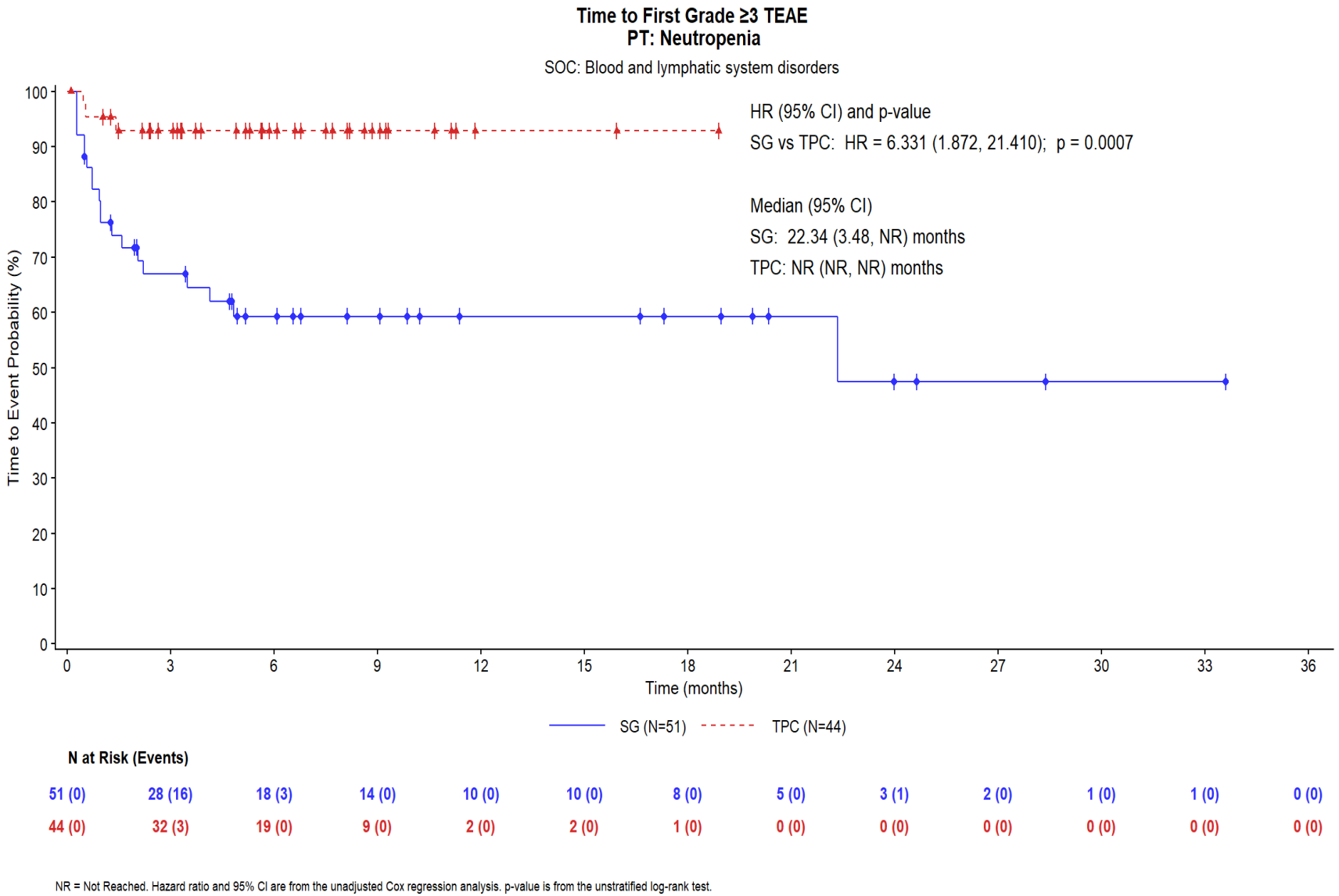
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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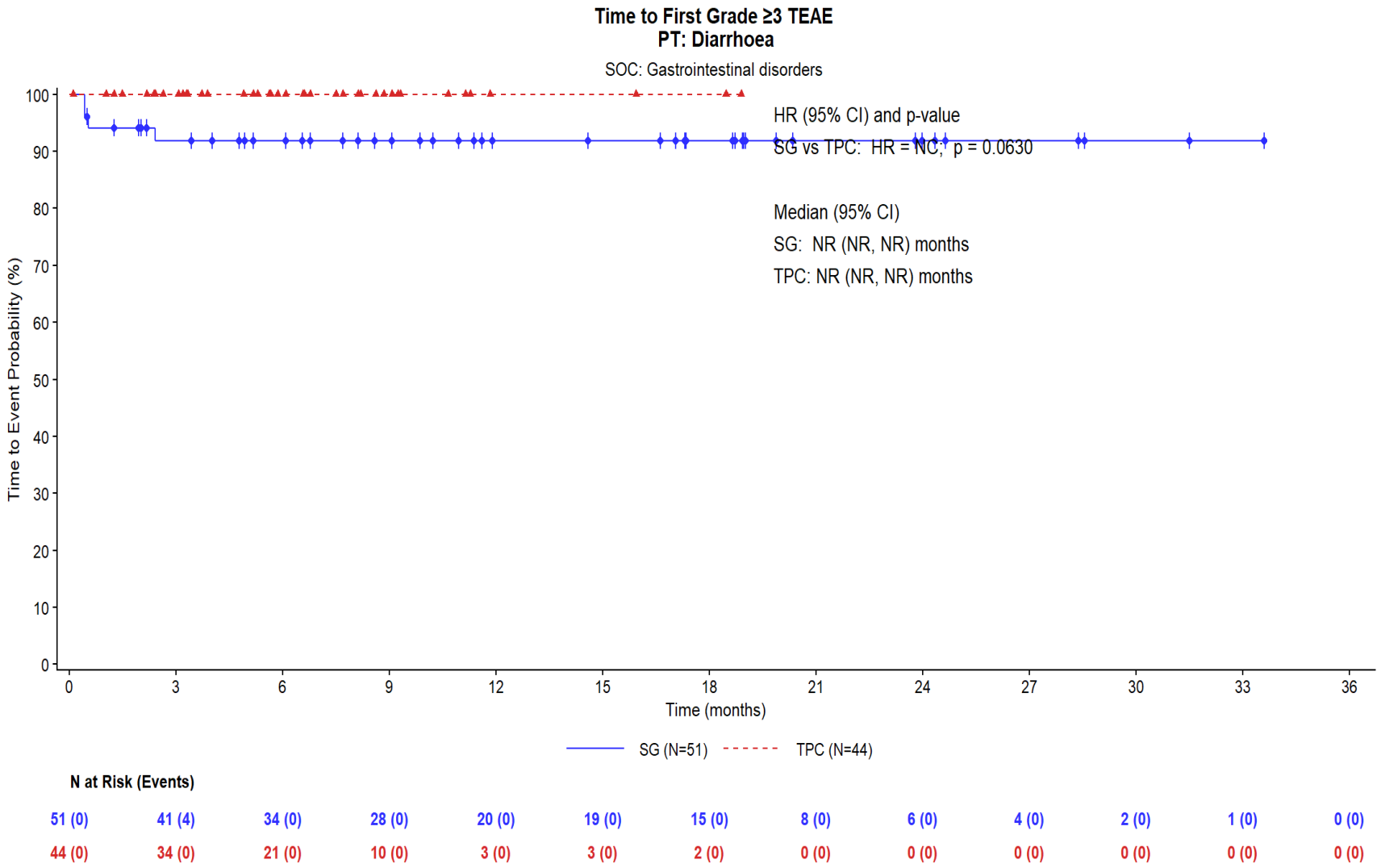
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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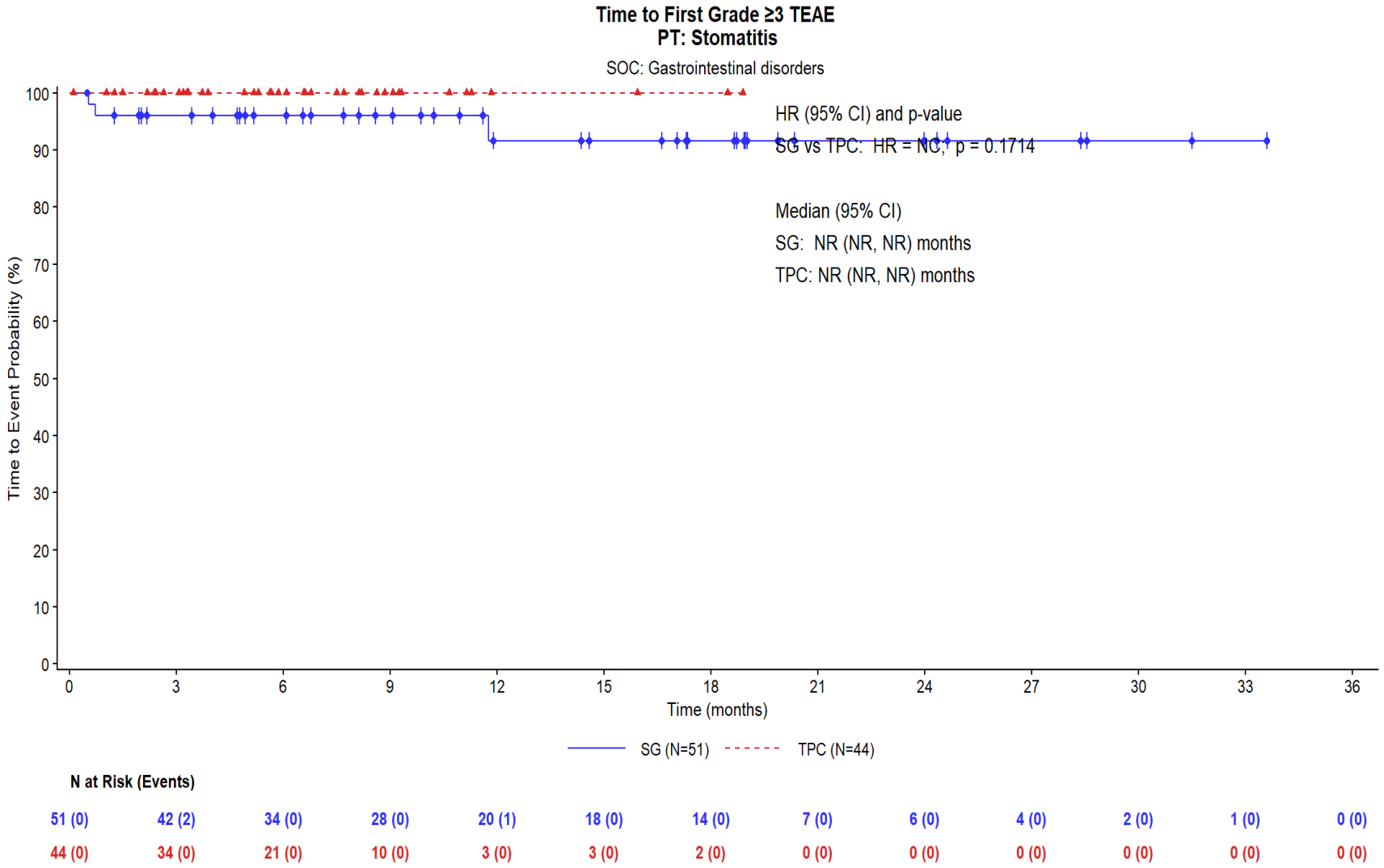
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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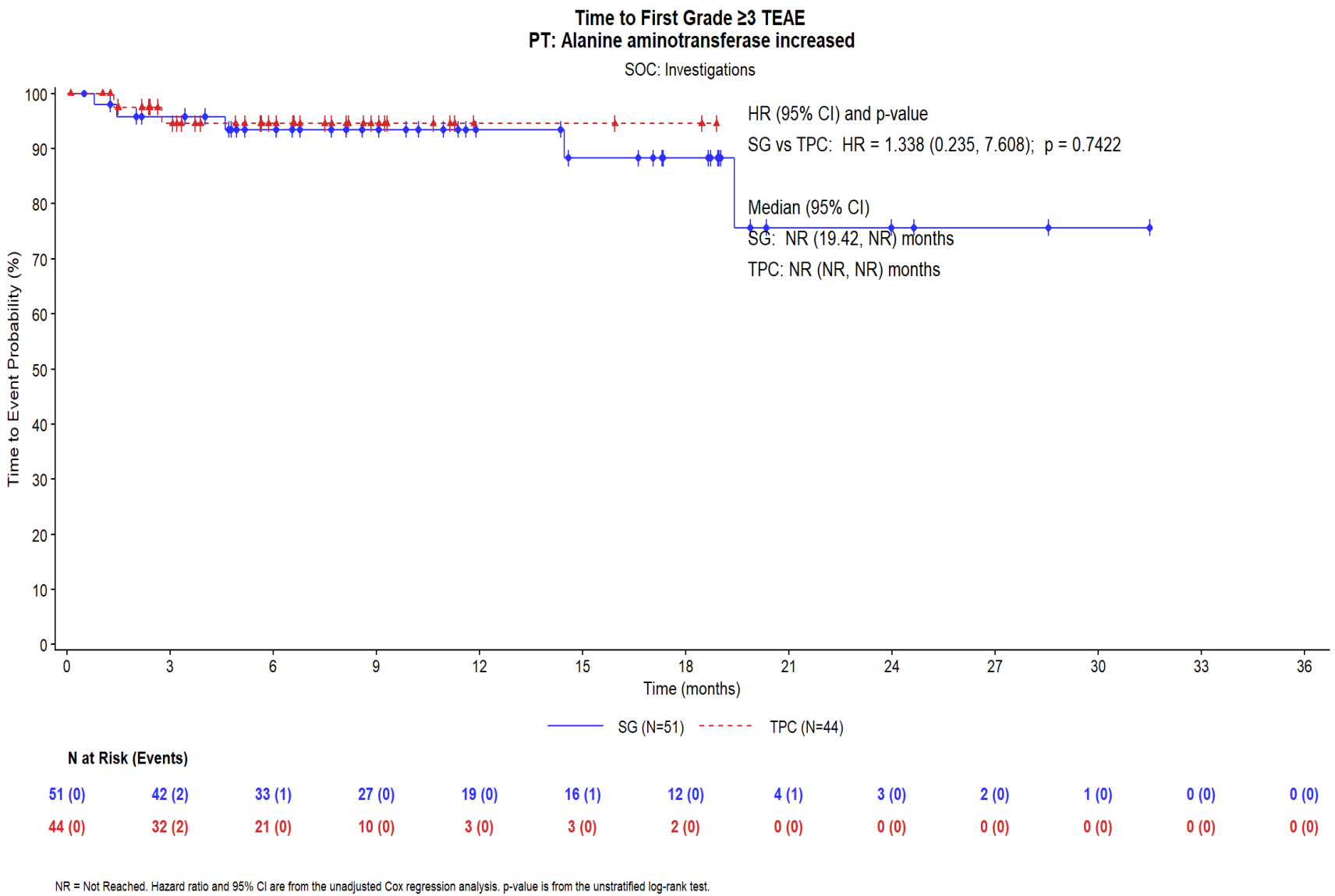
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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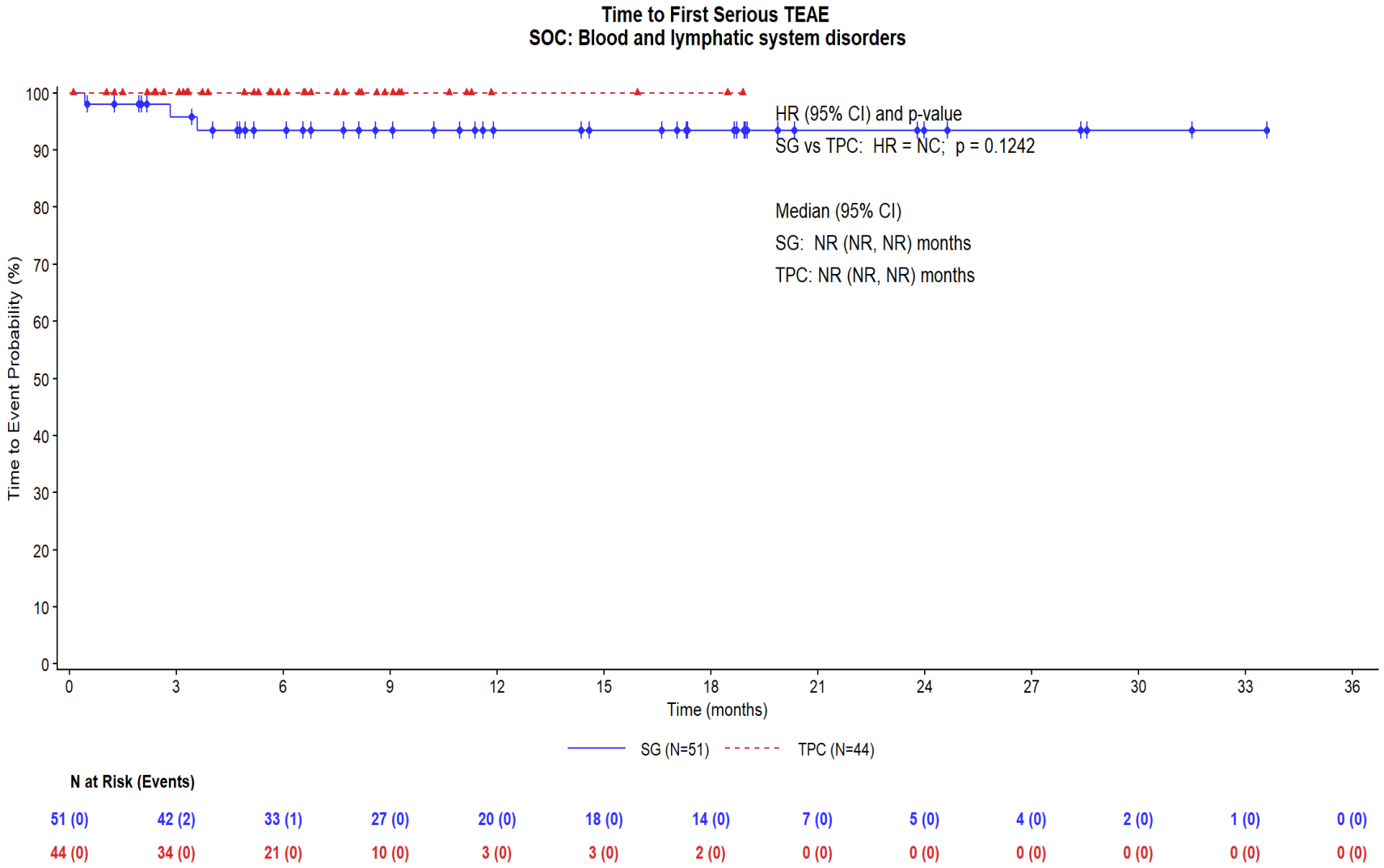
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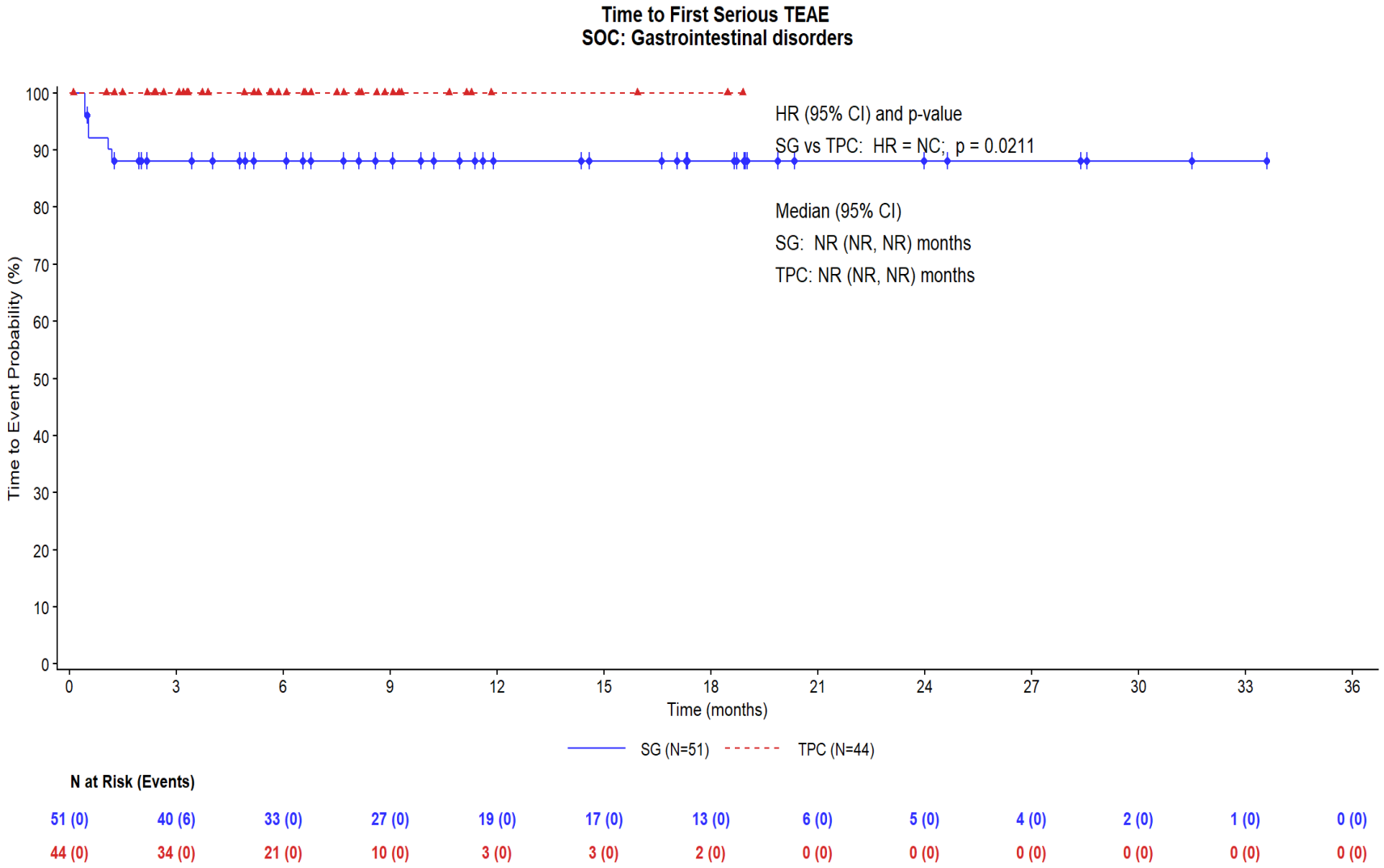
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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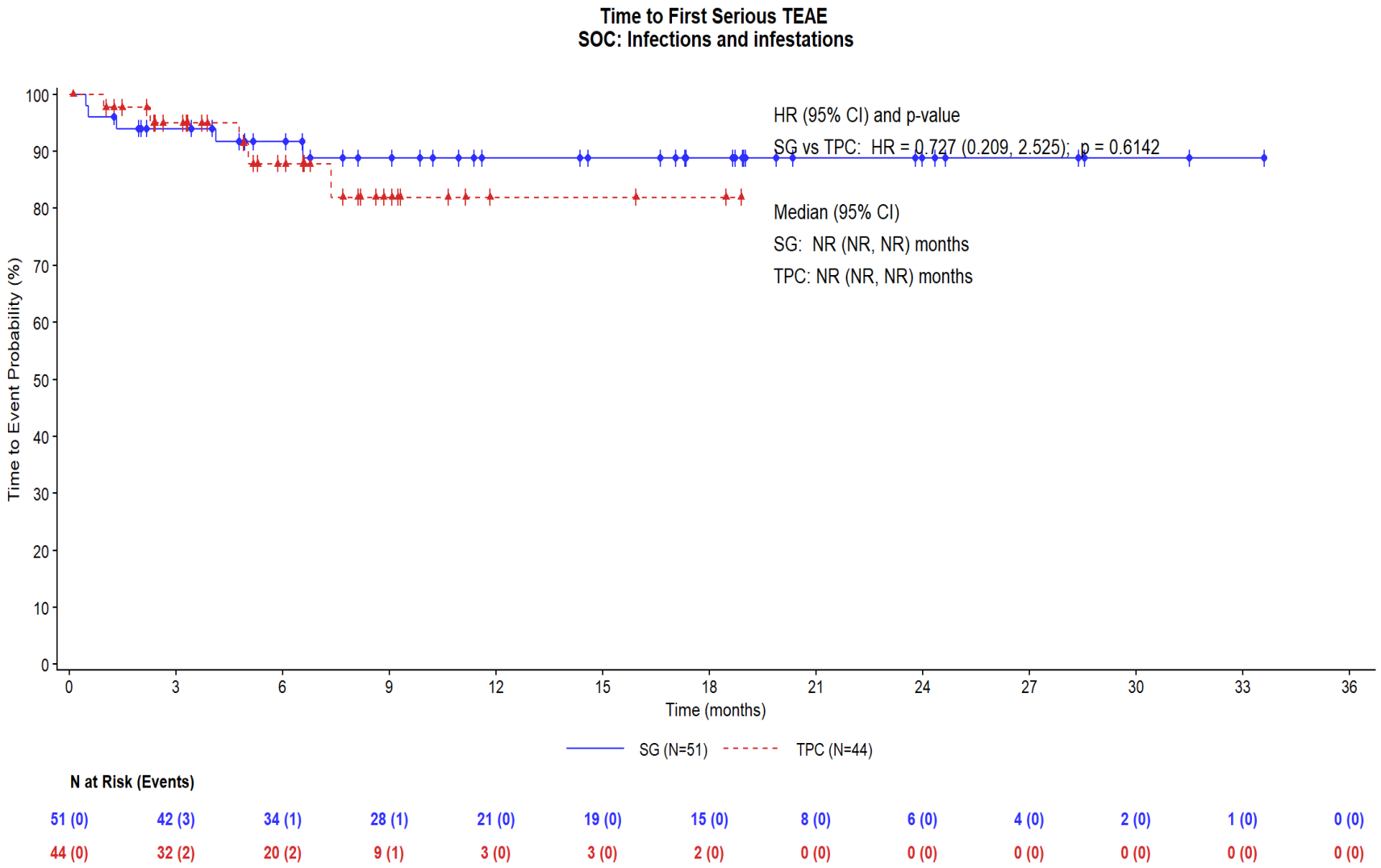
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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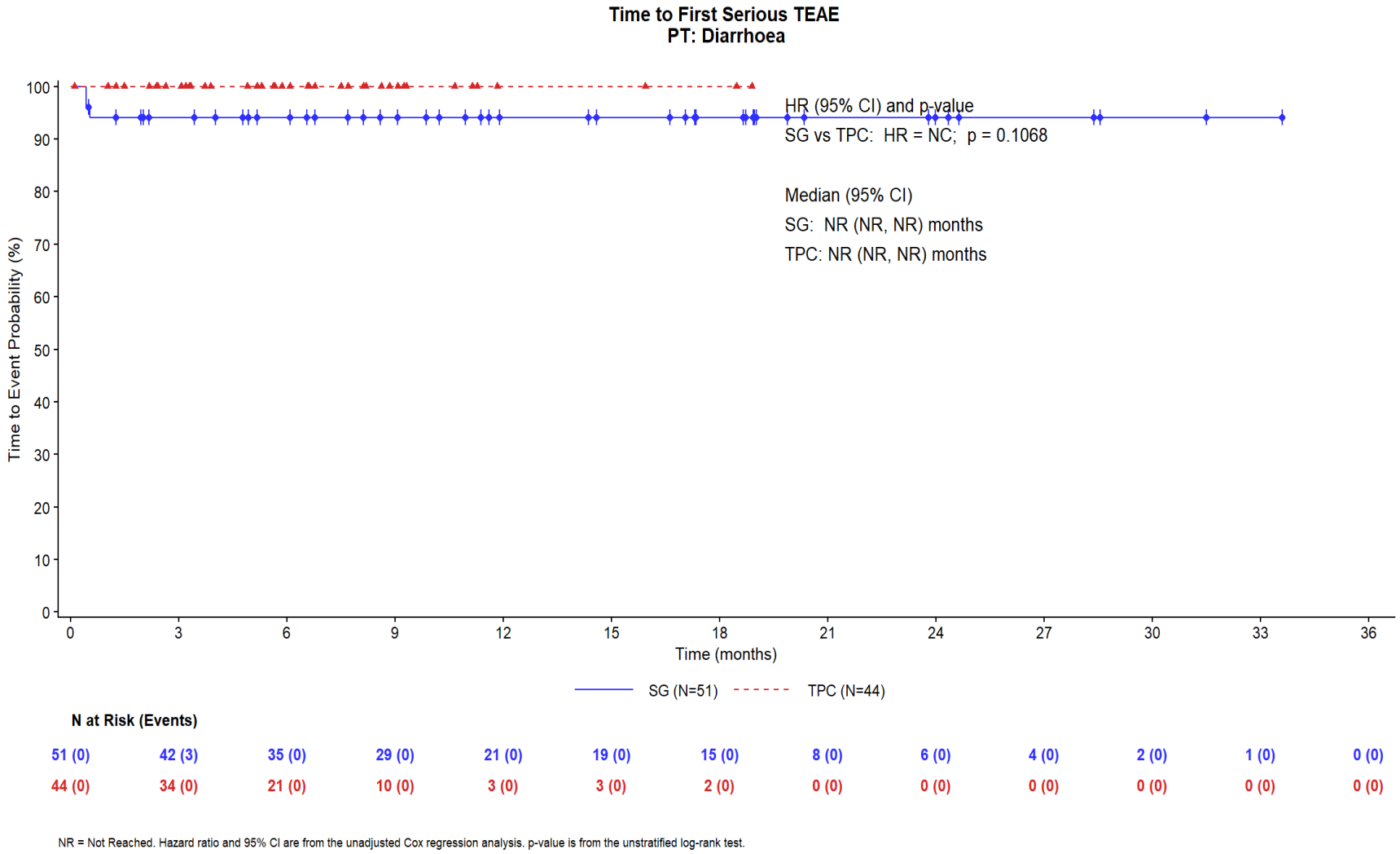
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

Table. Recurrence of diarrhoea TEAE — mSAF2: Excluding patients preselected to nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)			TPC (N=44)		
Incidence of diarrhoea TEAE	**1 event**	**2 events**	**>2 events**	**1 event**	**2 events**	**>2 events**
Grade 1	17 (33.3%)	5 (9.8%)	4 (7.8%)	7 (15.9%)	0	2 (4.5%)
Grade 2	8 (15.7%)	2 (3.9%)	0	3 (6.8%)	1 (2.3%)	1 (2.3%)
Grade ≥3	3 (5.9%)	1 (2.0%)	0	0	0	0
Grade 3	4 (7.8%)	0	0	0	0	0
Grade 4	1 (2.0%)	0	0	0	0	0
Grade 5	0	0	0	0	0	0

n = number of events per patient;

GS-US-592-6238-20788-92106 (SG): 2 diarrhoea episodes at Grade≥3 (1×Grade 3 + 1×Grade 4)

Data cut off:- 22 APR 2026

Descriptive Analysis of G-CSF Use Prior to First Febrile Neutropenia AE

	Febrile Neutropenia CTCAE Grade ≥3[1]			Febrile Neutropenia Serious Adverse Event (SAE)[2]		
Parameter	**SG (N=51)**	**TPC (N=44)**	**Overall (N=95)**	**SG (N=51)**	**TPC (N=44)**	**Overall (N=95)**
Total Patients in Safety Analysis Set	**51**	**44**	**95**	**51**	**44**	**95**
Patients with Febrile Neutropenia, n (%)	**3 (5.9%)**	**0 (0.0%)**	**3 (3.2%)**	**2 (3.9%)**	**0 (0.0%)**	**2 (2.1%)**
G-CSF Prophylaxis Prior to AE						
Yes	0 (0.0%)	0	0 (0.0%)	0 (0.0%)	0	0 (0.0%)
No	3 (100.0%)	0	3 (100.0%)	2 (100.0%)	0	2 (100.0%)
Patients Without Febrile Neutropenia, n (%)	**48 (94.1%)**	**44 (100.0%)**	**92 (96.8%)**	**49 (96.1%)**	**44 (100.0%)**	**93 (97.9%)**

n (%) = number of subjects and percentage of the relevant denominator.
Denominator for Total Patients, Patients with Febrile Neutropenia, and Patients without Febrile Neutropenia rows = total number of patients in each treatment arm (or overall) in the Safety Analysis Set.
Denominator for G-CSF Prophylaxis Yes/No rows = number of patients who experienced a febrile neutropenia event in the respective treatment arm or overall.
[a] Observation period is the time from first dose until the earliest of: the data cut-off (DCO) date; the date of study treatment discontinuation plus 30 days; or death; whichever occurs first and stops the collection of endpoint data. The same observation period applies to any adverse event and any serious adverse event, so the adverse-event and serious-adverse-event windows coincide. Only febrile neutropenia events with an onset date within this period are counted.
Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 28.1.

[1] Febrile neutropenia with CTCAE Grade ≥3: includes only febrile neutropenia events with a toxicity grade of 3 or higher and an onset date within the adverse-event observation period defined in footnote [a]. [2] Febrile neutropenia classified as a Serious Adverse Event (SAE): includes only febrile neutropenia events that met at least one seriousness criterion and had an onset date within the serious-adverse-event observation period defined in footnote [a].

1. Statistical Analysis for German Submission of ASCENT-03

2. Study : ASCENT-03

Population: Triple-Negative Breast Cancer (mTNBC)

Sub-Population:
- mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Data Cut Date: 27 October 2025
Report Date: 1 May2026

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4. Disposition - mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

4.1. Table 1.1.1: Participant Disposition — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Screened			97
mITT (Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)	52	45	97
Randomized but not Treated	1	1	2
Safety Analysis Set	51	44	95
Study Treatment Completion Status (Randomized Phase)			
Continuing Study Treatment	10 (19.2%)	1 (2.2%)	11 (11.3%)
Discontinued Study Treatment	42 (80.8%)	44 (97.8%)	86 (88.7%)
Adverse Event	4 (7.7%)	6 (13.3%)	10 (10.3%)
Pregnancy	0	0	0
Investigator's Discretion	2 (3.8%)	1 (2.2%)	3 (3.1%)
Non-Compliance with Study Drug	0	0	0
Subject Decision	2 (3.8%)	3 (6.7%)	5 (5.2%)
Study Terminated by Sponsor	0	0	0
Progressive Disease	33 (63.5%)	33 (73.3%)	66 (68.0%)
Lost to Follow-Up	0	0	0

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Death	1 (1.9%)	1 (2.2%)	2 (2.1%)
Received Study Treatment in Crossover Phase		22 (48.9%)	
Study Completion Status			
Continuing Study	30 (57.7%)	18 (40.0%)	48 (49.5%)
Discontinued Study	22 (42.3%)	27 (60.0%)	49 (50.5%)
Death	18 (34.6%)	27 (60.0%)	45 (46.4%)
Withdrew Consent	4 (7.7%)	0	4 (4.1%)
Lost to Follow-Up	0	0	0
Study Terminated by Sponsor	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Screened Population: Participants who have signed an informed consent and participated in the screening procedures at site to assess eligibility.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug.
Denominator of percentages is the number of participants in each treatment group.
Randomized Phase excludes crossover phase when participants in TPC arm started to receive SG.
Data Cut Date: 27 October 2025.

Source: mITT2/Table1.Disposition of participants.R

4.2. Table 1.1.2: Demographic and Baseline Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Age (years)			
N	52	45	97
Mean (Sd)	60.1 (12.4)	54.9 (12.6)	57.7 (12.7)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Median	59.0	55.0	58.0
Q1, Q3	52.0, 71.0	45.0, 63.0	49.0, 66.0
Min, Max	29.0, 84.0	32.0, 86.0	29.0, 86.0
Age Group			
< 65	35 (67.3%)	35 (77.8%)	70 (72.2%)
>= 65	17 (32.7%)	10 (22.2%)	27 (27.8%)
Sex at Birth			
F	52 (100.0%)	45 (100.0%)	97 (100.0%)
Race			
ASIAN	12 (23.1%)	12 (26.7%)	24 (24.7%)
BLACK OR AFRICAN AMERICAN	1 (1.9%)	1 (2.2%)	2 (2.1%)
NOT REPORTED	3 (5.8%)	3 (6.7%)	6 (6.2%)
OTHER	2 (3.8%)	1 (2.2%)	3 (3.1%)
WHITE	34 (65.4%)	27 (60.0%)	61 (62.9%)
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (2.2%)	1 (1.0%)
Ethnicity			
HISPANIC OR LATINO	9 (17.3%)	7 (15.6%)	16 (16.5%)
NOT HISPANIC OR LATINO	41 (78.8%)	36 (80.0%)	77 (79.4%)
NOT REPORTED	2 (3.8%)	2 (4.4%)	4 (4.1%)
Region			
Rest of the World	26 (50.0%)	28 (62.2%)	54 (55.7%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
US/Canada/Western Europe	26 (50.0%)	17 (37.8%)	43 (44.3%)
Country			
Argentina	2 (3.8%)	2 (4.4%)	4 (4.1%)
Belgium	1 (1.9%)	0	1 (1.0%)
Brazil	1 (1.9%)	1 (2.2%)	2 (2.1%)
Canada	2 (3.8%)	0	2 (2.1%)
Chile	3 (5.8%)	1 (2.2%)	4 (4.1%)
Czech Republic	2 (3.8%)	0	2 (2.1%)
France	7 (13.5%)	5 (11.1%)	12 (12.4%)
Germany	4 (7.7%)	2 (4.4%)	6 (6.2%)
Hungary	1 (1.9%)	2 (4.4%)	3 (3.1%)
Israel	2 (3.8%)	4 (8.9%)	6 (6.2%)
Italy	2 (3.8%)	2 (4.4%)	4 (4.1%)
Japan	10 (19.2%)	8 (17.8%)	18 (18.6%)
Korea, Republic of	2 (3.8%)	3 (6.7%)	5 (5.2%)
Mexico	2 (3.8%)	2 (4.4%)	4 (4.1%)
Netherlands	2 (3.8%)	1 (2.2%)	3 (3.1%)
Spain	4 (7.7%)	3 (6.7%)	7 (7.2%)
Turkey	1 (1.9%)	4 (8.9%)	5 (5.2%)
United States	4 (7.7%)	1 (2.2%)	5 (5.2%)
Austria	0	2 (4.4%)	2 (2.1%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Malaysia	0	1 (2.2%)	1 (1.0%)
United Kingdom	0	1 (2.2%)	1 (1.0%)
Weight (kg)			
N	52	45	97
Mean (Sd)	70.1 (16.4)	63.5 (11.3)	67.0 (14.6)
Median	70.5	61.0	65.0
Q1, Q3	58.0, 79.0	55.2, 71.0	57.0, 78.0
Min, Max	46.4, 130.0	42.0, 88.0	42.0, 130.0
Height (cm)			
N	52	45	97
Mean (Sd)	161.4 (7.2)	161.3 (6.3)	161.4 (6.8)
Median	161.0	162.0	161.9
Q1, Q3	158.0, 165.0	156.0, 166.0	157.0, 165.3
Min, Max	140.0, 180.0	149.4, 172.0	140.0, 180.0
BMI (kg/m2)			
N	52	45	97
Mean (Sd)	26.9 (6.3)	24.4 (4.2)	25.8 (5.5)
Median	26.0	23.6	24.3
Q1, Q3	22.7, 30.9	21.7, 27.1	22.3, 29.3
Min, Max	17.7, 50.8	16.8, 36.2	16.8, 50.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)

Age (in years) was collected on the date of first study drug administration (Day 1) if dosed, or randomization if not dosed.
Not Permitted = local regulators did not allow collection of race or ethnicity information or participant refused to provide information.
*Body Mass Index (BMI) (kg/m^2) = [Weight (kg) / Height (cm)^2]*10,000*
Data Cut Date: 27 October 2025.

Source: mITT2/Table2.Demographic and Baseline Characteristics.R

4.3. Table 1.1.3: Other Baseline Disease Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Baseline ECOG Score			
0	35 (67.3%)	26 (57.8%)	61 (62.9%)
1	17 (32.7%)	19 (42.2%)	36 (37.1%)
UGT1A1 Genotype			
*1/*1	25 (48.1%)	23 (51.1%)	48 (49.5%)
*1/*28	19 (36.5%)	16 (35.6%)	35 (36.1%)
*1/*6	3 (5.8%)	0 (0.0%)	3 (3.1%)
*28/*28	3 (5.8%)	4 (8.9%)	7 (7.2%)
*6/*6	1 (1.9%)	1 (2.2%)	2 (2.1%)
Missing/Not Done	1 (1.9%)	0 (0.0%)	1 (1.0%)
*6/*28	0 (0.0%)	1 (2.2%)	1 (1.0%)
Menopausal Status (Females Only)			
Post-menopausal	44 (84.6%)	31 (68.9%)	75 (77.3%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Pre-menopausal	8 (15.4%)	14 (31.1%)	22 (22.7%)
BRCA1 Mutation Status (Local testing)			
Mutant	3 (5.8%)	2 (4.4%)	5 (5.2%)
Unknown	25 (48.1%)	24 (53.3%)	49 (50.5%)
Wild Type	24 (46.2%)	19 (42.2%)	43 (44.3%)
BRCA2 Mutation Status (Local testing)			
Mutant	1 (1.9%)	1 (2.2%)	2 (2.1%)
Unknown	25 (48.1%)	24 (53.3%)	49 (50.5%)
Wild Type	26 (50.0%)	20 (44.4%)	46 (47.4%)
BRCA1/2 Mutation Status (Local testing)			
Mutant	3 (5.8%)	3 (6.7%)	6 (6.2%)
Unknown	25 (48.1%)	23 (51.1%)	48 (49.5%)
Wild Type	24 (46.2%)	19 (42.2%)	43 (44.3%)
BRCA1 Genotype (BRCA Central Testing)			
Mutant	2 (3.8%)	4 (8.9%)	6 (6.2%)
Unknown	11 (21.2%)	15 (33.3%)	26 (26.8%)
Wild Type	39 (75.0%)	26 (57.8%)	65 (67.0%)
BRCA2 Genotype (BRCA Central Testing)			
Mutant	4 (7.7%)	4 (8.9%)	8 (8.2%)
Unknown	11 (21.2%)	15 (33.3%)	26 (26.8%)
Wild Type	37 (71.2%)	26 (57.8%)	63 (64.9%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
BRCA1/BRCA2 Mutation Category (BRCA Central Testing)			
Mutant	6 (11.5%)	7 (15.6%)	13 (13.4%)
Unknown	11 (21.2%)	15 (33.3%)	26 (26.8%)
Wild Type	35 (67.3%)	23 (51.1%)	58 (59.8%)
BRCA1/2 Mutation Category (Central or local testing)			
Mutant	8 (15.4%)	7 (15.6%)	15 (15.5%)
Wild-type	40 (76.9%)	30 (66.7%)	70 (72.2%)
Unknown	4 (7.7%)	8 (17.8%)	12 (12.4%)
BRCA1 Genotype (Central or local testing)			
Mutant	4 (7.7%)	4 (8.9%)	8 (8.2%)
Wild-type	44 (84.6%)	33 (73.3%)	77 (79.4%)
Unknown	4 (7.7%)	8 (17.8%)	12 (12.4%)
BRCA2 Genotype (Central or local testing)			
Mutant	5 (9.6%)	4 (8.9%)	9 (9.3%)
Wild-type	43 (82.7%)	33 (73.3%)	76 (78.4%)
Unknown	4 (7.7%)	8 (17.8%)	12 (12.4%)
PD-L1 CPS			
1 to <10	28 (53.8%)	38 (84.4%)	66 (68.0%)
<1	23 (44.2%)	7 (15.6%)	30 (30.9%)
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Estrogen Receptor Status			

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Negative (< 1%)	51 (98.1%)	45 (100.0%)	96 (99.0%)
Progesterone Receptor Status			
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Negative (< 1%)	51 (98.1%)	45 (100.0%)	96 (99.0%)
HER2 Status			
Missing	1 (1.9%)	0 (0.0%)	1 (1.0%)
Negative	51 (98.1%)	45 (100.0%)	96 (99.0%)
Disease Stratification			
De novo	26 (50.0%)	23 (51.1%)	49 (50.5%)
Recurrent disease occurring > 12 months	23 (44.2%)	19 (42.2%)	42 (43.3%)
Recurrent disease within 6 to 12 months	3 (5.8%)	3 (6.7%)	6 (6.2%)
Pre-selected TPC Prior to Randomization			
Taxane	52 (100.0%)	45 (100.0%)	97 (100.0%)
Breast Cancer Stage at Initial Diagnosis			
STAGE 1	9 (17.3%)	4 (8.9%)	13 (13.4%)
STAGE 2	11 (21.2%)	13 (28.9%)	24 (24.7%)
STAGE 3	9 (17.3%)	5 (11.1%)	14 (14.4%)
STAGE 4	23 (44.2%)	23 (51.1%)	46 (47.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subtype of Cancer at Initial Diagnosis			

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
HR+/HER2+	2 (3.8%)	0 (0.0%)	2 (2.1%)
HR+/HER2-	5 (9.6%)	8 (17.8%)	13 (13.4%)
HR-/HER2+	1 (1.9%)	0 (0.0%)	1 (1.0%)
HR-/HER2- (TNBC)	43 (82.7%)	36 (80.0%)	79 (81.4%)
Missing	1 (1.9%)	1 (2.2%)	2 (2.1%)
Disease Status at Screening			
Locally advanced and Inoperable	1 (1.9%)		1 (1.0%)
Metastatic	51 (98.1%)	45 (100.0%)	96 (99.0%)
Site of Metastasis at Screening			
Bone	17 (32.7%)	19 (42.2%)	36 (37.1%)
Brain	2 (3.8%)	2 (4.4%)	4 (4.1%)
Liver	11 (21.2%)	13 (28.9%)	24 (24.7%)
Lung	28 (53.8%)	22 (48.9%)	50 (51.5%)
Lymph Node	33 (63.5%)	30 (66.7%)	63 (64.9%)
Other	15 (28.8%)	15 (33.3%)	30 (30.9%)
Time from Locally Advanced and Inoperable or Metastatic Disease to Randomization (months) [a]			
N	52	45	97
Mean (StD)	2.1 (1.40)	2.5 (2.20)	2.3 (1.81)
Median	1.7	2.0	1.9
Q1, Q3	1.2, 2.5	1.4, 2.8	1.3, 2.8
Min, Max	0.6, 8.3	0.8, 13.2	0.6, 13.2

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages for other baseline characteristics is the number of participants in each treatment group.
[a] Mutant denotes participant is either BRCA1 or BRCA2 mutant, or both mutant. Wild type denotes participant is both BRCA1 and BRCA2 wild type. Unknown denotes participant is BRCA1 unknown and BRCA2 wild type or unknown, or participant is BRCA1 wild type or unknown and BRCA2 unknown.
PD-L1 CPS (combined positive score) and TNBC status were collected centrally.
Data Cut Date: 27 October 2025.

Source: mITT2/Table3.Other Baseline Disease Characteristics.R

4.4. Table 1.1.4: Medical History by System Organ Class and Preferred Term — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Number (%) of Participants with Any Medical History	47 (90.4%)	39 (86.7%)	86 (88.7%)
Blood and lymphatic system disorders	3 (5.8%)	4 (8.9%)	7 (7.2%)
Anaemia	2 (3.8%)	4 (8.9%)	6 (6.2%)
Lymphadenopathy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Thrombocytopenia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Cardiac disorders	3 (5.8%)	4 (8.9%)	7 (7.2%)
Sinus tachycardia	1 (1.9%)	1 (2.2%)	2 (6.2%)
Arrhythmia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Atrial fibrillation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cardiac failure chronic	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cardiac failure congestive	1 (1.9%)	0 (0.0%)	1 (6.2%)
Carditis	0 (0.0%)	1 (2.2%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Myocardial infarction	0 (0.0%)	1 (2.2%)	1 (6.2%)
Congenital, familial and genetic disorders	2 (3.8%)	4 (8.9%)	6 (7.2%)
Adenomatous polyposis coli	0 (0.0%)	1 (2.2%)	1 (6.2%)
Congenital neuropathy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Developmental hip dysplasia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Factor V Leiden mutation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Renal fusion anomaly	1 (1.9%)	0 (0.0%)	1 (6.2%)
Thalassaemia sickle cell	0 (0.0%)	1 (2.2%)	1 (6.2%)
Ear and labyrinth disorders	5 (9.6%)	0 (0.0%)	5 (7.2%)
Vertigo	2 (3.8%)	0 (0.0%)	2 (6.2%)
Cholesteatoma	1 (1.9%)	0 (0.0%)	1 (6.2%)
Deafness	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hypoacusis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Vertigo positional	1 (1.9%)	0 (0.0%)	1 (6.2%)
Endocrine disorders	10 (19.2%)	7 (15.6%)	17 (7.2%)
Hypothyroidism	6 (11.5%)	5 (11.1%)	11 (6.2%)
Hyperparathyroidism	1 (1.9%)	1 (2.2%)	2 (6.2%)
Thyroid disorder	2 (3.8%)	0 (0.0%)	2 (6.2%)
Autoimmune thyroiditis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hyperthyroidism	0 (0.0%)	1 (2.2%)	1 (6.2%)
Eye disorders	5 (9.6%)	5 (11.1%)	10 (7.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Cataract	2 (3.8%)	3 (6.7%)	5 (6.2%)
Dry eye	2 (3.8%)	3 (6.7%)	5 (6.2%)
Glaucoma	1 (1.9%)	0 (0.0%)	1 (6.2%)
Myopia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Retinal haemorrhage	1 (1.9%)	0 (0.0%)	1 (6.2%)
Strabismus	0 (0.0%)	1 (2.2%)	1 (6.2%)
Gastrointestinal disorders	12 (23.1%)	7 (15.6%)	19 (7.2%)
Gastrooesophageal reflux disease	5 (9.6%)	1 (2.2%)	6 (6.2%)
Constipation	3 (5.8%)	2 (4.4%)	5 (6.2%)
Nausea	0 (0.0%)	2 (4.4%)	2 (6.2%)
Abdominal distension	1 (1.9%)	0 (0.0%)	1 (6.2%)
Anal incontinence	1 (1.9%)	0 (0.0%)	1 (6.2%)
Anal sphincter atony	1 (1.9%)	0 (0.0%)	1 (6.2%)
Coeliac disease	0 (0.0%)	1 (2.2%)	1 (6.2%)
Colitis ulcerative	0 (0.0%)	1 (2.2%)	1 (6.2%)
Crohn's disease	0 (0.0%)	1 (2.2%)	1 (6.2%)
Dyspepsia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Gastric ulcer	1 (1.9%)	0 (0.0%)	1 (6.2%)
Gastrointestinal pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Haemorrhoids	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hiatus hernia	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Large intestine polyp	1 (1.9%)	0 (0.0%)	1 (6.2%)
Mucosal prolapse syndrome	1 (1.9%)	0 (0.0%)	1 (6.2%)
Obstructive pancreatitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Oral pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Periodontal disease	1 (1.9%)	0 (0.0%)	1 (6.2%)
Stomatitis	1 (1.9%)	0 (0.0%)	1 (6.2%)
General disorders and administration site conditions	3 (5.8%)	5 (11.1%)	8 (7.2%)
Fatigue	2 (3.8%)	3 (6.7%)	5 (6.2%)
Asthenia	0 (0.0%)	2 (4.4%)	2 (6.2%)
Oedema peripheral	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hepatobiliary disorders	4 (7.7%)	2 (4.4%)	6 (7.2%)
Cholelithiasis	1 (1.9%)	1 (2.2%)	2 (6.2%)
Biliary fistula	1 (1.9%)	0 (0.0%)	1 (6.2%)
Cholangitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cholecystitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hepatic function abnormal	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hypertransaminasaemia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Liver disorder	1 (1.9%)	0 (0.0%)	1 (6.2%)
Metabolic dysfunction-associated steatohepatitis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Immune system disorders	7 (13.5%)	3 (6.7%)	10 (7.2%)
Seasonal allergy	6 (11.5%)	0 (0.0%)	6 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Drug hypersensitivity	2 (3.8%)	3 (6.7%)	5 (6.2%)
Iodine allergy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rubber sensitivity	0 (0.0%)	1 (2.2%)	1 (6.2%)
Infections and infestations	8 (15.4%)	6 (13.3%)	14 (7.2%)
Appendicitis	3 (5.8%)	0 (0.0%)	3 (6.2%)
Herpes zoster	2 (3.8%)	1 (2.2%)	3 (6.2%)
Pneumonia	1 (1.9%)	2 (4.4%)	3 (6.2%)
Breast abscess	0 (0.0%)	1 (2.2%)	1 (6.2%)
Helicobacter infection	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hepatitis viral	1 (1.9%)	0 (0.0%)	1 (6.2%)
Lung abscess	1 (1.9%)	0 (0.0%)	1 (6.2%)
Peritonitis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rhinitis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Viral pericarditis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Injury, poisoning and procedural complications	4 (7.7%)	0 (0.0%)	4 (7.2%)
Contusion	1 (1.9%)	0 (0.0%)	1 (6.2%)
Femur fracture	1 (1.9%)	0 (0.0%)	1 (6.2%)
Neck injury	1 (1.9%)	0 (0.0%)	1 (6.2%)
Radiation skin injury	1 (1.9%)	0 (0.0%)	1 (6.2%)
Investigations	10 (19.2%)	3 (6.7%)	13 (7.2%)
Aspartate aminotransferase increased	5 (9.6%)	0 (0.0%)	5 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Blood alkaline phosphatase increased	4 (7.7%)	0 (0.0%)	4 (6.2%)
Hepatic enzyme increased	2 (3.8%)	0 (0.0%)	2 (6.2%)
Alanine aminotransferase increased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Alpha 1 foetoprotein abnormal	1 (1.9%)	0 (0.0%)	1 (6.2%)
Biopsy skin	0 (0.0%)	1 (2.2%)	1 (6.2%)
Blood albumin decreased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Blood bilirubin increased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Blood glucose increased	1 (1.9%)	0 (0.0%)	1 (6.2%)
Blood triglycerides increased	0 (0.0%)	1 (2.2%)	1 (6.2%)
Electrocardiogram QT shortened	0 (0.0%)	1 (2.2%)	1 (6.2%)
Liver function test abnormal	1 (1.9%)	0 (0.0%)	1 (6.2%)
Metabolism and nutrition disorders	15 (28.8%)	8 (17.8%)	23 (7.2%)
Dyslipidaemia	3 (5.8%)	2 (4.4%)	5 (6.2%)
Diabetes mellitus	2 (3.8%)	2 (4.4%)	4 (6.2%)
Type 2 diabetes mellitus	2 (3.8%)	2 (4.4%)	4 (6.2%)
Glucose tolerance impaired	2 (3.8%)	1 (2.2%)	3 (6.2%)
Hypercholesterolaemia	3 (5.8%)	0 (0.0%)	3 (6.2%)
Hypoalbuminaemia	1 (1.9%)	1 (2.2%)	2 (6.2%)
Vitamin D deficiency	1 (1.9%)	1 (2.2%)	2 (6.2%)
Decreased appetite	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hypercalcaemia	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Hyperlipidaemia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hyperuricaemia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hypomagnesaemia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Lactose intolerance	1 (1.9%)	0 (0.0%)	1 (6.2%)
Sarcopenic obesity	1 (1.9%)	0 (0.0%)	1 (6.2%)
Musculoskeletal and connective tissue disorders	19 (36.5%)	10 (22.2%)	29 (7.2%)
Arthralgia	6 (11.5%)	2 (4.4%)	8 (6.2%)
Back pain	5 (9.6%)	2 (4.4%)	7 (6.2%)
Bone pain	2 (3.8%)	2 (4.4%)	4 (6.2%)
Osteoarthritis	2 (3.8%)	2 (4.4%)	4 (6.2%)
Intervertebral disc protrusion	3 (5.8%)	0 (0.0%)	3 (6.2%)
Osteoporosis	1 (1.9%)	2 (4.4%)	3 (6.2%)
Arthritis	1 (1.9%)	1 (2.2%)	2 (6.2%)
Fibromyalgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Groin pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Jaw cyst	1 (1.9%)	0 (0.0%)	1 (6.2%)
Muscular weakness	1 (1.9%)	0 (0.0%)	1 (6.2%)
Musculoskeletal pain	0 (0.0%)	1 (2.2%)	1 (6.2%)
Myalgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Neck pain	1 (1.9%)	0 (0.0%)	1 (6.2%)
Osteopenia	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Pain in extremity	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rheumatoid arthritis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Scoliosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Vertebral foraminal stenosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (9.6%)	12 (26.7%)	17 (7.2%)
Cancer pain	1 (1.9%)	4 (8.9%)	5 (6.2%)
Tumour pain	2 (3.8%)	2 (4.4%)	4 (6.2%)
Uterine leiomyoma	0 (0.0%)	3 (6.7%)	3 (6.2%)
Basal cell carcinoma	1 (1.9%)	1 (2.2%)	2 (6.2%)
Breast cancer	0 (0.0%)	2 (4.4%)	2 (6.2%)
Colorectal adenoma	0 (0.0%)	1 (2.2%)	1 (6.2%)
Follicular lymphoma	0 (0.0%)	1 (2.2%)	1 (6.2%)
Metastases to bone	0 (0.0%)	1 (2.2%)	1 (6.2%)
Prolactin-producing pituitary tumour	1 (1.9%)	0 (0.0%)	1 (6.2%)
Nervous system disorders	10 (19.2%)	4 (8.9%)	14 (7.2%)
Headache	3 (5.8%)	3 (6.7%)	6 (6.2%)
Migraine	2 (3.8%)	0 (0.0%)	2 (6.2%)
Neuropathy peripheral	2 (3.8%)	0 (0.0%)	2 (6.2%)
Presyncope	2 (3.8%)	0 (0.0%)	2 (6.2%)
Carotid arteriosclerosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Epilepsy	0 (0.0%)	1 (2.2%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Essential tremor	1 (1.9%)	0 (0.0%)	1 (6.2%)
Hydromyelia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Intercostal neuralgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Peripheral sensory neuropathy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Syncope	1 (1.9%)	0 (0.0%)	1 (6.2%)
Trigeminal neuralgia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Psychiatric disorders	10 (19.2%)	10 (22.2%)	20 (7.2%)
Insomnia	6 (11.5%)	4 (8.9%)	10 (6.2%)
Anxiety	2 (3.8%)	5 (11.1%)	7 (6.2%)
Depression	4 (7.7%)	1 (2.2%)	5 (6.2%)
Bipolar disorder	0 (0.0%)	1 (2.2%)	1 (6.2%)
Claustrophobia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Nightmare	1 (1.9%)	0 (0.0%)	1 (6.2%)
Post-traumatic stress disorder	1 (1.9%)	0 (0.0%)	1 (6.2%)
Schizophrenia	0 (0.0%)	1 (2.2%)	1 (6.2%)
Renal and urinary disorders	5 (9.6%)	0 (0.0%)	5 (7.2%)
Nephrolithiasis	2 (3.8%)	0 (0.0%)	2 (6.2%)
Urinary incontinence	2 (3.8%)	0 (0.0%)	2 (6.2%)
Chronic kidney disease	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pollakiuria	1 (1.9%)	0 (0.0%)	1 (6.2%)
Proteinuria	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Reproductive system and breast disorders	7 (13.5%)	3 (6.7%)	10 (7.2%)
Breast pain	3 (5.8%)	2 (4.4%)	5 (6.2%)
Ovarian cyst	2 (3.8%)	1 (2.2%)	3 (6.2%)
Menopausal symptoms	2 (3.8%)	0 (0.0%)	2 (6.2%)
Rectocele	1 (1.9%)	0 (0.0%)	1 (6.2%)
Uterovaginal prolapse	1 (1.9%)	0 (0.0%)	1 (6.2%)
Respiratory, thoracic and mediastinal disorders	9 (17.3%)	10 (22.2%)	19 (7.2%)
Cough	3 (5.8%)	4 (8.9%)	7 (6.2%)
Asthma	1 (1.9%)	3 (6.7%)	4 (6.2%)
Rhinitis allergic	2 (3.8%)	2 (4.4%)	4 (6.2%)
Chronic obstructive pulmonary disease	1 (1.9%)	0 (0.0%)	1 (6.2%)
Dysphonia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Dyspnoea	0 (0.0%)	1 (2.2%)	1 (6.2%)
Productive cough	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pulmonary artery thrombosis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Pulmonary toxicity	1 (1.9%)	0 (0.0%)	1 (6.2%)
Pulmonary venous thrombosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Sinus congestion	0 (0.0%)	1 (2.2%)	1 (6.2%)
Tracheal mass	1 (1.9%)	0 (0.0%)	1 (6.2%)
Skin and subcutaneous tissue disorders	8 (15.4%)	2 (4.4%)	10 (7.2%)
Dermatitis contact	2 (3.8%)	0 (0.0%)	2 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Actinic keratosis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Alopecia	1 (1.9%)	0 (0.0%)	1 (6.2%)
Erythema	1 (1.9%)	0 (0.0%)	1 (6.2%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.0%)	1 (2.2%)	1 (6.2%)
Pruritus	1 (1.9%)	0 (0.0%)	1 (6.2%)
Psoriasis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Rash	0 (0.0%)	1 (2.2%)	1 (6.2%)
Skin mass	1 (1.9%)	0 (0.0%)	1 (6.2%)
Social circumstances	3 (5.8%)	0 (0.0%)	3 (7.2%)
Ex-tobacco user	1 (1.9%)	0 (0.0%)	1 (6.2%)
Joint prosthesis user	1 (1.9%)	0 (0.0%)	1 (6.2%)
Menopause	1 (1.9%)	0 (0.0%)	1 (6.2%)
Surgical and medical procedures	13 (25.0%)	11 (24.4%)	24 (7.2%)
Hysterectomy	4 (7.7%)	2 (4.4%)	6 (6.2%)
Cholecystectomy	2 (3.8%)	2 (4.4%)	4 (6.2%)
Cardiac pacemaker insertion	2 (3.8%)	0 (0.0%)	2 (6.2%)
Hip arthroplasty	0 (0.0%)	2 (4.4%)	2 (6.2%)
Knee arthroplasty	2 (3.8%)	0 (0.0%)	2 (6.2%)
Ovarian cystectomy	0 (0.0%)	2 (4.4%)	2 (6.2%)
Salpingo-oophorectomy bilateral	1 (1.9%)	1 (2.2%)	2 (6.2%)
Aortic valve replacement	1 (1.9%)	0 (0.0%)	1 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Appendicectomy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Cartilage operation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Cataract operation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Constipation prophylaxis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Corneal transplant	1 (1.9%)	0 (0.0%)	1 (6.2%)
Eye excision	0 (0.0%)	1 (2.2%)	1 (6.2%)
Eye prosthesis insertion	0 (0.0%)	1 (2.2%)	1 (6.2%)
Gastrointestinal disorder prophylaxis	1 (1.9%)	0 (0.0%)	1 (6.2%)
Implantable cardiac monitor insertion	1 (1.9%)	0 (0.0%)	1 (6.2%)
Joint arthroplasty	0 (0.0%)	1 (2.2%)	1 (6.2%)
Lymphadenectomy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Oophorectomy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Oophorectomy bilateral	1 (1.9%)	0 (0.0%)	1 (6.2%)
Radical mastectomy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Retinal operation	0 (0.0%)	1 (2.2%)	1 (6.2%)
Spinal operation	1 (1.9%)	0 (0.0%)	1 (6.2%)
Thrombectomy	0 (0.0%)	1 (2.2%)	1 (6.2%)
Thyroidectomy	1 (1.9%)	0 (0.0%)	1 (6.2%)
Vascular disorders	23 (44.2%)	16 (35.6%)	39 (7.2%)
Hypertension	21 (40.4%)	16 (35.6%)	37 (6.2%)
Peripheral venous disease	2 (3.8%)	0 (0.0%)	2 (6.2%)

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Deep vein thrombosis	0 (0.0%)	1 (2.2%)	1 (6.2%)
Hot flush	0 (0.0%)	1 (2.2%)	1 (6.2%)
Lymphoedema	1 (1.9%)	0 (0.0%)	1 (6.2%)
Orthostatic hypotension	1 (1.9%)	0 (0.0%)	1 (6.2%)
Varicose vein	0 (0.0%)	1 (2.2%)	1 (6.2%)
White coat hypertension	0 (0.0%)	1 (2.2%)	1 (6.2%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Medical history was coded according to MedDRA Version 27.1.
Participants may report >=1 medical history per system organ class or preferred term. At each level of summarization, a participant was counted once if the participant reported 1 or more medical history.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
Data Cut Date: 27 October 2025.

Source: mITT2/Table4.Summary of Medical History.R

4.5. Table 1.1.5: Summary of Prior Systemic Therapy — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
Patients with Prior Systemic Therapy	25 (48.1%)	19 (42.2%)	44 (45.4%)
Number of Prior Regimens			
1	17 (32.7%)	12 (26.7%)	29 (29.9%)
2	3 (5.8%)	6 (13.3%)	9 (9.3%)
3	5 (9.6%)	1 (2.2%)	6 (6.2%)
Regimen Setting			

Characteristic	SG (N=52)	TPC (N=45)	Total (N=97)
ADJUVANT	20 (38.5%)	15 (33.3%)	35 (36.1%)
NEO-ADJUVANT	5 (9.6%)	4 (8.9%)	9 (9.3%)
Best Response to Prior Therapy			
Complete Remission	4 (7.7%)	4 (8.9%)	8 (8.2%)
Partial Remission	3 (5.8%)	0 (0.0%)	3 (3.1%)
Stable Disease	2 (3.8%)	0 (0.0%)	2 (2.1%)
Progressive Disease	1 (1.9%)	3 (6.7%)	4 (4.1%)
Not Available	11 (21.2%)	6 (13.3%)	17 (17.5%)
Unknown	4 (7.7%)	6 (13.3%)	10 (10.3%)
Progression After Prior Therapy			
Yes	22 (42.3%)	15 (33.3%)	37 (38.1%)
No	3 (5.8%)	4 (8.9%)	7 (7.2%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Data Cut Date: 27 October 2025.

Source: mITT2/Table5.Summary of Prior Systemic Therapy.R

4.6. Table 1.1.6: Prior Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Participants with Any Prior Anti-Cancer Therapy, n (%)	25 (48.1%)	19 (42.2%)	44 (45.4%)
Prior Neoadjuvant or Adjuvant Anti-cancer Therapy [a]			

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Yes	25 (48.1%)	19 (42.2%)	44 (45.4%)
Taxanes	18 (34.6%)	14 (31.1%)	32 (33.0%)
Anthracyclines	18 (34.6%)	13 (28.9%)	31 (32.0%)
Platinum	6 (11.5%)	4 (8.9%)	10 (10.3%)
Anti-PD-1/PD-L1 agents	2 (3.8%)	0	2 (2.1%)
Capecitabine	6 (11.5%)	3 (6.7%)	9 (9.3%)
PARP inhibitors	0	0	0
Other	21 (40.4%)	17 (37.8%)	38 (39.2%)
No	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
[a] Participants can receive multiple categories of prior neoadjuvant or adjuvant anti-cancer therapy. Participants who received any prior neoadjuvant or adjuvant anti-cancer therapy will be summarized as "Yes". Participants who received prior anti-cancer therapy but did not receive any prior neoadjuvant/adjuvant anti-cancer therapy will be summarized as "No".
Data Cut Date: 27 October 2025.

Source: mITT2/Table6.Prior Anti-Cancer Therapy.R

4.7. Table 1.1.7: Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Participants with Any Subsequent Anti Cancer Therapy, n (%)	29 (55.8%)	32 (71.1%)	61 (62.9%)
Taxanes	16 (30.8%)	3 (6.7%)	19 (19.6%)
DOCETAXEL	1 (1.9%)	0	1 (1.0%)
PACLITAXEL	14 (26.9%)	2 (4.4%)	16 (16.5%)

Category	SG (N=52)	TPC (N=45)	Total (N=97)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	2 (3.8%)	1 (2.2%)	3 (3.1%)
Anthracyclines	5 (9.6%)	9 (20.0%)	14 (14.4%)
DOXORUBICIN	1 (1.9%)	5 (11.1%)	6 (6.2%)
DOXORUBICIN HYDROCHLORIDE	0	1 (2.2%)	1 (1.0%)
EPIRUBICIN	3 (5.8%)	1 (2.2%)	4 (4.1%)
EPIRUBICIN HYDROCHLORIDE	1 (1.9%)	0	1 (1.0%)
LIPOSOMAL DOXORUBICIN	0	1 (2.2%)	1 (1.0%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	0	1 (2.2%)	1 (1.0%)
Platinum	7 (13.5%)	14 (31.1%)	21 (21.6%)
CARBOPLATIN	7 (13.5%)	11 (24.4%)	18 (18.6%)
CISPLATIN	0	3 (6.7%)	3 (3.1%)
Anti-PD-1/PD-L1 agents	3 (5.8%)	3 (6.7%)	6 (6.2%)
ATEZOLIZUMAB	1 (1.9%)	1 (2.2%)	2 (2.1%)
PEMBROLIZUMAB	2 (3.8%)	2 (4.4%)	4 (4.1%)
PARP inhibitors	1 (1.9%)	1 (2.2%)	2 (2.1%)
OLAPARIB	1 (1.9%)	1 (2.2%)	2 (2.1%)
ADC	6 (11.5%)	28 (62.2%)	34 (35.1%)
SACITUZUMAB GOVITECAN	0	28 (62.2%)	28 (28.9%)
TRASTUZUMAB DERUXTECAN	5 (9.6%)	6 (13.3%)	11 (11.3%)
TRASTUZUMAB DERUXTECAN NXKI	1 (1.9%)	0	1 (1.0%)
Other	20 (38.5%)	19 (42.2%)	39 (40.2%)

Category	SG (N=52)	TPC (N=45)	Total (N=97)
BEVACIZUMAB	1 (1.9%)	0	1 (1.0%)
CAPECITABINE	8 (15.4%)	10 (22.2%)	18 (18.6%)
CYCLOPHOSPHAMIDE	4 (7.7%)	3 (6.7%)	7 (7.2%)
ERIBULIN	7 (13.5%)	4 (8.9%)	11 (11.3%)
ERIBULIN MESILATE	2 (3.8%)	3 (6.7%)	5 (5.2%)
GEMCITABINE	1 (1.9%)	11 (24.4%)	12 (12.4%)
GEMCITABINE HYDROCHLORIDE	3 (5.8%)	3 (6.7%)	6 (6.2%)
GEN 1047	0	1 (2.2%)	1 (1.0%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	2 (3.8%)	0	2 (2.1%)
IMC 002	0	1 (2.2%)	1 (1.0%)
INVESTIGATIONAL DRUG	0	1 (2.2%)	1 (1.0%)
METHOTREXATE	0	1 (2.2%)	1 (1.0%)
PERTUZUMAB	1 (1.9%)	0	1 (1.0%)
RUCAPARIB	0	1 (2.2%)	1 (1.0%)
TRASTUZUMAB	1 (1.9%)	0	1 (1.0%)
TUCATINIB	1 (1.9%)	0	1 (1.0%)
VINORELBINE	0	1 (2.2%)	1 (1.0%)
VINORELBINE TARTRATE	1 (1.9%)	0	1 (1.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 27 October 2025.

Category	SG (N=52)	TPC (N=45)	Total (N=97)

Source: mITT2/Table10.Subsequent Anti cancer by preferred drug name.R

4.8. Table 1.1.8: First Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Category	SG (N=52)	TPC (N=45)	Total (N=97)
Participants with First Subsequent Anti-Cancer Therapy, n (%)	29 (55.8%)	32 (71.1%)	61 (62.9%)
Taxanes	14 (26.9%)	1 (2.2%)	15 (15.5%)
DOCETAXEL	1 (1.9%)	0	1 (1.0%)
PACLITAXEL	12 (23.1%)	0	12 (12.4%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	1 (1.9%)	1 (2.2%)	2 (2.1%)
Anthracyclines	2 (3.8%)	1 (2.2%)	3 (3.1%)
EPIRUBICIN	1 (1.9%)	1 (2.2%)	2 (2.1%)
EPIRUBICIN HYDROCHLORIDE	1 (1.9%)	0	1 (1.0%)
Platinum	4 (7.7%)	0	4 (4.1%)
CARBOPLATIN	4 (7.7%)	0	4 (4.1%)
Anti-PD-1/PD-L1 agents	2 (3.8%)	0	2 (2.1%)
ATEZOLIZUMAB	1 (1.9%)	0	1 (1.0%)
PEMBROLIZUMAB	1 (1.9%)	0	1 (1.0%)
PARP inhibitors	1 (1.9%)	0	1 (1.0%)
OLAPARIB	1 (1.9%)	0	1 (1.0%)
ADC	3 (5.8%)	27 (60.0%)	30 (30.9%)

Category	SG (N=52)	TPC (N=45)	Total (N=97)
SACITUZUMAB GOVITECAN	0	27 (60.0%)	27 (27.8%)
TRASTUZUMAB DERUXTECAN	2 (3.8%)	0	2 (2.1%)
TRASTUZUMAB DERUXTECAN NXKI	1 (1.9%)	0	1 (1.0%)
Other	12 (23.1%)	3 (6.7%)	15 (15.5%)
CAPECITABINE	3 (5.8%)	3 (6.7%)	6 (6.2%)
CYCLOPHOSPHAMIDE	2 (3.8%)	0	2 (2.1%)
ERIBULIN	4 (7.7%)	0	4 (4.1%)
ERIBULIN MESILATE	1 (1.9%)	0	1 (1.0%)
GEMCITABINE HYDROCHLORIDE	1 (1.9%)	0	1 (1.0%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (1.9%)	0	1 (1.0%)
PERTUZUMAB	1 (1.9%)	0	1 (1.0%)
TRASTUZUMAB	1 (1.9%)	0	1 (1.0%)
TUCATINIB	1 (1.9%)	0	1 (1.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name. Participants may be counted in more than one drug category if they received multiple drugs as part of their first subsequent anti-cancer therapy. The total number of participants with any subsequent anti-cancer therapy differs by 1 from the first subsequent therapy count because one patient in the TPC arm has a missing first subsequent therapy record but has two entries recorded for the fourth subsequent therapy. This patient is therefore counted in "Participants with any subsequent anti-cancer therapy" but not in "First subsequent anti-cancer therapy"
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 27 October 2025.

Source: mITT2/Table11.First Subsequent Anti cancer therapy by Preferred drug name.R

5. Efficacy - mITT — Excluding patients preselected to receive nab-paclitaxel

5.1. Table 1.1.1: Observation Period (Months) for Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	SG (N=52)	TPC (N=45)	Total (N=97)
Observation Period (months)			
N	52	45	97
Mean (SD)	19 (6.8)	16.7 (7.4)	17.9 (7.2)
Median	19.1	16.2	18.2
Q1, Q3	16, 22.8	12.5, 21.3	13.5, 22.8
Min, Max	0.5, 32.8	0.2, 34.2	0.2, 34.2

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Observation period is defined as time from randomisation to death date or the last date known alive.
Data Cut Date: 27 OCT 2025.

5.2. Table 1.1.2: Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events (Death)	19 (36.5%)	27 (60.0%)
Number (%) of Participants Censored	33 (63.5%)	18 (40.0%)
Ongoing [a]	30 (57.7%)	18 (40.0%)
Discontinued Study	3 (5.8%)	0
Kaplan-Meier Estimate of OS (Months) (95% CI) [b]		
Q1	16.00 (12.06, 20.90)	12.48 (7.69, 14.06)
Median	NR (20.86, NR)	19.75 (14.03, 28.75)

Parameter	SG (N=52)	TPC (N=45)
Q3	NR (NR, NR)	28.75 (24.38, NR)
Absolute Difference in Median OS, SG vs TPC (Months)	NA	
Kaplan-Meier Estimate of OS Rate (95% CI) [b]		
At 12 Months	0.885 (0.761, 0.946)	0.778 (0.626, 0.874)
At 18 Months	0.685 (0.537, 0.794)	0.503 (0.348, 0.640)
At 24 Months	0.570 (0.393, 0.714)	0.407 (0.252, 0.556)
At 30 Months	0.570 (0.393, 0.714)	0.178 (0.018, 0.477)
At 36 Months	NR (NR, NR)	NR (NR, NR)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.0352	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.522 (0.282, 0.965)	
Duration of OS Follow-up (Months) [e]		
N	52	45
Mean (StD)	18.96 (6.825)	16.73 (7.414)
Median	19.06	16.23
Q1, Q3	15.97, 22.81	12.48, 21.26
Min, Max	0.53, 32.82	0.16, 34.23
>=12 Months	45 (86.5%)	35 (77.8%)
>=18 Months	31 (59.6%)	18 (40.0%)
>=24 Months	10 (19.2%)	9 (20.0%)
>=30 Months	3 (5.8%)	1 (2.2%)
>=36 Months	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice; NR = Not Reached; IWRS = Interactive Web Response System.
[a] Ongoing participants are those who have not discontinued participation in the study by the data cutoff date.
[b] OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Based on Kaplan-Meier estimates with 95% CI using the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test, adjusted for randomization stratification factors (IWRS).
[d] Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).

Parameter	SG (N=52)	TPC (N=45)

[e] Duration of OS follow-up (months) = (date of death or censoring - date of randomization + 1) / 30.4375.
Data Cut Date: 27 OCT 2025.

5.3. Table 1.1.3: Subgroup Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

label	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.5566
Number (%) of Participants with Events (Death)	10 (38.5%)	12 (70.6%)	
Number (%) of Participants Censored	16 (61.5%)	5 (29.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (16.03, NR)	15.93 (11.17, NR)	
Log-Rank Test p-value (unstratified)	0.0348		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.413 (0.177, 0.963)		
Rest of the world	26	28	
Number (%) of Participants with Events (Death)	9 (34.6%)	15 (53.6%)	
Number (%) of Participants Censored	17 (65.4%)	13 (46.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (17.48, NR)	21.26 (14.03, NR)	
Log-Rank Test p-value (unstratified)	0.2219		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.600 (0.263, 1.373)		
Age group			
< 65	35	35	0.4689
Number (%) of Participants with Events (Death)	13 (37.1%)	20 (57.1%)	
Number (%) of Participants Censored	22 (62.9%)	15 (42.9%)	

label	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (20.86, NR)	20.24 (14.03, NR)	
Log-Rank Test p-value (unstratified)	0.1129		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.572 (0.284, 1.152)		
>= 65	17	10	
Number (%) of Participants with Events (Death)	6 (35.3%)	7 (70.0%)	
Number (%) of Participants Censored	11 (64.7%)	3 (30.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (12.71, NR)	16.66 (2.17, NR)	
Log-Rank Test p-value (unstratified)	0.0859		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.392 (0.130, 1.185)		
Baseline ECOG status			
0	35	26	0.7322
Number (%) of Participants with Events (Death)	12 (34.3%)	14 (53.8%)	
Number (%) of Participants Censored	23 (65.7%)	12 (46.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (20.86, NR)	20.24 (13.50, NR)	
Log-Rank Test p-value (unstratified)	0.1471		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.568 (0.262, 1.230)		
1	17	19	
Number (%) of Participants with Events (Death)	7 (41.2%)	13 (68.4%)	
Number (%) of Participants Censored	10 (58.8%)	6 (31.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (12.06, NR)	16.00 (6.11, 24.38)	

label	SG (N=52)	TPC (N=45)	Interaction
Log-Rank Test p-value (unstratified)	0.1440		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.510 (0.203, 1.280)		
History of liver metastasis			
Yes	11	13	0.6500
Number (%) of Participants with Events (Death)	6 (54.5%)	9 (69.2%)	
Number (%) of Participants Censored	5 (45.5%)	4 (30.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	23.52 (8.87, NR)	14.03 (3.91, NR)	
Log-Rank Test p-value (unstratified)	0.4828		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.692 (0.246, 1.948)		
No	41	32	
Number (%) of Participants with Events (Death)	13 (31.7%)	18 (56.2%)	
Number (%) of Participants Censored	28 (68.3%)	14 (43.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (20.90, NR)	21.26 (15.31, NR)	
Log-Rank Test p-value (unstratified)	0.0343		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.469 (0.229, 0.961)		
PD-L1 Status			
CPS < 1	23	7	0.7416
Number (%) of Participants with Events (Death)	7 (30.4%)	3 (42.9%)	
Number (%) of Participants Censored	16 (69.6%)	4 (57.1%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (13.24, NR)	NR (11.73, NR)	
Log-Rank Test p-value (unstratified)	0.6037		

label	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.700 (0.181, 2.712)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Death)	12 (42.9%)	24 (63.2%)	
Number (%) of Participants Censored	16 (57.1%)	14 (36.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	23.52 (17.54, NR)	17.38 (14.03, 24.38)	
Log-Rank Test p-value (unstratified)	0.0668		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.527 (0.263, 1.057)		
Menopausal status			
Pre-menopausal	8	14	0.3368
Number (%) of Participants with Events (Death)	4 (50.0%)	8 (57.1%)	
Number (%) of Participants Censored	4 (50.0%)	6 (42.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.86 (12.22, NR)	24.38 (12.81, NR)	
Log-Rank Test p-value (unstratified)	0.8951		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.922 (0.275, 3.095)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Death)	15 (34.1%)	19 (61.3%)	
Number (%) of Participants Censored	29 (65.9%)	12 (38.7%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (20.90, NR)	16.23 (12.48, NR)	
Log-Rank Test p-value (unstratified)	0.0160		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.443 (0.225, 0.875)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Median OS from Kaplan-Meier estimate. 95% CI based on log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

label	SG (N=52)	TPC (N=45)	Interaction

Log-rank test is unstratified.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Participants with unknown BRCA 1/2 status were excluded from that subgroup.
Disease stratification and geographic region are collected from IWRS.
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.4. Table 1.1.4: Follow-up Duration (Months) for PFS and Tumor Response by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	SG (N=52)	TPC (N=45)	Total (N=97)
Follow-up duration (months) for Progression-Free Survival by Blinded Independent Central Review (BICR) [a]			
N	52	45	97
Mean (SD)	9.6 (7.3)	5.1 (4.2)	7.5 (6.5)
Median	7.9	4	5.6
Q1, Q3	3.8, 15.3	2.2, 8.1	2.8, 11.1
Min, Max	0, 26.3	0, 18	0, 26.3
Tumor Response by Blinded Independent Central Review (BICR), n (%)			
CR	3 (5.8%)	2 (4.4%)	5 (5.2%)
PR	25 (48.1%)	21 (46.7%)	46 (47.4%)
SD	14 (26.9%)	11 (24.4%)	25 (25.8%)
PD	4 (7.7%)	5 (11.1%)	9 (9.3%)
NE	1 (1.9%)	1 (2.2%)	2 (2.1%)
NON-CR/NON-PD	1 (1.9%)	0 (0.0%)	1 (1.0%)
Missing/NE	4 (7.7%)	5 (11.1%)	9 (9.3%)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; BICR = blinded independent central review; IWRS = Interactive Web Response System; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE = not evaluable; NON-CR/NON-PD = non-complete response/non-progressive disease (applicable to non-measurable disease).
[a] Observation period for PFS is defined as time from randomisation to the event or censoring date of progression-free survival.
Tumour response assessed by BICR per RECIST v1.1; confirmed responses only.
Data Cut Date: 27 OCT 2025.

5.5. Table 1.1.5: Analysis of PFS by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events	29 (55.8%)	35 (77.8%)
Disease Progression (PD)	27 (51.9%)	33 (73.3%)
Death	2 (3.8%)	2 (4.4%)
Number (%) of Participants Censored	23 (44.2%)	10 (22.2%)
PD after Starting New Anti-Cancer Therapy	1 (1.9%)	0
PD right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	0	0
Death after Starting New Anti-Cancer Therapy	3 (5.8%)	2 (4.4%)
Death right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	2 (3.8%)	3 (6.7%)
No PD and No Death without New Anti-Cancer Therapy	11 (21.2%)	1 (2.2%)
No PD and No Death with New Anti-Cancer Therapy	4 (7.7%)	2 (4.4%)
No Baseline or Postbaseline Evaluable Assessment [a]	2 (3.8%)	2 (4.4%)
Kaplan-Meier Estimate of PFS (Months) (95% CI) [b]		
Q1	4.30 (3.29, 8.15)	2.86 (1.45, 3.98)
Median	12.71 (7.66, 15.34)	5.39 (3.06, 7.29)
Q3	NR (15.31, NR)	8.28 (6.93, 12.32)
Absolute Difference in Median PFS, SG vs TPC (Months)	7.33	
Kaplan-Meier Estimate of PFS Rate (95% CI) [c]		
At 3 Months	0.893 (0.761, 0.954)	0.691 (0.519, 0.811)
At 6 Months	0.714 (0.559, 0.823)	0.425 (0.267, 0.574)
At 9 Months	0.592 (0.431, 0.721)	0.187 (0.079, 0.331)
At 12 Months	0.516 (0.358, 0.654)	0.125 (0.041, 0.259)
At 18 Months	0.345 (0.201, 0.494)	NR (NR, NR)

Parameter	SG (N=52)	TPC (N=45)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [d]	<0.0001	
Stratified Hazard Ratio of SG vs TPC (95% CI) [e]	0.310 (0.174, 0.553)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
[a] Censoring due to no baseline or no postbaseline evaluable assessment does not include death events before the second scheduled postbaseline visit.
[b] PFS (months) = (date of event or censoring − date of randomisation + 1) / 30.4375. The 95% CI is based on the log-log transformation.
[c] PFS rate is the proportion of participants alive without progressive disease (PD). The 95% CI is based on the log-log transformation.
[d] The two-sided p-value is from stratified log-rank test.
[e] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 27 OCT 2025.

5.6. Table 1.1.6: Analysis of PFS by BICR – Subgroup — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

label	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.8794
Number (%) of Participants with Events	14 (53.8%)	12 (70.6%)	
Disease Progression (PD)	13 (50.0%)	12 (70.6%)	
Death	1 (3.8%)	0	
Number (%) of Participants Censored	12 (46.2%)	5 (29.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.27, 15.21)	5.55 (1.77, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.377 (0.167, 0.852)		
p-value (Log-Rank Test, Unstratified)	0.0152		
Rest of the world	26	28	
Number (%) of Participants with Events	15 (57.7%)	23 (82.1%)	
Disease Progression (PD)	14 (53.8%)	21 (75.0%)	

label	SG (N=52)	TPC (N=45)	Interaction
Death	1 (3.8%)	2 (7.1%)	
Number (%) of Participants Censored	11 (42.3%)	5 (17.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.31 (7.13, 19.32)	4.21 (3.06, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.287 (0.139, 0.591)		
p-value (Log-Rank Test, Unstratified)	0.0004		
Age group			
< 65	35	35	0.7329
Number (%) of Participants with Events	22 (62.9%)	29 (82.9%)	
Disease Progression (PD)	22 (62.9%)	28 (80.0%)	
Death	0	1 (2.9%)	
Number (%) of Participants Censored	13 (37.1%)	6 (17.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	11.10 (4.53, 15.34)	4.21 (2.89, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.350 (0.193, 0.638)		
p-value (Log-Rank Test, Unstratified)	0.0004		
>= 65	17	10	
Number (%) of Participants with Events	7 (41.2%)	6 (60.0%)	
Disease Progression (PD)	5 (29.4%)	5 (50.0%)	
Death	2 (11.8%)	1 (10.0%)	
Number (%) of Participants Censored	10 (58.8%)	4 (40.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.21 (4.30, NR)	5.39 (1.41, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.364 (0.119, 1.114)		

label	SG (N=52)	TPC (N=45)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0660		
Baseline ECOG status			
0	35	26	0.0671
Number (%) of Participants with Events	15 (42.9%)	21 (80.8%)	
Disease Progression (PD)	14 (40.0%)	21 (80.8%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	20 (57.1%)	5 (19.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.31 (11.10, NR)	5.55 (3.98, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.199 (0.096, 0.413)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
1	17	19	
Number (%) of Participants with Events	14 (82.4%)	14 (73.7%)	
Disease Progression (PD)	13 (76.5%)	12 (63.2%)	
Death	1 (5.9%)	2 (10.5%)	
Number (%) of Participants Censored	3 (17.6%)	5 (26.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.30 (2.92, 8.15)	3.81 (2.73, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.714 (0.334, 1.529)		
p-value (Log-Rank Test, Unstratified)	0.3779		
History of liver metastasis			
Yes	11	13	0.5003
Number (%) of Participants with Events	9 (81.8%)	11 (84.6%)	
Disease Progression (PD)	8 (72.7%)	9 (69.2%)	

label	SG (N=52)	TPC (N=45)	Interaction
Death	1 (9.1%)	2 (15.4%)	
Number (%) of Participants Censored	2 (18.2%)	2 (15.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.42 (1.51, NR)	2.76 (0.59, 4.21)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.243 (0.082, 0.719)		
p-value (Log-Rank Test, Unstratified)	0.0062		
No	41	32	
Number (%) of Participants with Events	20 (48.8%)	24 (75.0%)	
Disease Progression (PD)	19 (46.3%)	24 (75.0%)	
Death	1 (2.4%)	0	
Number (%) of Participants Censored	21 (51.2%)	8 (25.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.21 (7.66, NR)	7.29 (4.04, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.341 (0.180, 0.644)		
p-value (Log-Rank Test, Unstratified)	0.0005		
PD-L1 Status			
CPS < 1	23	7	0.6379
Number (%) of Participants with Events	14 (60.9%)	5 (71.4%)	
Disease Progression (PD)	13 (56.5%)	5 (71.4%)	
Death	1 (4.3%)	0	
Number (%) of Participants Censored	9 (39.1%)	2 (28.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.41 (3.98, 18.07)	4.04 (0.59, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.268 (0.086, 0.836)		

label	SG (N=52)	TPC (N=45)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0162		
CPS ≥ 1	28	38	
Number (%) of Participants with Events	15 (53.6%)	30 (78.9%)	
Disease Progression (PD)	14 (50.0%)	28 (73.7%)	
Death	1 (3.6%)	2 (5.3%)	
Number (%) of Participants Censored	13 (46.4%)	8 (21.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	15.21 (7.13, 19.32)	5.39 (3.06, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.314 (0.162, 0.612)		
p-value (Log-Rank Test, Unstratified)	0.0003		
Menopausal status			
Pre-menopausal	8	14	0.9719
Number (%) of Participants with Events	6 (75.0%)	12 (85.7%)	
Disease Progression (PD)	6 (75.0%)	12 (85.7%)	
Death	0	0	
Number (%) of Participants Censored	2 (25.0%)	2 (14.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	11.81 (2.92, NR)	4.88 (1.41, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.254 (0.079, 0.823)		
p-value (Log-Rank Test, Unstratified)	0.0143		
Post-menopausal	44	31	
Number (%) of Participants with Events	23 (52.3%)	23 (74.2%)	
Disease Progression (PD)	21 (47.7%)	21 (67.7%)	
Death	2 (4.5%)	2 (6.5%)	

label	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants Censored	21 (47.7%)	8 (25.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (7.13, 19.32)	5.39 (2.89, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.365 (0.199, 0.671)		
p-value (Log-Rank Test, Unstratified)	0.0008		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Intent-to-treat (ITT) Analysis Set includes all participants who were randomised in the study.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS (months) = (date of events or censoring − date of randomisation + 1) / 30.4375. 95% CI based on log-log transformation. Median PFS from Kaplan-Meier estimate.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
[a] Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.7. Table 1.1.7: Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events	30 (57.7%)	33 (73.3%)
Disease Progression (PD)	17 (32.7%)	20 (44.4%)
Death	13 (25.0%)	13 (28.9%)
Number (%) of Participants Censored	22 (42.3%)	12 (26.7%)
Alive Without PFS2 Event and Without Second Next-Line Therapy	6 (11.5%)	5 (11.1%)
Alive Without PFS2 Event and With Second Next-Line Therapy	0	3 (6.7%)
Discontinued Study	0	0
No Baseline or Postbaseline Evaluable Assessment	0	0
Kaplan-Meier Estimate of PFS2 (Months) (95% CI) [a]		

Parameter	SG (N=52)	TPC (N=45)
Q1	13.14 (6.70, 15.87)	9.53 (7.59, 9.95)
Median	20.90 (15.87, 27.66)	12.48 (9.69, 17.35)
Q3	27.66 (23.72, NR)	20.24 (14.32, NR)
Absolute Difference in Median PFS2, SG vs TPC (Months)	8.41	
Kaplan-Meier Estimate of PFS2 Rate (95% CI) [b]		
At 3 Months	0.981 (0.871, 0.997)	0.955 (0.832, 0.989)
At 6 Months	0.885 (0.761, 0.946)	0.910 (0.777, 0.965)
At 9 Months	0.827 (0.694, 0.906)	0.773 (0.619, 0.871)
At 12 Months	0.788 (0.651, 0.877)	0.500 (0.346, 0.636)
At 18 Months	0.548 (0.402, 0.673)	0.281 (0.146, 0.432)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [c]	0.0033	
Stratified Hazard Ratio of SG vs TPC (95% CI) [d]	0.449 (0.261, 0.775)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first. Next line therapy is defined as the first new systemic anti-cancer therapy (including crossover treatment) initiated after discontinuation of study treatment regardless of end of treatment reason.
[a] Quantile of PFS2 is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
Data Cut Date: 27 OCT 2025.

5.8. Table 1.1.8: Subgroup Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

label	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.7204
Number (%) of Participants with Events	20 (76.9%)	14 (82.4%)	

label	SG (N=52)	TPC (N=45)	Interaction
Disease Progression (PD)	19 (73.1%)	14 (82.4%)	
Death	1 (3.8%)	0	
Number (%) of Participants Censored	6 (23.1%)	3 (17.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.66 (4.14, 11.10)	4.16 (1.45, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.470 (0.228, 0.968)		
p-value (Log-Rank Test, Unstratified)	0.0365		
Rest of the world	26	28	
Number (%) of Participants with Events	19 (73.1%)	25 (89.3%)	
Disease Progression (PD)	18 (69.2%)	23 (82.1%)	
Death	1 (3.8%)	2 (7.1%)	
Number (%) of Participants Censored	7 (26.9%)	3 (10.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	13.17 (5.55, 18.07)	4.21 (2.89, 8.08)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.336 (0.173, 0.655)		
p-value (Log-Rank Test, Unstratified)	0.0009		
Age group			
< 65	35	35	0.7016
Number (%) of Participants with Events	29 (82.9%)	32 (91.4%)	
Disease Progression (PD)	29 (82.9%)	31 (88.6%)	
Death	0	1 (2.9%)	
Number (%) of Participants Censored	6 (17.1%)	3 (8.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.23 (4.17, 15.21)	4.21 (2.86, 7.16)	

label	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.423 (0.246, 0.730)		
p-value (Log-Rank Test, Unstratified)	0.0015		
>= 65	17	10	
Number (%) of Participants with Events	10 (58.8%)	7 (70.0%)	
Disease Progression (PD)	8 (47.1%)	6 (60.0%)	
Death	2 (11.8%)	1 (10.0%)	
Number (%) of Participants Censored	7 (41.2%)	3 (30.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (4.17, NR)	4.60 (1.41, 8.80)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.429 (0.156, 1.179)		
p-value (Log-Rank Test, Unstratified)	0.0918		
Baseline ECOG status			
0	35	26	0.4601
Number (%) of Participants with Events	23 (65.7%)	21 (80.8%)	
Disease Progression (PD)	22 (62.9%)	21 (80.8%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	12 (34.3%)	5 (19.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	13.63 (7.66, 18.07)	5.55 (3.98, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.331 (0.173, 0.630)		
p-value (Log-Rank Test, Unstratified)	0.0005		
1	17	19	
Number (%) of Participants with Events	16 (94.1%)	18 (94.7%)	
Disease Progression (PD)	15 (88.2%)	16 (84.2%)	

label	SG (N=52)	TPC (N=45)	Interaction
Death	1 (5.9%)	2 (10.5%)	
Number (%) of Participants Censored	1 (5.9%)	1 (5.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.27 (1.54, 8.15)	2.97 (1.64, 5.62)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.621 (0.307, 1.255)		
p-value (Log-Rank Test, Unstratified)	0.1771		
History of liver metastasis			
Yes	11	13	0.2263
Number (%) of Participants with Events	9 (81.8%)	12 (92.3%)	
Disease Progression (PD)	8 (72.7%)	10 (76.9%)	
Death	1 (9.1%)	2 (15.4%)	
Number (%) of Participants Censored	2 (18.2%)	1 (7.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.42 (1.51, NR)	2.74 (0.59, 4.21)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.228 (0.078, 0.665)		
p-value (Log-Rank Test, Unstratified)	0.0035		
No	41	32	
Number (%) of Participants with Events	30 (73.2%)	27 (84.4%)	
Disease Progression (PD)	29 (70.7%)	27 (84.4%)	
Death	1 (2.4%)	0	
Number (%) of Participants Censored	11 (26.8%)	5 (15.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.76 (5.55, 15.21)	6.93 (3.98, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.464 (0.266, 0.811)		

label	SG (N=52)	TPC (N=45)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0059		
PD-L1 Status			
CPS < 1	23	7	0.1849
Number (%) of Participants with Events	15 (65.2%)	6 (85.7%)	
Disease Progression (PD)	14 (60.9%)	6 (85.7%)	
Death	1 (4.3%)	0	
Number (%) of Participants Censored	8 (34.8%)	1 (14.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.41 (3.98, 18.07)	3.47 (0.59, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.231 (0.078, 0.678)		
p-value (Log-Rank Test, Unstratified)	0.0041		
CPS ≥ 1	28	38	
Number (%) of Participants with Events	24 (85.7%)	33 (86.8%)	
Disease Progression (PD)	23 (82.1%)	31 (81.6%)	
Death	1 (3.6%)	2 (5.3%)	
Number (%) of Participants Censored	4 (14.3%)	5 (13.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.39 (4.17, 15.21)	4.21 (2.92, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.472 (0.267, 0.835)		
p-value (Log-Rank Test, Unstratified)	0.0082		
Menopausal status			
Pre-menopausal	8	14	0.8468
Number (%) of Participants with Events	8 (100.0%)	13 (92.9%)	
Disease Progression (PD)	8 (100.0%)	13 (92.9%)	

label	SG (N=52)	TPC (N=45)	Interaction
Death	0	0	
Number (%) of Participants Censored	0	1 (7.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.23 (2.92, 15.31)	4.21 (1.41, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.284 (0.097, 0.837)		
p-value (Log-Rank Test, Unstratified)	0.0157		
Post-menopausal	44	31	
Number (%) of Participants with Events	31 (70.5%)	26 (83.9%)	
Disease Progression (PD)	29 (65.9%)	24 (77.4%)	
Death	2 (4.5%)	2 (6.5%)	
Number (%) of Participants Censored	13 (29.5%)	5 (16.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.07 (4.30, 15.21)	4.01 (2.86, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.445 (0.256, 0.773)		
p-value (Log-Rank Test, Unstratified)	0.0032		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from an unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.9. Table 1.1.9: Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Parameter	SG (N=52)	TPC (N=45)
Number (%) of Participants with Events	36 (69.2%)	41 (91.1%)
First Subsequent Therapy	29 (55.8%)	32 (71.1%)
Death	7 (13.5%)	9 (20.0%)
Number (%) of Participants Censored	16 (30.8%)	4 (8.9%)
Kaplan-Meier Estimate of TFST (Months) (95% CI) [a]		
Q1	7.64 (4.80, 11.66)	4.40 (2.43, 5.75)
Median	15.87 (11.66, 18.96)	7.59 (5.59, 9.53)
Q3	21.59 (18.96, NR)	11.53 (9.46, 15.44)
Absolute Difference in Median TFST, SG vs TPC (Months)	8.28	
Kaplan-Meier Estimate of TFST Rate (95% CI) [b]		
At 3 Months	0.923 (0.808, 0.970)	0.867 (0.727, 0.938)
At 6 Months	0.788 (0.651, 0.877)	0.622 (0.465, 0.746)
At 9 Months	0.712 (0.568, 0.815)	0.422 (0.278, 0.560)
At 12 Months	0.615 (0.470, 0.732)	0.178 (0.083, 0.301)
At 18 Months	0.391 (0.258, 0.523)	0.133 (0.054, 0.249)
At 24 Months	0.225 (0.105, 0.374)	NR (NR, NR)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	<0.0001	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.334 (0.200, 0.556)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomization to the start date of the first subsequent anti-cancer therapy after discontinuation of randomized treatment, or death due to any cause.
[a] Quantile of TFST is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] TFST rate is the proportion of participants alive without any subsequent therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors from Interactive Web Response System (IWRS).
Data Cut Date: 27 OCT 2025.

5.10. Table 1.1.10: Subgroup Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

label	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.540
Number (%) of Participants with Events	19 (73.1%)	15 (88.2%)	
First Subsequent Therapy	15 (57.7%)	12 (70.6%)	
Death	4 (15.4%)	3 (17.6%)	
Number (%) of Participants Censored	7 (26.9%)	2 (11.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.87 (8.15, 19.84)	7.69 (3.02, 11.66)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.450 (0.220, 0.921)		
p-value (Log-Rank Test, Unstratified)	0.025		
Rest of the world	26	28	
Number (%) of Participants with Events	17 (65.4%)	26 (92.9%)	
First Subsequent Therapy	14 (53.8%)	20 (71.4%)	
Death	3 (11.5%)	6 (21.4%)	
Number (%) of Participants Censored	9 (34.6%)	2 (7.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.79 (11.60, 21.59)	7.28 (5.13, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.314 (0.164, 0.603)		
p-value (Log-Rank Test, Unstratified)	<0.001		
Age group			
< 65	35	35	0.789
Number (%) of Participants with Events	26 (74.3%)	33 (94.3%)	

label	SG (N=52)	TPC (N=45)	Interaction
First Subsequent Therapy	24 (68.6%)	27 (77.1%)	
Death	2 (5.7%)	6 (17.1%)	
Number (%) of Participants Censored	9 (25.7%)	2 (5.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.00 (11.66, 19.58)	7.59 (5.75, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.355 (0.204, 0.617)		
p-value (Log-Rank Test, Unstratified)	<0.001		
>= 65	17	10	
Number (%) of Participants with Events	10 (58.8%)	8 (80.0%)	
First Subsequent Therapy	5 (29.4%)	5 (50.0%)	
Death	5 (29.4%)	3 (30.0%)	
Number (%) of Participants Censored	7 (41.2%)	2 (20.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	15.87 (7.13, NR)	7.56 (2.17, 11.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.464 (0.181, 1.191)		
p-value (Log-Rank Test, Unstratified)	0.102		
Baseline ECOG status			
0	35	26	0.387
Number (%) of Participants with Events	21 (60.0%)	23 (88.5%)	
First Subsequent Therapy	15 (42.9%)	19 (73.1%)	
Death	6 (17.1%)	4 (15.4%)	
Number (%) of Participants Censored	14 (40.0%)	3 (11.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	18.96 (15.01, 21.59)	8.26 (5.75, 11.53)	

label	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.302 (0.160, 0.569)		
p-value (Log-Rank Test, Unstratified)	<0.001		
1	17	19	
Number (%) of Participants with Events	15 (88.2%)	18 (94.7%)	
First Subsequent Therapy	14 (82.4%)	13 (68.4%)	
Death	1 (5.9%)	5 (26.3%)	
Number (%) of Participants Censored	2 (11.8%)	1 (5.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.47 (3.25, 13.86)	6.77 (3.02, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.509 (0.244, 1.064)		
p-value (Log-Rank Test, Unstratified)	0.068		
History of liver metastasis			
Yes	11	13	0.747
Number (%) of Participants with Events	9 (81.8%)	13 (100.0%)	
First Subsequent Therapy	6 (54.5%)	9 (69.2%)	
Death	3 (27.3%)	4 (30.8%)	
Number (%) of Participants Censored	2 (18.2%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.03 (4.80, NR)	5.13 (2.43, 7.69)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.291 (0.111, 0.764)		
p-value (Log-Rank Test, Unstratified)	0.009		
No	41	32	
Number (%) of Participants with Events	27 (65.9%)	28 (87.5%)	
First Subsequent Therapy	23 (56.1%)	23 (71.9%)	

label	SG (N=52)	TPC (N=45)	Interaction
Death	4 (9.8%)	5 (15.6%)	
Number (%) of Participants Censored	14 (34.1%)	4 (12.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.79 (12.65, 20.67)	9.49 (5.75, 11.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.374 (0.213, 0.657)		
p-value (Log-Rank Test, Unstratified)	<0.001		
PD-L1 Status			
CPS < 1	23	7	0.555
Number (%) of Participants with Events	15 (65.2%)	7 (100.0%)	
First Subsequent Therapy	12 (52.2%)	5 (71.4%)	
Death	3 (13.0%)	2 (28.6%)	
Number (%) of Participants Censored	8 (34.8%)	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	13.86 (11.60, NR)	7.59 (2.43, 11.73)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.236 (0.086, 0.648)		
p-value (Log-Rank Test, Unstratified)	0.002		
CPS ≥ 1	28	38	
Number (%) of Participants with Events	21 (75.0%)	34 (89.5%)	
First Subsequent Therapy	17 (60.7%)	27 (71.1%)	
Death	4 (14.3%)	7 (18.4%)	
Number (%) of Participants Censored	7 (25.0%)	4 (10.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.39 (6.01, 19.84)	7.33 (5.13, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.426 (0.236, 0.769)		

label	SG (N=52)	TPC (N=45)	Interaction
p-value (Log-Rank Test, Unstratified)	0.004		
Menopausal status			
Pre-menopausal	8	14	0.526
Number (%) of Participants with Events	7 (87.5%)	12 (85.7%)	
First Subsequent Therapy	7 (87.5%)	11 (78.6%)	
Death	0	1 (7.1%)	
Number (%) of Participants Censored	1 (12.5%)	2 (14.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	12.65 (3.25, 18.96)	6.03 (2.43, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.442 (0.153, 1.277)		
p-value (Log-Rank Test, Unstratified)	0.122		
Post-menopausal	44	31	
Number (%) of Participants with Events	29 (65.9%)	29 (93.5%)	
First Subsequent Therapy	22 (50.0%)	21 (67.7%)	
Death	7 (15.9%)	8 (25.8%)	
Number (%) of Participants Censored	15 (34.1%)	2 (6.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	16.02 (11.60, 20.67)	8.84 (5.59, 10.84)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.357 (0.207, 0.615)		
p-value (Log-Rank Test, Unstratified)	<0.001		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomisation to the start date of the first subsequent anti-cancer therapy after discontinuation of randomised treatment, or death due to any cause.
TFST rate is the proportion of participants alive without any subsequent therapy.
Hazard ratio and 95% CIs calculated using unstratified Cox proportional hazards model. Efron method used to handle ties. Reference arm = TPC.
Log-rank p-value is from an unstratified log-rank test.
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Data Cut Date: 27 OCT 2025.

6. Safety - mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

6.1. Table 1.1.1: Summary of Treatment Exposure - Treatment Duration (months) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	Taxane (N=44)	Any TPC (N=44)
Total Duration of Exposure to Study Drug			
Duration (months)			
N	51	44	44
Mean (StD)	10.48 (7.529)	5.40 (4.243)	5.40 (4.243)
Median	9.23	4.76	4.76
Q1, Q3	4.06, 17.12	2.17, 7.68	2.17, 7.68
Min, Max	0.26, 26.32	0.03, 17.91	0.03, 17.91
Cumulative Number (%) of Participants			
Exposed to Study Drug			
>= 3 months, n, (%)	42 (82.4%)	28 (63.6%)	28 (63.6%)
>= 6 months, n, (%)	32 (62.7%)	16 (36.4%)	16 (36.4%)
>= 12 months, n, (%)	21 (41.2%)	3 (6.8%)	3 (6.8%)
>= 24 months, n, (%)	2 (3.9%)	0 (0.0%)	0 (0.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, Gem = gemcitabine, Carbo = carboplatin.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug. Taxane includes participants who have received Paclitaxel. TPC column includes participants who have received any of Gem, Carbo or Paclitaxel.
Duration of exposure to study drug (months) = (last dosing date − first dosing date + 1)/30.4375.

6.2. Table 1.1.2: Observation Period (Months) for Safety — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Total (N=95)
Observation Period (months) for Safety [a]			
N	51	44	95
Mean (StD)	11.31 (7.375)	6.34 (4.233)	9.01 (6.582)
Median	10.22	5.75	7.49
Q1, Q3	5.04, 17.76	3.15, 8.67	3.79, 13.13
Min, Max	0.49, 27.30	0.10, 18.89	0.10, 27.30

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
[a] Observation period is defined as the time from first dose until Data cutoff date, study treatment discontinuation +30 days for any AE and any serious AE, or death, whichever comes first and stops the collection of endpoint data.

6.3. Table 1.1.3: Analysis of Time to First Treatment-Emergent Adverse Event (TEAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	51 (100.0%)	42 (95.5%)
Patients (%) Without Events (Censored)	0 (0.0%)	2 (4.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.10 (0.07, 0.26)	0.13 (0.07, 0.23)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.267 (0.826, 1.944)
p-value		0.2754

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=51)	TPC (N=44)

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.4. Table 1.1.4: Subgroup Analysis of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.3568
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	25 (100.0%)	15 (93.8%)	
Patients (%) Without Events (Censored)	0	1 (6.2%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.33)	0.16 (0.03, 0.26)	
Hazard Ratio (95% CI)		1.108 (0.571, 2.151)	
p-value		0.7387	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	26 (100.0%)	27 (96.4%)	
Patients (%) Without Events (Censored)	0	1 (3.6%)	
Median Time to First TEAE, months (95% CI)	0.08 (0.07, 0.20)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.452 (0.824, 2.557)	
p-value		0.1927	
Age group			0.7631
< 65			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	34	34	
Patients (%) With Events	34 (100.0%)	32 (94.1%)	
Patients (%) Without Events (Censored)	0	2 (5.9%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.07, 0.26)	0.16 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.264 (0.758, 2.108)	
p-value		0.3924	
>= 65			
Total Patients	17	10	
Patients (%) With Events	17 (100.0%)	10 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.03, 0.16)	0.11 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.233 (0.547, 2.782)	
p-value		0.5836	
Baseline ECOG status			0.3545
0			
Total Patients	34	25	
Patients (%) With Events	34 (100.0%)	23 (92.0%)	
Patients (%) Without Events (Censored)	0	2 (8.0%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.33)	0.20 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.191 (0.689, 2.059)	
p-value		0.5639	
1			
Total Patients	17	19	
Patients (%) With Events	17 (100.0%)	19 (100.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.03, 0.10)	0.13 (0.03, 0.23)	
Hazard Ratio (95% CI)		1.512 (0.757, 3.020)	
p-value		0.2478	
History of liver metastasis			0.4518
Yes			
Total Patients	11	12	
Patients (%) With Events	11 (100.0%)	10 (83.3%)	
Patients (%) Without Events (Censored)	0	2 (16.7%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.49)	0.13 (0.03, 1.41)	
Hazard Ratio (95% CI)		1.465 (0.601, 3.569)	
p-value		0.3947	
No			
Total Patients	40	32	
Patients (%) With Events	40 (100.0%)	32 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.07, 0.26)	0.16 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.153 (0.709, 1.875)	
p-value		0.5473	
PD-L1 Status			0.4697
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	23 (100.0%)	6 (100.0%)	
Patients (%) Without Events (Censored)	0	0	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.20 (0.03, NR)	
Hazard Ratio (95% CI)		2.257 (0.760, 6.704)	
p-value		0.1151	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	28 (100.0%)	36 (94.7%)	
Patients (%) Without Events (Censored)	0	2 (5.3%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.26)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.083 (0.652, 1.798)	
p-value		0.7399	
Menopausal status			0.1982
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	8 (100.0%)	14 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.31 (0.07, NR)	0.13 (0.03, 0.26)	
Hazard Ratio (95% CI)		0.835 (0.338, 2.061)	
p-value		0.6562	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	43 (100.0%)	28 (93.3%)	
Patients (%) Without Events (Censored)	0	2 (6.7%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.16 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.386 (0.842, 2.282)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.1749	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.5. Table 1.1.5: Analysis of Time to First Serious Treatment-Emergent Adverse Event (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	12 (23.5%)	8 (18.2%)
Patients (%) Without Events (Censored)	39 (76.5%)	36 (81.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.234 (0.504, 3.024)
p-value		0.6547

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.6. Table 1.1.6: Subgroup Analysis of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.4018
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	8 (32.0%)	3 (18.8%)	
Patients (%) Without Events (Censored)	17 (68.0%)	13 (81.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (4.76, NR)	
Hazard Ratio (95% CI)		1.761 (0.465, 6.669)	
p-value		0.4057	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	4 (15.4%)	5 (17.9%)	
Patients (%) Without Events (Censored)	22 (84.6%)	23 (82.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.769 (0.206, 2.874)	
p-value		0.6951	
Age group			0.2178
< 65			
Total Patients	34	34	
Patients (%) With Events	3 (8.8%)	5 (14.7%)	
Patients (%) Without Events (Censored)	31 (91.2%)	29 (85.3%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.537 (0.128, 2.258)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.3844	
>= 65			
Total Patients	17	10	
Patients (%) With Events	9 (52.9%)	3 (30.0%)	
Patients (%) Without Events (Censored)	8 (47.1%)	7 (70.0%)	
Median Time to First Serious TEAE, months (95% CI)	6.57 (0.53, NR)	NR (0.26, NR)	
Hazard Ratio (95% CI)		1.775 (0.479, 6.570)	
p-value		0.3902	
Baseline ECOG status			0.0024
0			
Total Patients	34	25	
Patients (%) With Events	11 (32.4%)	2 (8.0%)	
Patients (%) Without Events (Censored)	23 (67.6%)	23 (92.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.399 (0.974, 19.860)	
p-value		0.0359	
1			
Total Patients	17	19	
Patients (%) With Events	1 (5.9%)	6 (31.6%)	
Patients (%) Without Events (Censored)	16 (94.1%)	13 (68.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (2.76, NR)	
Hazard Ratio (95% CI)		0.146 (0.017, 1.223)	
p-value		0.0402	
History of liver metastasis			0.7548

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Yes			
Total Patients	11	12	
Patients (%) With Events	3 (27.3%)	3 (25.0%)	
Patients (%) Without Events (Censored)	8 (72.7%)	9 (75.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (0.43, NR)	NR (2.27, NR)	
Hazard Ratio (95% CI)		1.094 (0.220, 5.428)	
p-value		0.9274	
No			
Total Patients	40	32	
Patients (%) With Events	9 (22.5%)	5 (15.6%)	
Patients (%) Without Events (Censored)	31 (77.5%)	27 (84.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.381 (0.462, 4.123)	
p-value		0.5656	
PD-L1 Status			0.2496
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	5 (21.7%)	2 (33.3%)	
Patients (%) Without Events (Censored)	18 (78.3%)	4 (66.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (0.30, NR)	
Hazard Ratio (95% CI)		0.533 (0.102, 2.769)	
p-value		0.4386	
CPS ≥ 1			
Total Patients	28	38	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	7 (25.0%)	6 (15.8%)	
Patients (%) Without Events (Censored)	21 (75.0%)	32 (84.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.597 (0.536, 4.754)	
p-value		0.4034	
Menopausal status			0.7546
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	1 (12.5%)	1 (7.1%)	
Patients (%) Without Events (Censored)	7 (87.5%)	13 (92.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (3.58, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		1.254 (0.077, 20.400)	
p-value		0.8736	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	11 (25.6%)	7 (23.3%)	
Patients (%) Without Events (Censored)	32 (74.4%)	23 (76.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.045 (0.405, 2.698)	
p-value		0.9430	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
NC = Not Calculable: the hazard ratio and 95% CI are not estimable by the Cox model.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.7. Table 1.1.7: Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	34 (66.7%)	18 (40.9%)
Patients (%) Without Events (Censored)	17 (33.3%)	26 (59.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.04 (0.79, 6.41)	7.79 (2.27, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.827 (1.028, 3.249)
p-value		0.0375

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.8. Table 1.1.8: Subgroup Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.7623
US/Canada/Western Europe			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	25	16	
Patients (%) With Events	16 (64.0%)	6 (37.5%)	
Patients (%) Without Events (Censored)	9 (36.0%)	10 (62.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, NR)	7.79 (2.27, NR)	
Hazard Ratio (95% CI)		2.089 (0.813, 5.365)	
p-value		0.1187	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	18 (69.2%)	12 (42.9%)	
Patients (%) Without Events (Censored)	8 (30.8%)	16 (57.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.89 (0.56, NR)	NR (1.35, NR)	
Hazard Ratio (95% CI)		1.705 (0.814, 3.574)	
p-value		0.1550	
Age group			0.6398
< 65			
Total Patients	34	34	
Patients (%) With Events	21 (61.8%)	13 (38.2%)	
Patients (%) Without Events (Censored)	13 (38.2%)	21 (61.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.58 (0.95, 10.58)	NR (6.90, NR)	
Hazard Ratio (95% CI)		1.921 (0.960, 3.848)	
p-value		0.0623	
>= 65			
Total Patients	17	10	
Patients (%) With Events	13 (76.5%)	5 (50.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	4 (23.5%)	5 (50.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.56 (0.43, NR)	1.97 (0.26, NR)	
Hazard Ratio (95% CI)		1.495 (0.526, 4.246)	
p-value		0.4312	
Baseline ECOG status			0.0099
0			
Total Patients	34	25	
Patients (%) With Events	25 (73.5%)	7 (28.0%)	
Patients (%) Without Events (Censored)	9 (26.5%)	18 (72.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.53, 4.14)	NR (6.90, NR)	
Hazard Ratio (95% CI)		3.579 (1.543, 8.301)	
p-value		0.0016	
1			
Total Patients	17	19	
Patients (%) With Events	9 (52.9%)	11 (57.9%)	
Patients (%) Without Events (Censored)	8 (47.1%)	8 (42.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.41 (0.92, NR)	2.27 (0.30, NR)	
Hazard Ratio (95% CI)		0.766 (0.308, 1.907)	
p-value		0.5746	
History of liver metastasis			0.8692
Yes			
Total Patients	11	12	
Patients (%) With Events	7 (63.6%)	5 (41.7%)	
Patients (%) Without Events (Censored)	4 (36.4%)	7 (58.3%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.43, NR)	NR (0.53, NR)	
Hazard Ratio (95% CI)		1.746 (0.553, 5.516)	
p-value		0.3327	
No			
Total Patients	40	32	
Patients (%) With Events	27 (67.5%)	13 (40.6%)	
Patients (%) Without Events (Censored)	13 (32.5%)	19 (59.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, 10.58)	NR (1.97, NR)	
Hazard Ratio (95% CI)		1.895 (0.972, 3.696)	
p-value		0.0557	
PD-L1 Status			0.5852
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	16 (69.6%)	4 (66.7%)	
Patients (%) Without Events (Censored)	7 (30.4%)	2 (33.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.92 (0.53, 3.58)	1.69 (0.30, NR)	
Hazard Ratio (95% CI)		1.290 (0.430, 3.865)	
p-value		0.6552	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	18 (64.3%)	14 (36.8%)	
Patients (%) Without Events (Censored)	10 (35.7%)	24 (63.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	4.48 (0.95, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		1.794 (0.882, 3.650)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.1022	
Menopausal status			0.8996
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	5 (62.5%)	5 (35.7%)	
Patients (%) Without Events (Censored)	3 (37.5%)	9 (64.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.58 (0.72, NR)	NR (1.41, NR)	
Hazard Ratio (95% CI)		2.027 (0.576, 7.132)	
p-value		0.2620	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	29 (67.4%)	13 (43.3%)	
Patients (%) Without Events (Censored)	14 (32.6%)	17 (56.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.56, 10.58)	7.79 (1.97, NR)	
Hazard Ratio (95% CI)		1.690 (0.874, 3.266)	
p-value		0.1162	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.9. Table 1.1.9: Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Number of patients at risk	51 (100.0%)	44 (100.0%)
Number of patients with events	4 (7.8%)	6 (13.6%)
Sacituzumab Govitecan	4 (7.8%)	0
Paclitaxel	0	6 (13.6%)
Number of patients censored	47 (92.2%)	38 (86.4%)
Probability of being event-free [a] [95% CI] [b] at:		
Month 3	96.0 [85.1, 99.0]	95.2 [82.0, 98.8]
Month 6	91.5 [78.9, 96.7]	91.8 [76.2, 97.3]
Month 9	91.5 [78.9, 96.7]	75.2 [50.8, 88.7]
Month 12	91.5 [78.9, 96.7]	75.2 [50.8, 88.7]
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.450 (0.126, 1.611)
p-value		0.2086

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[a] Estimated from the Kaplan-Meier method.
[b] Calculated using the log-log transformation (Brookmeyer-Crowley method).
[c] Median 95% CI based on Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties. p-value is from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm in the Safety Analysis Set.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.10. Table 1.1.10: Subgroup Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.9215
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	3 (12.0%)	4 (25.0%)	
Patients (%) Without Events (Censored)	22 (88.0%)	12 (75.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.74, NR)	
Hazard Ratio (95% CI)		0.386 (0.085, 1.746)	
p-value		0.2000	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	1 (3.8%)	2 (7.1%)	
Patients (%) Without Events (Censored)	25 (96.2%)	26 (92.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.414 (0.037, 4.631)	
p-value		0.4605	
Age group			0.3959
< 65			
Total Patients	34	34	
Patients (%) With Events	1 (2.9%)	4 (11.8%)	
Patients (%) Without Events (Censored)	33 (97.1%)	30 (88.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.186 (0.021, 1.689)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.0953	
>= 65			
Total Patients	17	10	
Patients (%) With Events	3 (17.6%)	2 (20.0%)	
Patients (%) Without Events (Censored)	14 (82.4%)	8 (80.0%)	
Median Time to Discontinuation, months (95% CI)	NR (4.11, NR)	NR (1.97, NR)	
Hazard Ratio (95% CI)		0.676 (0.111, 4.126)	
p-value		0.6697	
Baseline ECOG status			0.0643
0			
Total Patients	34	25	
Patients (%) With Events	4 (11.8%)	3 (12.0%)	
Patients (%) Without Events (Censored)	30 (88.2%)	22 (88.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.845 (0.188, 3.806)	
p-value		0.8264	
1			
Total Patients	17	19	
Patients (%) With Events	0	3 (15.8%)	
Patients (%) Without Events (Censored)	17 (100.0%)	16 (84.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.67, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0627	
History of liver metastasis			1.0000

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Yes			
Total Patients	11	12	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	11 (100.0%)	12 (100.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		1.0000	
No			
Total Patients	40	32	
Patients (%) With Events	4 (10.0%)	6 (18.8%)	
Patients (%) Without Events (Censored)	36 (90.0%)	26 (81.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.465 (0.131, 1.659)	
p-value		0.2271	
PD-L1 Status			0.4478
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	1 (4.3%)	1 (16.7%)	
Patients (%) Without Events (Censored)	22 (95.7%)	5 (83.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (1.97, NR)	
Hazard Ratio (95% CI)		0.280 (0.017, 4.480)	
p-value		0.3360	
CPS ≥ 1			
Total Patients	28	38	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	3 (10.7%)	5 (13.2%)	
Patients (%) Without Events (Censored)	25 (89.3%)	33 (86.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.633 (0.150, 2.662)	
p-value		0.5288	
Menopausal status			0.2643
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	0	2 (14.3%)	
Patients (%) Without Events (Censored)	8 (100.0%)	12 (85.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.67, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.2132	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	4 (9.3%)	4 (13.3%)	
Patients (%) Without Events (Censored)	39 (90.7%)	26 (86.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.90, NR)	
Hazard Ratio (95% CI)		0.548 (0.136, 2.210)	
p-value		0.3911	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. NC = Not Calculable (HR is NC when one treatment arm has zero events; log-rank p-value remains valid).
Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.11. Table 1.1.11: Analysis of Time to First TEAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Blood and lymphatic system disorders		
Total Patients	51	44
Patients (%) With Events	38 (74.5%)	20 (45.5%)
Patients (%) Without Events (Censored)	13 (25.5%)	24 (54.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.72 (0.49, 1.02)	5.55 (2.30, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.441 (1.407, 4.233)
p-value		0.0013
Anaemia		
Total Patients	51	44
Patients (%) With Events	22 (43.1%)	12 (27.3%)
Patients (%) Without Events (Censored)	29 (56.9%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (2.76, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.600 (0.789, 3.247)
p-value		0.1912
Leukopenia		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	10 (19.6%)	2 (4.5%)
Patients (%) Without Events (Censored)	41 (80.4%)	42 (95.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.379 (0.958, 20.014)
p-value		0.0375
Lymphopenia		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	47 (92.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (9.20, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.562 (0.148, 2.128)
p-value		0.3866
Neutropenia		
Total Patients	51	44
Patients (%) With Events	33 (64.7%)	11 (25.0%)
Patients (%) Without Events (Censored)	18 (35.3%)	33 (75.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 3.02)	13.34 (13.34, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		3.398 (1.708, 6.759)
p-value		0.0003
Cardiac disorders		
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	3 (6.8%)
Patients (%) Without Events (Censored)	42 (82.4%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.562 (0.693, 9.468)
p-value		0.1434
Eye disorders		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	45 (88.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.743 (0.221, 2.499)
p-value		0.6305
Gastrointestinal disorders		
Total Patients	51	44
Patients (%) With Events	49 (96.1%)	24 (54.5%)
Patients (%) Without Events (Censored)	2 (3.9%)	20 (45.5%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.26 (0.10, 0.43)	2.89 (0.26, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.663 (1.614, 4.392)
p-value		0.0001
Abdominal pain		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	4 (9.1%)
Patients (%) Without Events (Censored)	43 (84.3%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.231 (0.356, 4.258)
p-value		0.7484
Constipation		
Total Patients	51	44
Patients (%) With Events	23 (45.1%)	9 (20.5%)
Patients (%) Without Events (Censored)	28 (54.9%)	35 (79.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (0.82, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.550 (1.179, 5.513)
p-value		0.0141
Diarrhoea		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	31 (60.8%)	10 (22.7%)
Patients (%) Without Events (Censored)	20 (39.2%)	34 (77.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.74 (0.72, 17.35)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.012 (1.469, 6.175)
p-value		0.0016
Nausea		
Total Patients	51	44
Patients (%) With Events	31 (60.8%)	12 (27.3%)
Patients (%) Without Events (Censored)	20 (39.2%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.83 (0.95, 5.09)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.586 (1.327, 5.039)
p-value		0.0036
Stomatitis		
Total Patients	51	44
Patients (%) With Events	15 (29.4%)	2 (4.5%)
Patients (%) Without Events (Censored)	36 (70.6%)	42 (95.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (11.76, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		6.585 (1.499, 28.925)
p-value		0.0040
Vomiting		
Total Patients	51	44
Patients (%) With Events	14 (27.5%)	5 (11.4%)
Patients (%) Without Events (Censored)	37 (72.5%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.469 (0.889, 6.857)
p-value		0.0725
General disorders and administration site conditions		
Total Patients	51	44
Patients (%) With Events	36 (70.6%)	22 (50.0%)
Patients (%) Without Events (Censored)	15 (29.4%)	22 (50.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.41 (0.59, 3.91)	3.98 (0.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.497 (0.880, 2.547)
p-value		0.1341
Fatigue		
Total Patients	51	44
Patients (%) With Events	30 (58.8%)	19 (43.2%)
Patients (%) Without Events (Censored)	21 (41.2%)	25 (56.8%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.79 (1.18, NR)	7.26 (3.78, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.472 (0.828, 2.616)
p-value		0.1860
Oedema peripheral		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	5 (11.4%)
Patients (%) Without Events (Censored)	48 (94.1%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (18.86, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.316 (0.071, 1.401)
p-value		0.1118
Pyrexia		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	4 (9.1%)
Patients (%) Without Events (Censored)	43 (84.3%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.210 (0.355, 4.119)
p-value		0.7603
Infections and infestations		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	34 (66.7%)	21 (47.7%)
Patients (%) Without Events (Censored)	17 (33.3%)	23 (52.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	4.76 (2.04, 7.46)	5.75 (2.27, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.220 (0.704, 2.113)
p-value		0.4778
Nasopharyngitis		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	3 (6.8%)
Patients (%) Without Events (Censored)	44 (86.3%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.411 (0.359, 5.552)
p-value		0.6204
Upper respiratory tract infection		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	45 (88.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		0.629 (0.187, 2.119)
p-value		0.4506
Urinary tract infection		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	7 (15.9%)
Patients (%) Without Events (Censored)	47 (92.2%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.430 (0.125, 1.477)
p-value		0.1672
Injury, poisoning and procedural complications		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	8 (18.2%)
Patients (%) Without Events (Censored)	45 (88.2%)	36 (81.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.498 (0.168, 1.473)
p-value		0.2016
Infusion related reaction		
Total Patients	51	44
Patients (%) With Events	1 (2.0%)	5 (11.4%)
Patients (%) Without Events (Censored)	50 (98.0%)	39 (88.6%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.161 (0.019, 1.377)
p-value		0.0569
Investigations		
Total Patients	51	44
Patients (%) With Events	25 (49.0%)	12 (27.3%)
Patients (%) Without Events (Censored)	26 (51.0%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	19.35 (3.45, NR)	NR (6.60, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.584 (0.784, 3.198)
p-value		0.1956
Alanine aminotransferase increased		
Total Patients	51	44
Patients (%) With Events	11 (21.6%)	5 (11.4%)
Patients (%) Without Events (Censored)	40 (78.4%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.389 (0.469, 4.114)
p-value		0.5474
Aspartate aminotransferase increased		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	5 (11.4%)
Patients (%) Without Events (Censored)	42 (82.4%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.187 (0.387, 3.644)
p-value		0.7628
Blood alkaline phosphatase increased		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	1 (2.3%)
Patients (%) Without Events (Censored)	44 (86.3%)	43 (97.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.481 (0.530, 37.886)
p-value		0.1322
Metabolism and nutrition disorders		
Total Patients	51	44
Patients (%) With Events	22 (43.1%)	15 (34.1%)
Patients (%) Without Events (Censored)	29 (56.9%)	29 (65.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	18.96 (3.45, NR)	NR (3.06, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		1.147 (0.589, 2.233)
p-value		0.6843
Decreased appetite		
Total Patients	51	44
Patients (%) With Events	10 (19.6%)	11 (25.0%)
Patients (%) Without Events (Censored)	41 (80.4%)	33 (75.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (6.90, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.647 (0.271, 1.546)
p-value		0.3231
Hyperglycaemia		
Total Patients	51	44
Patients (%) With Events	2 (3.9%)	5 (11.4%)
Patients (%) Without Events (Censored)	49 (96.1%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.296 (0.057, 1.545)
p-value		0.1258
Hypokalaemia		
Total Patients	51	44
Patients (%) With Events	8 (15.7%)	0 (0.0%)
Patients (%) Without Events (Censored)	43 (84.3%)	44 (100.0%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0127
Musculoskeletal and connective tissue disorders		
Total Patients	51	44
Patients (%) With Events	21 (41.2%)	19 (43.2%)
Patients (%) Without Events (Censored)	30 (58.8%)	25 (56.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	12.78 (6.08, NR)	5.16 (3.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.673 (0.355, 1.274)
p-value		0.2209
Arthralgia		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	46 (90.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.410 (0.106, 1.590)
p-value		0.1842
Back pain		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	5 (11.4%)
Patients (%) Without Events (Censored)	44 (86.3%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.984 (0.310, 3.126)
p-value		0.9778
Myalgia		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	7 (15.9%)
Patients (%) Without Events (Censored)	47 (92.2%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.383 (0.108, 1.356)
p-value		0.1233
Nervous system disorders		
Total Patients	51	44
Patients (%) With Events	21 (41.2%)	27 (61.4%)
Patients (%) Without Events (Censored)	30 (58.8%)	17 (38.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (4.47, NR)	3.12 (1.97, 6.24)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		0.411 (0.222, 0.762)
p-value		0.0035
Headache		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	5 (11.4%)
Patients (%) Without Events (Censored)	44 (86.3%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.972 (0.303, 3.121)
p-value		0.9623
Neuropathy peripheral		
Total Patients	51	44
Patients (%) With Events	1 (2.0%)	10 (22.7%)
Patients (%) Without Events (Censored)	50 (98.0%)	34 (77.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (6.90, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.057 (0.007, 0.453)
p-value		0.0003
Peripheral sensory neuropathy		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	9 (20.5%)
Patients (%) Without Events (Censored)	48 (94.1%)	35 (79.5%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (9.46, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.176 (0.045, 0.681)
p-value		0.0053
Psychiatric disorders		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	6 (13.6%)
Patients (%) Without Events (Censored)	44 (86.3%)	38 (86.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	16.53 (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.718 (0.226, 2.281)
p-value		0.5724
Renal and urinary disorders		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	7 (15.9%)
Patients (%) Without Events (Censored)	45 (88.2%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (8.74, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.562 (0.185, 1.703)
p-value		0.3017
Reproductive system and breast disorders		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	4 (9.1%)
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (10.61, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.121 (0.335, 3.749)
p-value		0.8528
Respiratory, thoracic and mediastinal disorders		
Total Patients	51	44
Patients (%) With Events	19 (37.3%)	12 (27.3%)
Patients (%) Without Events (Censored)	32 (62.7%)	32 (72.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (6.51, NR)	NR (6.44, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.043 (0.501, 2.173)
p-value		0.9059
Cough		
Total Patients	51	44
Patients (%) With Events	9 (17.6%)	4 (9.1%)
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		1.406 (0.423, 4.673)
p-value		0.5761
Dyspnoea		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	5 (11.4%)
Patients (%) Without Events (Censored)	45 (88.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.869 (0.264, 2.859)
p-value		0.8175
Skin and subcutaneous tissue disorders		
Total Patients	51	44
Patients (%) With Events	35 (68.6%)	22 (50.0%)
Patients (%) Without Events (Censored)	16 (31.4%)	22 (50.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 2.20)	3.29 (0.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.539 (0.901, 2.628)
p-value		0.1101
Alopecia		
Total Patients	51	44
Patients (%) With Events	29 (56.9%)	16 (36.4%)
Patients (%) Without Events (Censored)	22 (43.1%)	28 (63.6%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.41 (0.72, NR)	NR (1.84, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.717 (0.931, 3.164)
p-value		0.0788
Nail disorder		
Total Patients	51	44
Patients (%) With Events	0 (0.0%)	5 (11.4%)
Patients (%) Without Events (Censored)	51 (100.0%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0048
Vascular disorders		
Total Patients	51	44
Patients (%) With Events	7 (13.7%)	8 (18.2%)
Patients (%) Without Events (Censored)	44 (86.3%)	36 (81.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (11.20, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.474 (0.163, 1.377)
p-value		0.1621

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=51)	TPC (N=44)

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.12. Table 1.1.12.1: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.3462
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	14 (56.0%)	6 (37.5%)	
Patients (%) Without Events (Censored)	11 (44.0%)	10 (62.5%)	
Median Time to First TEAE, months (95% CI)	1.68 (0.69, NR)	5.55 (2.30, NR)	
Hazard Ratio (95% CI)		2.011 (0.768, 5.263)	
p-value		0.1518	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	24 (92.3%)	14 (50.0%)	
Patients (%) Without Events (Censored)	2 (7.7%)	14 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.71 (0.26, 0.72)	4.34 (0.49, NR)	
Hazard Ratio (95% CI)		3.348 (1.667, 6.726)	
p-value		0.0005	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Age group			0.4650
< 65			
Total Patients	34	34	
Patients (%) With Events	27 (79.4%)	15 (44.1%)	
Patients (%) Without Events (Censored)	7 (20.6%)	19 (55.9%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.49, 1.02)	5.55 (3.29, NR)	
Hazard Ratio (95% CI)		2.869 (1.505, 5.470)	
p-value		0.0011	
>= 65			
Total Patients	17	10	
Patients (%) With Events	11 (64.7%)	5 (50.0%)	
Patients (%) Without Events (Censored)	6 (35.3%)	5 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.26, NR)	4.90 (0.23, NR)	
Hazard Ratio (95% CI)		1.536 (0.532, 4.432)	
p-value		0.4352	
Baseline ECOG status			0.8597
0			
Total Patients	34	25	
Patients (%) With Events	26 (76.5%)	12 (48.0%)	
Patients (%) Without Events (Censored)	8 (23.5%)	13 (52.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.43, 1.25)	5.49 (2.30, NR)	
Hazard Ratio (95% CI)		2.616 (1.301, 5.261)	
p-value		0.0061	
1			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	17	19	
Patients (%) With Events	12 (70.6%)	8 (42.1%)	
Patients (%) Without Events (Censored)	5 (29.4%)	11 (57.9%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 3.02)	NR (0.66, NR)	
Hazard Ratio (95% CI)		2.110 (0.852, 5.226)	
p-value		0.1059	
History of liver metastasis			0.8106
Yes			
Total Patients	11	12	
Patients (%) With Events	10 (90.9%)	5 (41.7%)	
Patients (%) Without Events (Censored)	1 (9.1%)	7 (58.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 2.30)	NR (0.26, NR)	
Hazard Ratio (95% CI)		2.611 (0.884, 7.712)	
p-value		0.0683	
No			
Total Patients	40	32	
Patients (%) With Events	28 (70.0%)	15 (46.9%)	
Patients (%) Without Events (Censored)	12 (30.0%)	17 (53.1%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.30, 1.68)	5.55 (2.30, NR)	
Hazard Ratio (95% CI)		2.332 (1.231, 4.418)	
p-value		0.0095	
PD-L1 Status			0.1655
CPS < 1			
Total Patients	23	6	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	16 (69.6%)	5 (83.3%)	
Patients (%) Without Events (Censored)	7 (30.4%)	1 (16.7%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.43, 3.02)	3.79 (0.66, NR)	
Hazard Ratio (95% CI)		1.415 (0.511, 3.921)	
p-value		0.5407	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	22 (78.6%)	15 (39.5%)	
Patients (%) Without Events (Censored)	6 (21.4%)	23 (60.5%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 1.25)	NR (2.30, NR)	
Hazard Ratio (95% CI)		3.001 (1.531, 5.882)	
p-value		0.0009	
Menopausal status			0.3702
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	8 (100.0%)	6 (42.9%)	
Patients (%) Without Events (Censored)	0 (0.0%)	8 (57.1%)	
Median Time to First TEAE, months (95% CI)	0.87 (0.26, 2.30)	5.55 (1.41, NR)	
Hazard Ratio (95% CI)		6.314 (1.828, 21.816)	
p-value		0.0013	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	30 (69.8%)	14 (46.7%)	
Patients (%) Without Events (Censored)	13 (30.2%)	16 (53.3%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.72 (0.30, 1.25)	5.49 (0.66, NR)	
Hazard Ratio (95% CI)		1.941 (1.023, 3.685)	
p-value		0.0426	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.13. Table 1.1.12.2: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.6288
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	24 (96.0%)	10 (62.5%)	
Patients (%) Without Events (Censored)	1 (4.0%)	6 (37.5%)	
Median Time to First TEAE, months (95% CI)	0.36 (0.16, 0.53)	1.61 (0.26, NR)	
Hazard Ratio (95% CI)		2.943 (1.366, 6.337)	
p-value		0.0043	
Rest of the world			
Total Patients	26	28	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) With Events	25 (96.2%)	14 (50.0%)	
Patients (%) Without Events (Censored)	1 (3.8%)	14 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.07, 0.53)	5.98 (0.13, NR)	
Hazard Ratio (95% CI)		2.596 (1.330, 5.066)	
p-value		0.0036	
Age group			0.8271
< 65			
Total Patients	34	34	
Patients (%) With Events	32 (94.1%)	18 (52.9%)	
Patients (%) Without Events (Censored)	2 (5.9%)	16 (47.1%)	
Median Time to First TEAE, months (95% CI)	0.38 (0.10, 0.59)	3.94 (0.26, NR)	
Hazard Ratio (95% CI)		2.432 (1.346, 4.393)	
p-value		0.0021	
>= 65			
Total Patients	17	10	
Patients (%) With Events	17 (100.0%)	6 (60.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	4 (40.0%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.36)	1.61 (0.03, NR)	
Hazard Ratio (95% CI)		2.687 (1.025, 7.045)	
p-value		0.0386	
Baseline ECOG status			0.7432
0			
Total Patients	34	25	
Patients (%) With Events	32 (94.1%)	14 (56.0%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Patients (%) Without Events (Censored)	2 (5.9%)	11 (44.0%)	
Median Time to First TEAE, months (95% CI)	0.36 (0.10, 0.53)	3.94 (0.43, NR)	
Hazard Ratio (95% CI)		2.644 (1.396, 5.009)	
p-value		0.0021	
1			
Total Patients	17	19	
Patients (%) With Events	17 (100.0%)	10 (52.6%)	
Patients (%) Without Events (Censored)	0 (0.0%)	9 (47.4%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.07, 0.59)	1.91 (0.03, NR)	
Hazard Ratio (95% CI)		2.735 (1.181, 6.334)	
p-value		0.0123	
History of liver metastasis			0.7989
Yes			
Total Patients	11	12	
Patients (%) With Events	11 (100.0%)	6 (50.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	6 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.49)	4.75 (0.03, NR)	
Hazard Ratio (95% CI)		2.488 (0.909, 6.807)	
p-value		0.0585	
No			
Total Patients	40	32	
Patients (%) With Events	38 (95.0%)	18 (56.2%)	
Patients (%) Without Events (Censored)	2 (5.0%)	14 (43.8%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.13, 0.53)	2.89 (0.30, NR)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.696 (1.516, 4.794)	
p-value		0.0005	
PD-L1 Status			0.8758
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	23 (100.0%)	3 (50.0%)	
Patients (%) Without Events (Censored)	0 (0.0%)	3 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.36 (0.10, 0.59)	5.98 (0.03, NR)	
Hazard Ratio (95% CI)		3.233 (0.938, 11.142)	
p-value		0.0467	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	26 (92.9%)	21 (55.3%)	
Patients (%) Without Events (Censored)	2 (7.1%)	17 (44.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.07, 0.39)	1.91 (0.26, NR)	
Hazard Ratio (95% CI)		2.551 (1.419, 4.585)	
p-value		0.0012	
Menopausal status			0.9068
Pre-menopausal			
Total Patients	8	14	
Patients (%) With Events	7 (87.5%)	7 (50.0%)	
Patients (%) Without Events (Censored)	1 (12.5%)	7 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.43 (0.07, 4.07)	5.98 (0.13, NR)	
Hazard Ratio (95% CI)		2.180 (0.760, 6.254)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.1439	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	42 (97.7%)	17 (56.7%)	
Patients (%) Without Events (Censored)	1 (2.3%)	13 (43.3%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.10, 0.43)	1.61 (0.26, NR)	
Hazard Ratio (95% CI)		2.605 (1.463, 4.638)	
p-value		0.0007	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.14. Table 1.1.12.3: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Geographic region			0.6881
US/Canada/Western Europe			
Total Patients	25	16	
Patients (%) With Events	11 (44.0%)	10 (62.5%)	
Patients (%) Without Events (Censored)	14 (56.0%)	6 (37.5%)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (2.07, NR)	2.27 (1.41, NR)	
Hazard Ratio (95% CI)		0.519 (0.216, 1.248)	
p-value		0.1363	
Rest of the world			
Total Patients	26	28	
Patients (%) With Events	10 (38.5%)	17 (60.7%)	
Patients (%) Without Events (Censored)	16 (61.5%)	11 (39.3%)	
Median Time to First TEAE, months (95% CI)	NR (4.47, NR)	3.52 (1.97, 6.24)	
Hazard Ratio (95% CI)		0.334 (0.137, 0.816)	
p-value		0.0115	
Age group			0.3102
< 65			
Total Patients	34	34	
Patients (%) With Events	11 (32.4%)	21 (61.8%)	
Patients (%) Without Events (Censored)	23 (67.6%)	13 (38.2%)	
Median Time to First TEAE, months (95% CI)	NR (11.33, NR)	4.47 (1.94, 6.90)	
Hazard Ratio (95% CI)		0.233 (0.099, 0.549)	
p-value		0.0003	
>= 65			
Total Patients	17	10	
Patients (%) With Events	10 (58.8%)	6 (60.0%)	
Patients (%) Without Events (Censored)	7 (41.2%)	4 (40.0%)	
Median Time to First TEAE, months (95% CI)	2.10 (0.36, NR)	2.27 (0.03, NR)	
Hazard Ratio (95% CI)		0.686 (0.236, 1.997)	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
p-value		0.4899	
Baseline ECOG status			0.2933
0			
Total Patients	34	25	
Patients (%) With Events	13 (38.2%)	17 (68.0%)	
Patients (%) Without Events (Censored)	21 (61.8%)	8 (32.0%)	
Median Time to First TEAE, months (95% CI)	NR (6.44, NR)	3.12 (1.41, 6.90)	
Hazard Ratio (95% CI)		0.286 (0.127, 0.644)	
p-value		0.0013	
1			
Total Patients	17	19	
Patients (%) With Events	8 (47.1%)	10 (52.6%)	
Patients (%) Without Events (Censored)	9 (52.9%)	9 (47.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.30, NR)	2.92 (1.97, NR)	
Hazard Ratio (95% CI)		0.733 (0.286, 1.884)	
p-value		0.5122	
History of liver metastasis			0.4133
Yes			
Total Patients	11	12	
Patients (%) With Events	3 (27.3%)	7 (58.3%)	
Patients (%) Without Events (Censored)	8 (72.7%)	5 (41.7%)	
Median Time to First TEAE, months (95% CI)	NR (0.99, NR)	2.07 (0.39, NR)	
Hazard Ratio (95% CI)		0.344 (0.087, 1.357)	
p-value		0.1114	

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
No			
Total Patients	40	32	
Patients (%) With Events	18 (45.0%)	20 (62.5%)	
Patients (%) Without Events (Censored)	22 (55.0%)	12 (37.5%)	
Median Time to First TEAE, months (95% CI)	12.78 (3.91, NR)	4.47 (1.97, 6.24)	
Hazard Ratio (95% CI)		0.451 (0.226, 0.898)	
p-value		0.0197	
PD-L1 Status			0.7781
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	6 (26.1%)	3 (50.0%)	
Patients (%) Without Events (Censored)	17 (73.9%)	3 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (11.89, NR)	9.13 (2.20, NR)	
Hazard Ratio (95% CI)		0.393 (0.092, 1.677)	
p-value		0.1914	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	15 (53.6%)	24 (63.2%)	
Patients (%) Without Events (Censored)	13 (46.4%)	14 (36.8%)	
Median Time to First TEAE, months (95% CI)	11.33 (2.10, NR)	2.92 (1.84, 5.75)	
Hazard Ratio (95% CI)		0.530 (0.266, 1.055)	
p-value		0.0668	
Menopausal status			0.6033
Pre-menopausal			

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Total Patients	8	14	
Patients (%) With Events	2 (25.0%)	8 (57.1%)	
Patients (%) Without Events (Censored)	6 (75.0%)	6 (42.9%)	
Median Time to First TEAE, months (95% CI)	NR (0.26, NR)	5.09 (0.39, NR)	
Hazard Ratio (95% CI)		0.304 (0.062, 1.483)	
p-value		0.1213	
Post-menopausal			
Total Patients	43	30	
Patients (%) With Events	19 (44.2%)	19 (63.3%)	
Patients (%) Without Events (Censored)	24 (55.8%)	11 (36.7%)	
Median Time to First TEAE, months (95% CI)	12.78 (4.40, NR)	2.27 (1.84, 6.90)	
Hazard Ratio (95% CI)		0.417 (0.210, 0.826)	
p-value		0.0098	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.15. Table 1.1.12.4: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
Age group			0.6771
< 65			
Total Patients	34	34	
Patients (%) With Events	25 (73.5%)	10 (29.4%)	
Patients (%) Without Events (Censored)	9 (26.5%)	24 (70.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 2.33)	13.34 (13.34, NR)	
Hazard Ratio (95% CI)		3.472 (1.651, 7.304)	
p-value		0.0006	
>= 65			
Total Patients	17	10	
Patients (%) With Events	8 (47.1%)	1 (10.0%)	
Patients (%) Without Events (Censored)	9 (52.9%)	9 (90.0%)	
Median Time to First TEAE, months (95% CI)	9.00 (0.72, NR)	NR (0.46, NR)	
Hazard Ratio (95% CI)		5.090 (0.624, 41.517)	
p-value		0.0911	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.16. Table 1.1.12.5: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Diarrhoea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
History of liver metastasis			0.0105
Yes			
Total Patients	11	12	
Patients (%) With Events	7 (63.6%)	0 (0.0%)	
Patients (%) Without Events (Censored)	4 (36.4%)	12 (100.0%)	
Median Time to First TEAE, months (95% CI)	0.79 (0.26, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0017	
No			
Total Patients	40	32	
Patients (%) With Events	24 (60.0%)	10 (31.2%)	
Patients (%) Without Events (Censored)	16 (40.0%)	22 (68.8%)	
Median Time to First TEAE, months (95% CI)	2.27 (0.72, 17.35)	NR (3.94, NR)	
Hazard Ratio (95% CI)		2.045 (0.973, 4.299)	
p-value		0.0544	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.17. Table 1.1.12.6: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Nausea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)	Interaction p-value[1]
PD-L1 Status			0.0671
CPS < 1			
Total Patients	23	6	
Patients (%) With Events	13 (56.5%)	0 (0.0%)	
Patients (%) Without Events (Censored)	10 (43.5%)	6 (100.0%)	
Median Time to First TEAE, months (95% CI)	3.58 (0.53, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0305	
CPS ≥ 1			
Total Patients	28	38	
Patients (%) With Events	18 (64.3%)	12 (31.6%)	
Patients (%) Without Events (Censored)	10 (35.7%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	2.33 (0.36, NR)	NR (3.09, NR)	
Hazard Ratio (95% CI)		2.297 (1.105, 4.773)	
p-value		0.0208	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.

	SG (N=51)	TPC (N=44)	Interaction p-value[1]

Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.18. Table 1.1.13: Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Blood and lymphatic system disorders		
Total Patients	51	44
Patients (%) With Events	24 (47.1%)	7 (15.9%)
Patients (%) Without Events (Censored)	27 (52.9%)	37 (84.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	22.34 (2.04, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.369 (1.445, 7.858)
p-value		0.0029
Febrile neutropenia		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		NC
p-value		0.1161
Lymphopenia		
Total Patients	51	44
Patients (%) With Events	2 (3.9%)	3 (6.8%)
Patients (%) Without Events (Censored)	49 (96.1%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.456 (0.075, 2.772)
p-value		0.3824
Neutropenia		
Total Patients	51	44
Patients (%) With Events	20 (39.2%)	3 (6.8%)
Patients (%) Without Events (Censored)	31 (60.8%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	22.34 (3.48, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		6.331 (1.872, 21.410)
p-value		0.0007
Gastrointestinal disorders		
Total Patients	51	44
Patients (%) With Events	10 (19.6%)	1 (2.3%)
Patients (%) Without Events (Censored)	41 (80.4%)	43 (97.7%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.71, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		6.915 (0.869, 55.004)
p-value		0.0342
Diarrhoea		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	0 (0.0%)
Patients (%) Without Events (Censored)	47 (92.2%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0630
Stomatitis		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.1714
General disorders and administration site conditions		

	SG (N=51)	TPC (N=44)
Total Patients	51	44
Patients (%) With Events	1 (2.0%)	3 (6.8%)
Patients (%) Without Events (Censored)	50 (98.0%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.222 (0.023, 2.157)
p-value		0.1559
Infections and infestations		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	4 (9.1%)
Patients (%) Without Events (Censored)	46 (90.2%)	40 (90.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.920 (0.245, 3.446)
p-value		0.9011
Investigations		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	3 (6.8%)
Patients (%) Without Events (Censored)	45 (88.2%)	41 (93.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=51)	TPC (N=44)
Hazard Ratio (95% CI)		1.158 (0.269, 4.989)
p-value		0.8439
Alanine aminotransferase increased		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	2 (4.5%)
Patients (%) Without Events (Censored)	46 (90.2%)	42 (95.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.42, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.338 (0.235, 7.608)
p-value		0.7422
Metabolism and nutrition disorders		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	1 (2.3%)
Patients (%) Without Events (Censored)	47 (92.2%)	43 (97.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.407 (0.381, 30.481)
p-value		0.2436
Respiratory, thoracic and mediastinal disorders		
Total Patients	51	44
Patients (%) With Events	4 (7.8%)	3 (6.8%)
Patients (%) Without Events (Censored)	47 (92.2%)	41 (93.2%)

	SG (N=51)	TPC (N=44)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.030 (0.230, 4.617)
p-value		0.9697

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.19. Table 1.1.14: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

No Eligible subgroups

6.20. Table 1.1.15: Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Blood and lymphatic system disorders		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)

	SG (N=51)	TPC (N=44)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.1242
Gastrointestinal disorders		
Total Patients	51	44
Patients (%) With Events	6 (11.8%)	0 (0.0%)
Patients (%) Without Events (Censored)	45 (88.2%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0211
Diarrhoea		
Total Patients	51	44
Patients (%) With Events	3 (5.9%)	0 (0.0%)
Patients (%) Without Events (Censored)	48 (94.1%)	44 (100.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.1068
Infections and infestations		
Total Patients	51	44
Patients (%) With Events	5 (9.8%)	5 (11.4%)

	SG (N=51)	TPC (N=44)
Patients (%) Without Events (Censored)	46 (90.2%)	39 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.727 (0.209, 2.525)
p-value		0.6142

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.21. Table 1.1.16: Subgroup Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

No Eligible Subgroups

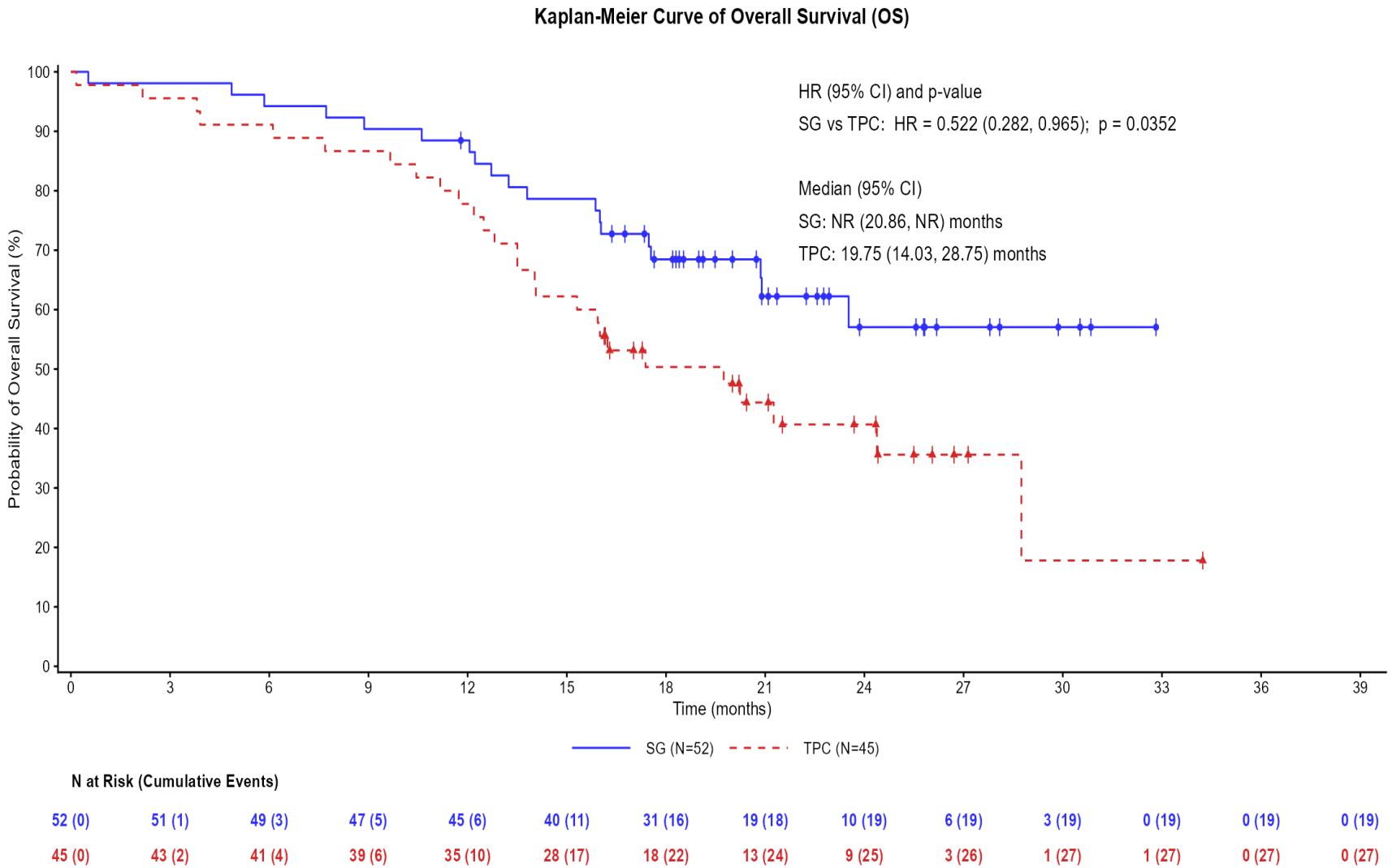
6.22. Table 1.1.17: Incidence of TEAE leading to Study Drug Discontinuation by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)	TPC (N=44)
Number (%) of Participants with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	4 (7.8%)	6 (13.6%)
Gastrointestinal disorders	1 (2.0%)	0
Diarrhoea	1 (2.0%)	0
General disorders and administration site conditions	0	1 (2.3%)
Fatigue	0	1 (2.3%)
Infections and infestations	1 (2.0%)	1 (2.3%)
Nail bed infection	0	1 (2.3%)
Urosepsis	1 (2.0%)	0
Injury, poisoning and procedural complications	0	1 (2.3%)
Infusion related reaction	0	1 (2.3%)
Musculoskeletal and connective tissue disorders	0	1 (2.3%)
Musculoskeletal pain	0	1 (2.3%)
Nervous system disorders	0	1 (2.3%)
Neuropathy peripheral	0	1 (2.3%)
Psychiatric disorders	1 (2.0%)	0
Restlessness	1 (2.0%)	0
Respiratory, thoracic and mediastinal disorders	1 (2.0%)	0
Interstitial lung disease	1 (2.0%)	0
Skin and subcutaneous tissue disorders	0	1 (2.3%)
Skin oedema	0	1 (2.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Adverse events were coded according to MedDRA Version 27.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

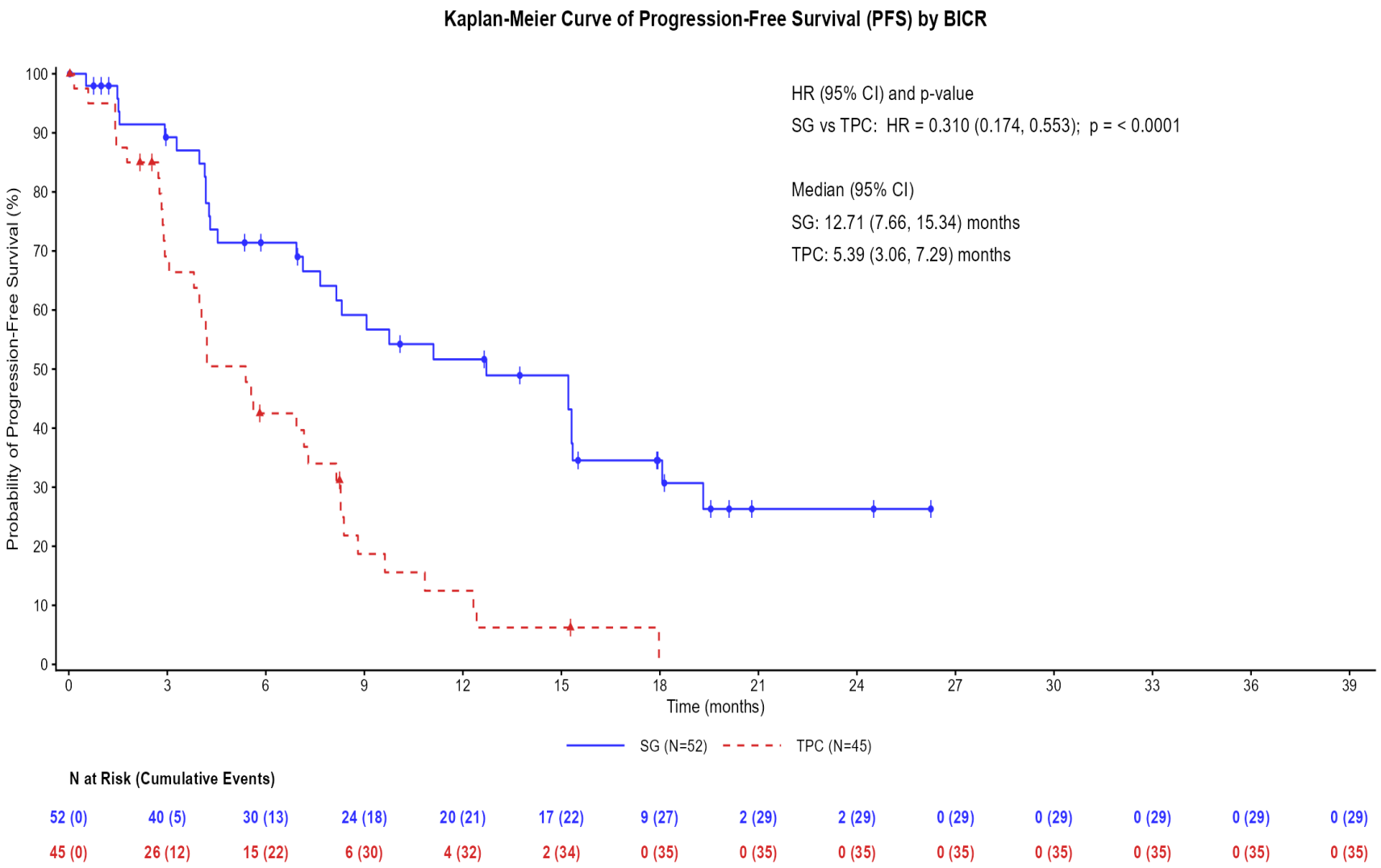
7. Efficacy - KM FIGURES - mITT - Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

7.1. Figure 1.1.1: Kaplan-Meier Curve of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



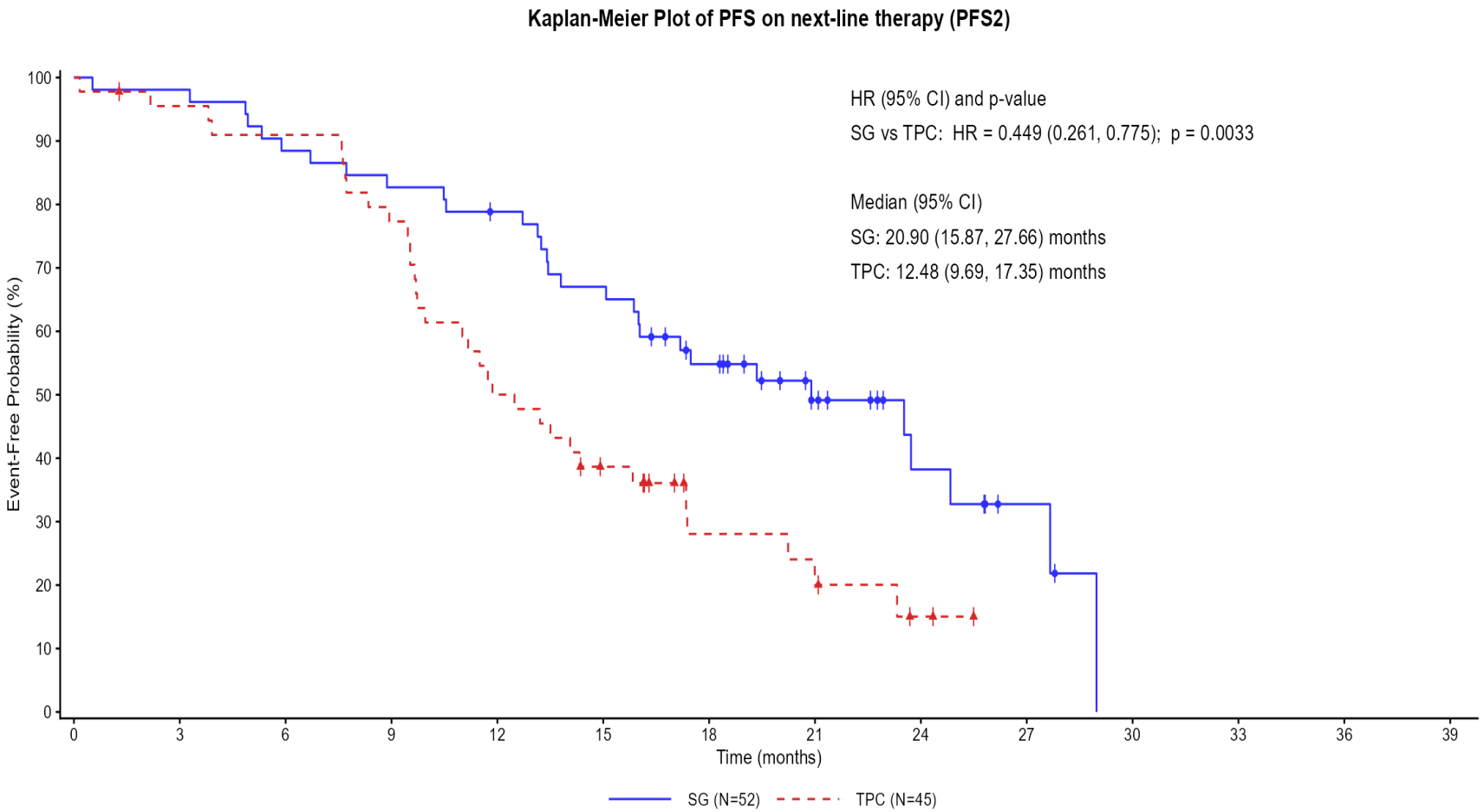
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

7.2. Figure 1.1.2: Kaplan-Meier Curve of Progression-Free Survival (PFS) by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



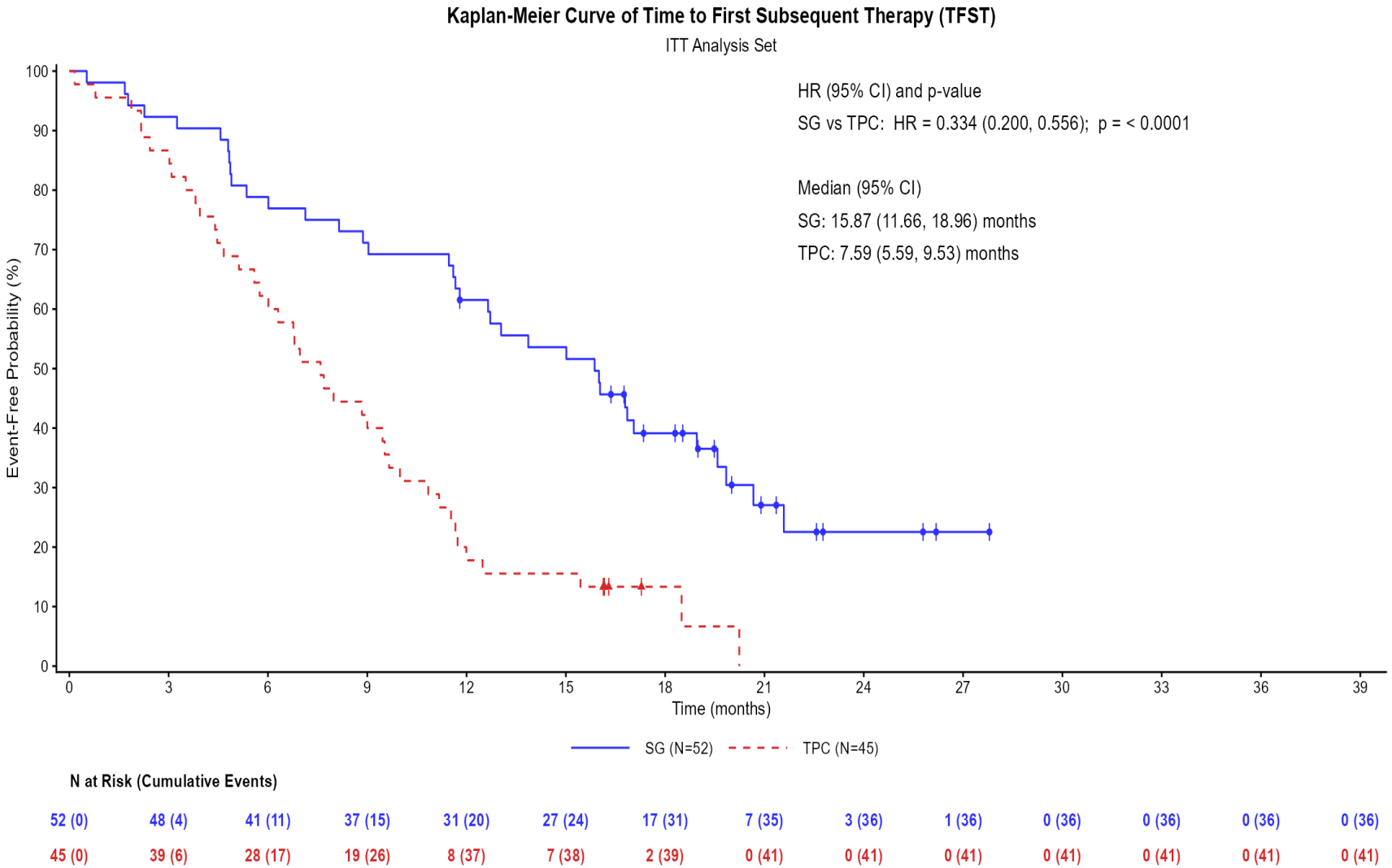
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

7.3. Figure 1.1.3: Kaplan-Meier Plot of PFS on next-line therapy (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

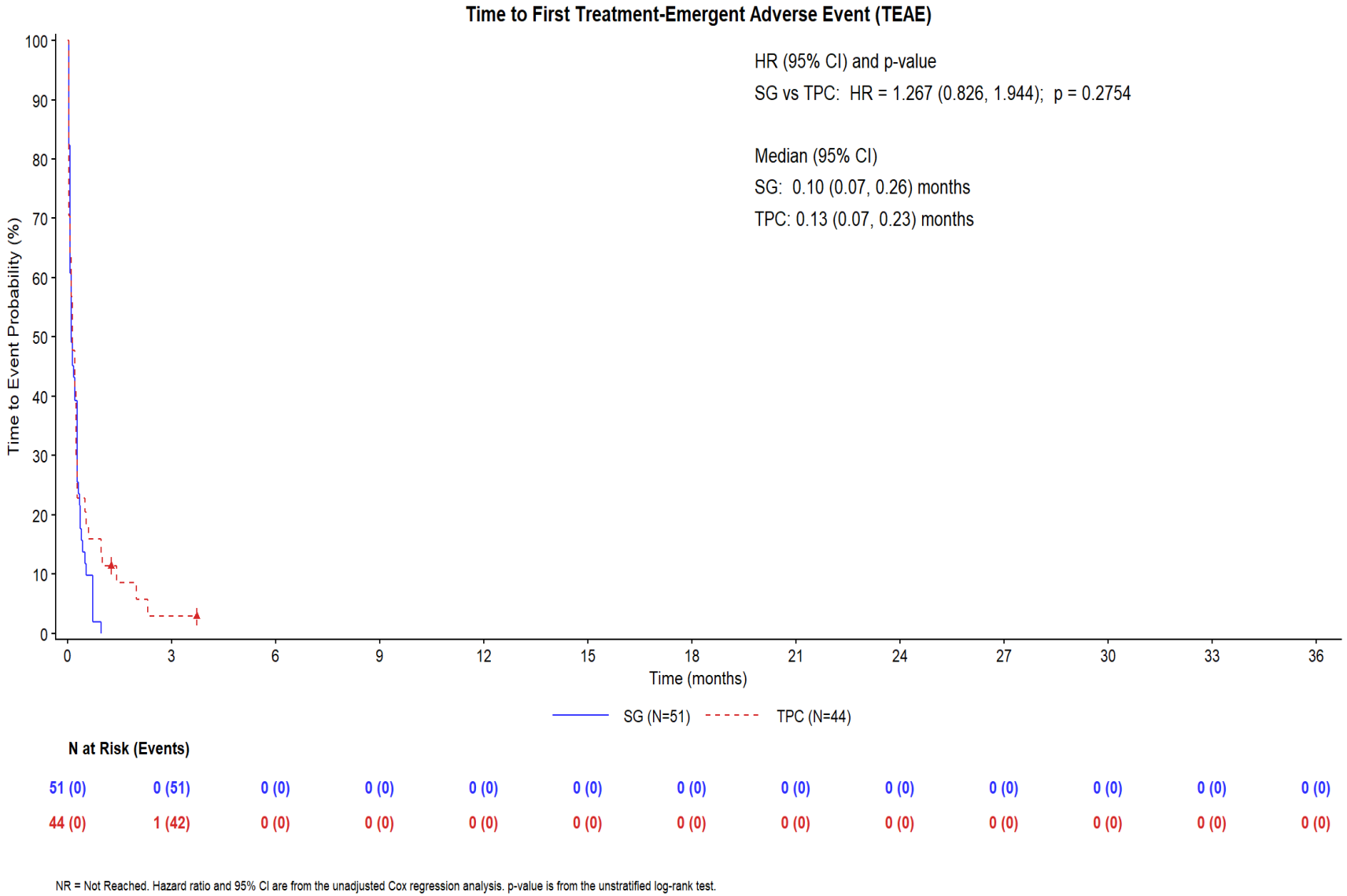
7.4. Figure 1.1.4: Kaplan-Meier Curve of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

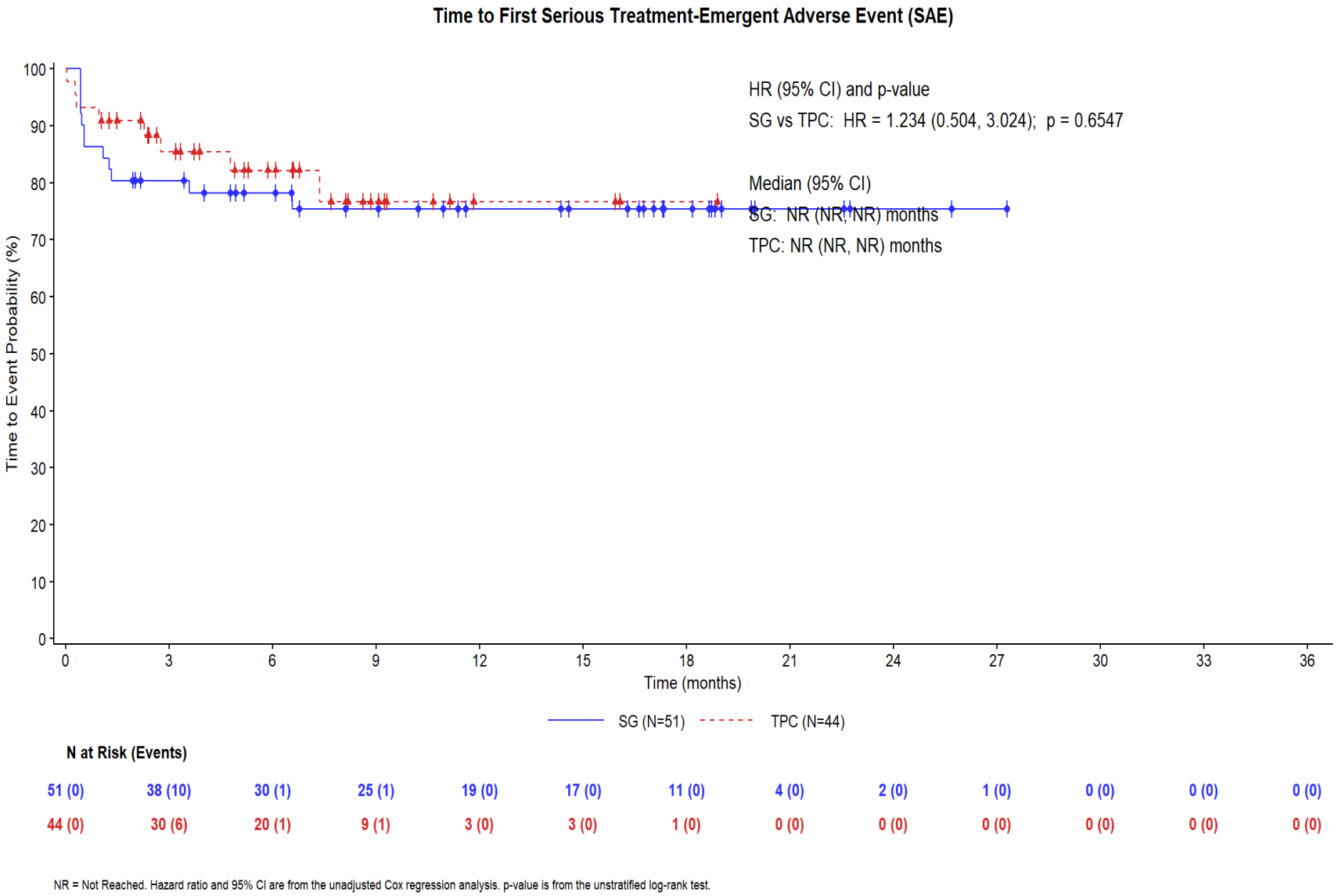
8. Safety - KM FIGURES – mSAF - Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

8.1. Figure 1.1.1: Kaplan Meier Plot of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



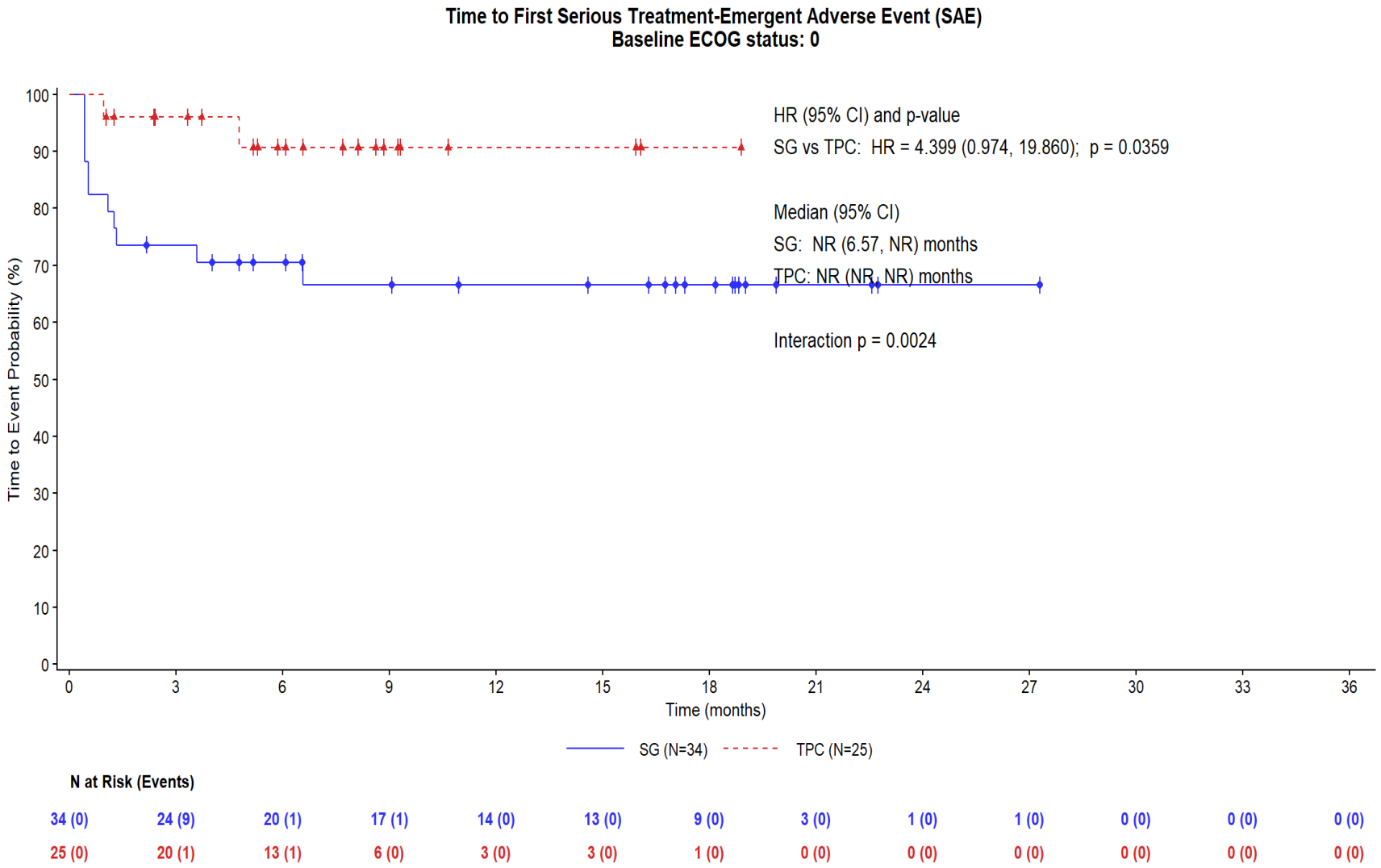
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.2. Figure 1.1.2: Kaplan Meier Plot of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



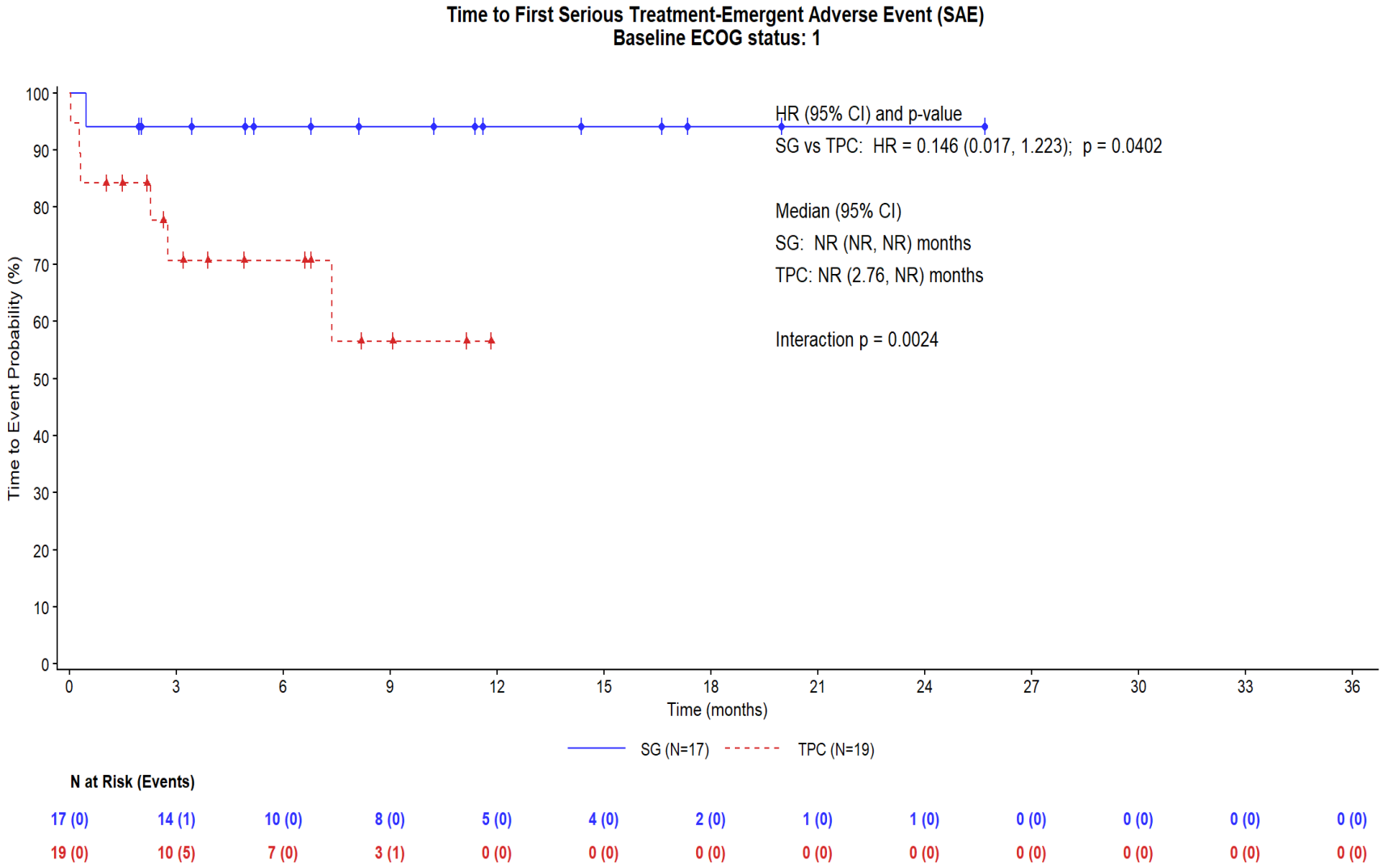
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.3. Figure 1.1.3: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Baseline ECOG status 0 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



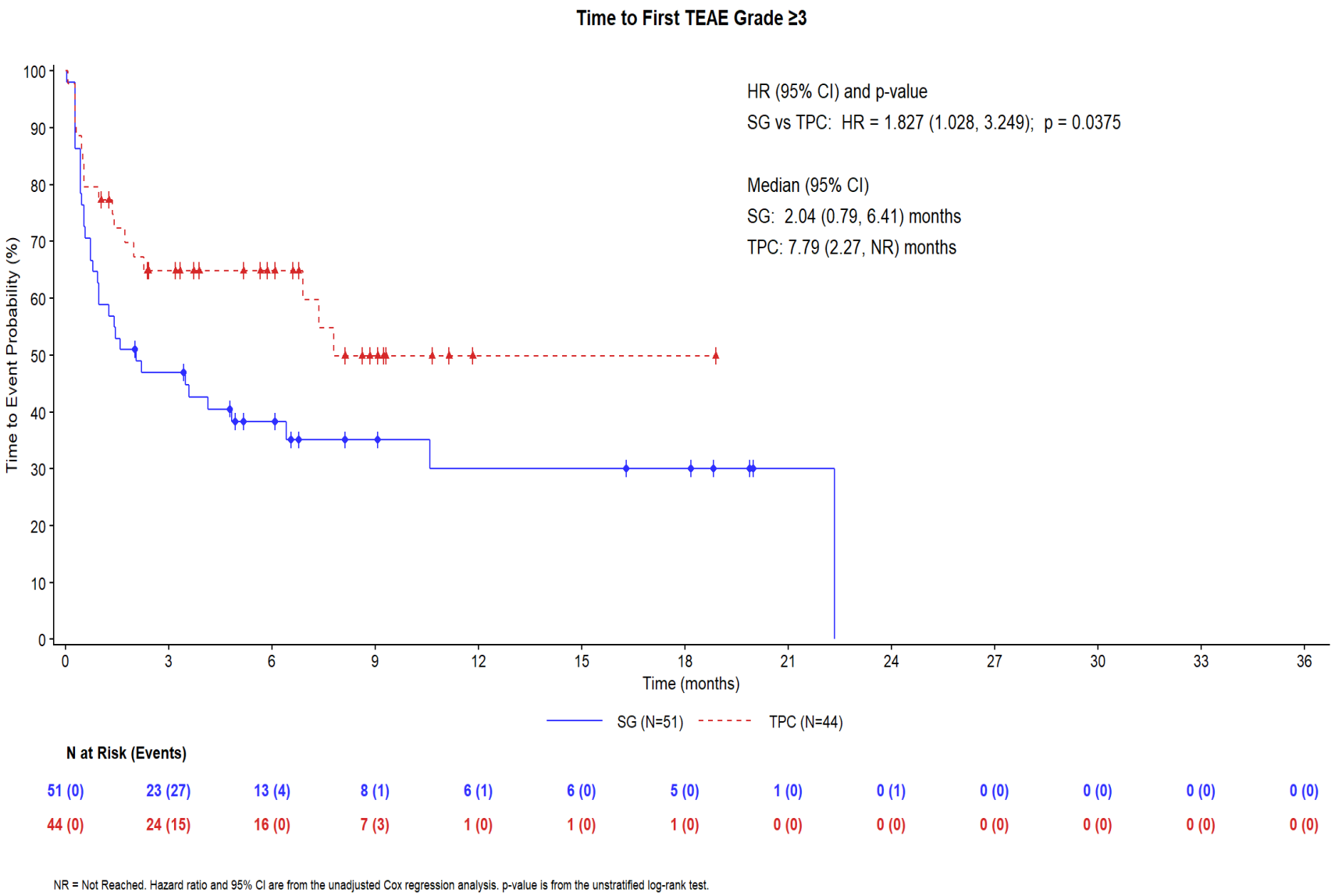
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.4. Figure 1.1.4: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Baseline ECOG status 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



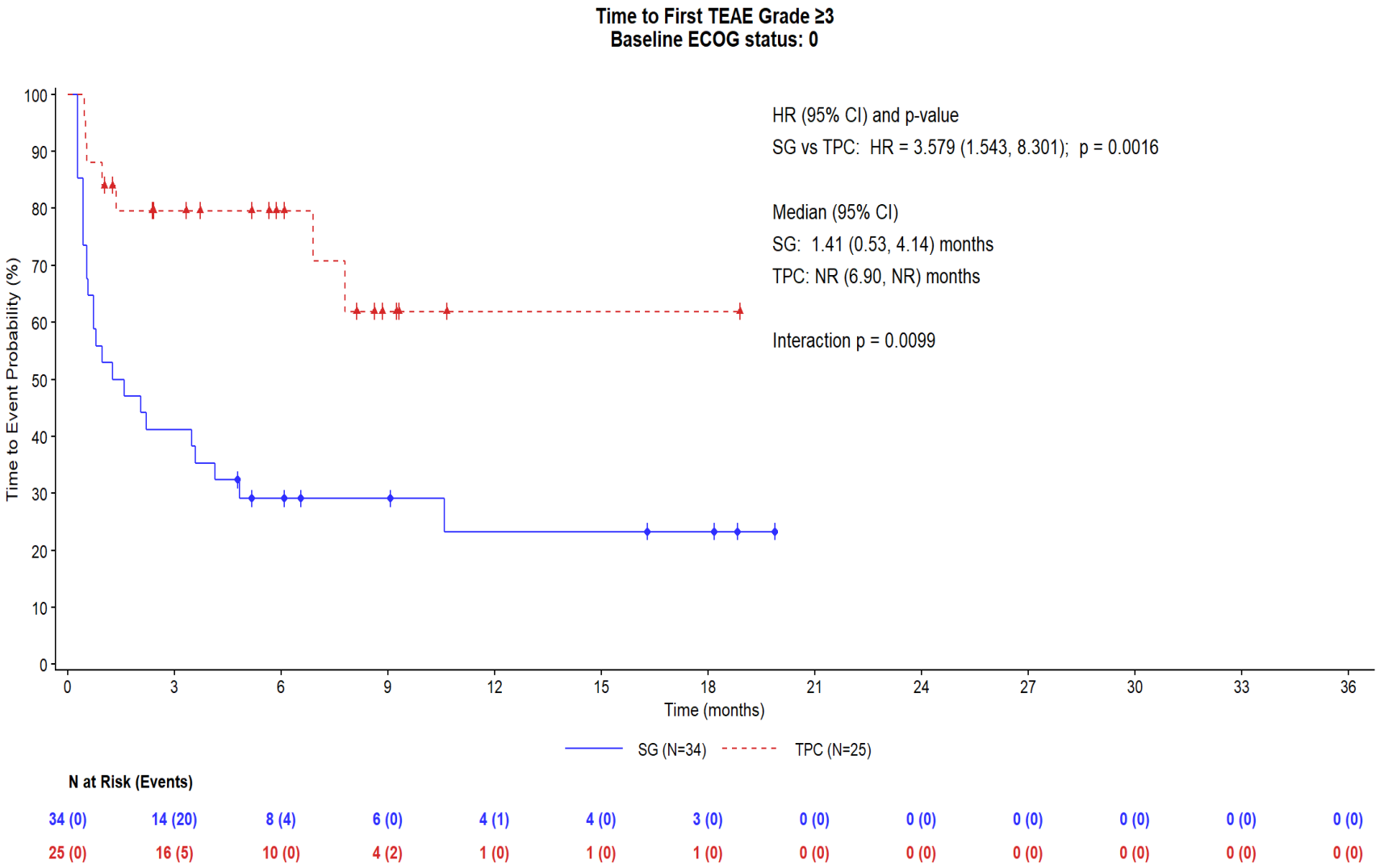
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.5. Figure 1.1.5: Kaplan Meier Plot of Time to First TEAE Grade 3 or higher — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



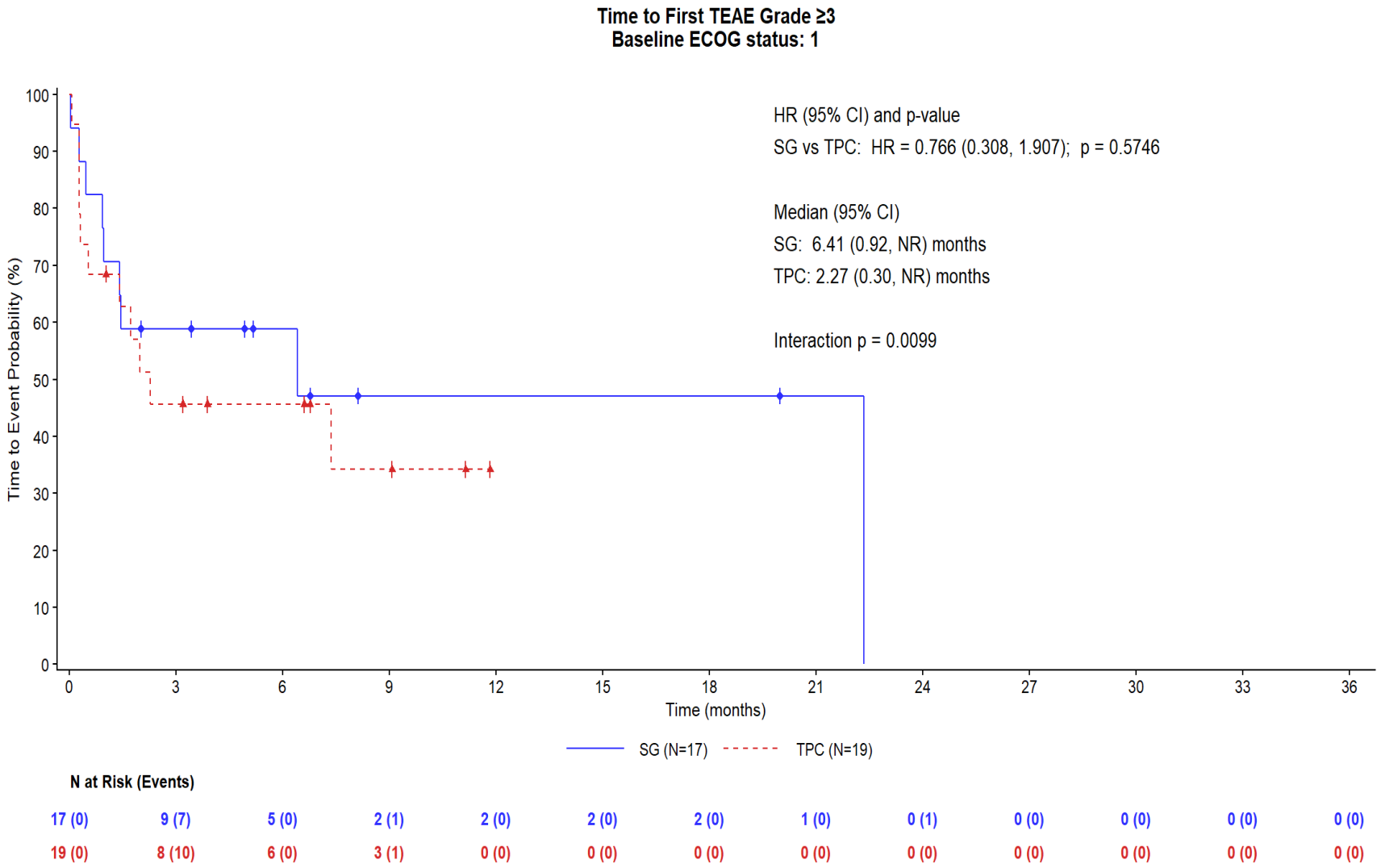
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.6. Figure 1.1.6: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Baseline ECOG status 0 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



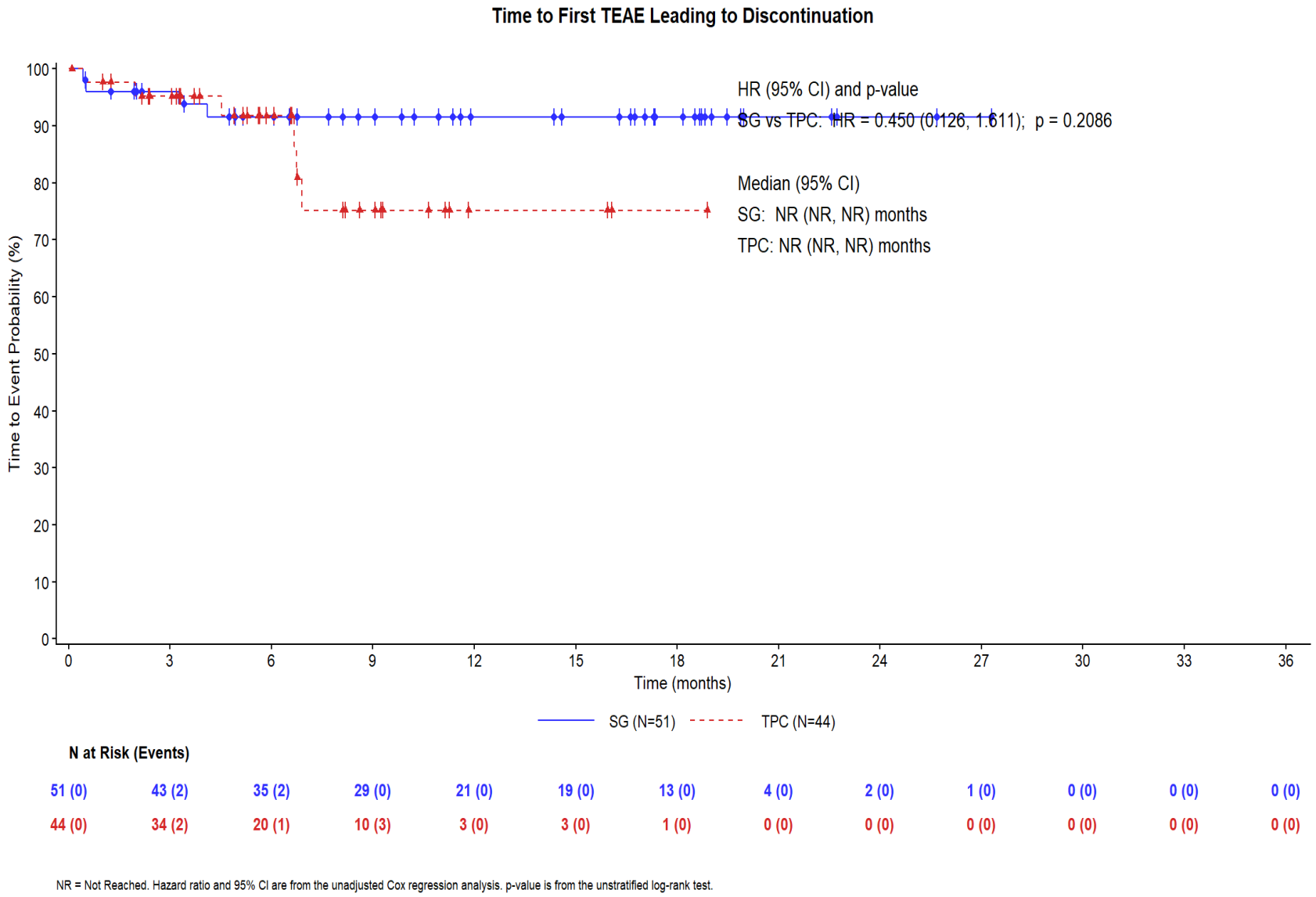
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.7. Figure 1.1.7: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Baseline ECOG status 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



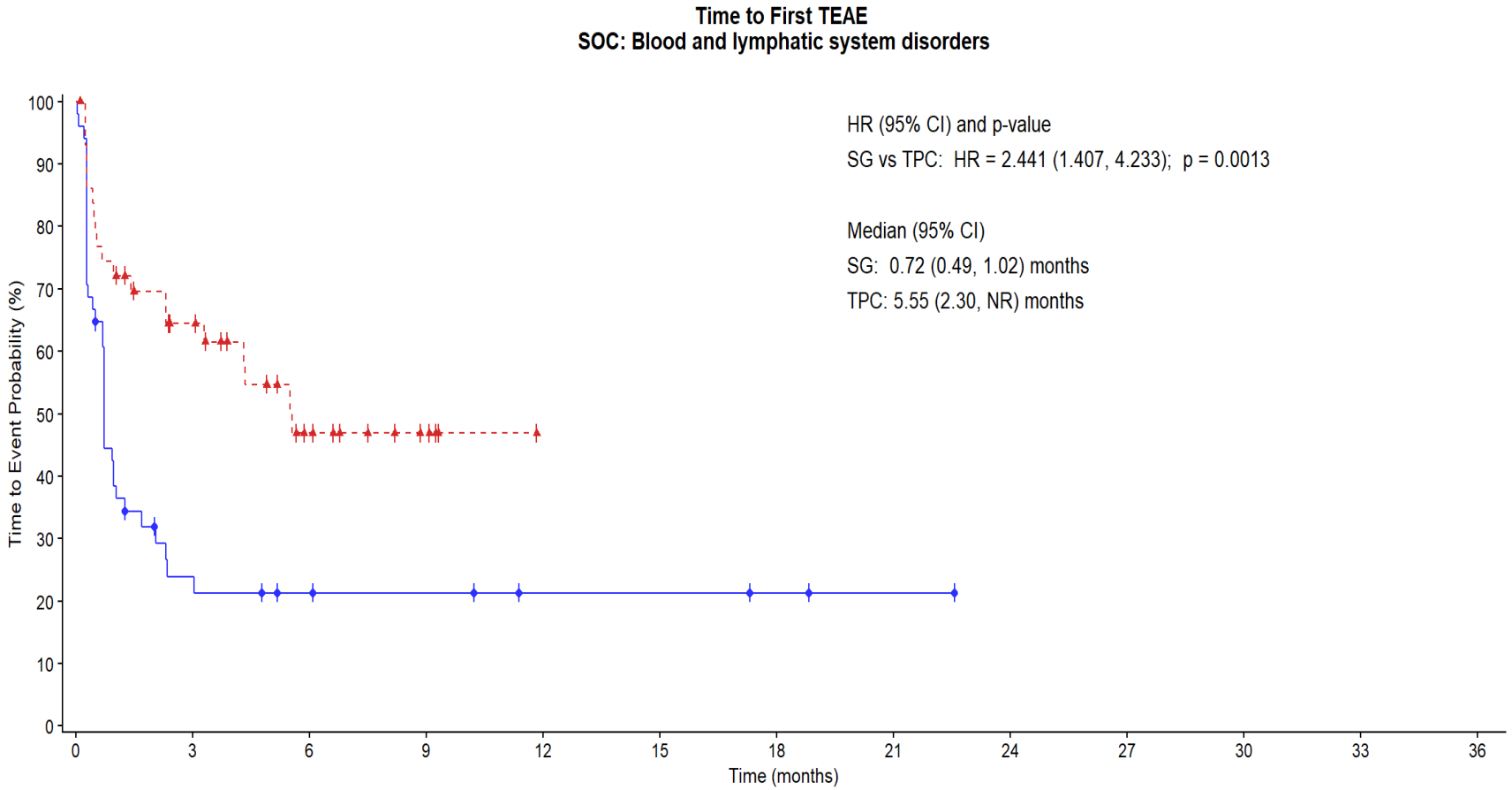
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.8. Figure 1.1.8: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



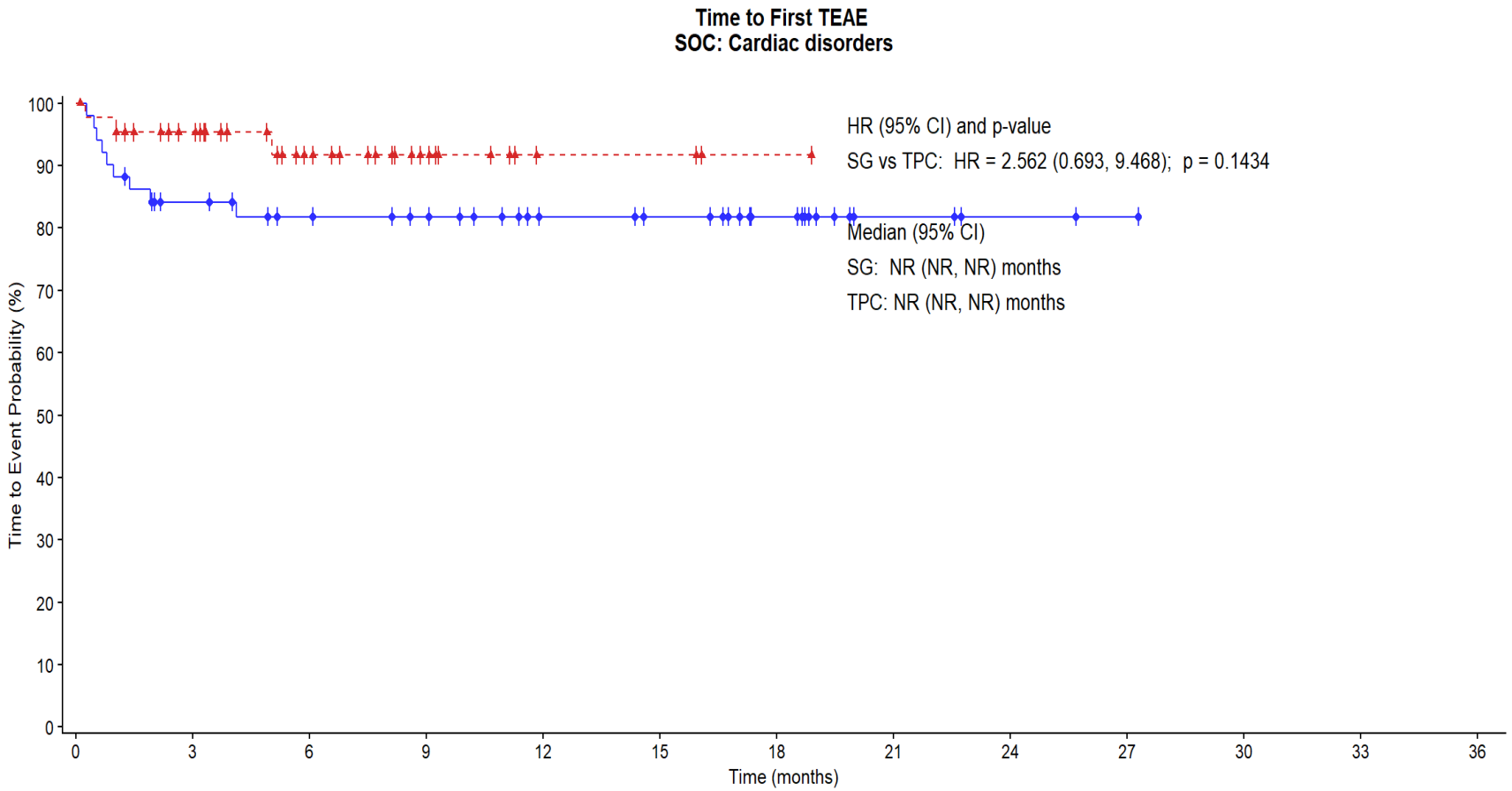
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.9. Figure 1.1.9: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



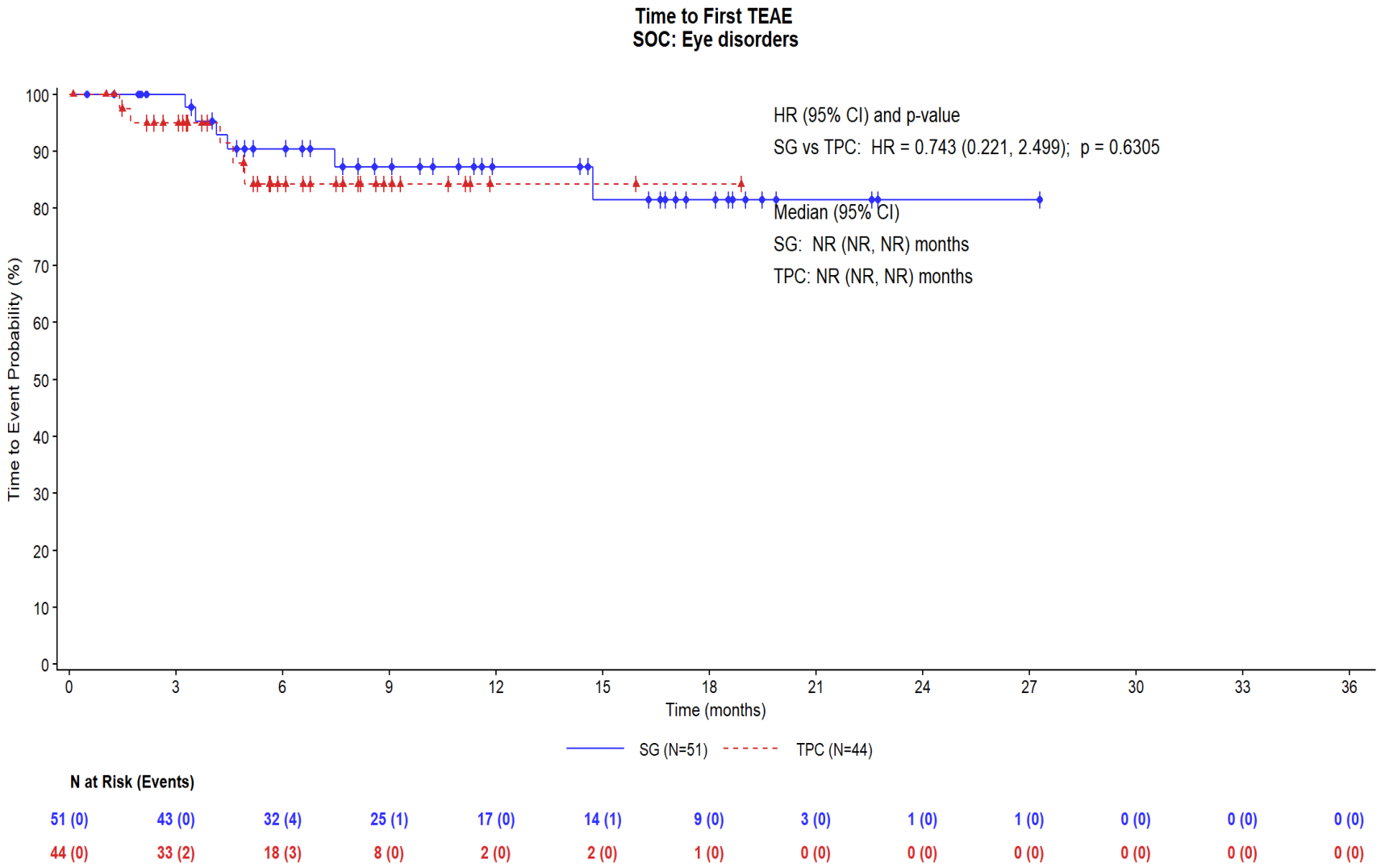
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.10. Figure 1.1.10: Kaplan Meier Plot of Time to First TEAE by SOC Cardiac disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



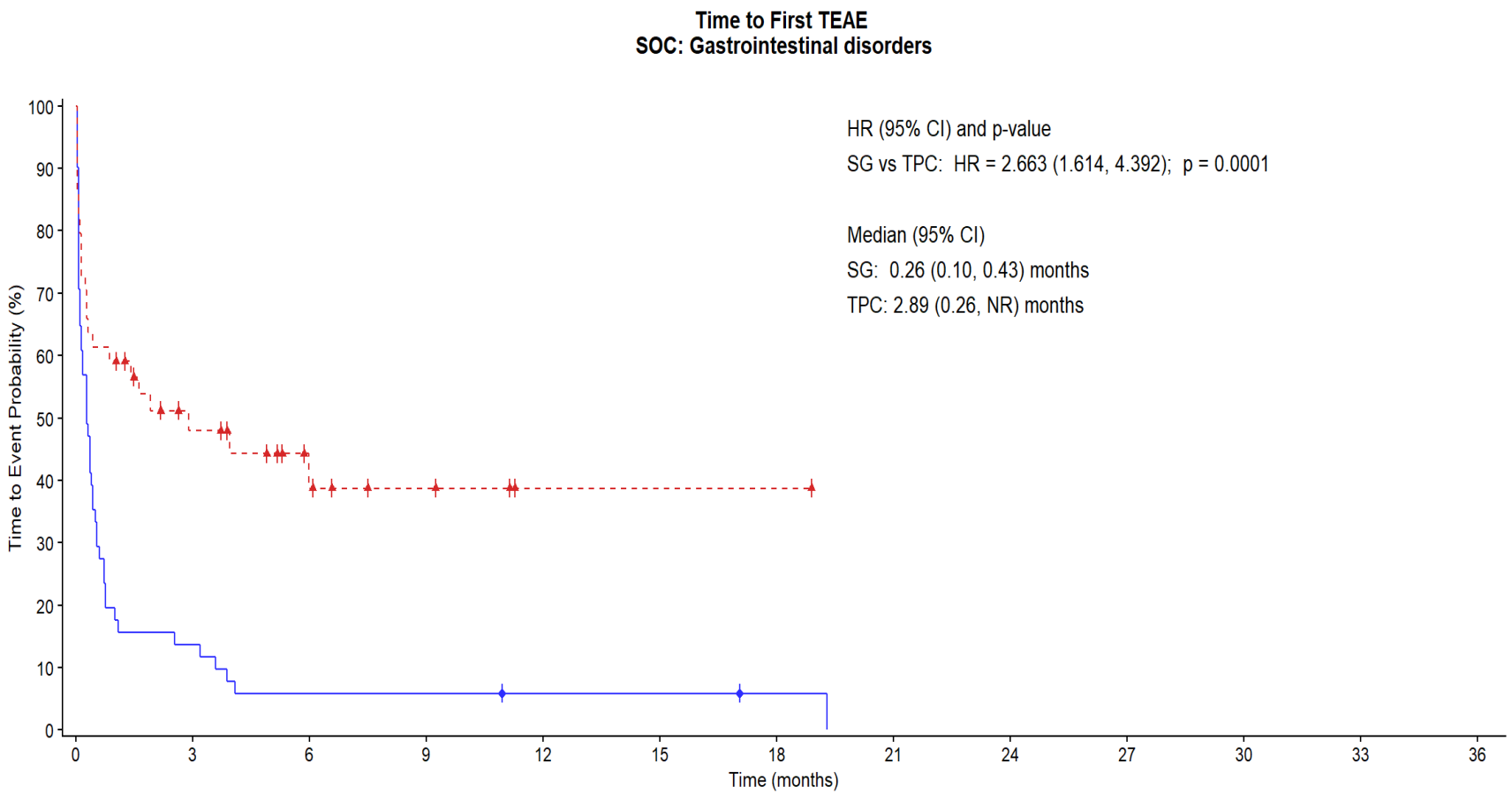
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.11. Figure 1.1.11: Kaplan Meier Plot of Time to First TEAE by SOC Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



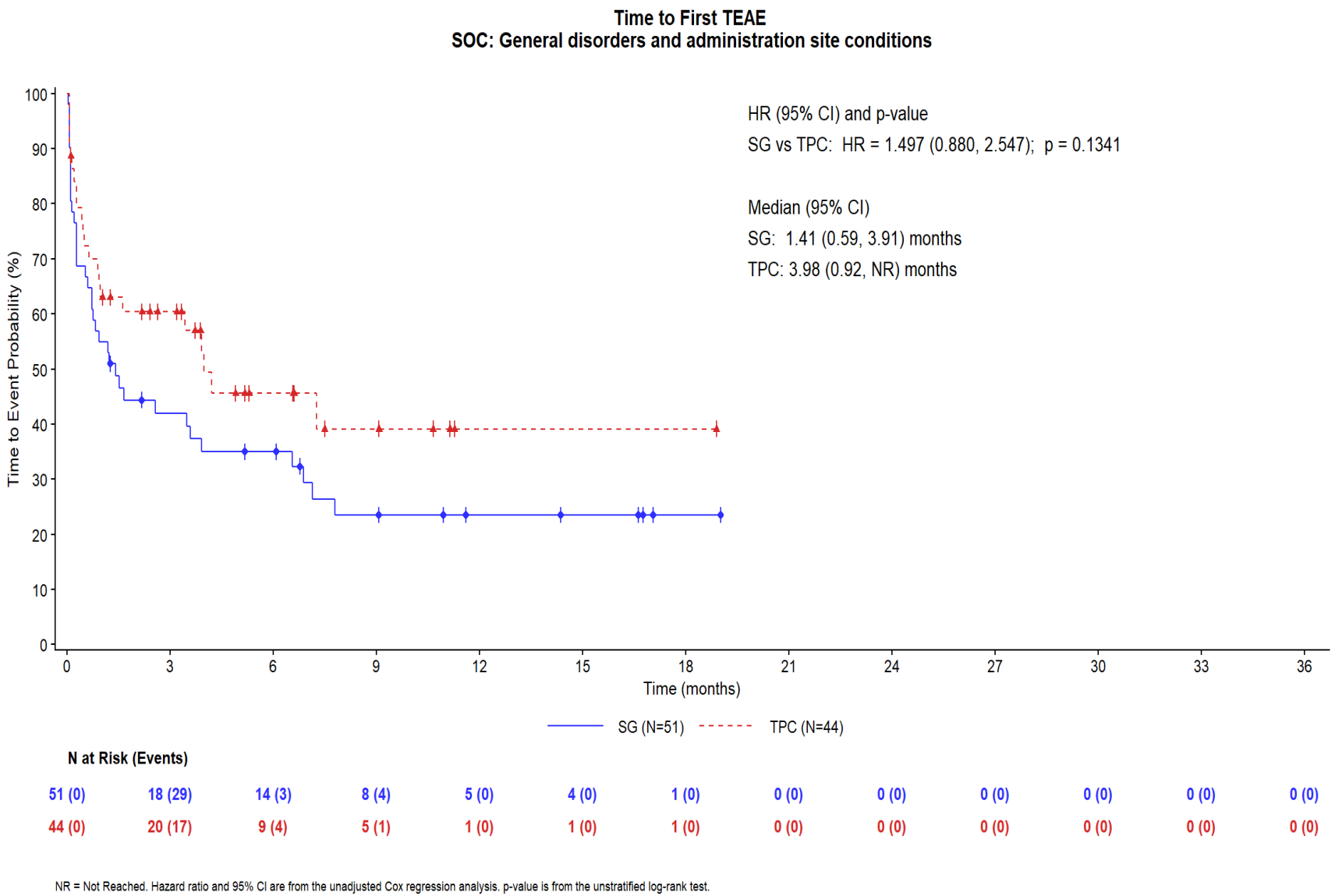
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.12. Figure 1.1.12: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



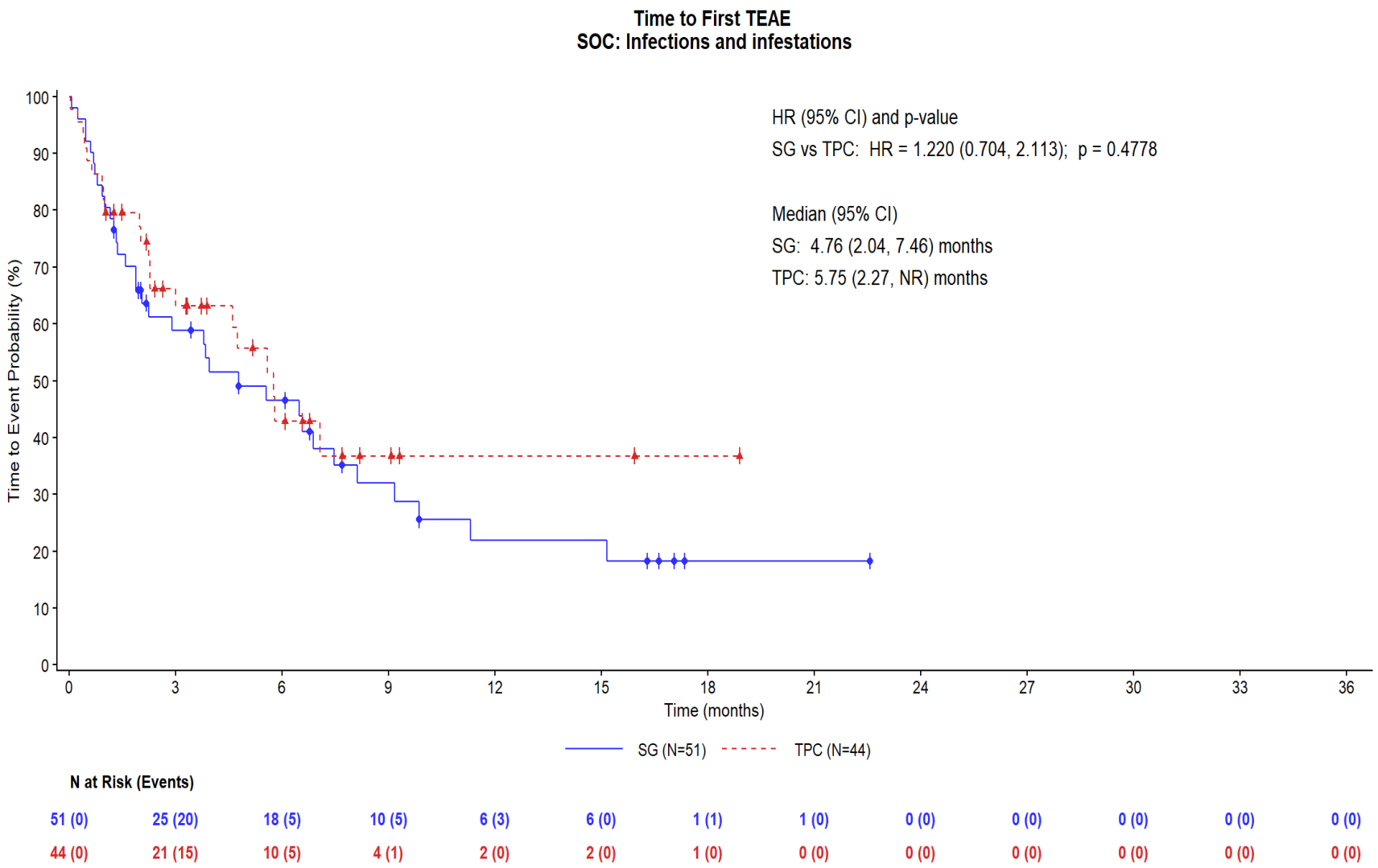
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.13. Figure 1.1.13: Kaplan Meier Plot of Time to First TEAE by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



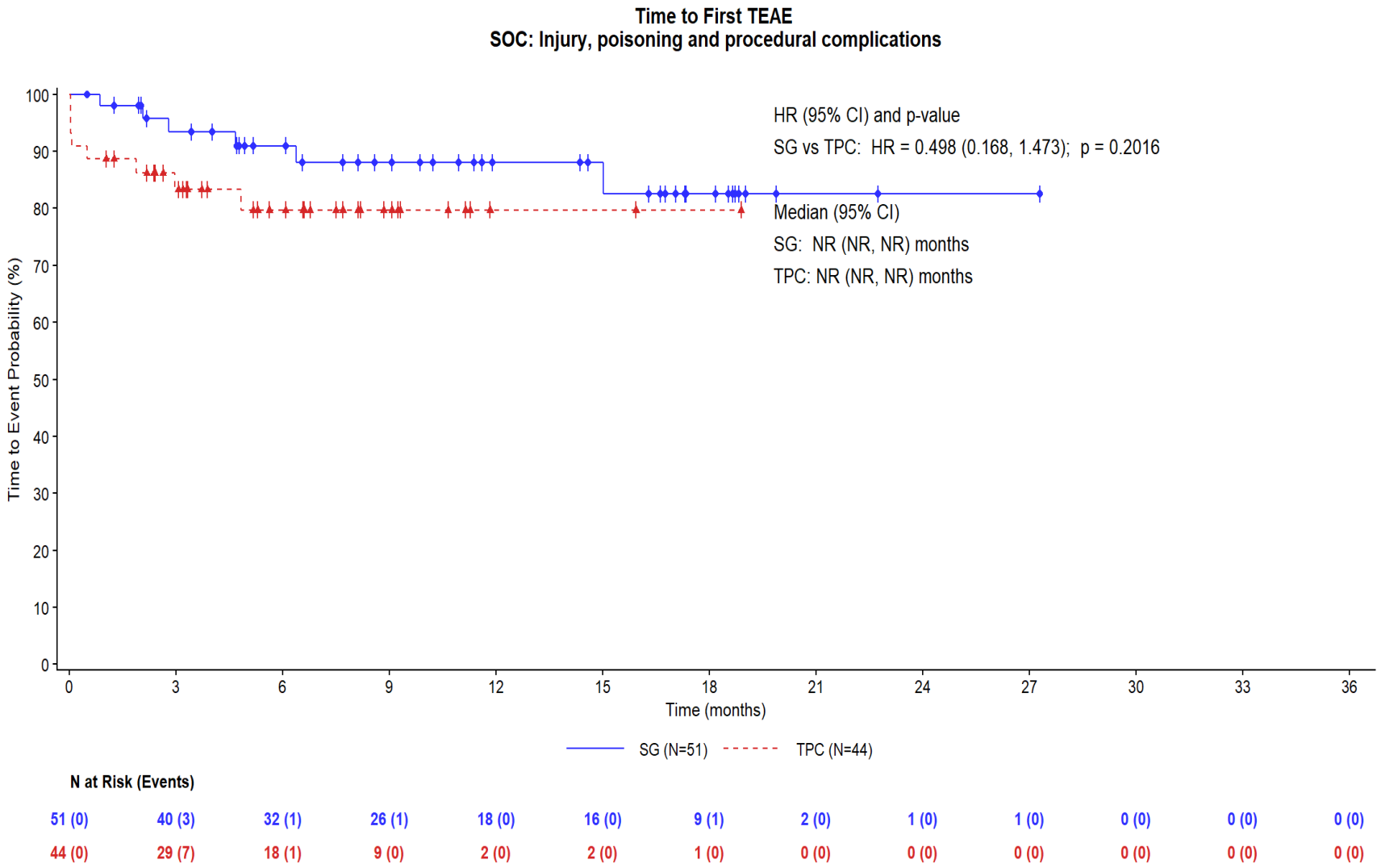
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.14. Figure 1.1.14: Kaplan Meier Plot of Time to First TEAE by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



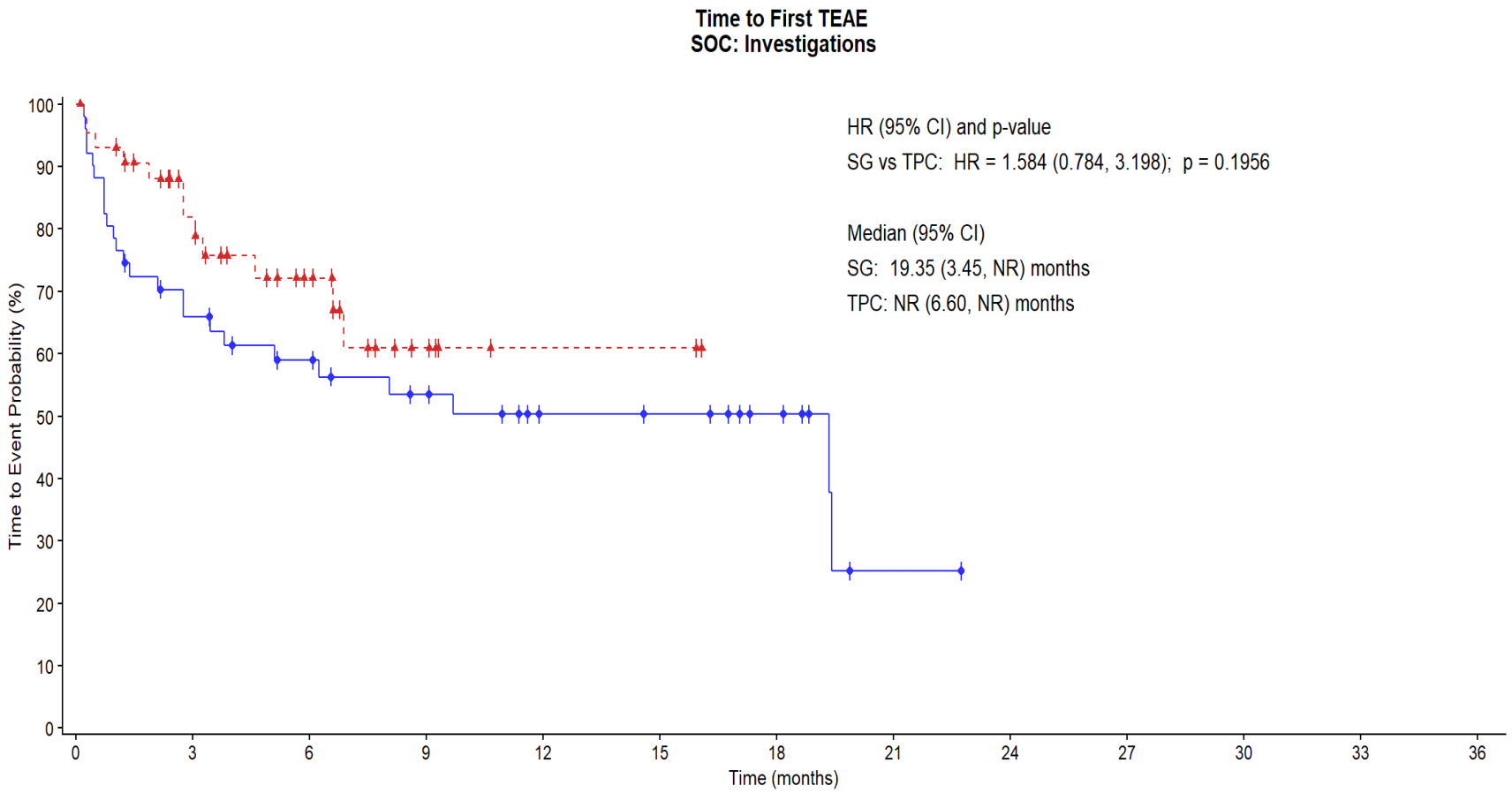
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.15. Figure 1.1.15: Kaplan Meier Plot of Time to First TEAE by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



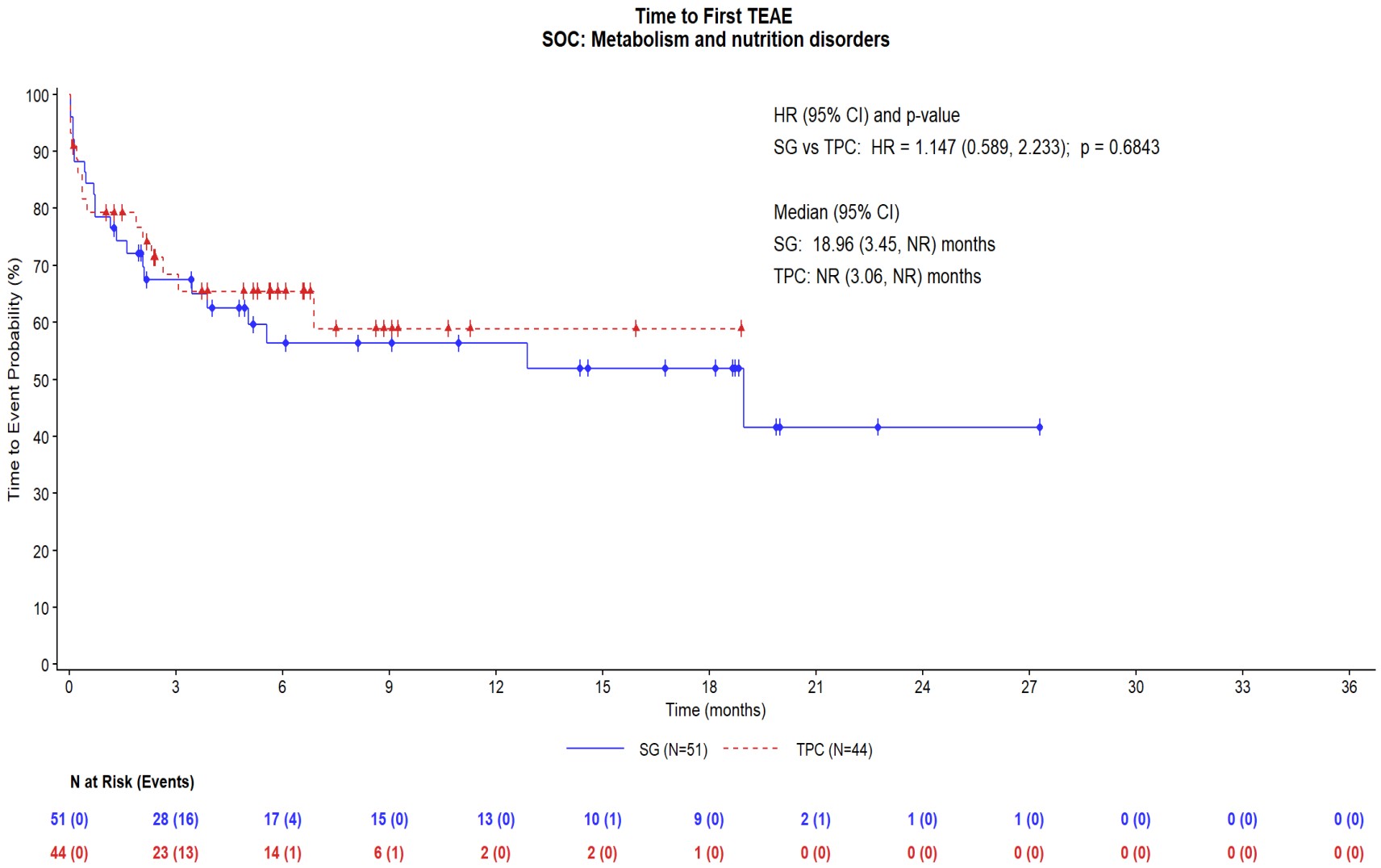
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.16. Figure 1.1.16: Kaplan Meier Plot of Time to First TEAE by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



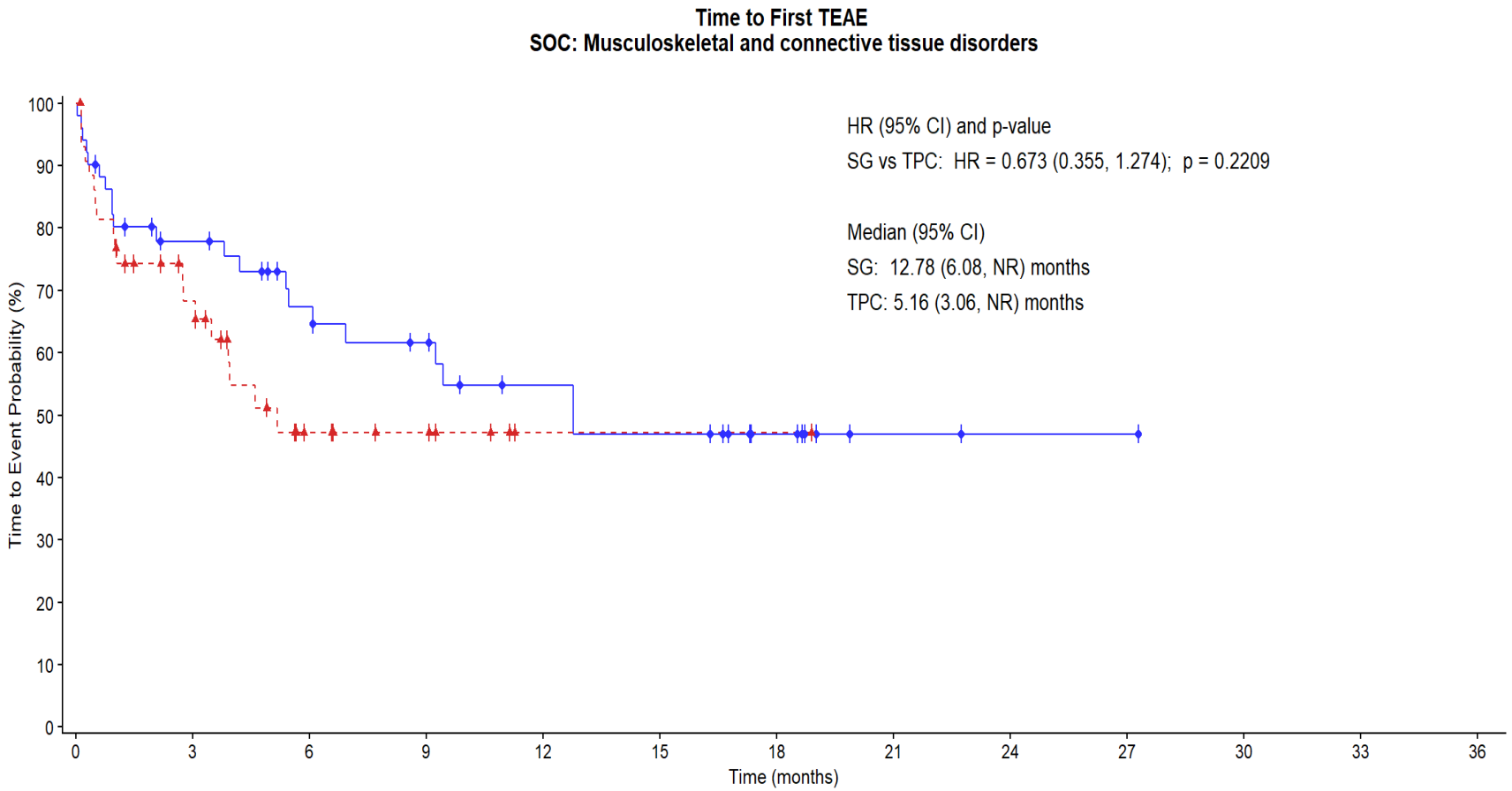
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.17. Figure 1.1.17: Kaplan Meier Plot of Time to First TEAE by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



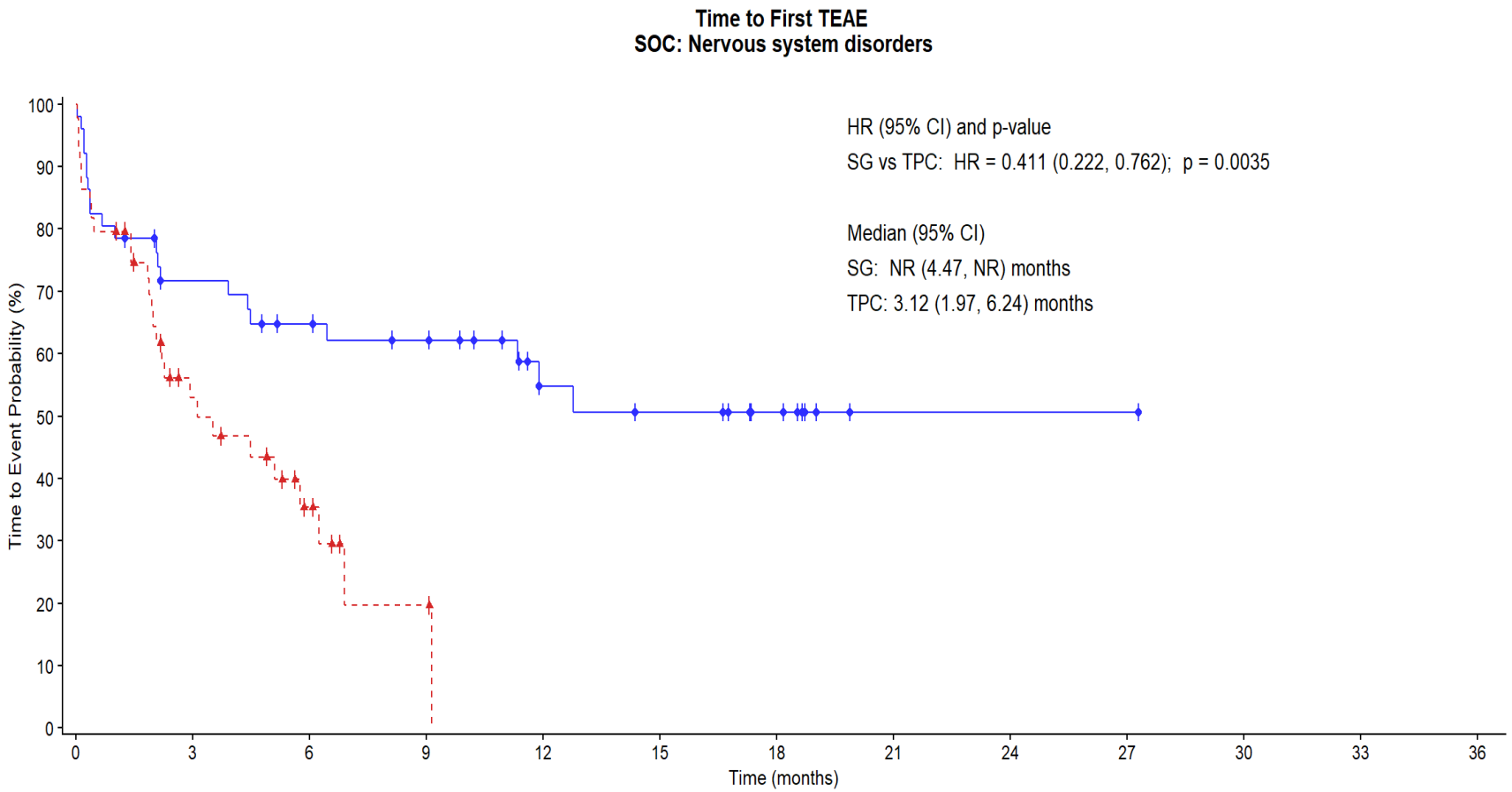
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.18. Figure 1.1.18: Kaplan Meier Plot of Time to First TEAE by SOC Musculoskeletal and connective tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



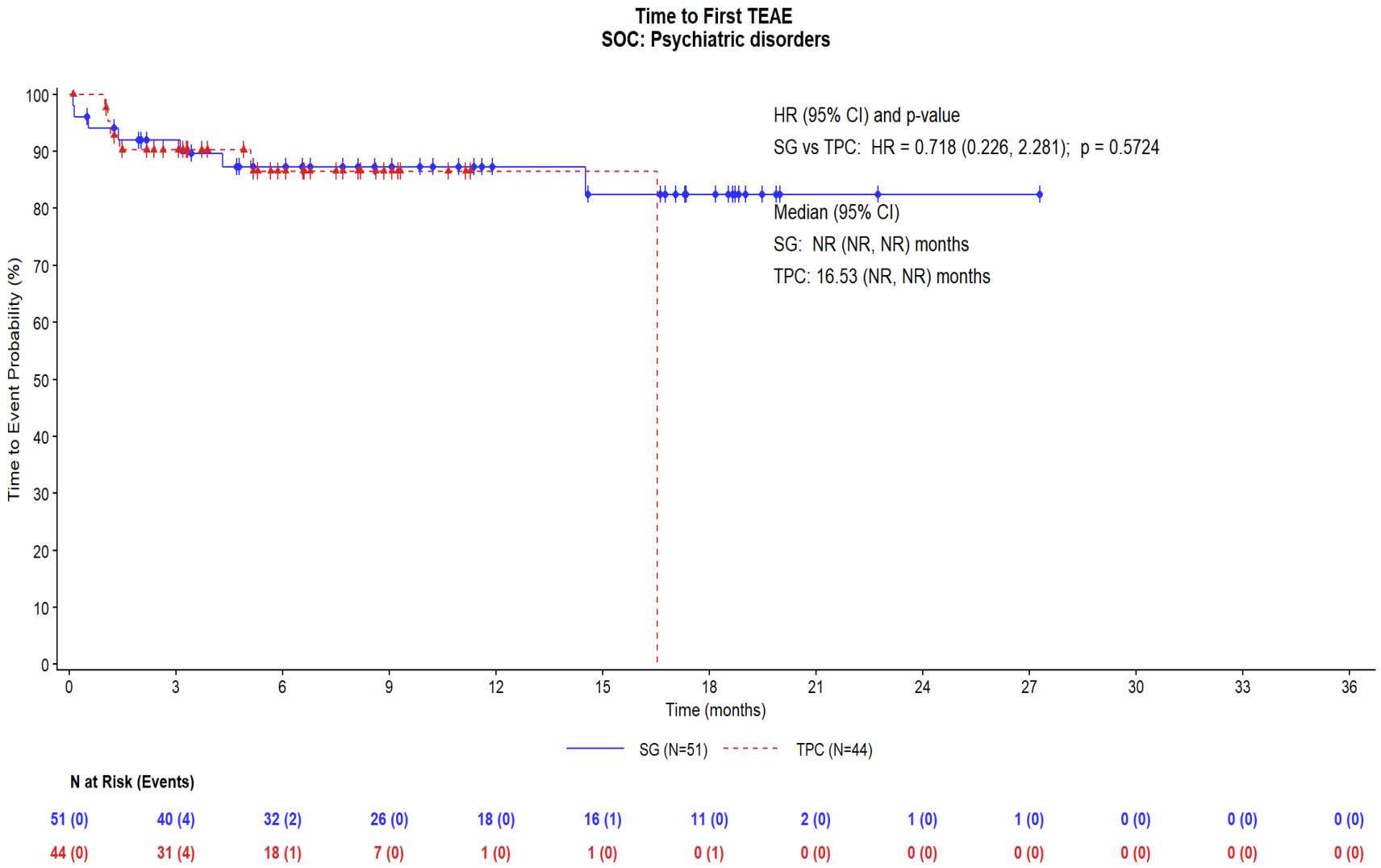
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.19. Figure 1.1.19: Kaplan Meier Plot of Time to First TEAE by SOC Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



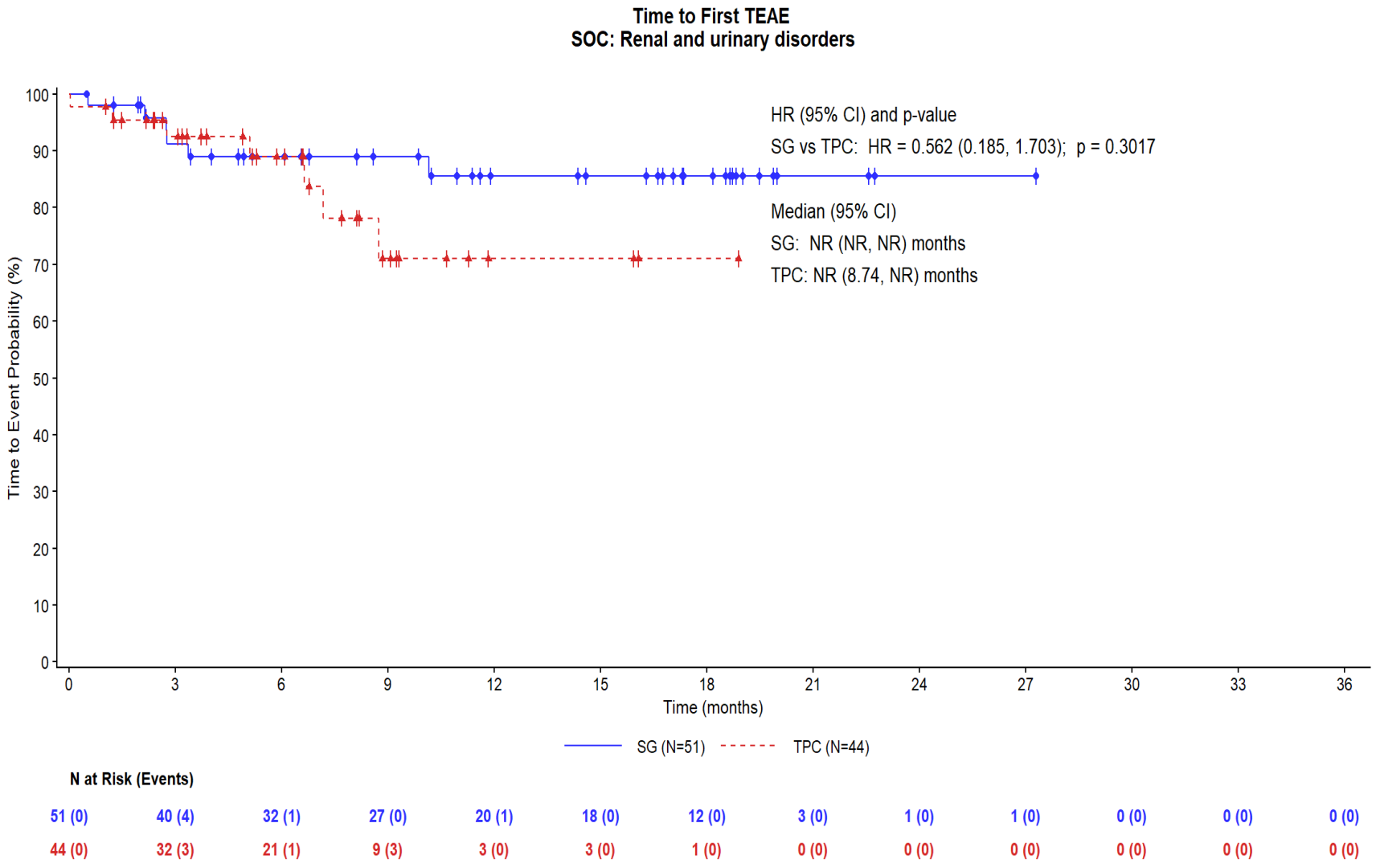
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.20. Figure 1.1.20: Kaplan Meier Plot of Time to First TEAE by SOC Psychiatric disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



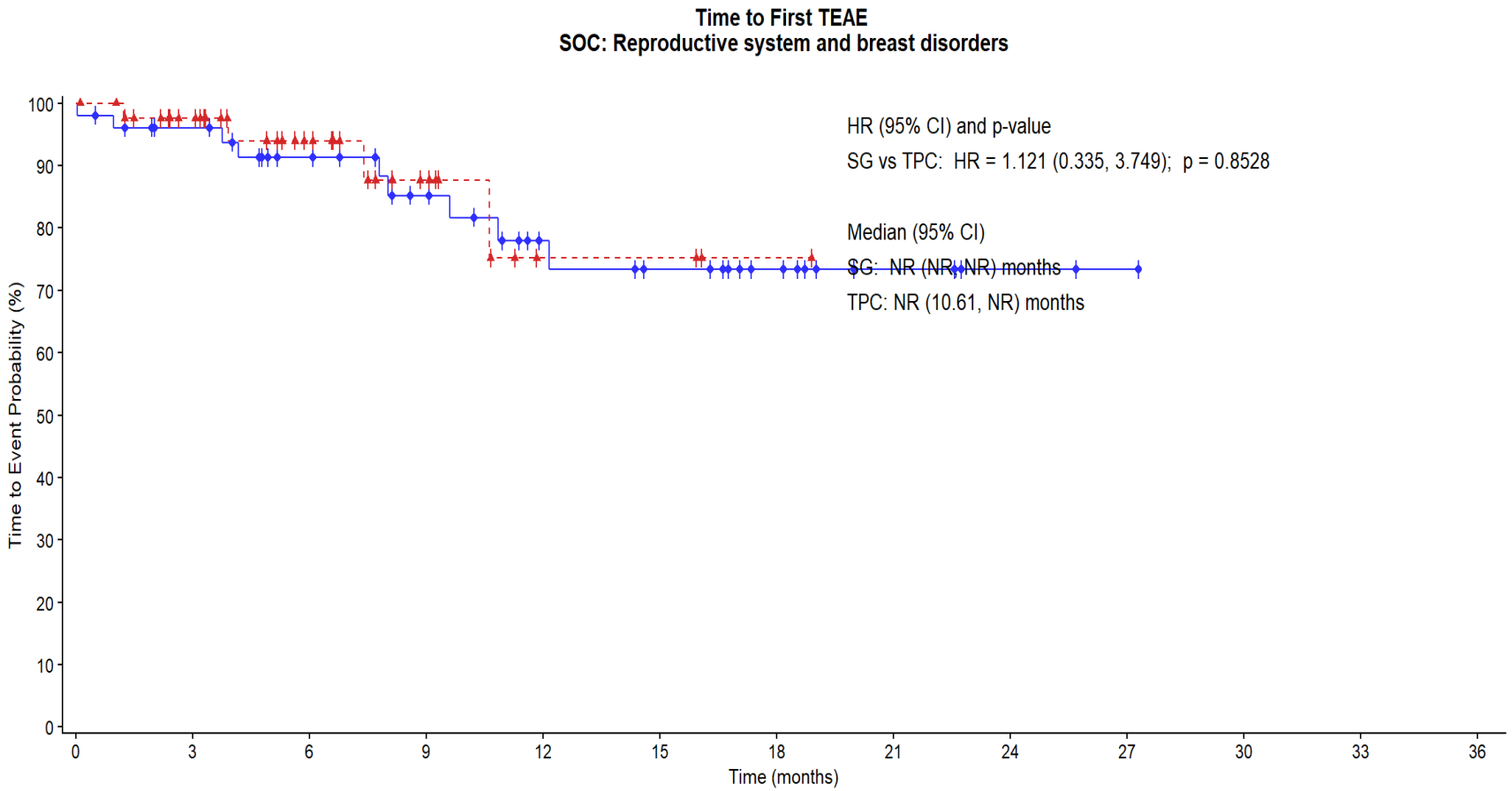
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.21. Figure 1.1.21: Kaplan Meier Plot of Time to First TEAE by SOC Renal and urinary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



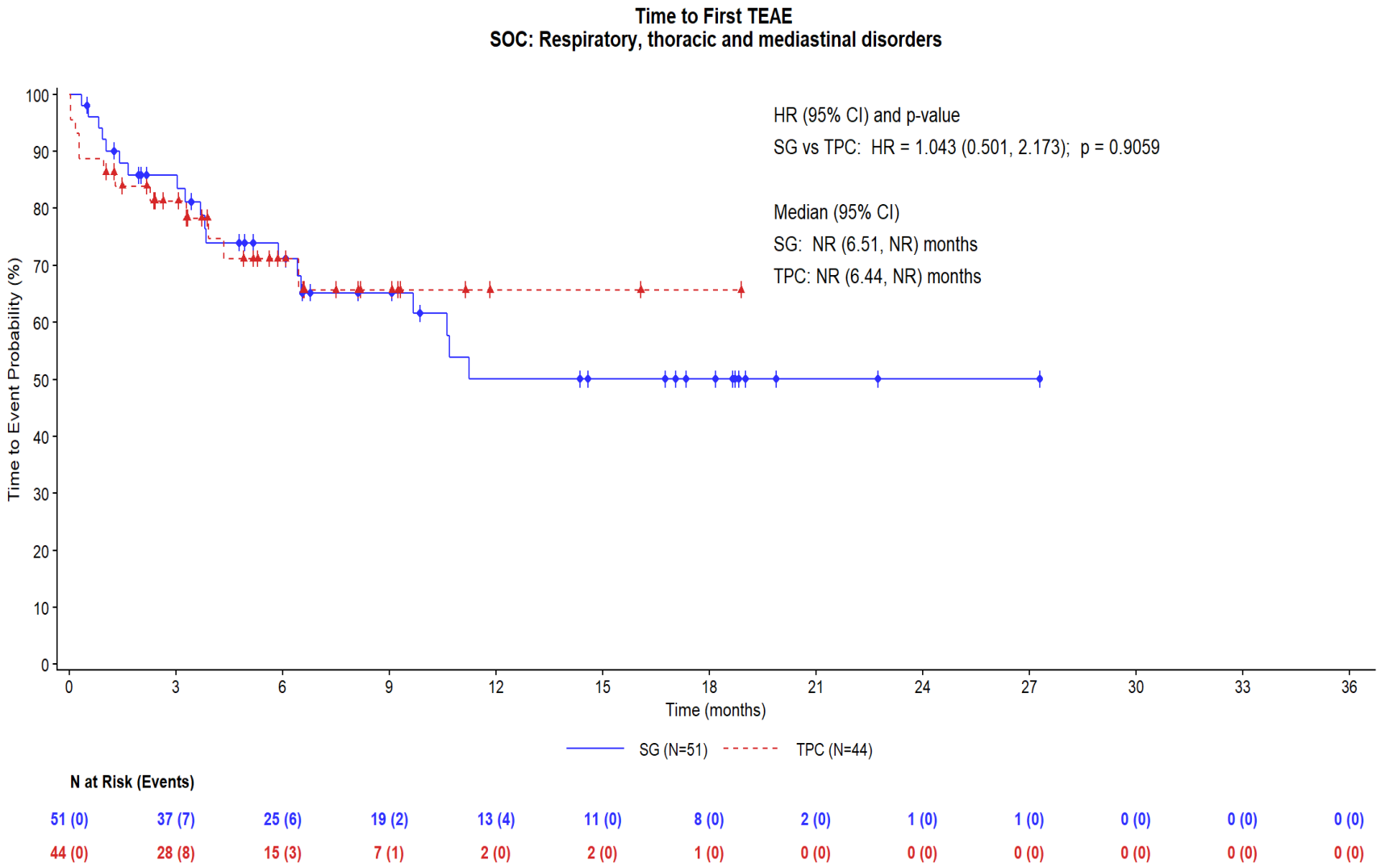
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.22. Figure 1.1.22: Kaplan Meier Plot of Time to First TEAE by SOC Reproductive system and breast disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



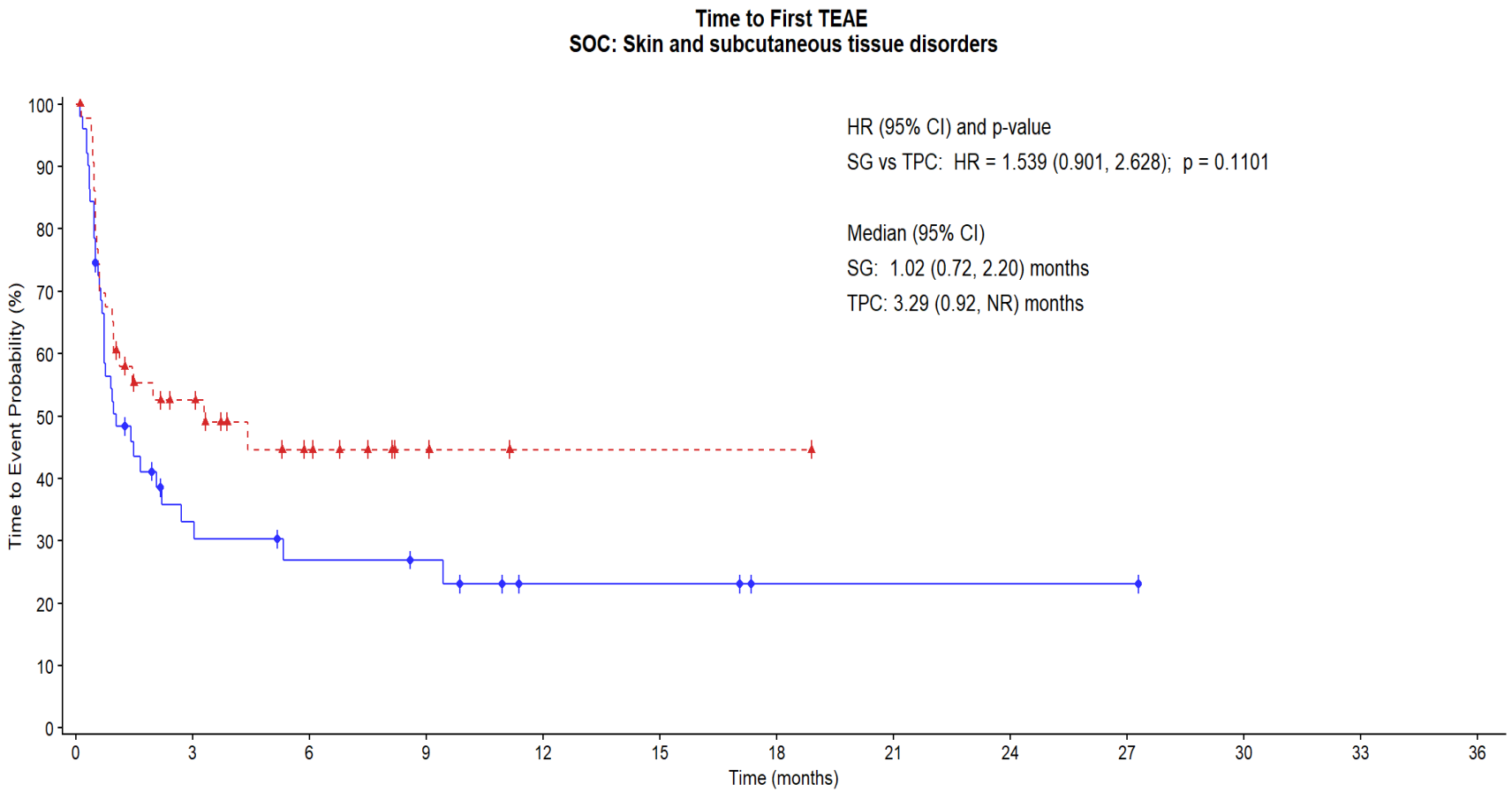
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.23. Figure 1.1.23: Kaplan Meier Plot of Time to First TEAE by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



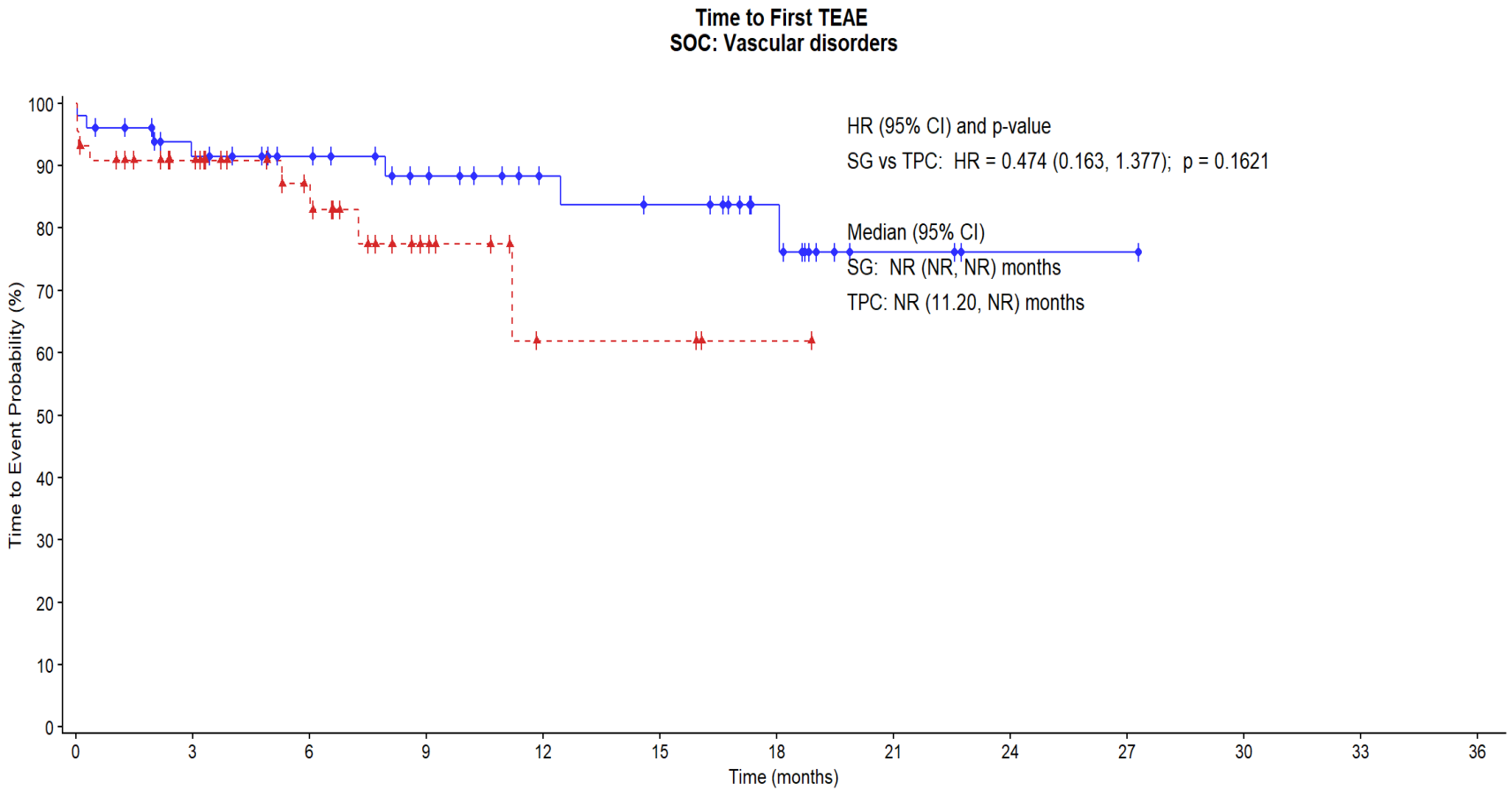
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.24. Figure 1.1.24: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



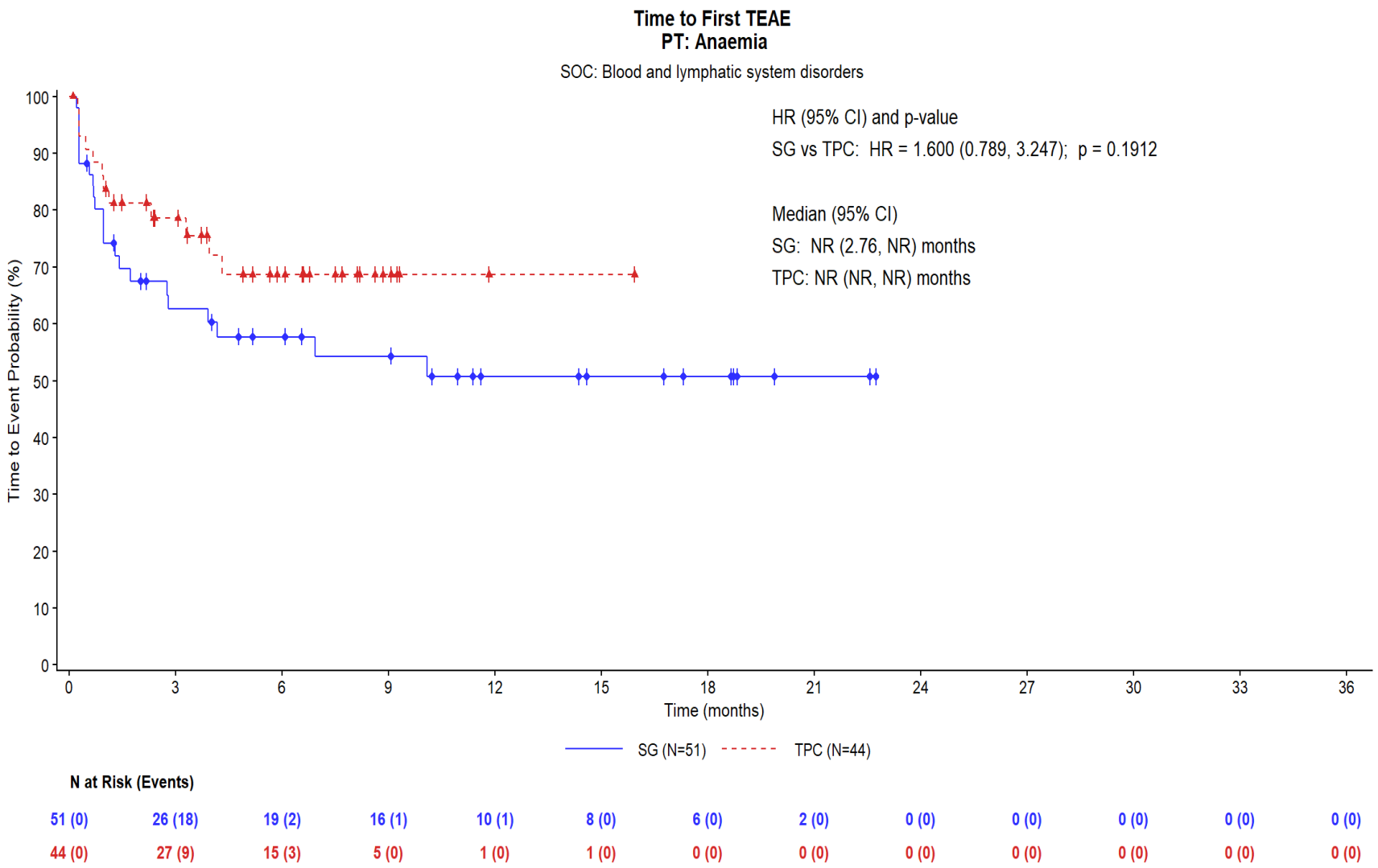
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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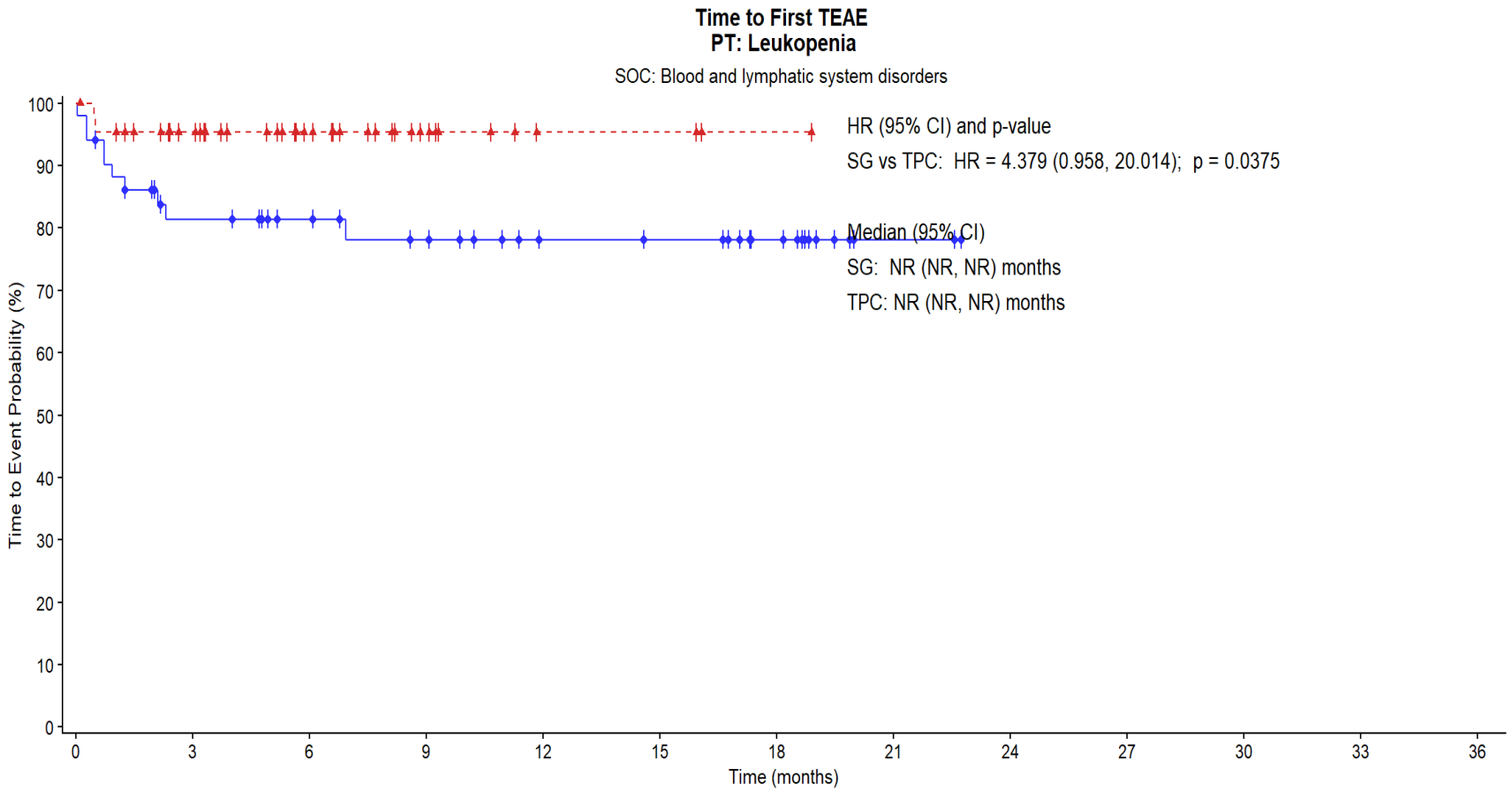
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.26. Figure 1.1.26: Kaplan Meier Plot of Time to First TEAE by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



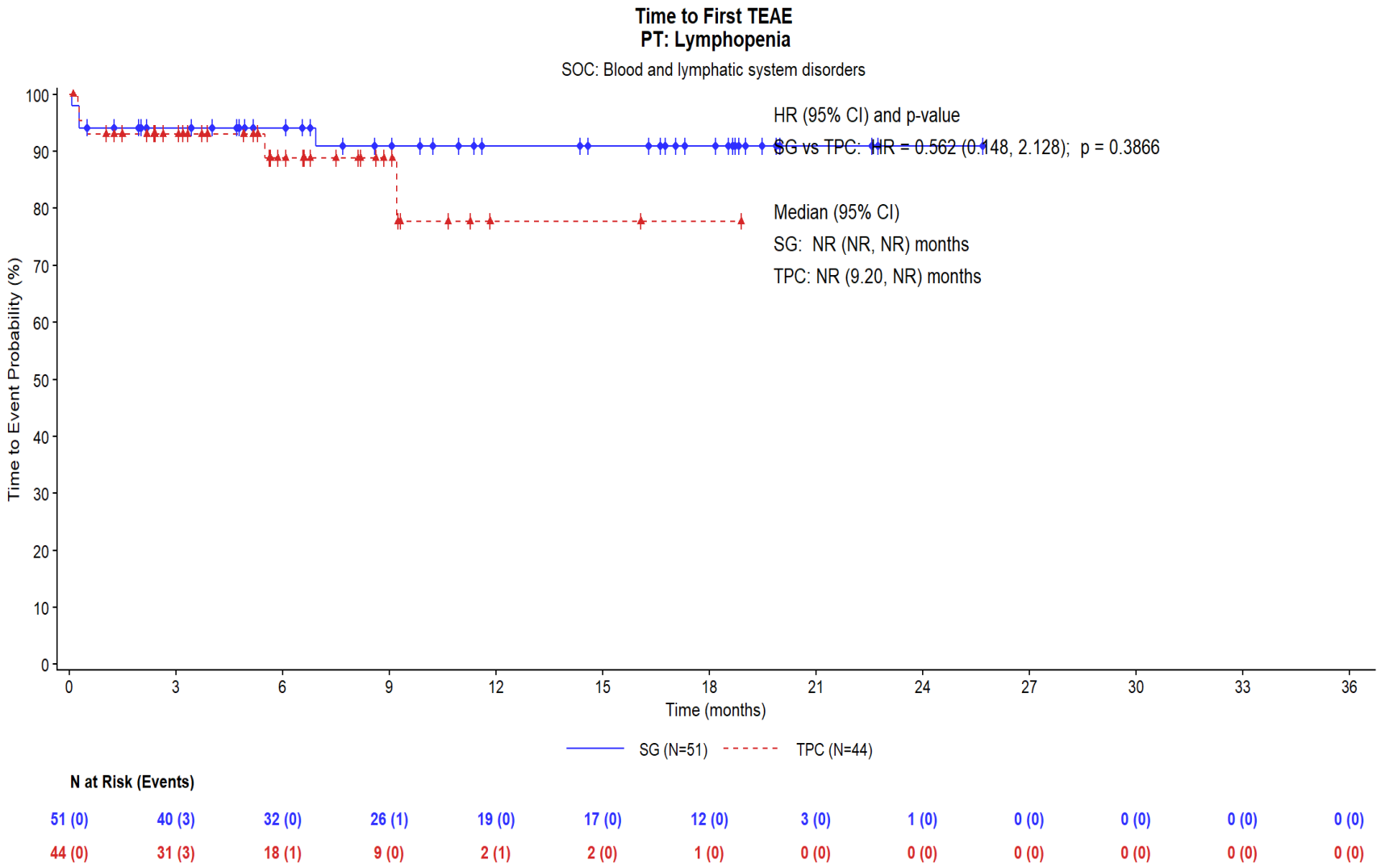
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8.27. Figure 1.1.27: Kaplan Meier Plot of Time to First TEAE by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



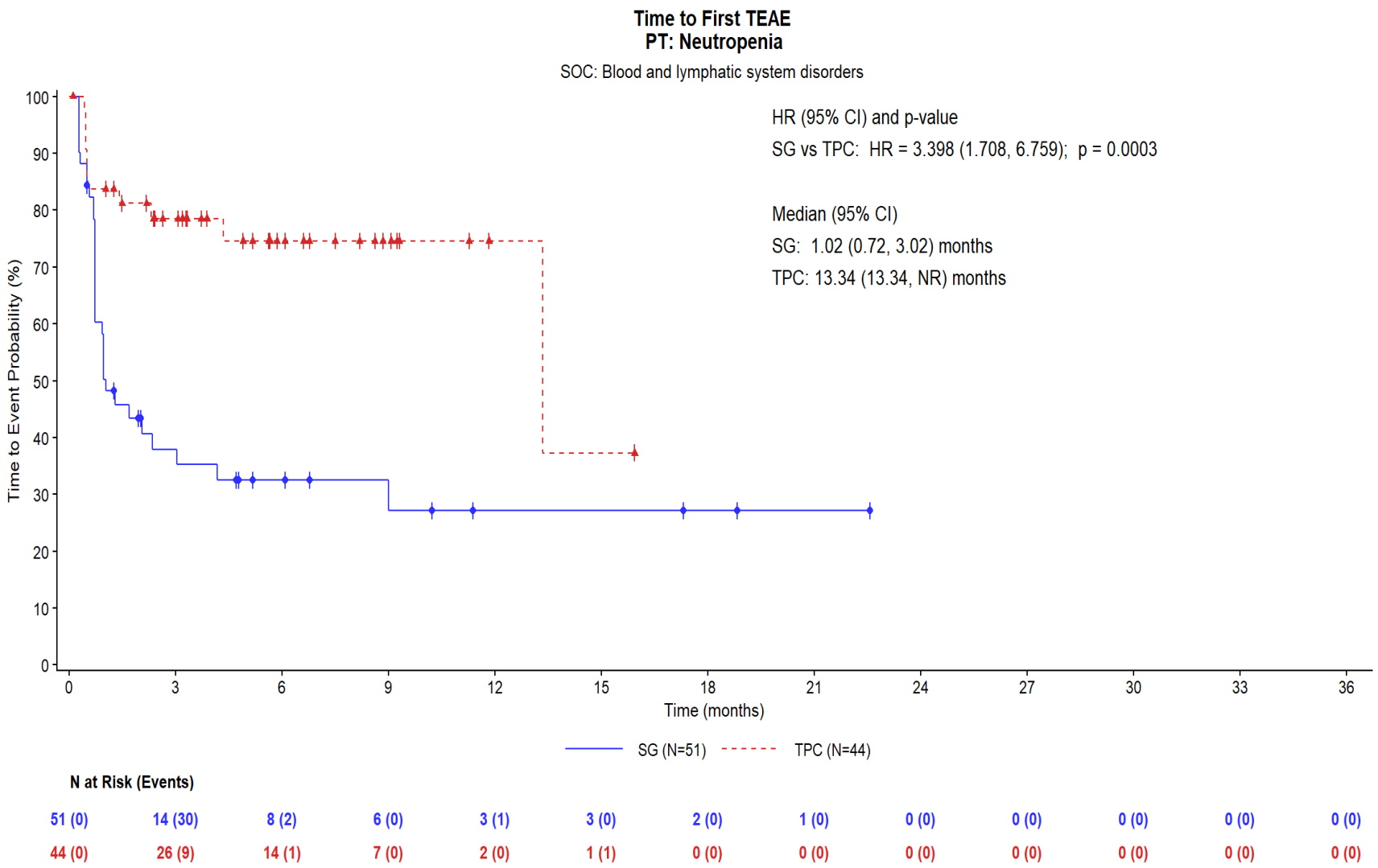
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8.28. Figure 1.1.28: Kaplan Meier Plot of Time to First TEAE by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



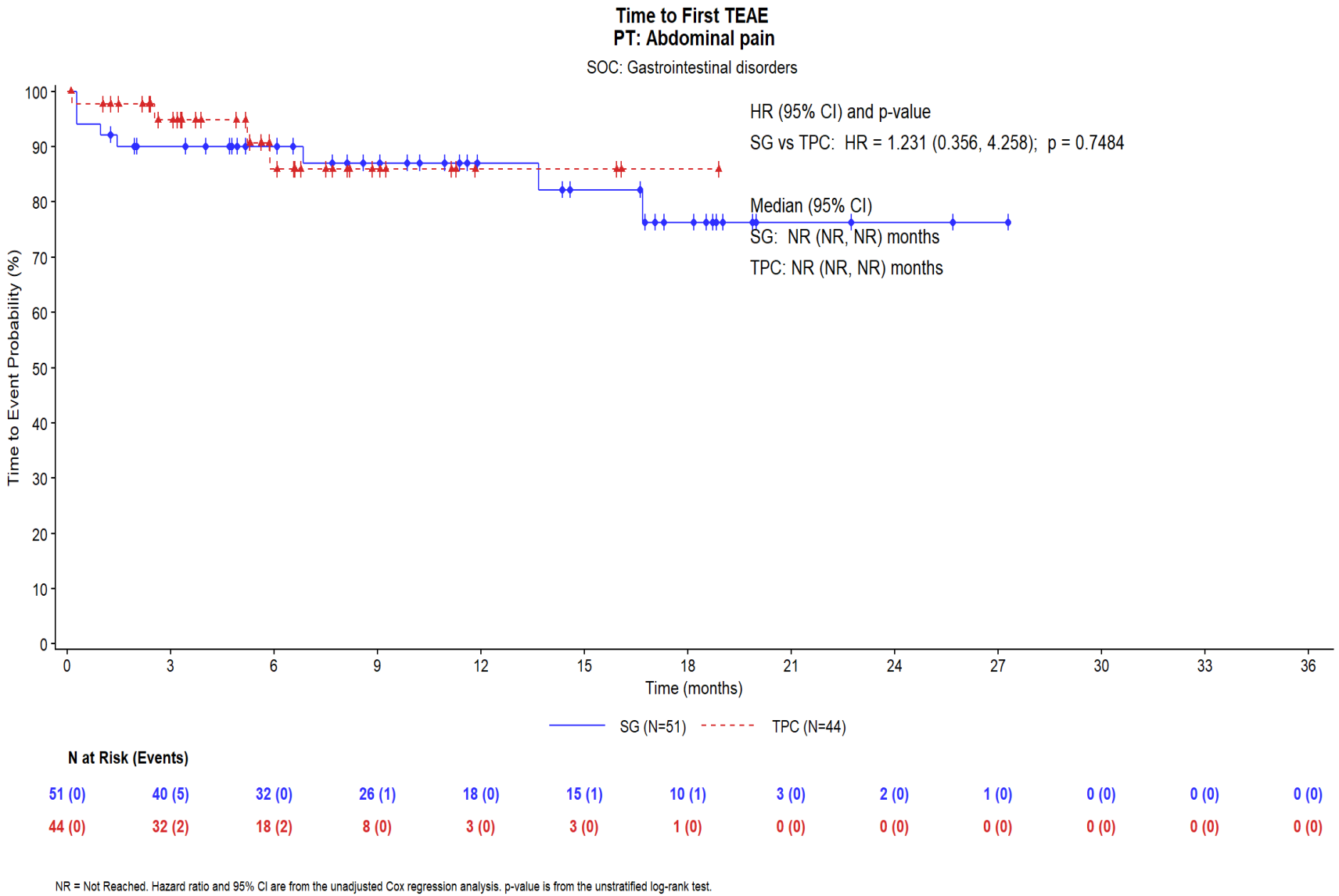
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.29. Figure 1.1.29: Kaplan Meier Plot of Time to First TEAE by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



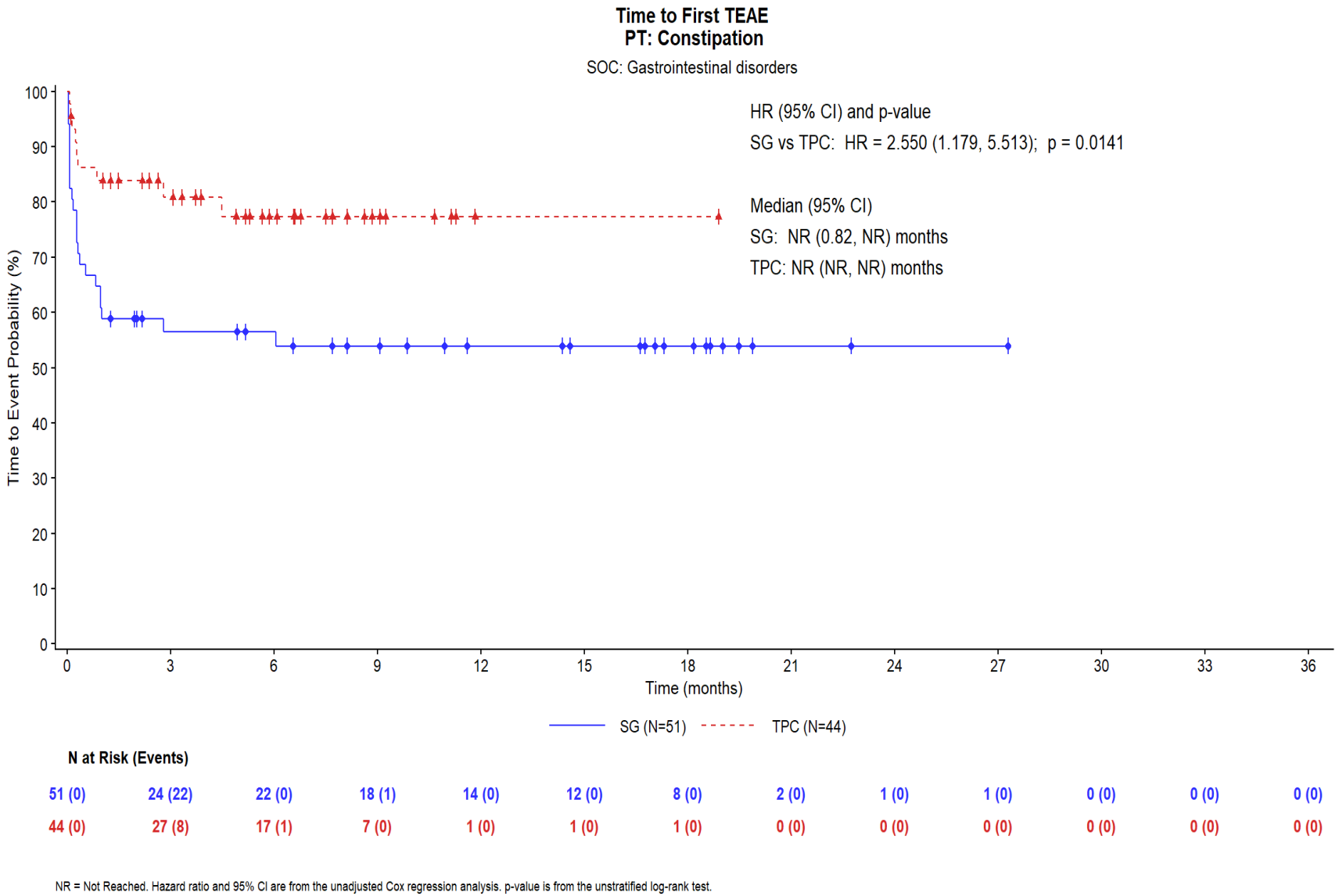
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.30. Figure 1.1.30: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



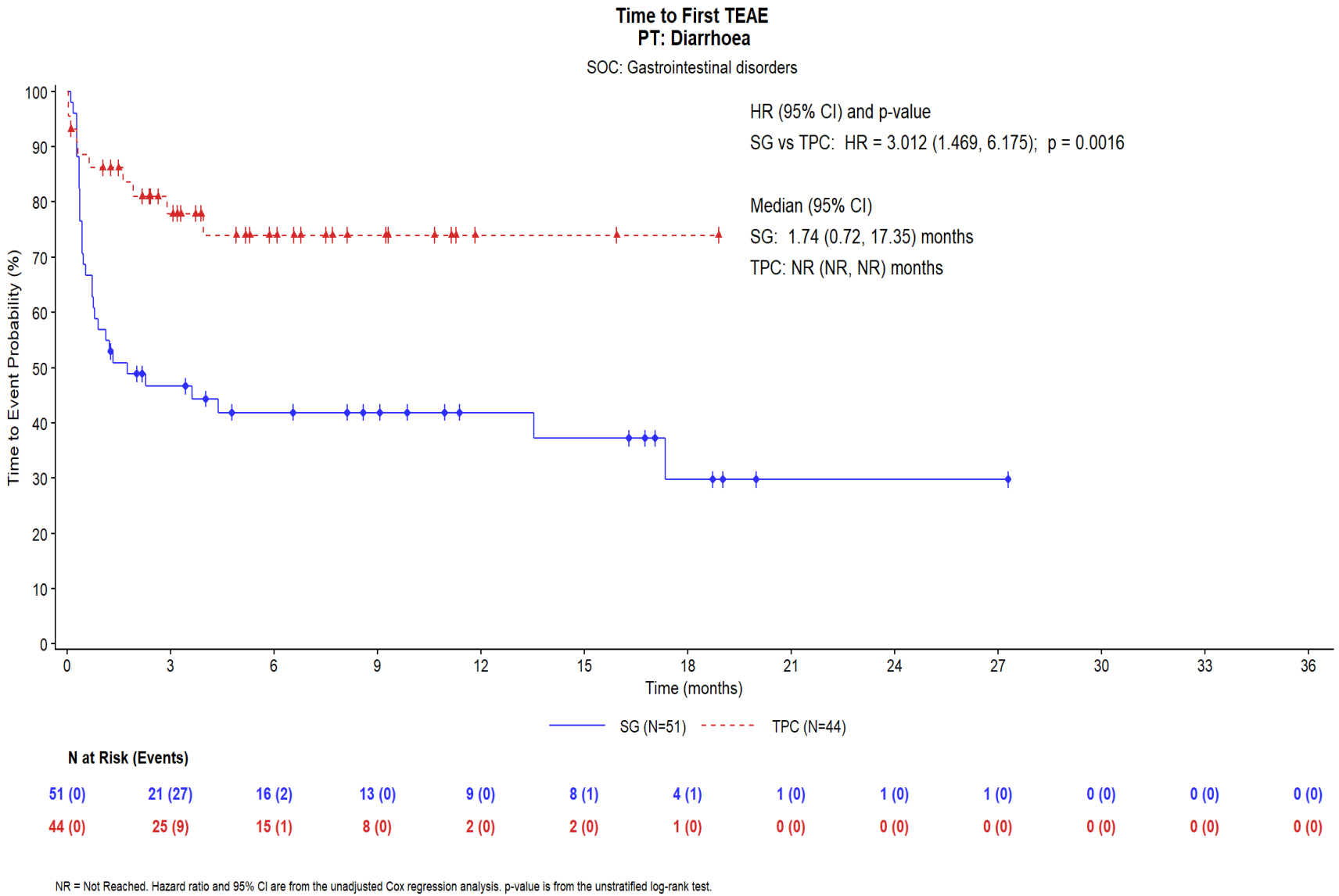
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.31. Figure 1.1.31: Kaplan Meier Plot of Time to First TEAE by PT Constipation — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



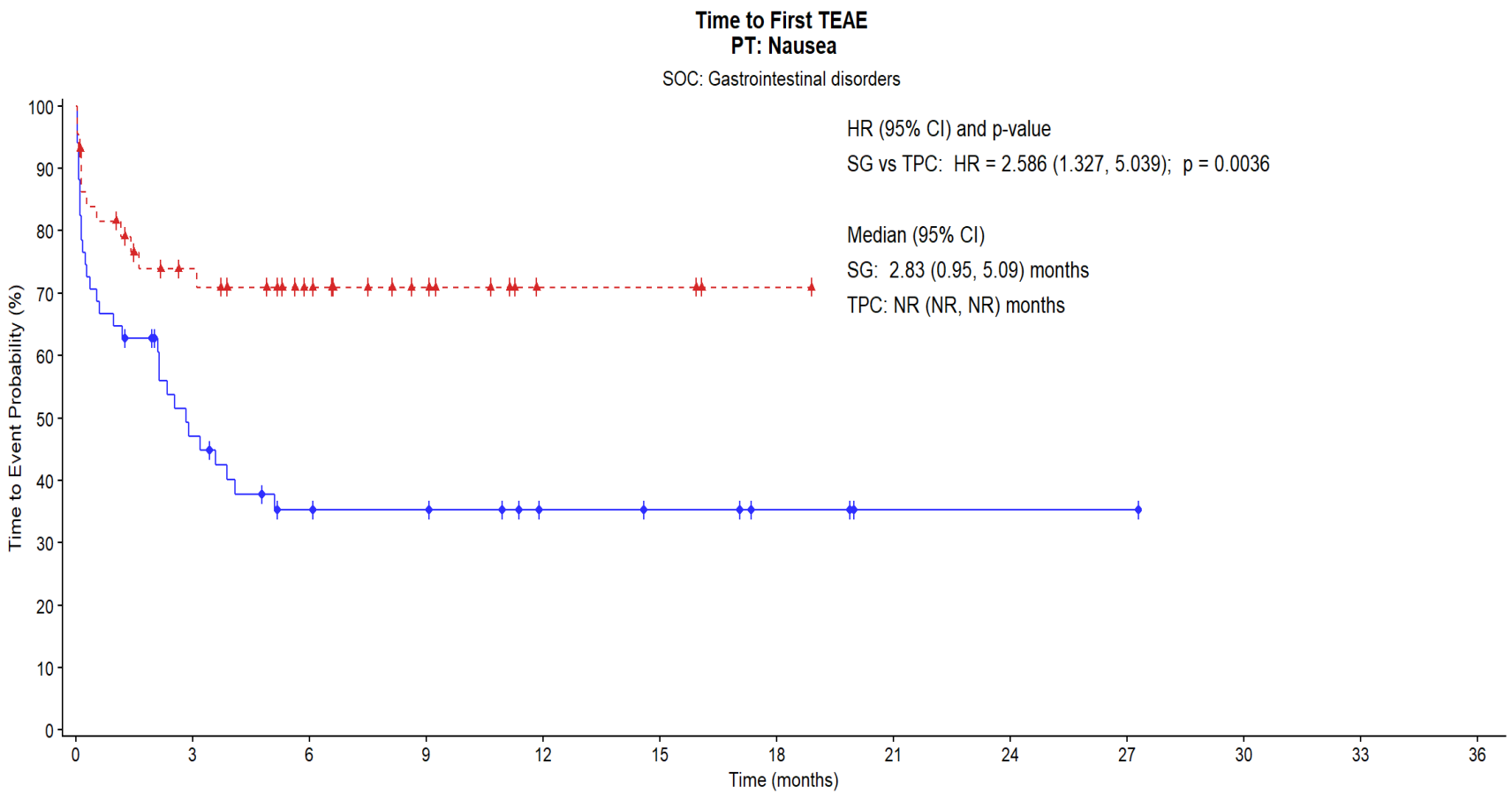
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.32. Figure 1.1.32: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



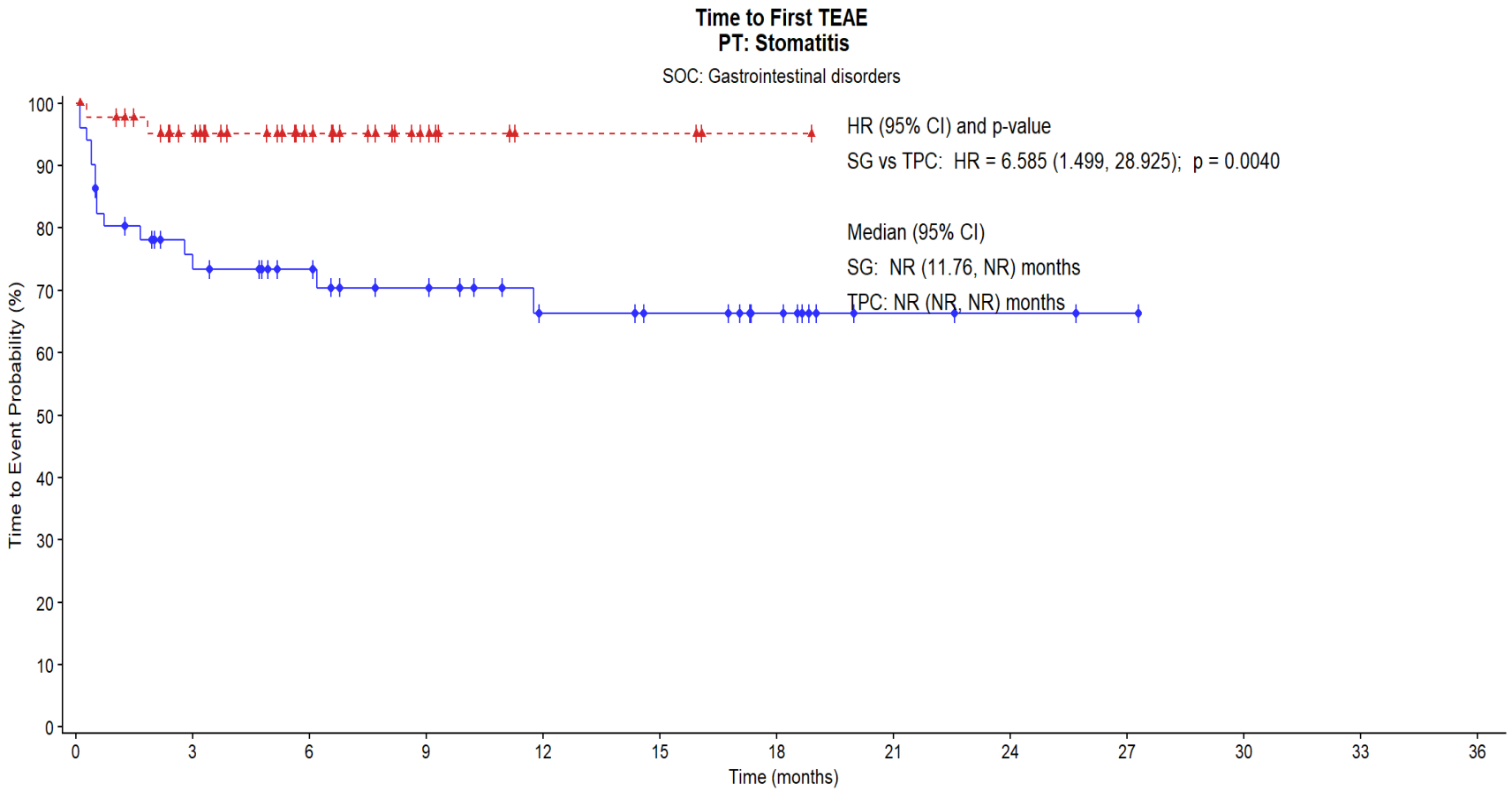
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.33. Figure 1.1.33: Kaplan Meier Plot of Time to First TEAE by PT Nausea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



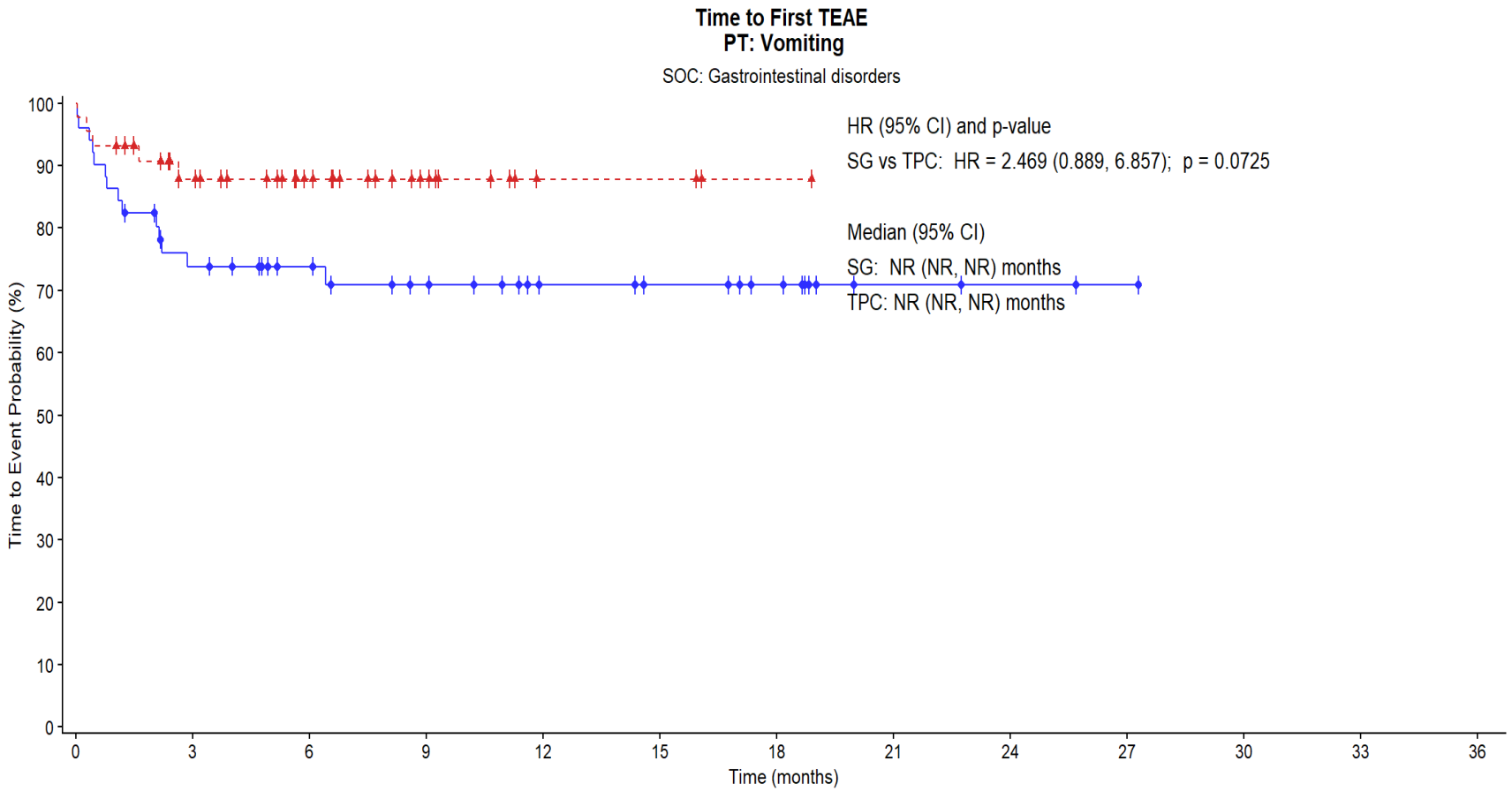
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.34. Figure 1.1.34: Kaplan Meier Plot of Time to First TEAE by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



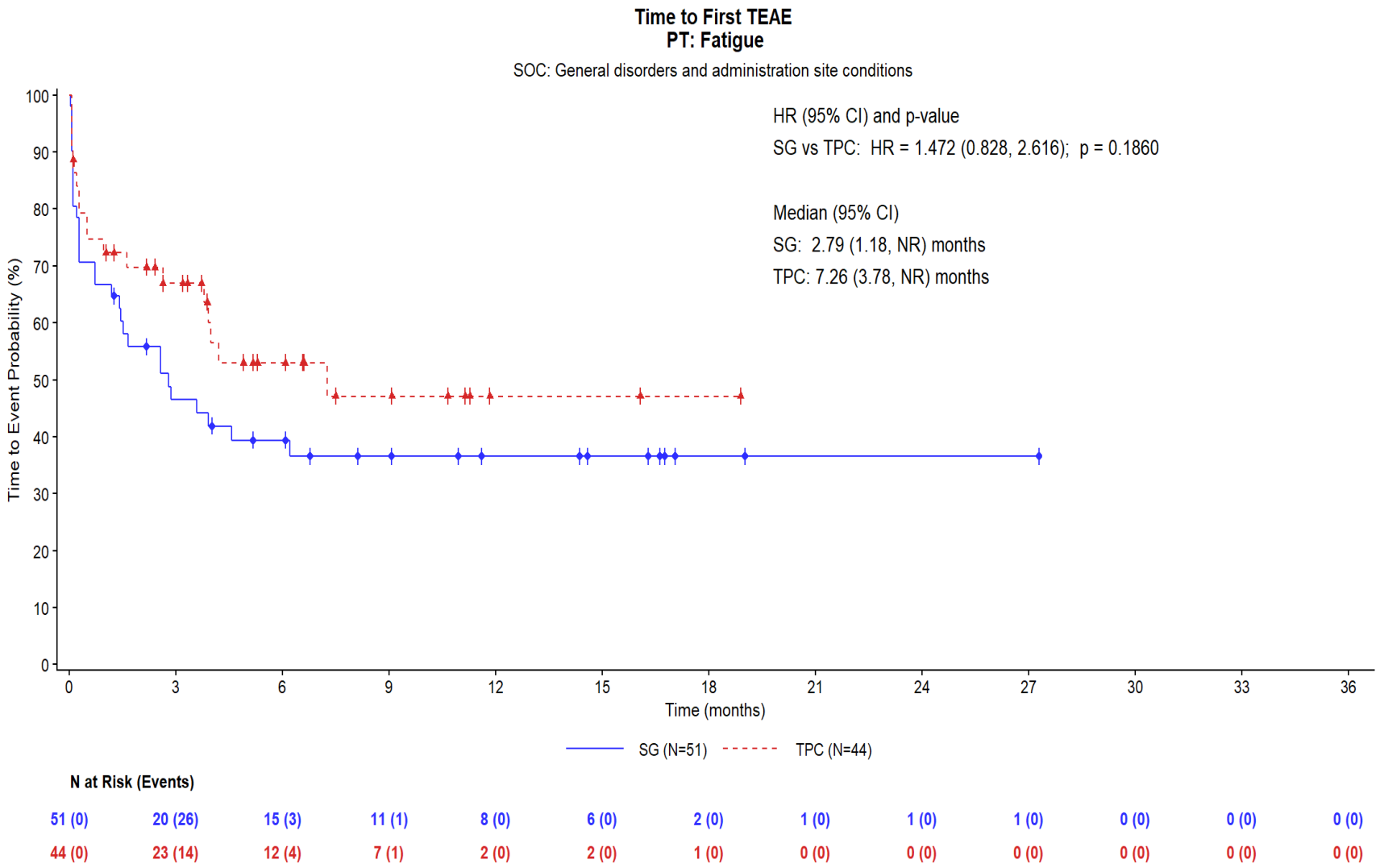
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8.35. Figure 1.1.35: Kaplan Meier Plot of Time to First TEAE by PT Vomiting — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



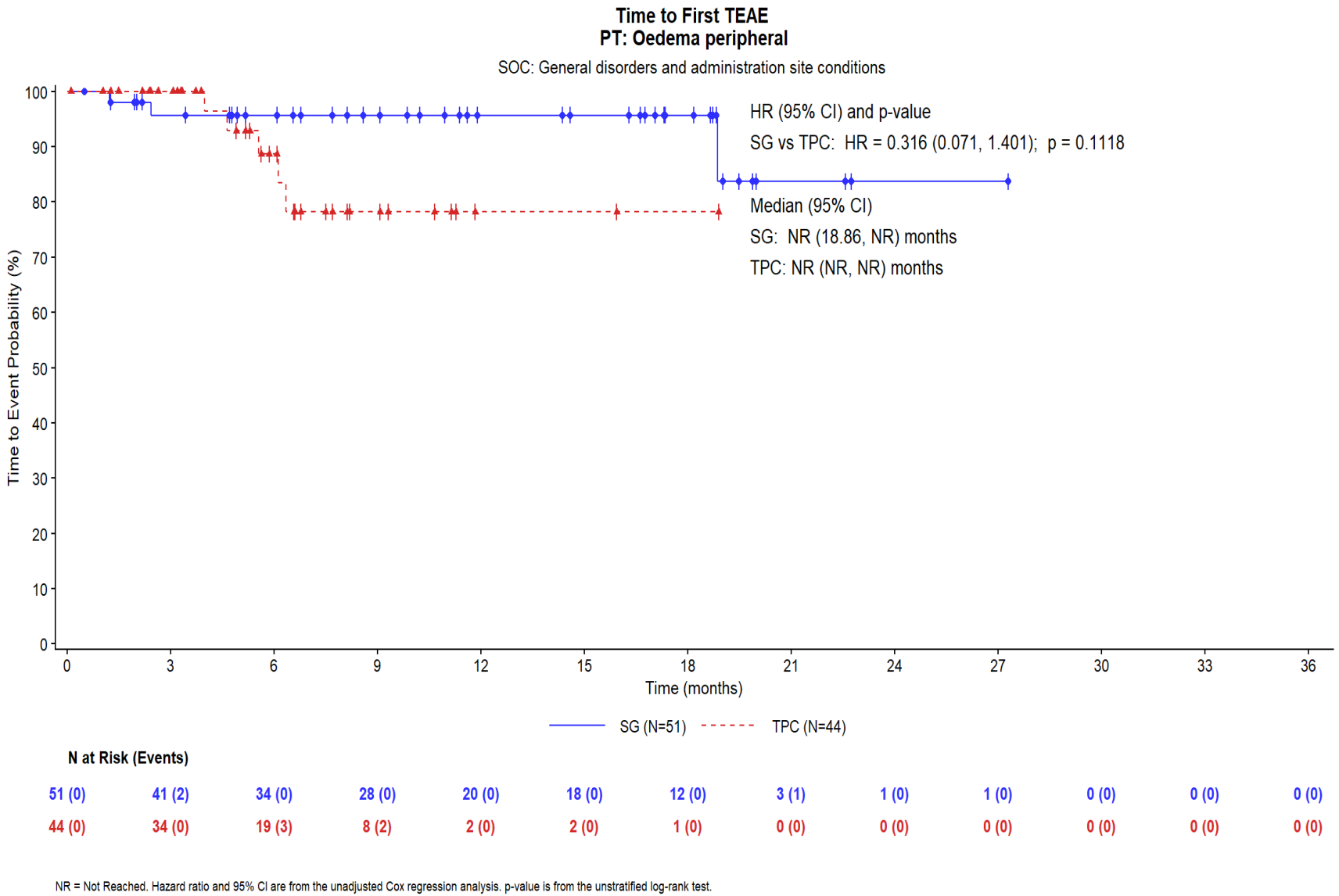
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.36. Figure 1.1.36: Kaplan Meier Plot of Time to First TEAE by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



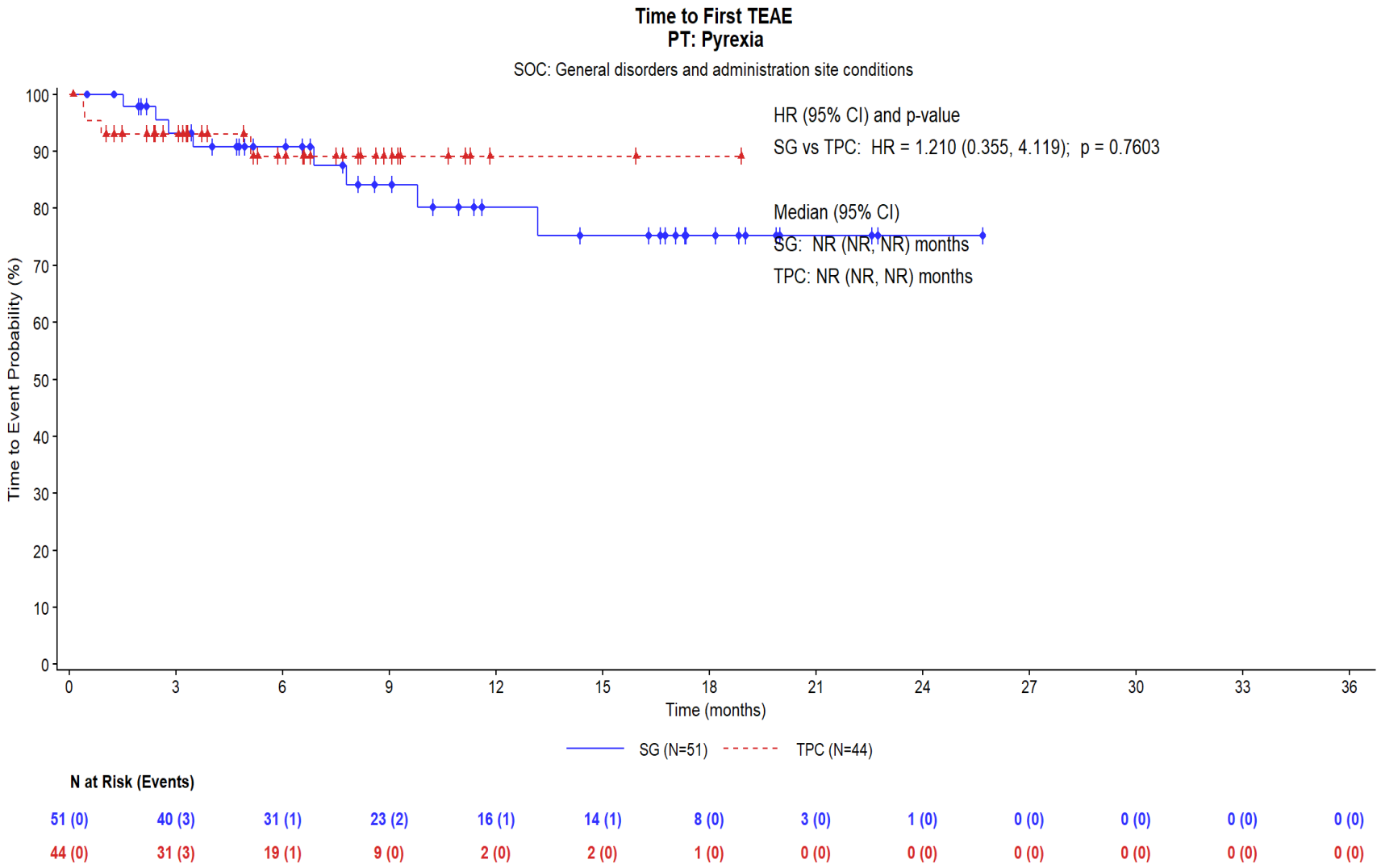
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.37. Figure 1.1.37: Kaplan Meier Plot of Time to First TEAE by PT Oedema peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



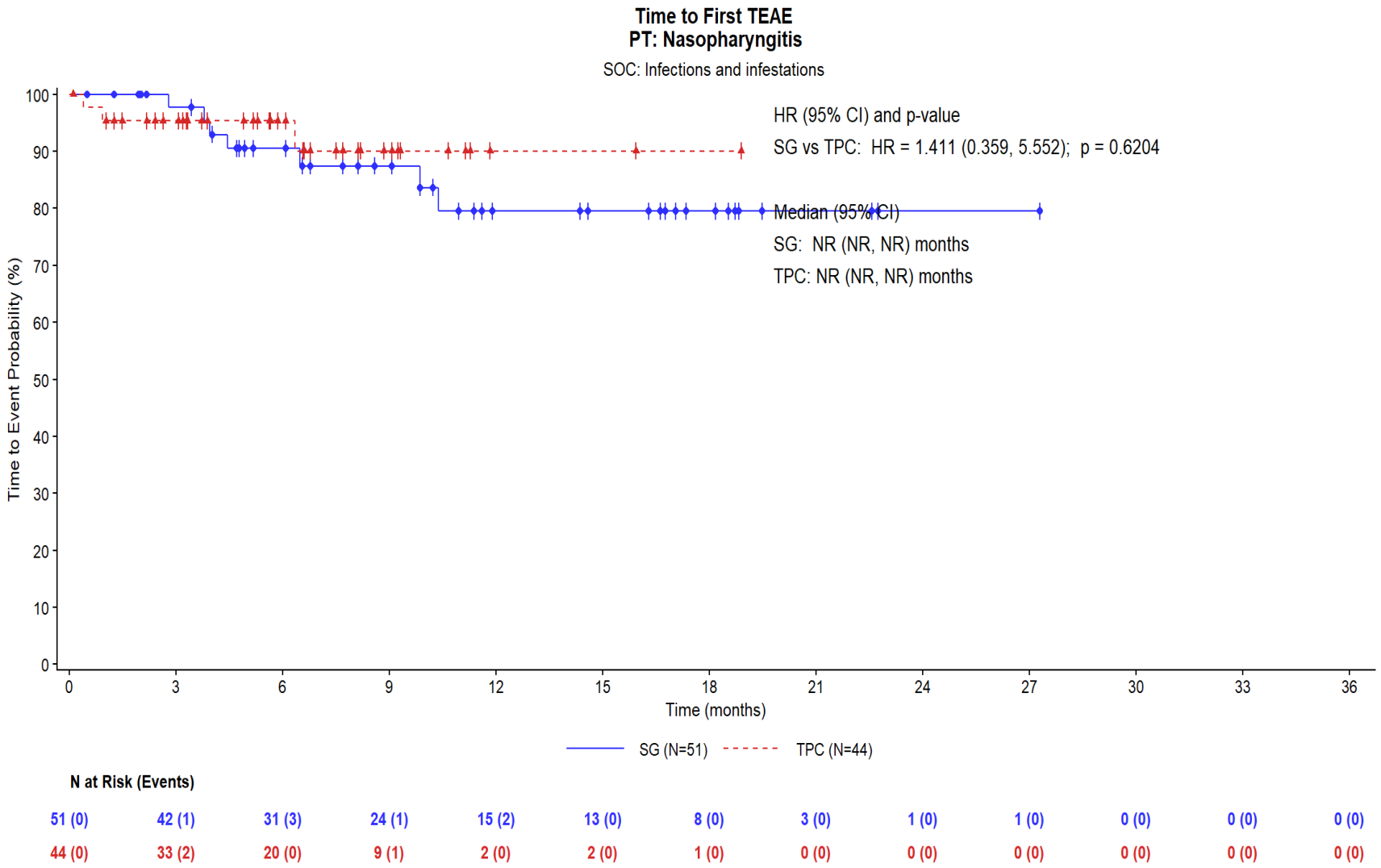
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.38. Figure 1.1.38: Kaplan Meier Plot of Time to First TEAE by PT Pyrexia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



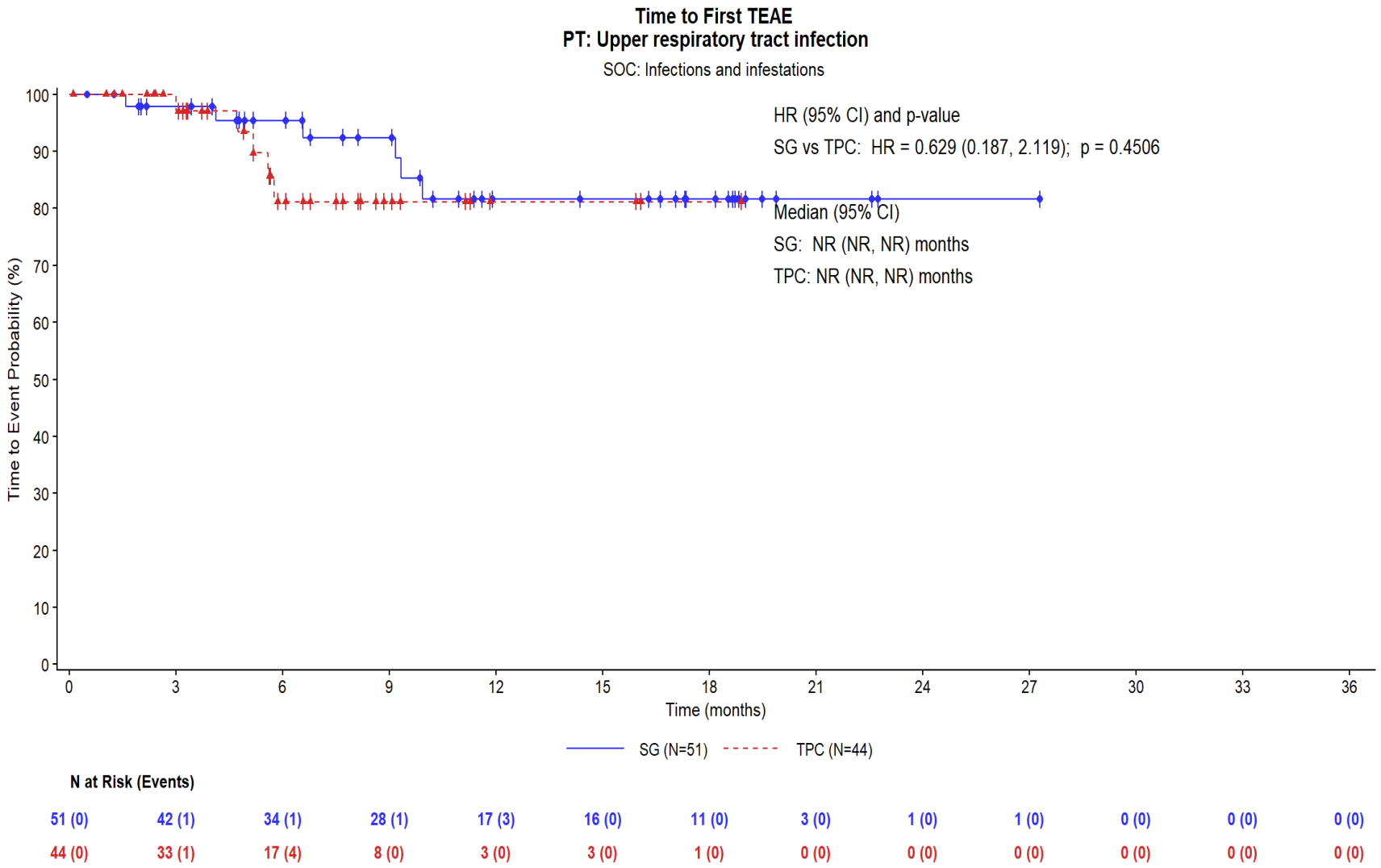
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.39. Figure 1.1.39: Kaplan Meier Plot of Time to First TEAE by PT Nasopharyngitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



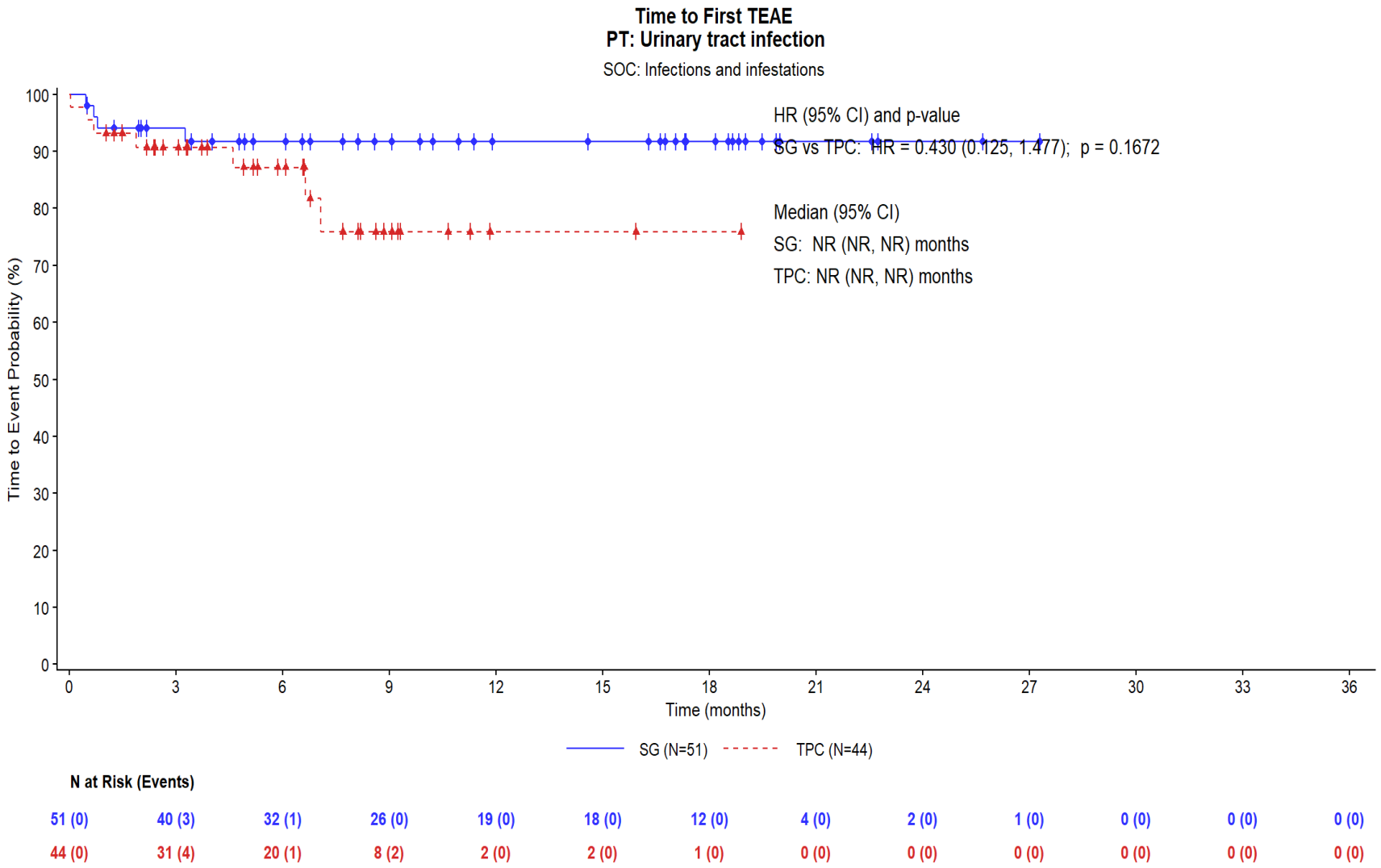
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.40. Figure 1.1.40: Kaplan Meier Plot of Time to First TEAE by PT Upper respiratory tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



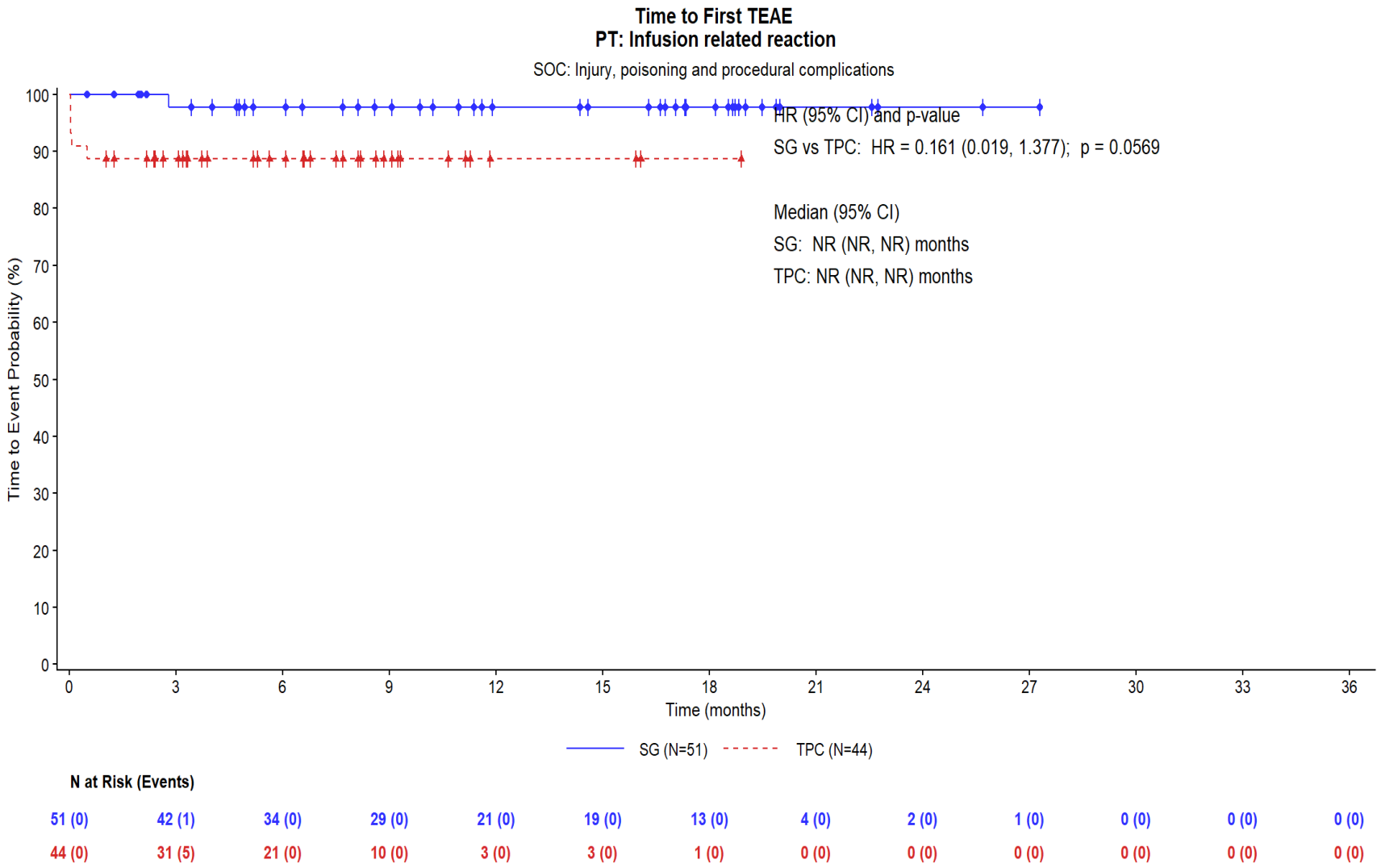
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.41. Figure 1.1.41: Kaplan Meier Plot of Time to First TEAE by PT Urinary tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



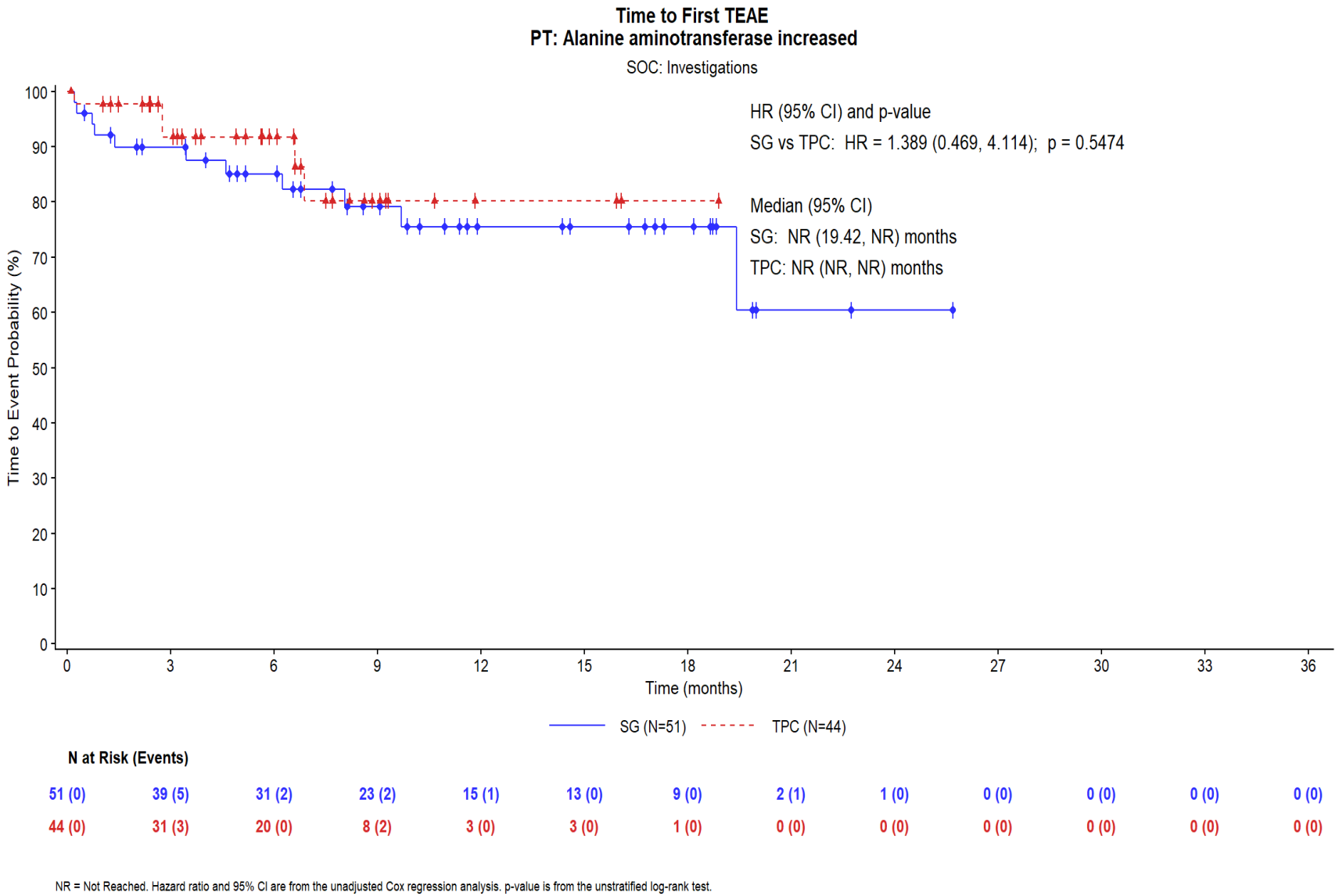
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.42. Figure 1.1.42: Kaplan Meier Plot of Time to First TEAE by PT Infusion related reaction — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



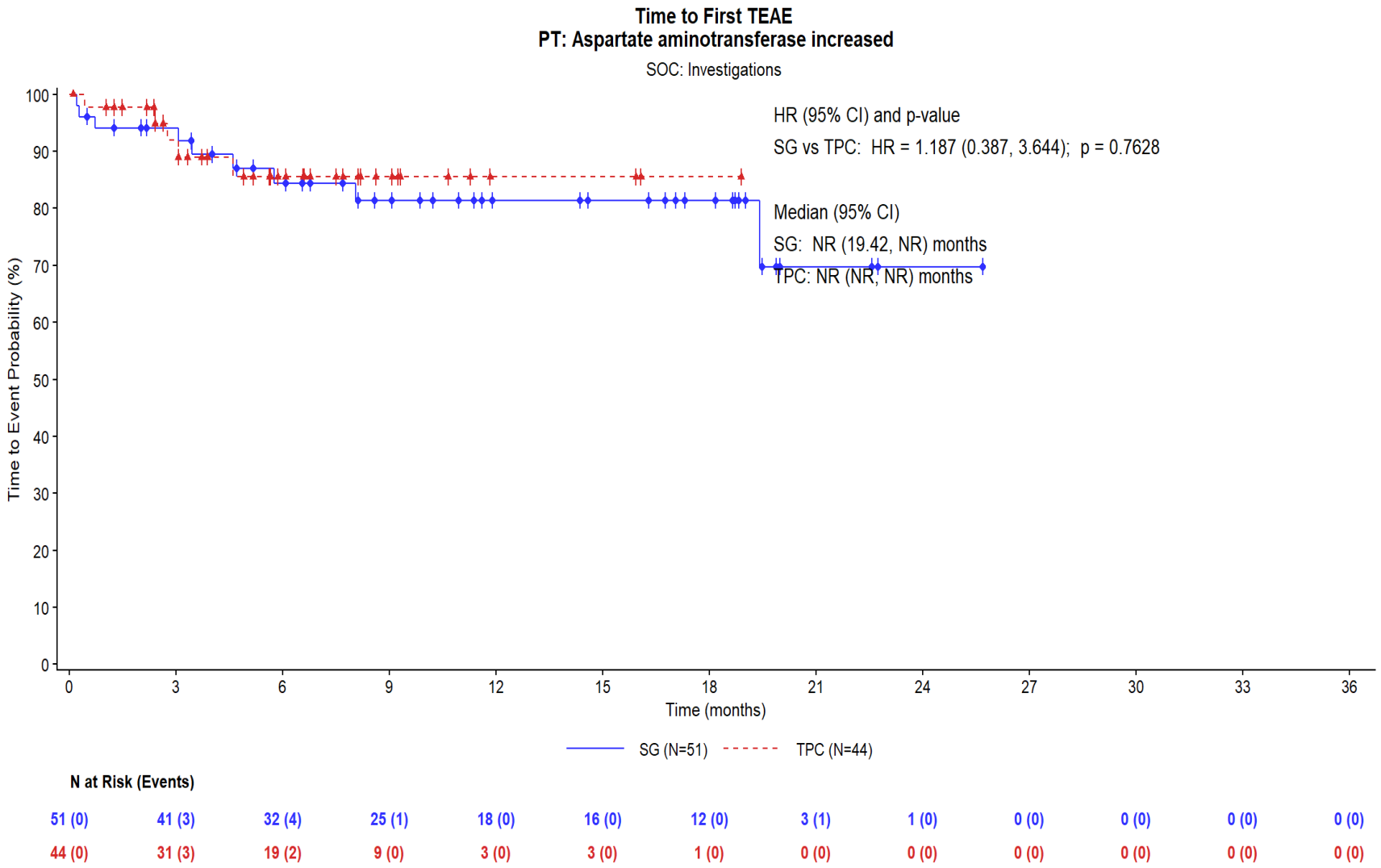
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.43. Figure 1.1.43: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



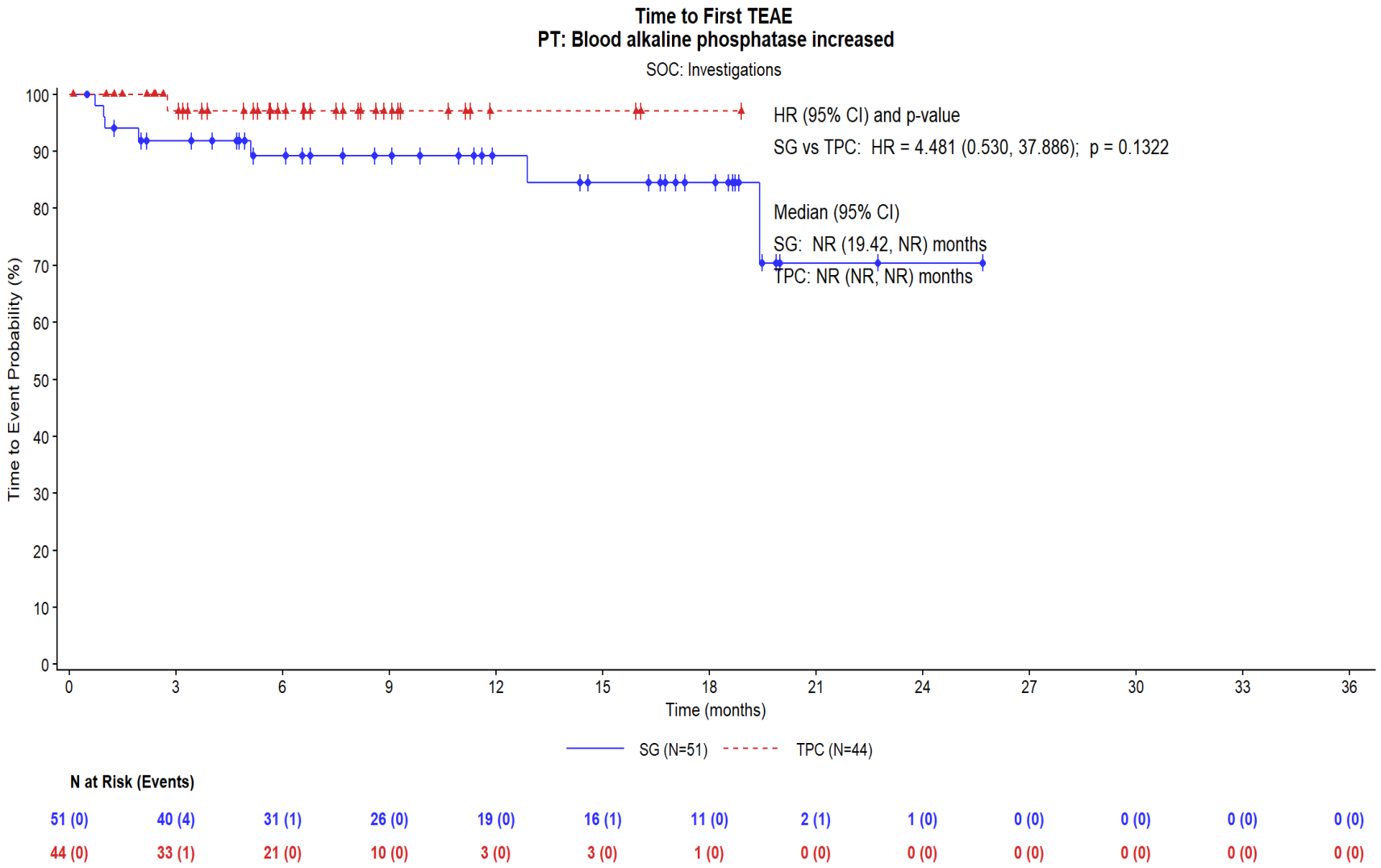
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.44. Figure 1.1.44: Kaplan Meier Plot of Time to First TEAE by PT Aspartate aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



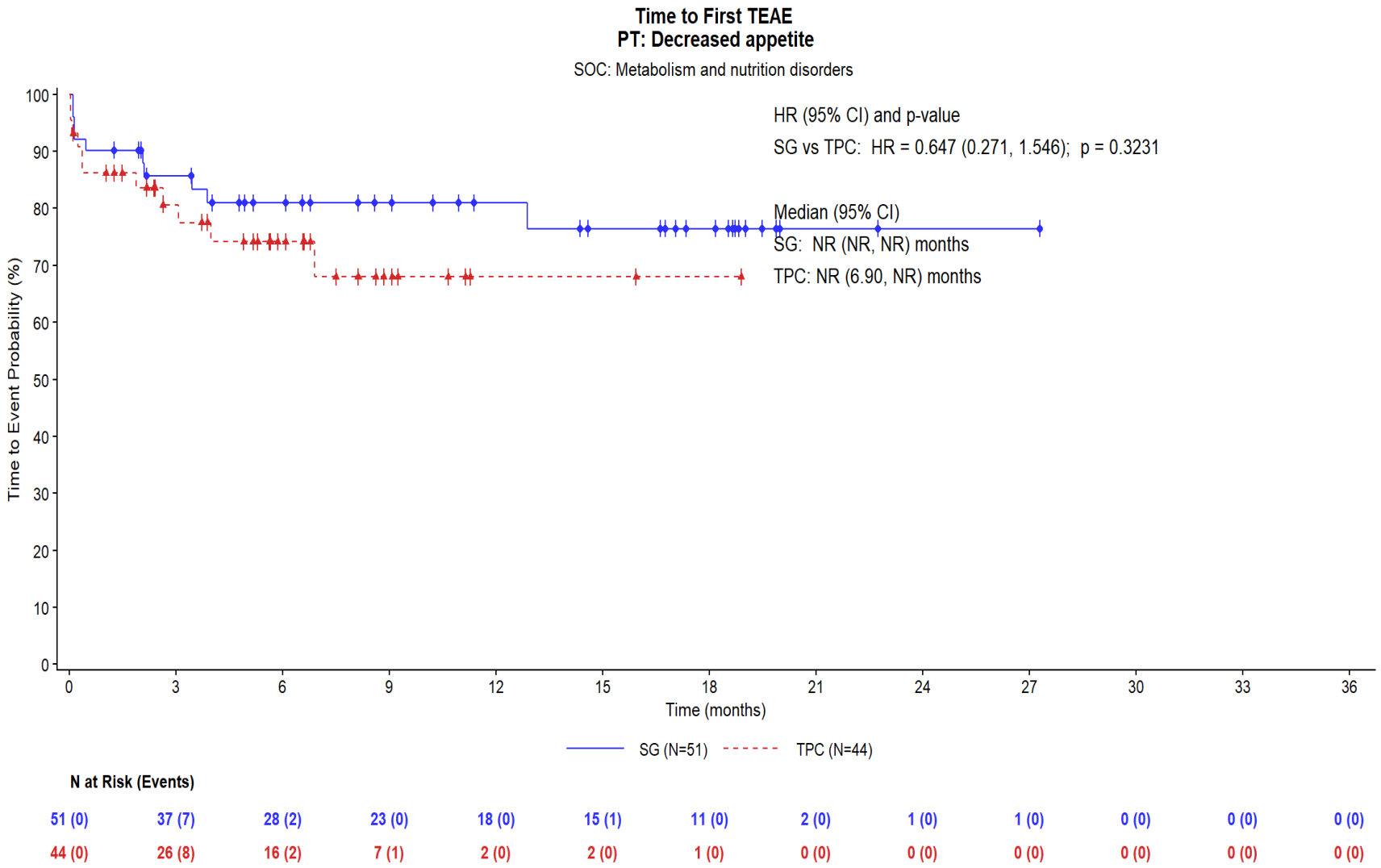
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.45. Figure 1.1.45: Kaplan Meier Plot of Time to First TEAE by PT Blood alkaline phosphatase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



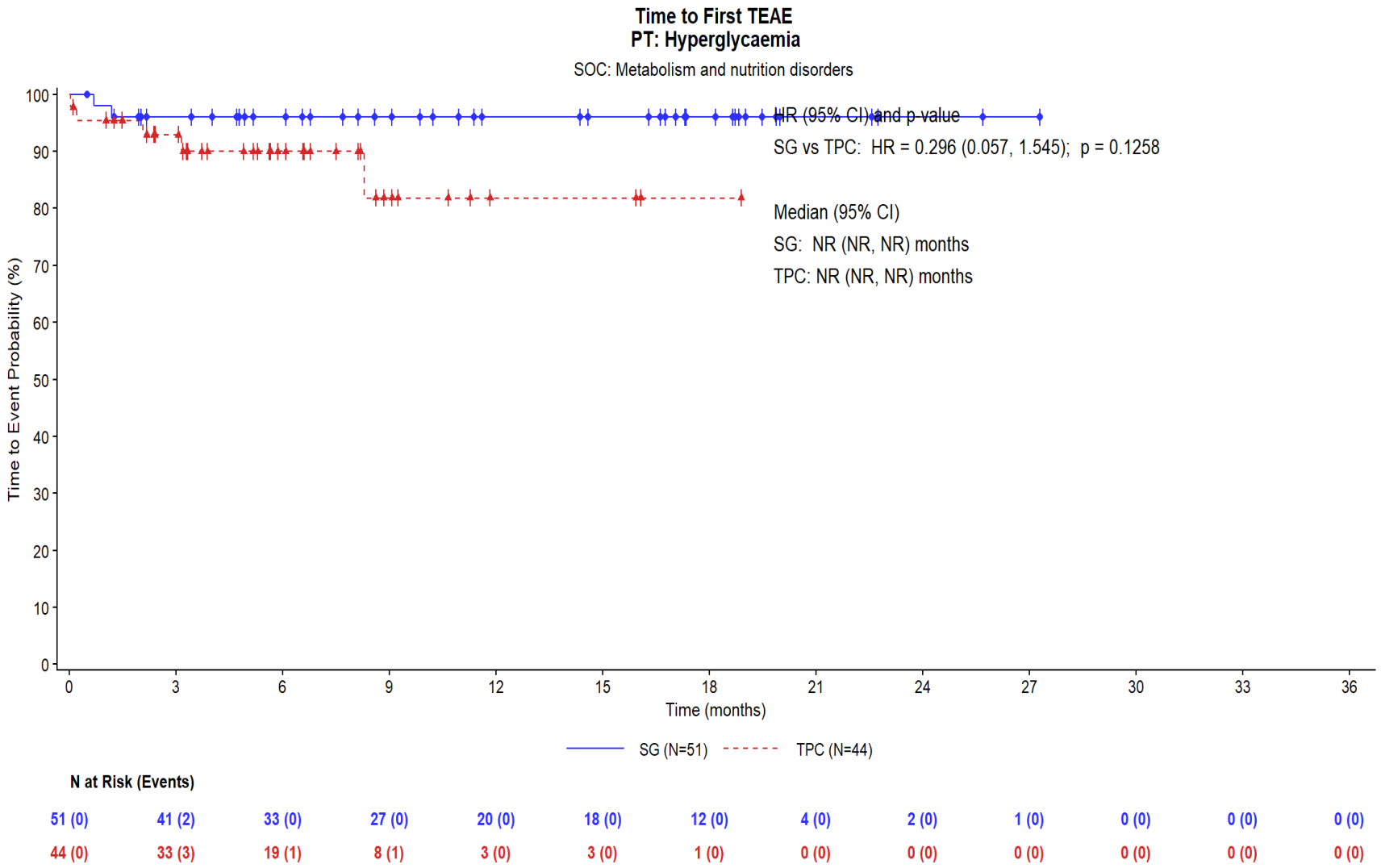
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.46. Figure 1.1.46: Kaplan Meier Plot of Time to First TEAE by PT Decreased appetite — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



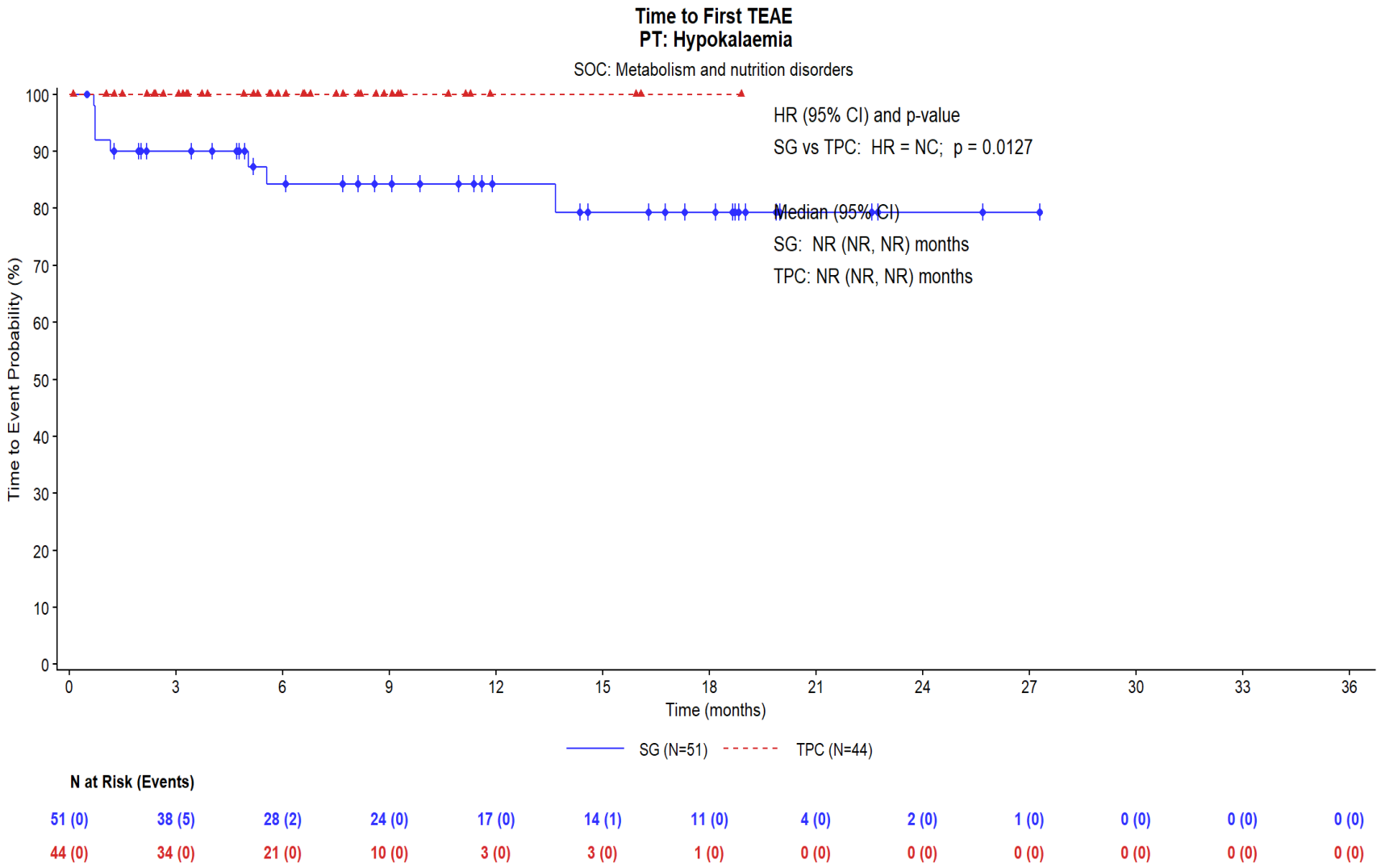
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.47. Figure 1.1.47: Kaplan Meier Plot of Time to First TEAE by PT Hyperglycaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



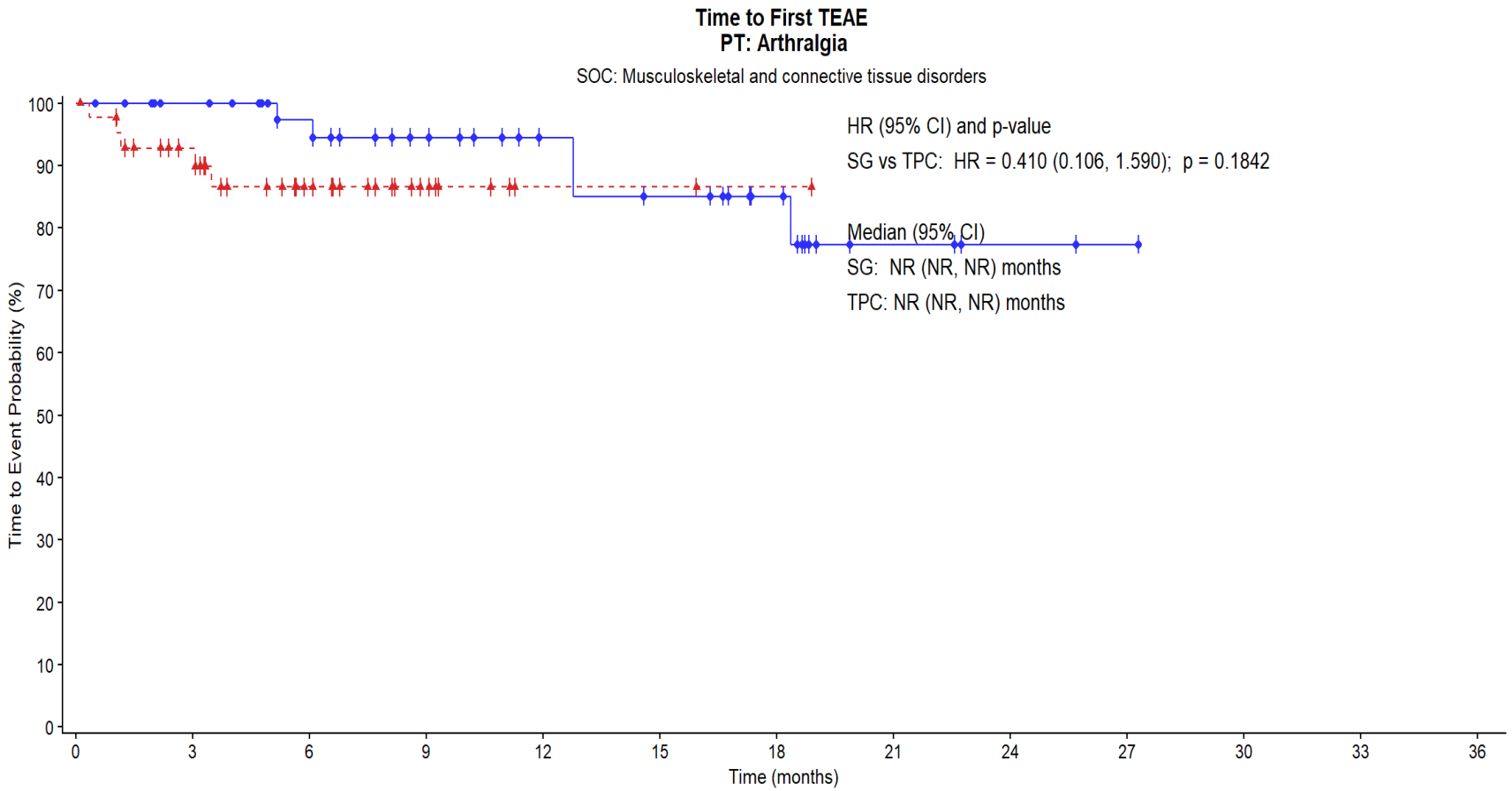
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.48. Figure 1.1.48: Kaplan Meier Plot of Time to First TEAE by PT Hypokalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



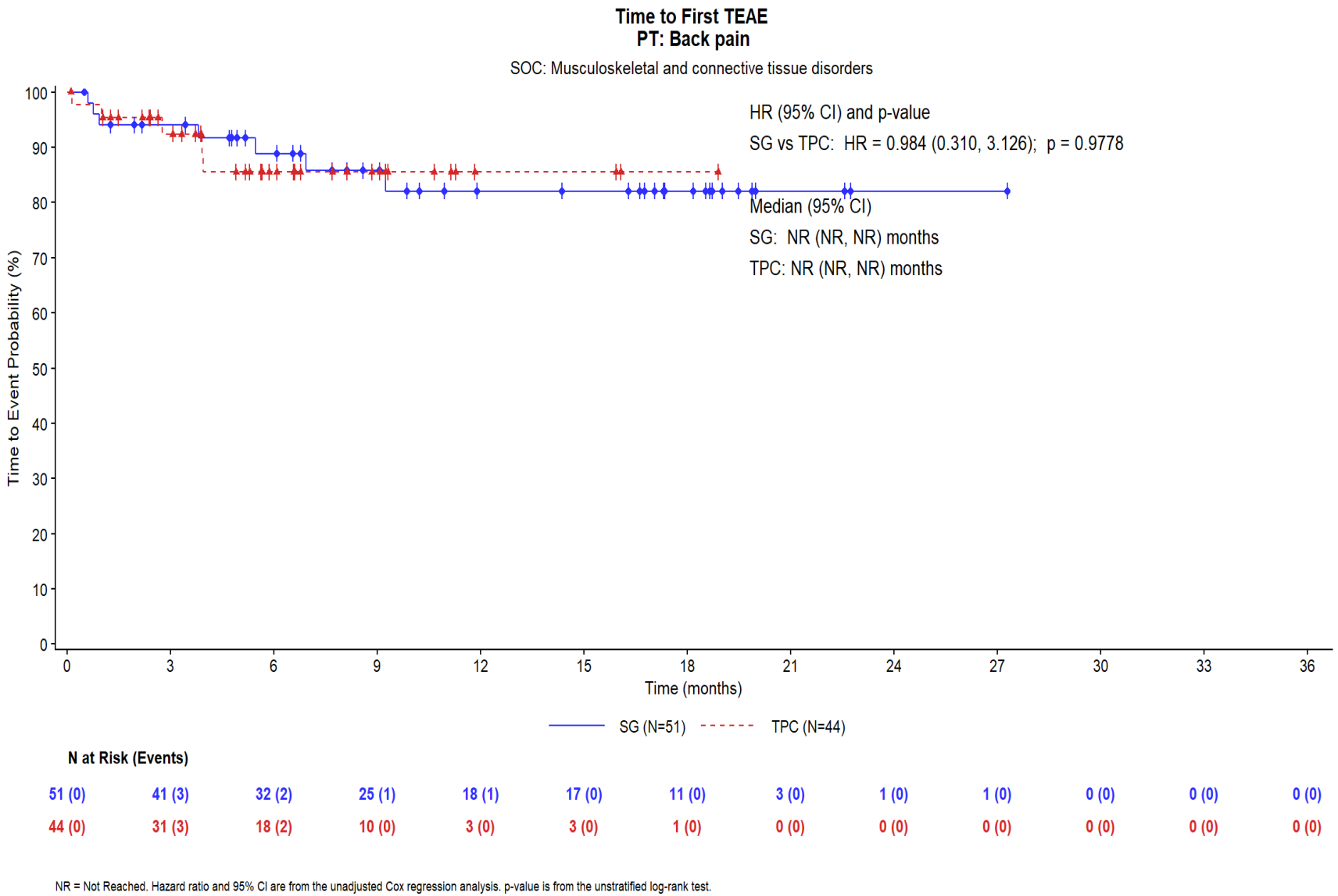
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.49. Figure 1.1.49: Kaplan Meier Plot of Time to First TEAE by PT Arthralgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



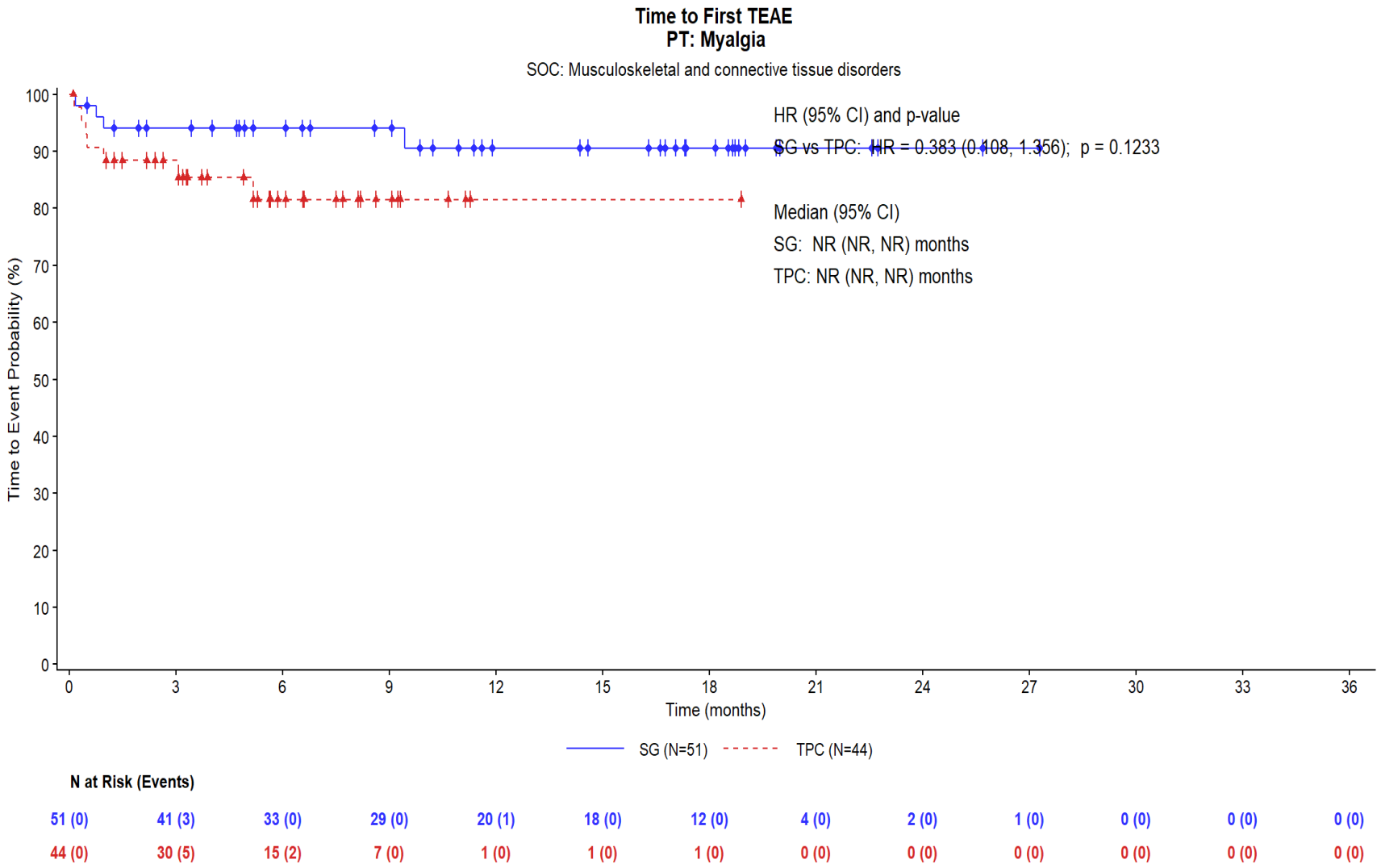
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.50. Figure 1.1.50: Kaplan Meier Plot of Time to First TEAE by PT Back pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



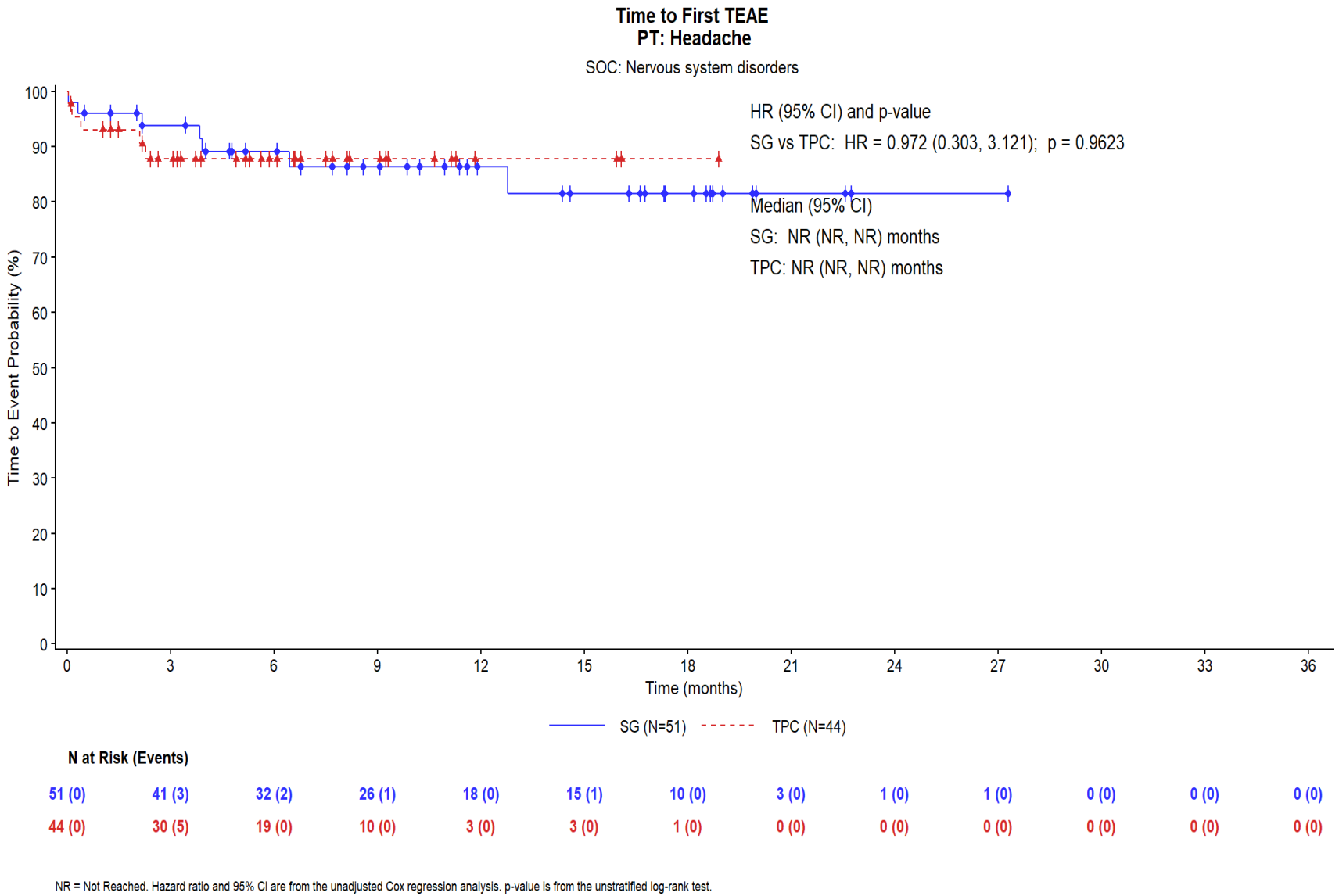
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.51. Figure 1.1.51: Kaplan Meier Plot of Time to First TEAE by PT Myalgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



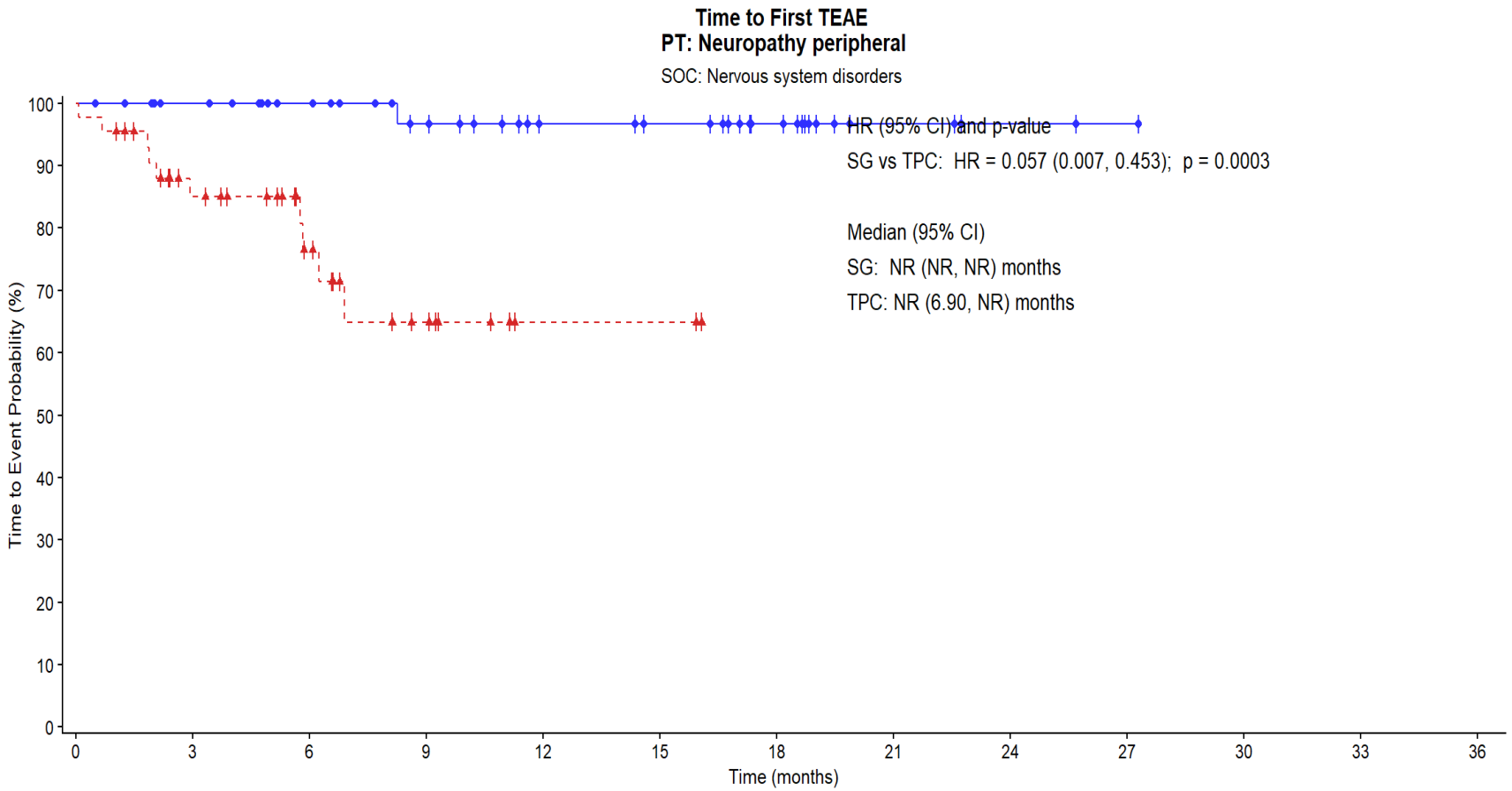
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.52. Figure 1.1.52: Kaplan Meier Plot of Time to First TEAE by PT Headache — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



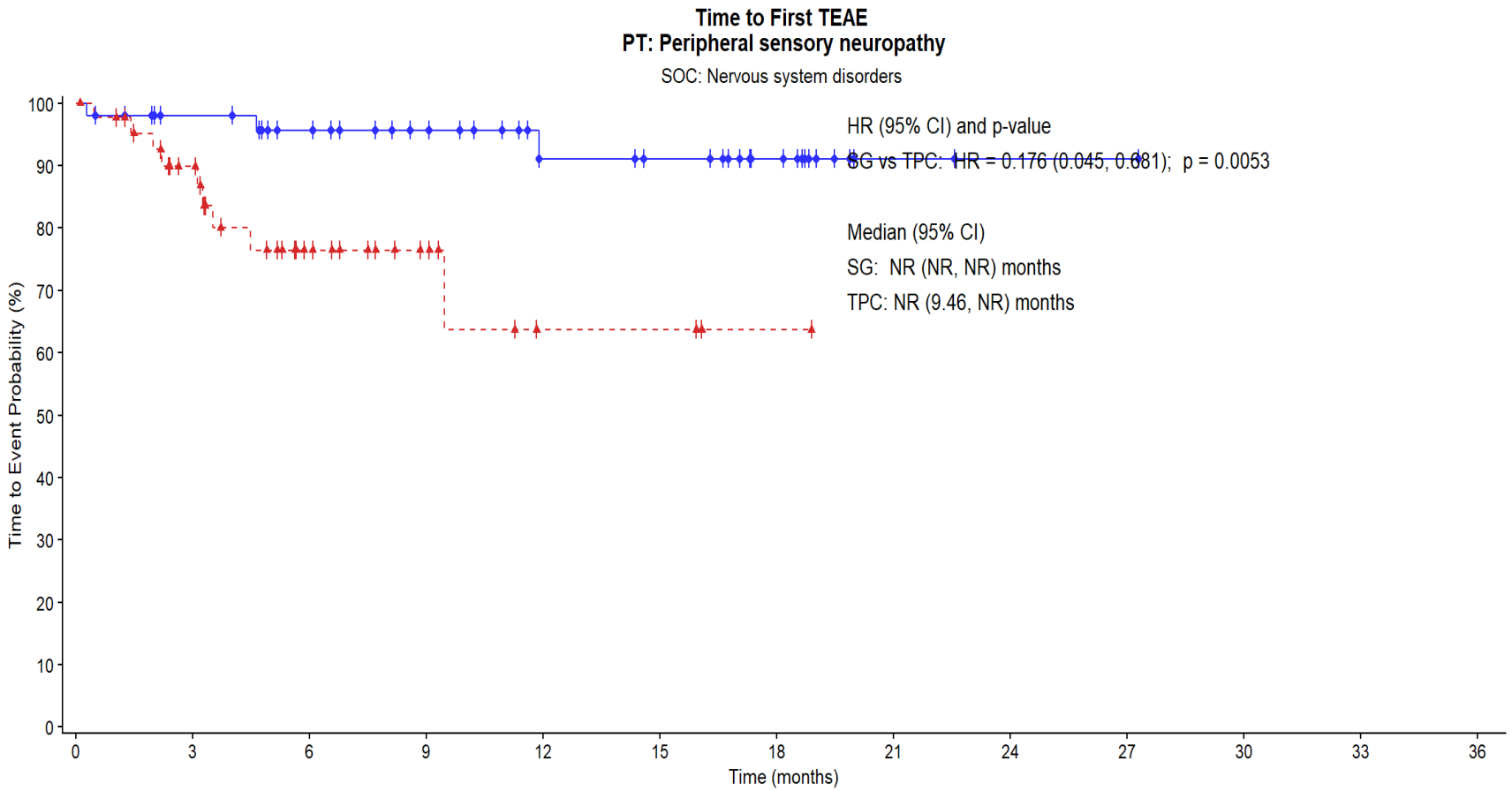
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.53. Figure 1.1.53: Kaplan Meier Plot of Time to First TEAE by PT Neuropathy peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



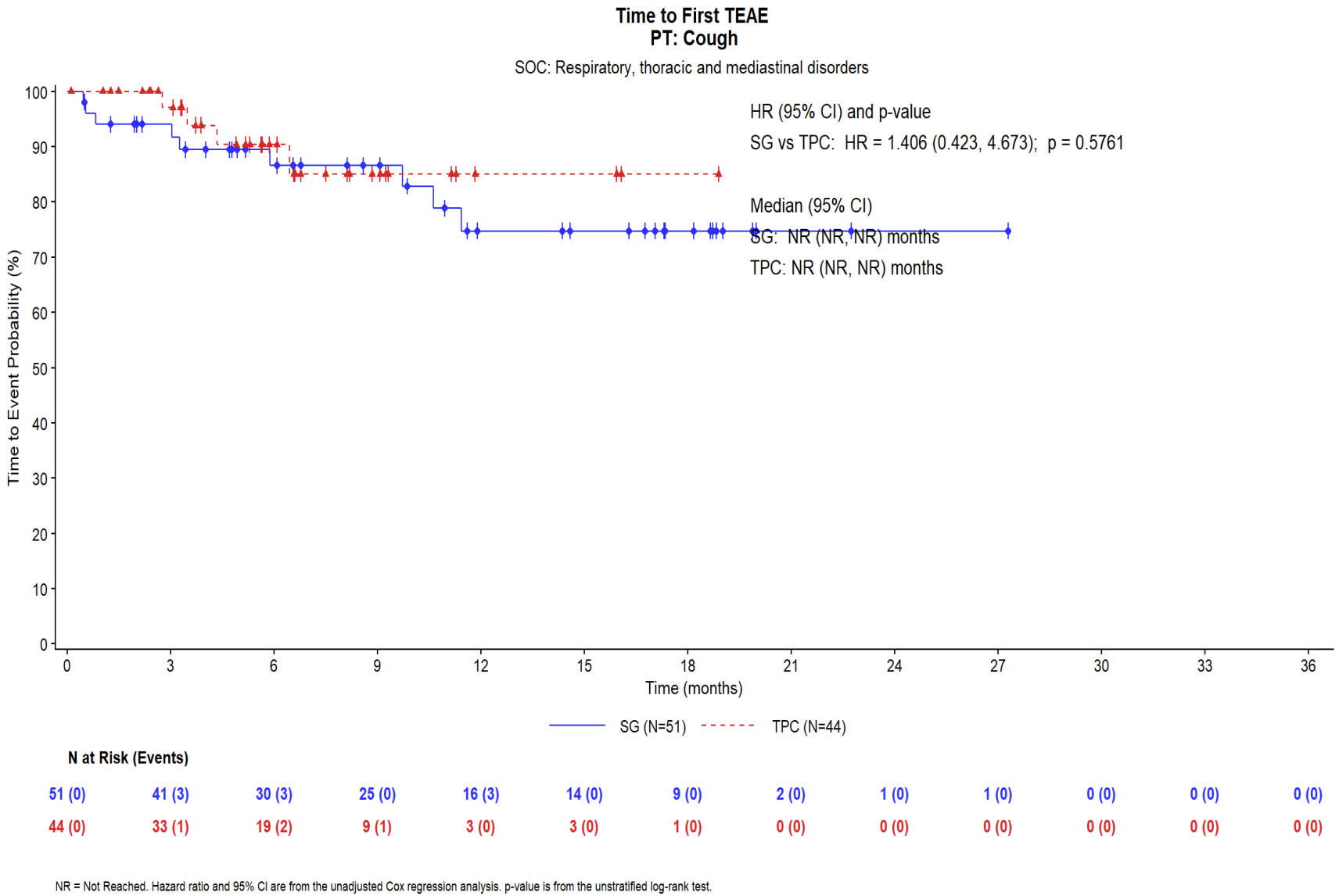
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.54. Figure 1.1.54: Kaplan Meier Plot of Time to First TEAE by PT Peripheral sensory neuropathy — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



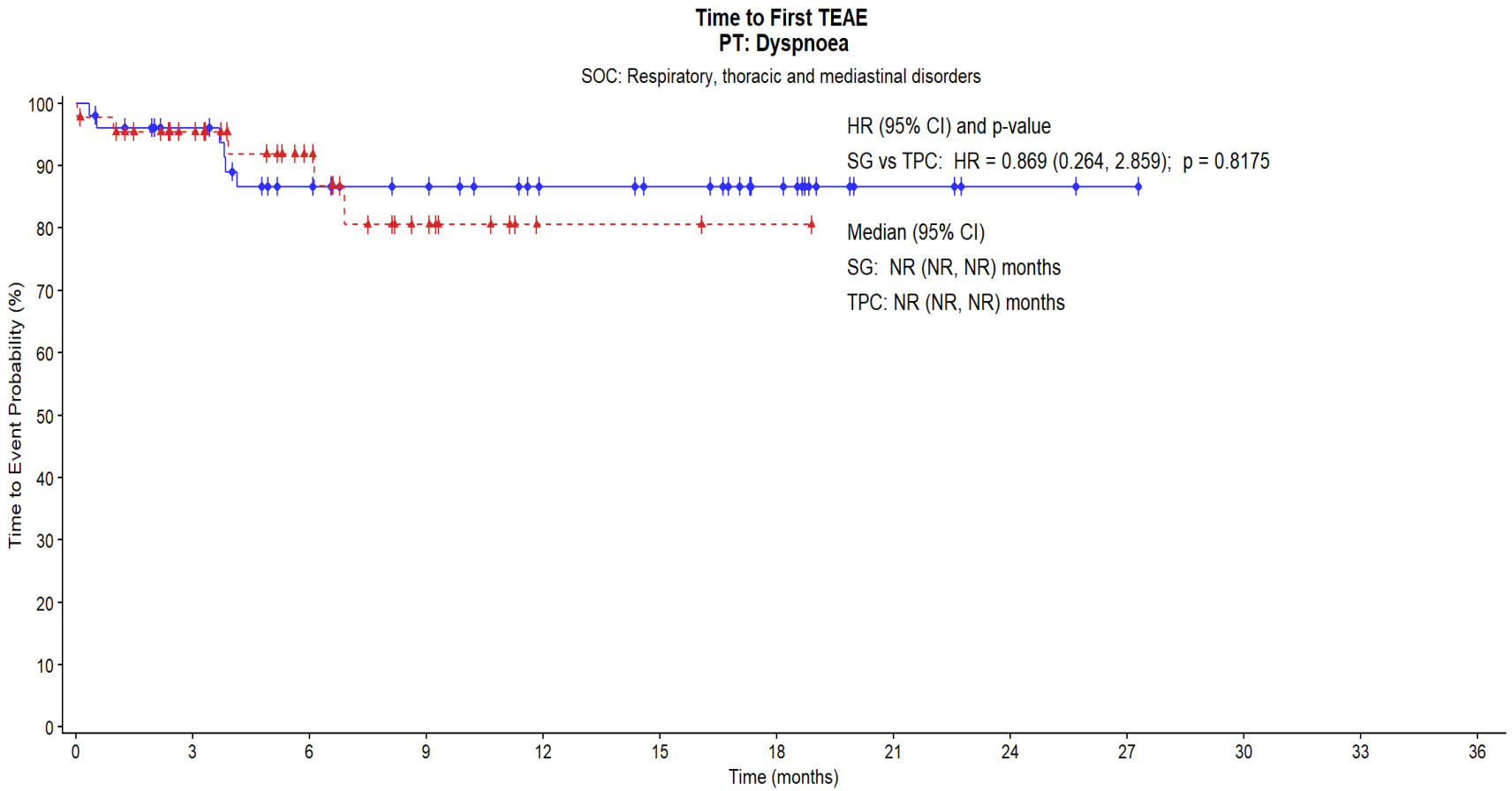
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.55. Figure 1.1.55: Kaplan Meier Plot of Time to First TEAE by PT Cough — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



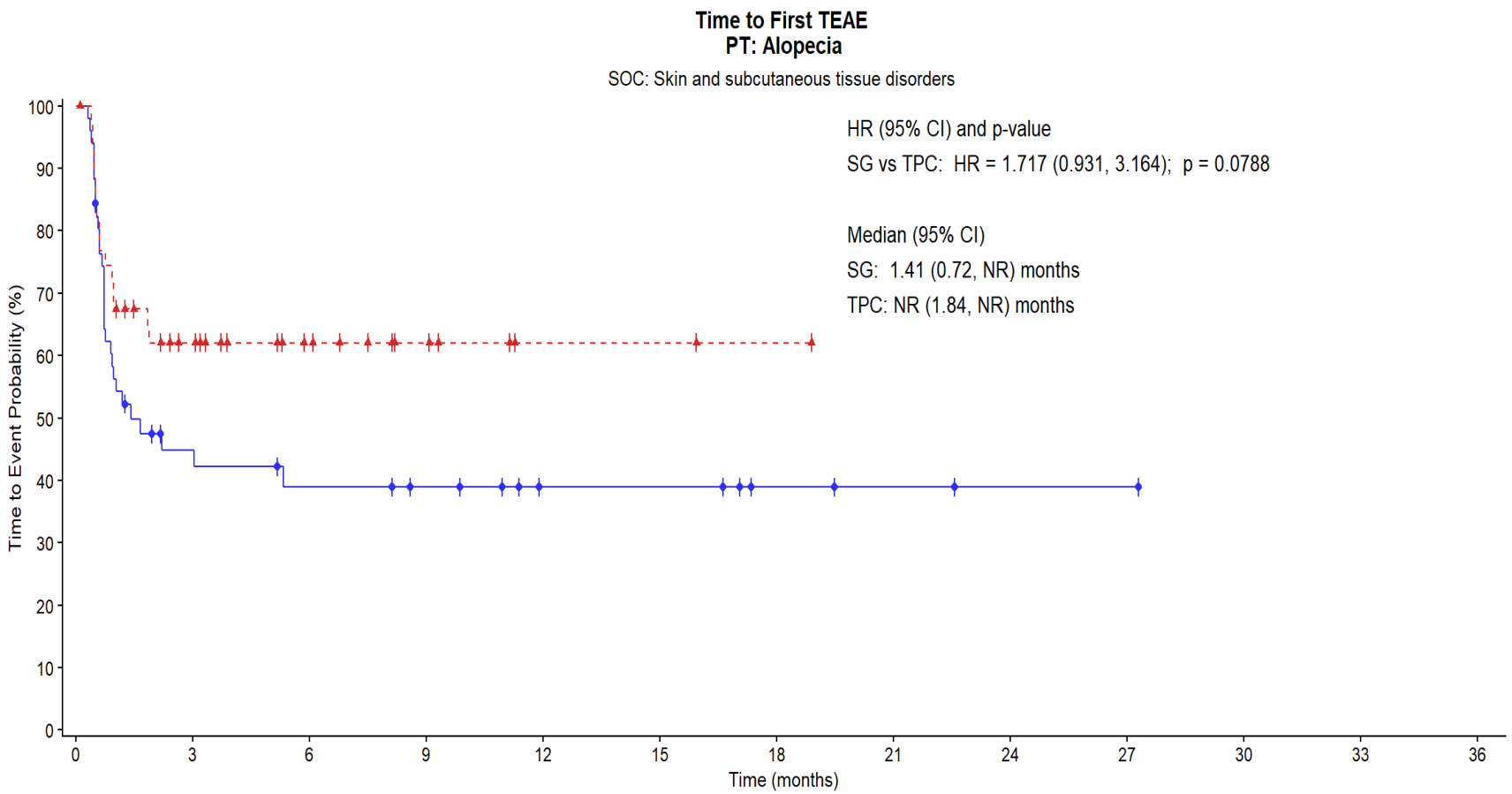
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.56. Figure 1.1.56: Kaplan Meier Plot of Time to First TEAE by PT Dyspnoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



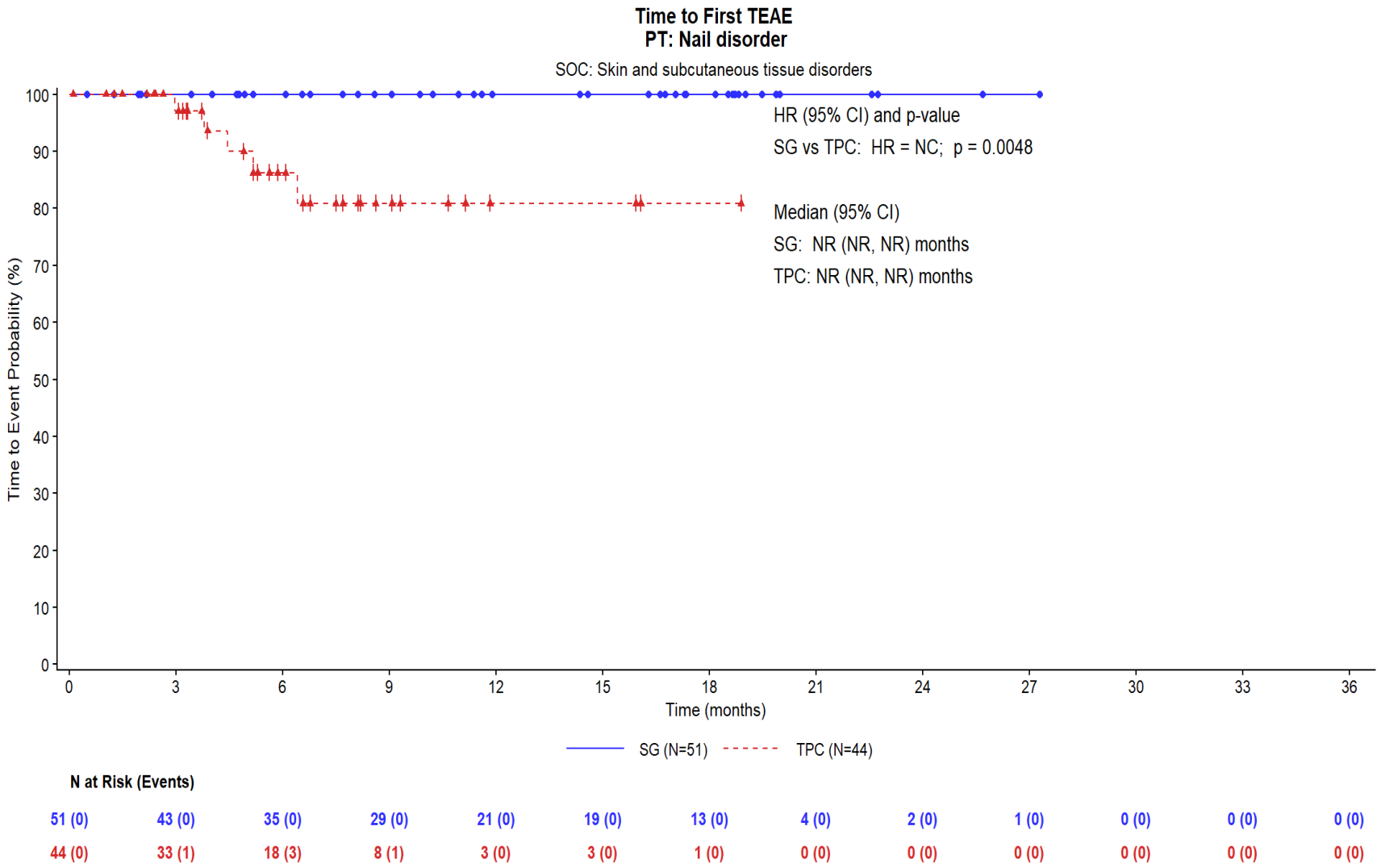
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.57. Figure 1.1.57: Kaplan Meier Plot of Time to First TEAE by PT Alopecia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



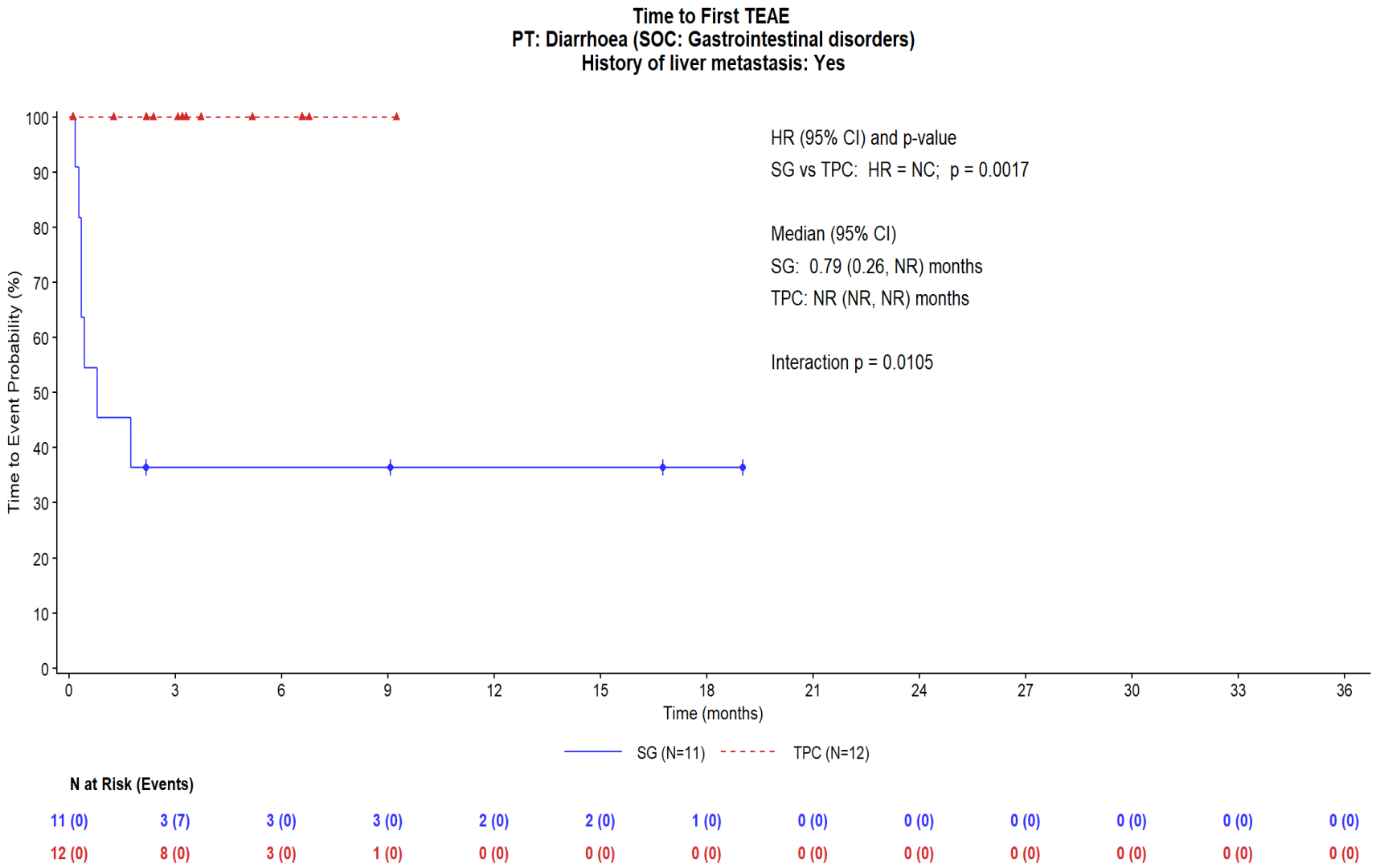
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.58. Figure 1.1.58: Kaplan Meier Plot of Time to First TEAE by PT Nail disorder — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



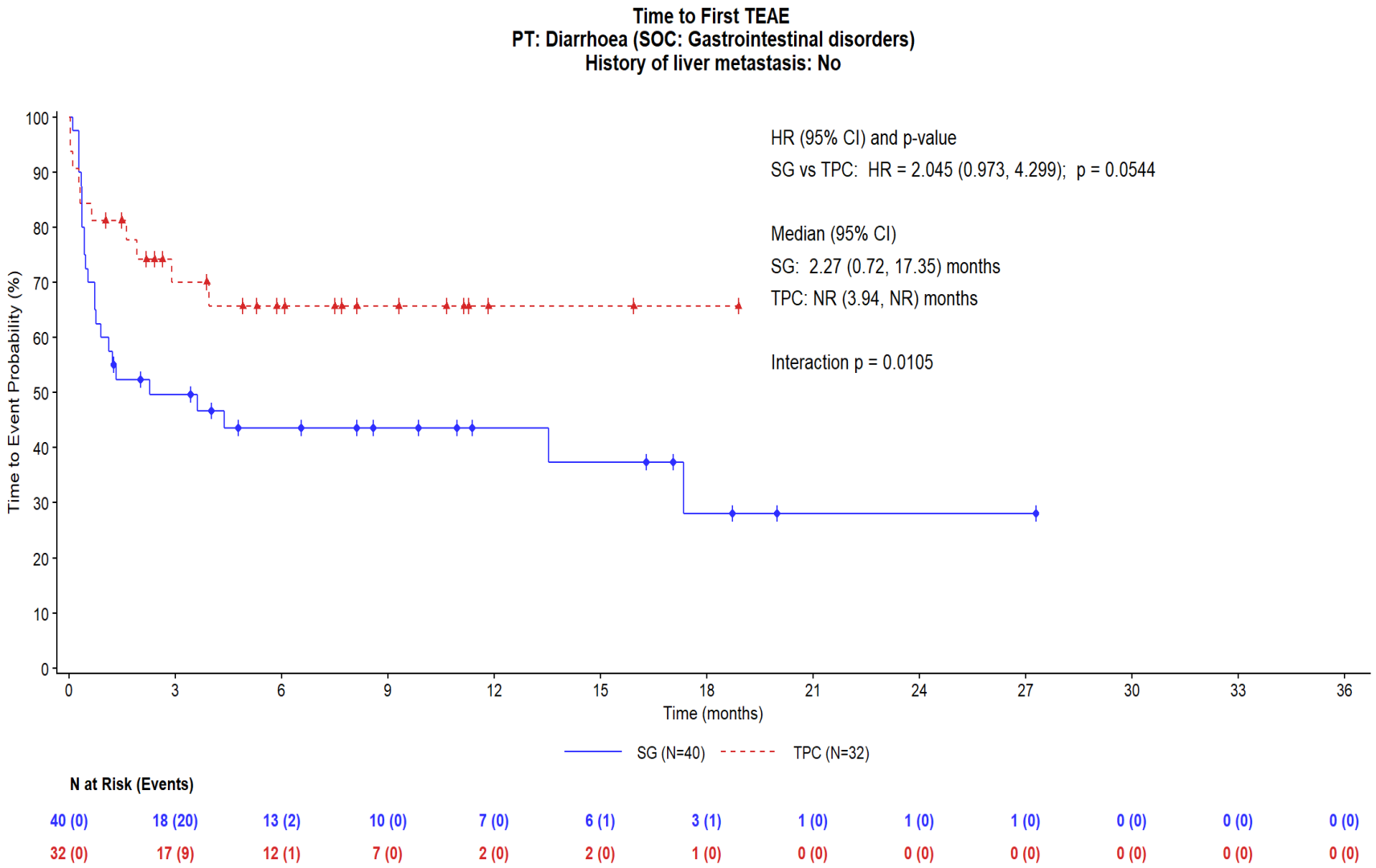
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.59. Figure 1.1.59: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) History of liver metastasis Yes — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



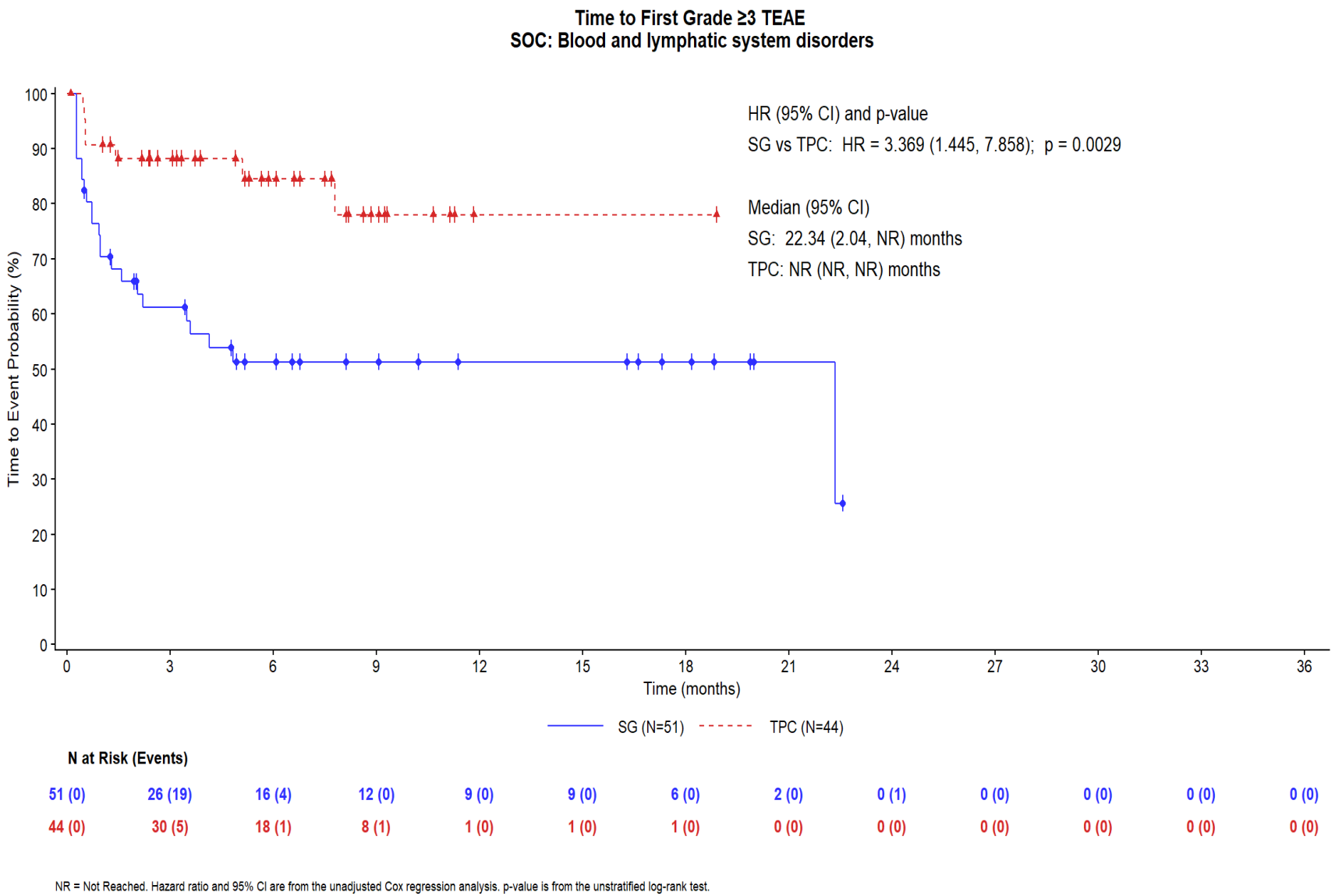
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.60. Figure 1.1.60: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) History of liver metastasis No — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



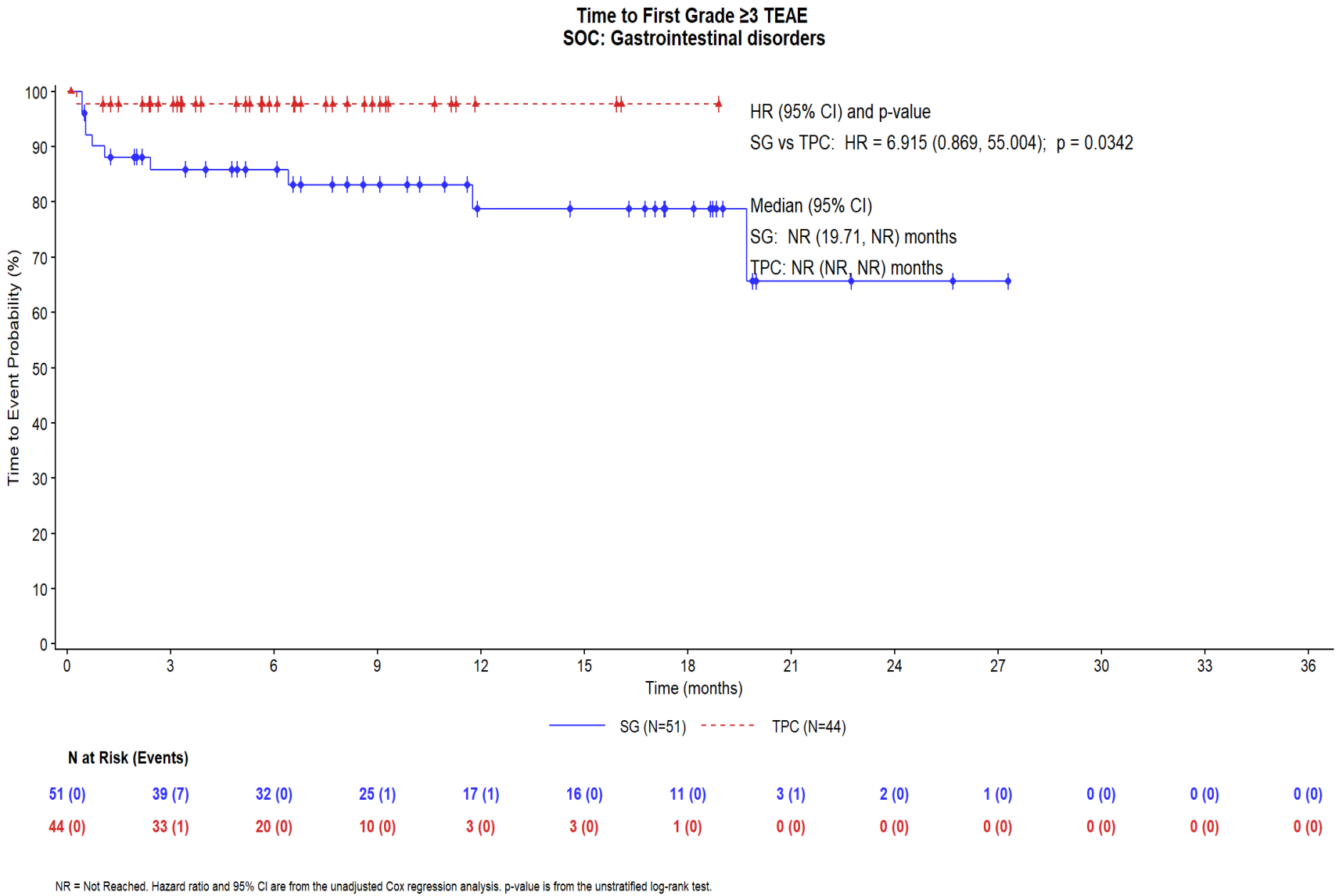
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.61. Figure 1.1.61: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



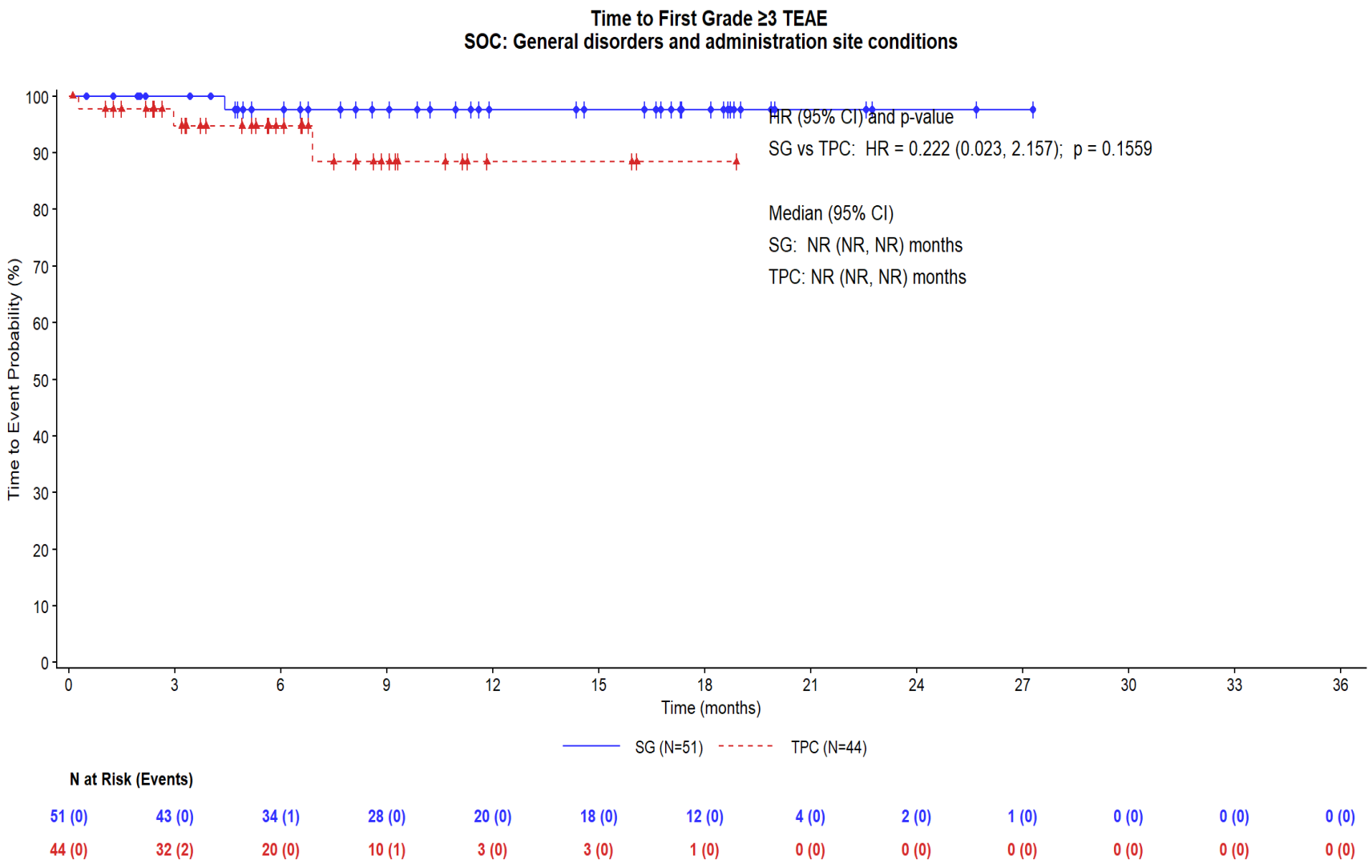
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.62. Figure 1.1.62: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



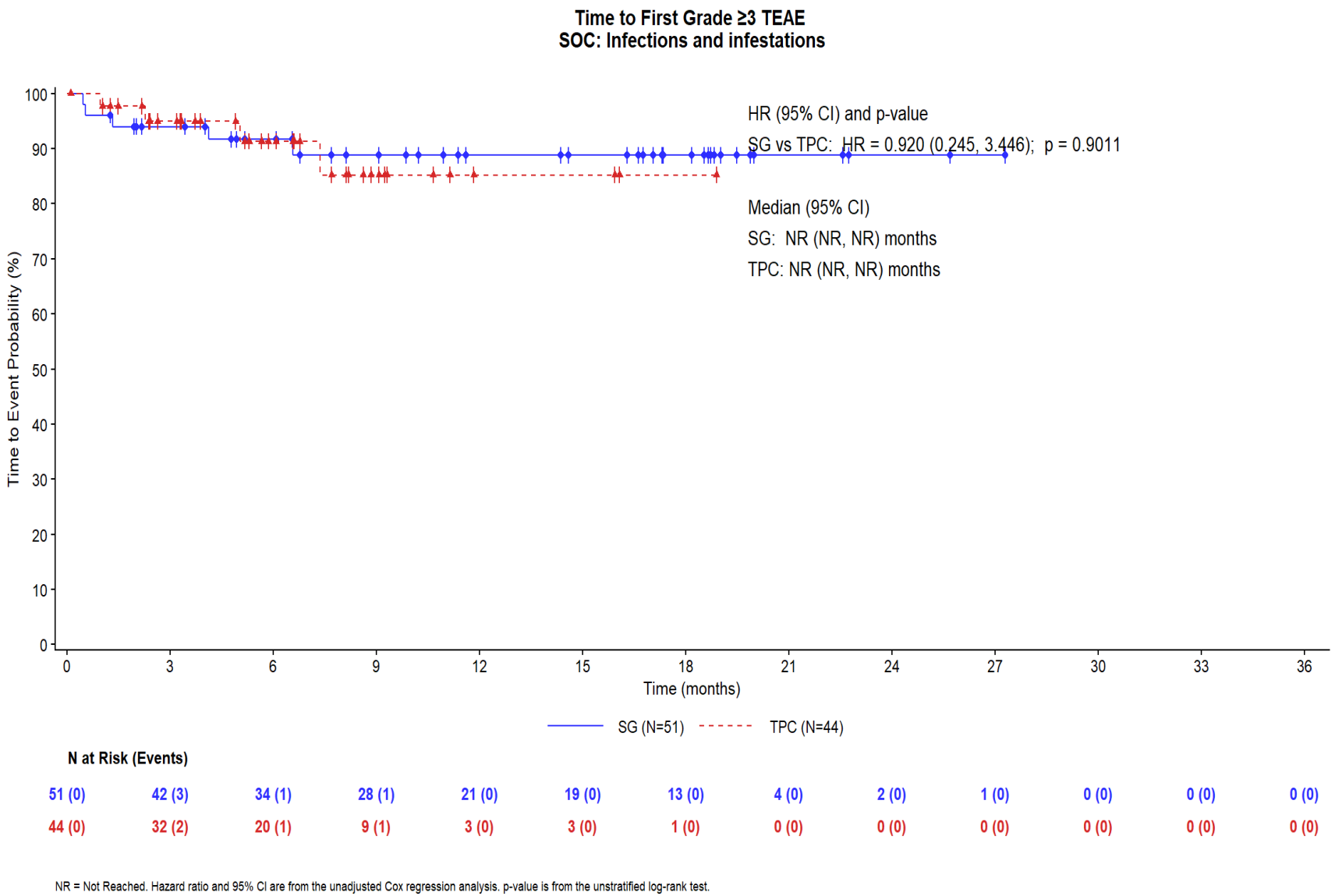
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.63. Figure 1.1.63: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



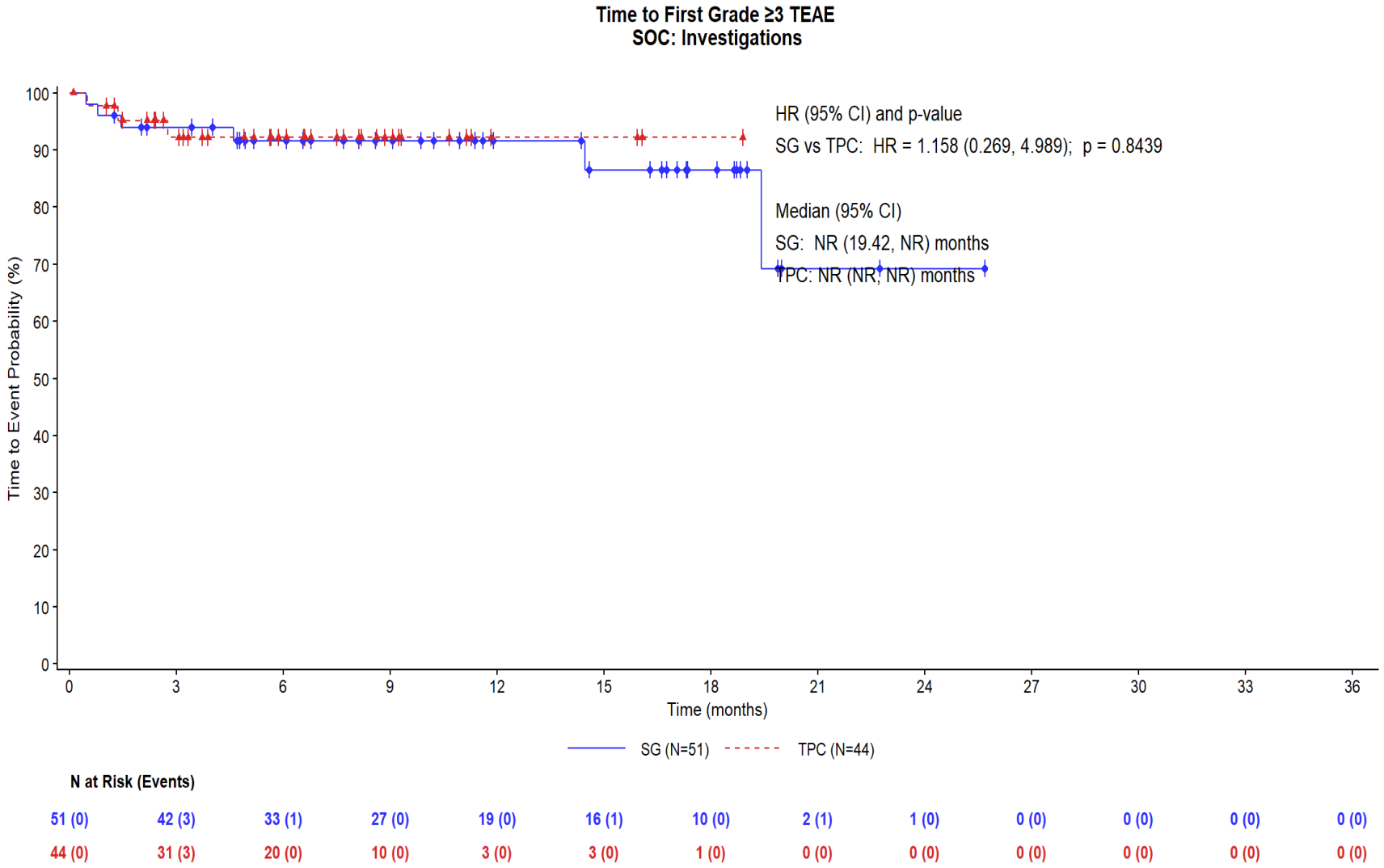
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.64. Figure 1.1.64: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



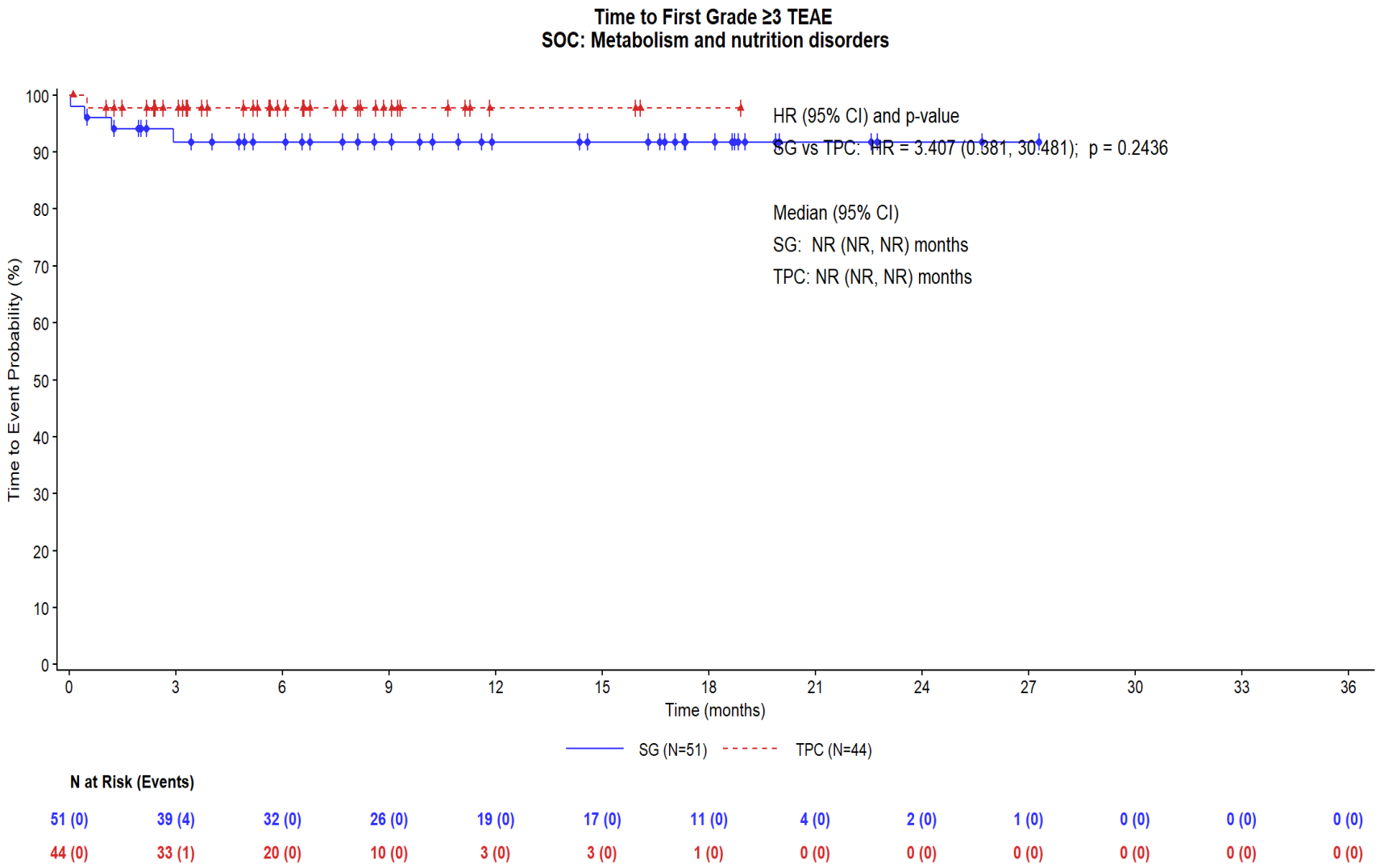
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.65. Figure 1.1.65: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



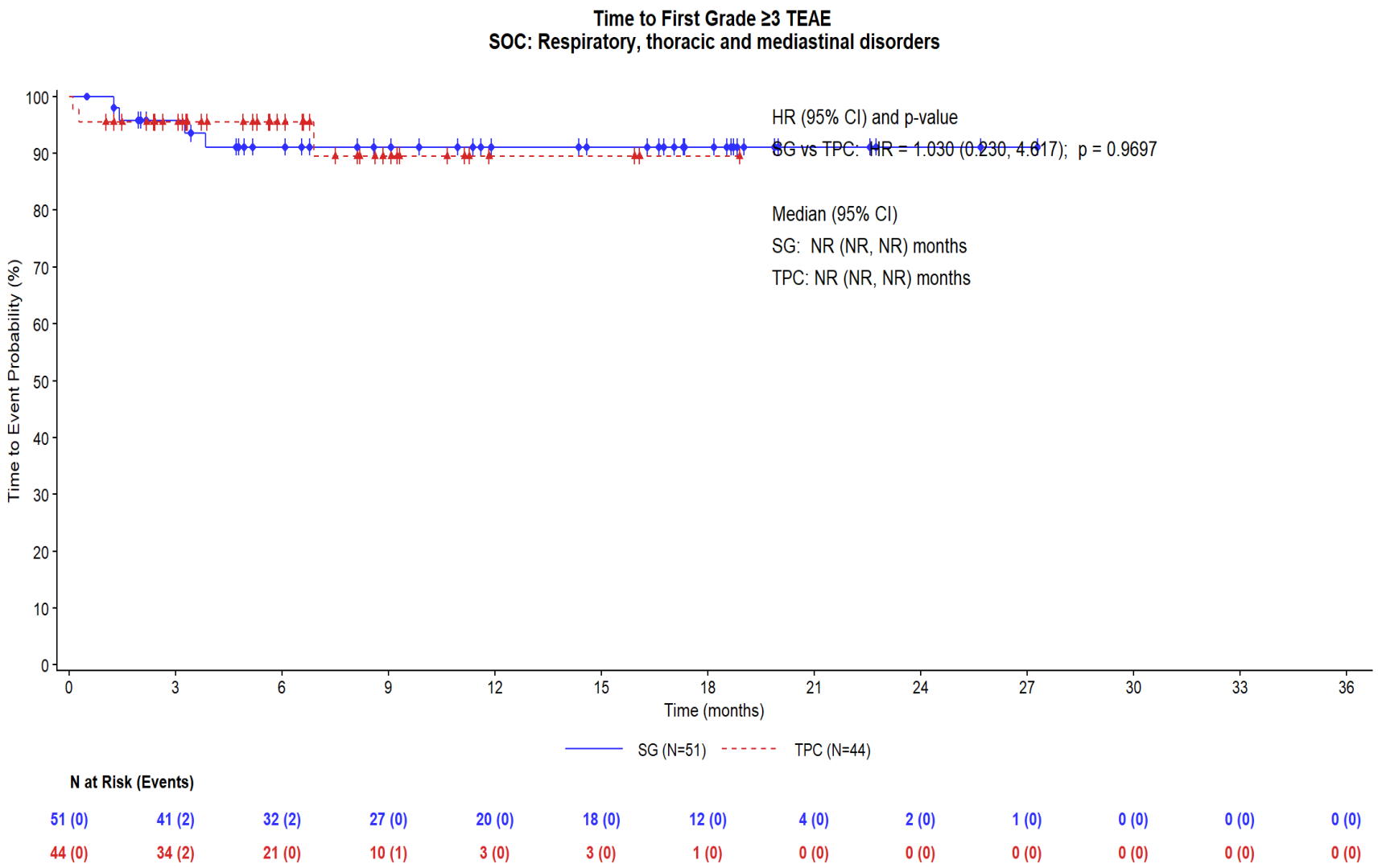
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.66. Figure 1.1.66: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



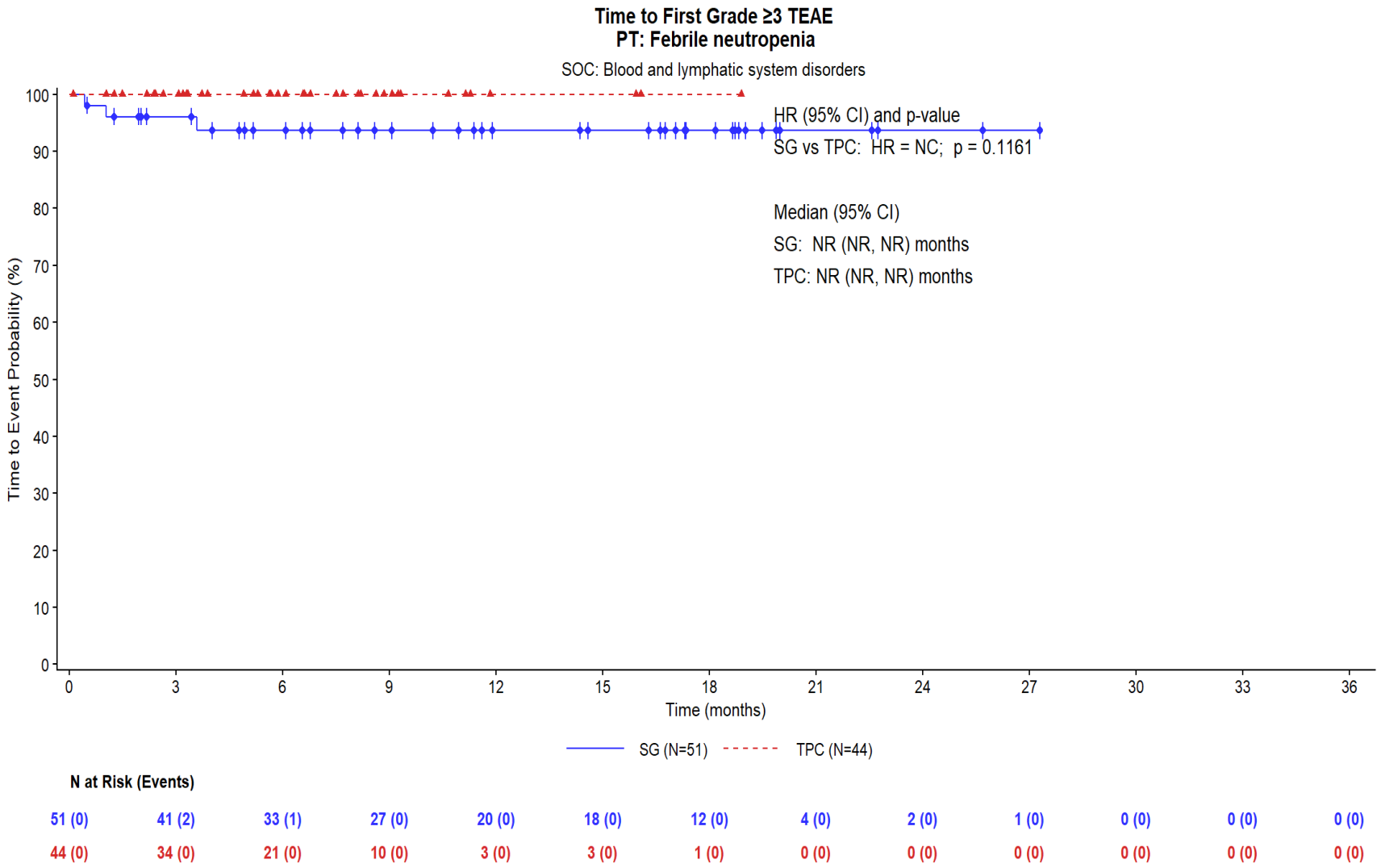
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.67. Figure 1.1.67: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



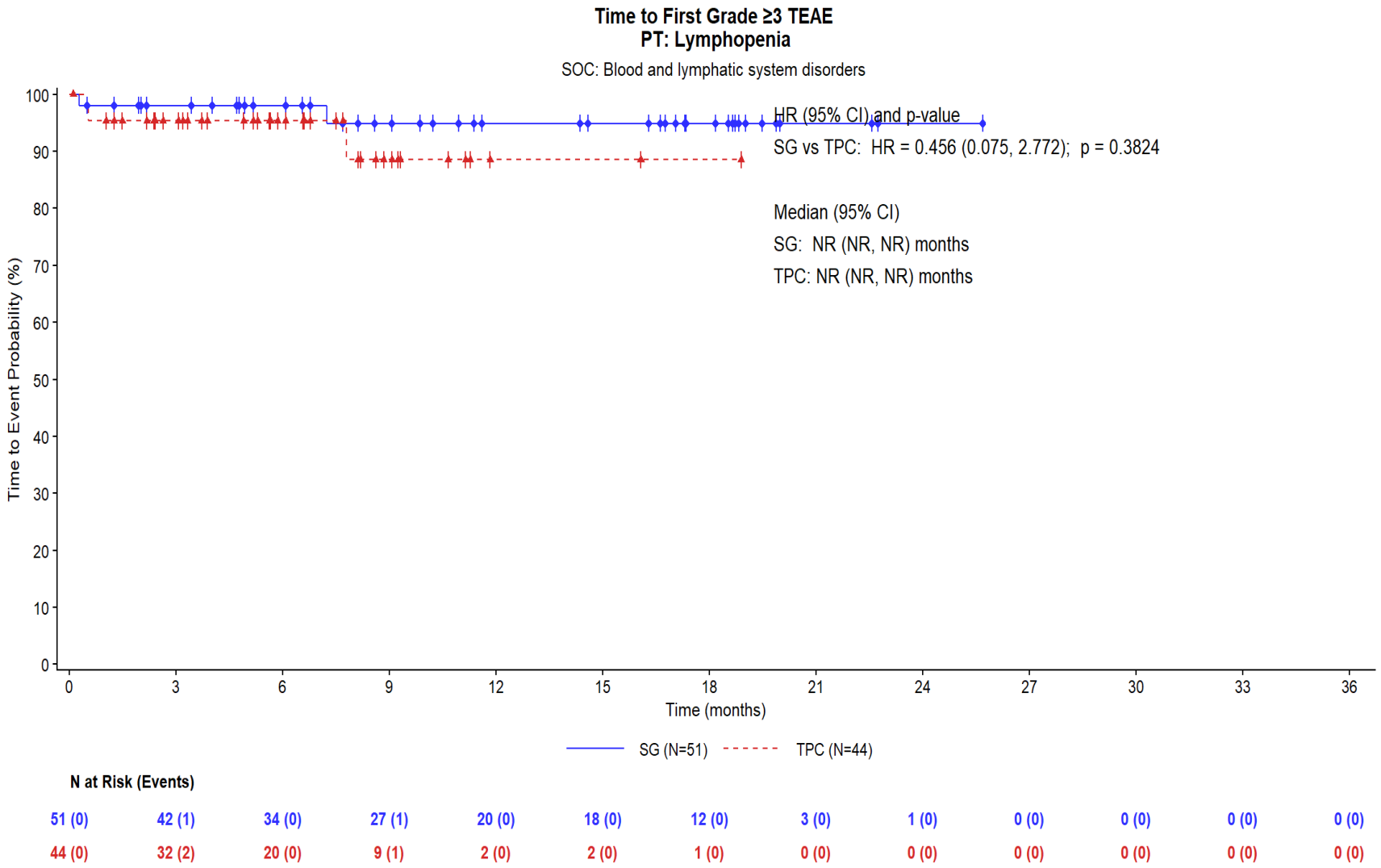
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.68. Figure 1.1.68: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Febrile neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



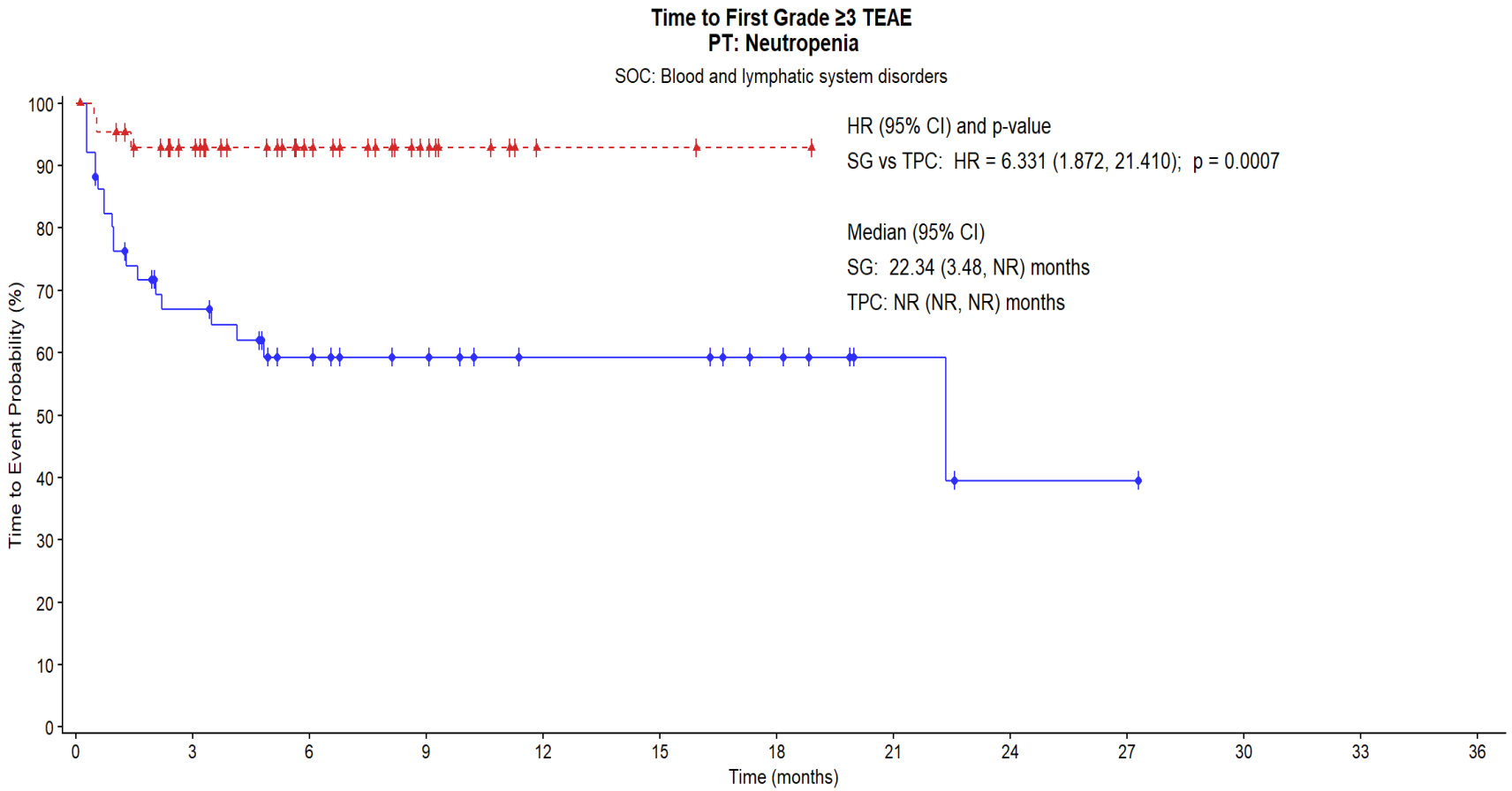
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.69. Figure 1.1.69: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



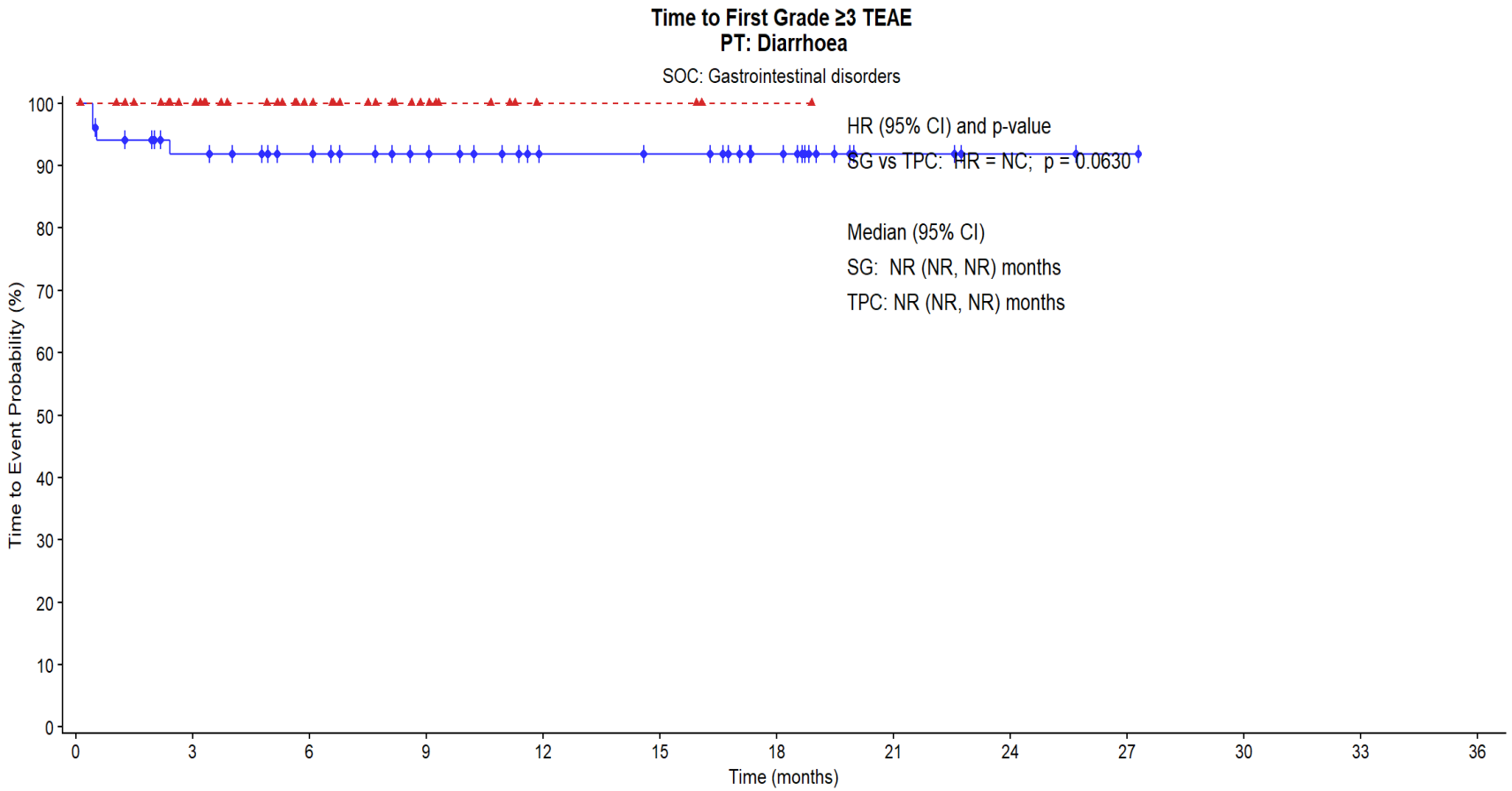
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.70. Figure 1.1.70: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



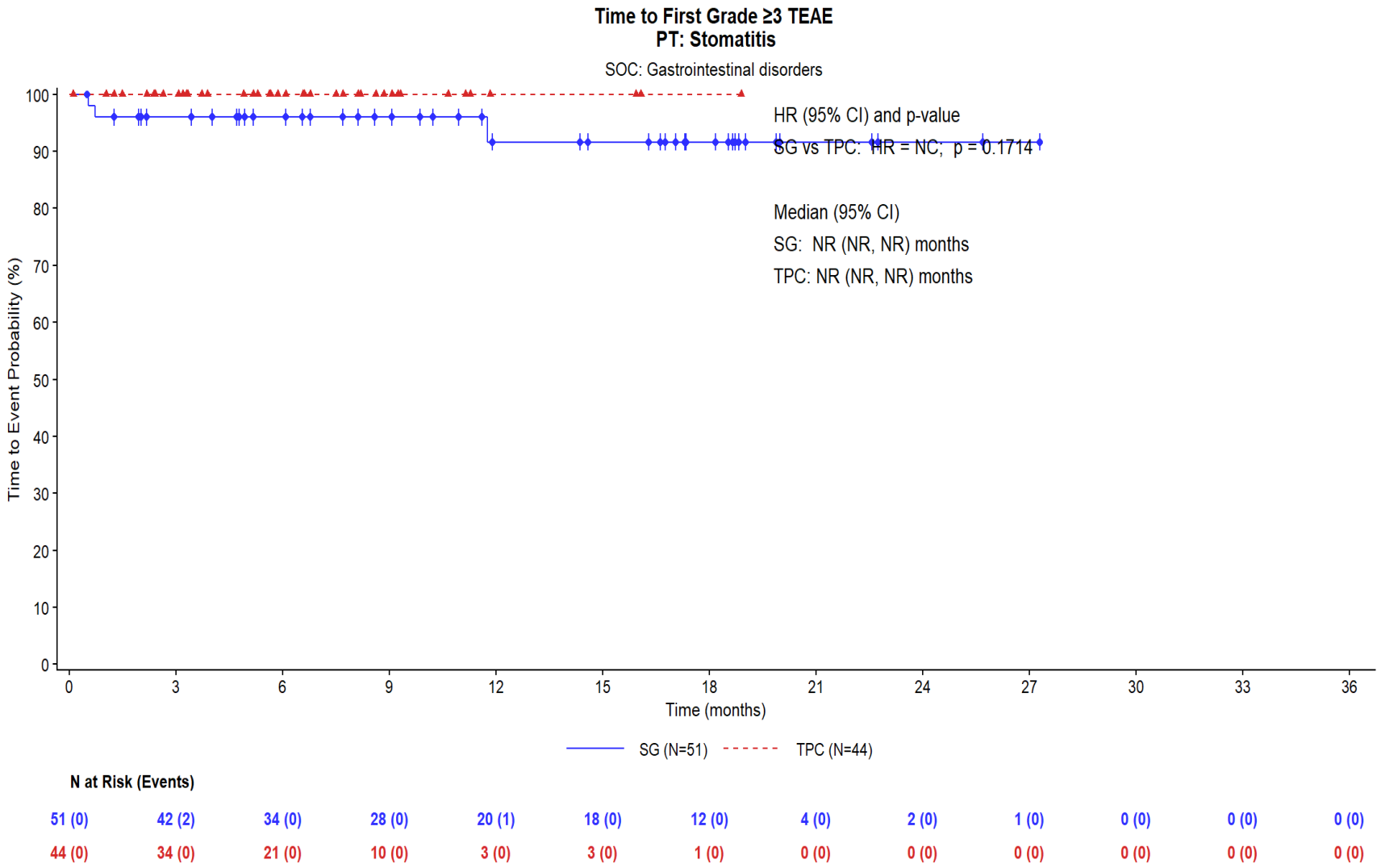
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.71. Figure 1.1.71: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



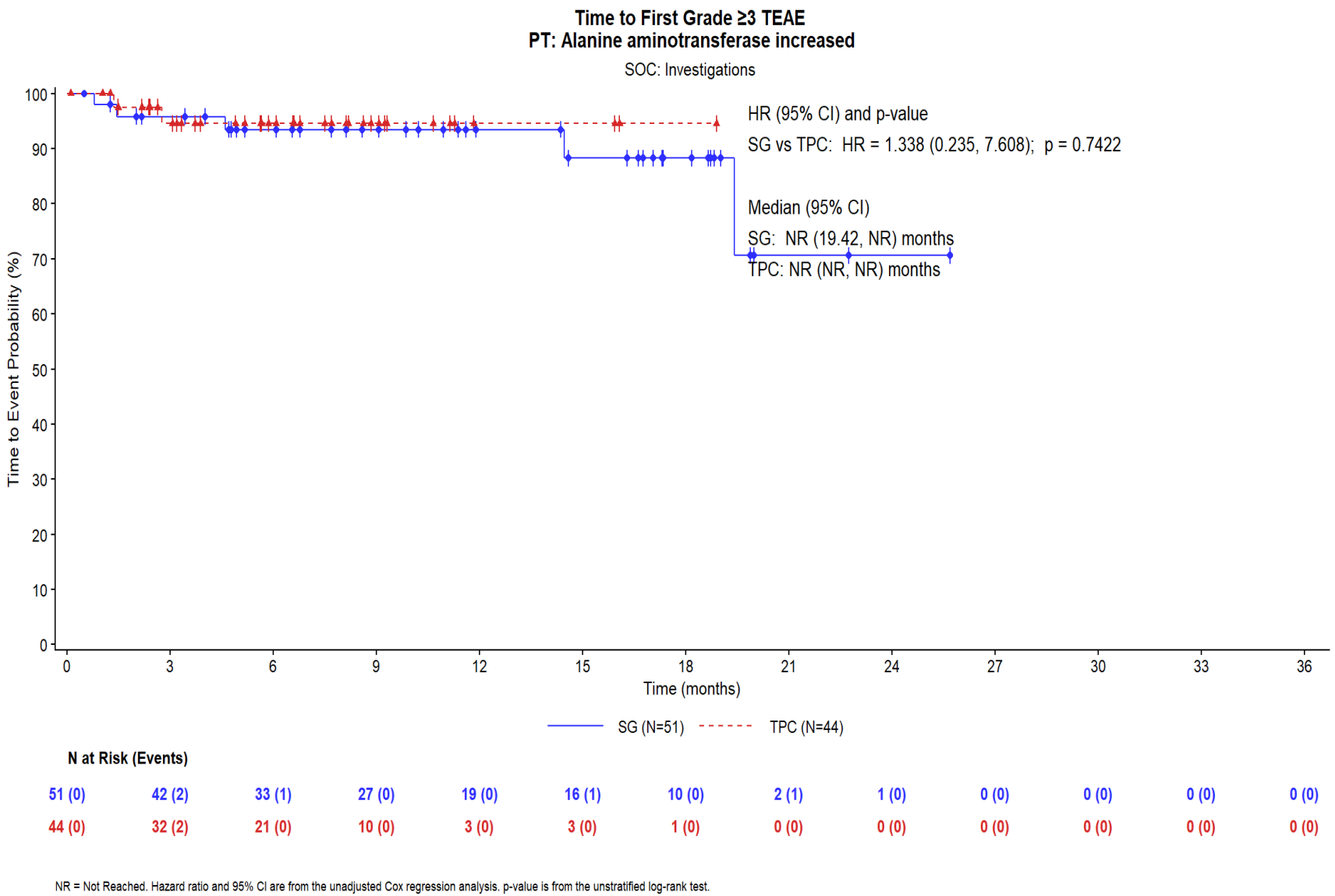
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.72. Figure 1.1.72: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



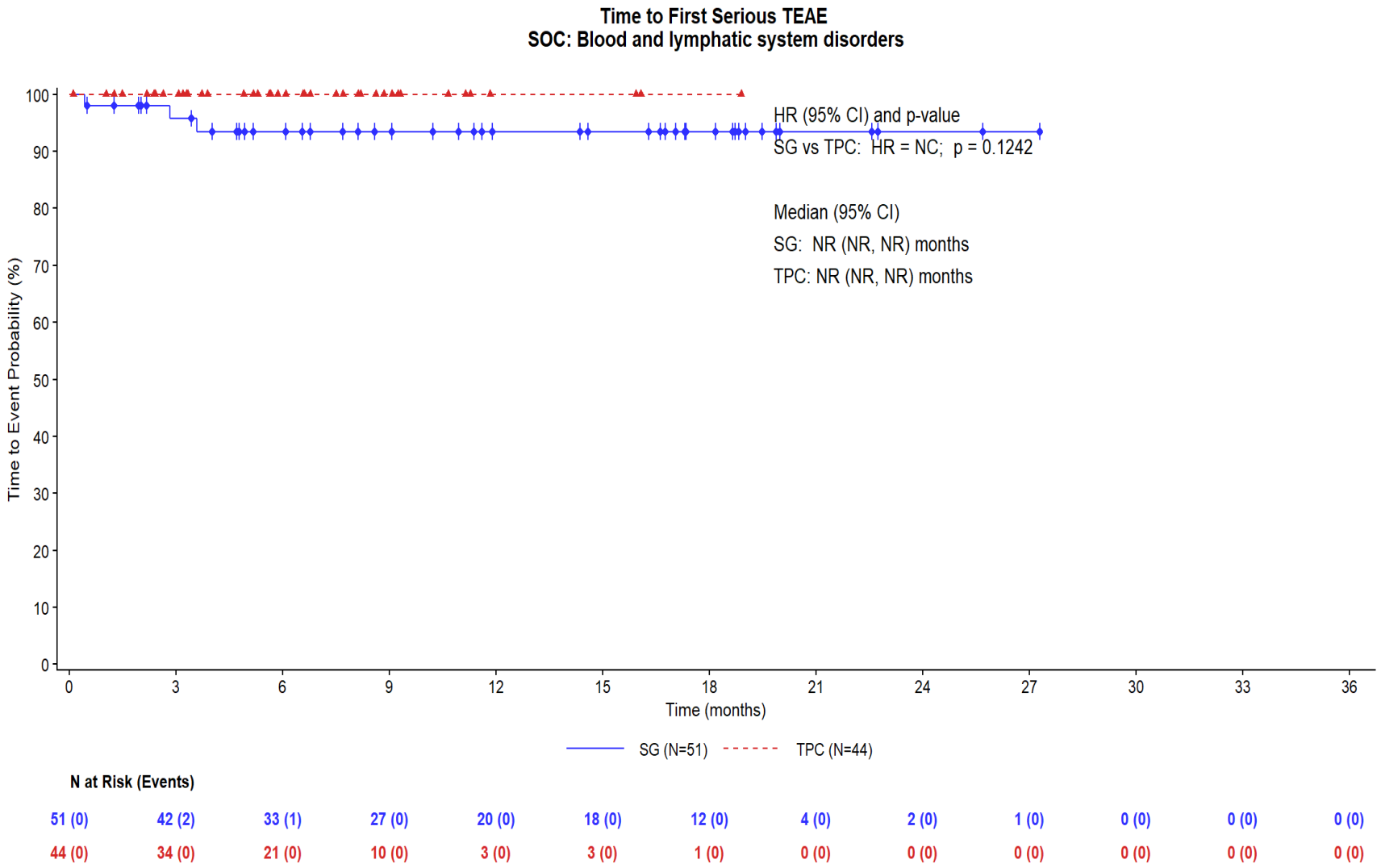
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.73. Figure 1.1.73: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



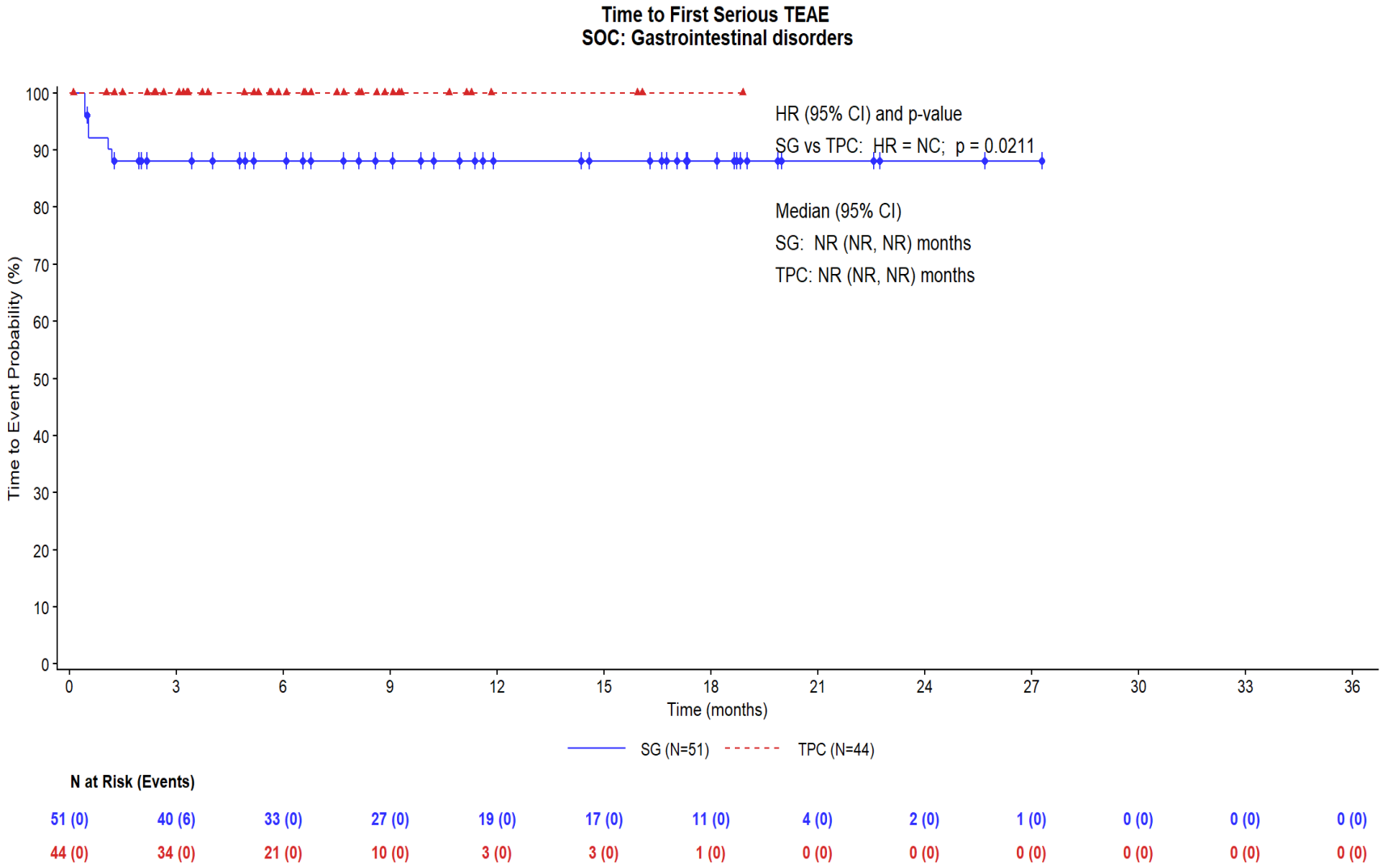
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.74. Figure 1.1.74: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



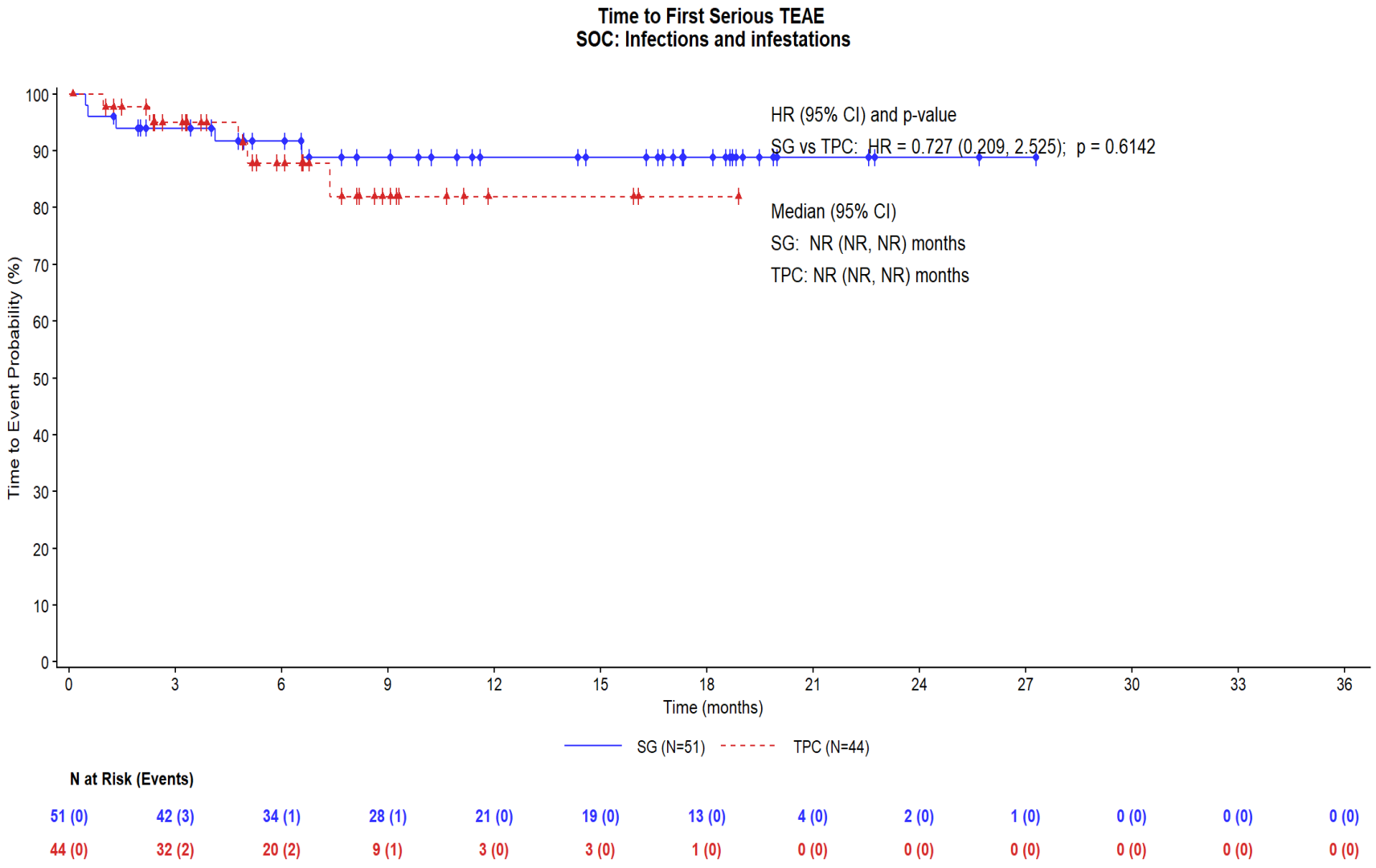
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.75. Figure 1.1.75: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



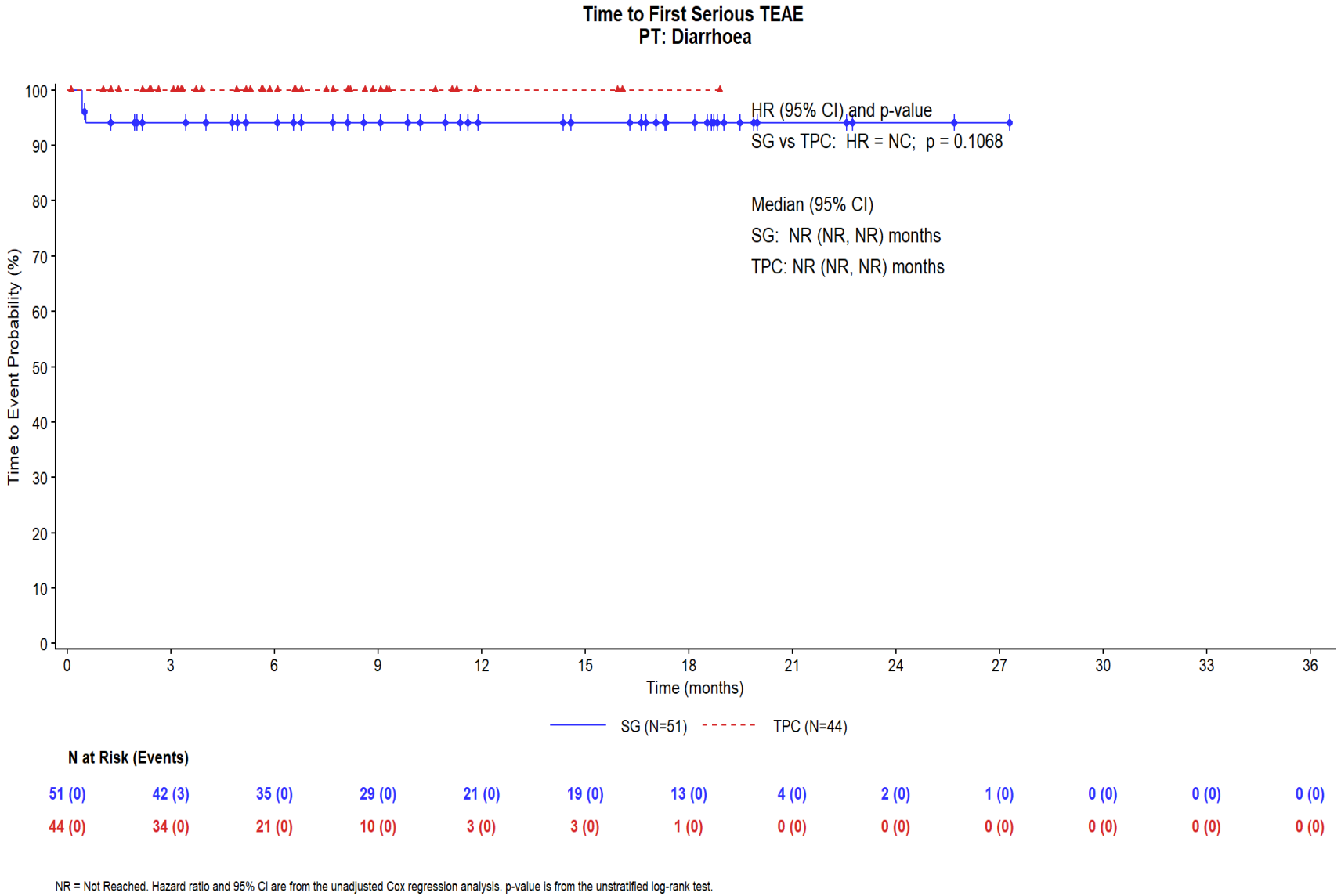
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.76. Figure 1.1.76: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.77. Figure 1.1.77: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

Table. Recurrence of diarrhoea TEAE — mSAF: Excluding patients preselected to nab-paclitaxel or gemcitabine+carboplatin

	SG (N=51)			TPC (N=44)		
Incidence of diarrhoea TEAE	**1 event**	**2 events**	**>2 events**	**1 event**	**2 events**	**>2 events**
Grade 1	17 (33.3%)	5 (9.8%)	4 (7.8%)	7 (15.9%)	0	2 (4.5%)
Grade 2	8 (15.7%)	2 (3.9%)	0	3 (6.8%)	1 (2.3%)	1 (2.3%)
Grade ≥3	3 (5.9%)	1 (2.0%)	0	0	0	0
Grade 3	4 (7.8%)	0	0	0	0	0
Grade 4	1 (2.0%)	0	0	0	0	0
Grade 5	0	0	0	0	0	0

n = number of events per patient;

GS-US-592-6238-20788-92106 (SG): 2 diarrhoea episodes at Grade≥3 (1×Grade 3 + 1×Grade 4)

Inhaltsverzeichnis – Patientenberichtete Endpunkte

Studie ASCENT-03 – Datenschnitt: 27. Oktober 2025

(Teil-)Population: Patient/-innen ohne hohen Remissionsdruck (Paclitaxel-Teilpopulation)

- Beobachtungsdauer
- Rücklaufquoten
- Ergebnisse:
    - EORTC QLQ-C30
    - EORTC QLQ-BR23
    - EQ-5D-5L VAS
    - PGI-C
    - PGI-S
- Subgruppenanalysen
- Abbildungen
    - Veränderung zu Baseline
    - Kaplan-Meier-Kurven
    - Kaplan-Meier-Kurven: Subgruppen

Table 1.2.1
Summary of Observation Period (Months) for EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Statistic	SG (N=52)	TPC (N=45)	Overall (N=97)
N	51	44	95
Mean (SD)	10.7 (7.55)	5.8 (4.21)	8.4 (6.67)
95% CI	8.6, 12.8	4.5, 7.1	7.1, 9.8
Median	10.0	5.7	6.9
Q1, Q3	4.4, 16.8	2.4, 8.5	3.2, 14.1
Min, Max	0.0, 27.5	0.0, 18.3	0.0, 27.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 1.2.2
Summary of Observation Period (Months) for EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Statistic	SG (N=52)	TPC (N=45)	Overall (N=97)
N	51	44	95
Mean (SD)	10.7 (7.55)	5.8 (4.27)	8.4 (6.70)
95% CI	8.6, 12.8	4.5, 7.1	7.1, 9.8
Median	10.0	5.7	6.9
Q1, Q3	4.4, 16.8	2.3, 8.5	3.2, 14.1
Min, Max	0.0, 27.5	0.0, 18.3	0.0, 27.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 1.2.3
Summary of Observation Period (Months) for EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Statistic	SG (N=52)	TPC (N=45)	Overall (N=97)
N	50	44	94
Mean (SD)	10.9 (7.47)	5.8 (4.27)	8.5 (6.68)
95% CI	8.8, 13.1	4.5, 7.1	7.1, 9.9
Median	10.1	5.7	7.0
Q1, Q3	4.4, 16.8	2.3, 8.5	3.2, 14.1
Min, Max	0.0, 27.5	0.0, 18.3	0.0, 27.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 1.2.4
Summary of Observation Period (Months) for PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Statistic	SG (N=52)	TPC (N=45)	Overall (N=97)
N	40	32	72
Mean (SD)	5.5 (0.88)	5.0 (0.99)	5.3 (0.96)
95% CI	5.2, 5.8	4.6, 5.4	5.1, 5.5
Median	5.7	5.5	5.6
Q1, Q3	5.4, 6.1	4.4, 5.6	4.7, 5.8
Min, Max	3.0, 6.5	2.8, 6.2	2.8, 6.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_obs_period.sas
Data Source: ADSL ADQSRun Date: 01MAY2026

Table 1.2.5
Summary of Observation Period (Months) for PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Statistic	SG (N=52)	TPC (N=45)	Overall (N=97)
N	49	43	92
Mean (SD)	4.5 (2.29)	3.7 (2.35)	4.1 (2.34)
95% CI	3.8, 5.2	3.0, 4.4	3.7, 4.6
Median	5.6	4.6	5.5
Q1, Q3	4.2, 6.0	0.0, 5.6	3.0, 5.8
Min, Max	0.0, 6.5	0.0, 6.2	0.0, 6.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_obs_period.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.2.1
Available Data Rate for the EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	38/52 (73.1%)	30/45 (66.7%)	68/97 (70.1%)
Week 7	40/52 (76.9%)	9/45 (20.0%)	49/97 (50.5%)
Week 10	36/52 (69.2%)	31/45 (68.9%)	67/97 (69.1%)
Week 13	34/52 (65.4%)	31/45 (68.9%)	65/97 (67.0%)
Week 16	36/52 (69.2%)	20/45 (44.4%)	56/97 (57.7%)
Week 19	31/52 (59.6%)	10/45 (22.2%)	41/97 (42.3%)
Week 22	30/52 (57.7%)	22/45 (48.9%)	52/97 (53.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	27/52 (51.9%)	13/45 (28.9%)	40/97 (41.2%)
Week 31	25/52 (48.1%)	5/45 (11.1%)	30/97 (30.9%)
Week 34	22/52 (42.3%)	9/45 (20.0%)	31/97 (32.0%)
Week 37	26/52 (50.0%)	8/45 (17.8%)	34/97 (35.1%)
Week 40	21/52 (40.4%)	5/45 (11.1%)	26/97 (26.8%)
Week 43	22/52 (42.3%)	3/45 (6.7%)	25/97 (25.8%)
Week 46	22/52 (42.3%)	4/45 (8.9%)	26/97 (26.8%)
Week 49	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 52	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 55	18/52 (34.6%)	2/45 (4.4%)	20/97 (20.6%)
Week 58	17/52 (32.7%)	3/45 (6.7%)	20/97 (20.6%)
Week 61	14/52 (26.9%)	3/45 (6.7%)	17/97 (17.5%)
Week 64	14/52 (26.9%)	2/45 (4.4%)	16/97 (16.5%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 67	15/52 (28.8%)	1/45 (2.2%)	16/97 (16.5%)
Week 70	17/52 (32.7%)	1/45 (2.2%)	18/97 (18.6%)
Week 73	13/52 (25.0%)	1/45 (2.2%)	14/97 (14.4%)
Week 76	10/52 (19.2%)	1/45 (2.2%)	11/97 (11.3%)
Week 79	10/52 (19.2%)	0/45 (0.0%)	10/97 (10.3%)
Week 82	6/52 (11.5%)	0/45 (0.0%)	6/97 (6.2%)
Week 85	6/52 (11.5%)	0/45 (0.0%)	6/97 (6.2%)
Week 88	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 91	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 94	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 97	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 100	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 103	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 106	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 109	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 112	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 115	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 121	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
End of Treatment	26/52 (50.0%)	30/45 (66.7%)	56/97 (57.7%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ITT = intent-to-treat.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.2.2
Available Data Rate for the EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	37/52 (71.2%)	30/45 (66.7%)	67/97 (69.1%)
Week 7	40/52 (76.9%)	8/45 (17.8%)	48/97 (49.5%)
Week 10	36/52 (69.2%)	31/45 (68.9%)	67/97 (69.1%)
Week 13	34/52 (65.4%)	30/45 (66.7%)	64/97 (66.0%)
Week 16	36/52 (69.2%)	19/45 (42.2%)	55/97 (56.7%)
Week 19	31/52 (59.6%)	10/45 (22.2%)	41/97 (42.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	27/52 (51.9%)	13/45 (28.9%)	40/97 (41.2%)
Week 31	25/52 (48.1%)	5/45 (11.1%)	30/97 (30.9%)
Week 34	22/52 (42.3%)	9/45 (20.0%)	31/97 (32.0%)
Week 37	26/52 (50.0%)	8/45 (17.8%)	34/97 (35.1%)
Week 40	21/52 (40.4%)	5/45 (11.1%)	26/97 (26.8%)
Week 43	22/52 (42.3%)	3/45 (6.7%)	25/97 (25.8%)
Week 46	22/52 (42.3%)	4/45 (8.9%)	26/97 (26.8%)
Week 49	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 52	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 55	18/52 (34.6%)	2/45 (4.4%)	20/97 (20.6%)
Week 58	17/52 (32.7%)	3/45 (6.7%)	20/97 (20.6%)
Week 61	14/52 (26.9%)	3/45 (6.7%)	17/97 (17.5%)
Week 64	14/52 (26.9%)	2/45 (4.4%)	16/97 (16.5%)
Week 67	15/52 (28.8%)	1/45 (2.2%)	16/97 (16.5%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 70	17/52 (32.7%)	1/45 (2.2%)	18/97 (18.6%)
Week 73	13/52 (25.0%)	1/45 (2.2%)	14/97 (14.4%)
Week 76	10/52 (19.2%)	1/45 (2.2%)	11/97 (11.3%)
Week 79	10/52 (19.2%)	0/45 (0.0%)	10/97 (10.3%)
Week 82	6/52 (11.5%)	0/45 (0.0%)	6/97 (6.2%)
Week 85	6/52 (11.5%)	0/45 (0.0%)	6/97 (6.2%)
Week 88	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 91	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 94	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 97	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 100	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 103	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 106	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 109	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 112	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 115	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 121	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
End of Treatment	26/52 (50.0%)	29/45 (64.4%)	55/97 (56.7%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer Module Questionnaire; ITT = intent-to-treat.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.2.3
Available Data Rate for the EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	49/52 (94.2%)	43/45 (95.6%)	92/97 (94.8%)
Week 4	37/52 (71.2%)	30/45 (66.7%)	67/97 (69.1%)
Week 7	40/52 (76.9%)	8/45 (17.8%)	48/97 (49.5%)
Week 10	36/52 (69.2%)	31/45 (68.9%)	67/97 (69.1%)
Week 13	34/52 (65.4%)	30/45 (66.7%)	64/97 (66.0%)
Week 16	36/52 (69.2%)	19/45 (42.2%)	55/97 (56.7%)
Week 19	31/52 (59.6%)	10/45 (22.2%)	41/97 (42.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	27/52 (51.9%)	13/45 (28.9%)	40/97 (41.2%)
Week 31	25/52 (48.1%)	5/45 (11.1%)	30/97 (30.9%)
Week 34	22/52 (42.3%)	9/45 (20.0%)	31/97 (32.0%)
Week 37	26/52 (50.0%)	8/45 (17.8%)	34/97 (35.1%)
Week 40	21/52 (40.4%)	5/45 (11.1%)	26/97 (26.8%)
Week 43	22/52 (42.3%)	3/45 (6.7%)	25/97 (25.8%)
Week 46	22/52 (42.3%)	4/45 (8.9%)	26/97 (26.8%)
Week 49	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 52	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 55	18/52 (34.6%)	2/45 (4.4%)	20/97 (20.6%)
Week 58	17/52 (32.7%)	3/45 (6.7%)	20/97 (20.6%)
Week 61	14/52 (26.9%)	3/45 (6.7%)	17/97 (17.5%)
Week 64	14/52 (26.9%)	2/45 (4.4%)	16/97 (16.5%)
Week 67	15/52 (28.8%)	1/45 (2.2%)	16/97 (16.5%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 70	17/52 (32.7%)	1/45 (2.2%)	18/97 (18.6%)
Week 73	13/52 (25.0%)	1/45 (2.2%)	14/97 (14.4%)
Week 76	10/52 (19.2%)	1/45 (2.2%)	11/97 (11.3%)
Week 79	10/52 (19.2%)	0/45 (0.0%)	10/97 (10.3%)
Week 82	6/52 (11.5%)	0/45 (0.0%)	6/97 (6.2%)
Week 85	6/52 (11.5%)	0/45 (0.0%)	6/97 (6.2%)
Week 88	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 91	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 94	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 97	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 100	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 103	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 106	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 109	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 112	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 115	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 121	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
End of Treatment	26/52 (50.0%)	29/45 (64.4%)	55/97 (56.7%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; VAS = Visual analogue scale.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.2.4
Available Data Rate for the PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 13	23/52 (44.2%)	29/45 (64.4%)	52/97 (53.6%)
Week 16	35/52 (67.3%)	19/45 (42.2%)	54/97 (55.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; PGIC = Patient Global Impression of Change.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.2.5
Available Data Rate for the PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	49/52 (94.2%)	43/45 (95.6%)	92/97 (94.8%)
Week 13	23/52 (44.2%)	29/45 (64.4%)	52/97 (53.6%)
Week 16	35/52 (67.3%)	19/45 (42.2%)	54/97 (55.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; PGIS = Patient Global Impression of Severity.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.3.1
Modified Available Data Rate for the EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	38/51 (74.5%)	30/44 (68.2%)	68/95 (71.6%)
Week 7	40/51 (78.4%)	9/44 (20.5%)	49/95 (51.6%)
Week 10	36/51 (70.6%)	31/44 (70.5%)	67/95 (70.5%)
Week 13	34/51 (66.7%)	31/43 (72.1%)	65/94 (69.1%)
Week 16	36/51 (70.6%)	20/43 (46.5%)	56/94 (59.6%)
Week 19	31/51 (60.8%)	10/41 (24.4%)	41/92 (44.6%)
Week 22	30/51 (58.8%)	22/41 (53.7%)	52/92 (56.5%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	27/49 (55.1%)	13/40 (32.5%)	40/89 (44.9%)
Week 31	25/49 (51.0%)	5/40 (12.5%)	30/89 (33.7%)
Week 34	22/49 (44.9%)	9/39 (23.1%)	31/88 (35.2%)
Week 37	26/48 (54.2%)	8/39 (20.5%)	34/87 (39.1%)
Week 40	21/47 (44.7%)	5/39 (12.8%)	26/86 (30.2%)
Week 43	22/47 (46.8%)	3/38 (7.9%)	25/85 (29.4%)
Week 46	22/47 (46.8%)	4/38 (10.5%)	26/85 (30.6%)
Week 49	16/46 (34.8%)	2/36 (5.6%)	18/82 (22.0%)
Week 52	16/46 (34.8%)	2/35 (5.7%)	18/81 (22.2%)
Week 55	18/44 (40.9%)	2/34 (5.9%)	20/78 (25.6%)
Week 58	17/43 (39.5%)	3/32 (9.4%)	20/75 (26.7%)
Week 61	14/41 (34.1%)	3/30 (10.0%)	17/71 (23.9%)
Week 64	14/41 (34.1%)	2/28 (7.1%)	16/69 (23.2%)
Week 67	15/41 (36.6%)	1/28 (3.6%)	16/69 (23.2%)
Week 70	17/39 (43.6%)	1/26 (3.8%)	18/65 (27.7%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 73	13/38 (34.2%)	1/24 (4.2%)	14/62 (22.6%)
Week 76	10/38 (26.3%)	1/24 (4.2%)	11/62 (17.7%)
Week 79	10/36 (27.8%)	0/23 (0.0%)	10/59 (16.9%)
Week 82	6/36 (16.7%)	0/23 (0.0%)	6/59 (10.2%)
Week 85	6/36 (16.7%)	0/23 (0.0%)	6/59 (10.2%)
Week 88	4/36 (11.1%)	0/22 (0.0%)	4/58 (6.9%)
Week 91	3/35 (8.6%)	0/21 (0.0%)	3/56 (5.4%)
Week 94	4/34 (11.8%)	0/20 (0.0%)	4/54 (7.4%)
Week 97	3/34 (8.8%)	0/20 (0.0%)	3/54 (5.6%)
Week 100	2/34 (5.9%)	0/20 (0.0%)	2/54 (3.7%)
Week 103	2/33 (6.1%)	0/20 (0.0%)	2/53 (3.8%)
Week 106	2/33 (6.1%)	0/20 (0.0%)	2/53 (3.8%)
Week 109	2/33 (6.1%)	0/19 (0.0%)	2/52 (3.8%)
Week 112	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
Week 115	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
Week 121	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
End of Treatment	26/39 (66.7%)	30/41 (73.2%)	56/80 (70.0%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ITT = intent-to-treat.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.3.2
Modified Available Data Rate for the EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	37/51 (72.5%)	30/44 (68.2%)	67/95 (70.5%)
Week 7	40/51 (78.4%)	8/44 (18.2%)	48/95 (50.5%)
Week 10	36/51 (70.6%)	31/44 (70.5%)	67/95 (70.5%)
Week 13	34/51 (66.7%)	30/43 (69.8%)	64/94 (68.1%)
Week 16	36/51 (70.6%)	19/43 (44.2%)	55/94 (58.5%)
Week 19	31/51 (60.8%)	10/41 (24.4%)	41/92 (44.6%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	27/49 (55.1%)	13/40 (32.5%)	40/89 (44.9%)
Week 31	25/49 (51.0%)	5/40 (12.5%)	30/89 (33.7%)
Week 34	22/49 (44.9%)	9/39 (23.1%)	31/88 (35.2%)
Week 37	26/48 (54.2%)	8/39 (20.5%)	34/87 (39.1%)
Week 40	21/47 (44.7%)	5/39 (12.8%)	26/86 (30.2%)
Week 43	22/47 (46.8%)	3/38 (7.9%)	25/85 (29.4%)
Week 46	22/47 (46.8%)	4/38 (10.5%)	26/85 (30.6%)
Week 49	16/46 (34.8%)	2/36 (5.6%)	18/82 (22.0%)
Week 52	16/46 (34.8%)	2/35 (5.7%)	18/81 (22.2%)
Week 55	18/44 (40.9%)	2/34 (5.9%)	20/78 (25.6%)
Week 58	17/43 (39.5%)	3/32 (9.4%)	20/75 (26.7%)
Week 61	14/41 (34.1%)	3/30 (10.0%)	17/71 (23.9%)
Week 64	14/41 (34.1%)	2/28 (7.1%)	16/69 (23.2%)
Week 67	15/41 (36.6%)	1/28 (3.6%)	16/69 (23.2%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 70	17/39 (43.6%)	1/26 (3.8%)	18/65 (27.7%)
Week 73	13/38 (34.2%)	1/24 (4.2%)	14/62 (22.6%)
Week 76	10/38 (26.3%)	1/24 (4.2%)	11/62 (17.7%)
Week 79	10/36 (27.8%)	0/23 (0.0%)	10/59 (16.9%)
Week 82	6/36 (16.7%)	0/23 (0.0%)	6/59 (10.2%)
Week 85	6/36 (16.7%)	0/23 (0.0%)	6/59 (10.2%)
Week 88	4/36 (11.1%)	0/22 (0.0%)	4/58 (6.9%)
Week 91	3/35 (8.6%)	0/21 (0.0%)	3/56 (5.4%)
Week 94	4/34 (11.8%)	0/20 (0.0%)	4/54 (7.4%)
Week 97	3/34 (8.8%)	0/20 (0.0%)	3/54 (5.6%)
Week 100	2/34 (5.9%)	0/20 (0.0%)	2/54 (3.7%)
Week 103	2/33 (6.1%)	0/20 (0.0%)	2/53 (3.8%)
Week 106	2/33 (6.1%)	0/20 (0.0%)	2/53 (3.8%)
Week 109	2/33 (6.1%)	0/19 (0.0%)	2/52 (3.8%)
Week 112	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
Week 115	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
Week 121	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
End of Treatment	26/39 (66.7%)	29/41 (70.7%)	55/80 (68.8%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer Module Questionnaire; ITT = intent-to-treat.

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Table 2.2.3.3
Modified Available Data Rate for the EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	49/52 (94.2%)	43/45 (95.6%)	92/97 (94.8%)
Week 4	37/51 (72.5%)	30/44 (68.2%)	67/95 (70.5%)
Week 7	40/51 (78.4%)	8/44 (18.2%)	48/95 (50.5%)
Week 10	36/51 (70.6%)	31/44 (70.5%)	67/95 (70.5%)
Week 13	34/51 (66.7%)	30/43 (69.8%)	64/94 (68.1%)
Week 16	36/51 (70.6%)	19/43 (44.2%)	55/94 (58.5%)
Week 19	31/51 (60.8%)	10/41 (24.4%)	41/92 (44.6%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	27/49 (55.1%)	13/40 (32.5%)	40/89 (44.9%)
Week 31	25/49 (51.0%)	5/40 (12.5%)	30/89 (33.7%)
Week 34	22/49 (44.9%)	9/39 (23.1%)	31/88 (35.2%)
Week 37	26/48 (54.2%)	8/39 (20.5%)	34/87 (39.1%)
Week 40	21/47 (44.7%)	5/39 (12.8%)	26/86 (30.2%)
Week 43	22/47 (46.8%)	3/38 (7.9%)	25/85 (29.4%)
Week 46	22/47 (46.8%)	4/38 (10.5%)	26/85 (30.6%)
Week 49	16/46 (34.8%)	2/36 (5.6%)	18/82 (22.0%)
Week 52	16/46 (34.8%)	2/35 (5.7%)	18/81 (22.2%)
Week 55	18/44 (40.9%)	2/34 (5.9%)	20/78 (25.6%)
Week 58	17/43 (39.5%)	3/32 (9.4%)	20/75 (26.7%)
Week 61	14/41 (34.1%)	3/30 (10.0%)	17/71 (23.9%)
Week 64	14/41 (34.1%)	2/28 (7.1%)	16/69 (23.2%)
Week 67	15/41 (36.6%)	1/28 (3.6%)	16/69 (23.2%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 70	17/39 (43.6%)	1/26 (3.8%)	18/65 (27.7%)
Week 73	13/38 (34.2%)	1/24 (4.2%)	14/62 (22.6%)
Week 76	10/38 (26.3%)	1/24 (4.2%)	11/62 (17.7%)
Week 79	10/36 (27.8%)	0/23 (0.0%)	10/59 (16.9%)
Week 82	6/36 (16.7%)	0/23 (0.0%)	6/59 (10.2%)
Week 85	6/36 (16.7%)	0/23 (0.0%)	6/59 (10.2%)
Week 88	4/36 (11.1%)	0/22 (0.0%)	4/58 (6.9%)
Week 91	3/35 (8.6%)	0/21 (0.0%)	3/56 (5.4%)
Week 94	4/34 (11.8%)	0/20 (0.0%)	4/54 (7.4%)
Week 97	3/34 (8.8%)	0/20 (0.0%)	3/54 (5.6%)
Week 100	2/34 (5.9%)	0/20 (0.0%)	2/54 (3.7%)
Week 103	2/33 (6.1%)	0/20 (0.0%)	2/53 (3.8%)
Week 106	2/33 (6.1%)	0/20 (0.0%)	2/53 (3.8%)
Week 109	2/33 (6.1%)	0/19 (0.0%)	2/52 (3.8%)
Week 112	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
Week 115	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
Week 121	1/33 (3.0%)	0/19 (0.0%)	1/52 (1.9%)
End of Treatment	26/39 (66.7%)	29/41 (70.7%)	55/80 (68.8%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; VAS = Visual analogue scale.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.3.4
Modified Available Data Rate for the PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 13	23/51 (45.1%)	29/43 (67.4%)	52/94 (55.3%)
Week 16	35/51 (68.6%)	19/43 (44.2%)	54/94 (57.4%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	15/49 (30.6%)	3/40 (7.5%)	18/89 (20.2%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; PGIC = Patient Global Impression of Change.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.2.3.5
Modified Available Data Rate for the PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	49/52 (94.2%)	43/45 (95.6%)	92/97 (94.8%)
Week 13	23/51 (45.1%)	29/43 (67.4%)	52/94 (55.3%)
Week 16	35/51 (68.6%)	19/43 (44.2%)	54/94 (57.4%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	15/49 (30.6%)	3/40 (7.5%)	18/89 (20.2%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; PGIS = Patient Global Impression of Severity.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 3.2.2.1
Distribution of Responses to PGIC by Visit
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Item	Visit	Response Level	SG (N=52)	TPC (N=45)	Overall (N=97)
PGIC	Week 13		N=23	N=29	N=52
		Very Much Improved	1 (4.3%)	3 (10.3%)	4 (7.7%)
		Much Improved	4 (17.4%)	5 (17.2%)	9 (17.3%)
		Minimally Improved	10 (43.5%)	9 (31.0%)	19 (36.5%)
		No Change	4 (17.4%)	4 (13.8%)	8 (15.4%)
		Minimally Worsened	3 (13.0%)	7 (24.1%)	10 (19.2%)
		Much Worsened	1 (4.3%)	1 (3.4%)	2 (3.8%)
	Week 16		N=35	N=19	N=54
		Very Much Improved	4 (11.4%)	1 (5.3%)	5 (9.3%)
		Much Improved	7 (20.0%)	6 (31.6%)	13 (24.1%)
		Minimally Improved	13 (37.1%)	5 (26.3%)	18 (33.3%)
		No Change	5 (14.3%)	3 (15.8%)	8 (14.8%)
		Minimally Worsened	4 (11.4%)	3 (15.8%)	7 (13.0%)
		Much Worsened	2 (5.7%)	1 (5.3%)	3 (5.6%)
	Week 19		N=31	N=11	N=42
		Very Much Improved	2 (6.5%)	0 (0.0%)	2 (4.8%)
		Much Improved	10 (32.3%)	2 (18.2%)	12 (28.6%)
		Minimally Improved	6 (19.4%)	2 (18.2%)	8 (19.0%)
		No Change	5 (16.1%)	4 (36.4%)	9 (21.4%)
		Minimally Worsened	7 (22.6%)	2 (18.2%)	9 (21.4%)
		Much Worsened	1 (3.2%)	1 (9.1%)	2 (4.8%)
	Week 22		N=30	N=21	N=51
		Very Much Improved	2 (6.7%)	2 (9.5%)	4 (7.8%)
		Much Improved	12 (40.0%)	6 (28.6%)	18 (35.3%)
		Minimally Improved	4 (13.3%)	3 (14.3%)	7 (13.7%)
		No Change	6 (20.0%)	4 (19.0%)	10 (19.6%)
		Minimally Worsened	5 (16.7%)	4 (19.0%)	9 (17.6%)
		Much Worsened	1 (3.3%)	2 (9.5%)	3 (5.9%)
	Week 25		N=30	N=17	N=47
		Very Much Improved	3 (10.0%)	1 (5.9%)	4 (8.5%)
		Much Improved	12 (40.0%)	6 (35.3%)	18 (38.3%)
		Minimally Improved	7 (23.3%)	2 (11.8%)	9 (19.1%)
		No Change	5 (16.7%)	2 (11.8%)	7 (14.9%)
		Minimally Worsened	2 (6.7%)	5 (29.4%)	7 (14.9%)
		Much Worsened	1 (3.3%)	1 (5.9%)	2 (4.3%)
	Week 28		N=15	N=3	N=18
		Very Much Improved	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Much Improved	3 (20.0%)	2 (66.7%)	5 (27.8%)
		Minimally Improved	7 (46.7%)	1 (33.3%)	8 (44.4%)
		No Change	2 (13.3%)	0 (0.0%)	2 (11.1%)
		Minimally Worsened	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Much Worsened	1 (6.7%)	0 (0.0%)	1 (5.6%)

Item	Visit	Response Level	SG (N=52)	TPC (N=45)	Overall (N=97)

PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 3.2.2.2
Distribution of Responses to PGIS by Visit
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Item	Visit	Response Level	SG (N=52)	TPC (N=45)	Overall (N=97)
PGIS	Baseline (Week 1)		N=49	N=43	N=92
		Very Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Poor	8 (16.3%)	8 (18.6%)	16 (17.4%)
		Fair	14 (28.6%)	13 (30.2%)	27 (29.3%)
		Good	23 (46.9%)	15 (34.9%)	38 (41.3%)
		Excellent	4 (8.2%)	7 (16.3%)	11 (12.0%)
	Week 13		N=23	N=29	N=52
		Very Poor	1 (4.3%)	0 (0.0%)	1 (1.9%)
		Poor	3 (13.0%)	2 (6.9%)	5 (9.6%)
		Fair	10 (43.5%)	14 (48.3%)	24 (46.2%)
		Good	8 (34.8%)	12 (41.4%)	20 (38.5%)
		Excellent	1 (4.3%)	1 (3.4%)	2 (3.8%)
	Week 16		N=35	N=19	N=54
		Very Poor	1 (2.9%)	0 (0.0%)	1 (1.9%)
		Poor	4 (11.4%)	4 (21.1%)	8 (14.8%)
		Fair	21 (60.0%)	6 (31.6%)	27 (50.0%)
		Good	7 (20.0%)	9 (47.4%)	16 (29.6%)
		Excellent	2 (5.7%)	0 (0.0%)	2 (3.7%)
	Week 19		N=31	N=11	N=42
		Very Poor	0 (0.0%)	2 (18.2%)	2 (4.8%)
		Poor	4 (12.9%)	0 (0.0%)	4 (9.5%)
		Fair	12 (38.7%)	5 (45.5%)	17 (40.5%)
		Good	14 (45.2%)	4 (36.4%)	18 (42.9%)
		Excellent	1 (3.2%)	0 (0.0%)	1 (2.4%)
	Week 22		N=30	N=21	N=51
		Very Poor	1 (3.3%)	0 (0.0%)	1 (2.0%)
		Poor	2 (6.7%)	6 (28.6%)	8 (15.7%)
		Fair	16 (53.3%)	6 (28.6%)	22 (43.1%)
		Good	11 (36.7%)	9 (42.9%)	20 (39.2%)
		Excellent	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 25		N=30	N=17	N=47
		Very Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Poor	6 (20.0%)	4 (23.5%)	10 (21.3%)
		Fair	10 (33.3%)	5 (29.4%)	15 (31.9%)
		Good	14 (46.7%)	8 (47.1%)	22 (46.8%)
		Excellent	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 28		N=15	N=3	N=18
		Very Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Poor	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Fair	10 (66.7%)	0 (0.0%)	10 (55.6%)
		Good	4 (26.7%)	2 (66.7%)	6 (33.3%)

Item	Visit	Response Level	SG (N=52)	TPC (N=45)	Overall (N=97)
		Excellent	0 (0.0%)	1 (33.3%)	1 (5.6%)

PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 5.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	32 (61.5%)	23 (51.1%)
The number (%) of patients censored [a]	20 (38.5%)	22 (48.9%)
Not at risk at baseline n (%) [a]	0 (0.0%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	10 (19.2%)	15 (33.3%)
Others n (%) [a]	0 (0.0%)	0 (0.0%)
Median time to event (95% CI) [b]	3.3 (1.5, 5.6)	4.7 (2.0, 7.3)
Q1	1.1 (0.7, 1.6)	1.9 (1.0, 3.7)
Q3	8.3 (5.4, NE)	7.6 (5.6, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	52.1% (36.5%, 65.6%)	66.3% (48.2%, 79.4%)
by 6 Months, % (95% CI)	30.6% (17.0%, 45.3%)	39.7% (22.1%, 56.8%)
by 12 Months, % (95% CI)	24.5% (12.2%, 39.1%)	NE (NE, NE)
by 18 Months, % (95% CI)	12.2% (1.4%, 35.7%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.609	
HR (95% CI) [d]	1.18 (0.68, 2.04)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 5.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	31 (59.6%)	23 (51.1%)
The number (%) of patients censored [a]	21 (40.4%)	22 (48.9%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	11 (21.2%)	17 (37.8%)
Others n (%) [a]	0 (0.0%)	0 (0.0%)
Median time to event (95% CI) [b]	3.0 (1.4, 4.3)	4.4 (1.9, 11.1)
Q1	0.9 (0.8, 1.6)	1.9 (1.0, 2.8)
Q3	9.2 (4.2, NE)	11.1 (4.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	50.0% (34.6%, 63.6%)	56.6% (39.0%, 70.9%)
by 6 Months, % (95% CI)	30.4% (16.5%, 45.6%)	34.0% (17.8%, 51.0%)
by 12 Months, % (95% CI)	16.2% (4.0%, 35.8%)	NE (NE, NE)
by 18 Months, % (95% CI)	16.2% (4.0%, 35.8%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.490	
HR (95% CI) [d]	1.31 (0.76, 2.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 5.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	31 (59.6%)	31 (68.9%)
The number (%) of patients censored [a]	21 (40.4%)	14 (31.1%)
Not at risk at baseline n (%) [a]	0 (0.0%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	0 (0.0%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	12 (23.1%)	8 (17.8%)
Others n (%) [a]	1 (1.9%)	0 (0.0%)
Median time to event (95% CI) [b]	1.5 (1.0, 3.6)	1.9 (1.4, 3.0)
Q1	0.8 (0.7, 1.2)	1.0 (0.9, 1.7)
Q3	NE (2.2, NE)	3.8 (2.8, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	36.4% (22.6%, 50.3%)	35.8% (20.8%, 51.0%)
by 6 Months, % (95% CI)	30.5% (17.4%, 44.8%)	14.9% (5.5%, 28.6%)
by 12 Months, % (95% CI)	27.2% (14.4%, 41.6%)	NE (NE, NE)
by 18 Months, % (95% CI)	27.2% (14.4%, 41.6%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.794	
HR (95% CI) [d]	0.94 (0.57, 1.56)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	23 (44.2%)	12 (26.7%)
The number (%) of patients censored [a]	29 (55.8%)	33 (73.3%)
Not at risk at baseline n (%) [a]	1 (1.9%)	2 (4.4%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	12 (23.1%)	25 (55.6%)
Others n (%) [a]	5 (9.6%)	0 (0.0%)
Median time to event (95% CI) [b]	8.4 (4.2, NE)	11.1 (6.5, NE)
Q1	3.0 (1.4, 4.3)	6.5 (1.9, 7.6)
Q3	NE (16.2, NE)	NE (11.1, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	76.3% (60.4%, 86.5%)	91.1% (75.0%, 97.1%)
by 6 Months, % (95% CI)	55.1% (38.3%, 69.0%)	76.0% (55.6%, 87.9%)
by 12 Months, % (95% CI)	41.9% (25.5%, 57.4%)	39.2% (13.6%, 64.4%)
by 18 Months, % (95% CI)	36.6% (20.1%, 53.4%)	39.2% (13.6%, 64.4%)
by 24 Months, % (95% CI)	36.6% (20.1%, 53.4%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.220	
HR (95% CI) [d]	1.48 (0.73, 3.02)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	28 (53.8%)	25 (55.6%)
The number (%) of patients censored [a]	24 (46.2%)	20 (44.4%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	11 (21.2%)	15 (33.3%)
Others n (%) [a]	3 (5.8%)	0 (0.0%)
Median time to event (95% CI) [b]	3.5 (1.7, 6.0)	3.8 (2.8, 5.8)
Q1	1.4 (0.8, 1.7)	1.9 (1.0, 3.7)
Q3	NE (5.3, NE)	6.5 (4.6, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	56.3% (40.3%, 69.5%)	64.4% (46.5%, 77.7%)
by 6 Months, % (95% CI)	34.1% (19.7%, 49.1%)	29.9% (14.9%, 46.6%)
by 12 Months, % (95% CI)	30.7% (16.7%, 45.9%)	NE (NE, NE)
by 18 Months, % (95% CI)	30.7% (16.7%, 45.9%)	NE (NE, NE)
by 24 Months, % (95% CI)	30.7% (16.7%, 45.9%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.931	
HR (95% CI) [d]	1.03 (0.58, 1.80)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	34 (65.4%)	23 (51.1%)
The number (%) of patients censored [a]	18 (34.6%)	22 (48.9%)
Not at risk at baseline n (%) [a]	0 (0.0%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	7 (13.5%)	16 (35.6%)
Others n (%) [a]	1 (1.9%)	0 (0.0%)
Median time to event (95% CI) [b]	2.2 (1.5, 3.6)	2.8 (1.5, NE)
Q1	1.1 (0.8, 1.6)	1.1 (0.9, 1.9)
Q3	7.6 (3.5, NE)	8.9 (3.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	44.6% (29.5%, 58.7%)	47.6% (30.4%, 62.9%)
by 6 Months, % (95% CI)	29.8% (16.8%, 43.8%)	35.7% (19.3%, 52.4%)
by 12 Months, % (95% CI)	22.3% (10.4%, 37.0%)	0.0% (NE, NE)
by 18 Months, % (95% CI)	14.9% (3.9%, 32.6%)	0.0% (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	0.0% (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.432	
HR (95% CI) [d]	1.17 (0.68, 2.03)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	36 (69.2%)	32 (71.1%)
The number (%) of patients censored [a]	16 (30.8%)	13 (28.9%)
Not at risk at baseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	1 (1.9%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	6 (11.5%)	6 (13.3%)
Others n (%) [a]	0 (0.0%)	0 (0.0%)
Median time to event (95% CI) [b]	1.2 (0.8, 1.7)	1.4 (1.1, 1.9)
Q1	0.8 (0.7, 0.8)	1.0 (1.0, 1.1)
Q3	2.4 (1.6, 5.8)	3.8 (1.9, 8.8)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	23.3% (12.0%, 36.6%)	32.5% (18.3%, 47.6%)
by 6 Months, % (95% CI)	9.3% (1.9%, 23.9%)	10.3% (2.3%, 25.5%)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.183	
HR (95% CI) [d]	1.29 (0.80, 2.10)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	29 (55.8%)	14 (31.1%)
The number (%) of patients censored [a]	23 (44.2%)	31 (68.9%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	10 (19.2%)	24 (53.3%)
Others n (%) [a]	2 (3.8%)	1 (2.2%)
Median time to event (95% CI) [b]	2.8 (1.5, 5.7)	NE (5.6, NE)
Q1	0.9 (0.7, 1.7)	1.9 (1.1, 6.5)
Q3	16.9 (5.0, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	46.5% (31.1%, 60.5%)	72.8% (55.1%, 84.4%)
by 6 Months, % (95% CI)	34.7% (20.2%, 49.6%)	60.6% (41.0%, 75.5%)
by 12 Months, % (95% CI)	31.2% (17.2%, 46.4%)	53.9% (32.5%, 71.2%)
by 18 Months, % (95% CI)	15.6% (1.7%, 43.1%)	53.9% (32.5%, 71.2%)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.044	
HR (95% CI) [d]	2.02 (1.06, 3.85)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	30 (57.7%)	24 (53.3%)
The number (%) of patients censored [a]	22 (42.3%)	21 (46.7%)
Not at risk at baseline n (%) [a]	3 (5.8%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	4 (7.7%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	7 (13.5%)	15 (33.3%)
Others n (%) [a]	0 (0.0%)	0 (0.0%)
Median time to event (95% CI) [b]	3.5 (1.6, 6.9)	3.1 (1.9, 6.9)
Q1	1.2 (0.8, 1.7)	1.1 (1.0, 2.8)
Q3	10.0 (5.6, NE)	NE (3.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	50.4% (34.1%, 64.6%)	53.3% (35.8%, 67.9%)
by 6 Months, % (95% CI)	34.8% (19.7%, 50.2%)	34.1% (18.7%, 50.1%)
by 12 Months, % (95% CI)	13.5% (3.8%, 29.4%)	NE (NE, NE)
by 18 Months, % (95% CI)	13.5% (3.8%, 29.4%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.692	
HR (95% CI) [d]	1.09 (0.63, 1.90)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	22 (42.3%)	24 (53.3%)
The number (%) of patients censored [a]	30 (57.7%)	21 (46.7%)
Not at risk at baseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	15 (28.8%)	14 (31.1%)
Others n (%) [a]	4 (7.7%)	0 (0.0%)
Median time to event (95% CI) [b]	7.2 (2.4, NE)	2.8 (1.5, 5.7)
Q1	1.5 (1.0, 3.5)	1.1 (1.0, 1.9)
Q3	NE (11.4, NE)	6.9 (4.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	64.9% (48.6%, 77.1%)	46.9% (29.8%, 62.2%)
by 6 Months, % (95% CI)	56.8% (40.3%, 70.3%)	32.4% (17.1%, 48.8%)
by 12 Months, % (95% CI)	40.1% (22.8%, 56.9%)	NE (NE, NE)
by 18 Months, % (95% CI)	40.1% (22.8%, 56.9%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.118	
HR (95% CI) [d]	0.58 (0.32, 1.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	21 (40.4%)	20 (44.4%)
The number (%) of patients censored [a]	31 (59.6%)	25 (55.6%)
Not at risk at baseline n (%) [a]	4 (7.7%)	3 (6.7%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	5 (9.6%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	11 (21.2%)	16 (35.6%)
Others n (%) [a]	3 (5.8%)	0 (0.0%)
Median time to event (95% CI) [b]	5.5 (2.8, NE)	4.1 (1.9, NE)
Q1	1.6 (0.9, 3.5)	1.4 (1.0, 2.0)
Q3	NE (19.2, NE)	NE (5.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	64.3% (47.2%, 77.1%)	53.8% (35.9%, 68.8%)
by 6 Months, % (95% CI)	47.4% (29.9%, 63.0%)	42.4% (24.9%, 58.9%)
by 12 Months, % (95% CI)	43.1% (25.7%, 59.4%)	NE (NE, NE)
by 18 Months, % (95% CI)	43.1% (25.7%, 59.4%)	NE (NE, NE)
by 24 Months, % (95% CI)	28.7% (7.7%, 54.5%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.383	
HR (95% CI) [d]	0.83 (0.44, 1.56)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	23 (44.2%)	16 (35.6%)
The number (%) of patients censored [a]	29 (55.8%)	29 (64.4%)
Not at risk at baseline n (%) [a]	2 (3.8%)	3 (6.7%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	14 (26.9%)	20 (44.4%)
Others n (%) [a]	2 (3.8%)	0 (0.0%)
Median time to event (95% CI) [b]	4.2 (1.7, NE)	7.3 (1.9, NE)
Q1	1.4 (0.7, 1.7)	1.9 (1.0, 4.9)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	51.6% (35.5%, 65.6%)	61.1% (42.4%, 75.4%)
by 6 Months, % (95% CI)	45.3% (29.2%, 60.0%)	53.0% (33.9%, 68.8%)
by 12 Months, % (95% CI)	41.5% (25.5%, 56.8%)	46.3% (26.2%, 64.3%)
by 18 Months, % (95% CI)	41.5% (25.5%, 56.8%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.417	
HR (95% CI) [d]	1.34 (0.71, 2.56)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	30 (57.7%)	17 (37.8%)
The number (%) of patients censored [a]	22 (42.3%)	28 (62.2%)
Not at risk at baseline n (%) [a]	0 (0.0%)	2 (4.4%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	10 (19.2%)	21 (46.7%)
Others n (%) [a]	1 (1.9%)	0 (0.0%)
Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	6.7 (3.7, NE)
Q1	1.0 (0.8, 1.5)	1.9 (0.9, 4.7)
Q3	11.4 (3.0, NE)	NE (6.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	39.5% (24.9%, 53.8%)	69.3% (51.2%, 81.8%)
by 6 Months, % (95% CI)	31.4% (17.9%, 45.8%)	53.4% (34.0%, 69.4%)
by 12 Months, % (95% CI)	23.5% (9.1%, 41.7%)	40.1% (19.7%, 59.7%)
by 18 Months, % (95% CI)	23.5% (9.1%, 41.7%)	40.1% (19.7%, 59.7%)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.076	
HR (95% CI) [d]	1.86 (1.01, 3.43)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	34 (65.4%)	24 (53.3%)
The number (%) of patients censored [a]	18 (34.6%)	21 (46.7%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	6 (11.5%)	15 (33.3%)
Others n (%) [a]	1 (1.9%)	0 (0.0%)
Median time to event (95% CI) [b]	1.7 (0.9, 2.2)	2.9 (1.9, 6.5)
Q1	0.8 (0.7, 1.2)	1.4 (1.0, 1.9)
Q3	4.2 (2.2, NE)	NE (4.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	35.7% (21.9%, 49.8%)	48.8% (31.4%, 64.2%)
by 6 Months, % (95% CI)	18.1% (7.7%, 32.1%)	35.5% (19.7%, 51.7%)
by 12 Months, % (95% CI)	18.1% (7.7%, 32.1%)	27.1% (12.6%, 43.8%)
by 18 Months, % (95% CI)	18.1% (7.7%, 32.1%)	NE (NE, NE)
by 24 Months, % (95% CI)	18.1% (7.7%, 32.1%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.079	
HR (95% CI) [d]	1.66 (0.98, 2.82)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	23 (44.2%)	18 (40.0%)
The number (%) of patients censored [a]	29 (55.8%)	27 (60.0%)
Not at risk at baseline n (%) [a]	0 (0.0%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	4 (7.7%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	15 (28.8%)	20 (44.4%)
Others n (%) [a]	2 (3.8%)	0 (0.0%)
Median time to event (95% CI) [b]	7.9 (5.0, NE)	4.7 (2.8, NE)
Q1	2.9 (1.0, 5.6)	1.9 (1.0, 3.7)
Q3	NE (9.8, NE)	10.2 (10.2, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	74.4% (58.5%, 85.0%)	65.4% (47.0%, 78.8%)
by 6 Months, % (95% CI)	59.4% (42.1%, 73.2%)	46.7% (28.3%, 63.2%)
by 12 Months, % (95% CI)	34.2% (18.1%, 51.0%)	NE (NE, NE)
by 18 Months, % (95% CI)	34.2% (18.1%, 51.0%)	NE (NE, NE)
by 24 Months, % (95% CI)	34.2% (18.1%, 51.0%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.452	
HR (95% CI) [d]	0.71 (0.38, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	31 (59.6%)	24 (53.3%)
The number (%) of patients censored [a]	21 (40.4%)	21 (46.7%)
Not at risk at baseline n (%) [a]	2 (3.8%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	8 (15.4%)	13 (28.9%)
Others n (%) [a]	1 (1.9%)	0 (0.0%)
Median time to event (95% CI) [b]	1.7 (1.0, 4.2)	2.8 (1.5, 6.5)
Q1	0.8 (0.8, 1.2)	1.2 (1.0, 1.9)
Q3	5.8 (3.5, NE)	9.3 (4.6, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	42.5% (27.4%, 56.8%)	46.8% (29.8%, 62.1%)
by 6 Months, % (95% CI)	24.3% (11.8%, 39.2%)	35.8% (19.8%, 52.1%)
by 12 Months, % (95% CI)	24.3% (11.8%, 39.2%)	NE (NE, NE)
by 18 Months, % (95% CI)	24.3% (11.8%, 39.2%)	NE (NE, NE)
by 24 Months, % (95% CI)	24.3% (11.8%, 39.2%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.302	
HR (95% CI) [d]	1.26 (0.73, 2.19)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	11 (21.2%)	12 (26.7%)
The number (%) of patients censored [a]	41 (78.8%)	33 (73.3%)
Not at risk at baseline n (%) [a]	1 (1.9%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	4 (7.7%)	4 (8.9%)
Premature treatment discontinuation n (%) [a]	22 (42.3%)	23 (51.1%)
Others n (%) [a]	6 (11.5%)	1 (2.2%)
Median time to event (95% CI) [b]	NE (15.8, NE)	NE (2.8, NE)
Q1	5.0 (2.8, NE)	2.1 (1.0, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	85.3% (70.2%, 93.1%)	67.4% (48.5%, 80.6%)
by 6 Months, % (95% CI)	73.3% (55.7%, 84.8%)	62.9% (43.2%, 77.3%)
by 12 Months, % (95% CI)	73.3% (55.7%, 84.8%)	62.9% (43.2%, 77.3%)
by 18 Months, % (95% CI)	66.0% (43.8%, 81.1%)	NE (NE, NE)
by 24 Months, % (95% CI)	66.0% (43.8%, 81.1%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.171	
HR (95% CI) [d]	0.55 (0.23, 1.32)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	1 (1.9%)	4 (8.9%)
The number (%) of patients censored [a]	51 (98.1%)	41 (91.1%)
Not at risk at baseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing baseline only n (%) [a]	8 (15.4%)	5 (11.1%)
Having baseline but no postbaseline visit n (%) [a]	5 (9.6%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	31 (59.6%)	26 (57.8%)
Missing PRO for two consecutive visits n (%) [a]	5 (9.6%)	3 (6.7%)
Premature treatment discontinuation n (%) [a]	1 (1.9%)	3 (6.7%)
Others n (%) [a]	0 (0.0%)	0 (0.0%)
Median time to event (95% CI) [b]	NE (1.1, NE)	NE (0.9, NE)
Q1	NE (1.1, NE)	1.0 (0.9, NE)
Q3	NE (1.1, NE)	NE (1.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	80.0% (20.4%, 96.9%)	NE (NE, NE)
by 6 Months, % (95% CI)	80.0% (20.4%, 96.9%)	NE (NE, NE)
by 12 Months, % (95% CI)	80.0% (20.4%, 96.9%)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.389	
HR (95% CI) [d]	0.31 (0.03, 2.80)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	19 (36.5%)	10 (22.2%)
The number (%) of patients censored [a]	33 (63.5%)	35 (77.8%)
Not at risk at baseline n (%) [a]	11 (21.2%)	13 (28.9%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	3 (6.7%)
Premature treatment discontinuation n (%) [a]	9 (17.3%)	14 (31.1%)
Others n (%) [a]	3 (5.8%)	0 (0.0%)
Median time to event (95% CI) [b]	5.5 (1.6, NE)	9.3 (3.0, NE)
Q1	1.5 (0.7, 3.6)	2.8 (1.0, 9.3)
Q3	NE (8.3, NE)	NE (9.3, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	63.3% (44.5%, 77.3%)	73.7% (50.3%, 87.3%)
by 6 Months, % (95% CI)	45.4% (27.2%, 61.9%)	63.9% (40.2%, 80.2%)
by 12 Months, % (95% CI)	36.1% (18.7%, 53.9%)	42.6% (14.8%, 68.3%)
by 18 Months, % (95% CI)	36.1% (18.7%, 53.9%)	NE (NE, NE)
by 24 Months, % (95% CI)	36.1% (18.7%, 53.9%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.586	
HR (95% CI) [d]	1.31 (0.59, 2.91)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	40 (76.9%)	33 (73.3%)
The number (%) of patients censored [a]	12 (23.1%)	12 (26.7%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	1 (1.9%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	2 (3.8%)	6 (13.3%)
Others n (%) [a]	1 (1.9%)	0 (0.0%)
Median time to event (95% CI) [b]	1.0 (0.8, 1.5)	1.1 (1.0, 1.9)
Q1	0.8 (0.7, 0.8)	1.0 (0.9, 1.0)
Q3	1.7 (1.4, 4.2)	3.8 (1.4, 5.6)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	15.9% (7.0%, 28.1%)	28.0% (14.8%, 42.9%)
by 6 Months, % (95% CI)	11.4% (4.2%, 22.6%)	7.8% (1.5%, 21.0%)
by 12 Months, % (95% CI)	8.5% (2.5%, 19.4%)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.102	
HR (95% CI) [d]	1.30 (0.80, 2.10)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	17 (32.7%)	7 (15.6%)
The number (%) of patients censored [a]	35 (67.3%)	38 (84.4%)
Not at risk at baseline n (%) [a]	3 (5.8%)	3 (6.7%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	5 (9.6%)	3 (6.7%)
Premature treatment discontinuation n (%) [a]	15 (28.8%)	26 (57.8%)
Others n (%) [a]	4 (7.7%)	1 (2.2%)
Median time to event (95% CI) [b]	NE (5.4, NE)	NE (9.8, NE)
Q1	3.5 (0.8, 7.2)	9.8 (1.9, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	75.4% (59.1%, 85.9%)	87.1% (68.9%, 95.0%)
by 6 Months, % (95% CI)	66.9% (49.7%, 79.4%)	83.3% (64.1%, 92.8%)
by 12 Months, % (95% CI)	51.9% (33.5%, 67.5%)	60.6% (25.5%, 83.2%)
by 18 Months, % (95% CI)	51.9% (33.5%, 67.5%)	NE (NE, NE)
by 24 Months, % (95% CI)	51.9% (33.5%, 67.5%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.075	
HR (95% CI) [d]	1.78 (0.72, 4.43)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	27 (51.9%)	20 (44.4%)
The number (%) of patients censored [a]	25 (48.1%)	25 (55.6%)
Not at risk at baseline n (%) [a]	0 (0.0%)	1 (2.2%)
Missing baseline only n (%) [a]	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	6 (11.5%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	12 (23.1%)	17 (37.8%)
Others n (%) [a]	2 (3.8%)	0 (0.0%)
Median time to event (95% CI) [b]	4.8 (1.7, 12.7)	3.8 (2.8, 9.3)
Q1	1.4 (0.8, 2.1)	1.9 (1.0, 2.8)
Q3	NE (10.7, NE)	9.3 (6.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	58.8% (42.8%, 71.7%)	52.2% (34.0%, 67.6%)
by 6 Months, % (95% CI)	41.5% (25.9%, 56.5%)	44.8% (27.0%, 61.1%)
by 12 Months, % (95% CI)	36.9% (21.1%, 52.8%)	18.7% (1.7%, 50.0%)
by 18 Months, % (95% CI)	25.3% (10.3%, 43.6%)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.707	
HR (95% CI) [d]	0.93 (0.50, 1.71)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	4 (7.7%)	6 (13.3%)
The number (%) of patients censored [a]	48 (92.3%)	39 (86.7%)
Not at risk at baseline n (%) [a]	1 (1.9%)	0 (0.0%)
Missing baseline only n (%) [a]	36 (69.2%)	32 (71.1%)
Having baseline but no postbaseline visit n (%) [a]	2 (3.8%)	3 (6.7%)
No baseline or any postbaseline n (%) [a]	5 (9.6%)	2 (4.4%)
Missing PRO for two consecutive visits n (%) [a]	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	2 (3.8%)	1 (2.2%)
Others n (%) [a]	0 (0.0%)	0 (0.0%)
Median time to event (95% CI) [b]	7.9 (0.7, NE)	1.0 (0.8, NE)
Q1	0.8 (0.7, 7.9)	1.0 (0.8, 1.0)
Q3	NE (3.5, NE)	1.9 (1.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	71.4% (25.8%, 92.0%)	21.4% (1.2%, 58.6%)
by 6 Months, % (95% CI)	53.6% (13.2%, 82.5%)	0.0% (NE, NE)
by 12 Months, % (95% CI)	NE (NE, NE)	0.0% (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	0.0% (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	0.0% (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.272	
HR (95% CI) [d]	0.41 (0.10, 1.79)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.1
Time to First Meaningful Deterioration for EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	27 (51.9%)	12 (26.7%)
The number (%) of patients censored [a]	25 (48.1%)	33 (73.3%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	1 (1.9%)	1 (2.2%)
Having baseline but no postbaseline visit n (%) [a]	5 (9.6%)	4 (8.9%)
No baseline or any postbaseline n (%) [a]	2 (3.8%)	1 (2.2%)
Missing PRO for two consecutive visits n (%) [a]	4 (7.7%)	3 (6.7%)
Premature treatment discontinuation n (%) [a]	11 (21.2%)	24 (53.3%)
Others n (%) [a]	2 (3.8%)	0 (0.0%)
Median time to event (95% CI) [b]	6.3 (3.2, 10.2)	11.1 (4.7, NE)
Q1	1.8 (0.8, 3.6)	2.8 (1.0, 11.1)
Q3	12.6 (8.1, NE)	NE (11.1, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	68.0% (52.0%, 79.6%)	73.1% (54.4%, 85.1%)
by 6 Months, % (95% CI)	54.4% (37.8%, 68.3%)	65.1% (45.2%, 79.3%)
by 12 Months, % (95% CI)	26.9% (12.1%, 44.2%)	43.4% (10.1%, 73.8%)
by 18 Months, % (95% CI)	21.5% (8.0%, 39.2%)	NE (NE, NE)
by 24 Months, % (95% CI)	21.5% (8.0%, 39.2%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.044	
HR (95% CI) [d]	1.80 (0.90, 3.62)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.

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Table 5.2.2
Time to First Meaningful Deterioration for PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	15 (28.8%)	13 (28.9%)
The number (%) of patients censored [a]	37 (71.2%)	32 (71.1%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	0 (0.0%)	0 (0.0%)
No baseline or any postbaseline n (%) [a]	12 (23.1%)	13 (28.9%)
Missing PRO for two consecutive visits n (%) [a]	1 (1.9%)	1 (2.2%)
Premature treatment discontinuation n (%) [a]	17 (32.7%)	18 (40.0%)
Others n (%) [a]	7 (13.5%)	0 (0.0%)
Median time to event (95% CI) [b]	6.4 (5.0, NE)	NE (3.7, NE)
Q1	4.2 (3.4, 6.4)	3.4 (2.8, 4.7)
Q3	NE (6.4, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	90.0% (75.5%, 96.1%)	78.1% (59.5%, 88.9%)
by 6 Months, % (95% CI)	62.3% (44.6%, 75.8%)	55.5% (35.4%, 71.7%)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.167	
HR (95% CI) [d]	0.59 (0.27, 1.29)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.2.3
Time to First Meaningful Deterioration for PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Parameter	SG (N=52)	TPC (N=45)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or	52	45
The number (%) of patients with an event [a]	6 (11.5%)	3 (6.7%)
The number (%) of patients censored [a]	46 (88.5%)	42 (93.3%)
Not at risk at baseline n (%) [a]	7 (13.5%)	6 (13.3%)
Missing baseline only n (%) [a]	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	9 (17.3%)	11 (24.4%)
No baseline or any postbaseline n (%) [a]	3 (5.8%)	2 (4.4%)
Missing PRO for two consecutive visits n (%) [a]	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation n (%) [a]	19 (36.5%)	21 (46.7%)
Others n (%) [a]	5 (9.6%)	0 (0.0%)
Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
Q1	NE (3.3, NE)	NE (3.7, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	93.5% (76.6%, 98.3%)	100.0% (100.0%, 100.0%)
by 6 Months, % (95% CI)	77.0% (54.7%, 89.3%)	NE (NE, NE)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.674	
HR (95% CI) [d]	1.44 (0.36, 5.78)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 7.2.1.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	16 (61.5%)	8 (47.1%)
	The number (%) of patients censored [a]	10 (38.5%)	9 (52.9%)
	Median time to event (95% CI) [b]	2.6 (1.2, 7.6)	4.8 (1.0, 7.6)
	Nominal p-value for unstratified log-rank test [c]	0.961	
	HR (95% CI) [d]	1.03 (0.43, 2.45)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	16 (61.5%)	15 (53.6%)
	The number (%) of patients censored [a]	10 (38.5%)	13 (46.4%)
	Median time to event (95% CI) [b]	3.5 (1.0, 5.6)	4.7 (1.9, 7.5)
	Nominal p-value for unstratified log-rank test [c]	0.531	
	HR (95% CI) [d]	1.25 (0.62, 2.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.961	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	15 (57.7%)	7 (41.2%)
	The number (%) of patients censored [a]	11 (42.3%)	10 (58.8%)
	Median time to event (95% CI) [b]	2.2 (1.0, 4.3)	3.7 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.265	
	HR (95% CI) [d]	1.66 (0.67, 4.11)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	16 (61.5%)	16 (57.1%)
	The number (%) of patients censored [a]	10 (38.5%)	12 (42.9%)
	Median time to event (95% CI) [b]	3.3 (0.8, 9.2)	4.6 (1.9, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.713	
	HR (95% CI) [d]	1.14 (0.56, 2.31)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.590	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	14 (53.8%)	11 (64.7%)
	The number (%) of patients censored [a]	12 (46.2%)	6 (35.3%)
	Median time to event (95% CI) [b]	1.4 (0.8, 8.3)	1.9 (1.2, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.917	
	HR (95% CI) [d]	0.97 (0.43, 2.17)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	17 (65.4%)	20 (71.4%)
	The number (%) of patients censored [a]	9 (34.6%)	8 (28.6%)
	Median time to event (95% CI) [b]	2.1 (0.8, 5.6)	1.9 (1.0, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.802	
	HR (95% CI) [d]	0.93 (0.48, 1.78)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.937	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	12 (46.2%)	4 (23.5%)
	The number (%) of patients censored [a]	14 (53.8%)	13 (76.5%)
	Median time to event (95% CI) [b]	5.5 (2.1, 9.7)	7.6 (5.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.172	
	HR (95% CI) [d]	2.16 (0.69, 6.75)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	11 (42.3%)	8 (28.6%)
	The number (%) of patients censored [a]	15 (57.7%)	20 (71.4%)
	Median time to event (95% CI) [b]	16.2 (4.2, NE)	11.1 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.695	
	HR (95% CI) [d]	1.20 (0.48, 3.05)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.363	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	15 (57.7%)	9 (52.9%)
	The number (%) of patients censored [a]	11 (42.3%)	8 (47.1%)
	Median time to event (95% CI) [b]	1.7 (0.9, 4.3)	3.7 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.602	
	HR (95% CI) [d]	1.25 (0.55, 2.87)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	13 (50.0%)	16 (57.1%)
	The number (%) of patients censored [a]	13 (50.0%)	12 (42.9%)
	Median time to event (95% CI) [b]	5.3 (1.7, NE)	4.0 (2.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.550	
	HR (95% CI) [d]	0.80 (0.38, 1.66)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.374	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	14 (53.8%)	7 (41.2%)
	The number (%) of patients censored [a]	12 (46.2%)	10 (58.8%)
	Median time to event (95% CI) [b]	2.2 (1.2, 3.6)	3.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.406	
	HR (95% CI) [d]	1.46 (0.59, 3.63)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	20 (76.9%)	16 (57.1%)
	The number (%) of patients censored [a]	6 (23.1%)	12 (42.9%)
	Median time to event (95% CI) [b]	2.2 (1.0, 7.2)	2.8 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.800	
	HR (95% CI) [d]	1.09 (0.55, 2.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.626	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	17 (65.4%)	11 (64.7%)
	The number (%) of patients censored [a]	9 (34.6%)	6 (35.3%)
	Median time to event (95% CI) [b]	1.4 (0.8, 1.7)	1.9 (1.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.189	
	HR (95% CI) [d]	1.68 (0.78, 3.61)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	19 (73.1%)	21 (75.0%)
	The number (%) of patients censored [a]	7 (26.9%)	7 (25.0%)
	Median time to event (95% CI) [b]	0.8 (0.8, 2.2)	1.1 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.622	
	HR (95% CI) [d]	1.17 (0.63, 2.19)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.458	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	14 (53.8%)	7 (41.2%)
	The number (%) of patients censored [a]	12 (46.2%)	10 (58.8%)
	Median time to event (95% CI) [b]	2.8 (0.9, 5.7)	5.6 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	1.63 (0.66, 4.05)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	15 (57.7%)	7 (25.0%)
	The number (%) of patients censored [a]	11 (42.3%)	21 (75.0%)
	Median time to event (95% CI) [b]	3.2 (0.8, NE)	NE (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.022	
	HR (95% CI) [d]	2.74 (1.12, 6.74)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.346	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	12 (46.2%)	9 (52.9%)
	The number (%) of patients censored [a]	14 (53.8%)	8 (47.1%)
	Median time to event (95% CI) [b]	4.4 (0.8, 11.8)	2.8 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.527	
	HR (95% CI) [d]	0.75 (0.31, 1.84)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	18 (69.2%)	15 (53.6%)
	The number (%) of patients censored [a]	8 (30.8%)	13 (46.4%)
	Median time to event (95% CI) [b]	2.3 (1.4, 6.9)	3.7 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.373	
	HR (95% CI) [d]	1.37 (0.69, 2.74)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.276	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	13 (50.0%)	9 (52.9%)
	The number (%) of patients censored [a]	13 (50.0%)	8 (47.1%)
	Median time to event (95% CI) [b]	3.5 (1.4, 10.1)	4.7 (1.2, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.897	
	HR (95% CI) [d]	0.95 (0.40, 2.26)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	9 (34.6%)	15 (53.6%)
	The number (%) of patients censored [a]	17 (65.4%)	13 (46.4%)
	Median time to event (95% CI) [b]	NE (3.1, NE)	2.8 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.026	
	HR (95% CI) [d]	0.38 (0.16, 0.91)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.099	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	11 (42.3%)	5 (29.4%)
	The number (%) of patients censored [a]	15 (57.7%)	12 (70.6%)
	Median time to event (95% CI) [b]	3.5 (1.5, NE)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	1.76 (0.61, 5.12)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	10 (38.5%)	15 (53.6%)
	The number (%) of patients censored [a]	16 (61.5%)	13 (46.4%)
	Median time to event (95% CI) [b]	19.2 (2.2, NE)	2.8 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.51 (0.22, 1.18)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.069	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	9 (34.6%)	4 (23.5%)
	The number (%) of patients censored [a]	17 (65.4%)	13 (76.5%)
	Median time to event (95% CI) [b]	5.0 (1.4, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.346	
	HR (95% CI) [d]	1.77 (0.54, 5.76)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	14 (53.8%)	12 (42.9%)
	The number (%) of patients censored [a]	12 (46.2%)	16 (57.1%)
	Median time to event (95% CI) [b]	2.2 (1.4, NE)	5.6 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.749	
	HR (95% CI) [d]	1.13 (0.52, 2.45)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.513	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	14 (53.8%)	4 (23.5%)
	The number (%) of patients censored [a]	12 (46.2%)	13 (76.5%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.6)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.041	
	HR (95% CI) [d]	3.09 (0.99, 9.58)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	16 (61.5%)	13 (46.4%)
	The number (%) of patients censored [a]	10 (38.5%)	15 (53.6%)
	Median time to event (95% CI) [b]	2.0 (0.8, 11.4)	6.7 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.298	
	HR (95% CI) [d]	1.47 (0.70, 3.07)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.343	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	17 (65.4%)	8 (47.1%)
	The number (%) of patients censored [a]	9 (34.6%)	9 (52.9%)
	Median time to event (95% CI) [b]	1.5 (0.8, 2.1)	1.9 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.066	
	HR (95% CI) [d]	2.25 (0.93, 5.46)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	17 (65.4%)	16 (57.1%)
	The number (%) of patients censored [a]	9 (34.6%)	12 (42.9%)
	Median time to event (95% CI) [b]	2.0 (0.8, 5.8)	3.3 (1.9, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.346	
	HR (95% CI) [d]	1.39 (0.70, 2.76)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.356	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	12 (46.2%)	7 (41.2%)
	The number (%) of patients censored [a]	14 (53.8%)	10 (58.8%)
	Median time to event (95% CI) [b]	5.0 (2.8, 10.5)	3.9 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.518	
	HR (95% CI) [d]	0.73 (0.28, 1.89)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	11 (42.3%)	11 (39.3%)
	The number (%) of patients censored [a]	15 (57.7%)	17 (60.7%)
	Median time to event (95% CI) [b]	9.8 (5.6, NE)	10.2 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.396	
	HR (95% CI) [d]	0.69 (0.29, 1.65)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.861	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	15 (57.7%)	8 (47.1%)
	The number (%) of patients censored [a]	11 (42.3%)	9 (52.9%)
	Median time to event (95% CI) [b]	1.4 (0.8, 3.5)	1.9 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.415	
	HR (95% CI) [d]	1.43 (0.60, 3.40)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	16 (61.5%)	16 (57.1%)
	The number (%) of patients censored [a]	10 (38.5%)	12 (42.9%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	3.7 (1.2, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.688	
	HR (95% CI) [d]	1.17 (0.58, 2.37)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.719	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	5 (19.2%)	6 (35.3%)
	The number (%) of patients censored [a]	21 (80.8%)	11 (64.7%)
	Median time to event (95% CI) [b]	15.8 (5.0, NE)	2.8 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.078	
	HR (95% CI) [d]	0.33 (0.09, 1.19)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	6 (23.1%)	6 (21.4%)
	The number (%) of patients censored [a]	20 (76.9%)	22 (78.6%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.807	
	HR (95% CI) [d]	0.87 (0.28, 2.69)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.350	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	0 (0.0%)	2 (11.8%)
	The number (%) of patients censored [a]	26 (100.0%)	15 (88.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.187	
	HR (95% CI) [d]	NE (NE, NE)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	1 (3.8%)	2 (7.1%)
	The number (%) of patients censored [a]	25 (96.2%)	26 (92.9%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.782	
	HR (95% CI) [d]	0.71 (0.06, 8.02)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.997	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	10 (38.5%)	0 (0.0%)
	The number (%) of patients censored [a]	16 (61.5%)	17 (100.0%)
	Median time to event (95% CI) [b]	4.5 (0.8, 8.3)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.023	
	HR (95% CI) [d]	NE (NE, NE)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	9 (34.6%)	10 (35.7%)
	The number (%) of patients censored [a]	17 (65.4%)	18 (64.3%)
	Median time to event (95% CI) [b]	11.3 (1.6, NE)	6.5 (2.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.637	
	HR (95% CI) [d]	0.81 (0.32, 2.03)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.989	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	19 (73.1%)	13 (76.5%)
	The number (%) of patients censored [a]	7 (26.9%)	4 (23.5%)
	Median time to event (95% CI) [b]	1.1 (0.8, 1.5)	1.0 (1.0, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	1.09 (0.53, 2.24)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	21 (80.8%)	20 (71.4%)
	The number (%) of patients censored [a]	5 (19.2%)	8 (28.6%)
	Median time to event (95% CI) [b]	0.9 (0.8, 2.1)	1.1 (1.0, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	1.54 (0.83, 2.85)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.464	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	7 (26.9%)	2 (11.8%)
	The number (%) of patients censored [a]	19 (73.1%)	15 (88.2%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	9.8 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.639	
	HR (95% CI) [d]	1.45 (0.30, 7.10)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	10 (38.5%)	5 (17.9%)
	The number (%) of patients censored [a]	16 (61.5%)	23 (82.1%)
	Median time to event (95% CI) [b]	NE (2.8, NE)	NE (6.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.199	
	HR (95% CI) [d]	2.01 (0.68, 5.93)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.945	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	14 (53.8%)	5 (29.4%)
	The number (%) of patients censored [a]	12 (46.2%)	12 (70.6%)
	Median time to event (95% CI) [b]	4.2 (1.4, 12.7)	2.9 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.445	
	HR (95% CI) [d]	1.49 (0.53, 4.16)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	13 (50.0%)	15 (53.6%)
	The number (%) of patients censored [a]	13 (50.0%)	13 (46.4%)
	Median time to event (95% CI) [b]	10.7 (1.6, NE)	3.8 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.372	
	HR (95% CI) [d]	0.70 (0.32, 1.55)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.209	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	26 (100.0%)	17 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	4 (15.4%)	6 (21.4%)
	The number (%) of patients censored [a]	22 (84.6%)	22 (78.6%)
	Median time to event (95% CI) [b]	7.9 (0.7, NE)	1.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.132	
	HR (95% CI) [d]	0.34 (0.08, 1.43)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	11 (42.3%)	2 (11.8%)
	The number (%) of patients censored [a]	15 (57.7%)	15 (88.2%)
	Median time to event (95% CI) [b]	9.0 (1.5, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	2.64 (0.58, 12.07)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	16 (61.5%)	10 (35.7%)
	The number (%) of patients censored [a]	10 (38.5%)	18 (64.3%)
	Median time to event (95% CI) [b]	5.8 (2.2, 12.6)	11.1 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.252	
	HR (95% CI) [d]	1.60 (0.72, 3.57)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.1.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.520	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.1.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	11 (42.3%)	4 (23.5%)
	The number (%) of patients censored [a]	15 (57.7%)	13 (76.5%)
	Median time to event (95% CI) [b]	3.6 (0.9, NE)	NE (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	2.03 (0.64, 6.39)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	14 (53.8%)	11 (39.3%)
	The number (%) of patients censored [a]	12 (46.2%)	17 (60.7%)
	Median time to event (95% CI) [b]	3.5 (1.0, NE)	4.9 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.745	
	HR (95% CI) [d]	1.15 (0.52, 2.54)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.392	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	11 (42.3%)	4 (23.5%)
	The number (%) of patients censored [a]	15 (57.7%)	13 (76.5%)
	Median time to event (95% CI) [b]	5.0 (3.5, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.993	
	HR (95% CI) [d]	0.99 (0.31, 3.18)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	4 (15.4%)	9 (32.1%)
	The number (%) of patients censored [a]	22 (84.6%)	19 (67.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.080	
	HR (95% CI) [d]	0.36 (0.11, 1.18)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.216	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	17
	The number (%) of patients with an event [a]	2 (7.7%)	0 (0.0%)
	The number (%) of patients censored [a]	24 (92.3%)	17 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.310	
	HR (95% CI) [d]	NE (NE, NE)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	26	28
	The number (%) of patients with an event [a]	4 (15.4%)	3 (10.7%)
	The number (%) of patients censored [a]	22 (84.6%)	25 (89.3%)
	Median time to event (95% CI) [b]	NE (5.6, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.980	
	HR (95% CI) [d]	0.98 (0.22, 4.43)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.1.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.995	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	24 (68.6%)	17 (48.6%)
	The number (%) of patients censored [a]	11 (31.4%)	18 (51.4%)
	Median time to event (95% CI) [b]	3.7 (1.6, 7.6)	4.7 (2.0, 7.5)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	1.20 (0.64, 2.26)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	8 (47.1%)	6 (60.0%)
	The number (%) of patients censored [a]	9 (52.9%)	4 (40.0%)
	Median time to event (95% CI) [b]	1.5 (0.7, NE)	4.4 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.767	
	HR (95% CI) [d]	1.20 (0.41, 3.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.846	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	23 (65.7%)	16 (45.7%)
	The number (%) of patients censored [a]	12 (34.3%)	19 (54.3%)
	Median time to event (95% CI) [b]	3.9 (2.1, 5.6)	5.6 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.336	
	HR (95% CI) [d]	1.37 (0.72, 2.61)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	8 (47.1%)	7 (70.0%)
	The number (%) of patients censored [a]	9 (52.9%)	3 (30.0%)
	Median time to event (95% CI) [b]	1.4 (0.7, NE)	2.3 (0.9, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.709	
	HR (95% CI) [d]	1.20 (0.43, 3.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.878	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	21 (60.0%)	24 (68.6%)
	The number (%) of patients censored [a]	14 (40.0%)	11 (31.4%)
	Median time to event (95% CI) [b]	2.2 (1.4, NE)	2.0 (1.5, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.469	
	HR (95% CI) [d]	0.81 (0.45, 1.46)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	10 (58.8%)	7 (70.0%)
	The number (%) of patients censored [a]	7 (41.2%)	3 (30.0%)
	Median time to event (95% CI) [b]	0.8 (0.7, 1.5)	1.2 (0.9, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.563	
	HR (95% CI) [d]	1.33 (0.50, 3.53)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.303	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	19 (54.3%)	7 (20.0%)
	The number (%) of patients censored [a]	16 (45.7%)	28 (80.0%)
	Median time to event (95% CI) [b]	6.0 (4.2, 16.2)	NE (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.050	
	HR (95% CI) [d]	2.34 (0.98, 5.62)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	4 (23.5%)	5 (50.0%)
	The number (%) of patients censored [a]	13 (76.5%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	7.6 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.346	
	HR (95% CI) [d]	0.53 (0.14, 2.01)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.051	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	20 (57.1%)	21 (60.0%)
	The number (%) of patients censored [a]	15 (42.9%)	14 (40.0%)
	Median time to event (95% CI) [b]	3.5 (1.7, NE)	3.8 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.833	
	HR (95% CI) [d]	0.93 (0.50, 1.74)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	8 (47.1%)	4 (40.0%)
	The number (%) of patients censored [a]	9 (52.9%)	6 (60.0%)
	Median time to event (95% CI) [b]	2.9 (0.8, NE)	6.5 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.766	
	HR (95% CI) [d]	1.20 (0.35, 4.12)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.748	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	25 (71.4%)	19 (54.3%)
	The number (%) of patients censored [a]	10 (28.6%)	16 (45.7%)
	Median time to event (95% CI) [b]	2.8 (1.6, 7.2)	2.8 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.723	
	HR (95% CI) [d]	1.11 (0.60, 2.06)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	9 (52.9%)	4 (40.0%)
	The number (%) of patients censored [a]	8 (47.1%)	6 (60.0%)
	Median time to event (95% CI) [b]	1.6 (0.8, 3.4)	1.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.800	
	HR (95% CI) [d]	1.16 (0.36, 3.80)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.844	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	26 (74.3%)	26 (74.3%)
	The number (%) of patients censored [a]	9 (25.7%)	9 (25.7%)
	Median time to event (95% CI) [b]	1.3 (0.8, 2.1)	1.4 (1.1, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.462	
	HR (95% CI) [d]	1.23 (0.71, 2.13)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	10 (58.8%)	6 (60.0%)
	The number (%) of patients censored [a]	7 (41.2%)	4 (40.0%)
	Median time to event (95% CI) [b]	0.8 (0.7, 2.2)	1.7 (0.9, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.531	
	HR (95% CI) [d]	1.42 (0.50, 4.03)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.811	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	22 (62.9%)	11 (31.4%)
	The number (%) of patients censored [a]	13 (37.1%)	24 (68.6%)
	Median time to event (95% CI) [b]	3.6 (1.4, 6.9)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.012	
	HR (95% CI) [d]	2.45 (1.19, 5.06)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	7 (41.2%)	3 (30.0%)
	The number (%) of patients censored [a]	10 (58.8%)	7 (70.0%)
	Median time to event (95% CI) [b]	2.8 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.603	
	HR (95% CI) [d]	1.45 (0.37, 5.64)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.464	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	22 (62.9%)	19 (54.3%)
	The number (%) of patients censored [a]	13 (37.1%)	16 (45.7%)
	Median time to event (95% CI) [b]	5.0 (1.6, 8.8)	3.1 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.922	
	HR (95% CI) [d]	1.03 (0.55, 1.93)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	8 (47.1%)	5 (50.0%)
	The number (%) of patients censored [a]	9 (52.9%)	5 (50.0%)
	Median time to event (95% CI) [b]	2.1 (0.7, NE)	1.2 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.820	
	HR (95% CI) [d]	1.12 (0.36, 3.47)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.846	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	17 (48.6%)	19 (54.3%)
	The number (%) of patients censored [a]	18 (51.4%)	16 (45.7%)
	Median time to event (95% CI) [b]	7.2 (2.4, NE)	2.8 (1.5, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.127	
	HR (95% CI) [d]	0.59 (0.30, 1.17)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	5 (29.4%)	5 (50.0%)
	The number (%) of patients censored [a]	12 (70.6%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	4.4 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.386	
	HR (95% CI) [d]	0.58 (0.16, 2.03)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.700	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	16 (45.7%)	16 (45.7%)
	The number (%) of patients censored [a]	19 (54.3%)	19 (54.3%)
	Median time to event (95% CI) [b]	5.5 (1.6, NE)	4.1 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.810	
	HR (95% CI) [d]	0.91 (0.45, 1.84)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	5 (29.4%)	4 (40.0%)
	The number (%) of patients censored [a]	12 (70.6%)	6 (60.0%)
	Median time to event (95% CI) [b]	5.4 (1.6, NE)	1.9 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.446	
	HR (95% CI) [d]	0.60 (0.16, 2.26)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.578	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	16 (45.7%)	11 (31.4%)
	The number (%) of patients censored [a]	19 (54.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	7.9 (1.7, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.383	
	HR (95% CI) [d]	1.41 (0.65, 3.04)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	7 (41.2%)	5 (50.0%)
	The number (%) of patients censored [a]	10 (58.8%)	5 (50.0%)
	Median time to event (95% CI) [b]	1.6 (0.7, NE)	1.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.793	
	HR (95% CI) [d]	0.87 (0.27, 2.77)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.484	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	23 (65.7%)	13 (37.1%)
	The number (%) of patients censored [a]	12 (34.3%)	22 (62.9%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	6.7 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.022	
	HR (95% CI) [d]	2.17 (1.09, 4.32)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	7 (41.2%)	4 (40.0%)
	The number (%) of patients censored [a]	10 (58.8%)	6 (60.0%)
	Median time to event (95% CI) [b]	2.4 (0.7, NE)	4.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.964	
	HR (95% CI) [d]	1.03 (0.29, 3.66)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.342	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	28 (80.0%)	19 (54.3%)
	The number (%) of patients censored [a]	7 (20.0%)	16 (45.7%)
	Median time to event (95% CI) [b]	1.6 (0.9, 2.1)	3.9 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.005	
	HR (95% CI) [d]	2.29 (1.27, 4.13)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	6 (35.3%)	5 (50.0%)
	The number (%) of patients censored [a]	11 (64.7%)	5 (50.0%)
	Median time to event (95% CI) [b]	3.6 (0.7, NE)	1.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.499	
	HR (95% CI) [d]	0.67 (0.20, 2.25)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.062	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	18 (51.4%)	13 (37.1%)
	The number (%) of patients censored [a]	17 (48.6%)	22 (62.9%)
	Median time to event (95% CI) [b]	7.9 (5.0, 10.5)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.650	
	HR (95% CI) [d]	0.84 (0.40, 1.75)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	5 (29.4%)	5 (50.0%)
	The number (%) of patients censored [a]	12 (70.6%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	3.9 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.333	
	HR (95% CI) [d]	0.55 (0.16, 1.93)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.465	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	24 (68.6%)	19 (54.3%)
	The number (%) of patients censored [a]	11 (31.4%)	16 (45.7%)
	Median time to event (95% CI) [b]	1.9 (1.0, 5.0)	2.8 (1.4, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.236	
	HR (95% CI) [d]	1.44 (0.79, 2.65)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	7 (41.2%)	5 (50.0%)
	The number (%) of patients censored [a]	10 (58.8%)	5 (50.0%)
	Median time to event (95% CI) [b]	1.5 (0.8, NE)	2.8 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.925	
	HR (95% CI) [d]	1.07 (0.33, 3.43)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.633	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	10 (28.6%)	9 (25.7%)
	The number (%) of patients censored [a]	25 (71.4%)	26 (74.3%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	NE (4.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.763	
	HR (95% CI) [d]	0.87 (0.34, 2.18)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	1 (5.9%)	3 (30.0%)
	The number (%) of patients censored [a]	16 (94.1%)	7 (70.0%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	2.8 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.024	
	HR (95% CI) [d]	0.11 (0.01, 1.09)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.093	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	1 (2.9%)	3 (8.6%)
	The number (%) of patients censored [a]	34 (97.1%)	32 (91.4%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.380	
	HR (95% CI) [d]	0.37 (0.04, 3.66)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	0 (0.0%)	1 (10.0%)
	The number (%) of patients censored [a]	17 (100.0%)	9 (90.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	1.0 (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	13 (37.1%)	8 (22.9%)
	The number (%) of patients censored [a]	22 (62.9%)	27 (77.1%)
	Median time to event (95% CI) [b]	8.3 (3.6, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.513	
	HR (95% CI) [d]	1.35 (0.56, 3.28)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	6 (35.3%)	2 (20.0%)
	The number (%) of patients censored [a]	11 (64.7%)	8 (80.0%)
	Median time to event (95% CI) [b]	1.4 (0.7, NE)	9.3 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.686	
	HR (95% CI) [d]	1.40 (0.28, 7.06)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.899	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	29 (82.9%)	27 (77.1%)
	The number (%) of patients censored [a]	6 (17.1%)	8 (22.9%)
	Median time to event (95% CI) [b]	1.1 (0.8, 1.6)	1.1 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.437	
	HR (95% CI) [d]	1.24 (0.73, 2.10)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	11 (64.7%)	6 (60.0%)
	The number (%) of patients censored [a]	6 (35.3%)	4 (40.0%)
	Median time to event (95% CI) [b]	0.9 (0.7, 1.5)	1.0 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.379	
	HR (95% CI) [d]	1.53 (0.52, 4.50)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.699	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	14 (40.0%)	6 (17.1%)
	The number (%) of patients censored [a]	21 (60.0%)	29 (82.9%)
	Median time to event (95% CI) [b]	10.1 (3.0, NE)	NE (6.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.139	
	HR (95% CI) [d]	2.06 (0.78, 5.43)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	3 (17.6%)	1 (10.0%)
	The number (%) of patients censored [a]	14 (82.4%)	9 (90.0%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.989	
	HR (95% CI) [d]	0.98 (0.10, 9.84)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.564	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	20 (57.1%)	17 (48.6%)
	The number (%) of patients censored [a]	15 (42.9%)	18 (51.4%)
	Median time to event (95% CI) [b]	4.5 (1.7, 15.0)	3.9 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.969	
	HR (95% CI) [d]	1.01 (0.52, 1.95)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	7 (41.2%)	3 (30.0%)
	The number (%) of patients censored [a]	10 (58.8%)	7 (70.0%)
	Median time to event (95% CI) [b]	10.7 (0.8, NE)	2.8 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.795	
	HR (95% CI) [d]	0.84 (0.20, 3.55)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.728	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	4 (11.4%)	5 (14.3%)
	The number (%) of patients censored [a]	31 (88.6%)	30 (85.7%)
	Median time to event (95% CI) [b]	5.7 (0.7, NE)	1.0 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.210	
	HR (95% CI) [d]	0.38 (0.09, 1.67)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	0 (0.0%)	1 (10.0%)
	The number (%) of patients censored [a]	17 (100.0%)	9 (90.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.995	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	20 (57.1%)	8 (22.9%)
	The number (%) of patients censored [a]	15 (42.9%)	27 (77.1%)
	Median time to event (95% CI) [b]	6.3 (3.6, 12.0)	11.1 (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.128	
	HR (95% CI) [d]	1.88 (0.82, 4.31)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	7 (41.2%)	4 (40.0%)
	The number (%) of patients censored [a]	10 (58.8%)	6 (60.0%)
	Median time to event (95% CI) [b]	1.5 (0.7, NE)	1.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.945	
	HR (95% CI) [d]	1.03 (0.29, 3.71)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.2.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.216	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.2.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	15 (42.9%)	10 (28.6%)
	The number (%) of patients censored [a]	20 (57.1%)	25 (71.4%)
	Median time to event (95% CI) [b]	13.6 (3.5, NE)	NE (4.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.555	
	HR (95% CI) [d]	1.28 (0.57, 2.86)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	10 (58.8%)	5 (50.0%)
	The number (%) of patients censored [a]	7 (41.2%)	5 (50.0%)
	Median time to event (95% CI) [b]	1.0 (0.7, 2.9)	2.8 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.486	
	HR (95% CI) [d]	1.47 (0.50, 4.36)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.937	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	10 (28.6%)	8 (22.9%)
	The number (%) of patients censored [a]	25 (71.4%)	27 (77.1%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	NE (4.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.739	
	HR (95% CI) [d]	0.85 (0.33, 2.21)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	5 (29.4%)	5 (50.0%)
	The number (%) of patients censored [a]	12 (70.6%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (3.4, NE)	2.8 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.110	
	HR (95% CI) [d]	0.35 (0.10, 1.24)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.175	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	35
	The number (%) of patients with an event [a]	4 (11.4%)	3 (8.6%)
	The number (%) of patients censored [a]	31 (88.6%)	32 (91.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.929	
	HR (95% CI) [d]	1.07 (0.24, 4.81)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	10
	The number (%) of patients with an event [a]	2 (11.8%)	0 (0.0%)
	The number (%) of patients censored [a]	15 (88.2%)	10 (100.0%)
	Median time to event (95% CI) [b]	NE (2.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.556	
	HR (95% CI) [d]	NE (NE, NE)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.2.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.995	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	23 (65.7%)	16 (61.5%)
	The number (%) of patients censored [a]	12 (34.3%)	10 (38.5%)
	Median time to event (95% CI) [b]	2.2 (1.4, 5.6)	4.5 (1.5, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.975	
	HR (95% CI) [d]	1.00 (0.52, 1.92)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	9 (52.9%)	7 (36.8%)
	The number (%) of patients censored [a]	8 (47.1%)	12 (63.2%)
	Median time to event (95% CI) [b]	3.6 (0.8, NE)	7.5 (2.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.414	
	HR (95% CI) [d]	1.51 (0.56, 4.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.655	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	22 (62.9%)	16 (61.5%)
	The number (%) of patients censored [a]	13 (37.1%)	10 (38.5%)
	Median time to event (95% CI) [b]	2.8 (1.5, 5.6)	3.7 (1.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.749	
	HR (95% CI) [d]	1.11 (0.58, 2.13)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	9 (52.9%)	7 (36.8%)
	The number (%) of patients censored [a]	8 (47.1%)	12 (63.2%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	4.4 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	1.85 (0.69, 5.00)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.490	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	21 (60.0%)	19 (73.1%)
	The number (%) of patients censored [a]	14 (40.0%)	7 (26.9%)
	Median time to event (95% CI) [b]	2.1 (1.2, 5.6)	1.9 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.530	
	HR (95% CI) [d]	0.82 (0.43, 1.54)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	12 (63.2%)
	The number (%) of patients censored [a]	7 (41.2%)	7 (36.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	2.0 (1.2, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.694	
	HR (95% CI) [d]	1.19 (0.51, 2.78)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.562	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	13 (37.1%)	7 (26.9%)
	The number (%) of patients censored [a]	22 (62.9%)	19 (73.1%)
	Median time to event (95% CI) [b]	16.2 (4.6, NE)	11.1 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.539	
	HR (95% CI) [d]	1.34 (0.53, 3.40)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	5 (26.3%)
	The number (%) of patients censored [a]	7 (41.2%)	14 (73.7%)
	Median time to event (95% CI) [b]	4.2 (2.3, 9.7)	NE (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.191	
	HR (95% CI) [d]	2.04 (0.69, 6.05)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.689	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	19 (54.3%)	17 (65.4%)
	The number (%) of patients censored [a]	16 (45.7%)	9 (34.6%)
	Median time to event (95% CI) [b]	3.5 (1.6, 7.6)	3.7 (2.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.758	
	HR (95% CI) [d]	0.90 (0.46, 1.74)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	9 (52.9%)	8 (42.1%)
	The number (%) of patients censored [a]	8 (47.1%)	11 (57.9%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	4.6 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.608	
	HR (95% CI) [d]	1.28 (0.49, 3.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.643	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	23 (65.7%)	15 (57.7%)
	The number (%) of patients censored [a]	12 (34.3%)	11 (42.3%)
	Median time to event (95% CI) [b]	2.2 (1.4, 7.2)	1.9 (1.1, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.847	
	HR (95% CI) [d]	1.06 (0.55, 2.07)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	11 (64.7%)	8 (42.1%)
	The number (%) of patients censored [a]	6 (35.3%)	11 (57.9%)
	Median time to event (95% CI) [b]	2.2 (0.8, 4.2)	3.0 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.442	
	HR (95% CI) [d]	1.43 (0.57, 3.57)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.526	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	26 (74.3%)	19 (73.1%)
	The number (%) of patients censored [a]	9 (25.7%)	7 (26.9%)
	Median time to event (95% CI) [b]	1.4 (0.8, 1.7)	1.9 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.216	
	HR (95% CI) [d]	1.47 (0.81, 2.66)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	13 (68.4%)
	The number (%) of patients censored [a]	7 (41.2%)	6 (31.6%)
	Median time to event (95% CI) [b]	0.9 (0.8, NE)	1.2 (1.1, 1.7)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.03 (0.44, 2.38)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.460	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	19 (54.3%)	8 (30.8%)
	The number (%) of patients censored [a]	16 (45.7%)	18 (69.2%)
	Median time to event (95% CI) [b]	2.8 (1.4, 16.9)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.047	
	HR (95% CI) [d]	2.26 (0.99, 5.18)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	6 (31.6%)
	The number (%) of patients censored [a]	7 (41.2%)	13 (68.4%)
	Median time to event (95% CI) [b]	2.8 (0.8, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.104	
	HR (95% CI) [d]	2.30 (0.82, 6.39)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.993	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	22 (62.9%)	15 (57.7%)
	The number (%) of patients censored [a]	13 (37.1%)	11 (42.3%)
	Median time to event (95% CI) [b]	3.5 (1.7, 6.9)	3.7 (1.0, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.794	
	HR (95% CI) [d]	0.91 (0.46, 1.79)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	8 (47.1%)	9 (47.4%)
	The number (%) of patients censored [a]	9 (52.9%)	10 (52.6%)
	Median time to event (95% CI) [b]	2.9 (0.8, 11.8)	3.0 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.476	
	HR (95% CI) [d]	1.45 (0.54, 3.92)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.522	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	14 (40.0%)	15 (57.7%)
	The number (%) of patients censored [a]	21 (60.0%)	11 (42.3%)
	Median time to event (95% CI) [b]	10.1 (2.2, NE)	2.8 (1.1, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.079	
	HR (95% CI) [d]	0.51 (0.23, 1.09)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	8 (47.1%)	9 (47.4%)
	The number (%) of patients censored [a]	9 (52.9%)	10 (52.6%)
	Median time to event (95% CI) [b]	4.3 (1.0, NE)	4.4 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.642	
	HR (95% CI) [d]	0.80 (0.31, 2.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.597	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	13 (37.1%)	12 (46.2%)
	The number (%) of patients censored [a]	22 (62.9%)	14 (53.8%)
	Median time to event (95% CI) [b]	19.2 (2.3, NE)	5.7 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.419	
	HR (95% CI) [d]	0.71 (0.32, 1.59)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	8 (47.1%)	8 (42.1%)
	The number (%) of patients censored [a]	9 (52.9%)	11 (57.9%)
	Median time to event (95% CI) [b]	4.2 (0.9, NE)	2.2 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.915	
	HR (95% CI) [d]	1.06 (0.39, 2.83)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.518	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	13 (37.1%)	10 (38.5%)
	The number (%) of patients censored [a]	22 (62.9%)	16 (61.5%)
	Median time to event (95% CI) [b]	7.9 (2.1, NE)	7.3 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.982	
	HR (95% CI) [d]	1.01 (0.44, 2.32)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	6 (31.6%)
	The number (%) of patients censored [a]	7 (41.2%)	13 (68.4%)
	Median time to event (95% CI) [b]	1.5 (0.7, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.129	
	HR (95% CI) [d]	2.17 (0.79, 5.98)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.294	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	20 (57.1%)	10 (38.5%)
	The number (%) of patients censored [a]	15 (42.9%)	16 (61.5%)
	Median time to event (95% CI) [b]	1.6 (0.9, 3.5)	5.6 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.046	
	HR (95% CI) [d]	2.14 (1.00, 4.61)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	7 (36.8%)
	The number (%) of patients censored [a]	7 (41.2%)	12 (63.2%)
	Median time to event (95% CI) [b]	3.5 (1.4, NE)	6.7 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.578	
	HR (95% CI) [d]	1.29 (0.48, 3.48)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.444	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	23 (65.7%)	13 (50.0%)
	The number (%) of patients censored [a]	12 (34.3%)	13 (50.0%)
	Median time to event (95% CI) [b]	1.7 (1.2, 3.6)	4.7 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.039	
	HR (95% CI) [d]	2.03 (1.02, 4.05)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	11 (64.7%)	11 (57.9%)
	The number (%) of patients censored [a]	6 (35.3%)	8 (42.1%)
	Median time to event (95% CI) [b]	1.4 (0.8, 4.2)	1.9 (1.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.421	
	HR (95% CI) [d]	1.42 (0.61, 3.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.556	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	17 (48.6%)	12 (46.2%)
	The number (%) of patients censored [a]	18 (51.4%)	14 (53.8%)
	Median time to event (95% CI) [b]	7.2 (4.5, 9.8)	4.7 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.593	
	HR (95% CI) [d]	0.81 (0.39, 1.72)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	6 (35.3%)	6 (31.6%)
	The number (%) of patients censored [a]	11 (64.7%)	13 (68.4%)
	Median time to event (95% CI) [b]	10.5 (1.4, NE)	4.6 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.514	
	HR (95% CI) [d]	0.67 (0.21, 2.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.681	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	22 (62.9%)	16 (61.5%)
	The number (%) of patients censored [a]	13 (37.1%)	10 (38.5%)
	Median time to event (95% CI) [b]	2.1 (1.2, 5.4)	2.8 (1.5, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.800	
	HR (95% CI) [d]	1.09 (0.57, 2.09)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	9 (52.9%)	8 (42.1%)
	The number (%) of patients censored [a]	8 (47.1%)	11 (57.9%)
	Median time to event (95% CI) [b]	0.8 (0.7, NE)	2.8 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	2.19 (0.84, 5.72)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.289	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	8 (22.9%)	7 (26.9%)
	The number (%) of patients censored [a]	27 (77.1%)	19 (73.1%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.394	
	HR (95% CI) [d]	0.63 (0.22, 1.81)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	3 (17.6%)	5 (26.3%)
	The number (%) of patients censored [a]	14 (82.4%)	14 (73.7%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.403	
	HR (95% CI) [d]	0.54 (0.13, 2.29)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.623	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.3

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	1 (2.9%)	4 (15.4%)
	The number (%) of patients censored [a]	34 (97.1%)	22 (84.6%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	1.0 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.279	
	HR (95% CI) [d]	0.30 (0.03, 2.80)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	17 (100.0%)	19 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.3

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.4

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	11 (31.4%)	4 (15.4%)
	The number (%) of patients censored [a]	24 (68.6%)	22 (84.6%)
	Median time to event (95% CI) [b]	11.3 (1.6, NE)	9.3 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.266	
	HR (95% CI) [d]	1.93 (0.61, 6.13)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	8 (47.1%)	6 (31.6%)
	The number (%) of patients censored [a]	9 (52.9%)	13 (68.4%)
	Median time to event (95% CI) [b]	2.2 (0.8, NE)	3.0 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.731	
	HR (95% CI) [d]	1.21 (0.42, 3.50)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.516	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	26 (74.3%)	21 (80.8%)
	The number (%) of patients censored [a]	9 (25.7%)	5 (19.2%)
	Median time to event (95% CI) [b]	1.2 (0.8, 1.6)	1.0 (1.0, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.971	
	HR (95% CI) [d]	1.00 (0.55, 1.79)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	14 (82.4%)	12 (63.2%)
	The number (%) of patients censored [a]	3 (17.6%)	7 (36.8%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.4)	1.4 (1.0, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.049	
	HR (95% CI) [d]	2.18 (1.00, 4.77)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.130	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	13 (37.1%)	4 (15.4%)
	The number (%) of patients censored [a]	22 (62.9%)	22 (84.6%)
	Median time to event (95% CI) [b]	10.1 (3.5, NE)	NE (6.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.157	
	HR (95% CI) [d]	2.23 (0.71, 6.94)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	4 (23.5%)	3 (15.8%)
	The number (%) of patients censored [a]	13 (76.5%)	16 (84.2%)
	Median time to event (95% CI) [b]	NE (3.0, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.977	
	HR (95% CI) [d]	1.02 (0.23, 4.60)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.373	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	17 (48.6%)	13 (50.0%)
	The number (%) of patients censored [a]	18 (51.4%)	13 (50.0%)
	Median time to event (95% CI) [b]	4.8 (1.5, NE)	2.9 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.878	
	HR (95% CI) [d]	0.94 (0.45, 1.94)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	7 (36.8%)
	The number (%) of patients censored [a]	7 (41.2%)	12 (63.2%)
	Median time to event (95% CI) [b]	5.0 (1.0, 15.0)	3.9 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.949	
	HR (95% CI) [d]	0.96 (0.35, 2.66)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.654	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.8

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	1 (2.9%)	2 (7.7%)
	The number (%) of patients censored [a]	34 (97.1%)	24 (92.3%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	1.0 (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.428	
	HR (95% CI) [d]	0.34 (0.03, 3.85)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	3 (17.6%)	4 (21.1%)
	The number (%) of patients censored [a]	14 (82.4%)	15 (78.9%)
	Median time to event (95% CI) [b]	3.5 (0.7, NE)	1.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.398	
	HR (95% CI) [d]	0.48 (0.09, 2.71)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.2.8

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.236	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	20 (57.1%)	8 (30.8%)
	The number (%) of patients censored [a]	15 (42.9%)	18 (69.2%)
	Median time to event (95% CI) [b]	6.2 (2.2, 10.2)	11.1 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.210	
	HR (95% CI) [d]	1.69 (0.74, 3.86)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	7 (41.2%)	4 (21.1%)
	The number (%) of patients censored [a]	10 (58.8%)	15 (78.9%)
	Median time to event (95% CI) [b]	6.3 (0.8, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.401	
	HR (95% CI) [d]	1.69 (0.49, 5.81)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.3.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.810	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.3.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	15 (42.9%)	8 (30.8%)
	The number (%) of patients censored [a]	20 (57.1%)	18 (69.2%)
	Median time to event (95% CI) [b]	13.6 (1.4, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.458	
	HR (95% CI) [d]	1.39 (0.59, 3.30)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	10 (58.8%)	7 (36.8%)
	The number (%) of patients censored [a]	7 (41.2%)	12 (63.2%)
	Median time to event (95% CI) [b]	3.5 (0.7, 3.6)	4.6 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.376	
	HR (95% CI) [d]	1.58 (0.60, 4.17)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.987	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	9 (25.7%)	9 (34.6%)
	The number (%) of patients censored [a]	26 (74.3%)	17 (65.4%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	0.50 (0.19, 1.32)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	6 (35.3%)	4 (21.1%)
	The number (%) of patients censored [a]	11 (64.7%)	15 (78.9%)
	Median time to event (95% CI) [b]	5.0 (3.4, NE)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.534	
	HR (95% CI) [d]	1.49 (0.42, 5.33)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.170	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	35	26
	The number (%) of patients with an event [a]	5 (14.3%)	2 (7.7%)
	The number (%) of patients censored [a]	30 (85.7%)	24 (92.3%)
	Median time to event (95% CI) [b]	NE (5.6, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.519	
	HR (95% CI) [d]	1.71 (0.33, 8.84)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	17	19
	The number (%) of patients with an event [a]	1 (5.9%)	1 (5.3%)
	The number (%) of patients censored [a]	16 (94.1%)	18 (94.7%)
	Median time to event (95% CI) [b]	NE (2.9, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.929	
	HR (95% CI) [d]	0.88 (0.05, 14.18)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.3.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.647	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	8 (72.7%)	5 (38.5%)
	The number (%) of patients censored [a]	3 (27.3%)	8 (61.5%)
	Median time to event (95% CI) [b]	1.7 (0.7, 3.6)	4.7 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.175	
	HR (95% CI) [d]	2.15 (0.70, 6.65)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	18 (56.3%)
	The number (%) of patients censored [a]	17 (41.5%)	14 (43.8%)
	Median time to event (95% CI) [b]	3.9 (1.5, 7.6)	4.8 (2.0, 7.5)
	Nominal p-value for unstratified log-rank test [c]	0.935	
	HR (95% CI) [d]	1.03 (0.56, 1.91)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.315	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	7 (63.6%)	5 (38.5%)
	The number (%) of patients censored [a]	4 (36.4%)	8 (61.5%)
	Median time to event (95% CI) [b]	3.8 (0.7, NE)	4.7 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.576	
	HR (95% CI) [d]	1.40 (0.42, 4.65)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	18 (56.3%)
	The number (%) of patients censored [a]	17 (41.5%)	14 (43.8%)
	Median time to event (95% CI) [b]	2.5 (1.4, 5.6)	3.7 (1.9, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.322	
	HR (95% CI) [d]	1.36 (0.74, 2.51)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.971	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	5 (45.5%)	8 (61.5%)
	The number (%) of patients censored [a]	6 (54.5%)	5 (38.5%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	1.5 (0.9, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.176	
	HR (95% CI) [d]	0.46 (0.15, 1.43)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	26 (63.4%)	23 (71.9%)
	The number (%) of patients censored [a]	15 (36.6%)	9 (28.1%)
	Median time to event (95% CI) [b]	1.4 (0.8, 2.2)	2.0 (1.7, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.628	
	HR (95% CI) [d]	1.16 (0.66, 2.04)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.091	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	5 (45.5%)	2 (15.4%)
	The number (%) of patients censored [a]	6 (54.5%)	11 (84.6%)
	Median time to event (95% CI) [b]	4.3 (1.2, NE)	NE (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.530	
	HR (95% CI) [d]	1.68 (0.32, 8.74)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	18 (43.9%)	10 (31.3%)
	The number (%) of patients censored [a]	23 (56.1%)	22 (68.8%)
	Median time to event (95% CI) [b]	8.4 (3.8, NE)	11.1 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.302	
	HR (95% CI) [d]	1.50 (0.69, 3.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.919	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	6 (54.5%)	5 (38.5%)
	The number (%) of patients censored [a]	5 (45.5%)	8 (61.5%)
	Median time to event (95% CI) [b]	4.2 (0.9, NE)	4.7 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.815	
	HR (95% CI) [d]	1.14 (0.34, 3.78)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	22 (53.7%)	20 (62.5%)
	The number (%) of patients censored [a]	19 (46.3%)	12 (37.5%)
	Median time to event (95% CI) [b]	3.5 (1.6, 7.6)	3.8 (2.8, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.916	
	HR (95% CI) [d]	0.97 (0.53, 1.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.925	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	10 (90.9%)	3 (23.1%)
	The number (%) of patients censored [a]	1 (9.1%)	10 (76.9%)
	Median time to event (95% CI) [b]	2.0 (0.7, 3.6)	NE (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.019	
	HR (95% CI) [d]	4.16 (1.14, 15.17)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	20 (62.5%)
	The number (%) of patients censored [a]	17 (41.5%)	12 (37.5%)
	Median time to event (95% CI) [b]	2.2 (1.4, 7.6)	1.9 (1.1, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.549	
	HR (95% CI) [d]	0.83 (0.45, 1.53)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.023	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	8 (72.7%)	8 (61.5%)
	The number (%) of patients censored [a]	3 (27.3%)	5 (38.5%)
	Median time to event (95% CI) [b]	1.5 (0.7, NE)	1.9 (0.9, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.969	
	HR (95% CI) [d]	1.02 (0.37, 2.84)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	28 (68.3%)	24 (75.0%)
	The number (%) of patients censored [a]	13 (31.7%)	8 (25.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.6)	1.2 (1.0, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.319	
	HR (95% CI) [d]	1.33 (0.77, 2.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.811	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	7 (63.6%)	4 (30.8%)
	The number (%) of patients censored [a]	4 (36.4%)	9 (69.2%)
	Median time to event (95% CI) [b]	2.8 (0.8, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.362	
	HR (95% CI) [d]	1.76 (0.51, 6.06)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	22 (53.7%)	10 (31.3%)
	The number (%) of patients censored [a]	19 (46.3%)	22 (68.8%)
	Median time to event (95% CI) [b]	2.8 (0.9, 6.9)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.022	
	HR (95% CI) [d]	2.35 (1.11, 4.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.688	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	6 (54.5%)	6 (46.2%)
	The number (%) of patients censored [a]	5 (45.5%)	7 (53.8%)
	Median time to event (95% CI) [b]	3.6 (0.7, NE)	2.8 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.906	
	HR (95% CI) [d]	0.92 (0.28, 3.06)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	18 (56.3%)
	The number (%) of patients censored [a]	17 (41.5%)	14 (43.8%)
	Median time to event (95% CI) [b]	3.5 (1.4, 6.9)	3.1 (1.2, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.598	
	HR (95% CI) [d]	1.18 (0.64, 2.19)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.599	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	3 (27.3%)	5 (38.5%)
	The number (%) of patients censored [a]	8 (72.7%)	8 (61.5%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	2.8 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.146	
	HR (95% CI) [d]	0.35 (0.08, 1.52)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	19 (46.3%)	19 (59.4%)
	The number (%) of patients censored [a]	22 (53.7%)	13 (40.6%)
	Median time to event (95% CI) [b]	6.3 (1.6, NE)	2.8 (1.2, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.183	
	HR (95% CI) [d]	0.65 (0.34, 1.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.420	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	5 (45.5%)	4 (30.8%)
	The number (%) of patients censored [a]	6 (54.5%)	9 (69.2%)
	Median time to event (95% CI) [b]	19.2 (0.8, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.838	
	HR (95% CI) [d]	1.14 (0.28, 4.60)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	16 (39.0%)	16 (50.0%)
	The number (%) of patients censored [a]	25 (61.0%)	16 (50.0%)
	Median time to event (95% CI) [b]	5.5 (2.8, NE)	4.1 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.508	
	HR (95% CI) [d]	0.79 (0.39, 1.58)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.710	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	5 (45.5%)	5 (38.5%)
	The number (%) of patients censored [a]	6 (54.5%)	8 (61.5%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	5.6 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.867	
	HR (95% CI) [d]	1.13 (0.32, 3.94)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	18 (43.9%)	11 (34.4%)
	The number (%) of patients censored [a]	23 (56.1%)	21 (65.6%)
	Median time to event (95% CI) [b]	4.2 (1.5, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.349	
	HR (95% CI) [d]	1.43 (0.67, 3.03)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.621	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	6 (54.5%)	4 (30.8%)
	The number (%) of patients censored [a]	5 (45.5%)	9 (69.2%)
	Median time to event (95% CI) [b]	2.6 (0.7, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.533	
	HR (95% CI) [d]	1.47 (0.41, 5.23)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	13 (40.6%)
	The number (%) of patients censored [a]	17 (41.5%)	19 (59.4%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	6.7 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.059	
	HR (95% CI) [d]	1.90 (0.96, 3.76)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.867	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	10 (90.9%)	3 (23.1%)
	The number (%) of patients censored [a]	1 (9.1%)	10 (76.9%)
	Median time to event (95% CI) [b]	1.5 (0.7, 3.6)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	5.07 (1.39, 18.50)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	21 (65.6%)
	The number (%) of patients censored [a]	17 (41.5%)	11 (34.4%)
	Median time to event (95% CI) [b]	1.7 (0.8, 3.9)	2.8 (1.2, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.466	
	HR (95% CI) [d]	1.24 (0.69, 2.25)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.054	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	5 (45.5%)	1 (7.7%)
	The number (%) of patients censored [a]	6 (54.5%)	12 (92.3%)
	Median time to event (95% CI) [b]	8.9 (0.7, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.318	
	HR (95% CI) [d]	2.95 (0.32, 27.22)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	18 (43.9%)	17 (53.1%)
	The number (%) of patients censored [a]	23 (56.1%)	15 (46.9%)
	Median time to event (95% CI) [b]	7.9 (5.0, NE)	3.9 (1.9, 10.2)
	Nominal p-value for unstratified log-rank test [c]	0.150	
	HR (95% CI) [d]	0.61 (0.31, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.124	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	6 (54.5%)	5 (38.5%)
	The number (%) of patients censored [a]	5 (45.5%)	8 (61.5%)
	Median time to event (95% CI) [b]	5.4 (0.7, NE)	4.7 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.902	
	HR (95% CI) [d]	0.93 (0.27, 3.16)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	25 (61.0%)	19 (59.4%)
	The number (%) of patients censored [a]	16 (39.0%)	13 (40.6%)
	Median time to event (95% CI) [b]	1.6 (0.8, 3.5)	2.6 (1.2, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.282	
	HR (95% CI) [d]	1.39 (0.76, 2.55)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.739	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	3 (27.3%)	3 (23.1%)
	The number (%) of patients censored [a]	8 (72.7%)	10 (76.9%)
	Median time to event (95% CI) [b]	NE (0.9, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.984	
	HR (95% CI) [d]	1.02 (0.20, 5.06)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	8 (19.5%)	9 (28.1%)
	The number (%) of patients censored [a]	33 (80.5%)	23 (71.9%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.164	
	HR (95% CI) [d]	0.50 (0.19, 1.35)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.583	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.3

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	1 (9.1%)	0 (0.0%)
	The number (%) of patients censored [a]	10 (90.9%)	13 (100.0%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.564	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	0 (0.0%)	4 (12.5%)
	The number (%) of patients censored [a]	41 (100.0%)	28 (87.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	1.0 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.212	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.997	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	4 (36.4%)	2 (15.4%)
	The number (%) of patients censored [a]	7 (63.6%)	11 (84.6%)
	Median time to event (95% CI) [b]	5.1 (0.7, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.557	
	HR (95% CI) [d]	1.66 (0.30, 9.13)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	15 (36.6%)	8 (25.0%)
	The number (%) of patients censored [a]	26 (63.4%)	24 (75.0%)
	Median time to event (95% CI) [b]	5.6 (1.6, NE)	9.3 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.387	
	HR (95% CI) [d]	1.47 (0.62, 3.48)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.957	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	9 (81.8%)	7 (53.8%)
	The number (%) of patients censored [a]	2 (18.2%)	6 (46.2%)
	Median time to event (95% CI) [b]	1.6 (0.7, 2.2)	1.0 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.822	
	HR (95% CI) [d]	1.10 (0.40, 2.99)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	31 (75.6%)	26 (81.3%)
	The number (%) of patients censored [a]	10 (24.4%)	6 (18.8%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.4)	1.1 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.246	
	HR (95% CI) [d]	1.37 (0.81, 2.32)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.753	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.6

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	3 (27.3%)	0 (0.0%)
	The number (%) of patients censored [a]	8 (72.7%)	13 (100.0%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.122	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	14 (34.1%)	7 (21.9%)
	The number (%) of patients censored [a]	27 (65.9%)	25 (78.1%)
	Median time to event (95% CI) [b]	10.1 (5.4, NE)	NE (6.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.385	
	HR (95% CI) [d]	1.50 (0.60, 3.74)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.991	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	3 (27.3%)	4 (30.8%)
	The number (%) of patients censored [a]	8 (72.7%)	9 (69.2%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.490	
	HR (95% CI) [d]	0.58 (0.13, 2.61)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	24 (58.5%)	16 (50.0%)
	The number (%) of patients censored [a]	17 (41.5%)	16 (50.0%)
	Median time to event (95% CI) [b]	3.3 (1.5, 10.7)	3.8 (1.9, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.825	
	HR (95% CI) [d]	1.07 (0.56, 2.05)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.300	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	1 (9.1%)	1 (7.7%)
	The number (%) of patients censored [a]	10 (90.9%)	12 (92.3%)
	Median time to event (95% CI) [b]	3.5 (NE, NE)	1.0 (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.317	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	3 (7.3%)	5 (15.6%)
	The number (%) of patients censored [a]	38 (92.7%)	27 (84.4%)
	Median time to event (95% CI) [b]	7.9 (0.7, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.167	
	HR (95% CI) [d]	0.32 (0.06, 1.74)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.820	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	7 (63.6%)	3 (23.1%)
	The number (%) of patients censored [a]	4 (36.4%)	10 (76.9%)
	Median time to event (95% CI) [b]	5.0 (0.7, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.420	
	HR (95% CI) [d]	1.76 (0.44, 7.11)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	20 (48.8%)	9 (28.1%)
	The number (%) of patients censored [a]	21 (51.2%)	23 (71.9%)
	Median time to event (95% CI) [b]	6.3 (3.2, 12.6)	11.1 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.245	
	HR (95% CI) [d]	1.60 (0.72, 3.55)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.4.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.708	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.4.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	6 (54.5%)	5 (38.5%)
	The number (%) of patients censored [a]	5 (45.5%)	8 (61.5%)
	Median time to event (95% CI) [b]	13.6 (0.3, NE)	5.6 (0.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.776	
	HR (95% CI) [d]	0.84 (0.24, 2.96)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	19 (46.3%)	10 (31.3%)
	The number (%) of patients censored [a]	22 (53.7%)	22 (68.8%)
	Median time to event (95% CI) [b]	3.5 (1.3, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.181	
	HR (95% CI) [d]	1.68 (0.78, 3.61)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.430	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	4 (36.4%)	2 (15.4%)
	The number (%) of patients censored [a]	7 (63.6%)	11 (84.6%)
	Median time to event (95% CI) [b]	6.4 (3.0, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.691	
	HR (95% CI) [d]	0.69 (0.11, 4.27)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	11 (26.8%)	11 (34.4%)
	The number (%) of patients censored [a]	30 (73.2%)	21 (65.6%)
	Median time to event (95% CI) [b]	NE (4.4, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.443	
	HR (95% CI) [d]	0.72 (0.31, 1.66)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.805	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	11	13
	The number (%) of patients with an event [a]	2 (18.2%)	1 (7.7%)
	The number (%) of patients censored [a]	9 (81.8%)	12 (92.3%)
	Median time to event (95% CI) [b]	NE (3.3, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	1.35 (0.12, 14.96)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	41	32
	The number (%) of patients with an event [a]	4 (9.8%)	2 (6.3%)
	The number (%) of patients censored [a]	37 (90.2%)	30 (93.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.703	
	HR (95% CI) [d]	1.39 (0.25, 7.61)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.4.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.904	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	6 (75.0%)	7 (50.0%)
	The number (%) of patients censored [a]	2 (25.0%)	7 (50.0%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	4.8 (3.0, 7.5)
	Nominal p-value for unstratified log-rank test [c]	0.173	
	HR (95% CI) [d]	2.15 (0.70, 6.58)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	26 (59.1%)	16 (51.6%)
	The number (%) of patients censored [a]	18 (40.9%)	15 (48.4%)
	Median time to event (95% CI) [b]	2.2 (1.4, 5.7)	3.7 (1.2, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.905	
	HR (95% CI) [d]	1.05 (0.56, 1.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.377	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	6 (42.9%)
	The number (%) of patients censored [a]	5 (62.5%)	8 (57.1%)
	Median time to event (95% CI) [b]	11.6 (0.8, NE)	6.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.271	
	HR (95% CI) [d]	0.41 (0.08, 2.09)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	28 (63.6%)	17 (54.8%)
	The number (%) of patients censored [a]	16 (36.4%)	14 (45.2%)
	Median time to event (95% CI) [b]	2.1 (1.2, 3.9)	3.7 (1.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.173	
	HR (95% CI) [d]	1.52 (0.83, 2.78)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.182	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	1 (12.5%)	11 (78.6%)
	The number (%) of patients censored [a]	7 (87.5%)	3 (21.4%)
	Median time to event (95% CI) [b]	NE (5.6, NE)	1.7 (0.9, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	0.07 (0.01, 0.58)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	30 (68.2%)	20 (64.5%)
	The number (%) of patients censored [a]	14 (31.8%)	11 (35.5%)
	Median time to event (95% CI) [b]	1.4 (0.8, 1.7)	2.0 (1.5, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.209	
	HR (95% CI) [d]	1.45 (0.82, 2.56)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.3

Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.006	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	5 (62.5%)	2 (14.3%)
	The number (%) of patients censored [a]	3 (37.5%)	12 (85.7%)
	Median time to event (95% CI) [b]	10.8 (2.3, NE)	NE (5.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.235	
	HR (95% CI) [d]	2.70 (0.49, 14.80)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	18 (40.9%)	10 (32.3%)
	The number (%) of patients censored [a]	26 (59.1%)	21 (67.7%)
	Median time to event (95% CI) [b]	8.4 (3.6, NE)	7.6 (4.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.582	
	HR (95% CI) [d]	1.24 (0.57, 2.70)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.342	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	11 (78.6%)
	The number (%) of patients censored [a]	5 (62.5%)	3 (21.4%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	3.7 (1.4, 4.7)
	Nominal p-value for unstratified log-rank test [c]	0.071	
	HR (95% CI) [d]	0.32 (0.09, 1.17)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	25 (56.8%)	14 (45.2%)
	The number (%) of patients censored [a]	19 (43.2%)	17 (54.8%)
	Median time to event (95% CI) [b]	2.9 (1.4, 5.3)	4.6 (2.8, 10.2)
	Nominal p-value for unstratified log-rank test [c]	0.330	
	HR (95% CI) [d]	1.39 (0.72, 2.67)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.048	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	7 (87.5%)	8 (57.1%)
	The number (%) of patients censored [a]	1 (12.5%)	6 (42.9%)
	Median time to event (95% CI) [b]	2.8 (0.8, NE)	3.0 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.645	
	HR (95% CI) [d]	1.28 (0.44, 3.71)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	27 (61.4%)	15 (48.4%)
	The number (%) of patients censored [a]	17 (38.6%)	16 (51.6%)
	Median time to event (95% CI) [b]	2.2 (1.4, 3.5)	2.8 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.592	
	HR (95% CI) [d]	1.19 (0.63, 2.25)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.963	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	5 (62.5%)	11 (78.6%)
	The number (%) of patients censored [a]	3 (37.5%)	3 (21.4%)
	Median time to event (95% CI) [b]	3.9 (0.8, NE)	1.9 (1.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.563	
	HR (95% CI) [d]	0.74 (0.25, 2.14)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	31 (70.5%)	21 (67.7%)
	The number (%) of patients censored [a]	13 (29.5%)	10 (32.3%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.5)	1.2 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.279	
	HR (95% CI) [d]	1.38 (0.79, 2.41)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.323	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	4 (50.0%)	4 (28.6%)
	The number (%) of patients censored [a]	4 (50.0%)	10 (71.4%)
	Median time to event (95% CI) [b]	16.9 (0.8, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.971	
	HR (95% CI) [d]	1.01 (0.22, 4.56)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	25 (56.8%)	10 (32.3%)
	The number (%) of patients censored [a]	19 (43.2%)	21 (67.7%)
	Median time to event (95% CI) [b]	2.2 (0.9, 5.0)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.015	
	HR (95% CI) [d]	2.43 (1.17, 5.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.422	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	4 (50.0%)	6 (42.9%)
	The number (%) of patients censored [a]	4 (50.0%)	8 (57.1%)
	Median time to event (95% CI) [b]	9.4 (4.4, NE)	6.9 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.306	
	HR (95% CI) [d]	0.47 (0.11, 2.03)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	26 (59.1%)	18 (58.1%)
	The number (%) of patients censored [a]	18 (40.9%)	13 (41.9%)
	Median time to event (95% CI) [b]	2.2 (1.4, 5.6)	2.8 (1.0, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.902	
	HR (95% CI) [d]	1.04 (0.57, 1.91)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.768	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	7 (50.0%)
	The number (%) of patients censored [a]	5 (62.5%)	7 (50.0%)
	Median time to event (95% CI) [b]	NE (2.4, NE)	5.7 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.217	
	HR (95% CI) [d]	0.43 (0.11, 1.70)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	19 (43.2%)	17 (54.8%)
	The number (%) of patients censored [a]	25 (56.8%)	14 (45.2%)
	Median time to event (95% CI) [b]	6.3 (1.6, NE)	2.4 (1.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.59 (0.30, 1.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.761	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	5 (62.5%)	8 (57.1%)
	The number (%) of patients censored [a]	3 (37.5%)	6 (42.9%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	4.1 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.905	
	HR (95% CI) [d]	1.08 (0.32, 3.62)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	16 (36.4%)	12 (38.7%)
	The number (%) of patients censored [a]	28 (63.6%)	19 (61.3%)
	Median time to event (95% CI) [b]	7.6 (2.8, NE)	3.8 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.610	
	HR (95% CI) [d]	0.82 (0.39, 1.73)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.565	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	2 (14.3%)
	The number (%) of patients censored [a]	5 (62.5%)	12 (85.7%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (7.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.580	
	HR (95% CI) [d]	1.67 (0.27, 10.53)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	20 (45.5%)	14 (45.2%)
	The number (%) of patients censored [a]	24 (54.5%)	17 (54.8%)
	Median time to event (95% CI) [b]	2.2 (1.4, NE)	1.9 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.866	
	HR (95% CI) [d]	1.07 (0.54, 2.12)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.467	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	5 (62.5%)	5 (35.7%)
	The number (%) of patients censored [a]	3 (37.5%)	9 (64.3%)
	Median time to event (95% CI) [b]	2.0 (0.8, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.335	
	HR (95% CI) [d]	1.83 (0.53, 6.32)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	25 (56.8%)	12 (38.7%)
	The number (%) of patients censored [a]	19 (43.2%)	19 (61.3%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	6.7 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.085	
	HR (95% CI) [d]	1.81 (0.90, 3.64)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.979	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	6 (75.0%)	6 (42.9%)
	The number (%) of patients censored [a]	2 (25.0%)	8 (57.1%)
	Median time to event (95% CI) [b]	1.5 (0.8, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.179	
	HR (95% CI) [d]	2.17 (0.70, 6.76)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	28 (63.6%)	18 (58.1%)
	The number (%) of patients censored [a]	16 (36.4%)	13 (41.9%)
	Median time to event (95% CI) [b]	1.7 (0.9, 3.5)	2.9 (1.9, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.208	
	HR (95% CI) [d]	1.46 (0.81, 2.66)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.392	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	4 (28.6%)
	The number (%) of patients censored [a]	5 (62.5%)	10 (71.4%)
	Median time to event (95% CI) [b]	NE (5.5, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.767	
	HR (95% CI) [d]	0.79 (0.17, 3.65)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	20 (45.5%)	14 (45.2%)
	The number (%) of patients censored [a]	24 (54.5%)	17 (54.8%)
	Median time to event (95% CI) [b]	7.9 (3.6, 10.5)	3.9 (1.9, 10.2)
	Nominal p-value for unstratified log-rank test [c]	0.288	
	HR (95% CI) [d]	0.69 (0.34, 1.38)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.905	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	7 (87.5%)	8 (57.1%)
	The number (%) of patients censored [a]	1 (12.5%)	6 (42.9%)
	Median time to event (95% CI) [b]	1.4 (0.8, 2.1)	2.8 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.165	
	HR (95% CI) [d]	2.03 (0.72, 5.70)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	24 (54.5%)	16 (51.6%)
	The number (%) of patients censored [a]	20 (45.5%)	15 (48.4%)
	Median time to event (95% CI) [b]	2.1 (0.9, 5.8)	2.8 (1.9, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.592	
	HR (95% CI) [d]	1.20 (0.63, 2.27)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.300	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	3 (21.4%)
	The number (%) of patients censored [a]	5 (62.5%)	11 (78.6%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.676	
	HR (95% CI) [d]	1.41 (0.28, 6.98)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	8 (18.2%)	9 (29.0%)
	The number (%) of patients censored [a]	36 (81.8%)	22 (71.0%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	NE (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.101	
	HR (95% CI) [d]	0.44 (0.16, 1.20)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.2

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.224	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	1 (12.5%)	2 (14.3%)
	The number (%) of patients censored [a]	7 (87.5%)	12 (85.7%)
	Median time to event (95% CI) [b]	1.1 (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.736	
	HR (95% CI) [d]	1.52 (0.13, 17.35)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	0 (0.0%)	2 (6.5%)
	The number (%) of patients censored [a]	44 (100.0%)	29 (93.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.127	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.3

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.997	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	4 (50.0%)	1 (7.1%)
	The number (%) of patients censored [a]	4 (50.0%)	13 (92.9%)
	Median time to event (95% CI) [b]	5.5 (1.6, NE)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.220	
	HR (95% CI) [d]	3.75 (0.39, 36.26)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	15 (34.1%)	9 (29.0%)
	The number (%) of patients censored [a]	29 (65.9%)	22 (71.0%)
	Median time to event (95% CI) [b]	5.6 (1.5, NE)	6.5 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.770	
	HR (95% CI) [d]	1.14 (0.50, 2.61)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.207	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	8 (100.0%)	12 (85.7%)
	The number (%) of patients censored [a]	0 (0.0%)	2 (14.3%)
	Median time to event (95% CI) [b]	1.2 (0.8, 3.5)	1.1 (0.9, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.618	
	HR (95% CI) [d]	1.27 (0.49, 3.24)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	32 (72.7%)	21 (67.7%)
	The number (%) of patients censored [a]	12 (27.3%)	10 (32.3%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	1.1 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.255	
	HR (95% CI) [d]	1.38 (0.79, 2.39)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.830	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.6

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	3 (37.5%)	3 (21.4%)
	The number (%) of patients censored [a]	5 (62.5%)	11 (78.6%)
	Median time to event (95% CI) [b]	10.0 (1.6, NE)	9.8 (6.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.689	
	HR (95% CI) [d]	0.68 (0.11, 4.43)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	14 (31.8%)	4 (12.9%)
	The number (%) of patients censored [a]	30 (68.2%)	27 (87.1%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.168	
	HR (95% CI) [d]	2.16 (0.71, 6.58)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.6

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.679	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	5 (62.5%)	8 (57.1%)
	The number (%) of patients censored [a]	3 (37.5%)	6 (42.9%)
	Median time to event (95% CI) [b]	2.5 (0.8, NE)	2.9 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.940	
	HR (95% CI) [d]	0.95 (0.31, 2.93)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	22 (50.0%)	12 (38.7%)
	The number (%) of patients censored [a]	22 (50.0%)	19 (61.3%)
	Median time to event (95% CI) [b]	5.0 (2.1, 12.7)	3.9 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.967	
	HR (95% CI) [d]	1.02 (0.49, 2.08)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.7

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.859	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.8

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	1 (12.5%)	2 (14.3%)
	The number (%) of patients censored [a]	7 (87.5%)	12 (85.7%)
	Median time to event (95% CI) [b]	3.5 (NE, NE)	1.4 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.225	
	HR (95% CI) [d]	NE (NE, NE)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	3 (6.8%)	4 (12.9%)
	The number (%) of patients censored [a]	41 (93.2%)	27 (87.1%)
	Median time to event (95% CI) [b]	7.9 (0.7, NE)	1.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.257	
	HR (95% CI) [d]	0.38 (0.07, 2.13)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.653	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	7 (87.5%)	2 (14.3%)
	The number (%) of patients censored [a]	1 (12.5%)	12 (85.7%)
	Median time to event (95% CI) [b]	6.3 (0.8, 9.0)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.058	
	HR (95% CI) [d]	4.23 (0.84, 21.23)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	20 (45.5%)	10 (32.3%)
	The number (%) of patients censored [a]	24 (54.5%)	21 (67.7%)
	Median time to event (95% CI) [b]	6.2 (2.5, 12.6)	11.1 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.717	
	HR (95% CI) [d]	1.16 (0.54, 2.49)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.5.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.072	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.5.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	1 (12.5%)	3 (21.4%)
	The number (%) of patients censored [a]	7 (87.5%)	11 (78.6%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.425	
	HR (95% CI) [d]	0.41 (0.04, 3.95)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	24 (54.5%)	12 (38.7%)
	The number (%) of patients censored [a]	20 (45.5%)	19 (61.3%)
	Median time to event (95% CI) [b]	2.8 (0.9, 13.6)	5.6 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.249	
	HR (95% CI) [d]	1.51 (0.75, 3.03)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.232	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	1 (12.5%)	5 (35.7%)
	The number (%) of patients censored [a]	7 (87.5%)	9 (64.3%)
	Median time to event (95% CI) [b]	NE (4.2, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.149	
	HR (95% CI) [d]	0.23 (0.03, 2.01)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	14 (31.8%)	8 (25.8%)
	The number (%) of patients censored [a]	30 (68.2%)	23 (74.2%)
	Median time to event (95% CI) [b]	6.4 (4.4, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.818	
	HR (95% CI) [d]	0.90 (0.37, 2.17)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.180	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	8	14
	The number (%) of patients with an event [a]	2 (25.0%)	1 (7.1%)
	The number (%) of patients censored [a]	6 (75.0%)	13 (92.9%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.413	
	HR (95% CI) [d]	2.65 (0.24, 29.65)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	44	31
	The number (%) of patients with an event [a]	4 (9.1%)	2 (6.5%)
	The number (%) of patients censored [a]	40 (90.9%)	29 (93.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.940	
	HR (95% CI) [d]	1.07 (0.20, 5.84)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.5.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.467	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	14 (60.9%)	4 (57.1%)
	The number (%) of patients censored [a]	9 (39.1%)	3 (42.9%)
	Median time to event (95% CI) [b]	3.7 (0.8, NE)	2.0 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.605	
	HR (95% CI) [d]	0.76 (0.24, 2.36)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	18 (64.3%)	19 (50.0%)
	The number (%) of patients censored [a]	10 (35.7%)	19 (50.0%)
	Median time to event (95% CI) [b]	2.2 (1.4, 7.6)	4.7 (3.0, 7.5)
	Nominal p-value for unstratified log-rank test [c]	0.327	
	HR (95% CI) [d]	1.39 (0.73, 2.65)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.307	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.2

Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	11 (47.8%)	4 (57.1%)
	The number (%) of patients censored [a]	12 (52.2%)	3 (42.9%)
	Median time to event (95% CI) [b]	4.3 (1.7, NE)	2.0 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.337	
	HR (95% CI) [d]	0.57 (0.18, 1.82)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	20 (71.4%)	19 (50.0%)
	The number (%) of patients censored [a]	8 (28.6%)	19 (50.0%)
	Median time to event (95% CI) [b]	1.6 (0.8, 4.2)	4.6 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.048	
	HR (95% CI) [d]	1.88 (0.99, 3.55)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.057	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	12 (52.2%)	3 (42.9%)
	The number (%) of patients censored [a]	11 (47.8%)	4 (57.1%)
	Median time to event (95% CI) [b]	2.5 (0.9, NE)	2.0 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.948	
	HR (95% CI) [d]	1.05 (0.29, 3.78)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	19 (67.9%)	28 (73.7%)
	The number (%) of patients censored [a]	9 (32.1%)	10 (26.3%)
	Median time to event (95% CI) [b]	1.4 (0.8, 2.2)	1.9 (1.4, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.726	
	HR (95% CI) [d]	1.11 (0.62, 2.00)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.818	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	11 (47.8%)	3 (42.9%)
	The number (%) of patients censored [a]	12 (52.2%)	4 (57.1%)
	Median time to event (95% CI) [b]	8.4 (4.2, NE)	7.3 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.268	
	HR (95% CI) [d]	0.47 (0.12, 1.80)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	12 (42.9%)	9 (23.7%)
	The number (%) of patients censored [a]	16 (57.1%)	29 (76.3%)
	Median time to event (95% CI) [b]	9.0 (2.2, NE)	11.1 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.112	
	HR (95% CI) [d]	2.00 (0.84, 4.77)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.106	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	11 (47.8%)	1 (14.3%)
	The number (%) of patients censored [a]	12 (52.2%)	6 (85.7%)
	Median time to event (95% CI) [b]	4.2 (1.6, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.302	
	HR (95% CI) [d]	2.82 (0.36, 21.87)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	17 (60.7%)	24 (63.2%)
	The number (%) of patients censored [a]	11 (39.3%)	14 (36.8%)
	Median time to event (95% CI) [b]	2.9 (1.4, 7.6)	3.7 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	0.99 (0.53, 1.86)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.381	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	15 (65.2%)	2 (28.6%)
	The number (%) of patients censored [a]	8 (34.8%)	5 (71.4%)
	Median time to event (95% CI) [b]	1.6 (0.8, 17.7)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.454	
	HR (95% CI) [d]	1.78 (0.39, 8.02)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	19 (67.9%)	21 (55.3%)
	The number (%) of patients censored [a]	9 (32.1%)	17 (44.7%)
	Median time to event (95% CI) [b]	2.8 (1.6, 3.6)	2.8 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.716	
	HR (95% CI) [d]	1.12 (0.60, 2.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.742	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	14 (60.9%)	5 (71.4%)
	The number (%) of patients censored [a]	9 (39.1%)	2 (28.6%)
	Median time to event (95% CI) [b]	0.9 (0.8, 5.0)	1.1 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.970	
	HR (95% CI) [d]	0.99 (0.35, 2.80)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	22 (78.6%)	27 (71.1%)
	The number (%) of patients censored [a]	6 (21.4%)	11 (28.9%)
	Median time to event (95% CI) [b]	1.4 (0.8, 1.7)	1.7 (1.0, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.097	
	HR (95% CI) [d]	1.61 (0.91, 2.85)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.273	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	10 (43.5%)	0 (0.0%)
	The number (%) of patients censored [a]	13 (56.5%)	7 (100.0%)
	Median time to event (95% CI) [b]	5.7 (0.9, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.091	
	HR (95% CI) [d]	NE (NE, NE)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	19 (67.9%)	14 (36.8%)
	The number (%) of patients censored [a]	9 (32.1%)	24 (63.2%)
	Median time to event (95% CI) [b]	2.6 (0.9, 3.6)	6.5 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.007	
	HR (95% CI) [d]	2.54 (1.27, 5.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.990	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	14 (60.9%)	4 (57.1%)
	The number (%) of patients censored [a]	9 (39.1%)	3 (42.9%)
	Median time to event (95% CI) [b]	5.0 (1.6, 10.0)	1.2 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.181	
	HR (95% CI) [d]	0.46 (0.14, 1.48)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	16 (57.1%)	20 (52.6%)
	The number (%) of patients censored [a]	12 (42.9%)	18 (47.4%)
	Median time to event (95% CI) [b]	2.2 (0.8, 6.9)	3.1 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.314	
	HR (95% CI) [d]	1.40 (0.72, 2.70)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.290	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	12 (52.2%)	3 (42.9%)
	The number (%) of patients censored [a]	11 (47.8%)	4 (57.1%)
	Median time to event (95% CI) [b]	6.3 (2.4, 11.4)	1.2 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.299	
	HR (95% CI) [d]	0.50 (0.13, 1.88)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	10 (35.7%)	21 (55.3%)
	The number (%) of patients censored [a]	18 (64.3%)	17 (44.7%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	2.8 (1.5, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.169	
	HR (95% CI) [d]	0.59 (0.28, 1.26)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.876	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	8 (34.8%)	5 (71.4%)
	The number (%) of patients censored [a]	15 (65.2%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (1.6, NE)	2.2 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.029	
	HR (95% CI) [d]	0.28 (0.08, 0.94)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	13 (46.4%)	15 (39.5%)
	The number (%) of patients censored [a]	15 (53.6%)	23 (60.5%)
	Median time to event (95% CI) [b]	5.5 (1.6, NE)	6.5 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.718	
	HR (95% CI) [d]	1.13 (0.53, 2.43)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.053	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	9 (39.1%)	2 (28.6%)
	The number (%) of patients censored [a]	14 (60.9%)	5 (71.4%)
	Median time to event (95% CI) [b]	7.9 (1.5, NE)	7.3 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.07 (0.23, 5.08)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	14 (50.0%)	14 (36.8%)
	The number (%) of patients censored [a]	14 (50.0%)	24 (63.2%)
	Median time to event (95% CI) [b]	2.3 (1.4, NE)	5.6 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.231	
	HR (95% CI) [d]	1.56 (0.74, 3.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.797	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	14 (60.9%)	1 (14.3%)
	The number (%) of patients censored [a]	9 (39.1%)	6 (85.7%)
	Median time to event (95% CI) [b]	1.7 (0.8, 3.6)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.127	
	HR (95% CI) [d]	4.27 (0.56, 32.49)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	16 (57.1%)	16 (42.1%)
	The number (%) of patients censored [a]	12 (42.9%)	22 (57.9%)
	Median time to event (95% CI) [b]	2.4 (1.4, NE)	6.7 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.269	
	HR (95% CI) [d]	1.47 (0.73, 2.96)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.318	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	14 (60.9%)	4 (57.1%)
	The number (%) of patients censored [a]	9 (39.1%)	3 (42.9%)
	Median time to event (95% CI) [b]	2.2 (0.9, 4.2)	1.2 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.729	
	HR (95% CI) [d]	0.82 (0.27, 2.52)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	20 (71.4%)	20 (52.6%)
	The number (%) of patients censored [a]	8 (28.6%)	18 (47.4%)
	Median time to event (95% CI) [b]	1.6 (0.8, 2.2)	3.3 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.013	
	HR (95% CI) [d]	2.17 (1.16, 4.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.170	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	12 (52.2%)	2 (28.6%)
	The number (%) of patients censored [a]	11 (47.8%)	5 (71.4%)
	Median time to event (95% CI) [b]	7.9 (4.5, 10.5)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.624	
	HR (95% CI) [d]	0.69 (0.13, 3.51)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	11 (39.3%)	16 (42.1%)
	The number (%) of patients censored [a]	17 (60.7%)	22 (57.9%)
	Median time to event (95% CI) [b]	8.3 (2.9, NE)	4.7 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.441	
	HR (95% CI) [d]	0.74 (0.34, 1.60)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.930	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	13 (56.5%)	2 (28.6%)
	The number (%) of patients censored [a]	10 (43.5%)	5 (71.4%)
	Median time to event (95% CI) [b]	1.7 (0.8, NE)	1.1 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	1.29 (0.28, 5.84)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	18 (64.3%)	22 (57.9%)
	The number (%) of patients censored [a]	10 (35.7%)	16 (42.1%)
	Median time to event (95% CI) [b]	1.8 (0.8, 5.0)	2.8 (1.9, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.175	
	HR (95% CI) [d]	1.53 (0.82, 2.86)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.695	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	5 (21.7%)	1 (14.3%)
	The number (%) of patients censored [a]	18 (78.3%)	6 (85.7%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.57 (0.06, 5.15)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	6 (21.4%)	11 (28.9%)
	The number (%) of patients censored [a]	22 (78.6%)	27 (71.1%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.437	
	HR (95% CI) [d]	0.67 (0.25, 1.82)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.850	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	23 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	1 (3.6%)	4 (10.5%)
	The number (%) of patients censored [a]	27 (96.4%)	34 (89.5%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	1.0 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.272	
	HR (95% CI) [d]	0.30 (0.03, 2.77)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	8 (34.8%)	2 (28.6%)
	The number (%) of patients censored [a]	15 (65.2%)	5 (71.4%)
	Median time to event (95% CI) [b]	11.3 (1.6, NE)	2.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.613	
	HR (95% CI) [d]	0.67 (0.14, 3.27)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	11 (39.3%)	8 (21.1%)
	The number (%) of patients censored [a]	17 (60.7%)	30 (78.9%)
	Median time to event (95% CI) [b]	3.6 (0.8, NE)	9.3 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.073	
	HR (95% CI) [d]	2.27 (0.91, 5.65)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.165	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	16 (69.6%)	2 (28.6%)
	The number (%) of patients censored [a]	7 (30.4%)	5 (71.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.1)	1.1 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.303	
	HR (95% CI) [d]	2.14 (0.49, 9.37)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	24 (85.7%)	31 (81.6%)
	The number (%) of patients censored [a]	4 (14.3%)	7 (18.4%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.5)	1.0 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.158	
	HR (95% CI) [d]	1.45 (0.84, 2.50)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.677	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	5 (21.7%)	2 (28.6%)
	The number (%) of patients censored [a]	18 (78.3%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (10.0, NE)	6.9 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.128	
	HR (95% CI) [d]	0.27 (0.04, 1.65)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	12 (42.9%)	5 (13.2%)
	The number (%) of patients censored [a]	16 (57.1%)	33 (86.8%)
	Median time to event (95% CI) [b]	6.4 (3.0, NE)	NE (9.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.018	
	HR (95% CI) [d]	3.28 (1.15, 9.33)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.027	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	11 (47.8%)	3 (42.9%)
	The number (%) of patients censored [a]	12 (52.2%)	4 (57.1%)
	Median time to event (95% CI) [b]	4.5 (1.6, NE)	1.1 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.088	
	HR (95% CI) [d]	0.32 (0.08, 1.26)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	16 (57.1%)	17 (44.7%)
	The number (%) of patients censored [a]	12 (42.9%)	21 (55.3%)
	Median time to event (95% CI) [b]	5.6 (1.4, 15.0)	3.9 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.864	
	HR (95% CI) [d]	1.06 (0.52, 2.16)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.146	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	2 (8.7%)	0 (0.0%)
	The number (%) of patients censored [a]	21 (91.3%)	7 (100.0%)
	Median time to event (95% CI) [b]	4.3 (0.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	2 (7.1%)	6 (15.8%)
	The number (%) of patients censored [a]	26 (92.9%)	32 (84.2%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	1.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.110	
	HR (95% CI) [d]	0.27 (0.05, 1.43)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	10 (43.5%)	1 (14.3%)
	The number (%) of patients censored [a]	13 (56.5%)	6 (85.7%)
	Median time to event (95% CI) [b]	9.0 (3.3, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.892	
	HR (95% CI) [d]	1.16 (0.14, 9.48)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	17 (60.7%)	11 (28.9%)
	The number (%) of patients censored [a]	11 (39.3%)	27 (71.1%)
	Median time to event (95% CI) [b]	5.8 (1.5, 10.2)	11.1 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.042	
	HR (95% CI) [d]	2.17 (1.01, 4.65)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.6.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.631	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.2.6.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	7 (30.4%)	1 (14.3%)
	The number (%) of patients censored [a]	16 (69.6%)	6 (85.7%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.705	
	HR (95% CI) [d]	1.50 (0.18, 12.54)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	18 (64.3%)	14 (36.8%)
	The number (%) of patients censored [a]	10 (35.7%)	24 (63.2%)
	Median time to event (95% CI) [b]	2.4 (0.7, 3.6)	5.6 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.041	
	HR (95% CI) [d]	2.05 (1.02, 4.14)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.776	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.5
Time to First Meaningful Deterioration for PGIC by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	4 (17.4%)	1 (14.3%)
	The number (%) of patients censored [a]	19 (82.6%)	6 (85.7%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	NE (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.835	
	HR (95% CI) [d]	0.79 (0.09, 7.12)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	11 (39.3%)	12 (31.6%)
	The number (%) of patients censored [a]	17 (60.7%)	26 (68.4%)
	Median time to event (95% CI) [b]	6.4 (4.2, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.837	
	HR (95% CI) [d]	0.91 (0.39, 2.11)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.5
Time to First Meaningful Deterioration for PGIC by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.910	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.6
Time to First Meaningful Deterioration for PGIS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	23	7
	The number (%) of patients with an event [a]	4 (17.4%)	0 (0.0%)
	The number (%) of patients censored [a]	19 (82.6%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.404	
	HR (95% CI) [d]	NE (NE, NE)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin	28	38
	The number (%) of patients with an event [a]	2 (7.1%)	3 (7.9%)
	The number (%) of patients censored [a]	26 (92.9%)	35 (92.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.890	
	HR (95% CI) [d]	0.88 (0.15, 5.29)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.2.6.6
Time to First Meaningful Deterioration for PGIS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

Subgroup	Parameter	SG (N=52)	TPC (N=45)
	P-value of subgroup*treatment interaction [e]	0.995	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 1.2.1.1
Observed Mean Change from Baseline in EORTC QLQ-C30 Global Health Status/QoL by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

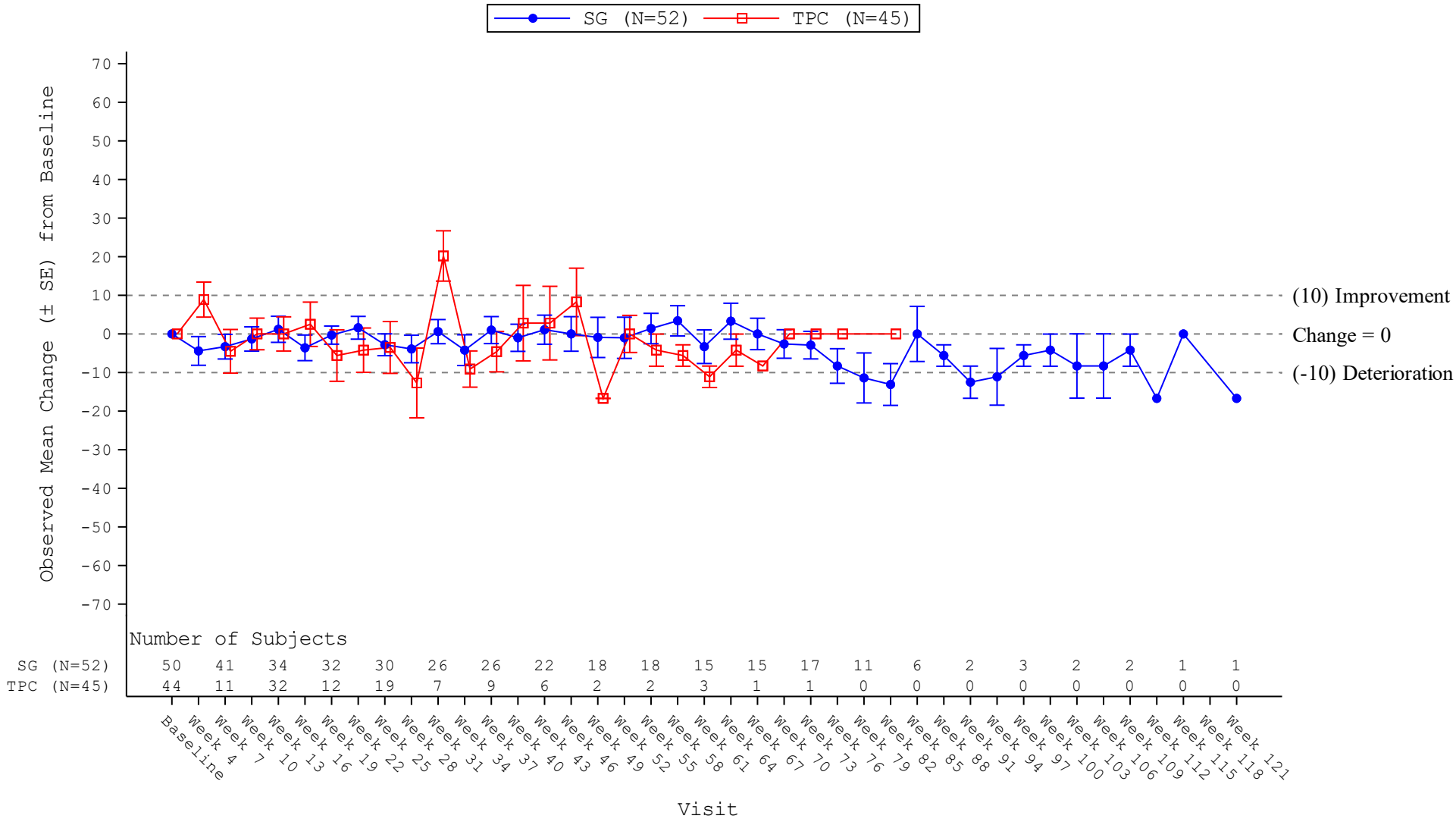


Figure 1.2.1.2
Observed Mean Change from Baseline in EORTC QLQ-C30 Physical Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

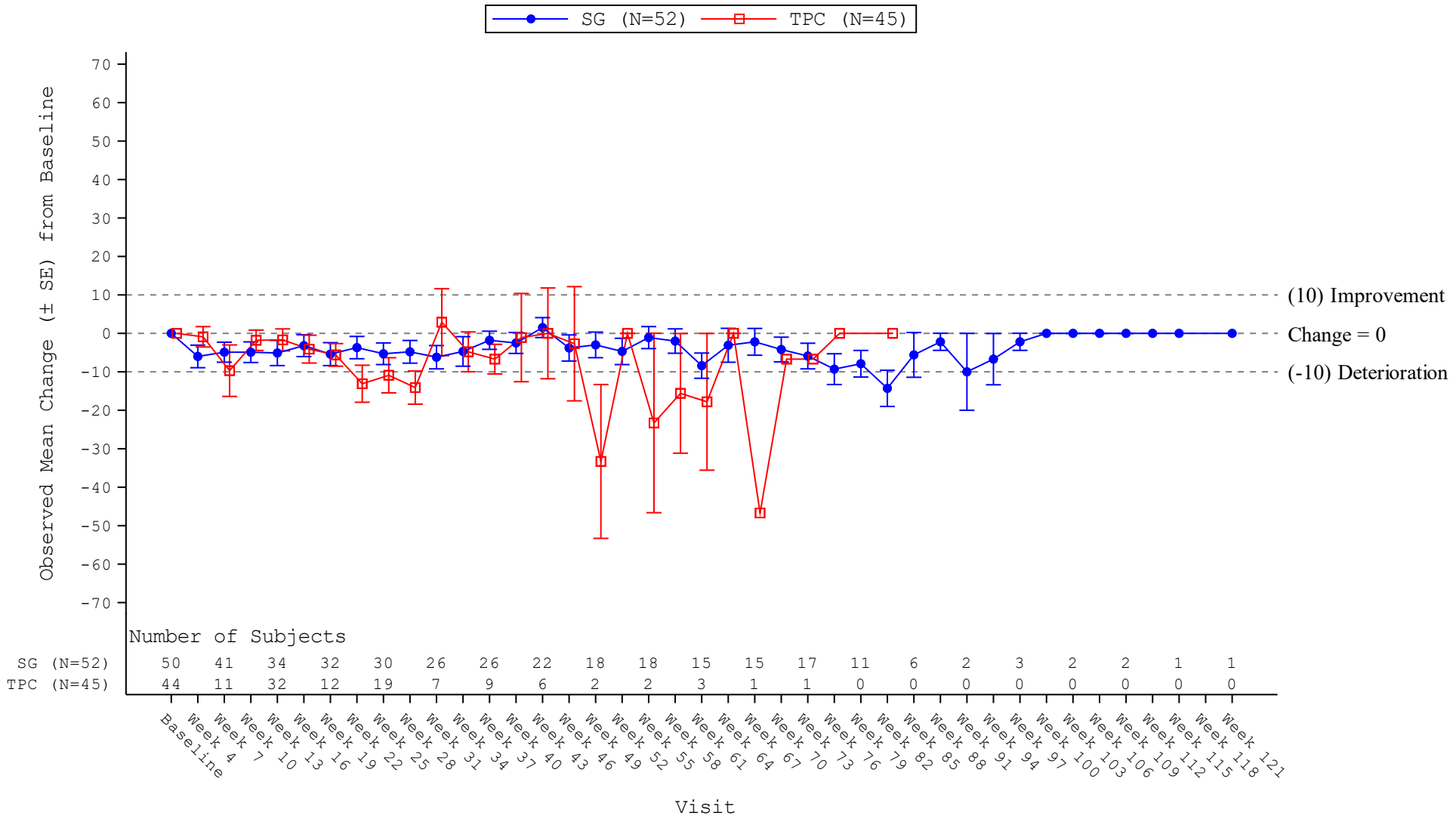


Figure 1.2.1.3
Observed Mean Change from Baseline in EORTC QLQ-C30 Role Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

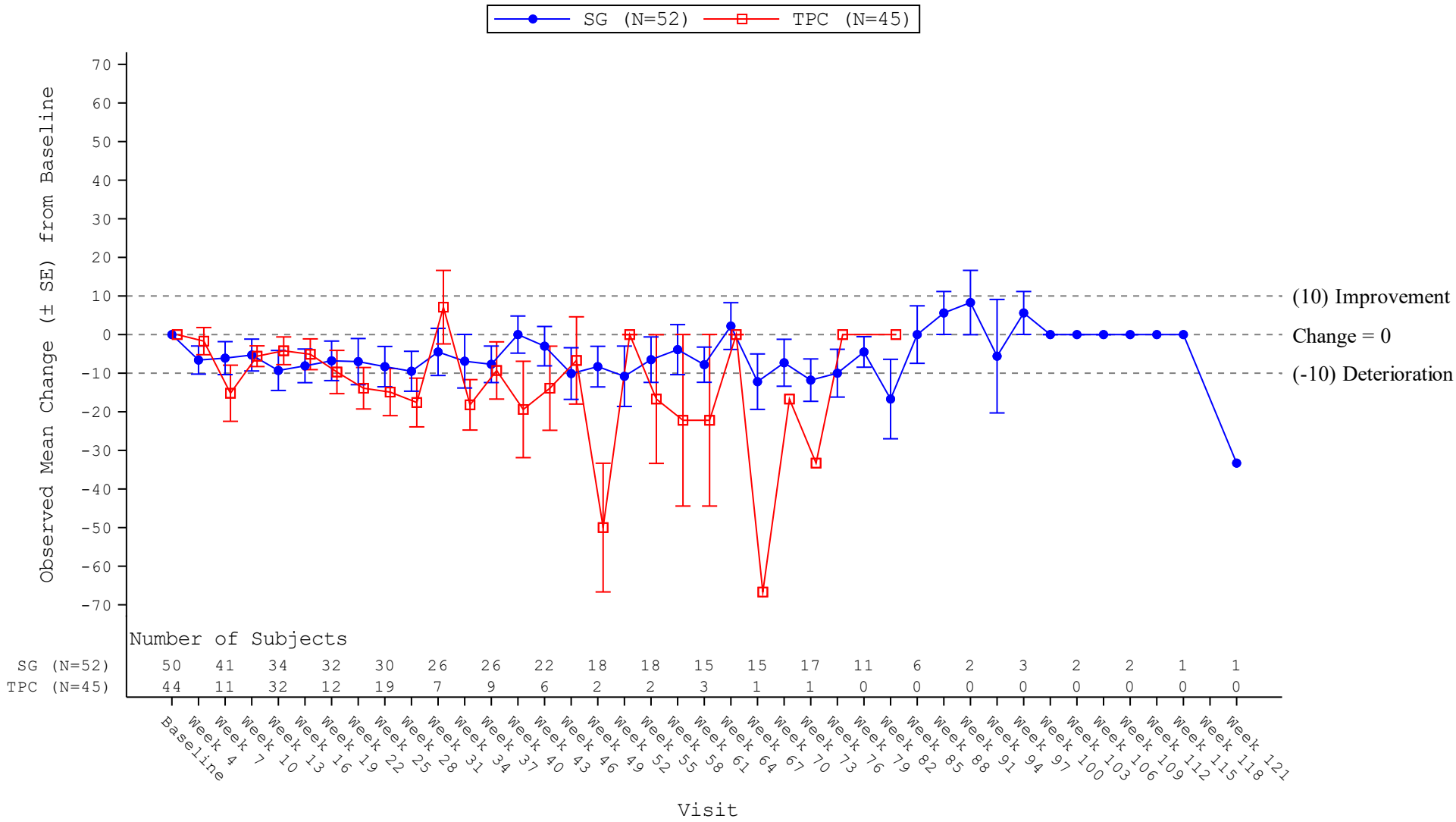


Figure 1.2.1.4
Observed Mean Change from Baseline in EORTC QLQ-C30 Emotional Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

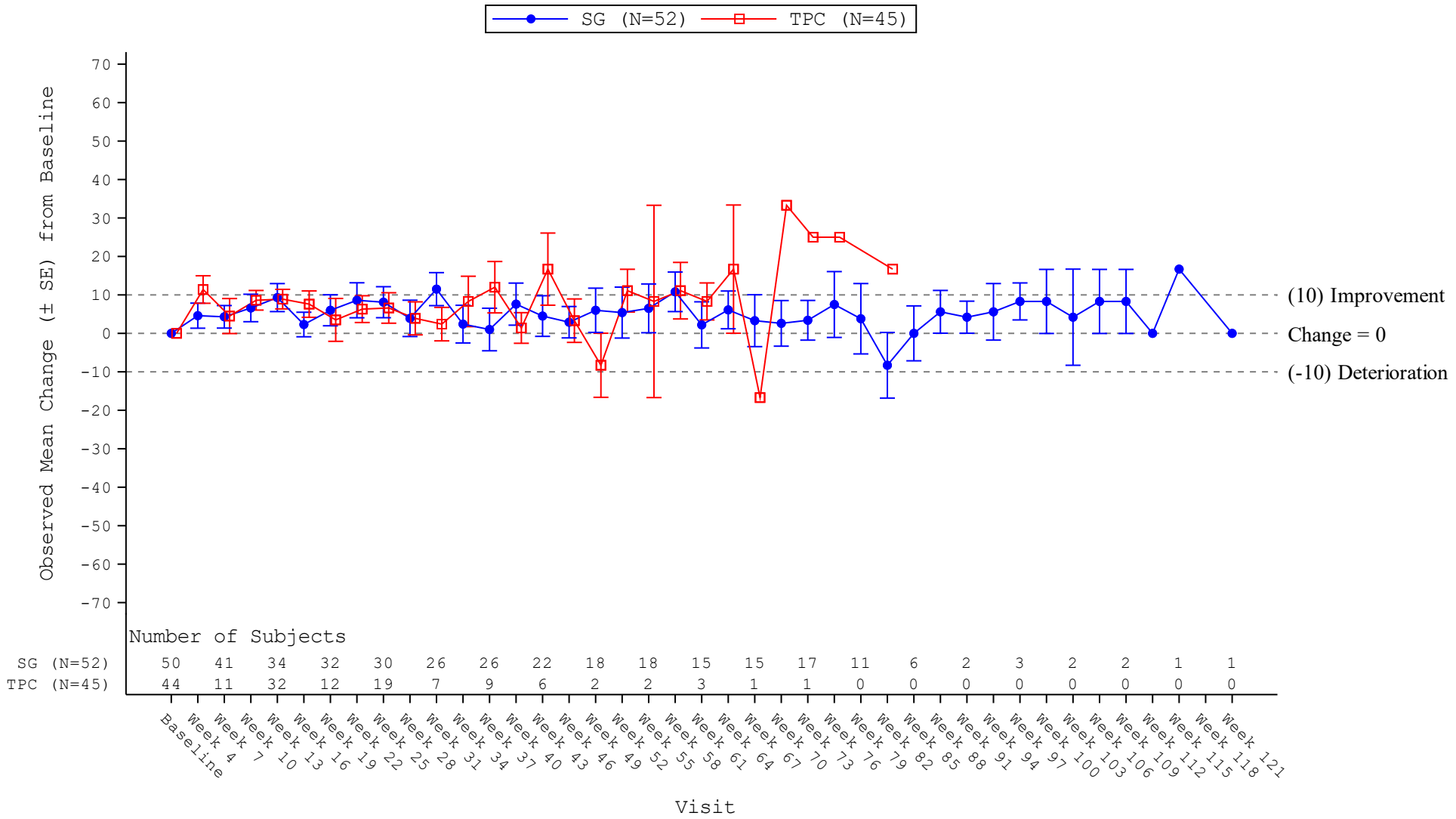


Figure 1.2.1.5
Observed Mean Change from Baseline in EORTC QLQ-C30 Cognitive Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

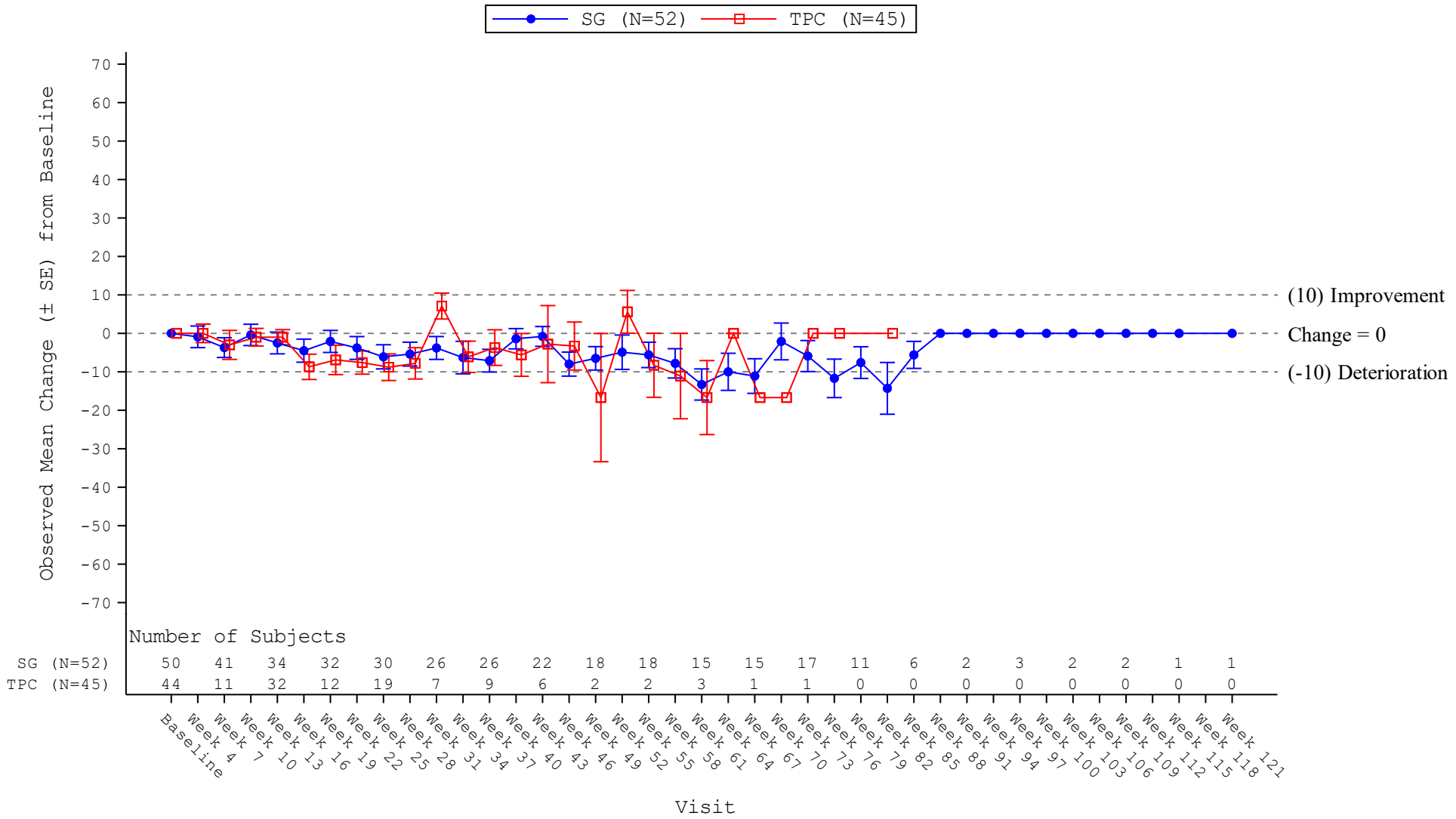


Figure 1.2.1.6
Observed Mean Change from Baseline in EORTC QLQ-C30 Social Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

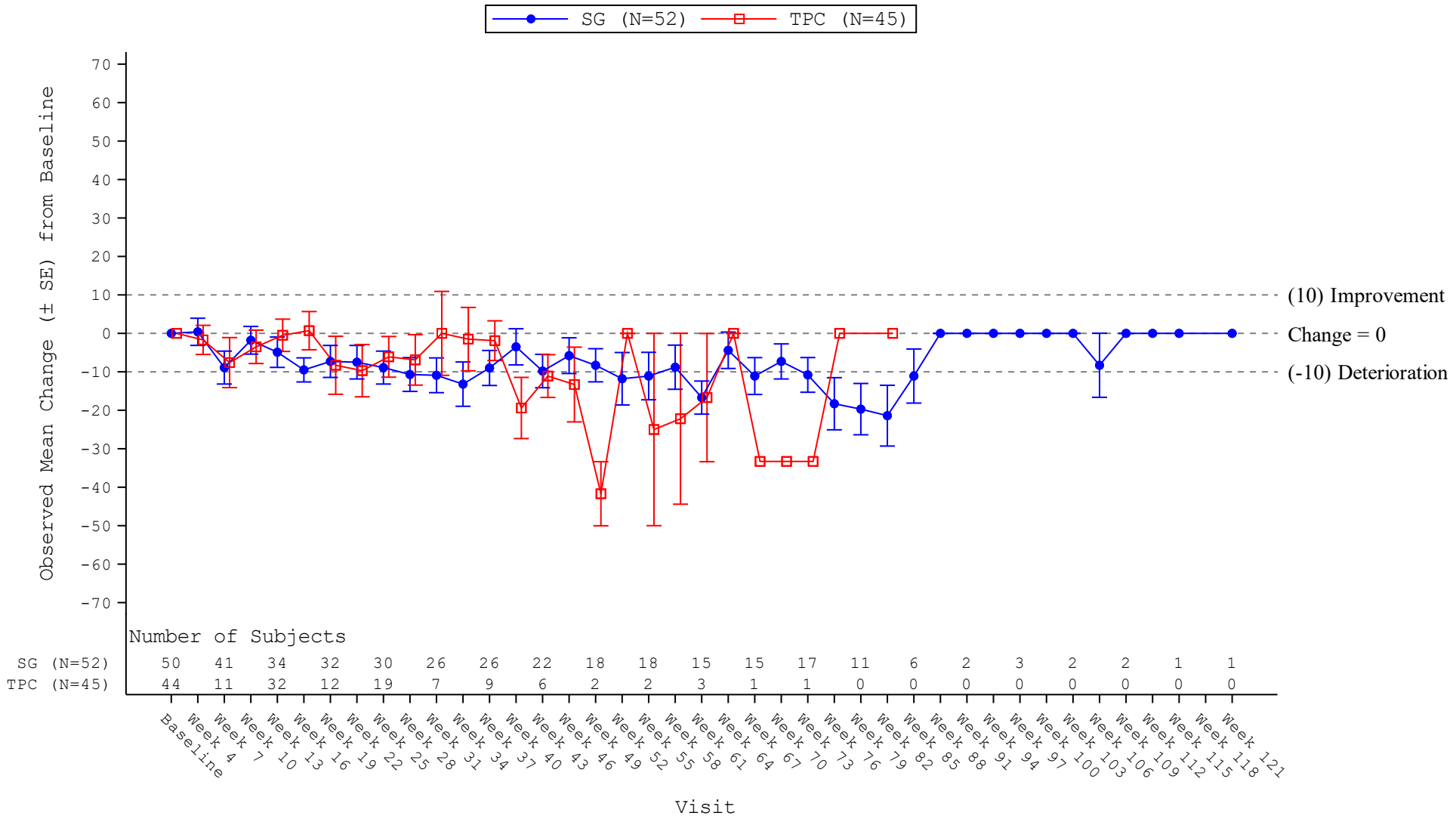


Figure 1.2.1.7
Observed Mean Change from Baseline in EORTC QLQ-C30 Fatigue by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

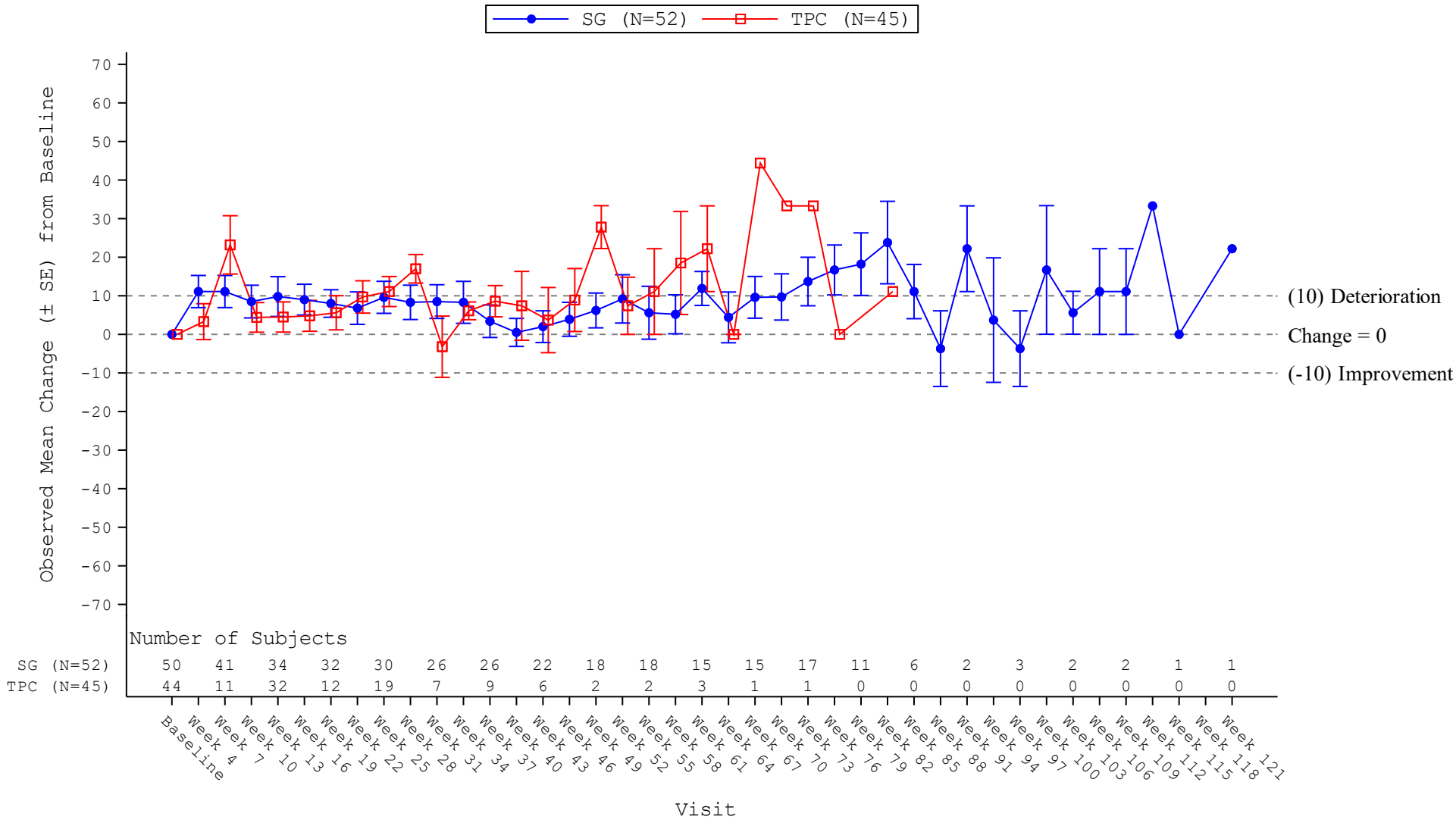


Figure 1.2.1.8
Observed Mean Change from Baseline in EORTC QLQ-C30 Nausea and Vomiting by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

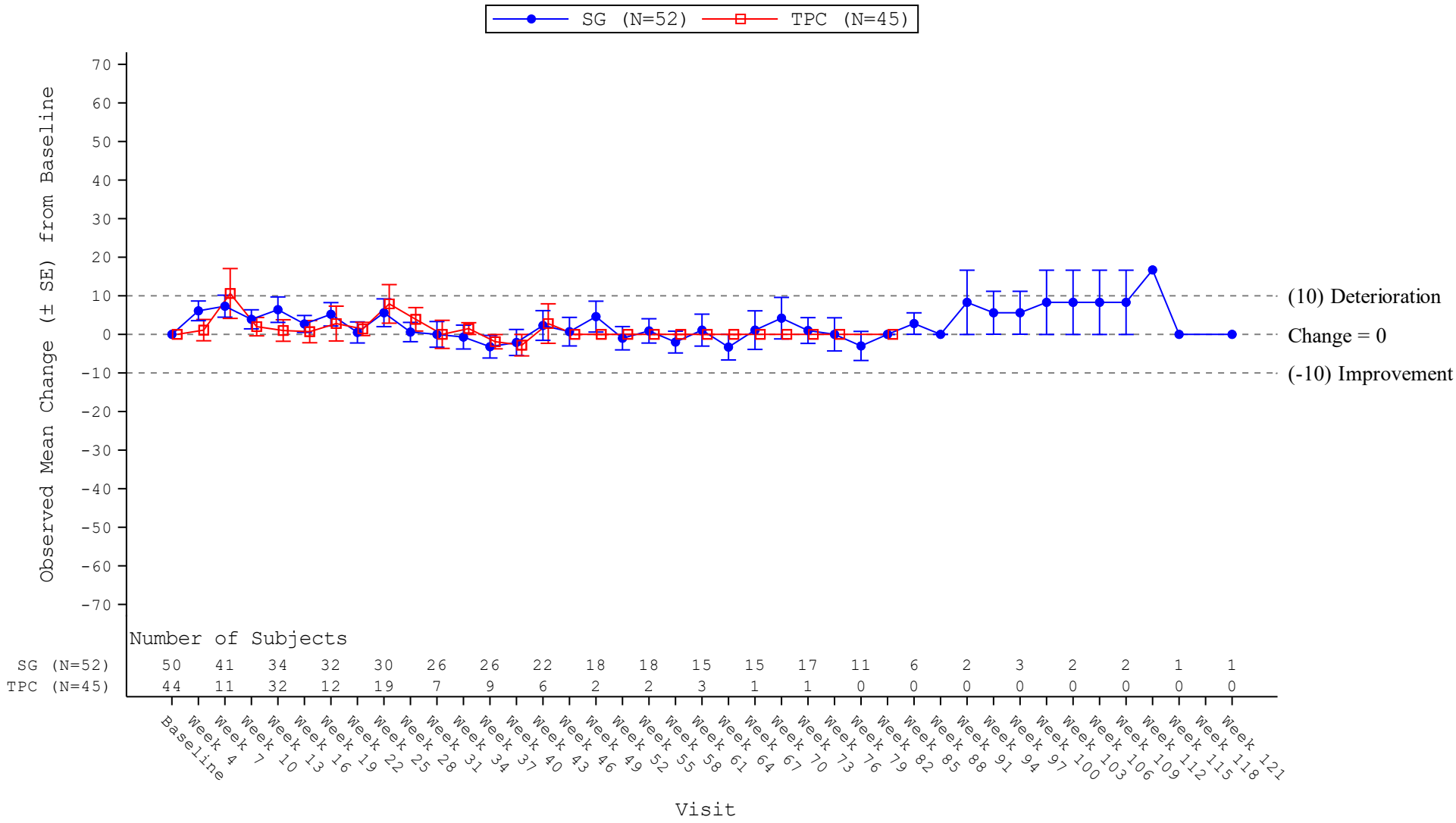


Figure 1.2.1.9
Observed Mean Change from Baseline in EORTC QLQ-C30 Pain by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

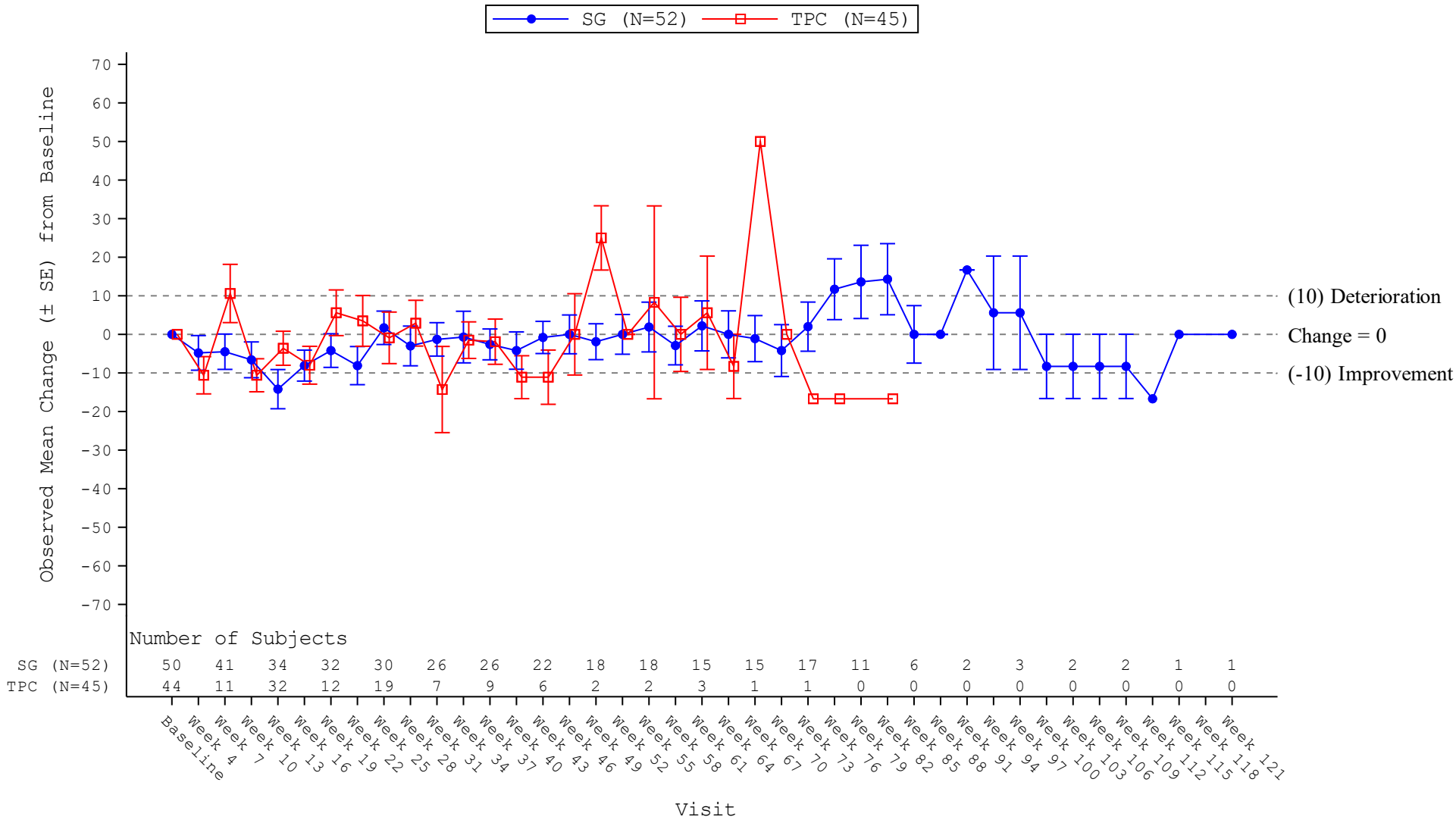


Figure 1.2.1.10
Observed Mean Change from Baseline in EORTC QLQ-C30 Dyspnea by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

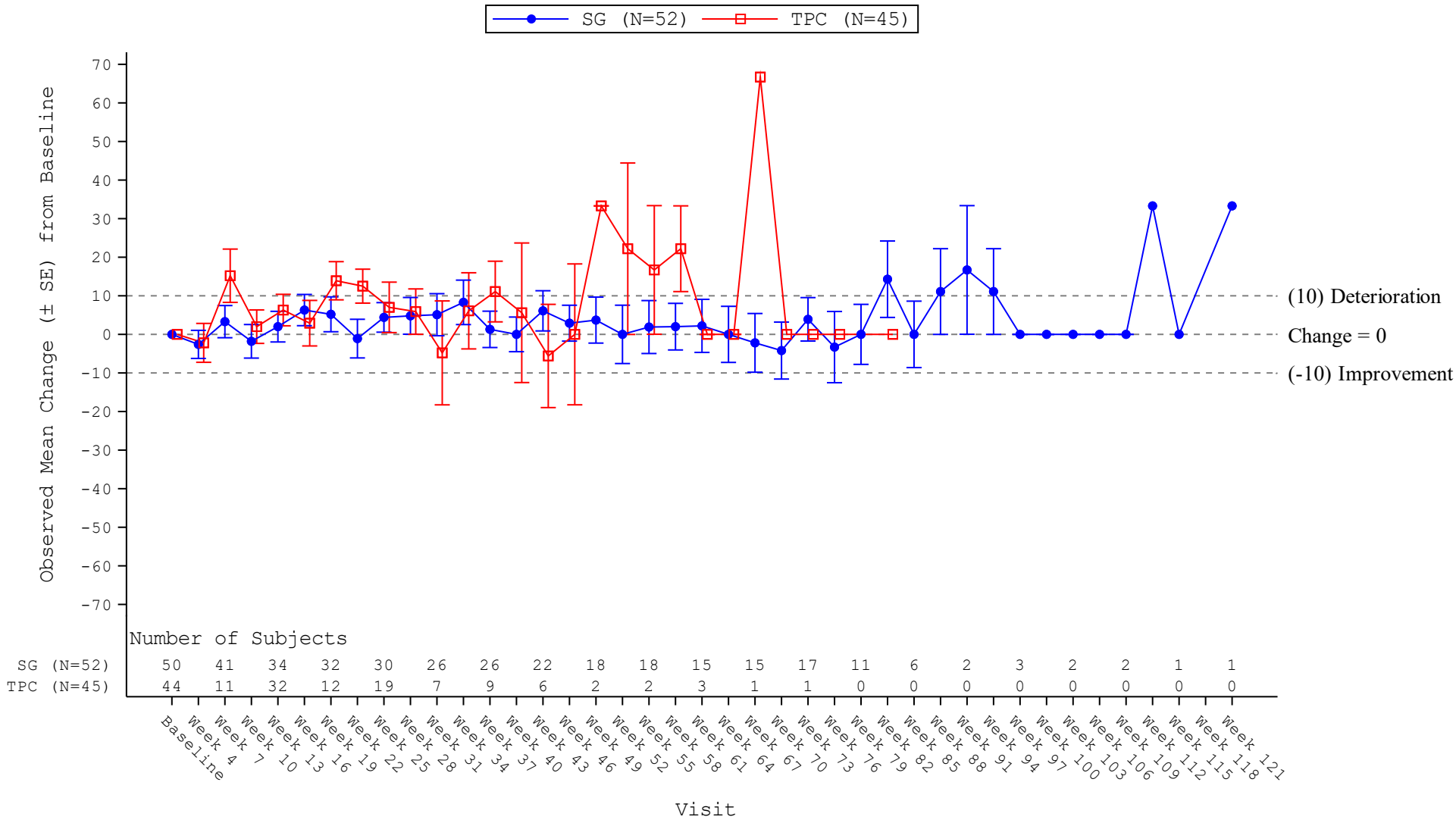


Figure 1.2.1.11
Observed Mean Change from Baseline in EORTC QLQ-C30 Insomnia by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

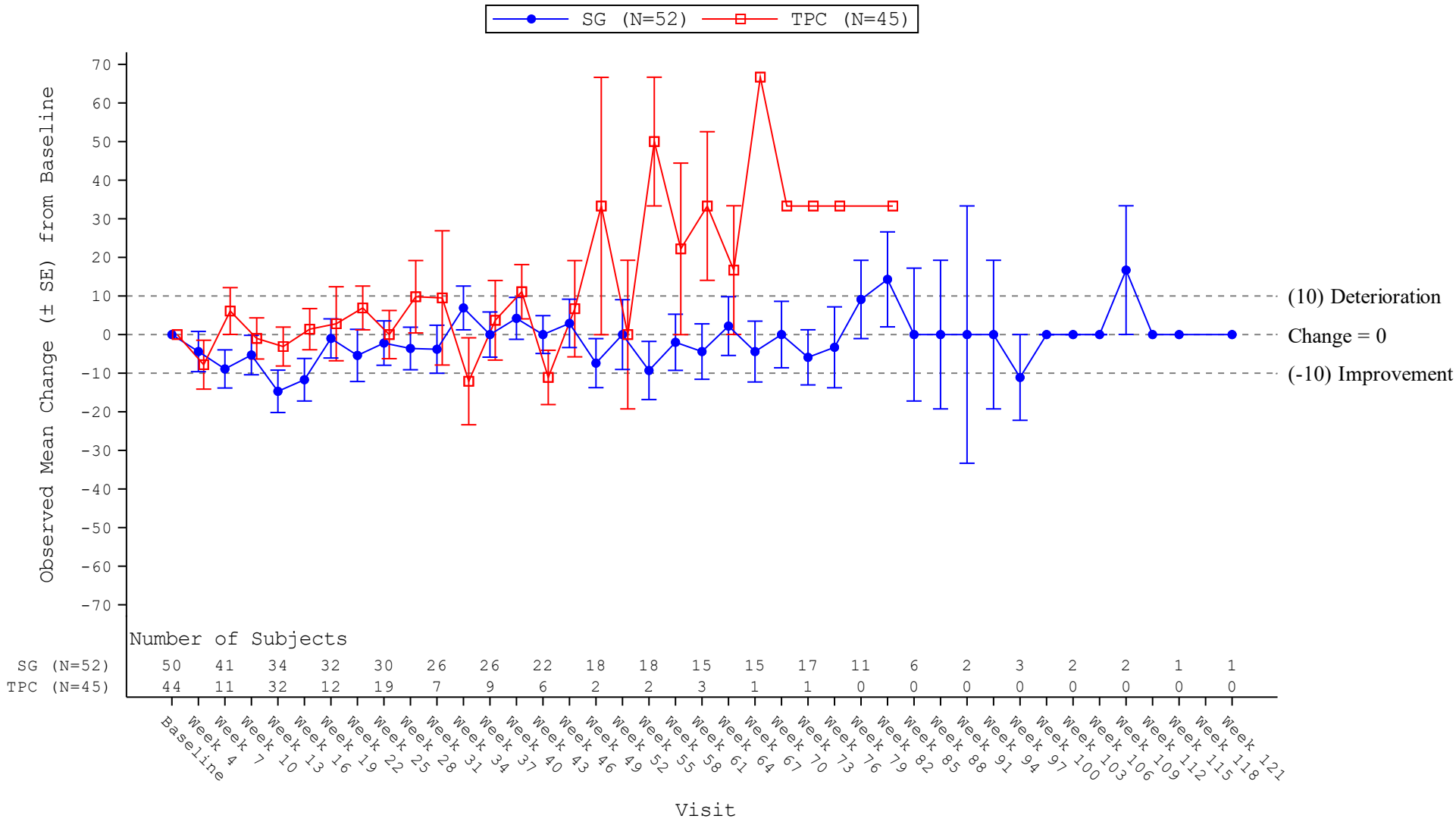


Figure 1.2.1.12
Observed Mean Change from Baseline in EORTC QLQ-C30 Appetite Loss by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

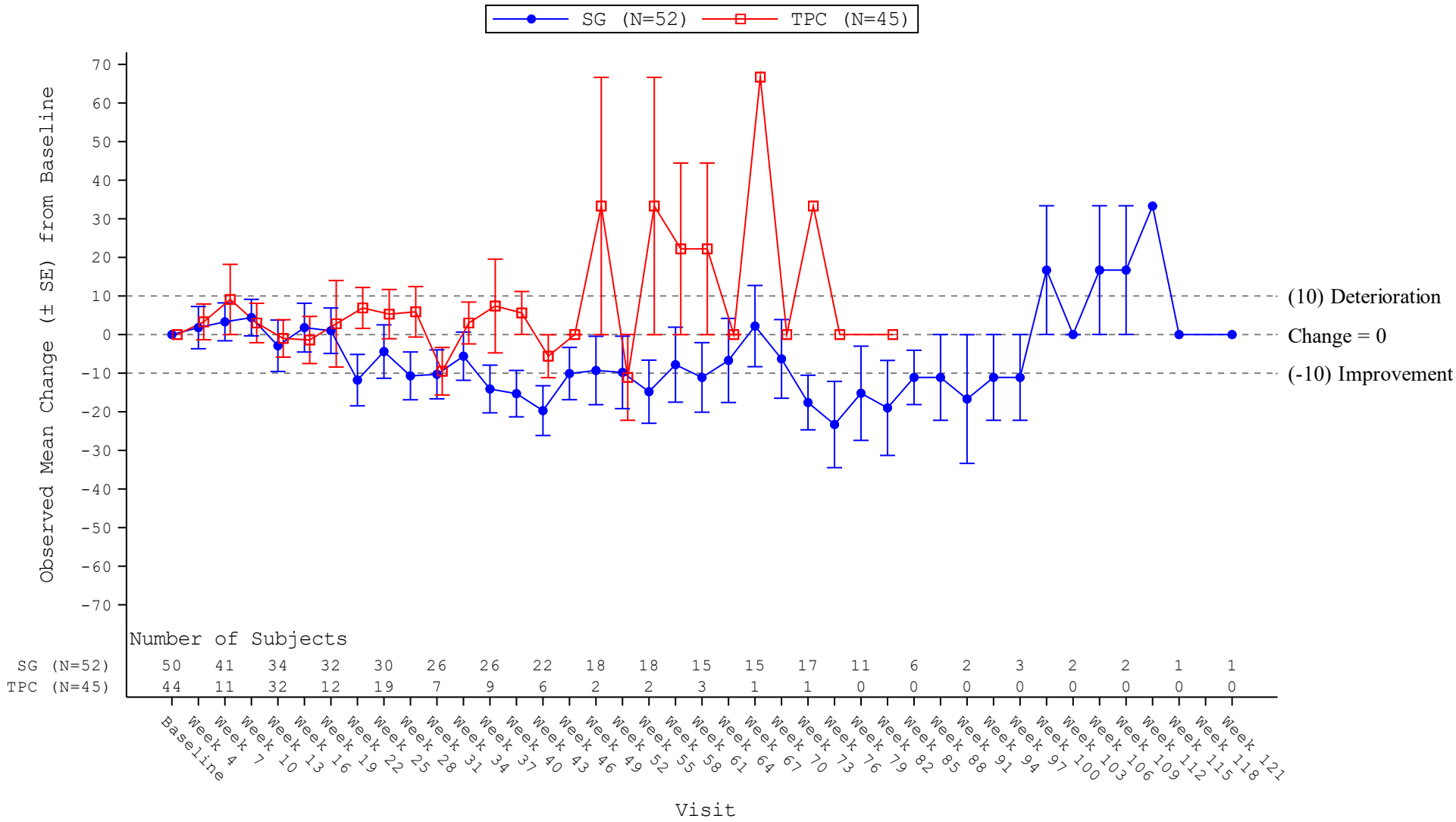


Figure 1.2.1.13
Observed Mean Change from Baseline in EORTC QLQ-C30 Constipation by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

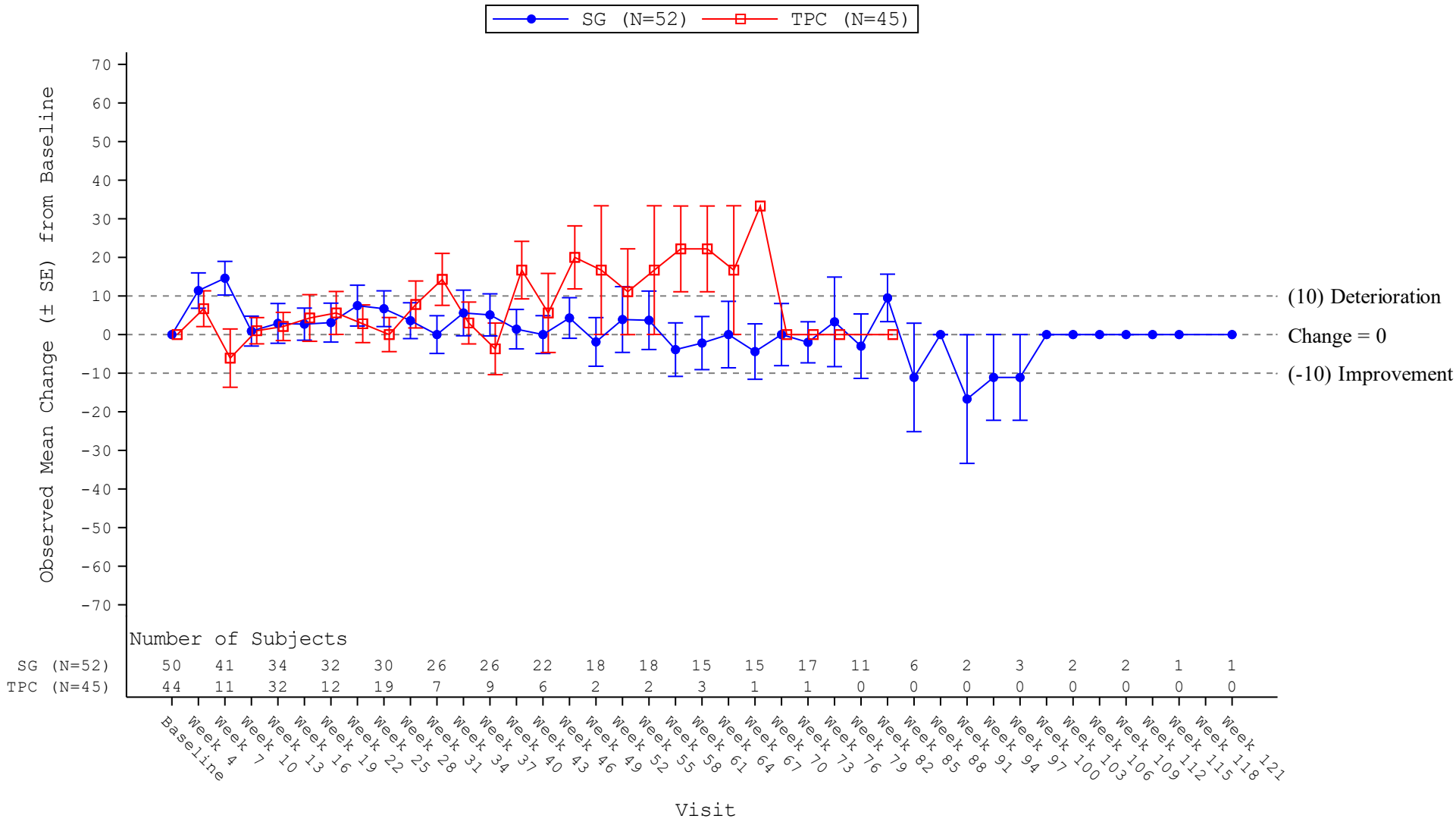


Figure 1.2.1.14
Observed Mean Change from Baseline in EORTC QLQ-C30 Diarrhea by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

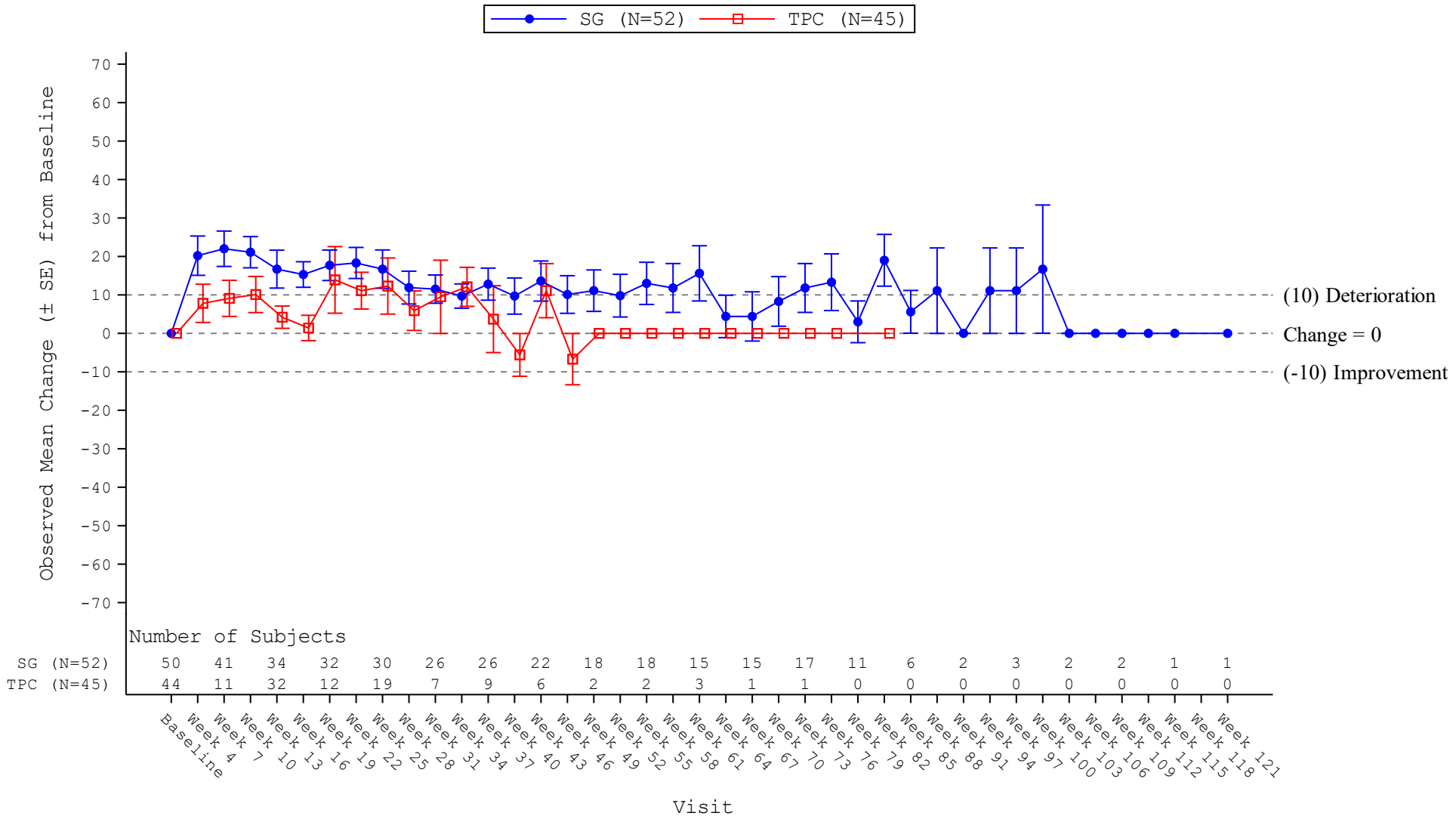


Figure 1.2.1.15
Observed Mean Change from Baseline in EORTC QLQ-C30 Financial Difficulties by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

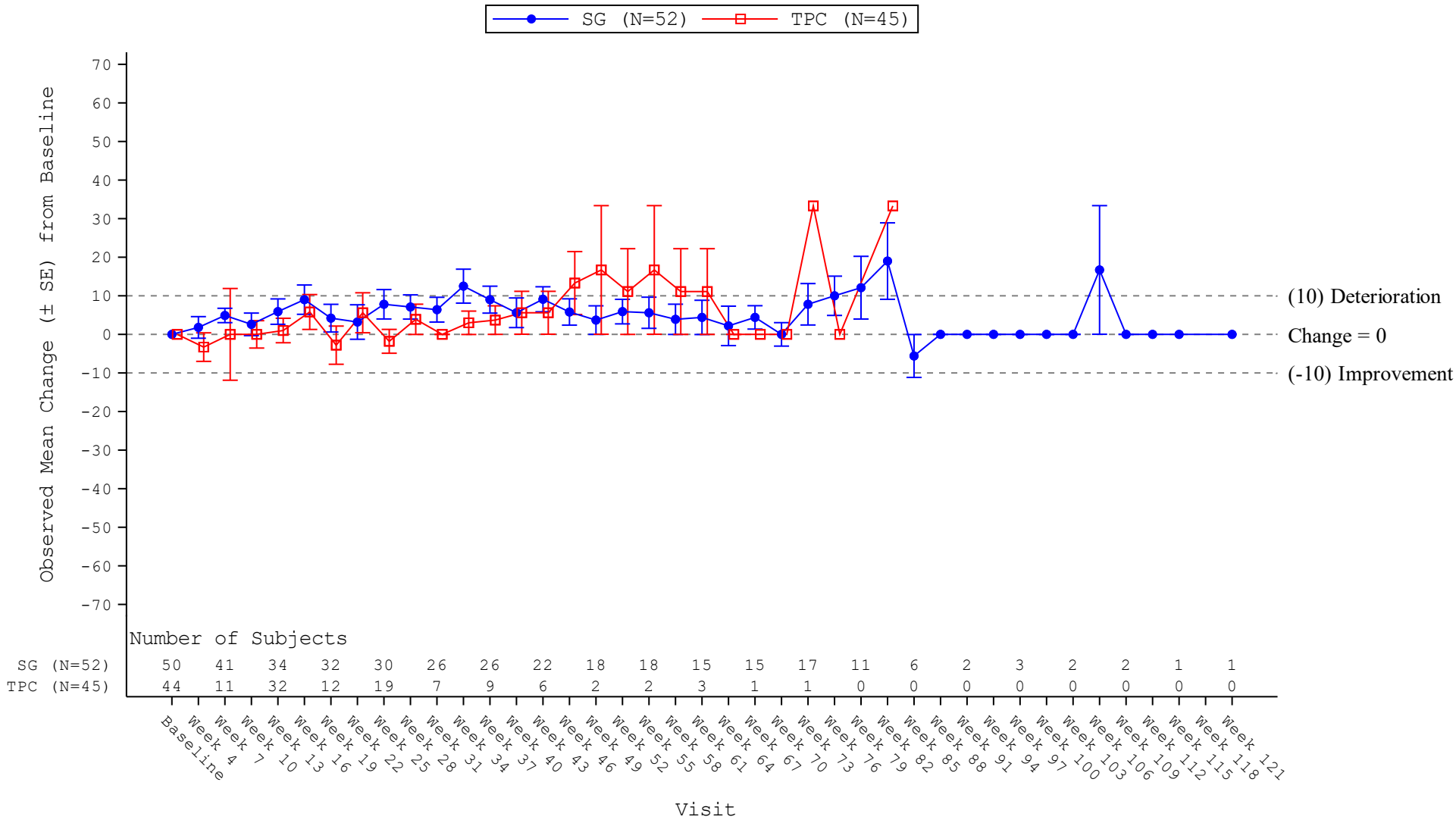


Figure 1.2.2.1
Observed Mean Change from Baseline in EORTC QLQ-BR23 Body Image by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

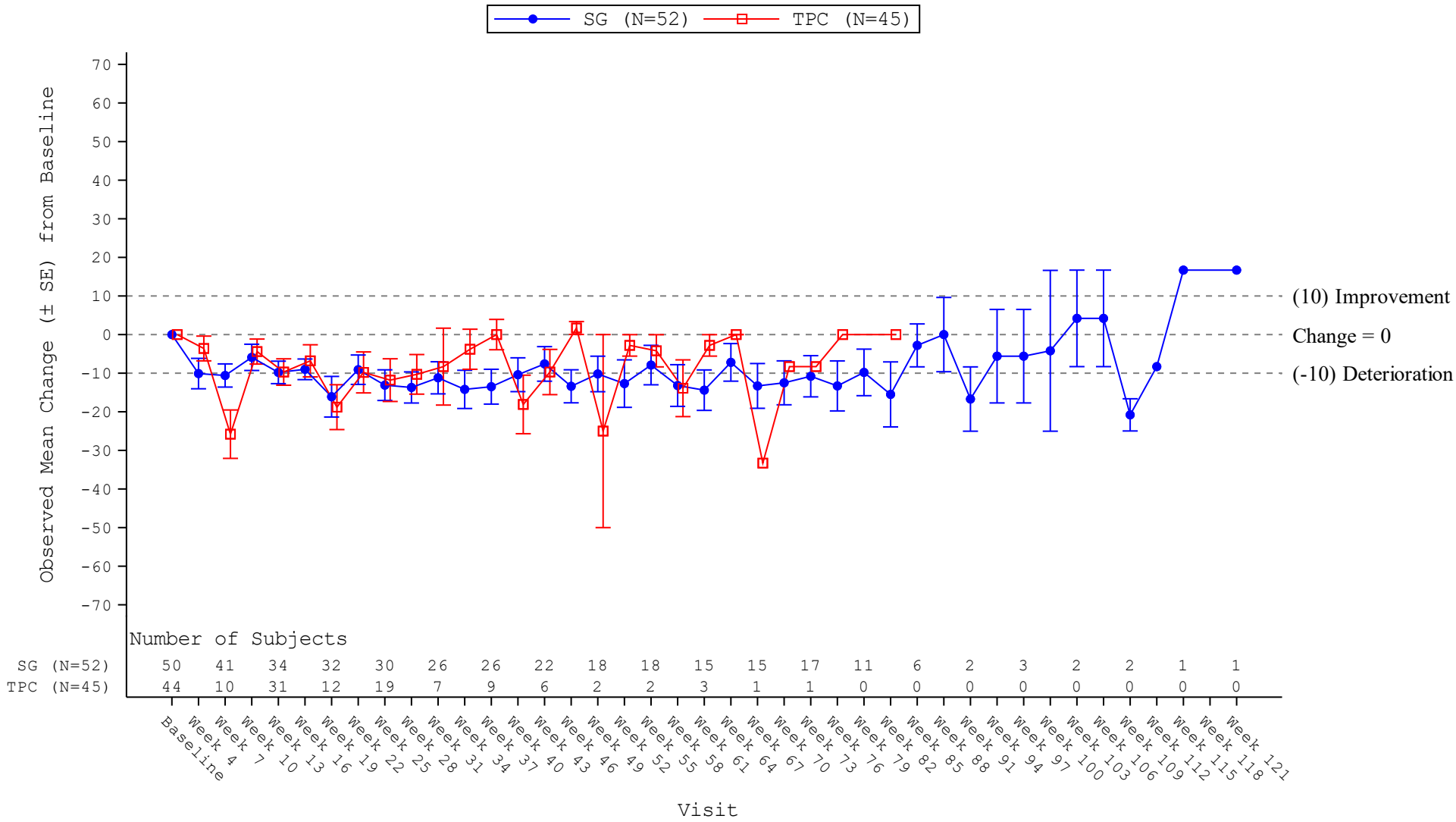


Figure 1.2.2.2
Observed Mean Change from Baseline in EORTC QLQ-BR23 Sexual Function by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

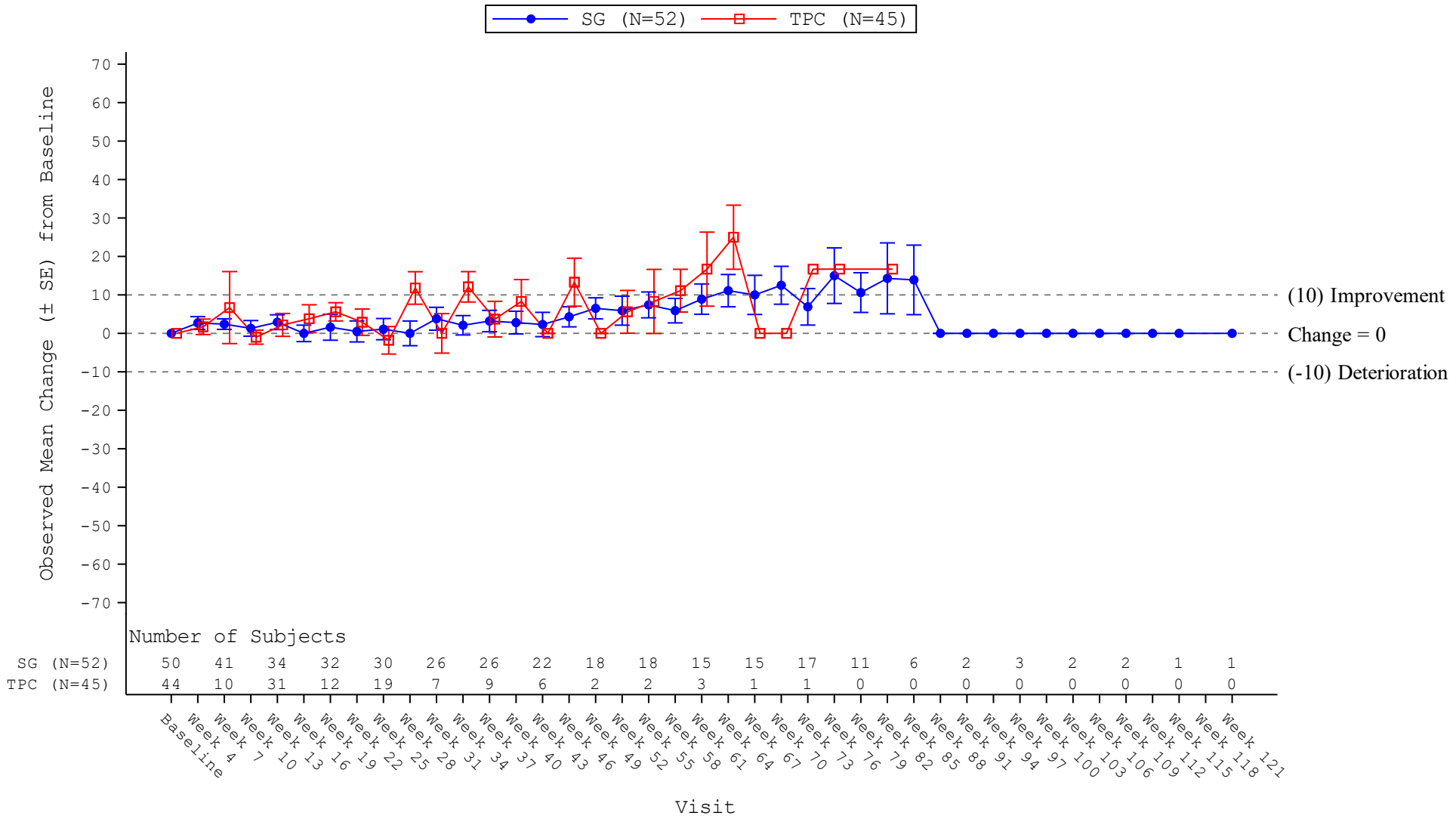


Figure 1.2.2.3
Observed Mean Change from Baseline in EORTC QLQ-BR23 Sexual Enjoyment by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

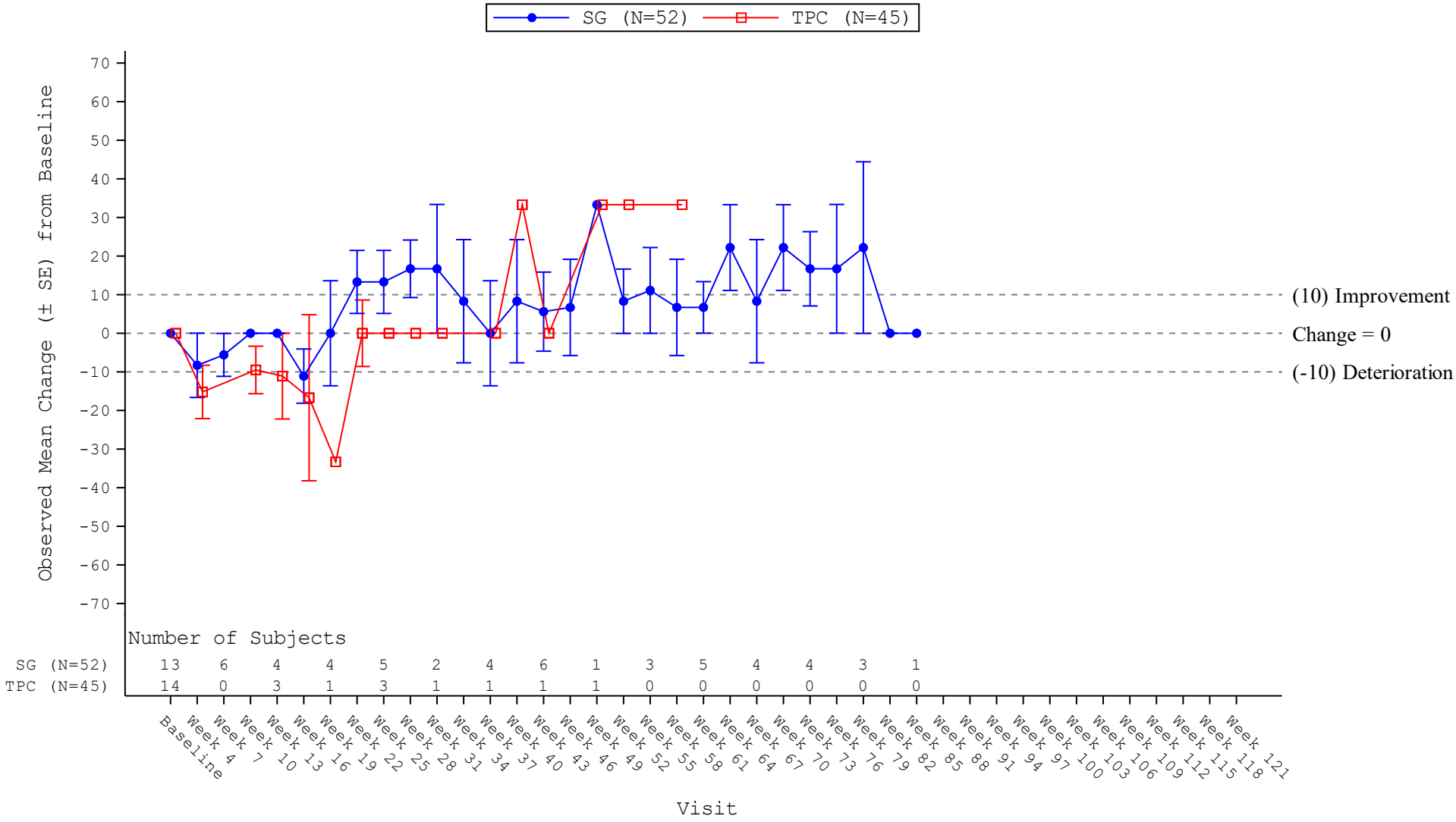


Figure 1.2.2.4
Observed Mean Change from Baseline in EORTC QLQ-BR23 Future Perspective by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

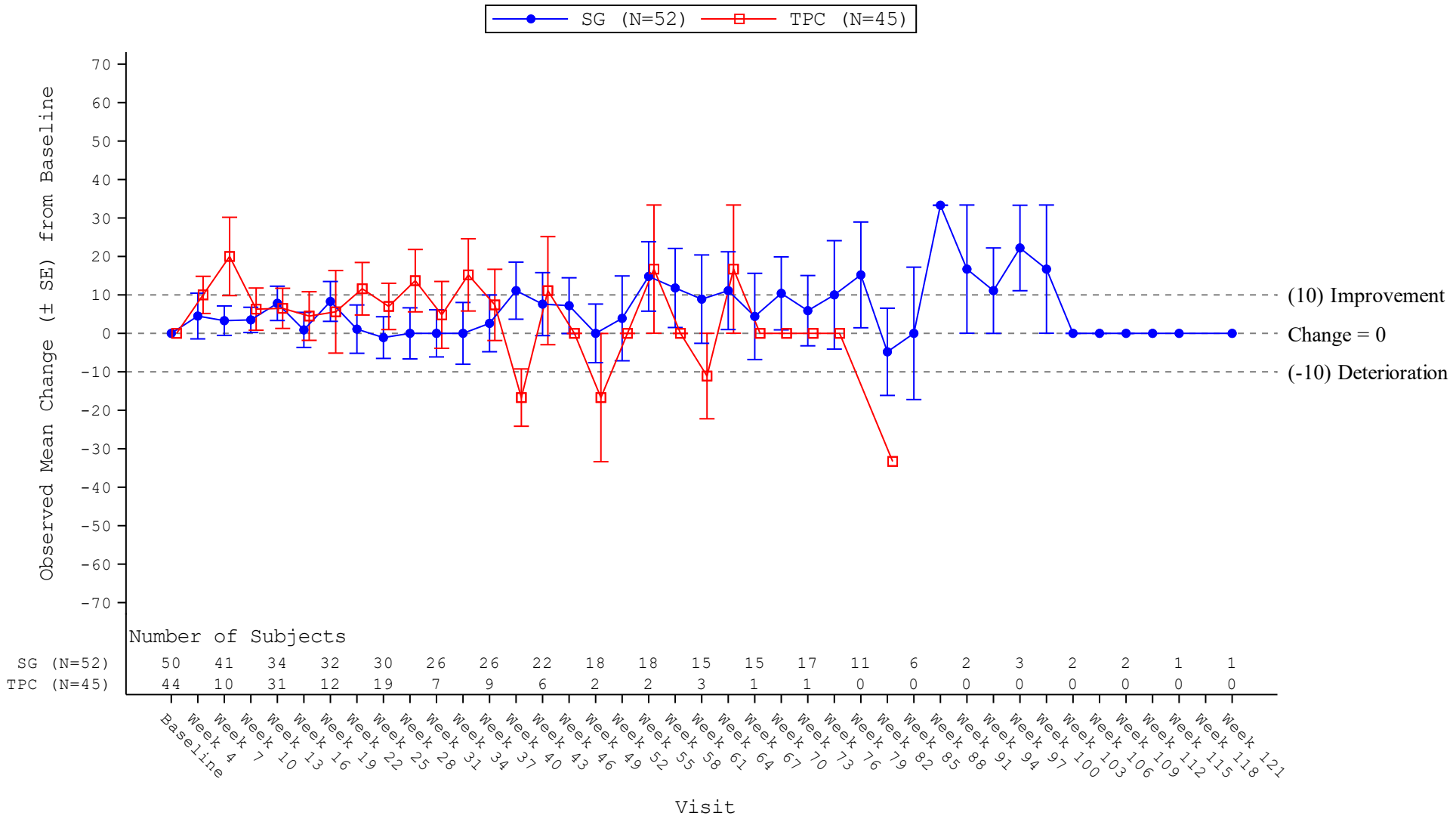


Figure 1.2.2.5
Observed Mean Change from Baseline in EORTC QLQ-BR23 Systemic Therapy Side Effects by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

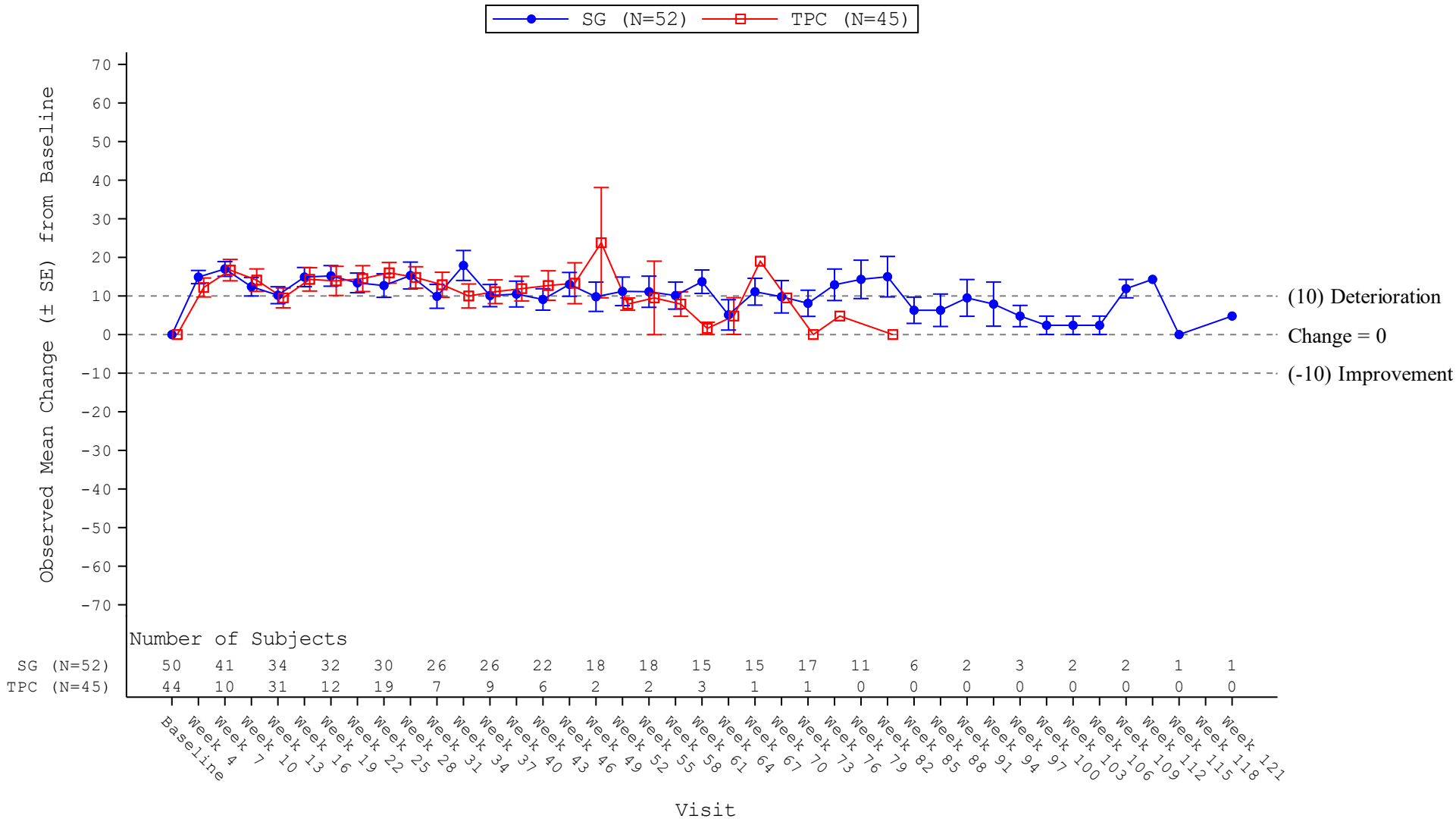


Figure 1.2.2.6
Observed Mean Change from Baseline in EORTC QLQ-BR23 Breast Symptoms by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

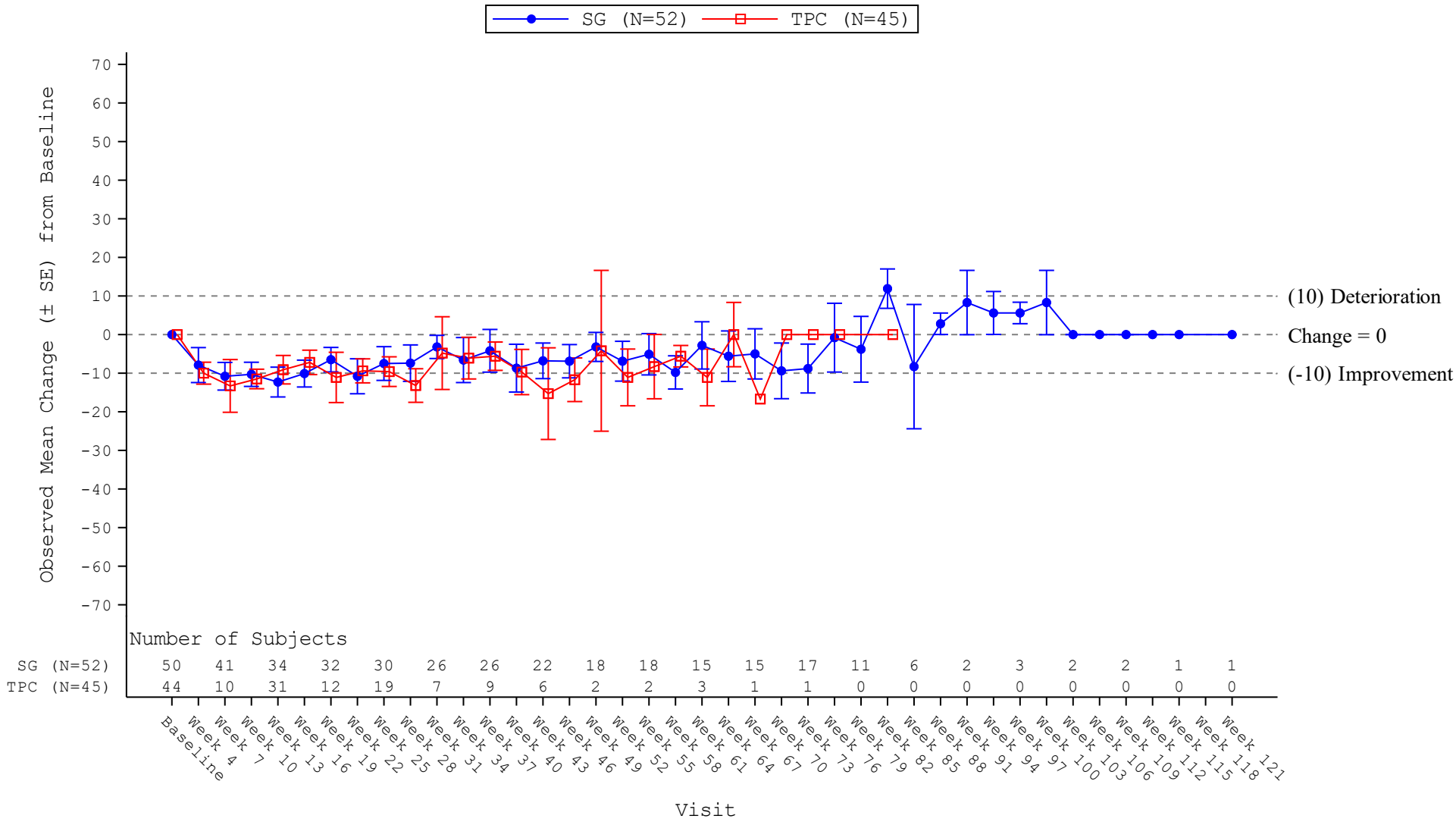


Figure 1.2.2.7
Observed Mean Change from Baseline in EORTC QLQ-BR23 Arm Symptoms by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

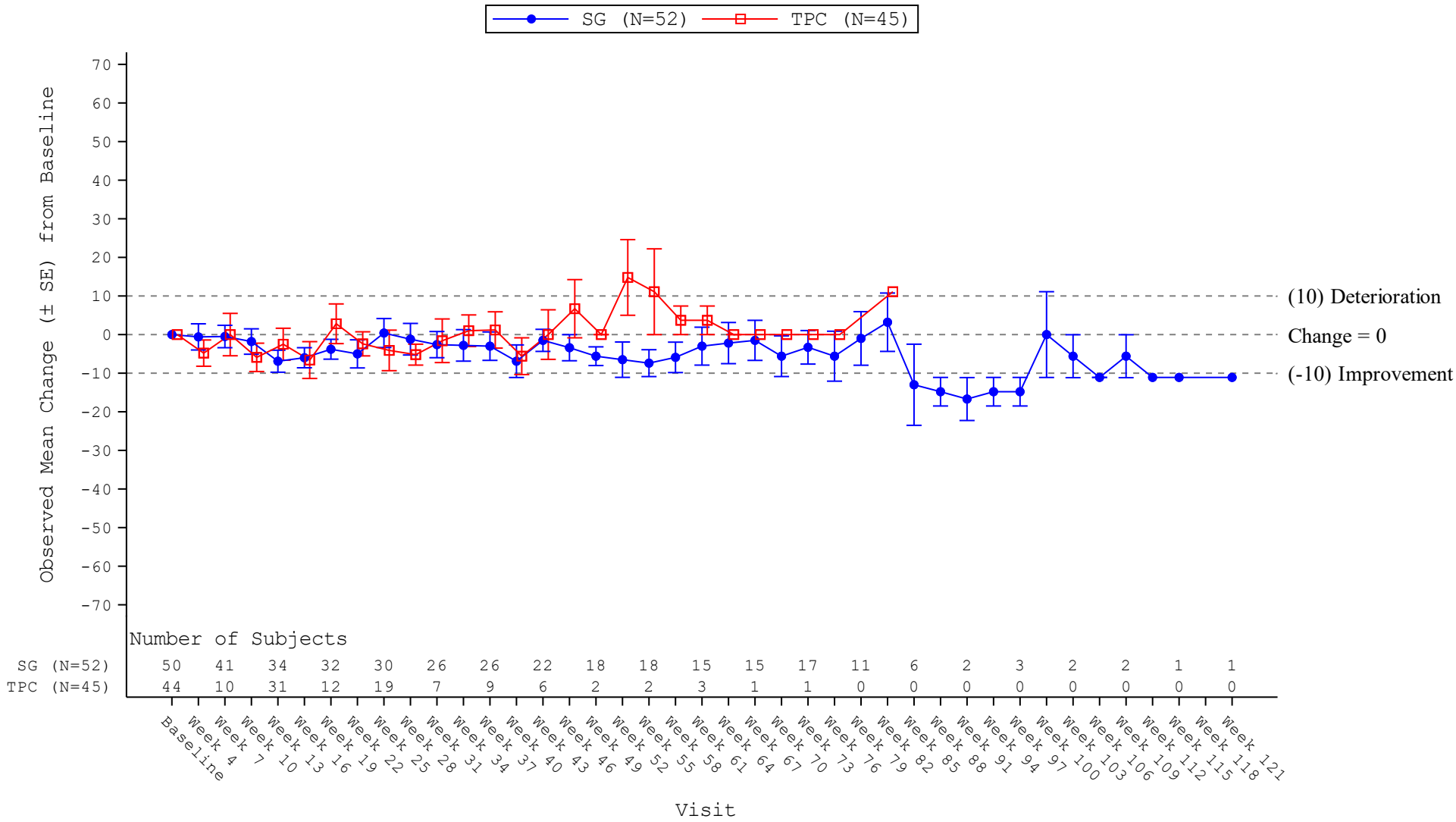


Figure 1.2.2.8
Observed Mean Change from Baseline in EORTC QLQ-BR23 Upset by Hair Loss by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

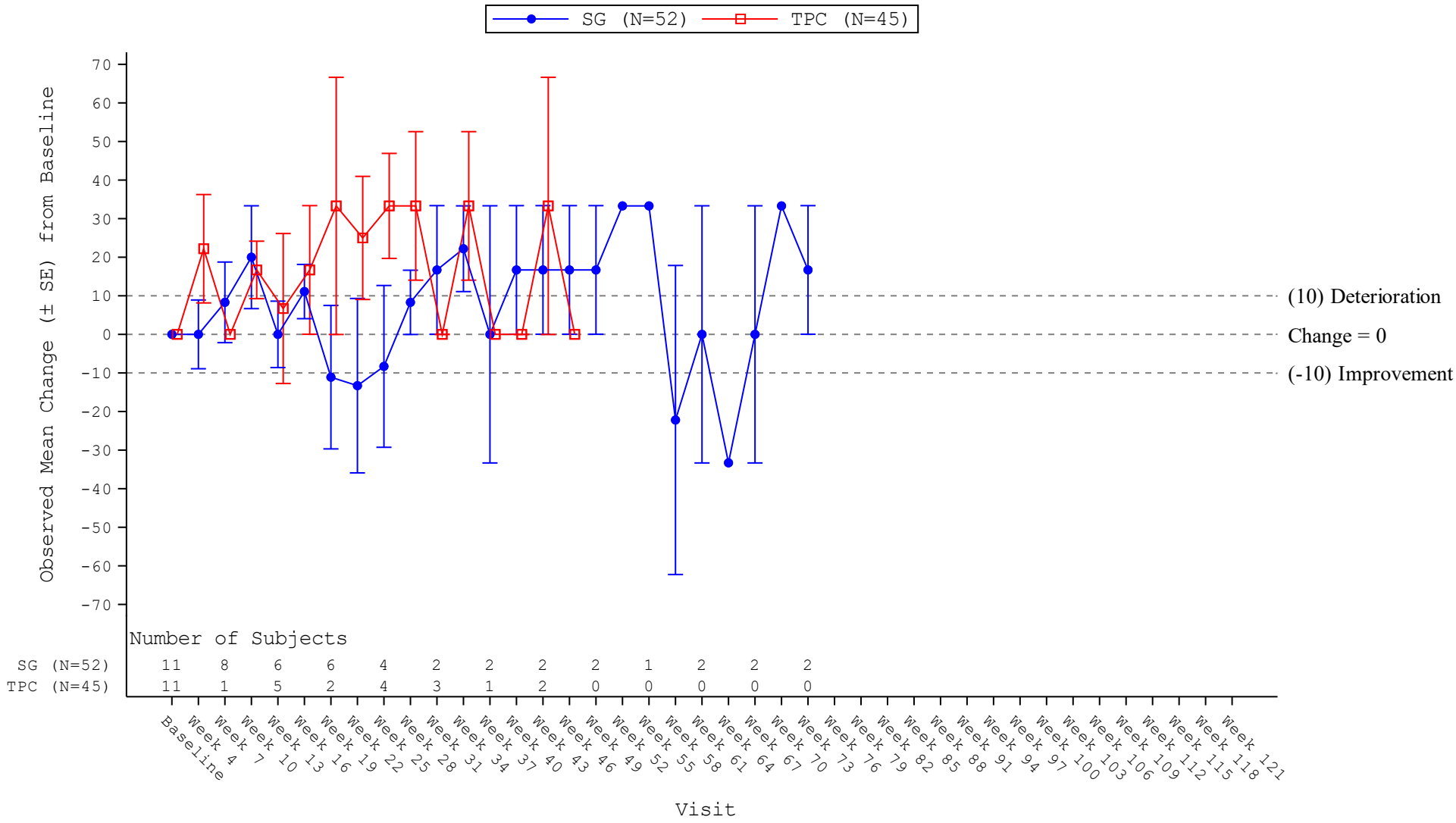


Figure 1.2.3
Observed Mean Change from Baseline in EQ-VAS by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)

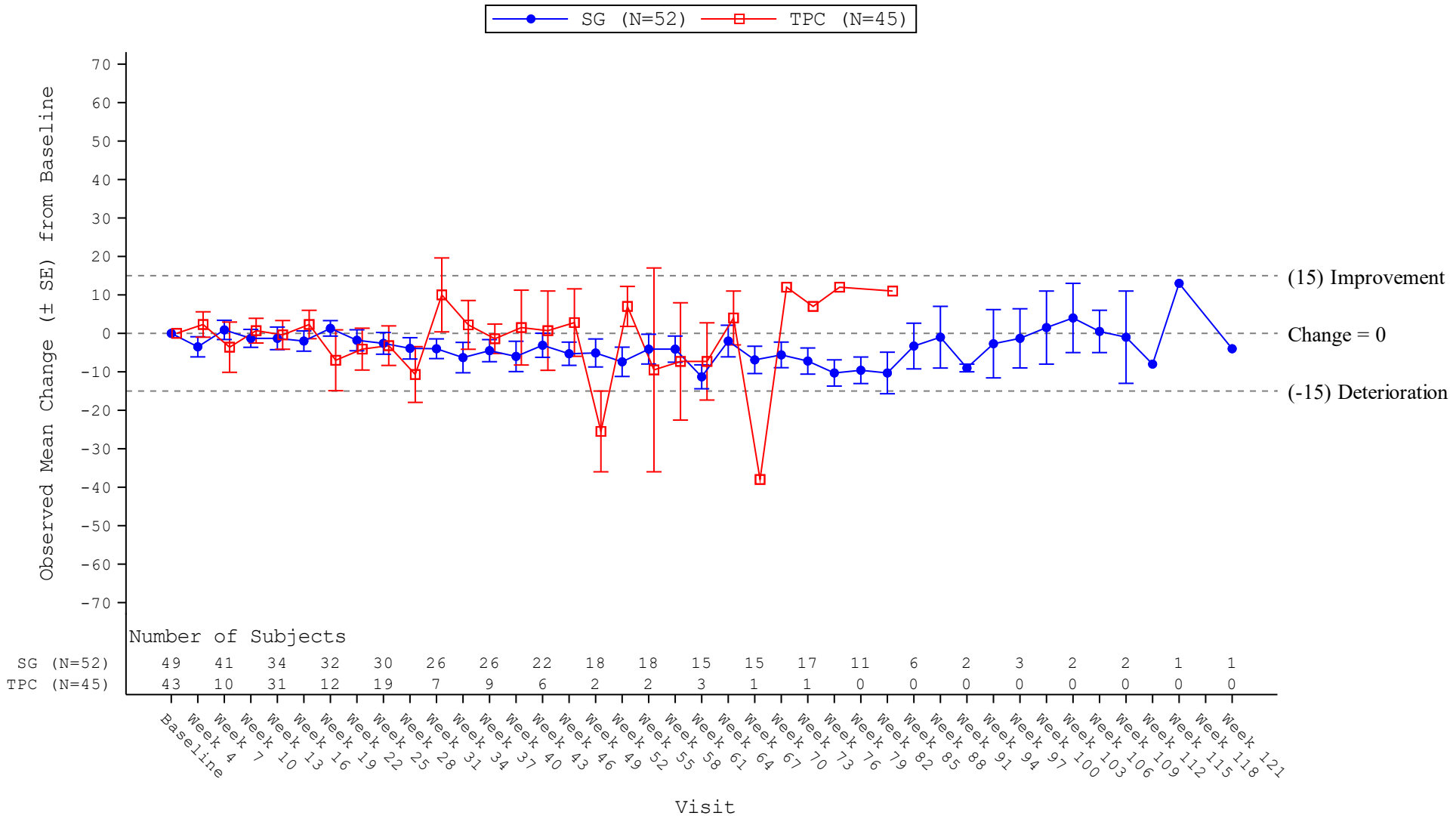
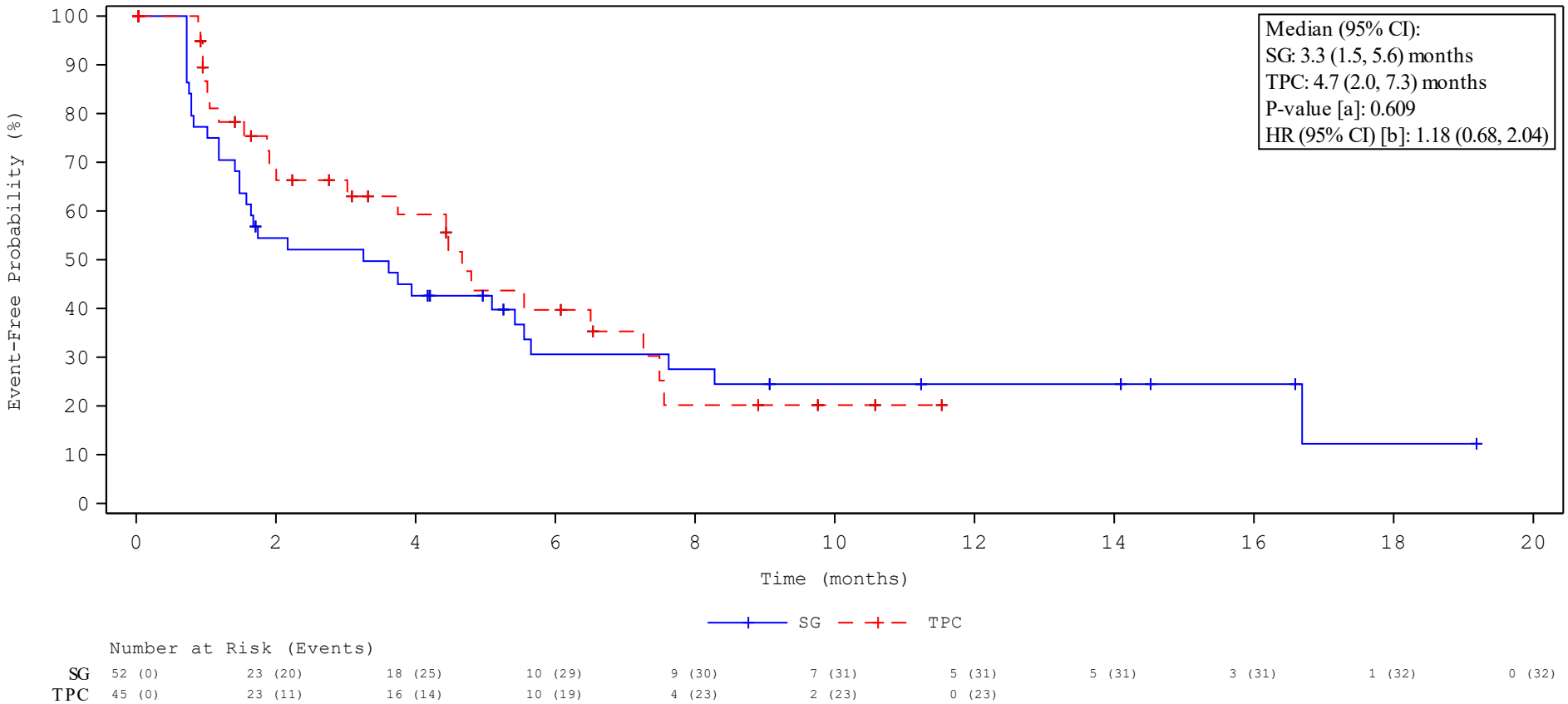


Figure 2.2.1.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



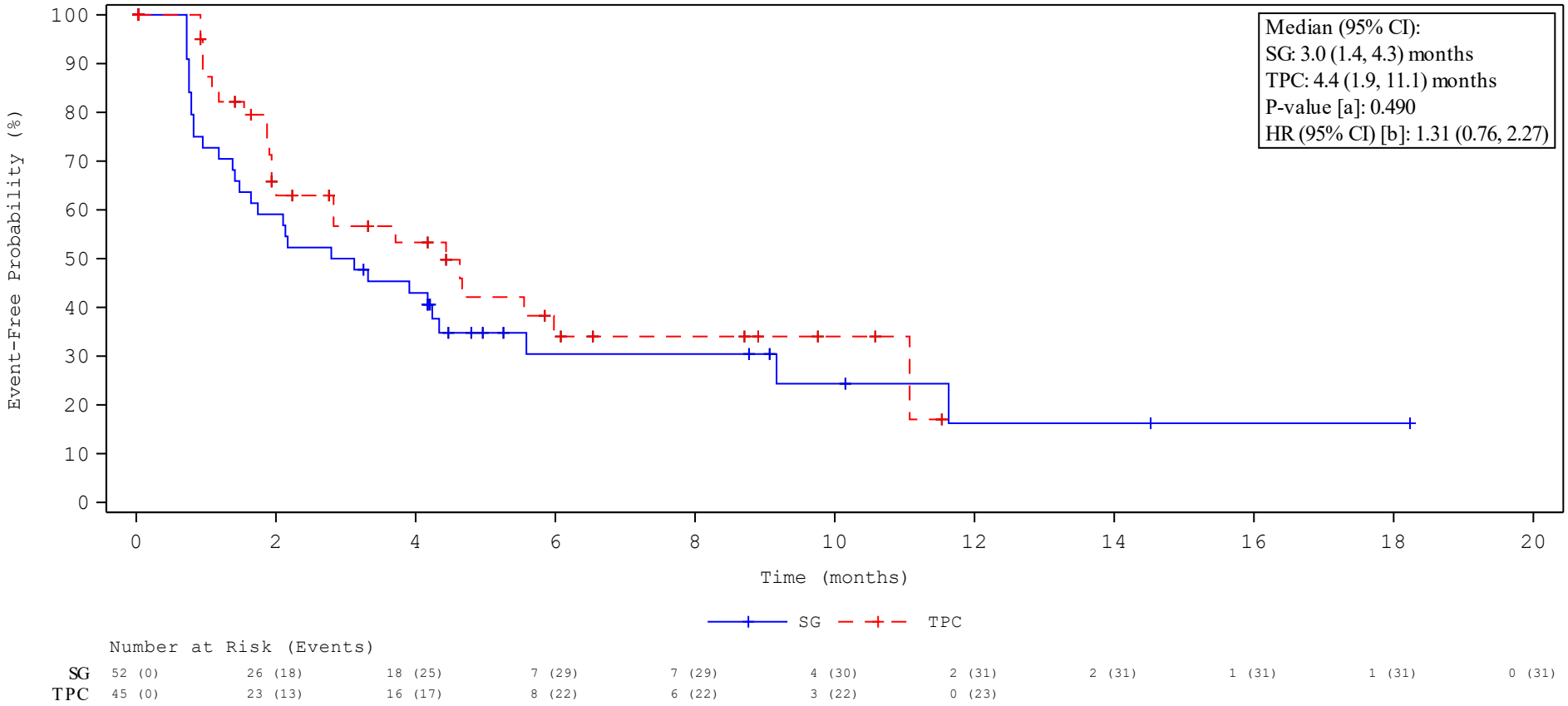
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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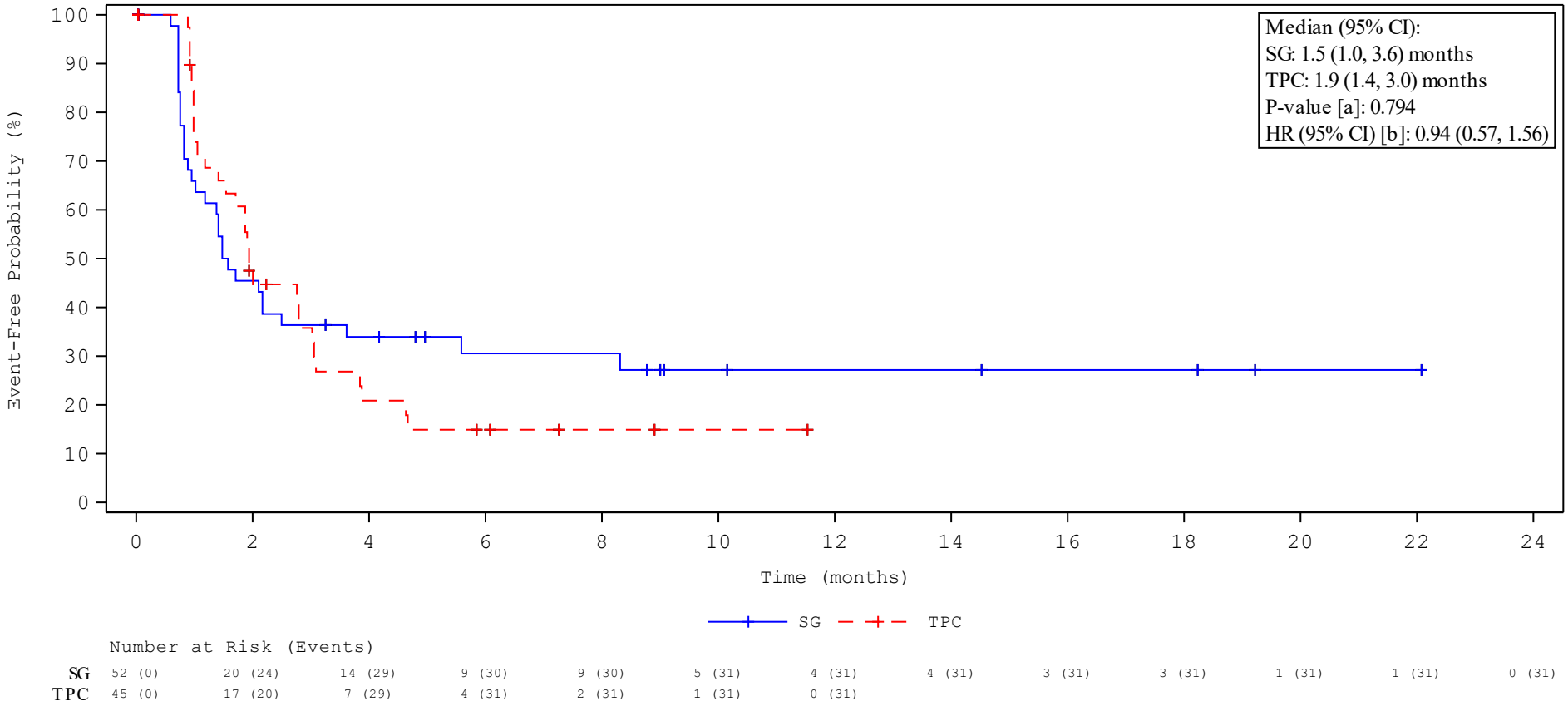
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Figure 2.2.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Physical Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



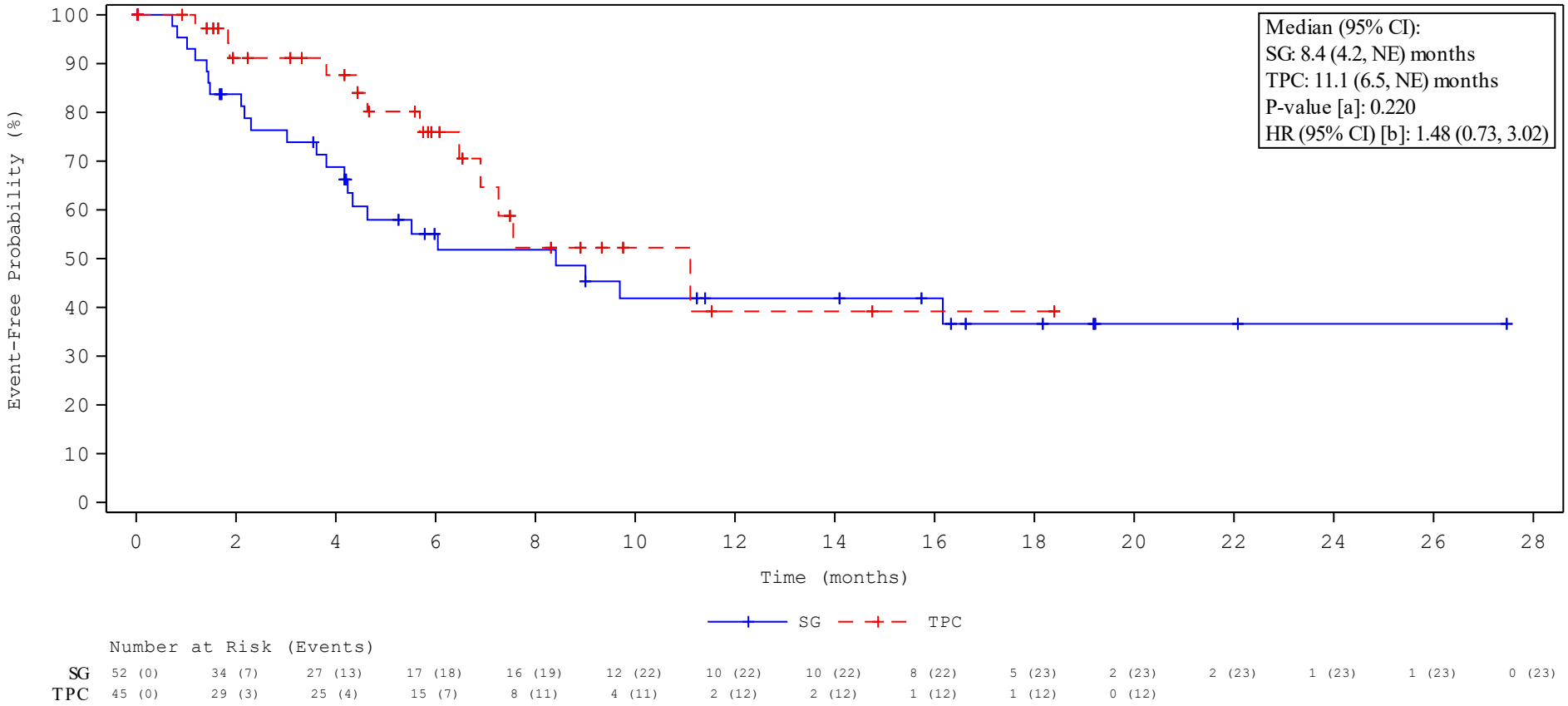
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



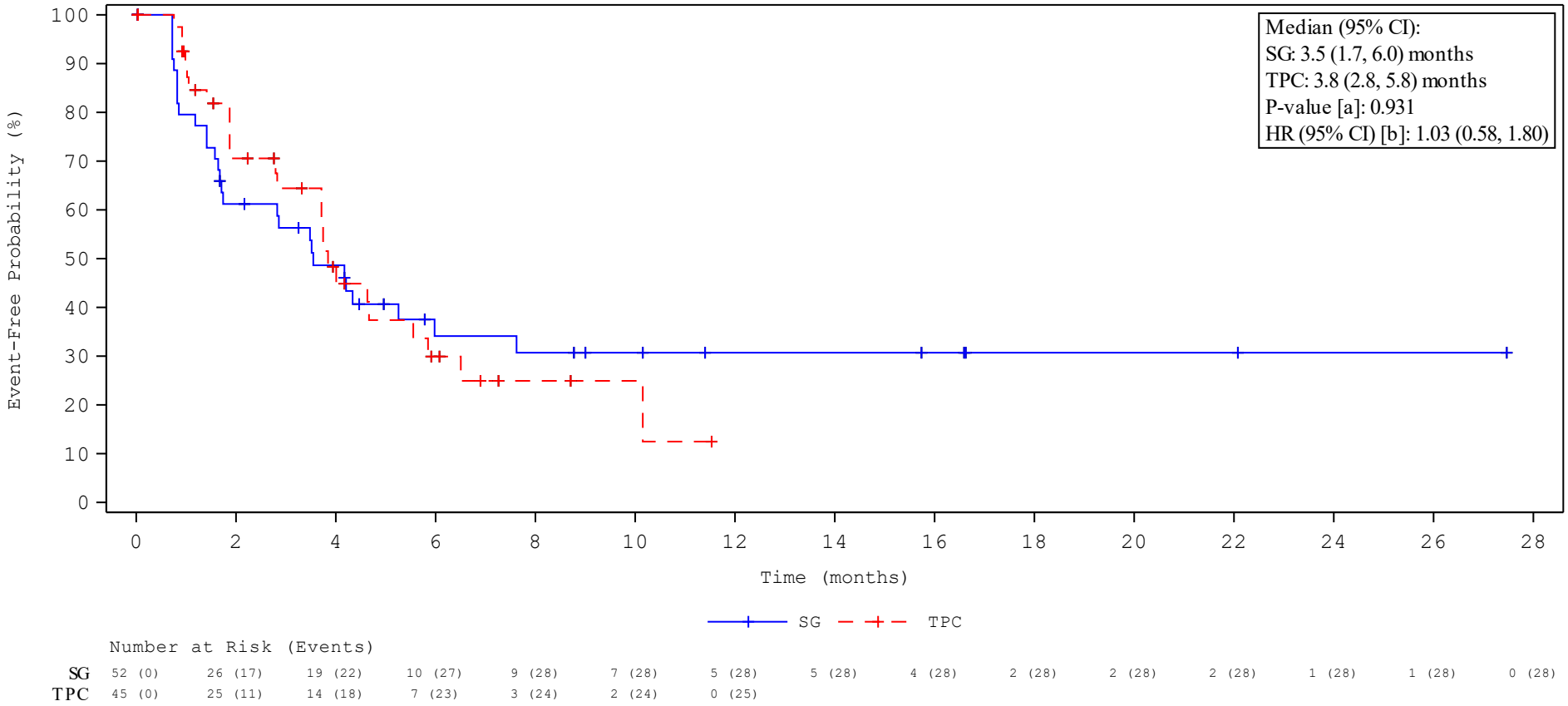
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Emotional Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



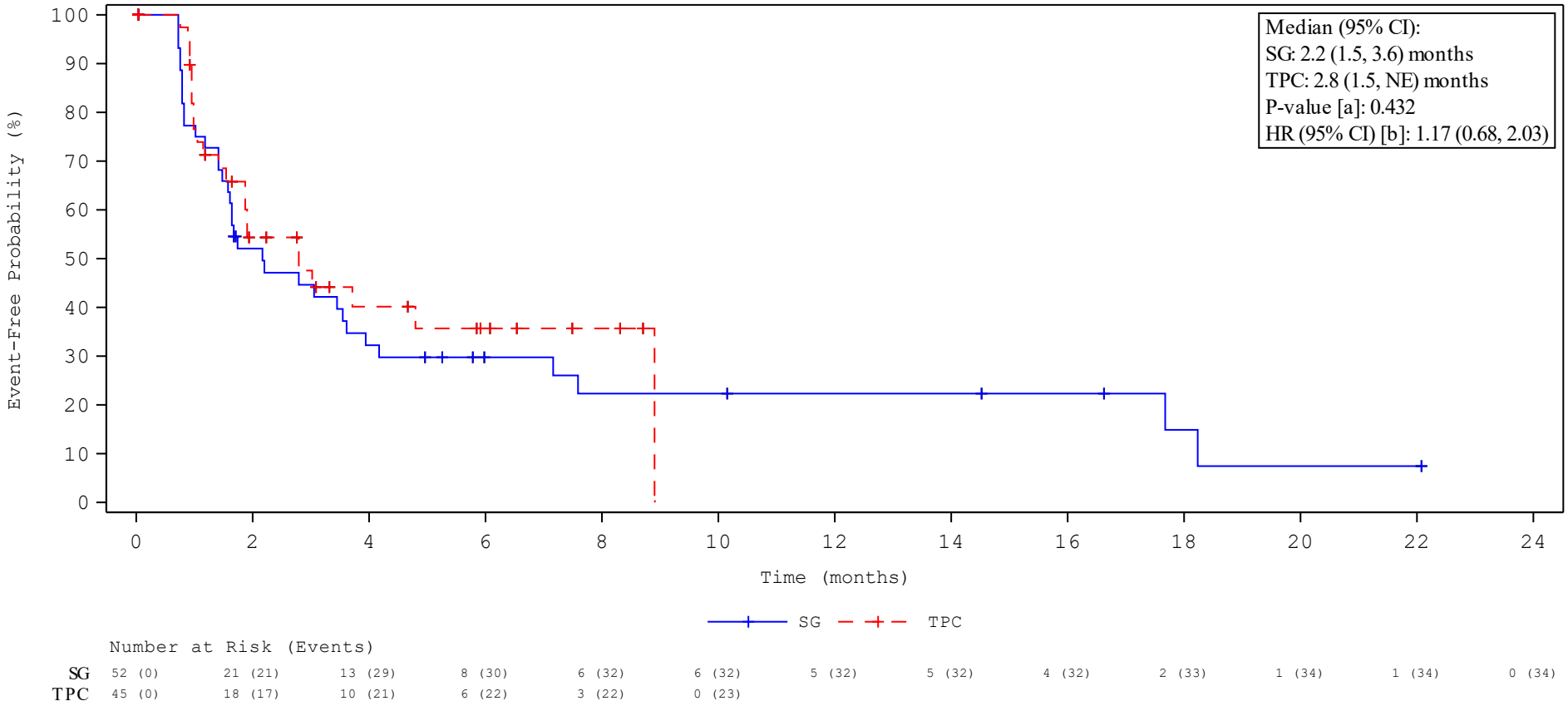
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



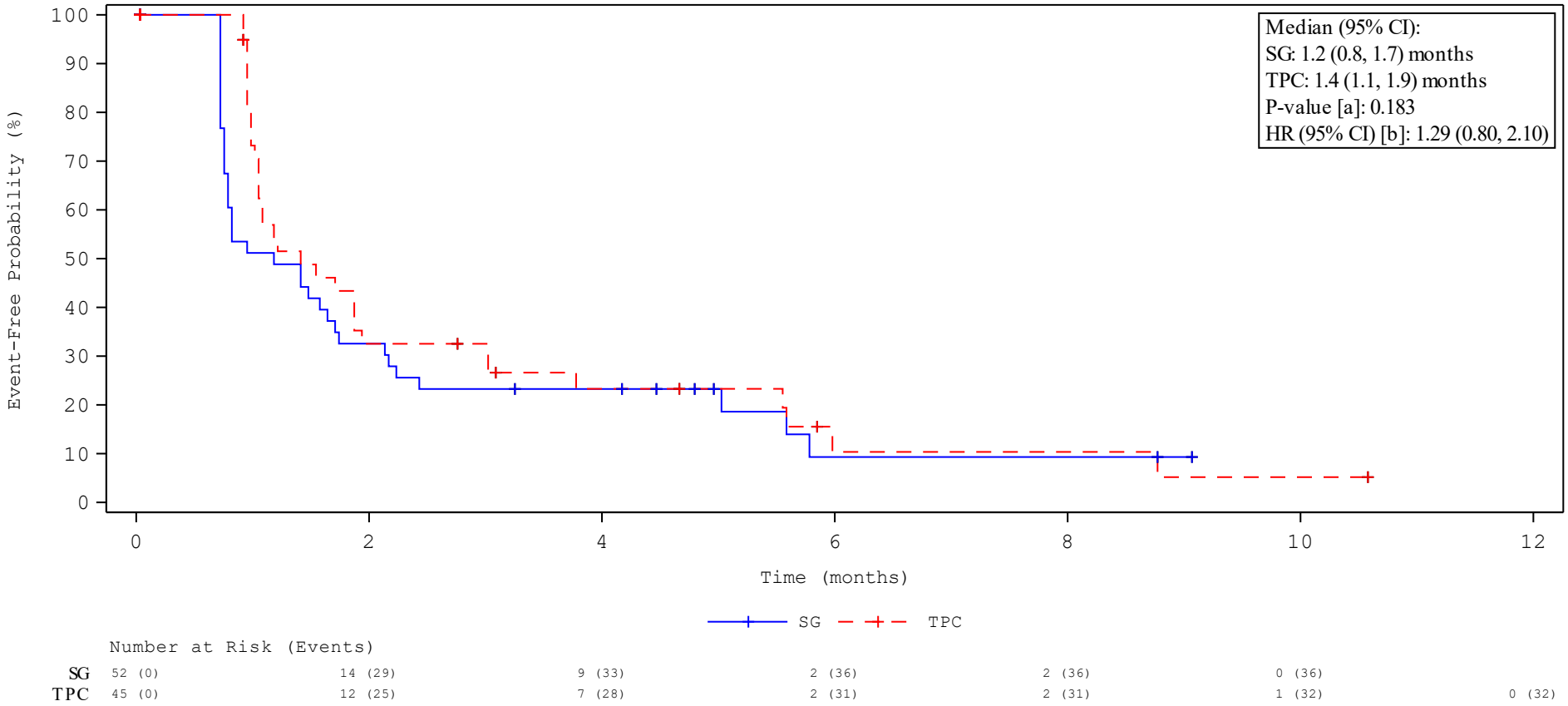
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.6
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



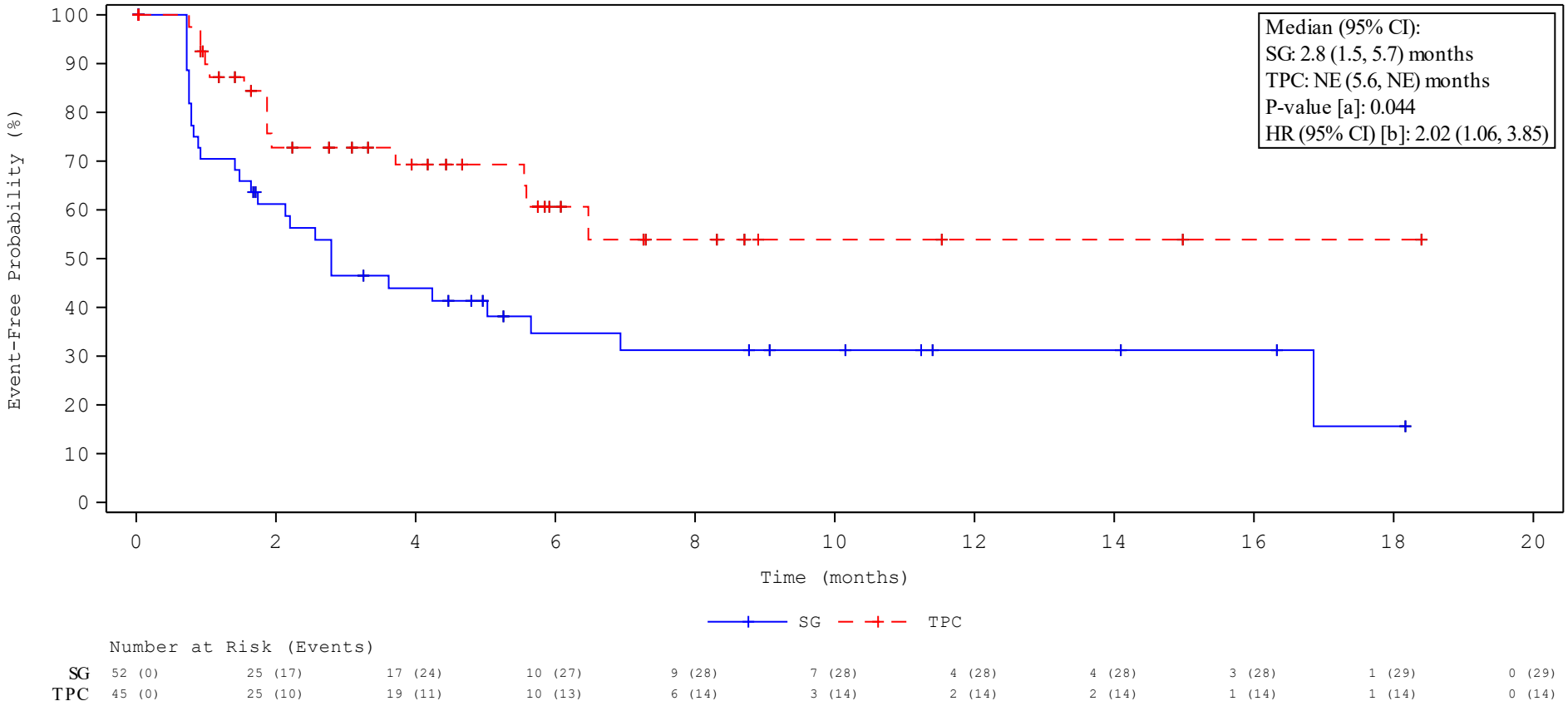
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.7
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



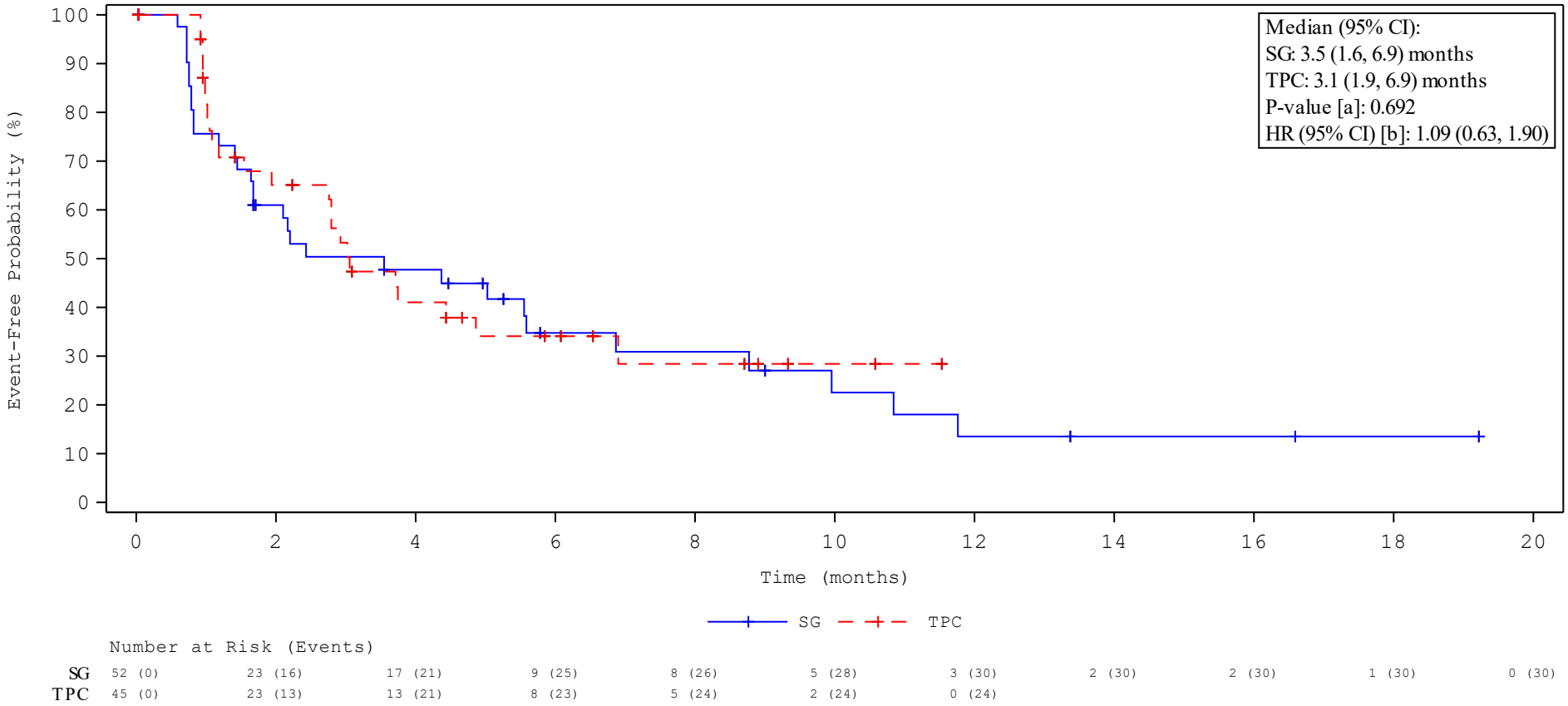
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.8
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



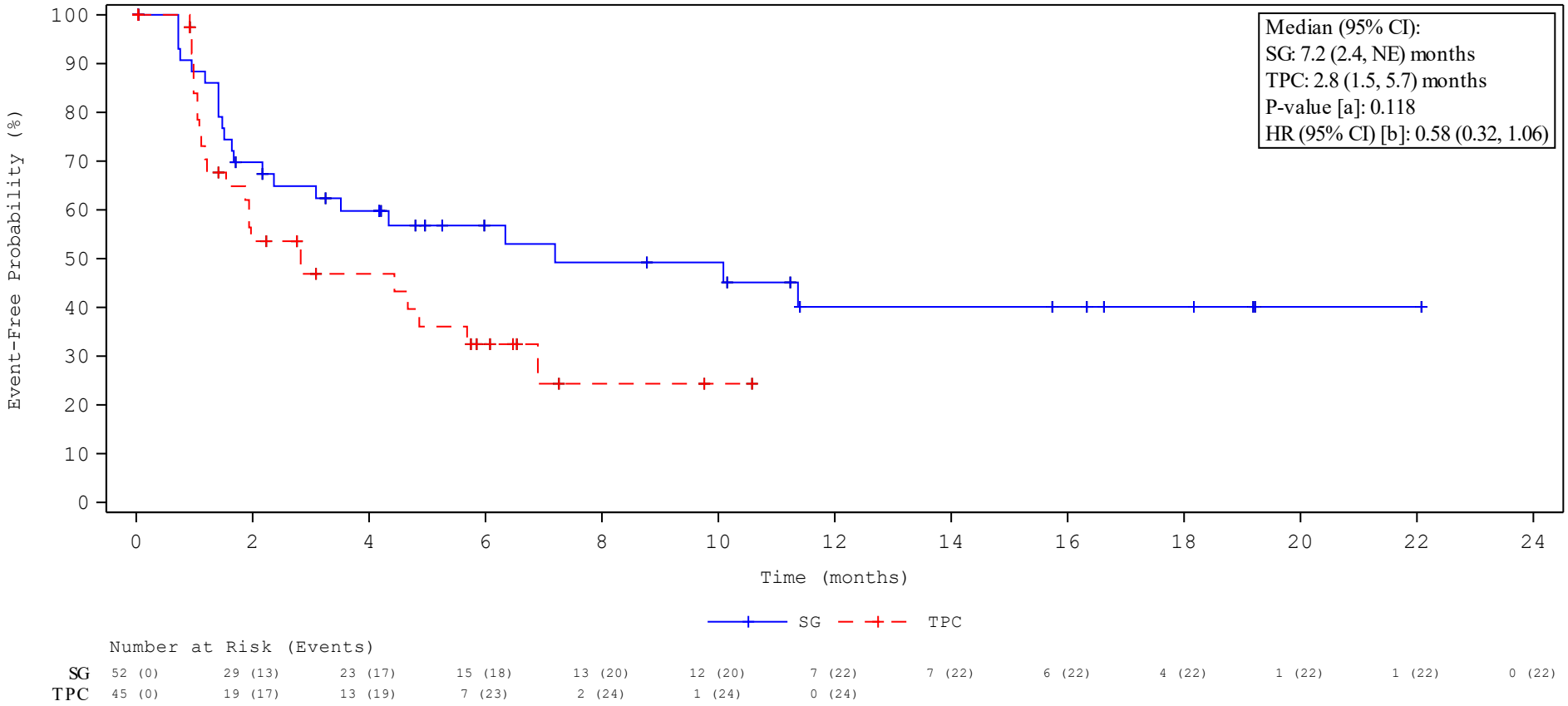
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.9
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Pain by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



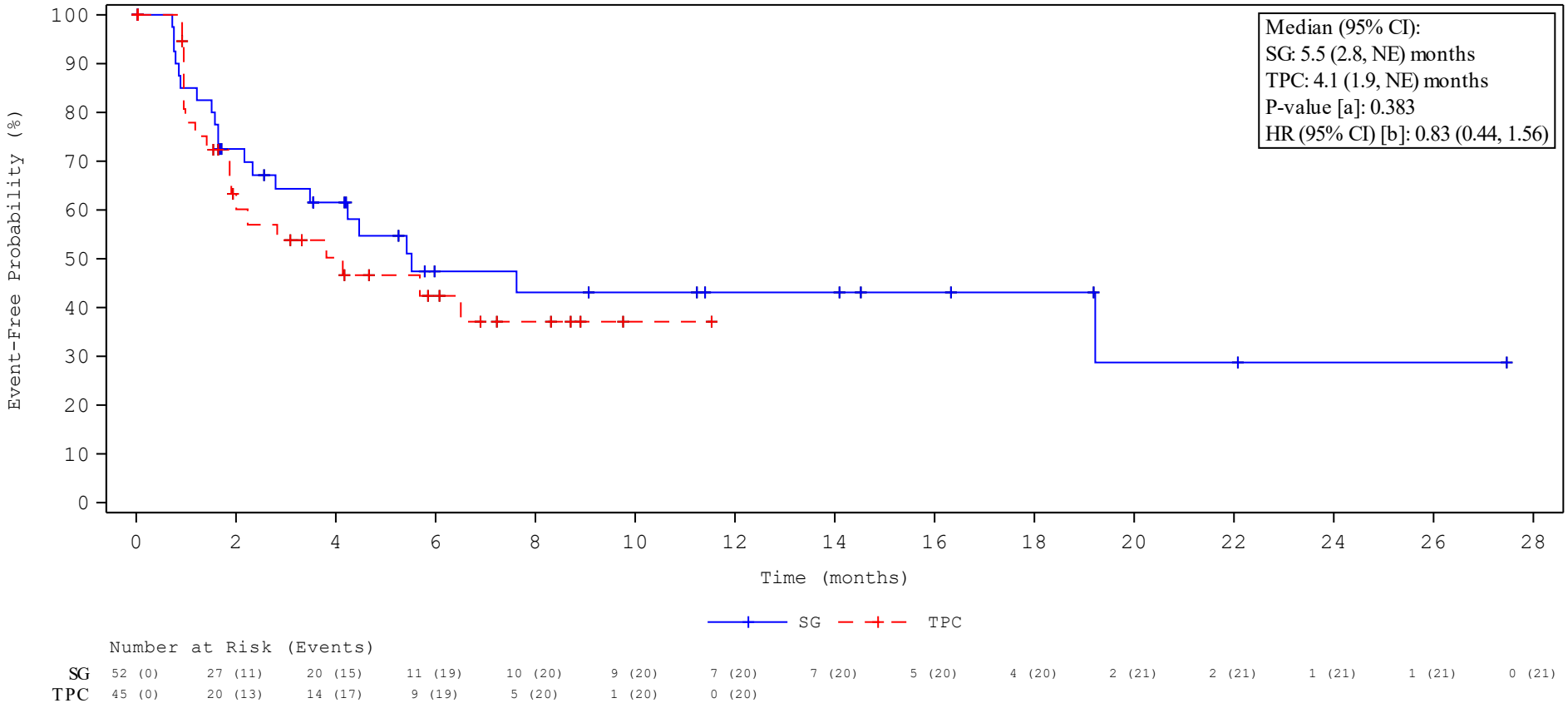
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.10
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Dyspnea by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



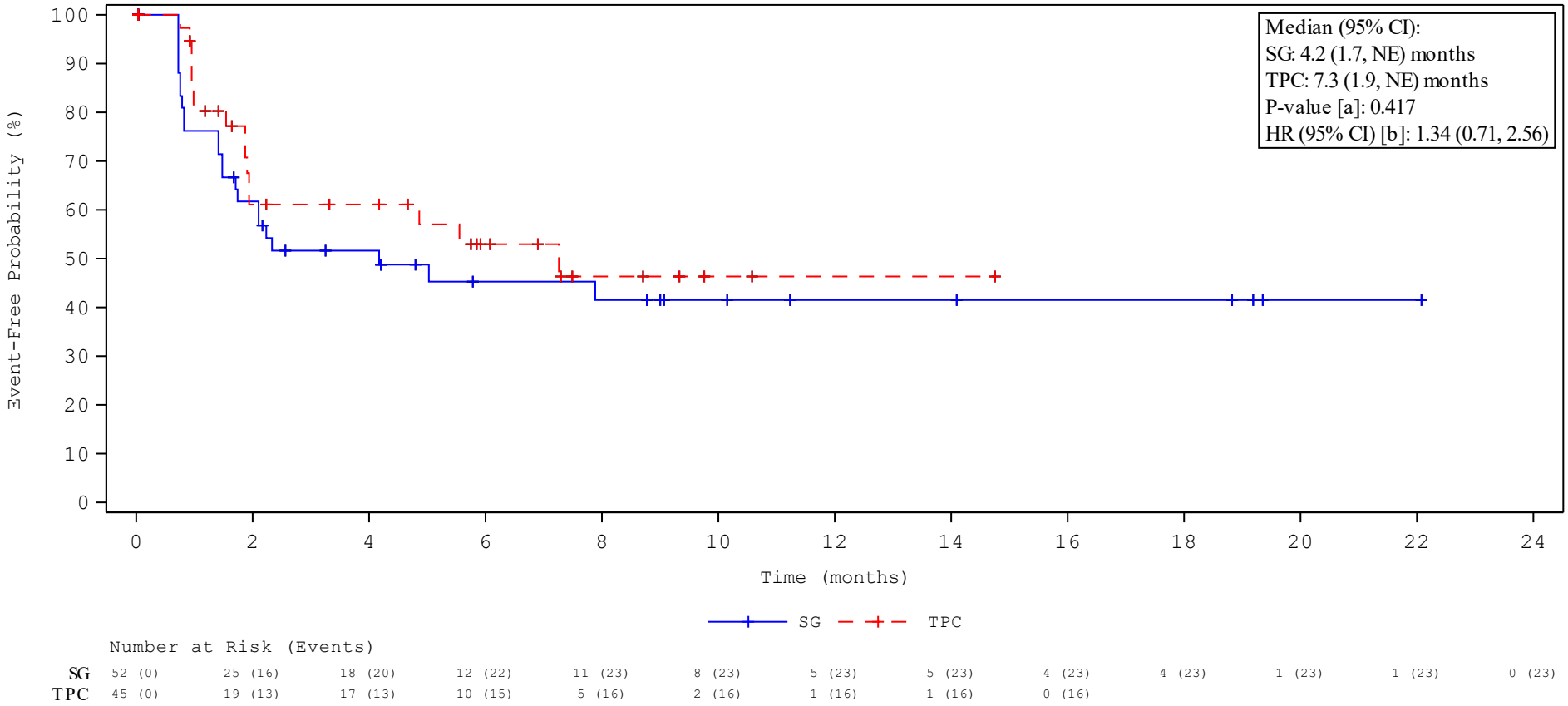
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.11
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Insomnia by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



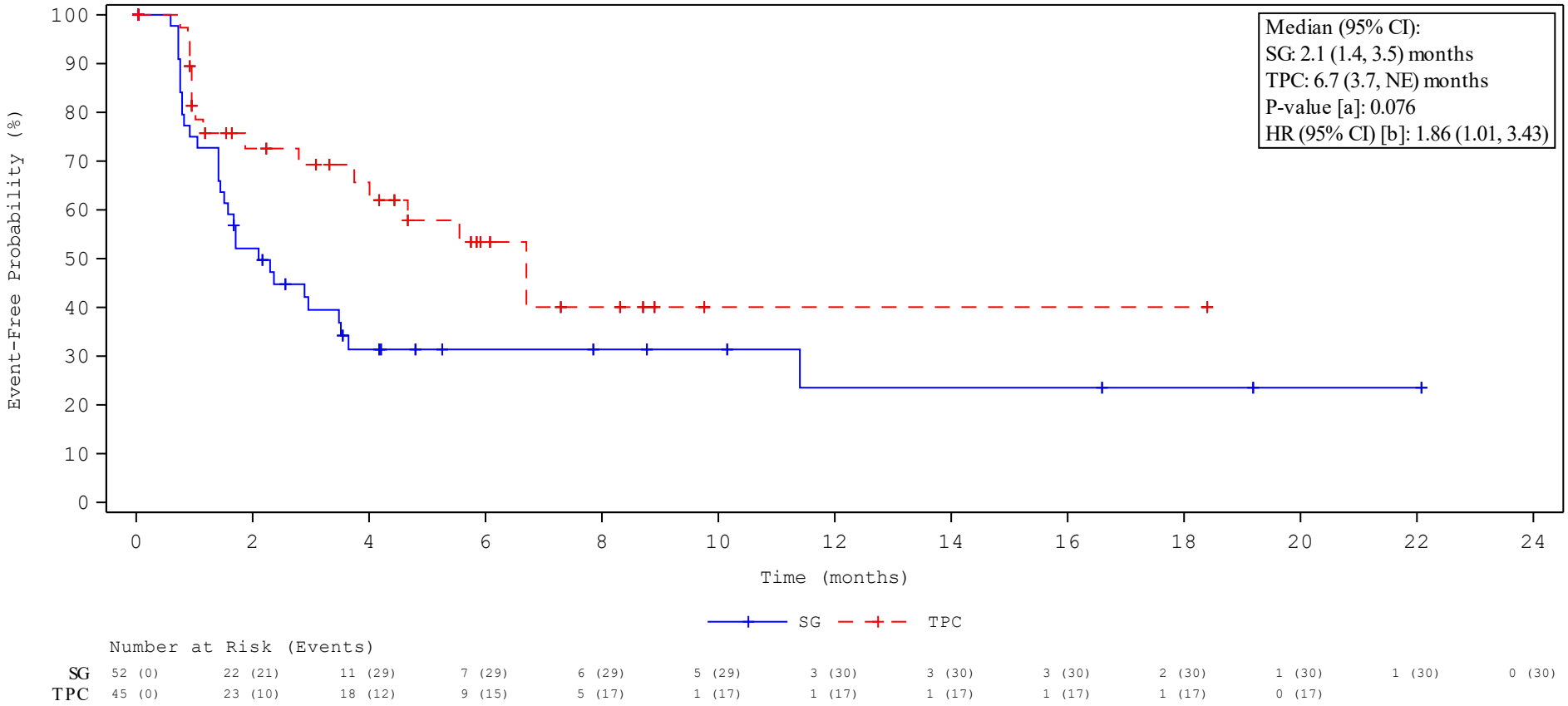
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.12
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Appetite Loss by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



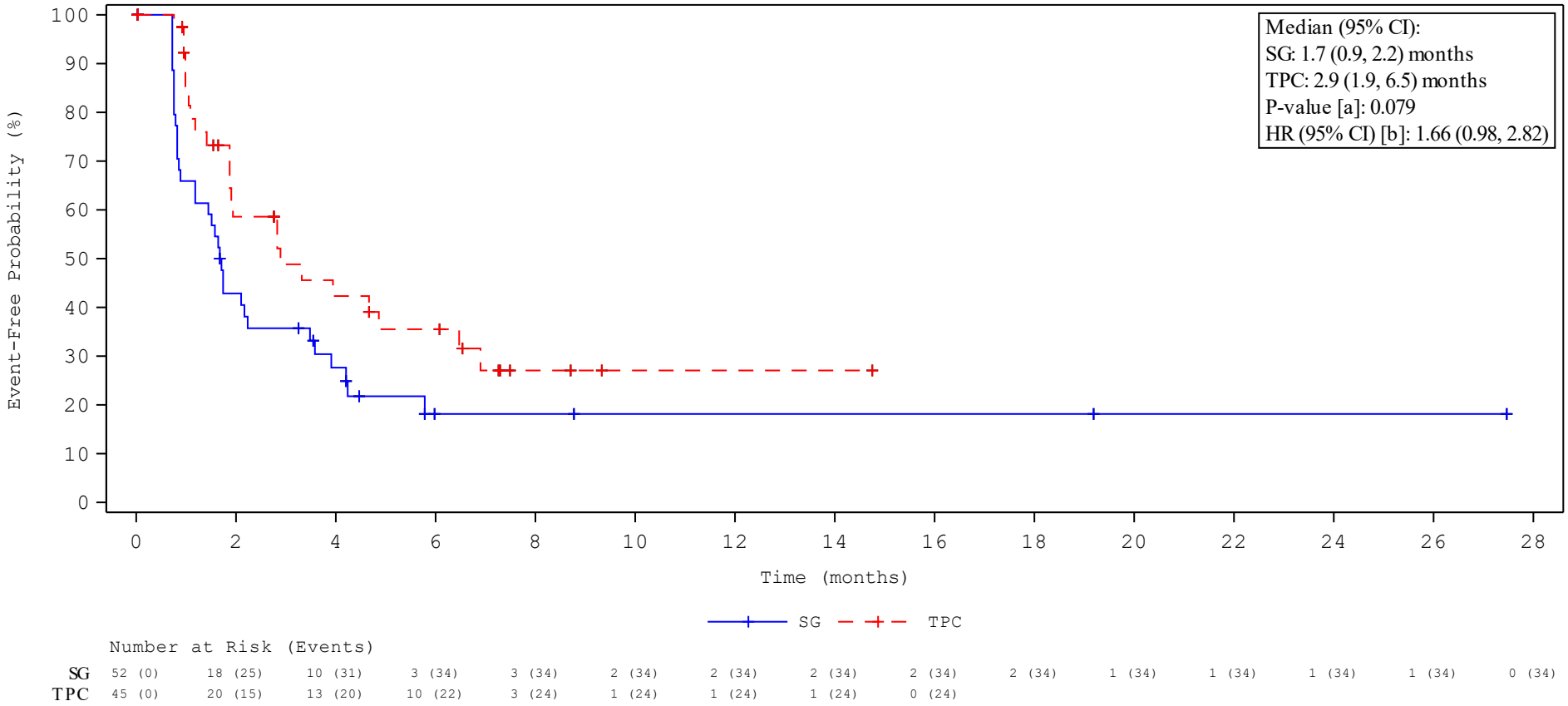
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.13
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Constipation by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



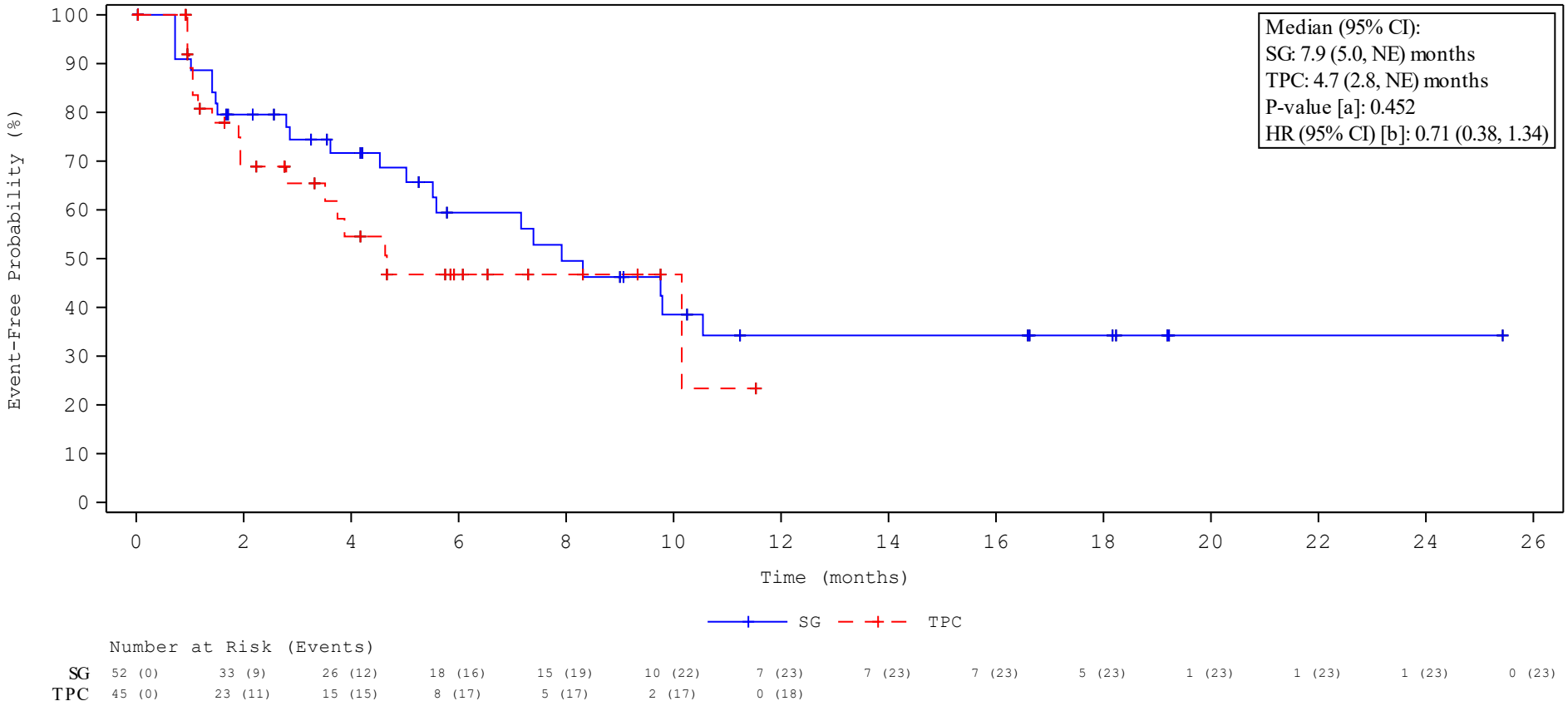
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.14
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



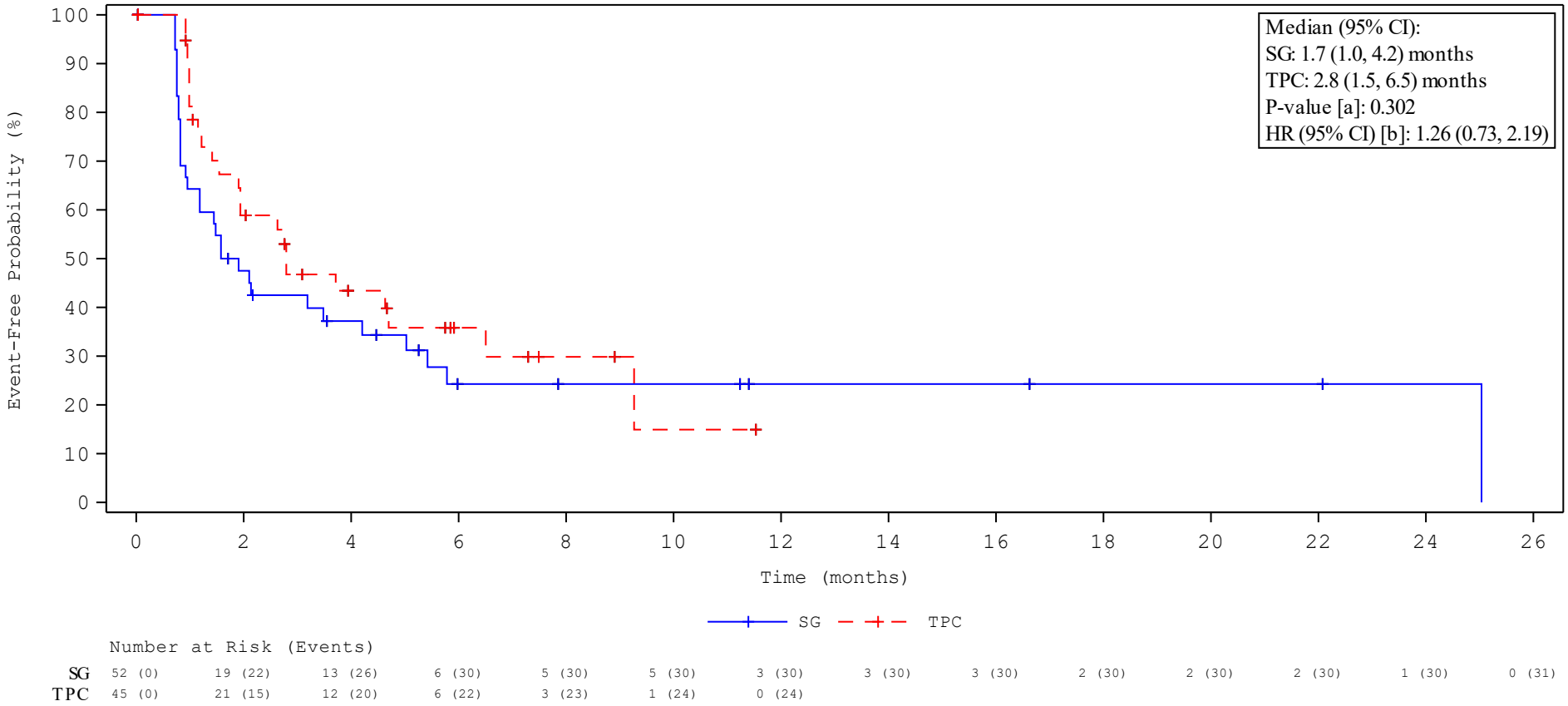
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.1.15
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Financial Difficulties by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



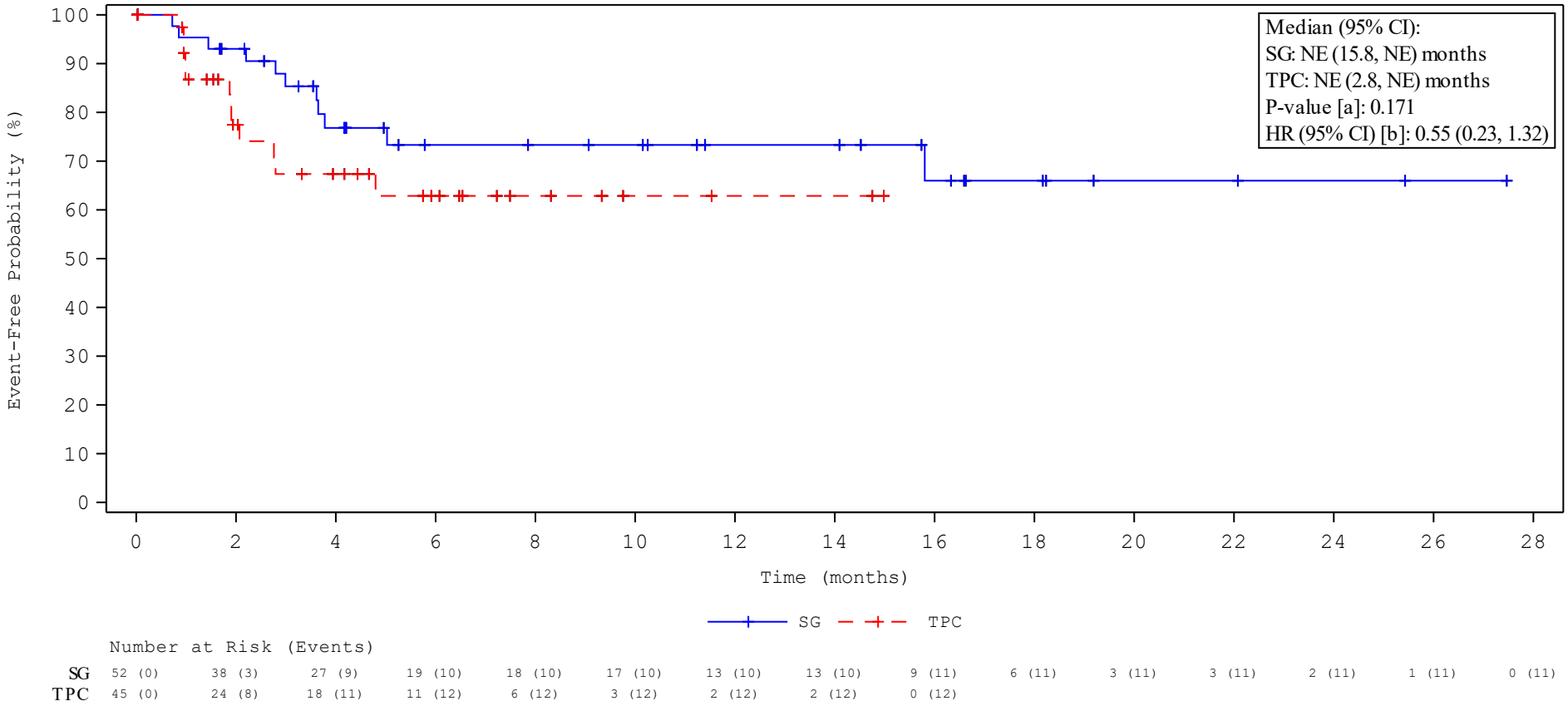
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Body Image by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



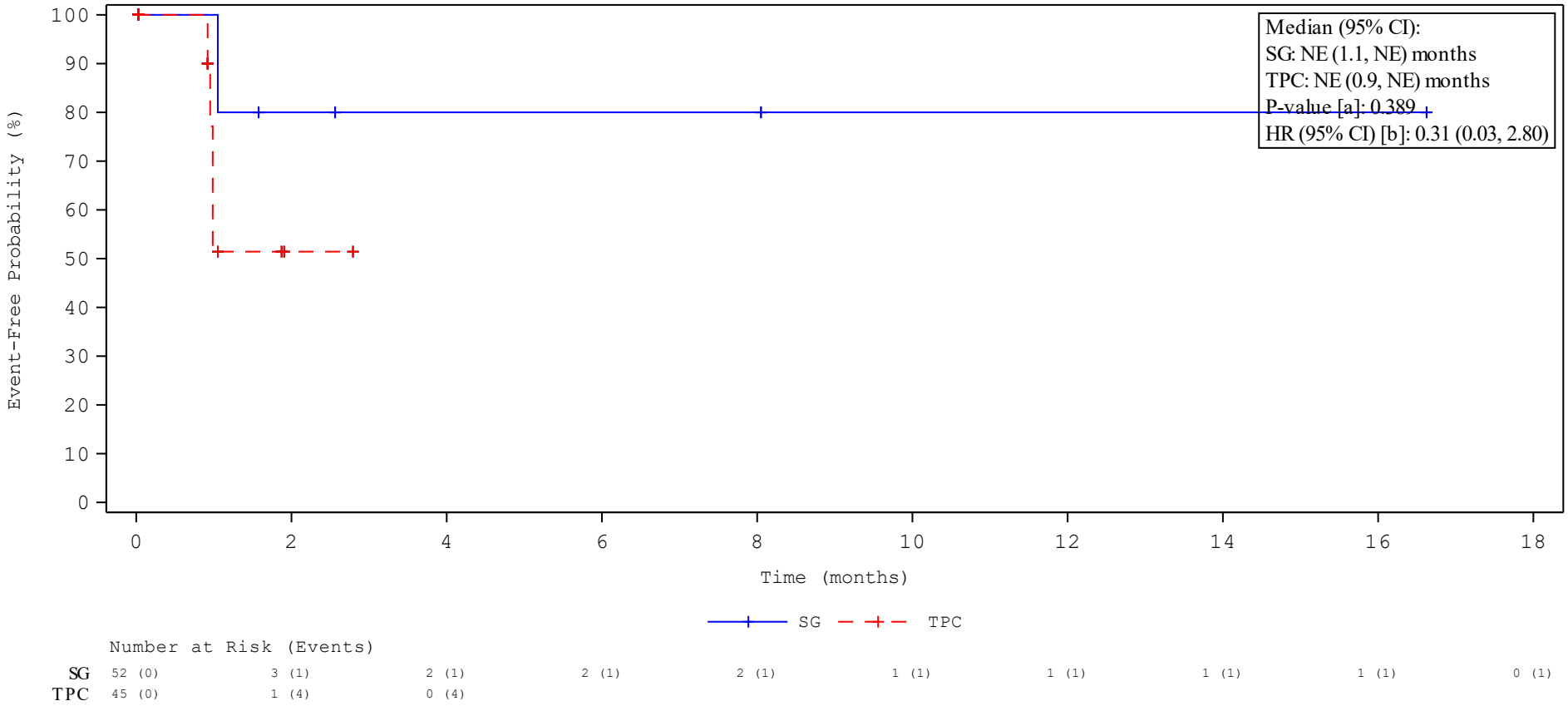
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Function by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



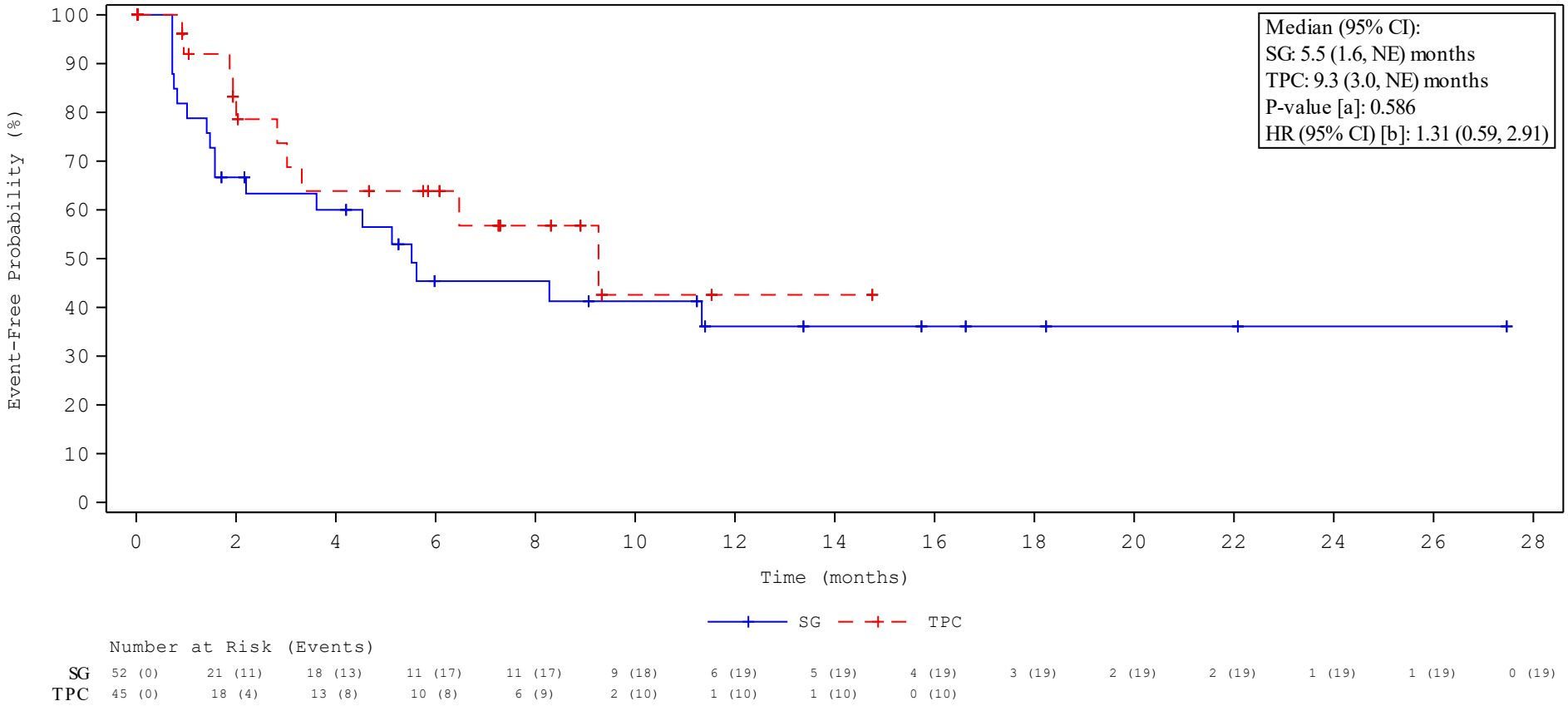
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Enjoyment by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



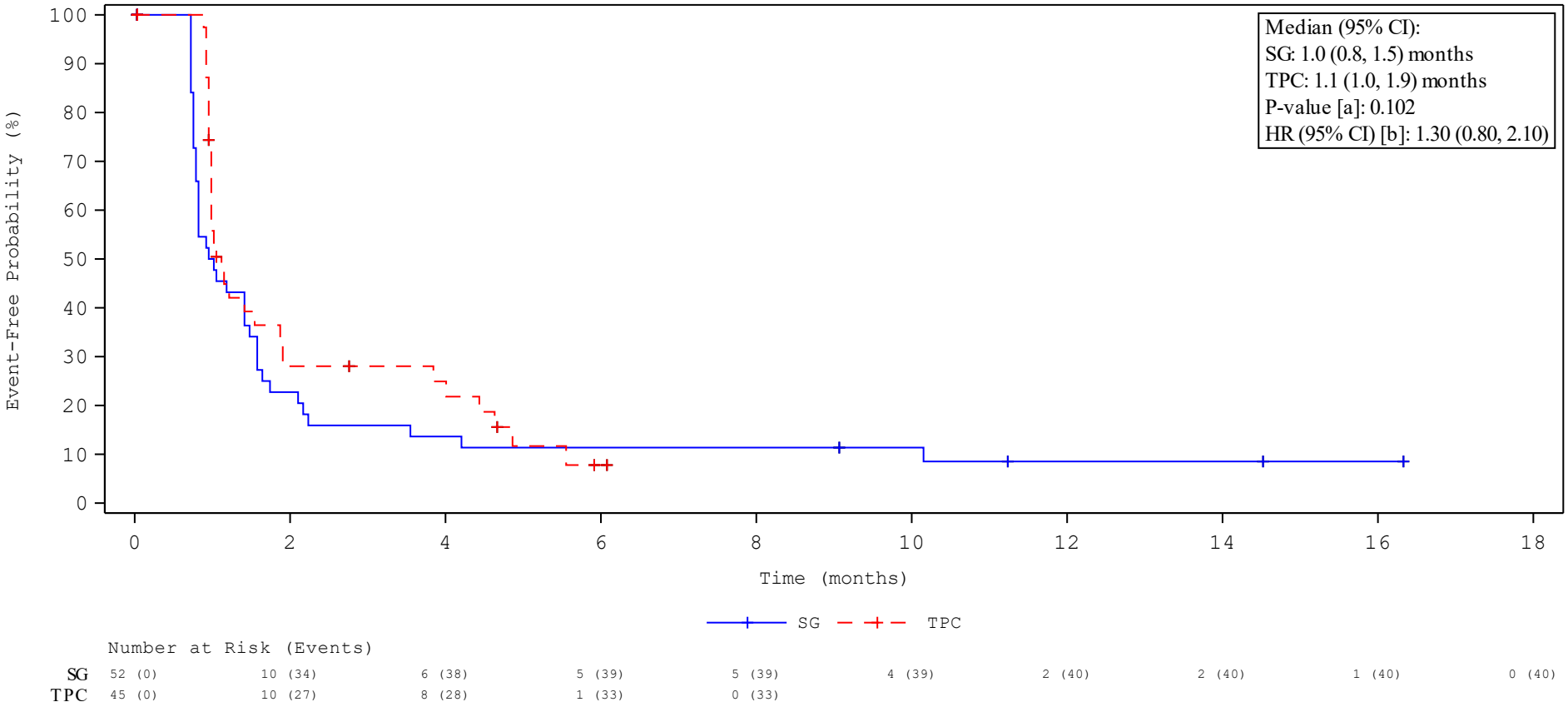
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Future Perspective by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



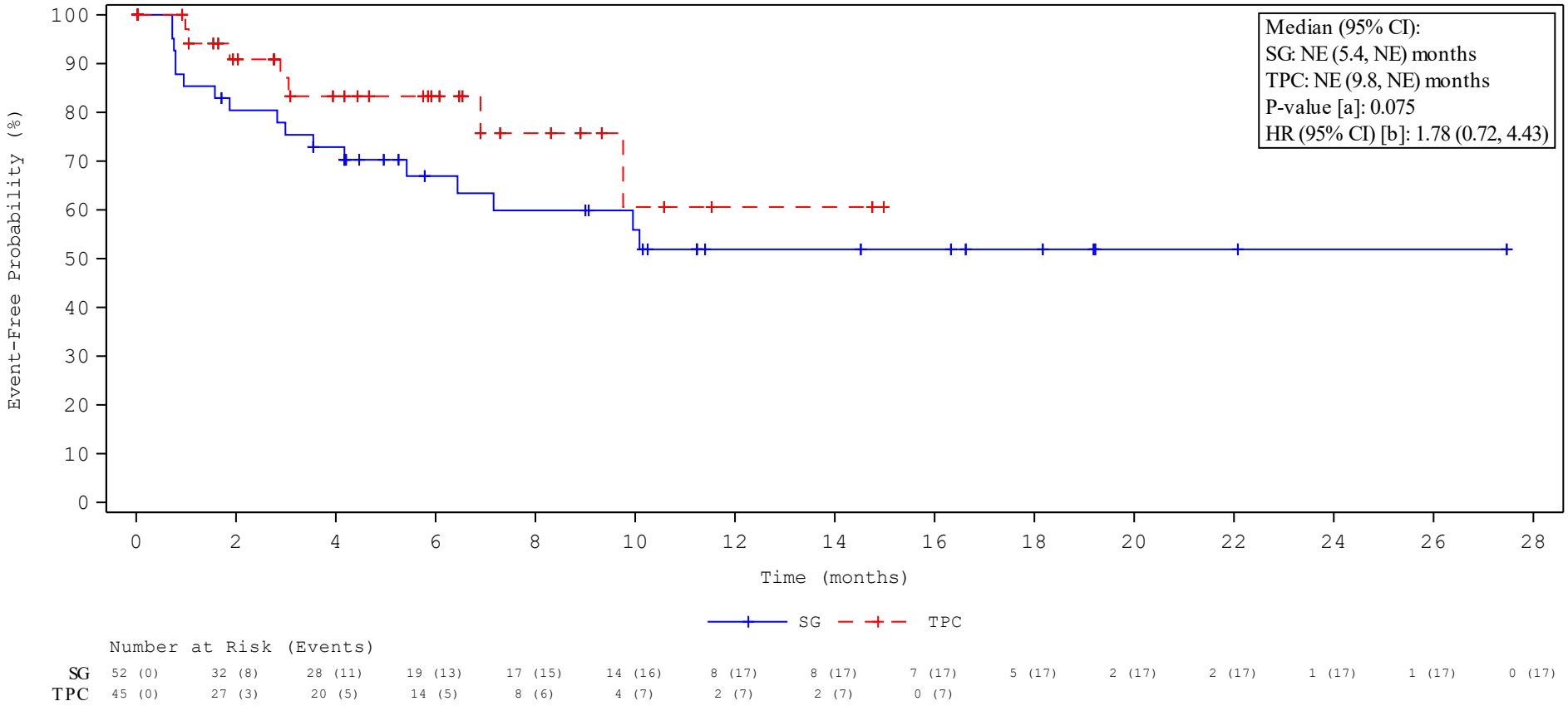
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Systemic Therapy Side Effects by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



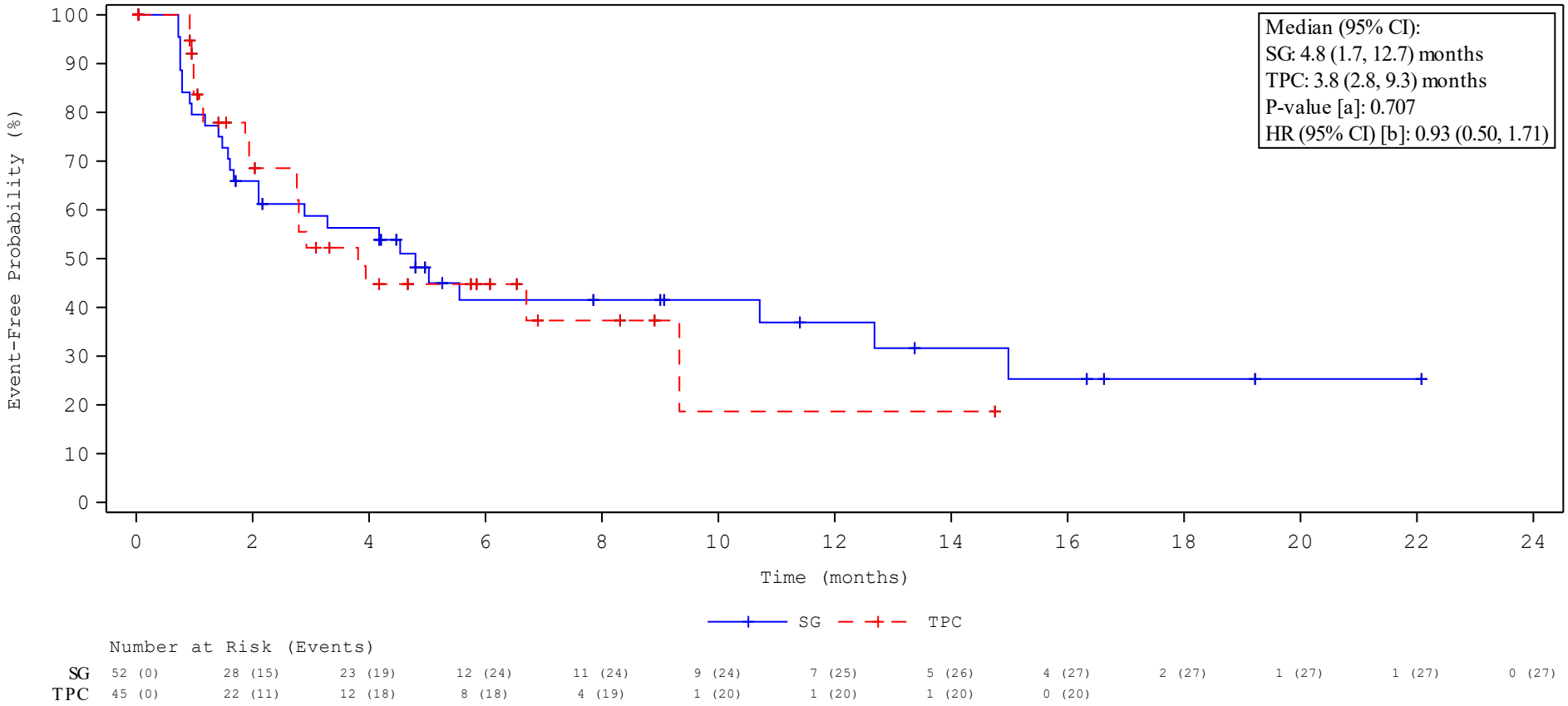
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.6
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Breast Symptoms by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



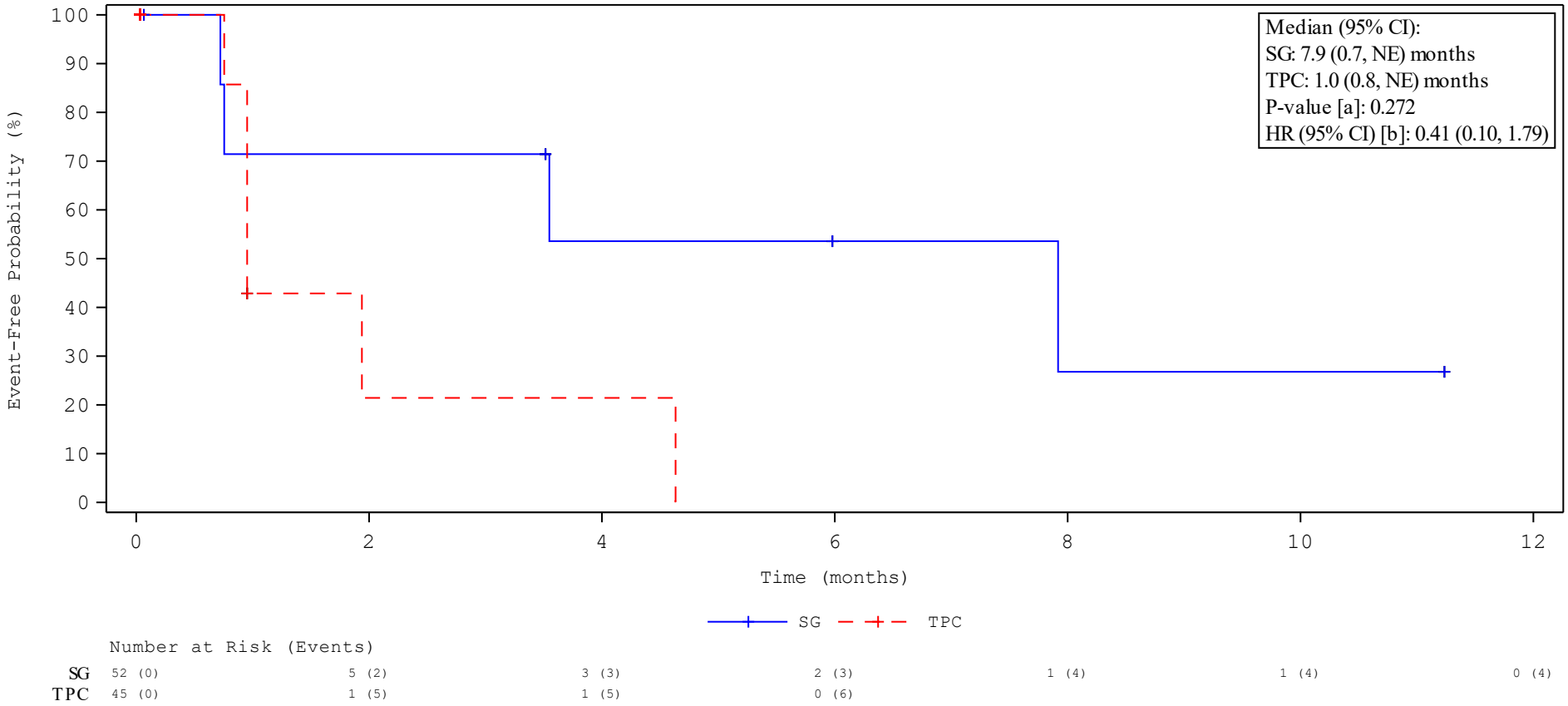
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.7
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Arm Symptoms by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



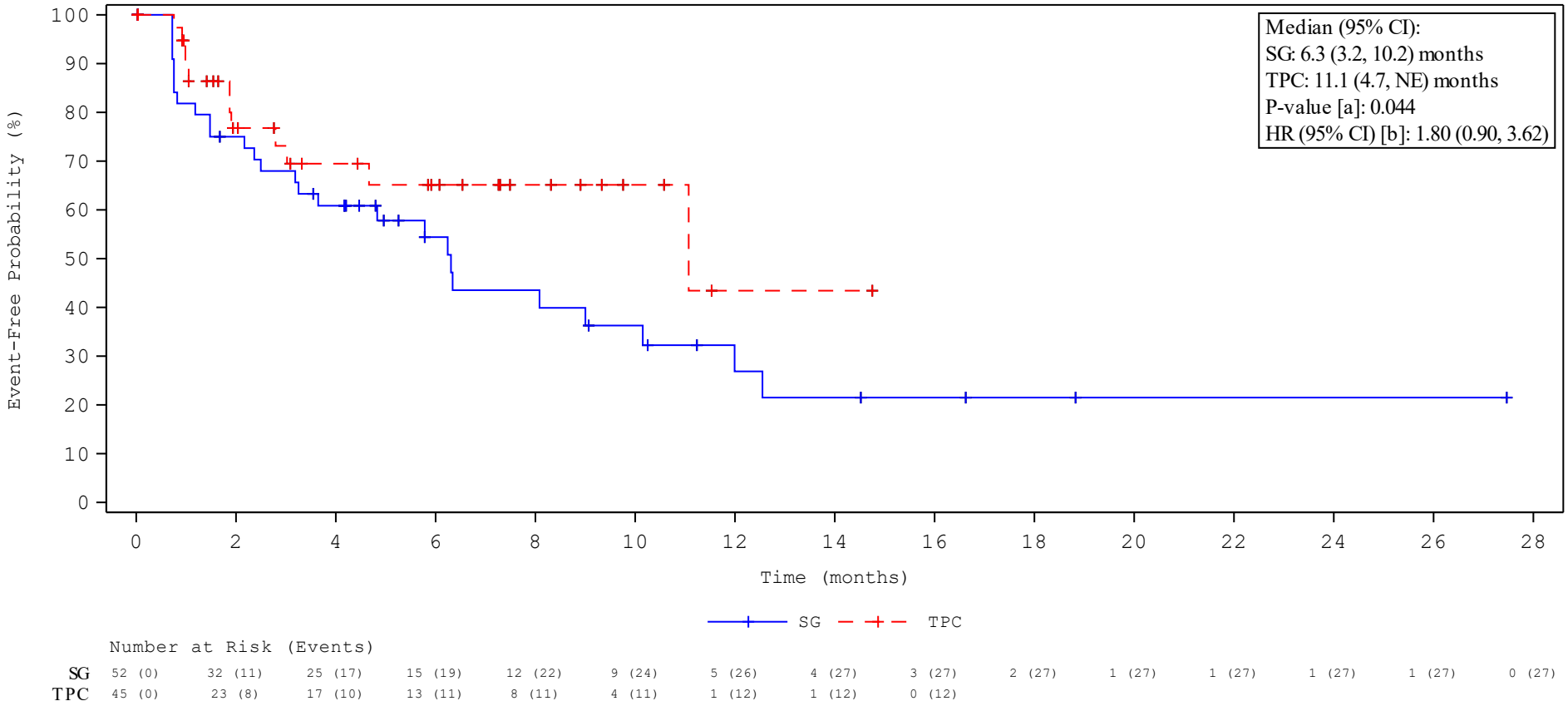
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.2.8
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Upset by Hair Loss by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



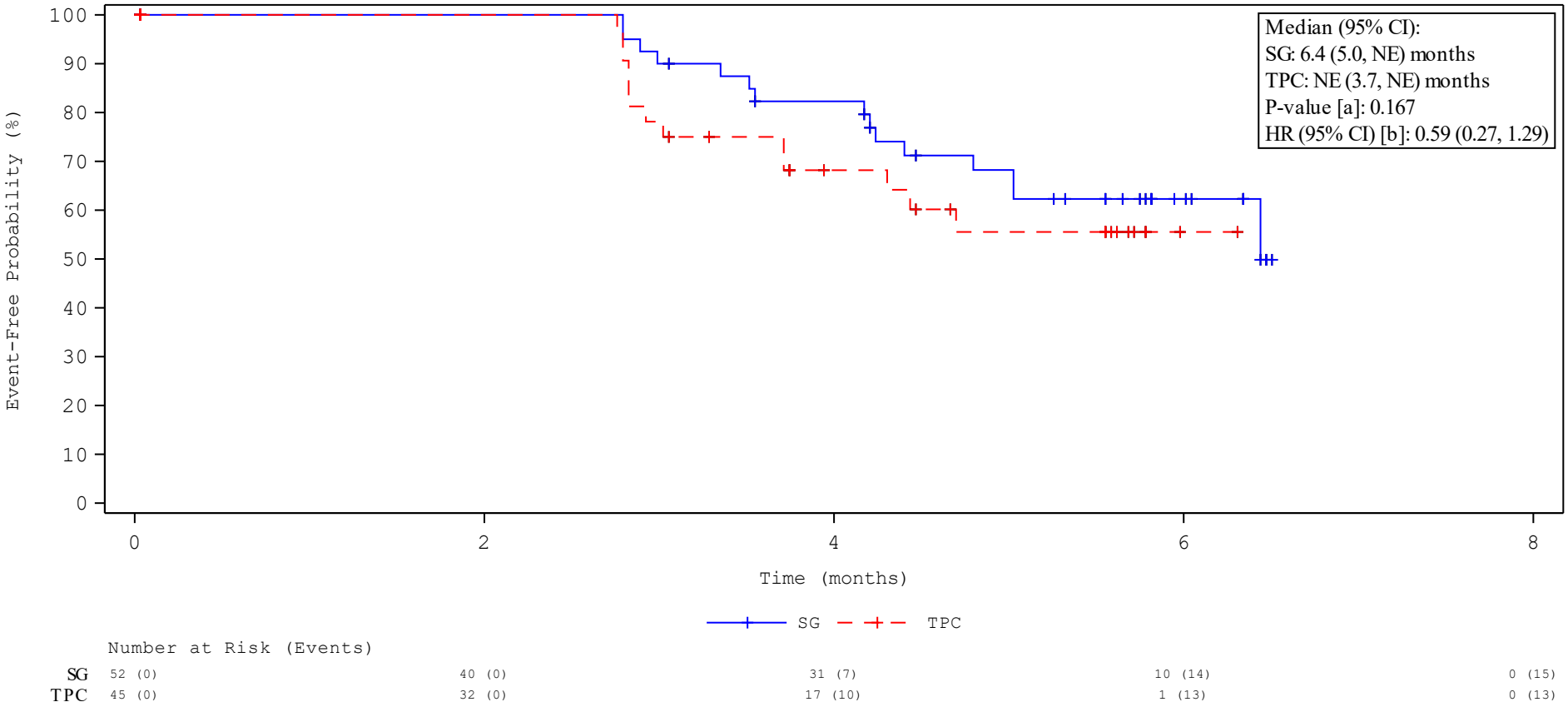
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.2.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EQ-VAS by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



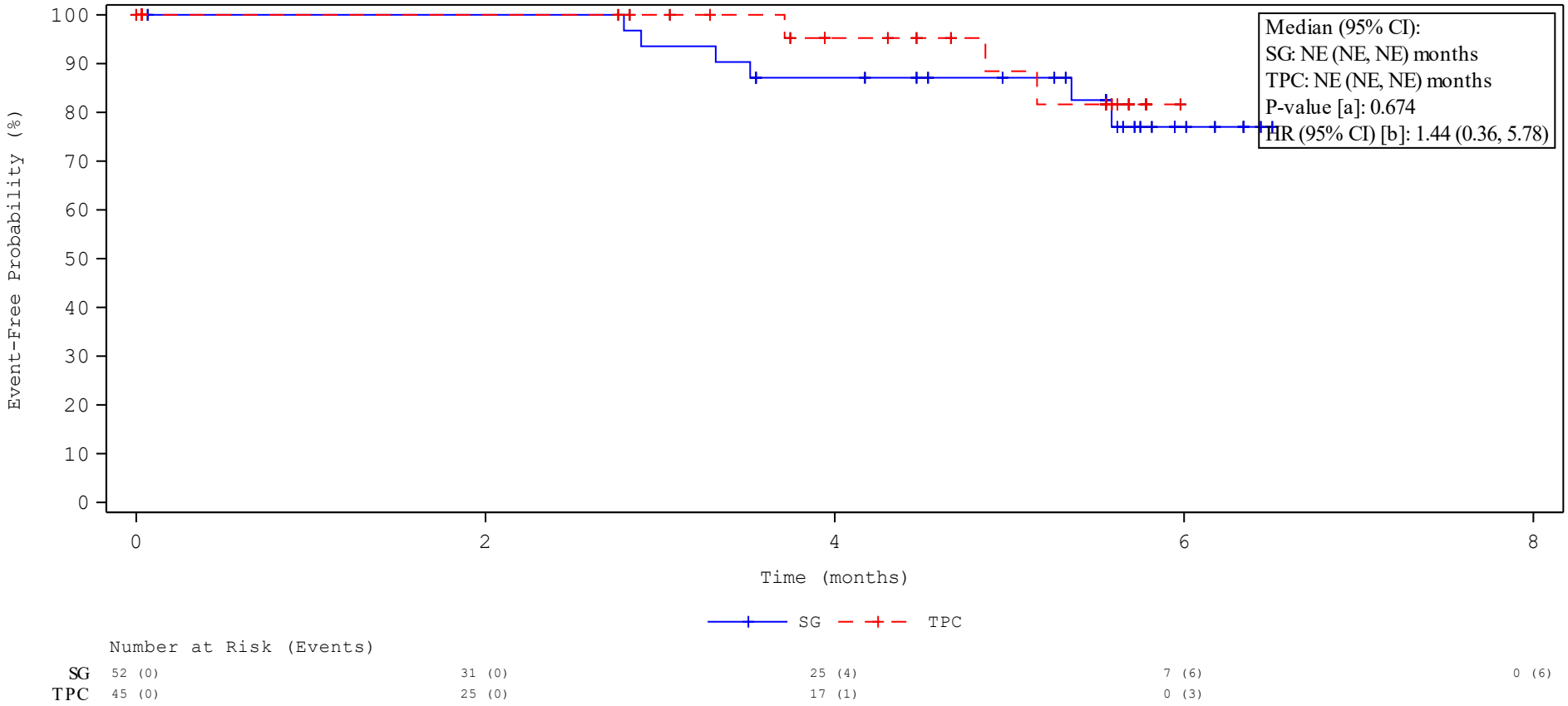
Note: The response threshold for EQ-VAS is ≥15 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Figure 2.2.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIC by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

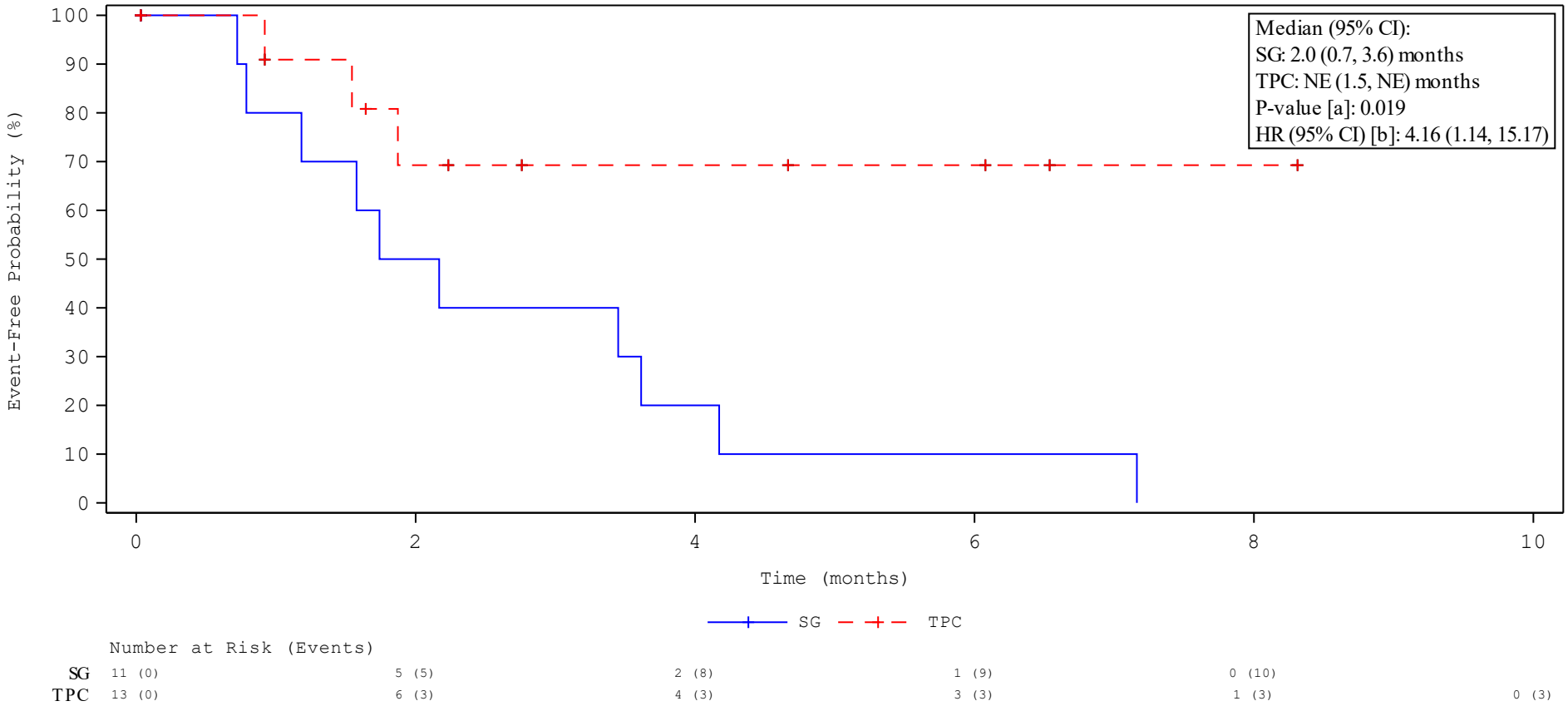
Figure 2.2.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIS by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: 'Very poor' and 'poor' are classified as responders.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.

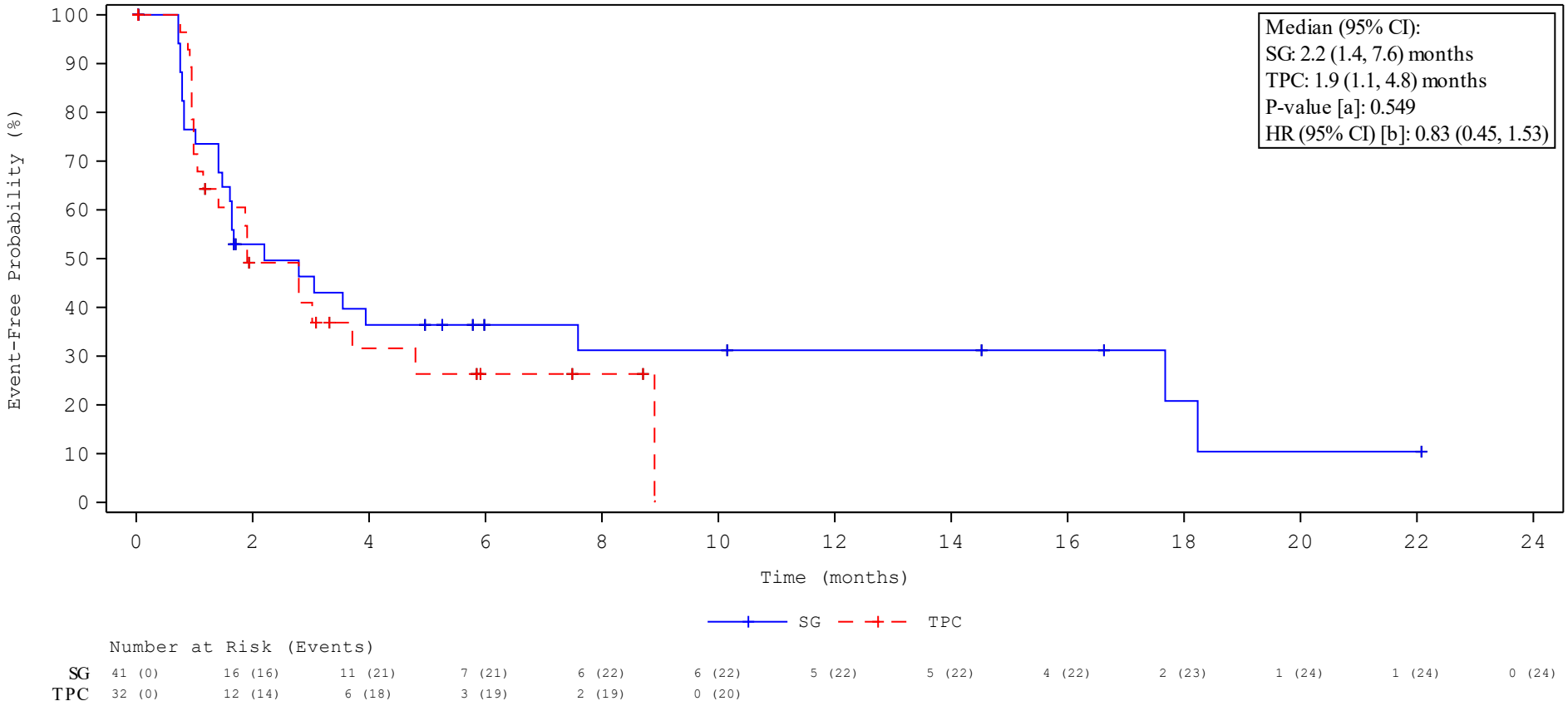
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.2.1.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group (Liver Metastasis = Yes)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



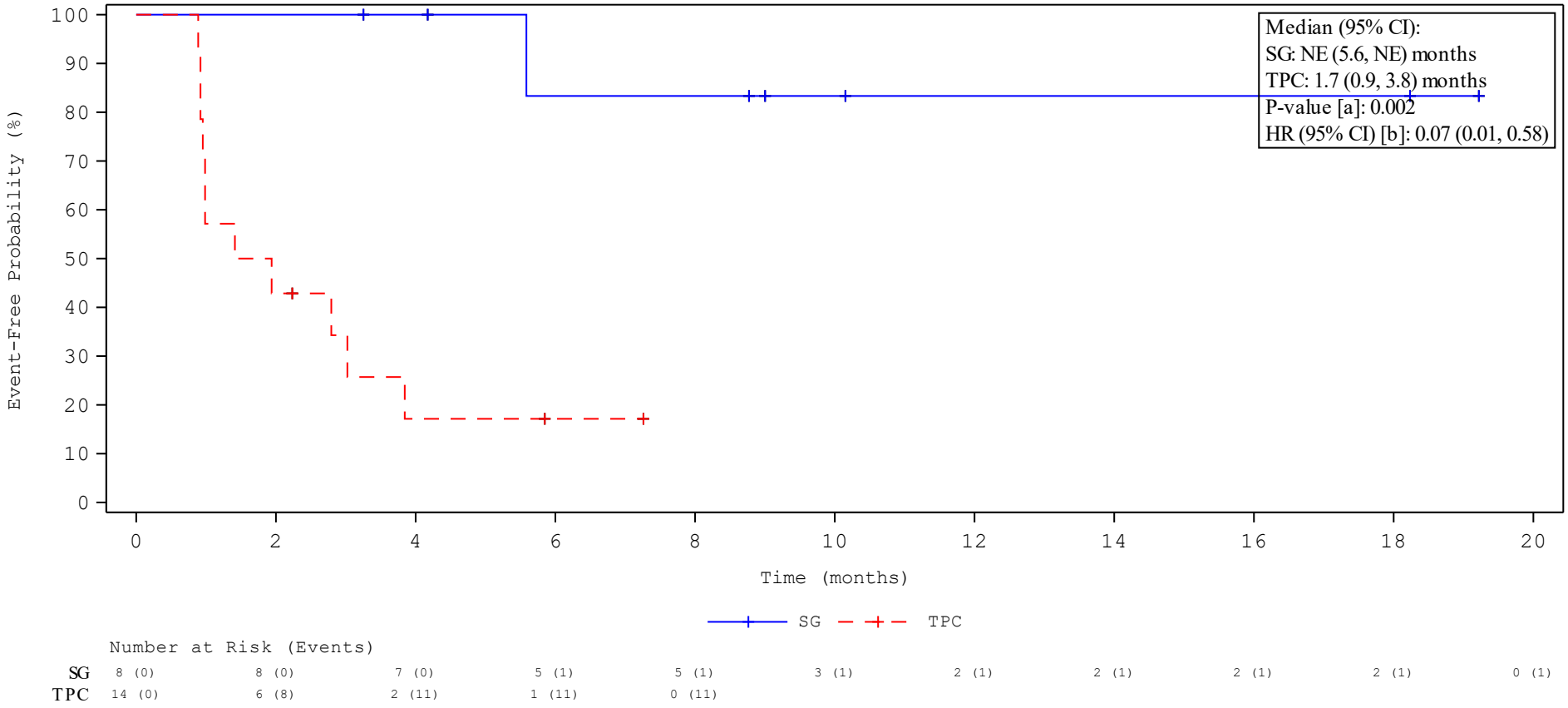
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.2.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group (Liver Metastasis = No)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



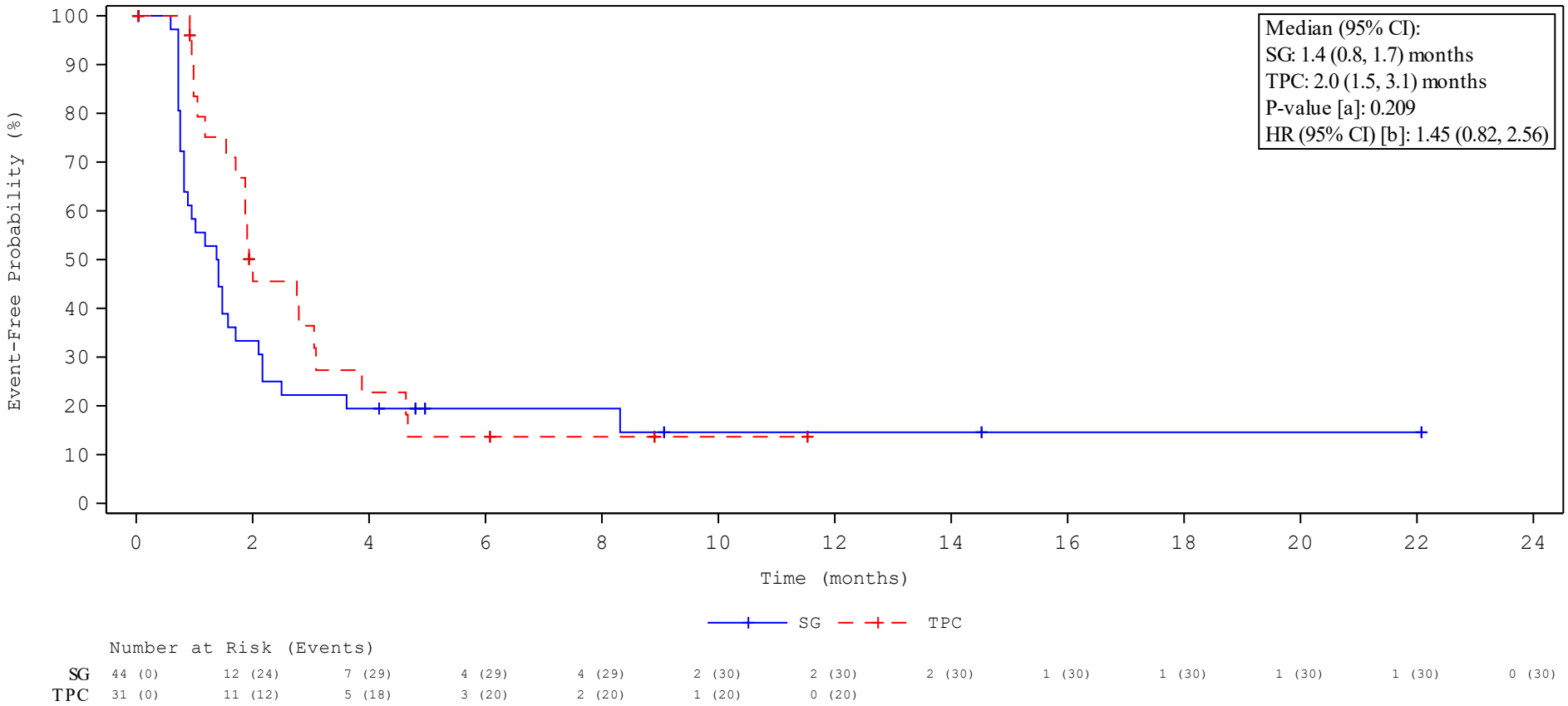
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.2.2.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Menopausal Status = Pre-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



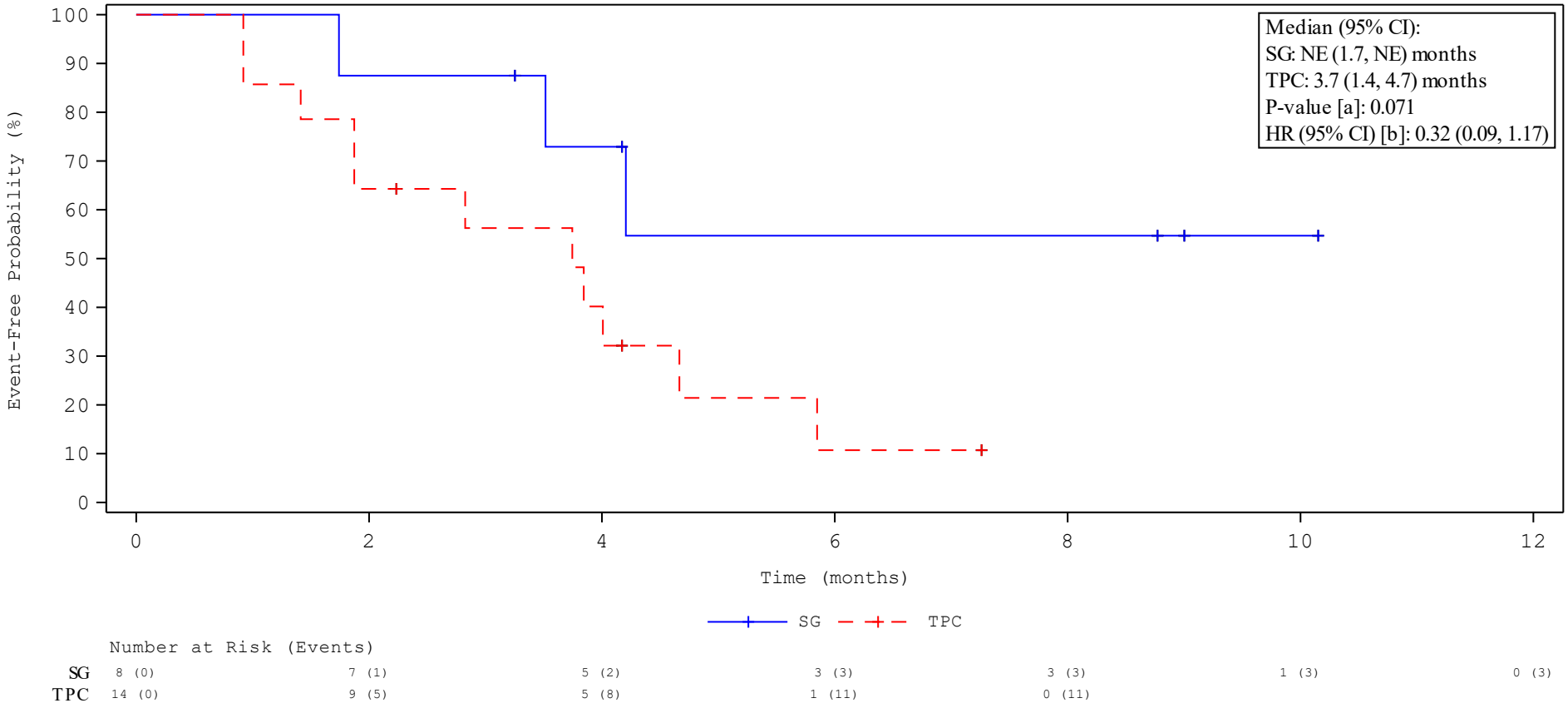
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.2.2.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Menopausal Status = Post-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



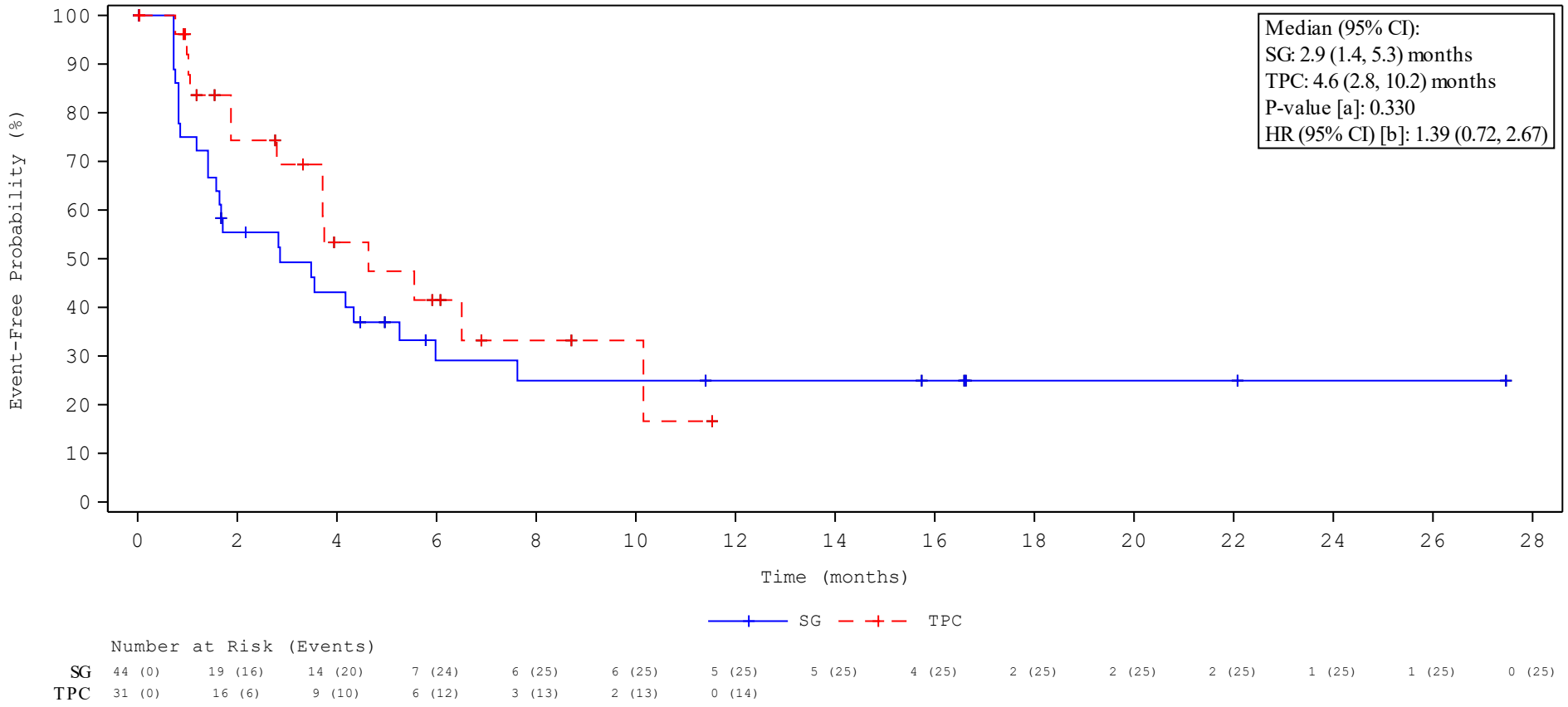
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.2.3.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group (Menopausal Status = Pre-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.2.3.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group (Menopausal Status = Post-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.

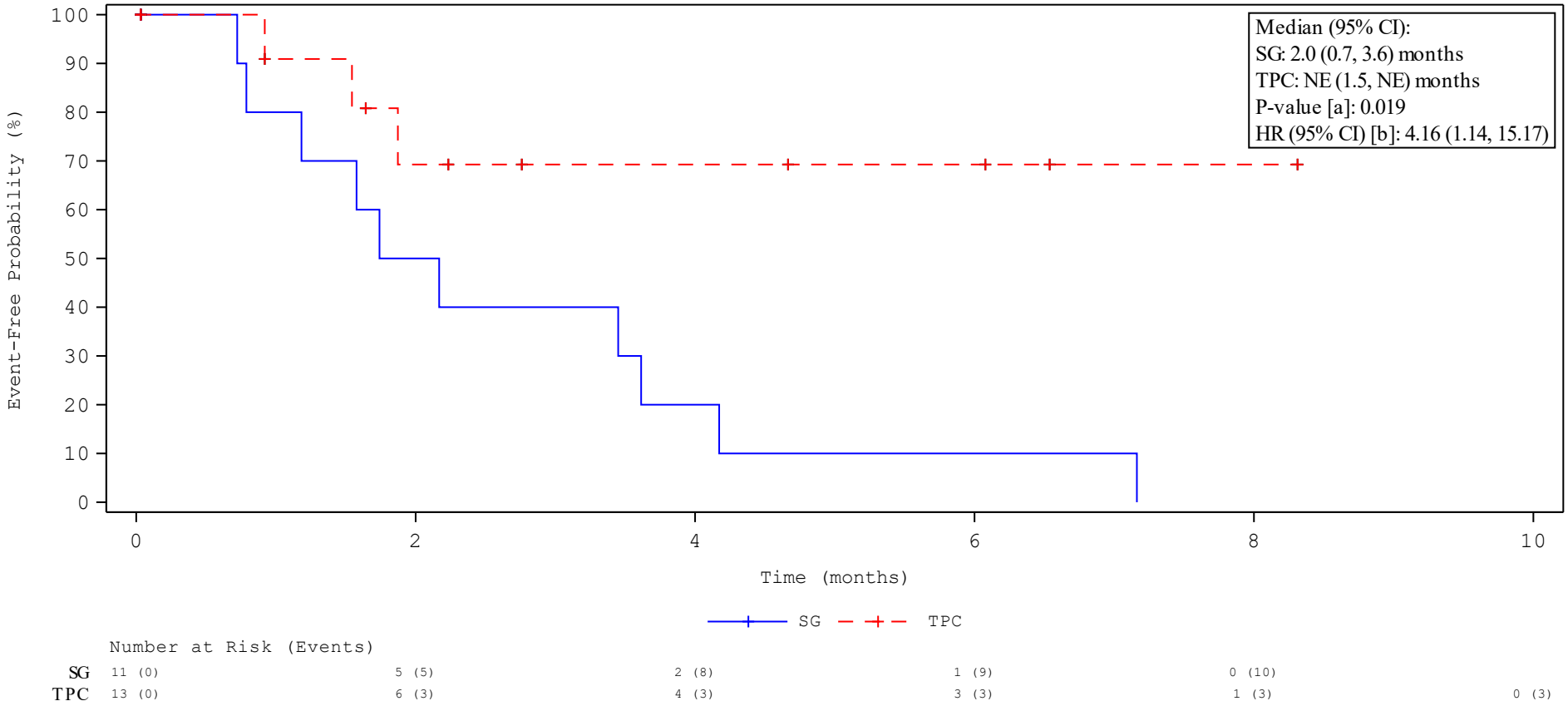
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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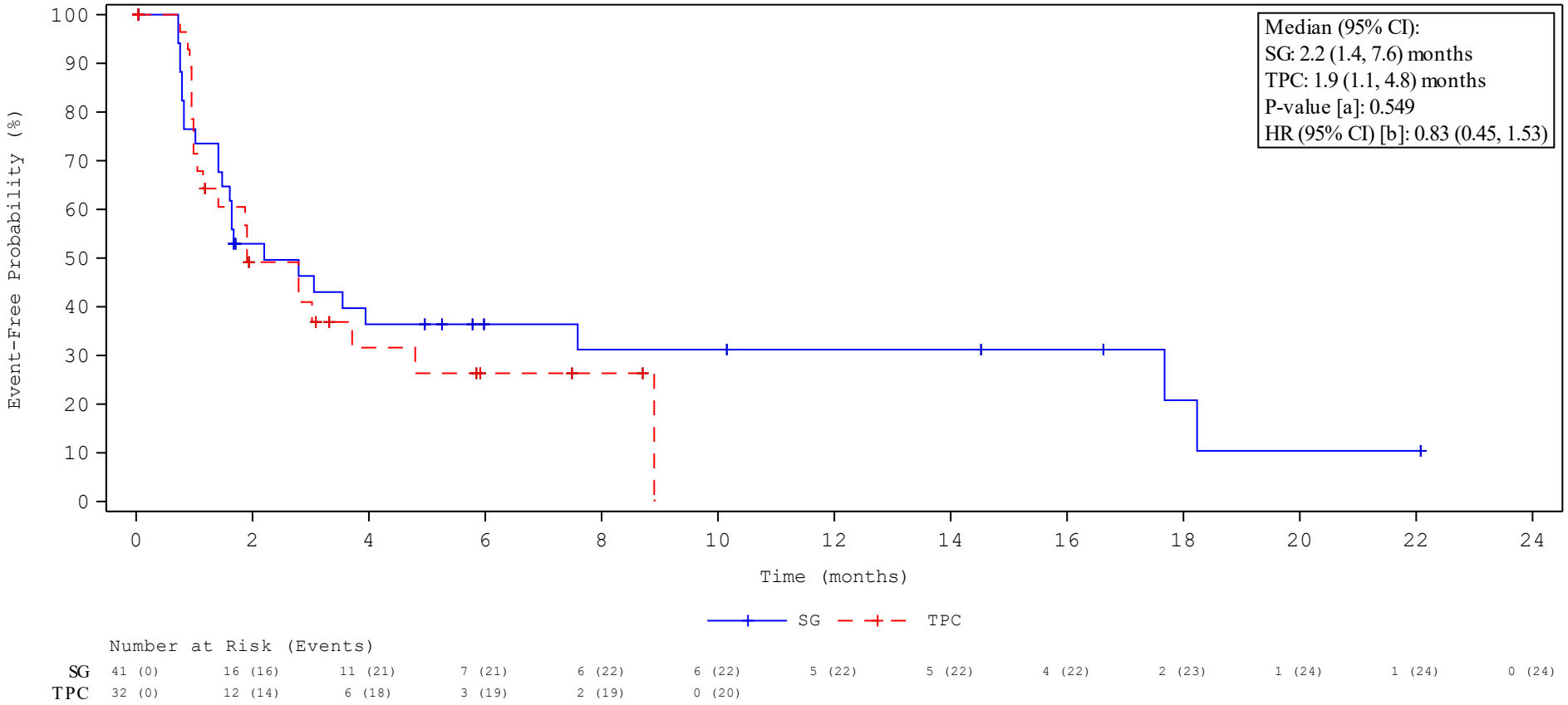
Figure 4.2.1.1

Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group (Liver Metastasis = Yes)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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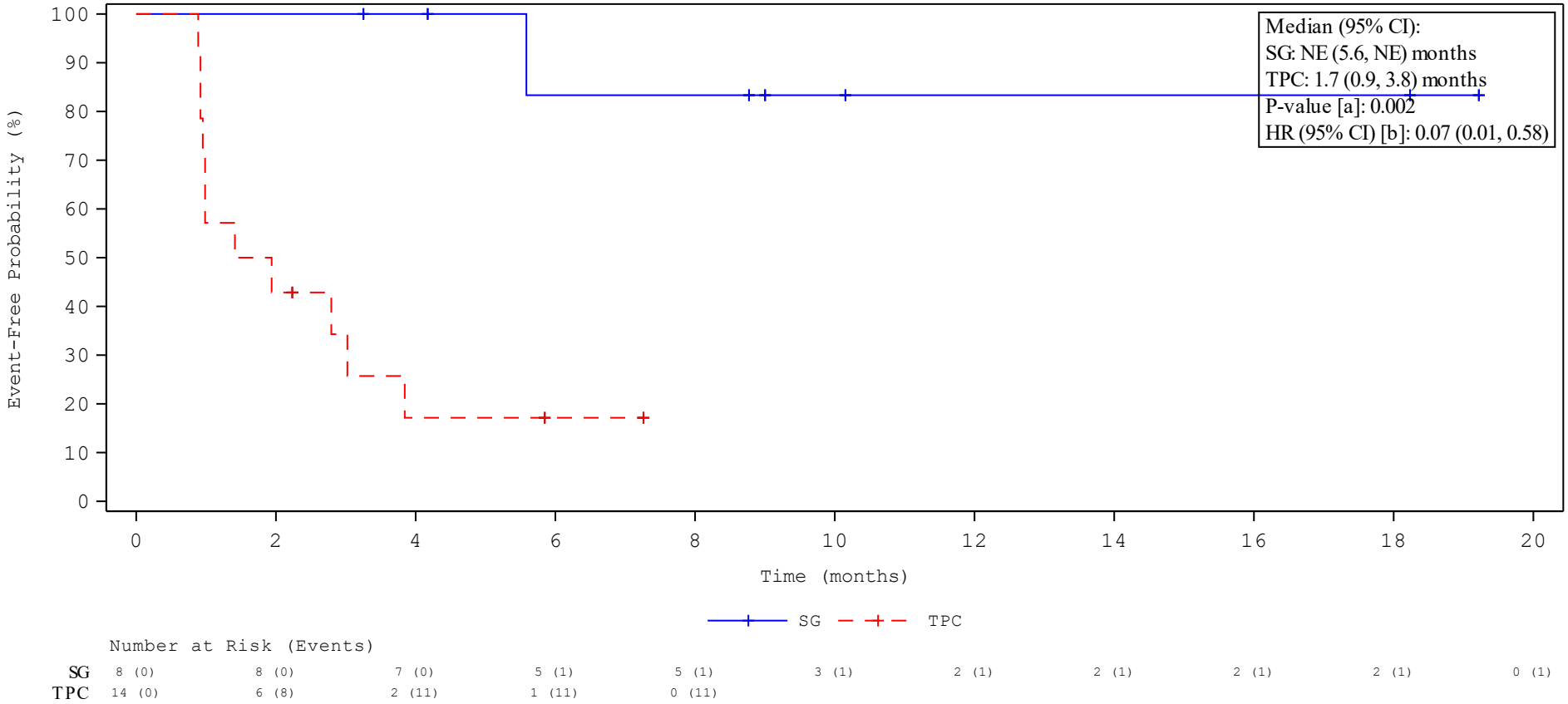
Figure 4.2.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group (Liver Metastasis = No)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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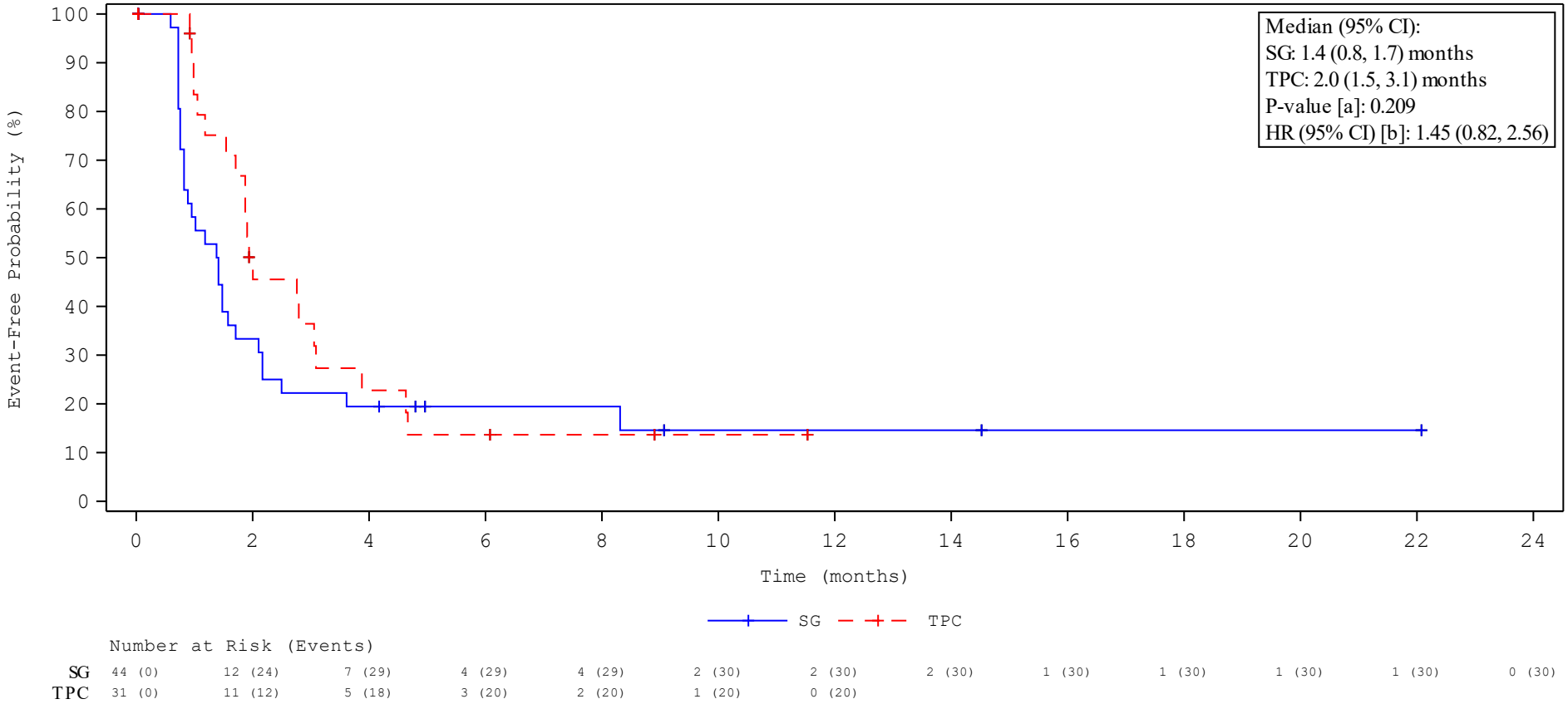
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Figure 4.2.2.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Menopausal Status = Pre-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



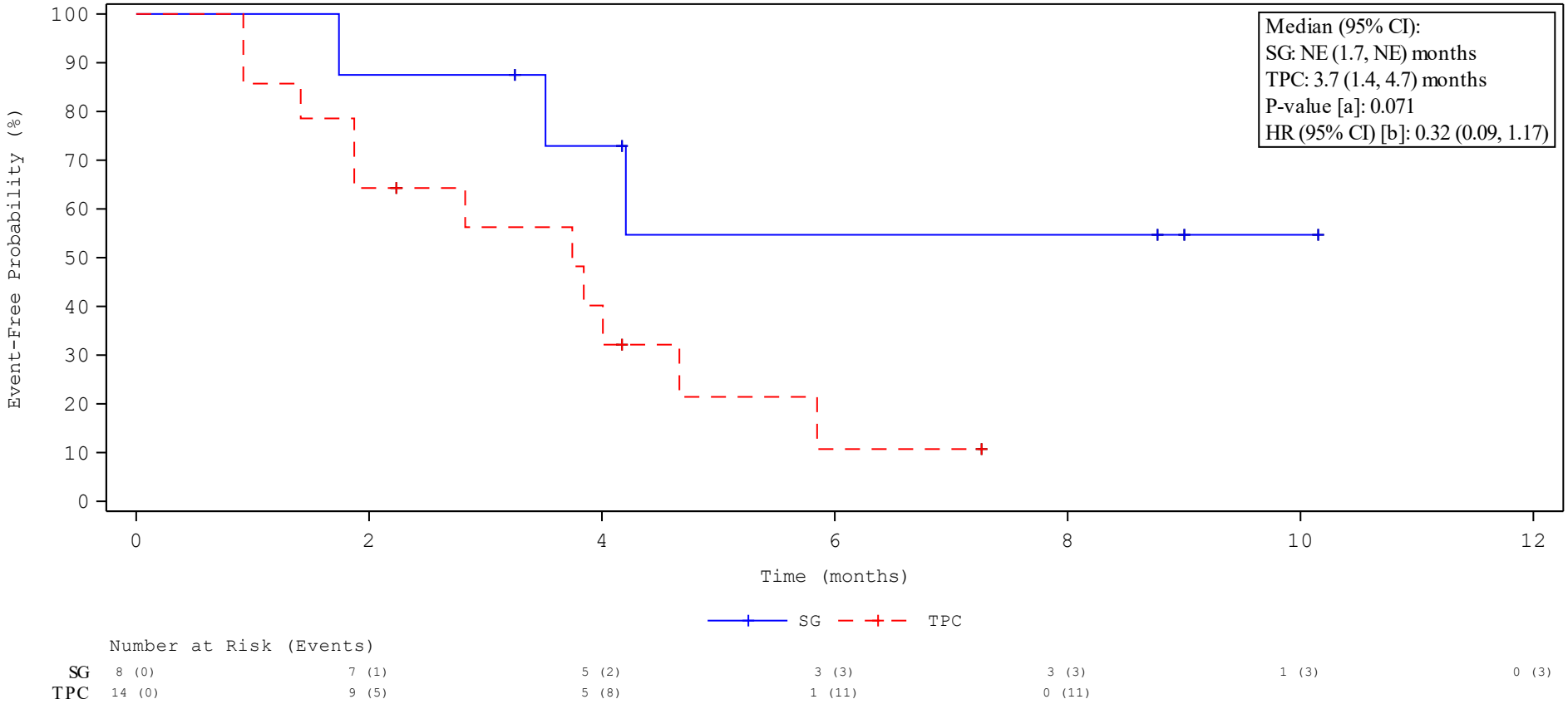
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.2.2.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Menopausal Status = Post-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



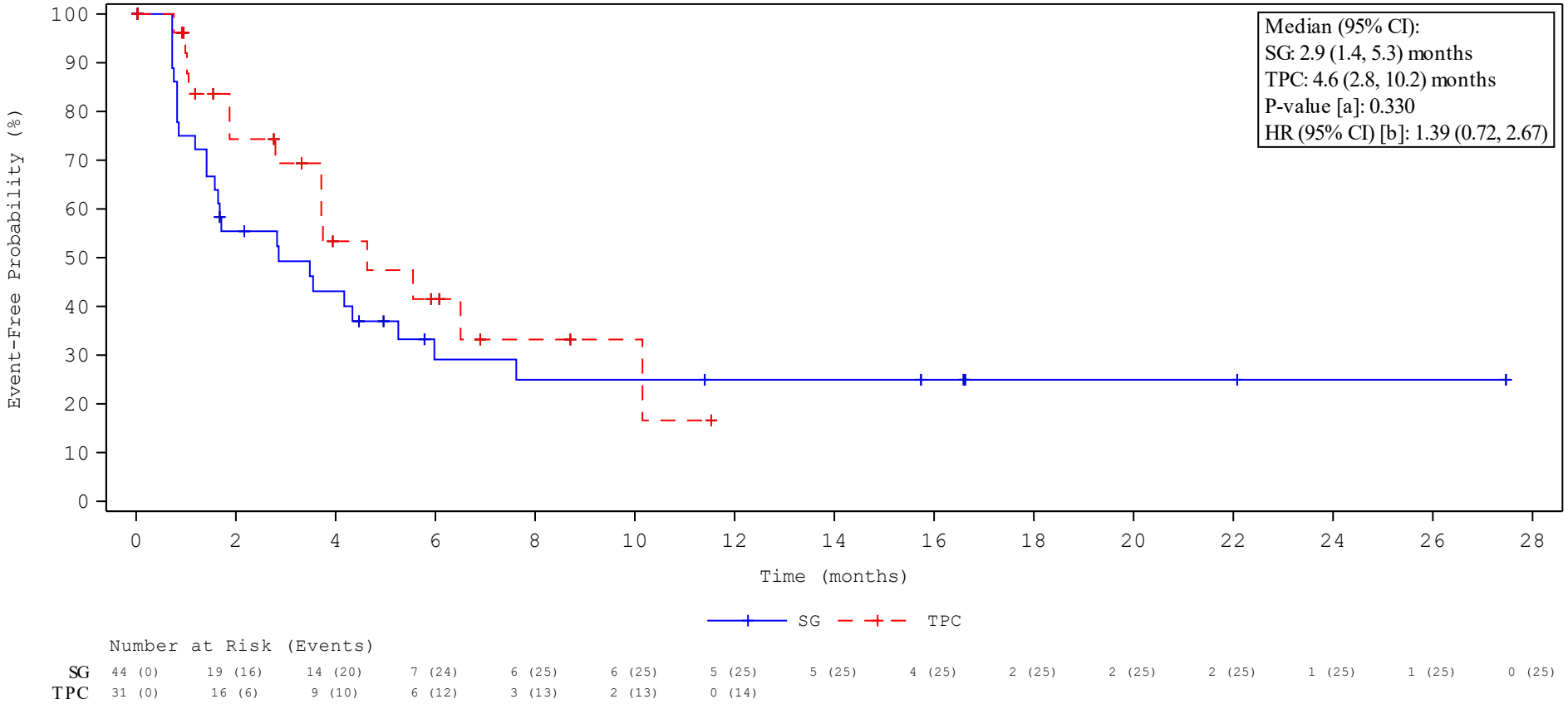
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.2.3.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group (Menopausal Status = Pre-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



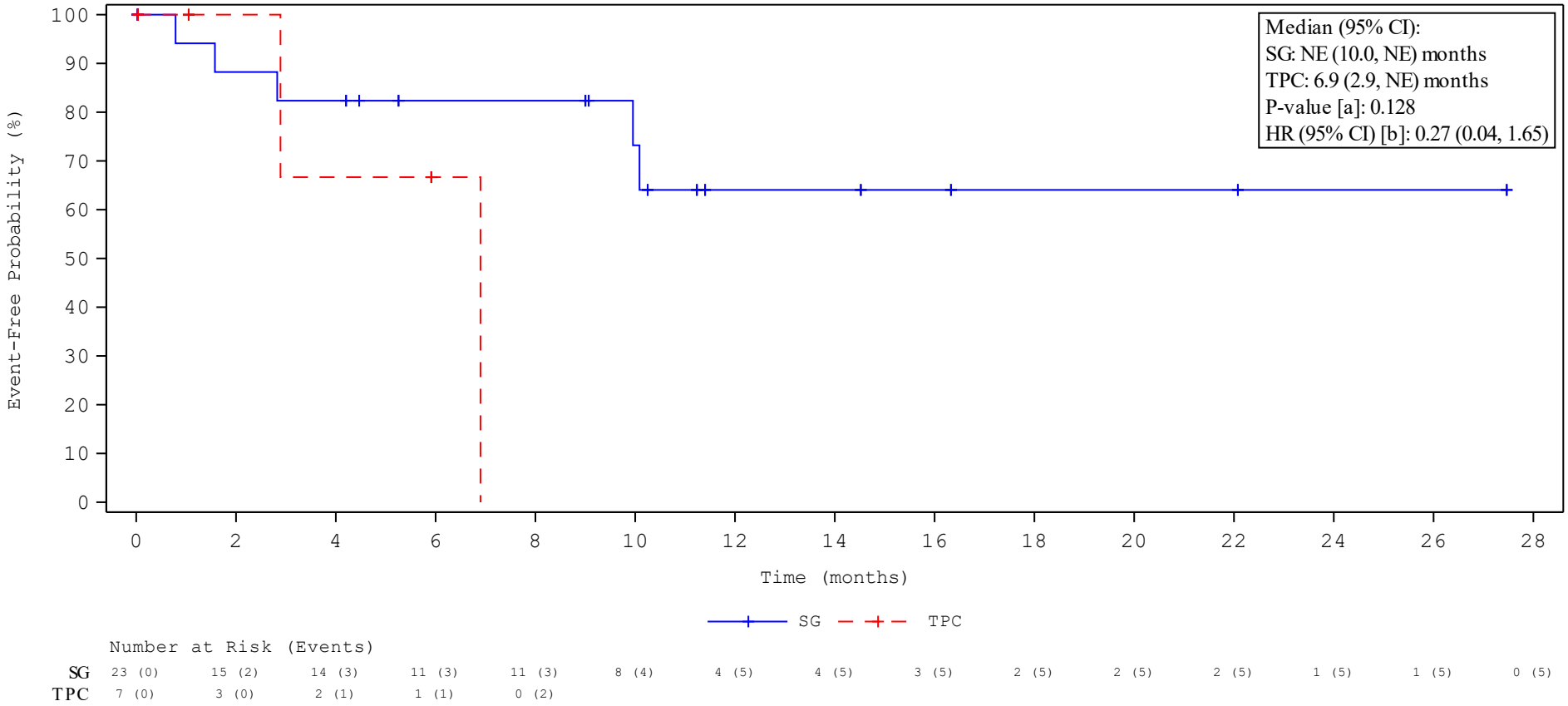
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.2.3.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group (Menopausal Status = Post-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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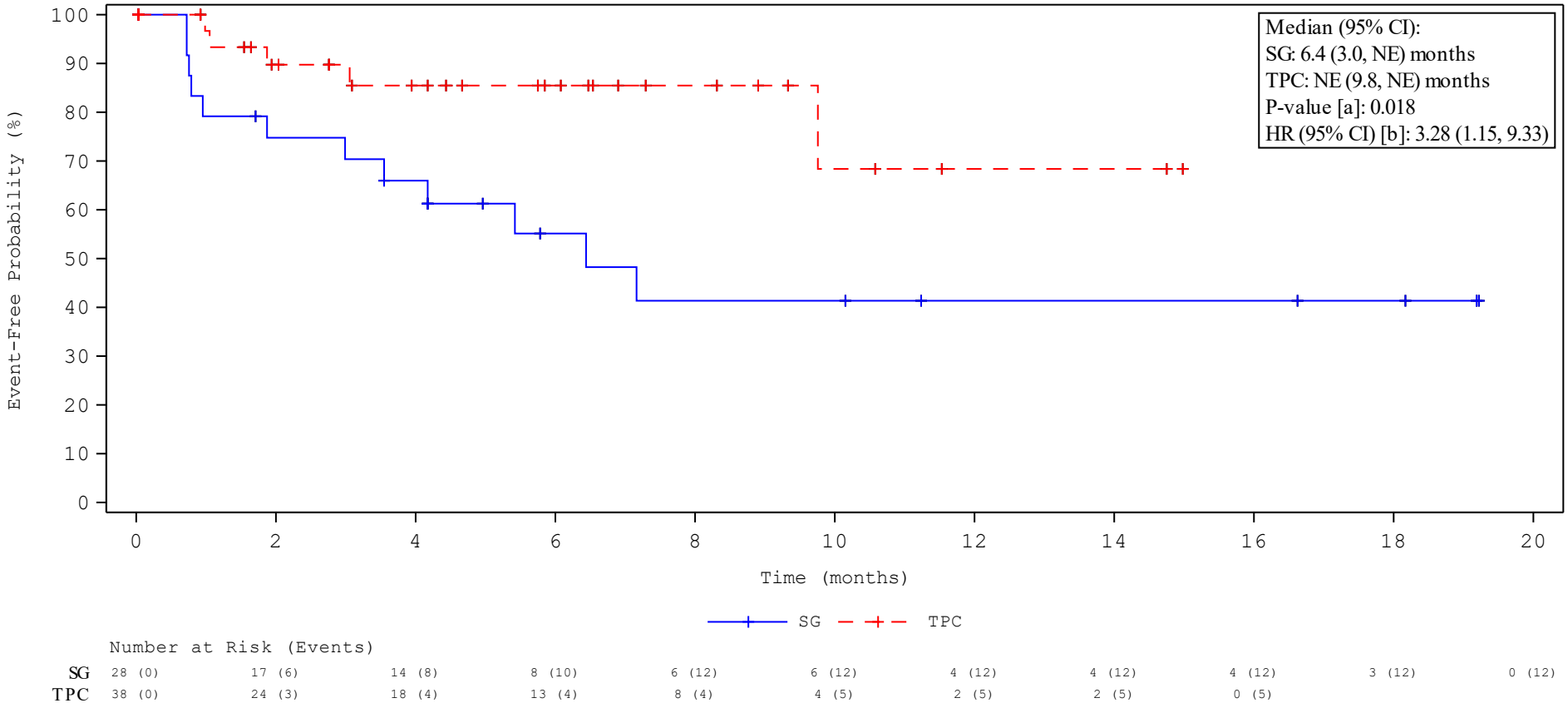
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(mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin)



Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS

Run Date: 03JUN2026

1. Statistical Analysis for German Submission of ASCENT-03

2. TFLs

Population: Triple-negative breast cancer (mTNBC)

Sub-Populations:
— Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Data Cut Date: 22 APR 2026
Report Date: 11 June 2026

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4. Disposition And Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

4.1. Table 1.1.1: Participant Disposition — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Screened			249
mITT	125	124	249
Randomized but not Treated	1	2	3
Safety Analysis Set	124	122	246
Study Treatment Completion Status (Randomized Phase)			
Continuing Study Treatment	13 (10.4%)	5 (4.0%)	18 (7.2%)
Discontinued Study Treatment	112 (89.6%)	119 (96.0%)	231 (92.8%)
Adverse Event	5 (4.0%)	11 (8.9%)	16 (6.4%)
Pregnancy	0	0	0
Investigator's Discretion	7 (5.6%)	5 (4.0%)	12 (4.8%)
Non-Compliance with Study Drug	0	0	0
Subject Decision	10 (8.0%)	11 (8.9%)	21 (8.4%)
Study Terminated by Sponsor	0	0	0
Progressive Disease	86 (68.8%)	92 (74.2%)	178 (71.5%)
Lost to Follow-Up	0	0	0
Death	4 (3.2%)	0	4 (1.6%)
Received Study Treatment in Crossover Phase		55 (44.4%)	
Study Completion Status			
Continuing Study	39 (31.2%)	37 (29.8%)	76 (30.5%)
Discontinued Study	86 (68.8%)	87 (70.2%)	173 (69.5%)
Death	83 (66.4%)	76 (61.3%)	159 (63.9%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Withdrew Consent	3 (2.4%)	11 (8.9%)	14 (5.6%)
Lost to Follow-Up	0	0	0
Study Terminated by Sponsor	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Screened Population: Participants who have signed an informed consent and participated in the screening procedures at site to assess eligibility.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug.
Denominator of percentages is the number of participants in each treatment group.
Randomized Phase excludes crossover phase when participants in TPC arm started to receive SG.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table1.Disposition of participants.R

4.2. Table 1.1.2: Demographic and Baseline Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Age (years)			
N	125	124	249
Mean (Sd)	54.8 (11.7)	53.3 (12.0)	54.0 (11.8)
Median	53.0	52.0	53.0
Q1, Q3	47.0, 62.0	44.8, 62.2	46.0, 62.0
Min, Max	28.0, 81.0	28.0, 77.0	28.0, 81.0
Age Group			
< 65	98 (78.4%)	96 (77.4%)	194 (77.9%)
>= 65	27 (21.6%)	28 (22.6%)	55 (22.1%)
Sex at Birth			
F	125 (100.0%)	123 (99.2%)	248 (99.6%)
M	0	1 (0.8%)	1 (0.4%)
Race			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
AMERICAN INDIAN OR ALASKA NATIVE	6 (4.8%)	10 (8.1%)	16 (6.4%)
ASIAN	26 (20.8%)	26 (21.0%)	52 (20.9%)
BLACK OR AFRICAN AMERICAN	4 (3.2%)	4 (3.2%)	8 (3.2%)
NOT REPORTED	2 (1.6%)	0	2 (0.8%)
OTHER	6 (4.8%)	7 (5.6%)	13 (5.2%)
WHITE	81 (64.8%)	77 (62.1%)	158 (63.5%)
Ethnicity			
HISPANIC OR LATINO	37 (29.6%)	43 (34.7%)	80 (32.1%)
NOT HISPANIC OR LATINO	87 (69.6%)	81 (65.3%)	168 (67.5%)
NOT REPORTED	1 (0.8%)	0	1 (0.4%)
Region			
Rest of the World	95 (76.0%)	89 (71.8%)	184 (73.9%)
US/Canada/Western Europe	30 (24.0%)	35 (28.2%)	65 (26.1%)
Country			
Argentina	8 (6.4%)	10 (8.1%)	18 (7.2%)
Australia	4 (3.2%)	0	4 (1.6%)
Belgium	1 (0.8%)	3 (2.4%)	4 (1.6%)
Brazil	17 (13.6%)	14 (11.3%)	31 (12.4%)
Canada	3 (2.4%)	1 (0.8%)	4 (1.6%)
Chile	1 (0.8%)	4 (3.2%)	5 (2.0%)
China	2 (1.6%)	5 (4.0%)	7 (2.8%)
Czech Republic	1 (0.8%)	2 (1.6%)	3 (1.2%)
France	3 (2.4%)	1 (0.8%)	4 (1.6%)
Germany	3 (2.4%)	1 (0.8%)	4 (1.6%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Hong Kong	1 (0.8%)	1 (0.8%)	2 (0.8%)
Hungary	2 (1.6%)	2 (1.6%)	4 (1.6%)
Israel	7 (5.6%)	1 (0.8%)	8 (3.2%)
Italy	8 (6.4%)	10 (8.1%)	18 (7.2%)
Japan	10 (8.0%)	7 (5.6%)	17 (6.8%)
Korea, Republic of	10 (8.0%)	6 (4.8%)	16 (6.4%)
Malaysia	3 (2.4%)	3 (2.4%)	6 (2.4%)
Mexico	10 (8.0%)	14 (11.3%)	24 (9.6%)
Netherlands	2 (1.6%)	1 (0.8%)	3 (1.2%)
Poland	1 (0.8%)	0	1 (0.4%)
South Africa	4 (3.2%)	5 (4.0%)	9 (3.6%)
Spain	3 (2.4%)	7 (5.6%)	10 (4.0%)
Turkey	14 (11.2%)	10 (8.1%)	24 (9.6%)
United States	7 (5.6%)	10 (8.1%)	17 (6.8%)
Romania	0	1 (0.8%)	1 (0.4%)
Slovakia	0	2 (1.6%)	2 (0.8%)
Taiwan	0	2 (1.6%)	2 (0.8%)
United Kingdom	0	1 (0.8%)	1 (0.4%)
Weight (kg)			
N	125	124	249
Mean (Sd)	70.5 (15.8)	69.3 (14.4)	69.9 (15.1)
Median	68.8	68.5	68.8
Q1, Q3	59.0, 81.0	56.9, 80.1	58.0, 80.6
Min, Max	38.1, 131.4	44.8, 113.0	38.1, 131.4

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Height (cm)			
N	125	124	249
Mean (Sd)	160.6 (7.6)	160.5 (7.3)	160.6 (7.5)
Median	161.0	160.0	160.0
Q1, Q3	155.8, 166.0	155.0, 166.0	155.0, 166.0
Min, Max	140.0, 178.0	145.0, 183.0	140.0, 183.0
BMI (kg/m2)			
N	125	124	249
Mean (Sd)	27.3 (5.8)	26.9 (5.3)	27.1 (5.6)
Median	26.5	26.2	26.3
Q1, Q3	23.5, 31.0	22.7, 30.2	22.9, 30.8
Min, Max	14.1, 54.8	17.5, 44.1	14.1, 54.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Age (in years) was collected on the date of first study drug administration (Day 1) if dosed, or randomization if not dosed.
Not Permitted = local regulators did not allow collection of race or ethnicity information or participant refused to provide information.
*Body Mass Index (BMI) (kg/m^2) = [Weight (kg) / Height (cm)^2]*10,000*
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table2.Demographic and Baseline Characteristics.R

4.3. Table 1.1.3: Other Baseline Disease Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Baseline ECOG Score			
0	81 (64.8%)	80 (64.5%)	161 (64.7%)
1	44 (35.2%)	44 (35.5%)	88 (35.3%)
UGT1A1 Genotype			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
*1/*1	51 (40.8%)	55 (44.4%)	106 (42.6%)
*1/*28	49 (39.2%)	39 (31.5%)	88 (35.3%)
*1/*6	7 (5.6%)	7 (5.6%)	14 (5.6%)
*28/*28	11 (8.8%)	14 (11.3%)	25 (10.0%)
*28/*37	2 (1.6%)	0 (0.0%)	2 (0.8%)
*6/*28	1 (0.8%)	1 (0.8%)	2 (0.8%)
Missing/Not Done	4 (3.2%)	6 (4.8%)	10 (4.0%)
*1/*37	0 (0.0%)	1 (0.8%)	1 (0.4%)
*27/*28	0 (0.0%)	1 (0.8%)	1 (0.4%)
Menopausal Status (Females Only)			
Post-menopausal	96 (76.8%)	88 (71.5%)	184 (74.2%)
Pre-menopausal	29 (23.2%)	35 (28.5%)	64 (25.8%)
BRCA1 Mutation Status			
Mutant	8 (6.4%)	6 (4.8%)	14 (5.6%)
Unknown	74 (59.2%)	71 (57.3%)	145 (58.2%)
Wild Type	43 (34.4%)	47 (37.9%)	90 (36.1%)
BRCA2 Mutation Status			
Mutant	2 (1.6%)	2 (1.6%)	4 (1.6%)
Unknown	74 (59.2%)	75 (60.5%)	149 (59.8%)
Wild Type	49 (39.2%)	47 (37.9%)	96 (38.6%)
BRCA1/2 Mutation Status			
Mutant	9 (7.2%)	7 (5.6%)	16 (6.4%)
Unknown	74 (59.2%)	71 (57.3%)	145 (58.2%)
Wild Type	42 (33.6%)	46 (37.1%)	88 (35.3%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
PD-L1 CPS			
1 to <10	80 (64.0%)	72 (58.1%)	152 (61.0%)
<1	44 (35.2%)	52 (41.9%)	96 (38.6%)
>=10	1 (0.8%)	0 (0.0%)	1 (0.4%)
Estrogen Receptor Status			
Negative (< 1%)	124 (99.2%)	124 (100.0%)	248 (99.6%)
Positive (>= 1%)	1 (0.8%)	0 (0.0%)	1 (0.4%)
Progesterone Receptor Status			
Negative (< 1%)	125 (100.0%)	124 (100.0%)	249 (100.0%)
HER2 Status			
Negative	125 (100.0%)	124 (100.0%)	249 (100.0%)
Pre-selected TPC Prior to Randomization			
Gemcitabine/Carboplatin	125 (100.0%)	124 (100.0%)	249 (100.0%)
Disease Stratification			
De novo	29 (23.2%)	26 (21.0%)	55 (22.1%)
Recurrent disease occurring > 12 months	65 (52.0%)	67 (54.0%)	132 (53.0%)
Recurrent disease within 6 to 12 months	31 (24.8%)	31 (25.0%)	62 (24.9%)
Breast Cancer Stage at Initial Diagnosis			
STAGE 1	18 (14.4%)	16 (12.9%)	34 (13.7%)
STAGE 2	49 (39.2%)	48 (38.7%)	97 (39.0%)
STAGE 3	31 (24.8%)	37 (29.8%)	68 (27.3%)
STAGE 4	27 (21.6%)	23 (18.5%)	50 (20.1%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subtype of Cancer at Initial Diagnosis			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
HR+/HER2+	1 (0.8%)	3 (2.4%)	4 (1.6%)
HR+/HER2-	17 (13.6%)	15 (12.1%)	32 (12.9%)
HR-/HER2+	2 (1.6%)	0 (0.0%)	2 (0.8%)
HR-/HER2- (TNBC)	105 (84.0%)	105 (84.7%)	210 (84.3%)
Missing	0 (0.0%)	1 (0.8%)	1 (0.4%)
Disease Status at Screening			
Locally advanced and Inoperable	3 (2.4%)	5 (4.0%)	8 (3.2%)
Metastatic	122 (97.6%)	119 (96.0%)	241 (96.8%)
Site of Metastasis at Screening			
Bone	46 (36.8%)	32 (25.8%)	78 (31.3%)
Brain	6 (4.8%)	7 (5.6%)	13 (5.2%)
Liver	36 (28.8%)	26 (21.0%)	62 (24.9%)
Lung	78 (62.4%)	81 (65.3%)	159 (63.9%)
Lymph Node	83 (66.4%)	77 (62.1%)	160 (64.3%)
Other	40 (32.0%)	44 (35.5%)	84 (33.7%)
Time from Locally Advanced and Inoperable or Metastatic Disease to Randomization (months) [a]			
N	124	124	248
Mean (StD)	2.2 (1.69)	2.4 (2.07)	2.3 (1.89)
Median	1.8	1.8	1.8
Q1, Q3	1.4, 2.5	1.2, 2.9	1.3, 2.7
Min, Max	0.5, 14.3	0.1, 13.1	0.1, 14.3

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages for other baseline characteristics is the number of participants in each treatment group.
[a] Mutant denotes participant is either BRCA1 or BRCA2 mutant, or both mutant. Wild type denotes participant is both BRCA1 and BRCA2 wild type. Unknown denotes participant is BRCA1 unknown and BRCA2 wild type or unknown, or participant is BRCA1 wild type or unknown and BRCA2 unknown.
PD-L1 CPS (combined positive score) and TNBC status were collected centrally.
Data Cut Date: 22 APR 2026.

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)

Source: Disposition and Characteristics/Table3.Other Baseline Disease Characteristics.R

4.4. Table 1.1.4: Medical History by System Organ Class and Preferred Term — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Number (%) of Participants with Any Medical History	113 (90.4%)	112 (90.3%)	225 (90.4%)
Blood and lymphatic system disorders	9 (7.2%)	13 (10.5%)	22 (8.8%)
Anaemia	8 (6.4%)	10 (8.1%)	18 (7.2%)
Lymphopenia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Coagulopathy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Increased tendency to bruise	1 (0.8%)	0 (0.0%)	1 (7.2%)
Leukopenia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Neutropenia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Thrombocytosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cardiac disorders	9 (7.2%)	11 (8.9%)	20 (8.8%)
Tachycardia	3 (2.4%)	1 (0.8%)	4 (7.2%)
Atrial fibrillation	2 (1.6%)	1 (0.8%)	3 (7.2%)
Ventricular extrasystoles	0 (0.0%)	3 (2.4%)	3 (7.2%)
Arrhythmia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Cardiomyopathy	1 (0.8%)	1 (0.8%)	2 (7.2%)
Sinus tachycardia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Angina pectoris	0 (0.0%)	1 (0.8%)	1 (7.2%)
Arrhythmia supraventricular	1 (0.8%)	0 (0.0%)	1 (7.2%)
Arteriosclerosis coronary artery	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Bradycardia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pericardial effusion	0 (0.0%)	1 (0.8%)	1 (7.2%)
Sinus bradycardia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Supraventricular extrasystoles	0 (0.0%)	1 (0.8%)	1 (7.2%)
Congenital, familial and genetic disorders	1 (0.8%)	4 (3.2%)	5 (8.8%)
Coarctation of the aorta	0 (0.0%)	1 (0.8%)	1 (7.2%)
Congenital musculoskeletal disorder of limbs	0 (0.0%)	1 (0.8%)	1 (7.2%)
Congenital neuropathy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Kidney duplex	0 (0.0%)	1 (0.8%)	1 (7.2%)
Venous angioma of brain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Ear and labyrinth disorders	3 (2.4%)	3 (2.4%)	6 (8.8%)
Vertigo	0 (0.0%)	2 (1.6%)	2 (7.2%)
Deafness	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hypoacusis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Meniere's disease	0 (0.0%)	1 (0.8%)	1 (7.2%)
Sudden hearing loss	1 (0.8%)	0 (0.0%)	1 (7.2%)
Endocrine disorders	15 (12.0%)	18 (14.5%)	33 (8.8%)
Hypothyroidism	10 (8.0%)	13 (10.5%)	23 (7.2%)
Hyperthyroidism	2 (1.6%)	4 (3.2%)	6 (7.2%)
Thyroid mass	2 (1.6%)	0 (0.0%)	2 (7.2%)
Autoimmune hypothyroidism	1 (0.8%)	0 (0.0%)	1 (7.2%)
Autoimmune thyroiditis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Goitre	0 (0.0%)	1 (0.8%)	1 (7.2%)
Eye disorders	11 (8.8%)	5 (4.0%)	16 (8.8%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Myopia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Presbyopia	2 (1.6%)	1 (0.8%)	3 (7.2%)
Astigmatism	0 (0.0%)	2 (1.6%)	2 (7.2%)
Glaucoma	0 (0.0%)	2 (1.6%)	2 (7.2%)
Cataract	1 (0.8%)	0 (0.0%)	1 (7.2%)
Conjunctivitis allergic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Dry eye	0 (0.0%)	1 (0.8%)	1 (7.2%)
Eye pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Fuchs' syndrome	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hypermetropia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Macular degeneration	1 (0.8%)	0 (0.0%)	1 (7.2%)
Macular oedema	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pterygium	1 (0.8%)	0 (0.0%)	1 (7.2%)
Retinal vein occlusion	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vision blurred	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gastrointestinal disorders	30 (24.0%)	36 (29.0%)	66 (8.8%)
Constipation	6 (4.8%)	12 (9.7%)	18 (7.2%)
Gastrooesophageal reflux disease	5 (4.0%)	6 (4.8%)	11 (7.2%)
Nausea	2 (1.6%)	6 (4.8%)	8 (7.2%)
Abdominal pain upper	3 (2.4%)	3 (2.4%)	6 (7.2%)
Diarrhoea	2 (1.6%)	2 (1.6%)	4 (7.2%)
Hiatus hernia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Irritable bowel syndrome	2 (1.6%)	2 (1.6%)	4 (7.2%)
Gastritis	1 (0.8%)	2 (1.6%)	3 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Tooth loss	2 (1.6%)	1 (0.8%)	3 (7.2%)
Abdominal pain	1 (0.8%)	1 (0.8%)	2 (7.2%)
Colitis ulcerative	1 (0.8%)	1 (0.8%)	2 (7.2%)
Dyspepsia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Dysphagia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Gastric ulcer	1 (0.8%)	1 (0.8%)	2 (7.2%)
Umbilical hernia	0 (0.0%)	2 (1.6%)	2 (7.2%)
Abdominal discomfort	0 (0.0%)	1 (0.8%)	1 (7.2%)
Ascites	1 (0.8%)	0 (0.0%)	1 (7.2%)
Chronic gastritis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Coeliac disease	1 (0.8%)	0 (0.0%)	1 (7.2%)
Crohn's disease	0 (0.0%)	1 (0.8%)	1 (7.2%)
Diverticulum	0 (0.0%)	1 (0.8%)	1 (7.2%)
Diverticulum intestinal	1 (0.8%)	0 (0.0%)	1 (7.2%)
Food poisoning	0 (0.0%)	1 (0.8%)	1 (7.2%)
Gastrointestinal disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Haemorrhoidal haemorrhage	1 (0.8%)	0 (0.0%)	1 (7.2%)
Haemorrhoids	0 (0.0%)	1 (0.8%)	1 (7.2%)
Inguinal hernia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Large intestine polyp	1 (0.8%)	0 (0.0%)	1 (7.2%)
Lumbar hernia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pancreatitis chronic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tongue pigmentation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vomiting	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
General disorders and administration site conditions	18 (14.4%)	15 (12.1%)	33 (8.8%)
Fatigue	5 (4.0%)	3 (2.4%)	8 (7.2%)
Pain	3 (2.4%)	4 (3.2%)	7 (7.2%)
Chest pain	2 (1.6%)	4 (3.2%)	6 (7.2%)
Asthenia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Oedema peripheral	3 (2.4%)	1 (0.8%)	4 (7.2%)
Peripheral swelling	1 (0.8%)	1 (0.8%)	2 (7.2%)
Pyrexia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Axillary pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Drug intolerance	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gait disturbance	0 (0.0%)	1 (0.8%)	1 (7.2%)
Non-cardiac chest pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Oedema	0 (0.0%)	1 (0.8%)	1 (7.2%)
Supraclavicular fossa pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hepatobiliary disorders	11 (8.8%)	6 (4.8%)	17 (8.8%)
Cholelithiasis	4 (3.2%)	4 (3.2%)	8 (7.2%)
Hepatic function abnormal	3 (2.4%)	0 (0.0%)	3 (7.2%)
Hepatic steatosis	2 (1.6%)	1 (0.8%)	3 (7.2%)
Cholecystitis chronic	2 (1.6%)	0 (0.0%)	2 (7.2%)
Hyperbilirubinaemia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Autoimmune hepatitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Jaundice cholestatic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Immune system disorders	10 (8.0%)	18 (14.5%)	28 (8.8%)
Drug hypersensitivity	3 (2.4%)	9 (7.3%)	12 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Seasonal allergy	2 (1.6%)	7 (5.6%)	9 (7.2%)
Contrast media allergy	2 (1.6%)	1 (0.8%)	3 (7.2%)
Hypersensitivity	1 (0.8%)	1 (0.8%)	2 (7.2%)
Allergy to arthropod sting	1 (0.8%)	0 (0.0%)	1 (7.2%)
Food allergy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Secondary immunodeficiency	0 (0.0%)	1 (0.8%)	1 (7.2%)
Infections and infestations	16 (12.8%)	14 (11.3%)	30 (8.8%)
COVID-19	5 (4.0%)	1 (0.8%)	6 (7.2%)
Urinary tract infection	1 (0.8%)	4 (3.2%)	5 (7.2%)
Appendicitis	2 (1.6%)	0 (0.0%)	2 (7.2%)
Empyema	1 (0.8%)	1 (0.8%)	2 (7.2%)
Labyrinthitis	2 (1.6%)	0 (0.0%)	2 (7.2%)
American trypanosomiasis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Anal abscess	0 (0.0%)	1 (0.8%)	1 (7.2%)
Conjunctivitis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Dengue fever	0 (0.0%)	1 (0.8%)	1 (7.2%)
Erysipelas	1 (0.8%)	0 (0.0%)	1 (7.2%)
Furuncle	0 (0.0%)	1 (0.8%)	1 (7.2%)
Genital herpes	0 (0.0%)	1 (0.8%)	1 (7.2%)
Gingivitis	1 (0.8%)	0 (0.0%)	1 (7.2%)
HIV infection	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hepatitis B	0 (0.0%)	1 (0.8%)	1 (7.2%)
Herpes zoster	1 (0.8%)	0 (0.0%)	1 (7.2%)
Nosocomial infection	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Periodontitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pneumonia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pyelonephritis acute	1 (0.8%)	0 (0.0%)	1 (7.2%)
Rash pustular	0 (0.0%)	1 (0.8%)	1 (7.2%)
Rhinitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Skin candida	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tonsillitis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tuberculosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Upper respiratory tract infection	0 (0.0%)	1 (0.8%)	1 (7.2%)
Injury, poisoning and procedural complications	6 (4.8%)	1 (0.8%)	7 (8.8%)
Pelvic fracture	2 (1.6%)	0 (0.0%)	2 (7.2%)
Ankle fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Compression fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Foot fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Humerus fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Joint dislocation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Postoperative ileus	1 (0.8%)	0 (0.0%)	1 (7.2%)
Procedural pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Upper limb fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Wound complication	1 (0.8%)	0 (0.0%)	1 (7.2%)
Investigations	16 (12.8%)	19 (15.3%)	35 (8.8%)
Aspartate aminotransferase increased	5 (4.0%)	5 (4.0%)	10 (7.2%)
Blood cholesterol increased	3 (2.4%)	5 (4.0%)	8 (7.2%)
Blood alkaline phosphatase increased	4 (3.2%)	2 (1.6%)	6 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Blood lactate dehydrogenase increased	2 (1.6%)	3 (2.4%)	5 (7.2%)
Alanine aminotransferase increased	3 (2.4%)	1 (0.8%)	4 (7.2%)
Arthroscopy	1 (0.8%)	1 (0.8%)	2 (7.2%)
Blood uric acid increased	0 (0.0%)	2 (1.6%)	2 (7.2%)
Gamma-glutamyltransferase increased	1 (0.8%)	1 (0.8%)	2 (7.2%)
Bile acids increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Biopsy breast	1 (0.8%)	0 (0.0%)	1 (7.2%)
Biopsy liver	1 (0.8%)	0 (0.0%)	1 (7.2%)
Biopsy lung	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood bilirubin increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood chloride increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood glucose abnormal	1 (0.8%)	0 (0.0%)	1 (7.2%)
Blood glucose increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood potassium increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood pressure increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood sodium increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood triglycerides increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood urea increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cardiac murmur functional	0 (0.0%)	1 (0.8%)	1 (7.2%)
Ejection fraction decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hepatic enzyme increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hepatitis B core antibody positive	1 (0.8%)	0 (0.0%)	1 (7.2%)
Low density lipoprotein increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lymph node palpable	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Lymphocyte count decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
Platelet count decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
Transaminases increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Weight decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
White blood cells urine positive	0 (0.0%)	1 (0.8%)	1 (7.2%)
Metabolism and nutrition disorders	39 (31.2%)	33 (26.6%)	72 (8.8%)
Diabetes mellitus	14 (11.2%)	5 (4.0%)	19 (7.2%)
Dyslipidaemia	10 (8.0%)	5 (4.0%)	15 (7.2%)
Hypercholesterolaemia	10 (8.0%)	4 (3.2%)	14 (7.2%)
Type 2 diabetes mellitus	3 (2.4%)	4 (3.2%)	7 (7.2%)
Hyperglycaemia	3 (2.4%)	3 (2.4%)	6 (7.2%)
Hyperlipidaemia	2 (1.6%)	4 (3.2%)	6 (7.2%)
Hypertriglyceridaemia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Hyponatraemia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Obesity	2 (1.6%)	2 (1.6%)	4 (7.2%)
Decreased appetite	0 (0.0%)	3 (2.4%)	3 (7.2%)
Hypoalbuminaemia	1 (0.8%)	2 (1.6%)	3 (7.2%)
Vitamin D deficiency	1 (0.8%)	2 (1.6%)	3 (7.2%)
Hypercalcaemia	0 (0.0%)	2 (1.6%)	2 (7.2%)
Hypomagnesaemia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Insulin resistance	2 (1.6%)	0 (0.0%)	2 (7.2%)
Food intolerance	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gout	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hyperuricaemia	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Hypocalcaemia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hypoglycaemia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lactose intolerance	1 (0.8%)	0 (0.0%)	1 (7.2%)
Malnutrition	0 (0.0%)	1 (0.8%)	1 (7.2%)
Tetany	0 (0.0%)	1 (0.8%)	1 (7.2%)
Vitamin B12 deficiency	1 (0.8%)	0 (0.0%)	1 (7.2%)
Musculoskeletal and connective tissue disorders	35 (28.0%)	33 (26.6%)	68 (8.8%)
Back pain	8 (6.4%)	10 (8.1%)	18 (7.2%)
Arthralgia	7 (5.6%)	8 (6.5%)	15 (7.2%)
Osteoarthritis	2 (1.6%)	7 (5.6%)	9 (7.2%)
Osteoporosis	6 (4.8%)	2 (1.6%)	8 (7.2%)
Pain in extremity	5 (4.0%)	3 (2.4%)	8 (7.2%)
Musculoskeletal chest pain	0 (0.0%)	5 (4.0%)	5 (7.2%)
Arthritis	1 (0.8%)	2 (1.6%)	3 (7.2%)
Bone pain	2 (1.6%)	1 (0.8%)	3 (7.2%)
Intervertebral disc protrusion	2 (1.6%)	1 (0.8%)	3 (7.2%)
Osteopenia	1 (0.8%)	2 (1.6%)	3 (7.2%)
Fibromyalgia	2 (1.6%)	0 (0.0%)	2 (7.2%)
Muscle spasms	1 (0.8%)	1 (0.8%)	2 (7.2%)
Axillary mass	1 (0.8%)	0 (0.0%)	1 (7.2%)
Foot deformity	1 (0.8%)	0 (0.0%)	1 (7.2%)
Groin pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Intervertebral disc compression	1 (0.8%)	0 (0.0%)	1 (7.2%)
Intervertebral disc degeneration	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Joint contracture	0 (0.0%)	1 (0.8%)	1 (7.2%)
Muscular weakness	0 (0.0%)	1 (0.8%)	1 (7.2%)
Myalgia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Neck pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Rheumatic disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Rheumatoid arthritis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Sacral pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Spinal osteoarthritis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Trigger finger	0 (0.0%)	1 (0.8%)	1 (7.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	19 (15.2%)	23 (18.5%)	42 (8.8%)
Cancer pain	11 (8.8%)	7 (5.6%)	18 (7.2%)
Uterine leiomyoma	2 (1.6%)	4 (3.2%)	6 (7.2%)
Breast cancer	2 (1.6%)	2 (1.6%)	4 (7.2%)
Tumour pain	2 (1.6%)	2 (1.6%)	4 (7.2%)
Basal cell carcinoma	2 (1.6%)	0 (0.0%)	2 (7.2%)
Tumour ulceration	2 (1.6%)	0 (0.0%)	2 (7.2%)
Cervix carcinoma	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dysplastic naevus	0 (0.0%)	1 (0.8%)	1 (7.2%)
Haemangioma of liver	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hormone receptor positive breast cancer	0 (0.0%)	1 (0.8%)	1 (7.2%)
Infected neoplasm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Intraductal papillary mucinous neoplasm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lymphangiosis carcinomatosa	0 (0.0%)	1 (0.8%)	1 (7.2%)
Mediastinum neoplasm	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Ovarian cancer	1 (0.8%)	0 (0.0%)	1 (7.2%)
Ovarian cancer recurrent	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pituitary tumour benign	0 (0.0%)	1 (0.8%)	1 (7.2%)
Squamous cell carcinoma of skin	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tumour exudation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tumour inflammation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Tumour thrombosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nervous system disorders	18 (14.4%)	30 (24.2%)	48 (8.8%)
Peripheral sensory neuropathy	4 (3.2%)	5 (4.0%)	9 (7.2%)
Migraine	3 (2.4%)	4 (3.2%)	7 (7.2%)
Neuropathy peripheral	4 (3.2%)	3 (2.4%)	7 (7.2%)
Headache	3 (2.4%)	3 (2.4%)	6 (7.2%)
Polyneuropathy	1 (0.8%)	2 (1.6%)	3 (7.2%)
Cerebrovascular accident	2 (1.6%)	0 (0.0%)	2 (7.2%)
Cervicobrachial syndrome	1 (0.8%)	1 (0.8%)	2 (7.2%)
Epilepsy	1 (0.8%)	1 (0.8%)	2 (7.2%)
Paraesthesia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Sciatica	0 (0.0%)	2 (1.6%)	2 (7.2%)
Amnesia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Brain fog	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cerebral small vessel ischaemic disease	0 (0.0%)	1 (0.8%)	1 (7.2%)
Complex regional pain syndrome	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hypoaesthesia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nervous system disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Neurotoxicity	0 (0.0%)	1 (0.8%)	1 (7.2%)
Peripheral motor neuropathy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Petit mal epilepsy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Restless legs syndrome	0 (0.0%)	1 (0.8%)	1 (7.2%)
Spinal cord compression	0 (0.0%)	1 (0.8%)	1 (7.2%)
Taste disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Trigeminal neuropathy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Psychiatric disorders	27 (21.6%)	24 (19.4%)	51 (8.8%)
Anxiety	11 (8.8%)	9 (7.3%)	20 (7.2%)
Depression	9 (7.2%)	11 (8.9%)	20 (7.2%)
Insomnia	11 (8.8%)	9 (7.3%)	20 (7.2%)
Burnout syndrome	0 (0.0%)	2 (1.6%)	2 (7.2%)
Affective disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Anxiety disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Attention deficit hyperactivity disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Bipolar disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Generalised anxiety disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Irritability	1 (0.8%)	0 (0.0%)	1 (7.2%)
Schizophrenia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Sleep disorder due to general medical condition, insomnia type	0 (0.0%)	1 (0.8%)	1 (7.2%)
Suicidal ideation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Renal and urinary disorders	5 (4.0%)	4 (3.2%)	9 (8.8%)
Stress urinary incontinence	1 (0.8%)	1 (0.8%)	2 (7.2%)
Calculus bladder	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Chronic kidney disease	1 (0.8%)	0 (0.0%)	1 (7.2%)
Haematuria	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hydronephrosis	1 (0.8%)	0 (0.0%)	1 (7.2%)
IgA nephropathy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Renal colic	0 (0.0%)	1 (0.8%)	1 (7.2%)
Urge incontinence	1 (0.8%)	0 (0.0%)	1 (7.2%)
Urinary incontinence	1 (0.8%)	0 (0.0%)	1 (7.2%)
Reproductive system and breast disorders	10 (8.0%)	14 (11.3%)	24 (8.8%)
Breast pain	8 (6.4%)	6 (4.8%)	14 (7.2%)
Amenorrhoea	1 (0.8%)	0 (0.0%)	1 (7.2%)
Breast discomfort	1 (0.8%)	0 (0.0%)	1 (7.2%)
Breast mass	0 (0.0%)	1 (0.8%)	1 (7.2%)
Breast ulceration	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cervical dysplasia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Endometriosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Menopausal symptoms	0 (0.0%)	1 (0.8%)	1 (7.2%)
Menstrual disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Premenstrual dysphoric disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Vaginal prolapse	0 (0.0%)	1 (0.8%)	1 (7.2%)
Respiratory, thoracic and mediastinal disorders	32 (25.6%)	30 (24.2%)	62 (8.8%)
Cough	16 (12.8%)	16 (12.9%)	32 (7.2%)
Dyspnoea	7 (5.6%)	7 (5.6%)	14 (7.2%)
Rhinitis allergic	6 (4.8%)	4 (3.2%)	10 (7.2%)
Asthma	6 (4.8%)	2 (1.6%)	8 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Pleural effusion	1 (0.8%)	5 (4.0%)	6 (7.2%)
Sleep apnoea syndrome	1 (0.8%)	1 (0.8%)	2 (7.2%)
Bronchial hyperreactivity	1 (0.8%)	0 (0.0%)	1 (7.2%)
Bronchospasm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dysphonia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dyspnoea exertional	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hyperventilation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nasal septum deviation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Oropharyngeal pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pleuritic pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Productive cough	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pulmonary arterial hypertension	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pulmonary embolism	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pulmonary hypertension	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pulmonary mass	1 (0.8%)	0 (0.0%)	1 (7.2%)
Skin and subcutaneous tissue disorders	10 (8.0%)	6 (4.8%)	16 (8.8%)
Dermatitis atopic	2 (1.6%)	1 (0.8%)	3 (7.2%)
Dry skin	1 (0.8%)	2 (1.6%)	3 (7.2%)
Eczema	1 (0.8%)	1 (0.8%)	2 (7.2%)
Dermatitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dermatitis acneiform	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dermatitis allergic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Henoch-Schonlein purpura	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nail bed bleeding	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Pruritus	1 (0.8%)	0 (0.0%)	1 (7.2%)
Rash erythematous	1 (0.8%)	0 (0.0%)	1 (7.2%)
Skin ulcer	1 (0.8%)	0 (0.0%)	1 (7.2%)
Xeroderma	1 (0.8%)	0 (0.0%)	1 (7.2%)
Social circumstances	2 (1.6%)	4 (3.2%)	6 (8.8%)
Edentulous	2 (1.6%)	0 (0.0%)	2 (7.2%)
Postmenopause	0 (0.0%)	2 (1.6%)	2 (7.2%)
Menopause	0 (0.0%)	1 (0.8%)	1 (7.2%)
Orthodontic appliance user	0 (0.0%)	1 (0.8%)	1 (7.2%)
Surgical and medical procedures	33 (26.4%)	22 (17.7%)	55 (8.8%)
Hysterectomy	10 (8.0%)	5 (4.0%)	15 (7.2%)
Cholecystectomy	9 (7.2%)	3 (2.4%)	12 (7.2%)
Caesarean section	5 (4.0%)	3 (2.4%)	8 (7.2%)
Female sterilisation	3 (2.4%)	4 (3.2%)	7 (7.2%)
Tonsillectomy	1 (0.8%)	3 (2.4%)	4 (7.2%)
Appendicectomy	3 (2.4%)	0 (0.0%)	3 (7.2%)
Breast conserving surgery	2 (1.6%)	1 (0.8%)	3 (7.2%)
Hysterosalpingo-oophorectomy	3 (2.4%)	0 (0.0%)	3 (7.2%)
Mastectomy	3 (2.4%)	0 (0.0%)	3 (7.2%)
Salpingo-oophorectomy bilateral	1 (0.8%)	2 (1.6%)	3 (7.2%)
Central venous catheterisation	2 (1.6%)	0 (0.0%)	2 (7.2%)
Fracture treatment	1 (0.8%)	1 (0.8%)	2 (7.2%)
Axillary lymphadenectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Breast reconstruction	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Corneal operation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Corneal transplant	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gastric ulcer surgery	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hernia repair	1 (0.8%)	0 (0.0%)	1 (7.2%)
Knee operation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lung operation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Mammoplasty	0 (0.0%)	1 (0.8%)	1 (7.2%)
Metabolic surgery	1 (0.8%)	0 (0.0%)	1 (7.2%)
Myomectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Myopia correction	1 (0.8%)	0 (0.0%)	1 (7.2%)
Nasal septal operation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Oophorectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Ovarian operation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Peptic ulcer repair	1 (0.8%)	0 (0.0%)	1 (7.2%)
Red blood cell transfusion	1 (0.8%)	0 (0.0%)	1 (7.2%)
Salpingo-oophorectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Salpingo-oophorectomy unilateral	0 (0.0%)	1 (0.8%)	1 (7.2%)
Skin graft	1 (0.8%)	0 (0.0%)	1 (7.2%)
Sterilisation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Surgery	1 (0.8%)	0 (0.0%)	1 (7.2%)
Synovectomy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Thyroid nodule removal	0 (0.0%)	1 (0.8%)	1 (7.2%)
Thyroidectomy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Tracheostomy	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Transfusion	1 (0.8%)	0 (0.0%)	1 (7.2%)
Varicose vein operation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vascular access placement	1 (0.8%)	0 (0.0%)	1 (7.2%)
Wisdom teeth removal	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vascular disorders	46 (36.8%)	37 (29.8%)	83 (8.8%)
Hypertension	38 (30.4%)	33 (26.6%)	71 (7.2%)
Lymphoedema	3 (2.4%)	4 (3.2%)	7 (7.2%)
Deep vein thrombosis	4 (3.2%)	1 (0.8%)	5 (7.2%)
Varicose vein	3 (2.4%)	1 (0.8%)	4 (7.2%)
Aneurysm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hot flush	1 (0.8%)	0 (0.0%)	1 (7.2%)
Peripheral venous disease	1 (0.8%)	0 (0.0%)	1 (7.2%)
Raynaud's phenomenon	1 (0.8%)	0 (0.0%)	1 (7.2%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Medical history was coded according to MedDRA Version 27.1.
Participants may report >=1 medical history per system organ class or preferred term. At each level of summarization, a participant was counted once if the participant reported 1 or more medical history.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table4.Summary of Medical History.R

4.5. Table 1.1.5: Summary of Prior Systemic Therapy — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Patients with Prior Systemic Therapy	92 (73.6%)	99 (79.8%)	191 (76.7%)
Number of Prior Regimens			
1	45 (36.0%)	53 (42.7%)	98 (39.4%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
2	34 (27.2%)	32 (25.8%)	66 (26.5%)
3	12 (9.6%)	10 (8.1%)	22 (8.8%)
4	1 (0.8%)	4 (3.2%)	5 (2.0%)
Regimen Setting			
ADJUVANT	65 (52.0%)	58 (46.8%)	123 (49.4%)
NEO-ADJUVANT	27 (21.6%)	40 (32.3%)	67 (26.9%)
METASTATIC	0 (0.0%)	1 (0.8%)	1 (0.4%)
Best Response to Prior Therapy			
Complete Remission	14 (11.2%)	15 (12.1%)	29 (11.6%)
Partial Remission	11 (8.8%)	14 (11.3%)	25 (10.0%)
Stable Disease	5 (4.0%)	10 (8.1%)	15 (6.0%)
Progressive Disease	6 (4.8%)	10 (8.1%)	16 (6.4%)
Unevaluable	6 (4.8%)	5 (4.0%)	11 (4.4%)
Not Available	29 (23.2%)	23 (18.5%)	52 (20.9%)
Unknown	21 (16.8%)	22 (17.7%)	43 (17.3%)
Progression After Prior Therapy			
Yes	75 (60.0%)	79 (63.7%)	154 (61.8%)
No	17 (13.6%)	20 (16.1%)	37 (14.9%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table5.Summary of Prior Systemic Therapy.R

4.6. Table 1.1.6: Prior Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Participants with Any Prior Anti-Cancer Therapy, n (%)	92 (73.6%)	99 (79.8%)	191 (76.7%)
Prior Neoadjuvant or Adjuvant Anti-cancer Therapy [a]			
Yes	92 (73.6%)	98 (79.0%)	190 (76.3%)
Taxanes	83 (66.4%)	88 (71.0%)	171 (68.7%)
Anthracyclines	75 (60.0%)	84 (67.7%)	159 (63.9%)
Platinum	17 (13.6%)	17 (13.7%)	34 (13.7%)
Anti-PD-1/PD-L1 agents	7 (5.6%)	5 (4.0%)	12 (4.8%)
Capecitabine	27 (21.6%)	28 (22.6%)	55 (22.1%)
PARP inhibitors	1 (0.8%)	0	1 (0.4%)
Other	86 (68.8%)	86 (69.4%)	172 (69.1%)
No	0	1 (0.8%)	1 (0.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
[a] Participants can receive multiple categories of prior neoadjuvant or adjuvant anti-cancer therapy.
Participants who received any prior neoadjuvant or adjuvant anti-cancer therapy will be summarized as "Yes".
Participants who received prior anti-cancer therapy but did not receive any prior neoadjuvant/adjuvant anti-cancer therapy will be summarized as "No".
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table6.Prior Anti-Cancer Therapy.R

4.7. Table 1.1.7: Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Participants with Any Subsequent Anti Cancer Therapy, n (%)	77 (61.6%)	92 (74.2%)	169 (67.9%)
Taxanes	29 (23.2%)	18 (14.5%)	47 (18.9%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.8%)	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
DOCETAXEL	3 (2.4%)	4 (3.2%)	7 (2.8%)
PACLITAXEL	22 (17.6%)	12 (9.7%)	34 (13.7%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	5 (4.0%)	1 (0.8%)	6 (2.4%)
Anthracyclines	15 (12.0%)	9 (7.3%)	24 (9.6%)
DOXORUBICIN	5 (4.0%)	2 (1.6%)	7 (2.8%)
DOXORUBICIN HYDROCHLORIDE	1 (0.8%)	3 (2.4%)	4 (1.6%)
EPIRUBICIN	3 (2.4%)	3 (2.4%)	6 (2.4%)
LIPOSOMAL DOXORUBICIN	2 (1.6%)	0	2 (0.8%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	5 (4.0%)	1 (0.8%)	6 (2.4%)
Platinum	41 (32.8%)	11 (8.9%)	52 (20.9%)
CARBOPLATIN	35 (28.0%)	10 (8.1%)	45 (18.1%)
CISPLATIN	6 (4.8%)	1 (0.8%)	7 (2.8%)
Anti-PD-1/PD-L1 agents	6 (4.8%)	6 (4.8%)	12 (4.8%)
ATEZOLIZUMAB	0	1 (0.8%)	1 (0.4%)
PEMBROLIZUMAB	6 (4.8%)	3 (2.4%)	9 (3.6%)
SINTILIMAB	0	1 (0.8%)	1 (0.4%)
TISLELIZUMAB	0	1 (0.8%)	1 (0.4%)
PARP inhibitors	3 (2.4%)	2 (1.6%)	5 (2.0%)
OLAPARIB	3 (2.4%)	1 (0.8%)	4 (1.6%)
TALAZOPARIB	0	1 (0.8%)	1 (0.4%)
ADC	17 (13.6%)	80 (64.5%)	97 (39.0%)
SACITUZUMAB GOVITECAN	2 (1.6%)	79 (63.7%)	81 (32.5%)
TRASTUZUMAB DERUXTECAN	14 (11.2%)	15 (12.1%)	29 (11.6%)
TRASTUZUMAB DERUXTECAN NXKI	1 (0.8%)	0	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Other	59 (47.2%)	51 (41.1%)	110 (44.2%)
ABBV 400	1 (0.8%)	0	1 (0.4%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.8%)	0	1 (0.4%)
BEVACIZUMAB	5 (4.0%)	3 (2.4%)	8 (3.2%)
CAPECITABINE	21 (16.8%)	25 (20.2%)	46 (18.5%)
CATEQUENTINIB HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
CHLORINE DIOXIDE	0	1 (0.8%)	1 (0.4%)
CYCLOPHOSPHAMIDE	7 (5.6%)	9 (7.3%)	16 (6.4%)
ERIBULIN	17 (13.6%)	11 (8.9%)	28 (11.2%)
ERIBULIN MESILATE	5 (4.0%)	7 (5.6%)	12 (4.8%)
ETOPOSIDE	0	1 (0.8%)	1 (0.4%)
FLUOROURACIL	3 (2.4%)	3 (2.4%)	6 (2.4%)
GEMCITABINE	21 (16.8%)	1 (0.8%)	22 (8.8%)
GEMCITABINE HYDROCHLORIDE	6 (4.8%)	2 (1.6%)	8 (3.2%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	2 (1.6%)	0	2 (0.8%)
INVESTIGATIONAL DRUG	2 (1.6%)	1 (0.8%)	3 (1.2%)
IXABEPILONE	0	1 (0.8%)	1 (0.4%)
LAROTRECTINIB	0	1 (0.8%)	1 (0.4%)
METHOTREXATE	2 (1.6%)	2 (1.6%)	4 (1.6%)
NADUNOLIMAB	1 (0.8%)	0	1 (0.4%)
NATURAL KILLER CELLS	1 (0.8%)	0	1 (0.4%)
NIVOLUMAB	0	3 (2.4%)	3 (1.2%)
ONDANSETRON	1 (0.8%)	0	1 (0.4%)
PEGYLATED LIPOSOMAL DOXORUBICIN	0	1 (0.8%)	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
PROGESTERONE	0	1 (0.8%)	1 (0.4%)
REPOTRECTINIB	0	1 (0.8%)	1 (0.4%)
TALAZOPARIB TOSYLATE	0	1 (0.8%)	1 (0.4%)
TUMOR-INFILTRATING LYMPHOCYTES	0	1 (0.8%)	1 (0.4%)
VINORELBINE	7 (5.6%)	4 (3.2%)	11 (4.4%)
VINORELBINE TARTRATE	3 (2.4%)	4 (3.2%)	7 (2.8%)
XMT 1660	1 (0.8%)	0	1 (0.4%)
ZEN 3694	0	1 (0.8%)	1 (0.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table10.Subsequent Anti cancer by preferred drug name.R

4.8. Table 1.1.8: First Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Participants with First Subsequent Anti Cancer Therapy, n (%)	77 (61.6%)	91 (73.4%)	168 (67.5%)
Taxanes	23 (18.4%)	4 (3.2%)	27 (10.8%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.8%)	1 (0.4%)
DOCETAXEL	1 (0.8%)	1 (0.8%)	2 (0.8%)
PACLITAXEL	18 (14.4%)	2 (1.6%)	20 (8.0%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	4 (3.2%)	0	4 (1.6%)
Anthracyclines	5 (4.0%)	1 (0.8%)	6 (2.4%)
DOXORUBICIN	1 (0.8%)	0	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
EPIRUBICIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
LIPOSOMAL DOXORUBICIN	1 (0.8%)	0	1 (0.4%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	2 (1.6%)	0	2 (0.8%)
Platinum	32 (25.6%)	2 (1.6%)	34 (13.7%)
CARBOPLATIN	26 (20.8%)	2 (1.6%)	28 (11.2%)
CISPLATIN	6 (4.8%)	0	6 (2.4%)
Anti-PD-1/PD-L1 agents	4 (3.2%)	2 (1.6%)	6 (2.4%)
ATEZOLIZUMAB	0	1 (0.8%)	1 (0.4%)
PEMBROLIZUMAB	4 (3.2%)	0	4 (1.6%)
SINTILIMAB	0	1 (0.8%)	1 (0.4%)
PARP inhibitors	2 (1.6%)	2 (1.6%)	4 (1.6%)
OLAPARIB	2 (1.6%)	1 (0.8%)	3 (1.2%)
TALAZOPARIB	0	1 (0.8%)	1 (0.4%)
ADC	8 (6.4%)	73 (58.9%)	81 (32.5%)
SACITUZUMAB GOVITECAN	1 (0.8%)	71 (57.3%)	72 (28.9%)
TRASTUZUMAB DERUXTECAN	6 (4.8%)	2 (1.6%)	8 (3.2%)
TRASTUZUMAB DERUXTECAN NXKI	1 (0.8%)	0	1 (0.4%)
Other	50 (40.0%)	12 (9.7%)	62 (24.9%)
ABBV 400	1 (0.8%)	0	1 (0.4%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.8%)	0	1 (0.4%)
BEVACIZUMAB	5 (4.0%)	0	5 (2.0%)
CAPECITABINE	13 (10.4%)	7 (5.6%)	20 (8.0%)
CYCLOPHOSPHAMIDE	2 (1.6%)	1 (0.8%)	3 (1.2%)
ERIBULIN	11 (8.8%)	1 (0.8%)	12 (4.8%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
ERIBULIN MESILATE	1 (0.8%)	0	1 (0.4%)
GEMCITABINE	18 (14.4%)	1 (0.8%)	19 (7.6%)
GEMCITABINE HYDROCHLORIDE	3 (2.4%)	1 (0.8%)	4 (1.6%)
INVESTIGATIONAL DRUG	1 (0.8%)	0	1 (0.4%)
LAROTRECTINIB	0	1 (0.8%)	1 (0.4%)
NADUNOLIMAB	1 (0.8%)	0	1 (0.4%)
NATURAL KILLER CELLS	1 (0.8%)	0	1 (0.4%)
VINORELBINE	2 (1.6%)	0	2 (0.8%)
VINORELBINE TARTRATE	1 (0.8%)	0	1 (0.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table11.First Subsequent Anti cancer therapy by Preferred drug name.R

5. Efficacy - mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

5.1. Table 1.1.1: Observation Period (Months) for Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	SG (N=125)	TPC (N=124)	Total (N=249)
Observation Period (months)			
N	125	124	249
Mean (SD)	18.4 (9.9)	18.4 (9.2)	18.4 (9.5)
Median	19	19.7	19.2
Q1, Q3	11.2, 25.6	11, 25.3	11.1, 25.5

Statistic	SG (N=125)	TPC (N=124)	Total (N=249)
Min, Max	0.6, 40.8	0, 36.1	0, 40.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Observation period is defined as time from randomisation to death date or the last date known alive.
Data Cut Date: 22 APR 2026.

5.2. Table 1.1.2: Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events (Death)	85 (68.0%)	81 (65.3%)
Number (%) of Participants Censored	40 (32.0%)	43 (34.7%)
Ongoing [a]	39 (31.2%)	37 (29.8%)
Discontinued Study	1 (0.8%)	6 (4.8%)
Kaplan-Meier Estimate of OS (Months) (95% CI) [b]		
Q1	11.20 (7.26, 13.31)	11.47 (9.10, 14.85)
Median	19.09 (16.62, 22.14)	19.91 (18.00, 22.93)
Q3	36.57 (26.55, NR)	33.31 (27.56, NR)
Absolute Difference in Median OS, SG vs TPC (Months)	-0.82	
Kaplan-Meier Estimate of OS Rate (95% CI) [b]		
At 12 Months	0.711 (0.622, 0.782)	0.728 (0.640, 0.799)
At 18 Months	0.533 (0.442, 0.616)	0.596 (0.503, 0.677)
At 24 Months	0.390 (0.304, 0.476)	0.394 (0.305, 0.481)
At 30 Months	0.286 (0.200, 0.378)	0.280 (0.192, 0.375)
At 36 Months	0.254 (0.162, 0.357)	0.224 (0.115, 0.354)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.8295	

Parameter	SG (N=125)	TPC (N=124)
Hazard Ratio of SG vs TPC (95% CI) [d]	1.033 (0.760, 1.404)	
Duration of OS Follow-up (Months) [e]		
N	125	124
Mean (StD)	18.35 (9.865)	18.45 (9.190)
Median	18.99	19.66
Q1, Q3	11.17, 25.63	10.97, 25.31
Min, Max	0.56, 40.80	0.03, 36.07
>=12 Months	88 (70.4%)	88 (71.0%)
>=18 Months	66 (52.8%)	72 (58.1%)
>=24 Months	37 (29.6%)	36 (29.0%)
>=30 Months	14 (11.2%)	15 (12.1%)
>=36 Months	4 (3.2%)	1 (0.8%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice; NR = Not Reached; IWRS = Interactive Web Response System.
[a] Ongoing participants are those who have not discontinued participation in the study by the data cutoff date.
[b] OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Based on Kaplan-Meier estimates with 95% CI using the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test, adjusted for randomization stratification factors (IWRS).
[d] Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
[e] Duration of OS follow-up (months) = (date of death or censoring - date of randomization + 1) / 30.4375.
Data Cut Date: 22 APR 2026.

5.3. Table 1.1.3: Subgroup Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.3895
Number (%) of Participants with Events (Death)	19 (65.5%)	18 (69.2%)	
Number (%) of Participants Censored	10 (34.5%)	8 (30.8%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.65 (12.94, 29.17)	19.53 (11.10, 25.17)	
Log-Rank Test p-value (unstratified)	0.6208		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.849 (0.444, 1.623)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Death)	21 (67.7%)	23 (74.2%)	
Number (%) of Participants Censored	10 (32.3%)	8 (25.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.51 (14.82, 26.55)	17.71 (13.70, 22.44)	
Log-Rank Test p-value (unstratified)	0.5887		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.849 (0.470, 1.536)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Death)	45 (69.2%)	40 (59.7%)	
Number (%) of Participants Censored	20 (30.8%)	27 (40.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.22 (15.34, 25.53)	22.93 (18.10, 28.94)	
Log-Rank Test p-value (unstratified)	0.3035		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.252 (0.815, 1.922)		
Geographic region			
US/Canada/Western Europe	30	35	0.8491
Number (%) of Participants with Events (Death)	22 (73.3%)	24 (68.6%)	
Number (%) of Participants Censored	8 (26.7%)	11 (31.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.64 (15.93, 26.55)	20.60 (11.53, 25.17)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.8049		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.931 (0.517, 1.676)		
Rest of the world	95	89	
Number (%) of Participants with Events (Death)	63 (66.3%)	57 (64.0%)	
Number (%) of Participants Censored	32 (33.7%)	32 (36.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.15 (15.80, 22.14)	19.78 (16.99, 23.20)	
Log-Rank Test p-value (unstratified)	0.7142		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.070 (0.747, 1.531)		
Age group			
< 65	98	96	0.4900
Number (%) of Participants with Events (Death)	65 (66.3%)	62 (64.6%)	
Number (%) of Participants Censored	33 (33.7%)	34 (35.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.14 (17.41, 24.02)	19.91 (17.22, 22.64)	
Log-Rank Test p-value (unstratified)	0.9842		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.997 (0.704, 1.412)		
>= 65	27	28	
Number (%) of Participants with Events (Death)	20 (74.1%)	19 (67.9%)	
Number (%) of Participants Censored	7 (25.9%)	9 (32.1%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.34 (3.88, 33.02)	20.76 (14.55, 26.38)	
Log-Rank Test p-value (unstratified)	0.4705		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.266 (0.667, 2.403)		

	SG (N=125)	TPC (N=124)	Interaction
Race			
White	81	77	0.5257
Number (%) of Participants with Events (Death)	58 (71.6%)	53 (68.8%)	
Number (%) of Participants Censored	23 (28.4%)	24 (31.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.10 (15.77, 22.14)	19.68 (15.41, 24.41)	
Log-Rank Test p-value (unstratified)	0.8514		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.036 (0.713, 1.507)		
Asian	26	26	
Number (%) of Participants with Events (Death)	15 (57.7%)	14 (53.8%)	
Number (%) of Participants Censored	11 (42.3%)	12 (46.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.48 (14.82, NR)	22.93 (19.65, NR)	
Log-Rank Test p-value (unstratified)	0.5555		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.243 (0.599, 2.579)		
Other	16	21	
Number (%) of Participants with Events (Death)	10 (62.5%)	14 (66.7%)	
Number (%) of Participants Censored	6 (37.5%)	7 (33.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	26.55 (7.43, NR)	18.00 (11.30, NR)	
Log-Rank Test p-value (unstratified)	0.5450		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.777 (0.343, 1.762)		
Baseline ECOG status			
0	81	80	0.8916

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Death)	48 (59.3%)	46 (57.5%)	
Number (%) of Participants Censored	33 (40.7%)	34 (42.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (17.74, 29.17)	22.64 (19.65, 29.17)	
Log-Rank Test p-value (unstratified)	0.7867		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.058 (0.706, 1.585)		
1	44	44	
Number (%) of Participants with Events (Death)	37 (84.1%)	35 (79.5%)	
Number (%) of Participants Censored	7 (15.9%)	9 (20.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.80 (9.33, 19.15)	15.15 (10.38, 19.78)	
Log-Rank Test p-value (unstratified)	0.9131		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.026 (0.644, 1.636)		
History of liver metastasis			
Yes	36	26	0.4954
Number (%) of Participants with Events (Death)	30 (83.3%)	21 (80.8%)	
Number (%) of Participants Censored	6 (16.7%)	5 (19.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.31 (10.02, 18.20)	11.47 (6.67, 18.04)	
Log-Rank Test p-value (unstratified)	0.4003		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.784 (0.443, 1.385)		
No	89	98	
Number (%) of Participants with Events (Death)	55 (61.8%)	60 (61.2%)	
Number (%) of Participants Censored	34 (38.2%)	38 (38.8%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.41, 26.55)	21.75 (19.38, 27.27)	
Log-Rank Test p-value (unstratified)	0.9351		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.016 (0.703, 1.467)		
History of brain metastasis			
Yes	6	7	0.6168
Number (%) of Participants with Events (Death)	6 (100.0%)	7 (100.0%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.48 (0.85, NR)	13.50 (2.66, 19.91)	
Log-Rank Test p-value (unstratified)	0.1853		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.404 (0.102, 1.609)		
No	119	117	
Number (%) of Participants with Events (Death)	79 (66.4%)	74 (63.2%)	
Number (%) of Participants Censored	40 (33.6%)	43 (36.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.09 (16.62, 23.26)	20.83 (18.04, 24.41)	
Log-Rank Test p-value (unstratified)	0.7181		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.060 (0.771, 1.458)		
PD-L1 Status			
CPS < 1	44	52	0.5691
Number (%) of Participants with Events (Death)	32 (72.7%)	38 (73.1%)	
Number (%) of Participants Censored	12 (27.3%)	14 (26.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	18.22 (12.75, 23.26)	19.78 (11.99, 22.93)	
Log-Rank Test p-value (unstratified)	0.7471		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.925 (0.577, 1.483)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Death)	53 (65.4%)	43 (59.7%)	
Number (%) of Participants Censored	28 (34.6%)	29 (40.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.15 (16.95, 24.02)	20.83 (17.84, 28.94)	
Log-Rank Test p-value (unstratified)	0.5215		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.141 (0.762, 1.710)		
BRCA 1/2 status			
Wild-Type	42	46	0.1047
Number (%) of Participants with Events (Death)	28 (66.7%)	31 (67.4%)	
Number (%) of Participants Censored	14 (33.3%)	15 (32.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.26 (12.75, 20.80)	19.68 (11.53, 25.17)	
Log-Rank Test p-value (unstratified)	0.9802		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.007 (0.603, 1.680)		
Mutant	9	7	
Number (%) of Participants with Events (Death)	7 (77.8%)	2 (28.6%)	
Number (%) of Participants Censored	2 (22.2%)	5 (71.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.09 (3.15, 26.55)	NR (7.72, NR)	
Log-Rank Test p-value (unstratified)	0.0953		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.556 (0.728, 17.372)		
Menopausal status			
Pre-menopausal	29	35	0.6467
Number (%) of Participants with Events (Death)	20 (69.0%)	23 (65.7%)	
Number (%) of Participants Censored	9 (31.0%)	12 (34.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.50 (10.15, 26.55)	19.68 (14.85, 27.27)	
Log-Rank Test p-value (unstratified)	0.5841		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.180 (0.647, 2.152)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Death)	65 (67.7%)	58 (65.9%)	
Number (%) of Participants Censored	31 (32.3%)	30 (34.1%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.15 (16.95, 24.02)	19.91 (16.99, 24.41)	
Log-Rank Test p-value (unstratified)	0.9827		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.996 (0.698, 1.422)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Median OS from Kaplan-Meier estimate. 95% CI based on log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
Log-rank test is unstratified.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Participants with unknown BRCA 1/2 status were excluded from that subgroup.
Disease stratification and geographic region are collected from IWRS.
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5.4. Table 1.1.4: Follow-up Duration (Months) for PFS and Tumor Response by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	SG (N=125)	TPC (N=124)	Total (N=249)
Follow-up duration (months) for Progression-Free Survival by Blinded Independent Central Review (BICR) [a]			
N	125	124	249
Mean (SD)	9.3 (8.3)	7.8 (7.1)	8.6 (7.7)
Median	6.9	5.7	5.8
Q1, Q3	3, 12.6	3.2, 9	3.1, 11.1
Min, Max	0, 37.6	0, 31.9	0, 37.6
Tumor Response by Blinded Independent Central Review (BICR), n (%)			
CR	14 (11.2%)	9 (7.3%)	23 (9.2%)
PR	60 (48.0%)	55 (44.4%)	115 (46.2%)
SD	34 (27.2%)	41 (33.1%)	75 (30.1%)
PD	11 (8.8%)	13 (10.5%)	24 (9.6%)
NE	0 (0.0%)	0 (0.0%)	0 (0.0%)
NON-CR/NON-PD	0 (0.0%)	1 (0.8%)	1 (0.4%)
Missing/NE	6 (4.8%)	5 (4.0%)	11 (4.4%)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; BICR = blinded independent central review; IWRS = Interactive Web Response System; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE = not evaluable; NON-CR/NON-PD = non-complete response/non-progressive disease (applicable to non-measurable disease).
[a] Observation period for PFS is defined as time from randomisation to the event or censoring date of progression-free survival.
Tumour response assessed by BICR per RECIST v1.1; confirmed responses only.
Data Cut Date: 22 APR 2026.

5.5. Table 1.1.5: Analysis of PFS by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events	87 (69.6%)	84 (67.7%)
Disease Progression (PD)	76 (60.8%)	81 (65.3%)

Parameter	SG (N=125)	TPC (N=124)
Death	11 (8.8%)	3 (2.4%)
Number (%) of Participants Censored	38 (30.4%)	40 (32.3%)
PD after Starting New Anti-Cancer Therapy	0	1 (0.8%)
PD right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	1 (0.8%)	3 (2.4%)
Death after Starting New Anti-Cancer Therapy	16 (12.8%)	14 (11.3%)
Death right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	0	2 (1.6%)
No PD and No Death without New Anti-Cancer Therapy	15 (12.0%)	11 (8.9%)
No PD and No Death with New Anti-Cancer Therapy	6 (4.8%)	6 (4.8%)
No Baseline or Postbaseline Evaluable Assessment [a]	0	3 (2.4%)
Kaplan-Meier Estimate of PFS (Months) (95% CI) [b]		
Q1	4.07 (2.92, 5.39)	4.24 (3.98, 5.49)
Median	8.34 (6.90, 9.92)	8.08 (5.65, 8.34)
Q3	17.91 (12.71, 31.93)	12.68 (9.46, 16.66)
Absolute Difference in Median PFS, SG vs TPC (Months)	0.26	
Kaplan-Meier Estimate of PFS Rate (95% CI) [c]		
At 3 Months	0.808 (0.726, 0.868)	0.869 (0.792, 0.919)
At 6 Months	0.610 (0.514, 0.693)	0.583 (0.484, 0.670)
At 9 Months	0.466 (0.370, 0.556)	0.369 (0.275, 0.464)
At 12 Months	0.375 (0.284, 0.466)	0.299 (0.210, 0.393)
At 18 Months	0.242 (0.163, 0.331)	0.136 (0.071, 0.222)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [d]	0.1410	
Stratified Hazard Ratio of SG vs TPC (95% CI) [e]	0.792 (0.580, 1.081)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
[a] Censoring due to no baseline or no postbaseline evaluable assessment does not include death events before the second scheduled postbaseline visit.
[b] PFS (months) = (date of event or censoring − date of randomisation + 1) / 30.4375. The 95% CI is based on the log-log transformation.

Parameter	SG (N=125)	TPC (N=124)

[c] PFS rate is the proportion of participants alive without progressive disease (PD). The 95% CI is based on the log-log transformation.
[d] The two-sided p-value is from stratified log-rank test.
[e] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.6. Table 1.1.6: Analysis of PFS by BICR – Subgroup — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.6925
Number (%) of Participants with Events	21 (72.4%)	21 (80.8%)	
Disease Progression (PD)	17 (58.6%)	20 (76.9%)	
Death	4 (13.8%)	1 (3.8%)	
Number (%) of Participants Censored	8 (27.6%)	5 (19.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (4.30, 15.21)	5.75 (4.40, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.705 (0.379, 1.312)		
p-value (Log-Rank Test, Unstratified)	0.2691		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events	25 (80.6%)	22 (71.0%)	
Disease Progression (PD)	24 (77.4%)	22 (71.0%)	
Death	1 (3.2%)	0	
Number (%) of Participants Censored	6 (19.4%)	9 (29.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.44, 9.92)	6.74 (5.42, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.745 (0.415, 1.337)		

	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.3228		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events	41 (63.1%)	41 (61.2%)	
Disease Progression (PD)	35 (53.8%)	39 (58.2%)	
Death	6 (9.2%)	2 (3.0%)	
Number (%) of Participants Censored	24 (36.9%)	26 (38.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.59 (6.90, 13.86)	8.34 (5.59, 13.70)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.955 (0.617, 1.479)		
p-value (Log-Rank Test, Unstratified)	0.8353		
Geographic region			
US/Canada/Western Europe	30	35	0.5853
Number (%) of Participants with Events	20 (66.7%)	20 (57.1%)	
Disease Progression (PD)	19 (63.3%)	20 (57.1%)	
Death	1 (3.3%)	0	
Number (%) of Participants Censored	10 (33.3%)	15 (42.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (6.14, 15.51)	7.06 (5.49, 9.76)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.707 (0.377, 1.324)		
p-value (Log-Rank Test, Unstratified)	0.2749		
Rest of the world	95	89	
Number (%) of Participants with Events	67 (70.5%)	64 (71.9%)	
Disease Progression (PD)	57 (60.0%)	61 (68.5%)	
Death	10 (10.5%)	3 (3.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	28 (29.5%)	25 (28.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.23 (5.55, 9.92)	8.08 (5.59, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.899 (0.636, 1.270)		
p-value (Log-Rank Test, Unstratified)	0.5438		
Age group			
< 65	98	96	0.0980
Number (%) of Participants with Events	68 (69.4%)	66 (68.8%)	
Disease Progression (PD)	61 (62.2%)	64 (66.7%)	
Death	7 (7.1%)	2 (2.1%)	
Number (%) of Participants Censored	30 (30.6%)	30 (31.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.90, 10.32)	7.13 (5.52, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.759 (0.539, 1.068)		
p-value (Log-Rank Test, Unstratified)	0.1117		
>= 65	27	28	
Number (%) of Participants with Events	19 (70.4%)	18 (64.3%)	
Disease Progression (PD)	15 (55.6%)	17 (60.7%)	
Death	4 (14.8%)	1 (3.6%)	
Number (%) of Participants Censored	8 (29.6%)	10 (35.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (2.79, 13.86)	8.54 (5.49, 15.21)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.336 (0.688, 2.594)		
p-value (Log-Rank Test, Unstratified)	0.3904		

	SG (N=125)	TPC (N=124)	Interaction
Race			
White	81	77	0.7604
Number (%) of Participants with Events	56 (69.1%)	48 (62.3%)	
Disease Progression (PD)	50 (61.7%)	46 (59.7%)	
Death	6 (7.4%)	2 (2.6%)	
Number (%) of Participants Censored	25 (30.9%)	29 (37.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (5.55, 9.92)	7.79 (5.49, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.917 (0.622, 1.353)		
p-value (Log-Rank Test, Unstratified)	0.6615		
Asian	26	26	
Number (%) of Participants with Events	18 (69.2%)	20 (76.9%)	
Disease Progression (PD)	15 (57.7%)	20 (76.9%)	
Death	3 (11.5%)	0	
Number (%) of Participants Censored	8 (30.8%)	6 (23.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.82 (3.88, 15.21)	8.08 (5.49, 11.07)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.717 (0.376, 1.368)		
p-value (Log-Rank Test, Unstratified)	0.3103		
Other	16	21	
Number (%) of Participants with Events	11 (68.8%)	16 (76.2%)	
Disease Progression (PD)	10 (62.5%)	15 (71.4%)	
Death	1 (6.2%)	1 (4.8%)	
Number (%) of Participants Censored	5 (31.2%)	5 (23.8%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (5.52, 23.29)	8.31 (5.39, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.738 (0.337, 1.615)		
p-value (Log-Rank Test, Unstratified)	0.4499		
Baseline ECOG status			
0	81	80	0.7281
Number (%) of Participants with Events	56 (69.1%)	54 (67.5%)	
Disease Progression (PD)	51 (63.0%)	52 (65.0%)	
Death	5 (6.2%)	2 (2.5%)	
Number (%) of Participants Censored	25 (30.9%)	26 (32.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.92 (8.31, 12.45)	8.31 (7.13, 9.76)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.581, 1.236)		
p-value (Log-Rank Test, Unstratified)	0.3897		
1	44	44	
Number (%) of Participants with Events	31 (70.5%)	30 (68.2%)	
Disease Progression (PD)	25 (56.8%)	29 (65.9%)	
Death	6 (13.6%)	1 (2.3%)	
Number (%) of Participants Censored	13 (29.5%)	14 (31.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.21, 7.26)	5.52 (4.17, 7.06)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.857 (0.515, 1.425)		
p-value (Log-Rank Test, Unstratified)	0.5540		
History of liver metastasis			

	SG (N=125)	TPC (N=124)	Interaction
Yes	36	26	0.3890
Number (%) of Participants with Events	29 (80.6%)	17 (65.4%)	
Disease Progression (PD)	26 (72.2%)	15 (57.7%)	
Death	3 (8.3%)	2 (7.7%)	
Number (%) of Participants Censored	7 (19.4%)	9 (34.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.16 (2.96, 9.59)	4.21 (2.79, 5.49)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.677 (0.364, 1.259)		
p-value (Log-Rank Test, Unstratified)	0.2179		
No	89	98	
Number (%) of Participants with Events	58 (65.2%)	67 (68.4%)	
Disease Progression (PD)	50 (56.2%)	66 (67.3%)	
Death	8 (9.0%)	1 (1.0%)	
Number (%) of Participants Censored	31 (34.8%)	31 (31.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (6.90, 12.71)	8.31 (6.93, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.825 (0.578, 1.177)		
p-value (Log-Rank Test, Unstratified)	0.2883		
History of brain metastasis			
Yes	6	7	0.5103
Number (%) of Participants with Events	5 (83.3%)	5 (71.4%)	
Disease Progression (PD)	4 (66.7%)	5 (71.4%)	
Death	1 (16.7%)	0	
Number (%) of Participants Censored	1 (16.7%)	2 (28.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (0.85, NR)	8.08 (0.30, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.704 (0.448, 6.484)		
p-value (Log-Rank Test, Unstratified)	0.4296		
No	119	117	
Number (%) of Participants with Events	82 (68.9%)	79 (67.5%)	
Disease Progression (PD)	72 (60.5%)	76 (65.0%)	
Death	10 (8.4%)	3 (2.6%)	
Number (%) of Participants Censored	37 (31.1%)	38 (32.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.90, 10.32)	7.79 (5.65, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.842 (0.617, 1.150)		
p-value (Log-Rank Test, Unstratified)	0.2795		
PD-L1 Status			
CPS < 1	44	52	0.4020
Number (%) of Participants with Events	33 (75.0%)	32 (61.5%)	
Disease Progression (PD)	28 (63.6%)	31 (59.6%)	
Death	5 (11.4%)	1 (1.9%)	
Number (%) of Participants Censored	11 (25.0%)	20 (38.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (6.14, 12.32)	8.28 (5.42, 12.52)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.022 (0.628, 1.665)		
p-value (Log-Rank Test, Unstratified)	0.9328		
CPS ≥ 1	81	72	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events	54 (66.7%)	52 (72.2%)	
Disease Progression (PD)	48 (59.3%)	50 (69.4%)	
Death	6 (7.4%)	2 (2.8%)	
Number (%) of Participants Censored	27 (33.3%)	20 (27.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.77 (5.55, 11.27)	7.79 (5.65, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.778 (0.529, 1.145)		
p-value (Log-Rank Test, Unstratified)	0.2022		
BRCA 1/2 status			
Wild-Type	42	46	0.2964
Number (%) of Participants with Events	29 (69.0%)	30 (65.2%)	
Disease Progression (PD)	25 (59.5%)	29 (63.0%)	
Death	4 (9.5%)	1 (2.2%)	
Number (%) of Participants Censored	13 (31.0%)	16 (34.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.14 (4.21, 12.45)	6.87 (4.40, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.867 (0.519, 1.450)		
p-value (Log-Rank Test, Unstratified)	0.5803		
Mutant	9	7	
Number (%) of Participants with Events	6 (66.7%)	4 (57.1%)	
Disease Progression (PD)	5 (55.6%)	4 (57.1%)	
Death	1 (11.1%)	0	
Number (%) of Participants Censored	3 (33.3%)	3 (42.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	8.31 (1.51, NR)	14.09 (4.21, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.023 (0.551, 7.430)		
p-value (Log-Rank Test, Unstratified)	0.2802		
Menopausal status			
Pre-menopausal	29	35	0.9463
Number (%) of Participants with Events	19 (65.5%)	25 (71.4%)	
Disease Progression (PD)	17 (58.6%)	24 (68.6%)	
Death	2 (6.9%)	1 (2.9%)	
Number (%) of Participants Censored	10 (34.5%)	10 (28.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.14 (4.27, 12.45)	6.74 (4.40, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.916 (0.504, 1.666)		
p-value (Log-Rank Test, Unstratified)	0.7813		
Post-menopausal	96	88	
Number (%) of Participants with Events	68 (70.8%)	58 (65.9%)	
Disease Progression (PD)	59 (61.5%)	56 (63.6%)	
Death	9 (9.4%)	2 (2.3%)	
Number (%) of Participants Censored	28 (29.2%)	30 (34.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.54 (7.00, 10.32)	8.28 (5.65, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.830 (0.582, 1.183)		
p-value (Log-Rank Test, Unstratified)	0.3014		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Intent-to-treat (ITT) Analysis Set includes all participants who were randomised in the study.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS (months) = (date of events or censoring − date of randomisation + 1) / 30.4375. 95% CI based on log-log transformation. Median PFS from Kaplan-Meier estimate.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=125)	TPC (N=124)	Interaction

The two-sided p-value is from Unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5.7. Table 1.1.7: Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events	94 (75.2%)	100 (80.6%)
Disease Progression (PD)	50 (40.0%)	74 (59.7%)
Death	44 (35.2%)	26 (21.0%)
Number (%) of Participants Censored	31 (24.8%)	24 (19.4%)
Alive Without PFS2 Event and Without Second Next-Line Therapy	6 (4.8%)	6 (4.8%)
Alive Without PFS2 Event and With Second Next-Line Therapy	5 (4.0%)	3 (2.4%)
Discontinued Study	0	0
No Baseline or Postbaseline Evaluable Assessment	0	0
Kaplan-Meier Estimate of PFS2 (Months) (95% CI) [a]		
Q1	9.20 (6.24, 10.68)	9.03 (6.54, 10.38)
Median	14.82 (12.68, 16.66)	13.70 (11.30, 15.64)
Q3	26.51 (22.87, 34.14)	20.67 (18.99, 25.17)
Absolute Difference in Median PFS2, SG vs TPC (Months)	1.12	
Kaplan-Meier Estimate of PFS2 Rate (95% CI) [b]		
At 3 Months	0.952 (0.896, 0.978)	0.967 (0.915, 0.988)
At 6 Months	0.832 (0.754, 0.887)	0.861 (0.785, 0.911)
At 9 Months	0.750 (0.664, 0.817)	0.754 (0.667, 0.821)

Parameter	SG (N=125)	TPC (N=124)
At 12 Months	0.602 (0.510, 0.682)	0.559 (0.466, 0.643)
At 18 Months	0.410 (0.322, 0.496)	0.348 (0.263, 0.433)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [c]	0.1447	
Stratified Hazard Ratio of SG vs TPC (95% CI) [d]	0.805 (0.602, 1.076)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first. Next line therapy is defined as the first new systemic anti-cancer therapy (including crossover treatment) initiated after discontinuation of study treatment regardless of end of treatment reason.
[a] Quantile of PFS2 is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.8. Table 1.1.8: Subgroup Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.3225
Number (%) of Participants with Events	27 (93.1%)	24 (92.3%)	
Disease Progression (PD)	23 (79.3%)	23 (88.5%)	
Death	4 (13.8%)	1 (3.8%)	
Number (%) of Participants Censored	2 (6.9%)	2 (7.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (2.92, 12.45)	5.70 (4.21, 8.25)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.788 (0.447, 1.391)		
p-value (Log-Rank Test, Unstratified)	0.4102		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events	27 (87.1%)	27 (87.1%)	
Disease Progression (PD)	26 (83.9%)	27 (87.1%)	
Death	1 (3.2%)	0	
Number (%) of Participants Censored	4 (12.9%)	4 (12.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.37, 9.82)	5.63 (4.40, 7.13)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.581 (0.334, 1.011)		
p-value (Log-Rank Test, Unstratified)	0.0524		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events	60 (92.3%)	60 (89.6%)	
Disease Progression (PD)	54 (83.1%)	58 (86.6%)	
Death	6 (9.2%)	2 (3.0%)	
Number (%) of Participants Censored	5 (7.7%)	7 (10.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.90 (4.07, 8.77)	6.06 (4.34, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.006 (0.701, 1.445)		
p-value (Log-Rank Test, Unstratified)	0.9752		
Geographic region			
US/Canada/Western Europe	30	35	0.4783
Number (%) of Participants with Events	28 (93.3%)	31 (88.6%)	
Disease Progression (PD)	27 (90.0%)	31 (88.6%)	
Death	1 (3.3%)	0	
Number (%) of Participants Censored	2 (6.7%)	4 (11.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	8.11 (5.36, 9.92)	5.62 (3.02, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.695 (0.412, 1.170)		
p-value (Log-Rank Test, Unstratified)	0.1695		
Rest of the world	95	89	
Number (%) of Participants with Events	86 (90.5%)	80 (89.9%)	
Disease Progression (PD)	76 (80.0%)	77 (86.5%)	
Death	10 (10.5%)	3 (3.4%)	
Number (%) of Participants Censored	9 (9.5%)	9 (10.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.30, 8.31)	6.01 (5.32, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.899 (0.661, 1.223)		
p-value (Log-Rank Test, Unstratified)	0.4970		
Age group			
< 65	98	96	0.0835
Number (%) of Participants with Events	88 (89.8%)	85 (88.5%)	
Disease Progression (PD)	81 (82.7%)	83 (86.5%)	
Death	7 (7.1%)	2 (2.1%)	
Number (%) of Participants Censored	10 (10.2%)	11 (11.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.06 (5.36, 8.77)	5.62 (4.40, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.758 (0.561, 1.025)		
p-value (Log-Rank Test, Unstratified)	0.0702		
>= 65	27	28	
Number (%) of Participants with Events	26 (96.3%)	26 (92.9%)	

	SG (N=125)	TPC (N=124)	Interaction
Disease Progression (PD)	22 (81.5%)	25 (89.3%)	
Death	4 (14.8%)	1 (3.6%)	
Number (%) of Participants Censored	1 (3.7%)	2 (7.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	3.15 (1.91, 7.92)	6.41 (4.53, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.272 (0.730, 2.218)		
p-value (Log-Rank Test, Unstratified)	0.3918		
Race			
White	81	77	0.8247
Number (%) of Participants with Events	76 (93.8%)	67 (87.0%)	
Disease Progression (PD)	70 (86.4%)	65 (84.4%)	
Death	6 (7.4%)	2 (2.6%)	
Number (%) of Participants Censored	5 (6.2%)	10 (13.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.30, 8.31)	5.62 (4.34, 6.87)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.635, 1.232)		
p-value (Log-Rank Test, Unstratified)	0.4678		
Asian	26	26	
Number (%) of Participants with Events	22 (84.6%)	25 (96.2%)	
Disease Progression (PD)	19 (73.1%)	25 (96.2%)	
Death	3 (11.5%)	0	
Number (%) of Participants Censored	4 (15.4%)	1 (3.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.95 (1.91, 12.85)	6.16 (4.14, 8.31)	

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.718 (0.402, 1.284)		
p-value (Log-Rank Test, Unstratified)	0.2621		
Other	16	21	
Number (%) of Participants with Events	14 (87.5%)	19 (90.5%)	
Disease Progression (PD)	13 (81.2%)	18 (85.7%)	
Death	1 (6.2%)	1 (4.8%)	
Number (%) of Participants Censored	2 (12.5%)	2 (9.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.36 (2.33, 17.81)	6.34 (4.40, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.791 (0.391, 1.601)		
p-value (Log-Rank Test, Unstratified)	0.5195		
Baseline ECOG status			
0	81	80	0.4724
Number (%) of Participants with Events	73 (90.1%)	71 (88.8%)	
Disease Progression (PD)	68 (84.0%)	69 (86.2%)	
Death	5 (6.2%)	2 (2.5%)	
Number (%) of Participants Censored	8 (9.9%)	9 (11.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (5.32, 9.82)	6.93 (5.49, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.867 (0.624, 1.206)		
p-value (Log-Rank Test, Unstratified)	0.3981		
1	44	44	
Number (%) of Participants with Events	41 (93.2%)	40 (90.9%)	
Disease Progression (PD)	35 (79.5%)	39 (88.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Death	6 (13.6%)	1 (2.3%)	
Number (%) of Participants Censored	3 (6.8%)	4 (9.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.47 (3.12, 7.13)	4.53 (4.14, 5.65)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.770 (0.494, 1.203)		
p-value (Log-Rank Test, Unstratified)	0.2498		
History of liver metastasis			
Yes	36	26	0.0887
Number (%) of Participants with Events	33 (91.7%)	23 (88.5%)	
Disease Progression (PD)	30 (83.3%)	21 (80.8%)	
Death	3 (8.3%)	2 (7.7%)	
Number (%) of Participants Censored	3 (8.3%)	3 (11.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.83 (2.89, 8.31)	4.14 (1.87, 4.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.599 (0.345, 1.040)		
p-value (Log-Rank Test, Unstratified)	0.0663		
No	89	98	
Number (%) of Participants with Events	81 (91.0%)	88 (89.8%)	
Disease Progression (PD)	73 (82.0%)	87 (88.8%)	
Death	8 (9.0%)	1 (1.0%)	
Number (%) of Participants Censored	8 (9.0%)	10 (10.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (5.36, 9.26)	6.80 (5.62, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.649, 1.194)		

	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.4133		
History of brain metastasis			
Yes	6	7	0.6954
Number (%) of Participants with Events	6 (100.0%)	7 (100.0%)	
Disease Progression (PD)	5 (83.3%)	7 (100.0%)	
Death	1 (16.7%)	0	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.72 (0.85, NR)	5.78 (0.30, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.329 (0.423, 4.176)		
p-value (Log-Rank Test, Unstratified)	0.6257		
No	119	117	
Number (%) of Participants with Events	108 (90.8%)	104 (88.9%)	
Disease Progression (PD)	98 (82.4%)	101 (86.3%)	
Death	10 (8.4%)	3 (2.6%)	
Number (%) of Participants Censored	11 (9.2%)	13 (11.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.90 (5.22, 8.48)	5.65 (5.32, 6.90)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.847 (0.645, 1.111)		
p-value (Log-Rank Test, Unstratified)	0.2300		
PD-L1 Status			
CPS < 1	44	52	0.7629
Number (%) of Participants with Events	41 (93.2%)	45 (86.5%)	
Disease Progression (PD)	36 (81.8%)	44 (84.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Death	5 (11.4%)	1 (1.9%)	
Number (%) of Participants Censored	3 (6.8%)	7 (13.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.08 (4.44, 9.72)	5.49 (4.17, 7.06)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.917 (0.598, 1.404)		
p-value (Log-Rank Test, Unstratified)	0.6857		
CPS ≥ 1	81	72	
Number (%) of Participants with Events	73 (90.1%)	66 (91.7%)	
Disease Progression (PD)	67 (82.7%)	64 (88.9%)	
Death	6 (7.4%)	2 (2.8%)	
Number (%) of Participants Censored	8 (9.9%)	6 (8.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.59 (4.30, 8.74)	6.34 (5.39, 7.20)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.828 (0.590, 1.160)		
p-value (Log-Rank Test, Unstratified)	0.2717		
BRCA 1/2 status			
Wild-Type	42	46	0.1130
Number (%) of Participants with Events	39 (92.9%)	42 (91.3%)	
Disease Progression (PD)	35 (83.3%)	41 (89.1%)	
Death	4 (9.5%)	1 (2.2%)	
Number (%) of Participants Censored	3 (7.1%)	4 (8.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.34 (4.01, 7.13)	5.40 (3.09, 6.70)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.866 (0.559, 1.342)		

	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.5156		
Mutant	9	7	
Number (%) of Participants with Events	9 (100.0%)	5 (71.4%)	
Disease Progression (PD)	8 (88.9%)	5 (71.4%)	
Death	1 (11.1%)	0	
Number (%) of Participants Censored	0	2 (28.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.26 (1.51, 9.30)	11.55 (4.21, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.164 (0.709, 6.603)		
p-value (Log-Rank Test, Unstratified)	0.1658		
Menopausal status			
Pre-menopausal	29	35	0.4839
Number (%) of Participants with Events	26 (89.7%)	31 (88.6%)	
Disease Progression (PD)	24 (82.8%)	30 (85.7%)	
Death	2 (6.9%)	1 (2.9%)	
Number (%) of Participants Censored	3 (10.3%)	4 (11.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.52 (2.92, 7.23)	5.45 (4.14, 7.06)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.964 (0.571, 1.626)		
p-value (Log-Rank Test, Unstratified)	0.8977		
Post-menopausal	96	88	
Number (%) of Participants with Events	88 (91.7%)	79 (89.8%)	
Disease Progression (PD)	79 (82.3%)	77 (87.5%)	
Death	9 (9.4%)	2 (2.3%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	8 (8.3%)	9 (10.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.15 (4.44, 9.26)	6.01 (5.32, 8.08)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.798 (0.587, 1.085)		
p-value (Log-Rank Test, Unstratified)	0.1481		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from an unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5.9. Table 1.1.9: Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events	105 (84.0%)	109 (87.9%)
First Subsequent Therapy	77 (61.6%)	92 (74.2%)
Death	28 (22.4%)	17 (13.7%)
Number (%) of Participants Censored	20 (16.0%)	15 (12.1%)
Kaplan-Meier Estimate of TFST (Months) (95% CI) [a]		
Q1	4.80 (3.58, 6.05)	4.99 (4.01, 6.05)
Median	9.69 (7.43, 11.40)	7.79 (6.54, 9.30)
Q3	19.19 (14.92, 21.65)	13.37 (10.84, 16.62)
Absolute Difference in Median TFST, SG vs TPC (Months)	1.91	
Kaplan-Meier Estimate of TFST Rate (95% CI) [b]		

Parameter	SG (N=125)	TPC (N=124)
At 3 Months	0.880 (0.809, 0.926)	0.902 (0.835, 0.943)
At 6 Months	0.679 (0.590, 0.753)	0.691 (0.601, 0.765)
At 9 Months	0.534 (0.442, 0.617)	0.446 (0.357, 0.531)
At 12 Months	0.388 (0.303, 0.473)	0.306 (0.226, 0.388)
At 18 Months	0.283 (0.207, 0.364)	0.173 (0.112, 0.246)
At 24 Months	0.167 (0.107, 0.238)	0.129 (0.076, 0.196)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.0464	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.807 (0.616, 1.057)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomization to the start date of the first subsequent anti-cancer therapy after discontinuation of randomized treatment, or death due to any cause.
[a] Quantile of TFST is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] TFST rate is the proportion of participants alive without any subsequent therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d]Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.10. Table 1.1.10: Subgroup Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.5531
Number (%) of Participants with Events	24 (82.8%)	25 (96.2%)	
First Subsequent Therapy	16 (55.2%)	19 (73.1%)	
Death	8 (27.6%)	6 (23.1%)	
Number (%) of Participants Censored	5 (17.2%)	1 (3.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	10.32 (5.82, 17.97)	7.11 (4.99, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.649 (0.367, 1.146)		
p-value (Log-Rank Test, Unstratified)	0.1341		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events	27 (87.1%)	27 (87.1%)	
First Subsequent Therapy	21 (67.7%)	23 (74.2%)	
Death	6 (19.4%)	4 (12.9%)	
Number (%) of Participants Censored	4 (12.9%)	4 (12.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.33 (6.74, 12.94)	7.24 (6.11, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.671 (0.392, 1.150)		
p-value (Log-Rank Test, Unstratified)	0.1416		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events	54 (83.1%)	57 (85.1%)	
First Subsequent Therapy	40 (61.5%)	50 (74.6%)	
Death	14 (21.5%)	7 (10.4%)	
Number (%) of Participants Censored	11 (16.9%)	10 (14.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.97 (6.05, 11.96)	8.48 (6.24, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.946 (0.651, 1.374)		
p-value (Log-Rank Test, Unstratified)	0.7704		
Geographic region			
US/Canada/Western Europe	30	35	0.3027
Number (%) of Participants with Events	28 (93.3%)	34 (97.1%)	

	SG (N=125)	TPC (N=124)	Interaction
First Subsequent Therapy	23 (76.7%)	30 (85.7%)	
Death	5 (16.7%)	4 (11.4%)	
Number (%) of Participants Censored	2 (6.7%)	1 (2.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.46 (6.74, 12.94)	6.24 (5.36, 8.21)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.637 (0.384, 1.056)		
p-value (Log-Rank Test, Unstratified)	0.0776		
Rest of the world	95	89	
Number (%) of Participants with Events	77 (81.1%)	75 (84.3%)	
First Subsequent Therapy	54 (56.8%)	62 (69.7%)	
Death	23 (24.2%)	13 (14.6%)	
Number (%) of Participants Censored	18 (18.9%)	14 (15.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.76 (7.26, 12.68)	8.48 (6.74, 10.84)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.891 (0.648, 1.227)		
p-value (Log-Rank Test, Unstratified)	0.4797		
Age group			
< 65	98	96	0.3338
Number (%) of Participants with Events	81 (82.7%)	82 (85.4%)	
First Subsequent Therapy	62 (63.3%)	72 (75.0%)	
Death	19 (19.4%)	10 (10.4%)	
Number (%) of Participants Censored	17 (17.3%)	14 (14.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.32 (8.57, 12.75)	7.39 (6.21, 9.92)	

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.773 (0.568, 1.052)		
p-value (Log-Rank Test, Unstratified)	0.1011		
>= 65	27	28	
Number (%) of Participants with Events	24 (88.9%)	27 (96.4%)	
First Subsequent Therapy	15 (55.6%)	20 (71.4%)	
Death	9 (33.3%)	7 (25.0%)	
Number (%) of Participants Censored	3 (11.1%)	1 (3.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	4.73 (3.15, 10.91)	8.33 (6.47, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.053 (0.604, 1.835)		
p-value (Log-Rank Test, Unstratified)	0.8537		
Race			
White	81	77	0.5716
Number (%) of Participants with Events	72 (88.9%)	68 (88.3%)	
First Subsequent Therapy	53 (65.4%)	56 (72.7%)	
Death	19 (23.5%)	12 (15.6%)	
Number (%) of Participants Censored	9 (11.1%)	9 (11.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.23 (6.77, 11.24)	7.62 (6.01, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.901 (0.646, 1.256)		
p-value (Log-Rank Test, Unstratified)	0.5393		
Asian	26	26	
Number (%) of Participants with Events	19 (73.1%)	23 (88.5%)	
First Subsequent Therapy	16 (61.5%)	23 (88.5%)	

	SG (N=125)	TPC (N=124)	Interaction
Death	3 (11.5%)	0	
Number (%) of Participants Censored	7 (26.9%)	3 (11.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.86 (4.11, 18.46)	8.13 (6.14, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.695 (0.374, 1.292)		
p-value (Log-Rank Test, Unstratified)	0.2508		
Other	16	21	
Number (%) of Participants with Events	12 (75.0%)	18 (85.7%)	
First Subsequent Therapy	7 (43.8%)	13 (61.9%)	
Death	5 (31.2%)	5 (23.8%)	
Number (%) of Participants Censored	4 (25.0%)	3 (14.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.52 (7.26, 19.15)	10.18 (6.47, 12.22)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.549 (0.259, 1.167)		
p-value (Log-Rank Test, Unstratified)	0.1145		
Baseline ECOG status			
0	81	80	0.6252
Number (%) of Participants with Events	67 (82.7%)	68 (85.0%)	
First Subsequent Therapy	54 (66.7%)	61 (76.2%)	
Death	13 (16.0%)	7 (8.8%)	
Number (%) of Participants Censored	14 (17.3%)	12 (15.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.47 (8.97, 14.52)	9.36 (7.39, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.840 (0.599, 1.178)		

	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.3117		
1	44	44	
Number (%) of Participants with Events	38 (86.4%)	41 (93.2%)	
First Subsequent Therapy	23 (52.3%)	31 (70.5%)	
Death	15 (34.1%)	10 (22.7%)	
Number (%) of Participants Censored	6 (13.6%)	3 (6.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.26 (4.30, 9.33)	6.23 (5.29, 7.79)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.797 (0.510, 1.246)		
p-value (Log-Rank Test, Unstratified)	0.3185		
Physician's choice of chemotherapy			
Gemcitabine/Carboplatin	125	124	NE
Number (%) of Participants with Events	105 (84.0%)	109 (87.9%)	
First Subsequent Therapy	77 (61.6%)	92 (74.2%)	
Death	28 (22.4%)	17 (13.7%)	
Number (%) of Participants Censored	20 (16.0%)	15 (12.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.69 (7.43, 11.40)	7.79 (6.54, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.627, 1.074)		
p-value (Log-Rank Test, Unstratified)	0.1494		
History of liver metastasis			
Yes	36	26	0.1579
Number (%) of Participants with Events	32 (88.9%)	25 (96.2%)	
First Subsequent Therapy	22 (61.1%)	19 (73.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Death	10 (27.8%)	6 (23.1%)	
Number (%) of Participants Censored	4 (11.1%)	1 (3.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.44 (4.73, 9.76)	4.99 (3.91, 6.01)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.605 (0.354, 1.034)		
p-value (Log-Rank Test, Unstratified)	0.0638		
No	89	98	
Number (%) of Participants with Events	73 (82.0%)	84 (85.7%)	
First Subsequent Therapy	55 (61.8%)	73 (74.5%)	
Death	18 (20.2%)	11 (11.2%)	
Number (%) of Participants Censored	16 (18.0%)	14 (14.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.74 (7.26, 12.94)	9.03 (7.39, 10.55)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.843 (0.615, 1.156)		
p-value (Log-Rank Test, Unstratified)	0.2874		
History of brain metastasis			
Yes	6	7	0.4697
Number (%) of Participants with Events	6 (100.0%)	7 (100.0%)	
First Subsequent Therapy	5 (83.3%)	5 (71.4%)	
Death	1 (16.7%)	2 (28.6%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	6.85 (0.85, NR)	8.38 (2.66, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.562 (0.498, 4.896)		

	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.4404		
No	119	117	
Number (%) of Participants with Events	99 (83.2%)	102 (87.2%)	
First Subsequent Therapy	72 (60.5%)	87 (74.4%)	
Death	27 (22.7%)	15 (12.8%)	
Number (%) of Participants Censored	20 (16.8%)	15 (12.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.15 (7.56, 11.99)	7.66 (6.47, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.815 (0.617, 1.076)		
p-value (Log-Rank Test, Unstratified)	0.1480		
PD-L1 Status			
CPS < 1	44	52	0.7470
Number (%) of Participants with Events	38 (86.4%)	47 (90.4%)	
First Subsequent Therapy	29 (65.9%)	39 (75.0%)	
Death	9 (20.5%)	8 (15.4%)	
Number (%) of Participants Censored	6 (13.6%)	5 (9.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.49 (6.24, 12.75)	6.93 (5.36, 8.48)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.790 (0.514, 1.214)		
p-value (Log-Rank Test, Unstratified)	0.2797		
CPS ≥ 1	81	72	
Number (%) of Participants with Events	67 (82.7%)	62 (86.1%)	
First Subsequent Therapy	48 (59.3%)	53 (73.6%)	
Death	19 (23.5%)	9 (12.5%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	14 (17.3%)	10 (13.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.76 (6.77, 12.68)	9.03 (6.60, 10.68)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.599, 1.201)		
p-value (Log-Rank Test, Unstratified)	0.3523		
BRCA 1/2 status			
Wild-Type	42	46	0.0720
Number (%) of Participants with Events	39 (92.9%)	43 (93.5%)	
First Subsequent Therapy	29 (69.0%)	36 (78.3%)	
Death	10 (23.8%)	7 (15.2%)	
Number (%) of Participants Censored	3 (7.1%)	3 (6.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.69 (5.82, 11.99)	6.23 (4.99, 7.85)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.758 (0.490, 1.173)		
p-value (Log-Rank Test, Unstratified)	0.2144		
Mutant	9	7	
Number (%) of Participants with Events	8 (88.9%)	5 (71.4%)	
First Subsequent Therapy	6 (66.7%)	4 (57.1%)	
Death	2 (22.2%)	1 (14.3%)	
Number (%) of Participants Censored	1 (11.1%)	2 (28.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.08 (3.15, 16.39)	16.33 (4.99, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.271 (0.731, 7.056)		
p-value (Log-Rank Test, Unstratified)	0.1458		

	SG (N=125)	TPC (N=124)	Interaction
Menopausal status			
Pre-menopausal	29	35	0.3488
Number (%) of Participants with Events	24 (82.8%)	29 (82.9%)	
First Subsequent Therapy	21 (72.4%)	27 (77.1%)	
Death	3 (10.3%)	2 (5.7%)	
Number (%) of Participants Censored	5 (17.2%)	6 (17.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.03 (4.44, 12.68)	7.39 (6.24, 9.92)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.006 (0.585, 1.731)		
p-value (Log-Rank Test, Unstratified)	0.9752		
Post-menopausal	96	88	
Number (%) of Participants with Events	81 (84.4%)	79 (89.8%)	
First Subsequent Therapy	56 (58.3%)	64 (72.7%)	
Death	25 (26.0%)	15 (17.0%)	
Number (%) of Participants Censored	15 (15.6%)	9 (10.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.25 (8.31, 11.99)	7.85 (6.11, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.553, 1.031)		
p-value (Log-Rank Test, Unstratified)	0.0759		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomisation to the start date of the first subsequent anti-cancer therapy after discontinuation of randomised treatment, or death due to any cause.
TFST rate is the proportion of participants alive without any subsequent therapy.
Hazard ratio and 95% CIs calculated using unstratified Cox proportional hazards model. Efron method used to handle ties. Reference arm = TPC.
Log-rank p-value is from an unstratified log-rank test.
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Data Cut Date: 22 APR 2026.

6. Safety - mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

6.1. Table 1.1.1: Summary of Treatment Exposure - Treatment Duration (months) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	Gemcitabine (N=122)	Carboplatin (N=122)	Gem/Carbo (N=122)	Any TPC (N=122)
Total Duration of Exposure to Study Drug					
Duration (months)					
N	124	122	122	122	122
Mean (StD)	10.03 (8.661)	8.15 (7.306)	7.23 (6.016)	7.15 (5.986)	7.15 (5.986)
Median	7.05	6.09	5.77	5.77	5.77
Q1, Q3	3.69, 15.27	3.76, 9.68	3.50, 9.49	3.50, 9.20	3.50, 9.20
Min, Max	0.20, 40.74	0.03, 33.84	0.03, 31.28	0.03, 31.28	0.03, 31.28
Cumulative Number (%) of Participants					
Exposed to Study Drug					
>= 3 months, n, (%)	98 (79.0%)	95 (77.9%)	95 (77.9%)	95 (77.9%)	95 (77.9%)
>= 6 months, n, (%)	70 (56.5%)	62 (50.8%)	58 (47.5%)	58 (47.5%)	58 (47.5%)
>= 12 months, n, (%)	37 (29.8%)	24 (19.7%)	18 (14.8%)	17 (13.9%)	17 (13.9%)
>= 24 months, n, (%)	11 (8.9%)	8 (6.6%)	5 (4.1%)	5 (4.1%)	5 (4.1%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, Gem = gemcitabine, Carbo = carboplatin.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug. Taxane includes participants who have received Paclitaxel. TPC column includes participants who have received any of Gem, Carbo or Paclitaxel.
Duration of exposure to study drug (months) = (last dosing date − first dosing date + 1)/30.4375.
Data Cut Date: 22 APR 2026.

6.2. Table 1.1.2: Observation Period (Months) for Safety — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Total (N=246)
Observation Period (months) for Safety [a]			
N	124	122	246
Mean (StD)	10.90 (8.512)	9.19 (7.238)	10.05 (7.936)
Median	8.03	7.21	7.46
Q1, Q3	4.67, 16.25	4.75, 10.92	4.70, 13.12
Min, Max	0.46, 40.77	1.02, 33.84	0.46, 40.77

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
[a] Observation period is defined as the time from first dose until Data cutoff date, study treatment discontinuation +30 days for any AE and any serious AE, or death, whichever comes first and stops the collection of endpoint data.
Data Cut Date: 22 APR 2026.

6.3. Table 1.1.3: Analysis of Time to First Treatment-Emergent Adverse Event (TEAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	124 (100.0%)	121 (99.2%)
Patients (%) Without Events (Censored)	0 (0.0%)	1 (0.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.11 (0.10, 0.20)	0.20 (0.10, 0.23)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.244 (0.965, 1.604)
p-value		0.0771

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.

	SG (N=124)	TPC (N=122)

Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.4. Table 1.1.4: Subgroup Analysis of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8681
De novo			
Total Patients	29	26	
Patients (%) With Events	29 (100.0%)	26 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.15 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.287 (0.747, 2.216)	
p-value		0.3427	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	31 (100.0%)	30 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.26)	0.21 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.124 (0.673, 1.876)	
p-value		0.6618	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	64 (100.0%)	65 (98.5%)	
Patients (%) Without Events (Censored)	0	1 (1.5%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.335 (0.938, 1.900)	
p-value		0.0931	
Geographic region			0.8760
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	30 (100.0%)	34 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.08 (0.03, 0.16)	0.20 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.453 (0.881, 2.396)	
p-value		0.1614	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	94 (100.0%)	87 (98.9%)	
Patients (%) Without Events (Censored)	0	1 (1.1%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.285 (0.950, 1.738)	
p-value		0.0890	
Age group			0.6162
< 65			
Total Patients	98	94	
Patients (%) With Events	98 (100.0%)	93 (98.9%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	0	1 (1.1%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.16)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.279 (0.959, 1.706)	
p-value		0.0849	
>= 65			
Total Patients	26	28	
Patients (%) With Events	26 (100.0%)	28 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.18 (0.07, 0.26)	0.15 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.106 (0.639, 1.913)	
p-value		0.6673	
Race			0.9294
White			
Total Patients	80	75	
Patients (%) With Events	80 (100.0%)	74 (98.7%)	
Patients (%) Without Events (Censored)	0	1 (1.3%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.23 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.203 (0.875, 1.654)	
p-value		0.2223	
Asian			
Total Patients	26	26	
Patients (%) With Events	26 (100.0%)	26 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.26)	0.08 (0.07, 0.23)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.239 (0.692, 2.216)	
p-value		0.5134	
Other			
Total Patients	16	21	
Patients (%) With Events	16 (100.0%)	21 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.03, 0.26)	0.13 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.197 (0.609, 2.354)	
p-value		0.5819	
Baseline ECOG status			0.3260
0			
Total Patients	81	79	
Patients (%) With Events	81 (100.0%)	79 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.16)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.346 (0.980, 1.849)	
p-value		0.0612	
1			
Total Patients	43	43	
Patients (%) With Events	43 (100.0%)	42 (97.7%)	
Patients (%) Without Events (Censored)	0	1 (2.3%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.26)	0.23 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.070 (0.697, 1.643)	
p-value		0.7049	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of liver metastasis			0.7864
Yes			
Total Patients	36	25	
Patients (%) With Events	36 (100.0%)	24 (96.0%)	
Patients (%) Without Events (Censored)	0	1 (4.0%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.10 (0.03, 0.26)	
Hazard Ratio (95% CI)		1.130 (0.671, 1.903)	
p-value		0.5845	
No			
Total Patients	88	97	
Patients (%) With Events	88 (100.0%)	97 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.243 (0.927, 1.666)	
p-value		0.1271	
History of brain metastasis			0.2536
Yes			
Total Patients	6	7	
Patients (%) With Events	6 (100.0%)	7 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.03, NR)	0.20 (0.10, 1.64)	
Hazard Ratio (95% CI)		2.107 (0.639, 6.949)	
p-value		0.2119	
No			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	118	115	
Patients (%) With Events	118 (100.0%)	114 (99.1%)	
Patients (%) Without Events (Censored)	0	1 (0.9%)	
Median Time to First TEAE, months (95% CI)	0.11 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.197 (0.923, 1.553)	
p-value		0.1488	
PD-L1 Status			0.8052
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	43 (100.0%)	51 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.13)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.330 (0.874, 2.023)	
p-value		0.1542	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	81 (100.0%)	70 (98.6%)	
Patients (%) Without Events (Censored)	0	1 (1.4%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.23)	0.20 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.236 (0.894, 1.709)	
p-value		0.1952	
BRCA 1/2 status			0.4905
Wild-Type			
Total Patients	42	45	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	42 (100.0%)	44 (97.8%)	
Patients (%) Without Events (Censored)	0	1 (2.2%)	
Median Time to First TEAE, months (95% CI)	0.11 (0.10, 0.26)	0.26 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.176 (0.768, 1.803)	
p-value		0.4078	
Mutant			
Total Patients	9	7	
Patients (%) With Events	9 (100.0%)	7 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.03, NR)	0.10 (0.03, 0.33)	
Hazard Ratio (95% CI)		1.991 (0.651, 6.090)	
p-value		0.2488	
Menopausal status			0.0940
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	29 (100.0%)	34 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.07, 0.16)	0.16 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.798 (1.047, 3.085)	
p-value		0.0291	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	95 (100.0%)	86 (98.9%)	
Patients (%) Without Events (Censored)	0	1 (1.1%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.123 (0.837, 1.506)	
p-value		0.3939	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.5. Table 1.1.5: Analysis of Time to First Serious Treatment-Emergent Adverse Event (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	40 (32.3%)	45 (36.9%)
Patients (%) Without Events (Censored)	84 (67.7%)	77 (63.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (18.66, NR)	18.92 (9.10, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.792 (0.515, 1.217)
p-value		0.2824

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.

	SG (N=124)	TPC (N=122)

Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.6. Table 1.1.6: Subgroup Analysis of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.9151
De novo			
Total Patients	29	26	
Patients (%) With Events	12 (41.4%)	11 (42.3%)	
Patients (%) Without Events (Censored)	17 (58.6%)	15 (57.7%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (3.12, NR)	12.22 (3.06, NR)	
Hazard Ratio (95% CI)		0.802 (0.345, 1.867)	
p-value		0.6057	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	8 (25.8%)	7 (23.3%)	
Patients (%) Without Events (Censored)	23 (74.2%)	23 (76.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.10, NR)	29.01 (NR, NR)	
Hazard Ratio (95% CI)		0.966 (0.346, 2.696)	
p-value		0.9510	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	20 (31.2%)	27 (40.9%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	44 (68.8%)	39 (59.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.40, NR)	9.76 (5.62, NR)	
Hazard Ratio (95% CI)		0.719 (0.402, 1.288)	
p-value		0.2632	
Geographic region			0.7103
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	10 (33.3%)	11 (32.4%)	
Patients (%) Without Events (Censored)	20 (66.7%)	23 (67.6%)	
Median Time to First Serious TEAE, months (95% CI)	NR (5.55, NR)	12.22 (5.32, NR)	
Hazard Ratio (95% CI)		0.936 (0.394, 2.223)	
p-value		0.8772	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	30 (31.9%)	34 (38.6%)	
Patients (%) Without Events (Censored)	64 (68.1%)	54 (61.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	18.92 (6.90, NR)	
Hazard Ratio (95% CI)		0.756 (0.460, 1.241)	
p-value		0.2653	
Age group			0.0820
< 65			
Total Patients	98	94	
Patients (%) With Events	30 (30.6%)	37 (39.4%)	
Patients (%) Without Events (Censored)	68 (69.4%)	57 (60.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	29.01 (6.47, NR)	
Hazard Ratio (95% CI)		0.655 (0.403, 1.066)	
p-value		0.0858	
>= 65			
Total Patients	26	28	
Patients (%) With Events	10 (38.5%)	8 (28.6%)	
Patients (%) Without Events (Censored)	16 (61.5%)	20 (71.4%)	
Median Time to First Serious TEAE, months (95% CI)	11.40 (1.38, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		1.643 (0.640, 4.215)	
p-value		0.2986	
Race			0.3487
White			
Total Patients	80	75	
Patients (%) With Events	22 (27.5%)	28 (37.3%)	
Patients (%) Without Events (Censored)	58 (72.5%)	47 (62.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.40, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.691 (0.392, 1.219)	
p-value		0.1970	
Asian			
Total Patients	26	26	
Patients (%) With Events	8 (30.8%)	10 (38.5%)	
Patients (%) Without Events (Censored)	18 (69.2%)	16 (61.5%)	
Median Time to First Serious TEAE, months (95% CI)	NR (8.05, NR)	NR (4.63, NR)	
Hazard Ratio (95% CI)		0.715 (0.278, 1.841)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.4847	
Other			
Total Patients	16	21	
Patients (%) With Events	9 (56.2%)	7 (33.3%)	
Patients (%) Without Events (Censored)	7 (43.8%)	14 (66.7%)	
Median Time to First Serious TEAE, months (95% CI)	12.11 (0.66, NR)	29.01 (5.62, NR)	
Hazard Ratio (95% CI)		1.673 (0.610, 4.588)	
p-value		0.3127	
Baseline ECOG status			0.0904
0			
Total Patients	81	79	
Patients (%) With Events	20 (24.7%)	30 (38.0%)	
Patients (%) Without Events (Censored)	61 (75.3%)	49 (62.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (6.90, NR)	
Hazard Ratio (95% CI)		0.581 (0.328, 1.028)	
p-value		0.0587	
1			
Total Patients	43	43	
Patients (%) With Events	20 (46.5%)	15 (34.9%)	
Patients (%) Without Events (Censored)	23 (53.5%)	28 (65.1%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (2.50, NR)	12.22 (4.63, NR)	
Hazard Ratio (95% CI)		1.326 (0.673, 2.613)	
p-value		0.4168	
History of liver metastasis			0.6214

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Yes			
Total Patients	36	25	
Patients (%) With Events	15 (41.7%)	9 (36.0%)	
Patients (%) Without Events (Censored)	21 (58.3%)	16 (64.0%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (3.81, NR)	12.22 (3.06, NR)	
Hazard Ratio (95% CI)		0.895 (0.379, 2.118)	
p-value		0.7811	
No			
Total Patients	88	97	
Patients (%) With Events	25 (28.4%)	36 (37.1%)	
Patients (%) Without Events (Censored)	63 (71.6%)	61 (62.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.708 (0.424, 1.184)	
p-value		0.1858	
History of brain metastasis			0.1834
Yes			
Total Patients	6	7	
Patients (%) With Events	4 (66.7%)	3 (42.9%)	
Patients (%) Without Events (Censored)	2 (33.3%)	4 (57.1%)	
Median Time to First Serious TEAE, months (95% CI)	2.38 (0.26, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		1.718 (0.383, 7.712)	
p-value		0.4745	
No			
Total Patients	118	115	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	36 (30.5%)	42 (36.5%)	
Patients (%) Without Events (Censored)	82 (69.5%)	73 (63.5%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	18.92 (9.10, NR)	
Hazard Ratio (95% CI)		0.738 (0.471, 1.158)	
p-value		0.1827	
PD-L1 Status			0.0980
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	12 (27.9%)	23 (45.1%)	
Patients (%) Without Events (Censored)	31 (72.1%)	28 (54.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.40, NR)	12.22 (4.63, NR)	
Hazard Ratio (95% CI)		0.487 (0.240, 0.990)	
p-value		0.0406	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	28 (34.6%)	22 (31.0%)	
Patients (%) Without Events (Censored)	53 (65.4%)	49 (69.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (13.14, NR)	31.47 (9.10, NR)	
Hazard Ratio (95% CI)		1.102 (0.628, 1.935)	
p-value		0.7379	
BRCA 1/2 status			0.0622
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	11 (26.2%)	12 (26.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	31 (73.8%)	33 (73.3%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (12.22, NR)	
Hazard Ratio (95% CI)		0.856 (0.376, 1.949)	
p-value		0.7108	
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	2 (28.6%)	
Patients (%) Without Events (Censored)	4 (44.4%)	5 (71.4%)	
Median Time to First Serious TEAE, months (95% CI)	1.41 (0.20, NR)	23.97 (18.92, NR)	
Hazard Ratio (95% CI)		5.904 (0.679, 51.367)	
p-value		0.0695	
Menopausal status			0.7481
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	8 (27.6%)	13 (38.2%)	
Patients (%) Without Events (Censored)	21 (72.4%)	21 (61.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (8.05, NR)	9.10 (5.82, NR)	
Hazard Ratio (95% CI)		0.739 (0.300, 1.823)	
p-value		0.5072	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	32 (33.7%)	32 (36.8%)	
Patients (%) Without Events (Censored)	63 (66.3%)	55 (63.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (13.14, NR)	18.92 (9.76, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.816 (0.498, 1.340)	
p-value		0.4188	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
NC = Not Calculable: the hazard ratio and 95% CI are not estimable by the Cox model.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.7. Table 1.1.7: Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	87 (70.2%)	109 (89.3%)
Patients (%) Without Events (Censored)	37 (29.8%)	13 (10.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.51 (0.72, 3.68)	1.18 (0.95, 1.77)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.633 (0.473, 0.847)
p-value		0.0017

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=124)	TPC (N=122)

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.8. Table 1.1.8: Subgroup Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.9725
De novo			
Total Patients	29	26	
Patients (%) With Events	22 (75.9%)	24 (92.3%)	
Patients (%) Without Events (Censored)	7 (24.1%)	2 (7.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.25 (0.43, 2.63)	0.94 (0.72, 2.10)	
Hazard Ratio (95% CI)		0.702 (0.387, 1.273)	
p-value		0.2431	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	22 (71.0%)	28 (93.3%)	
Patients (%) Without Events (Censored)	9 (29.0%)	2 (6.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.69 (0.43, 11.10)	0.95 (0.72, 1.64)	
Hazard Ratio (95% CI)		0.706 (0.397, 1.257)	
p-value		0.2158	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	43 (67.2%)	57 (86.4%)	
Patients (%) Without Events (Censored)	21 (32.8%)	9 (13.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.52 (0.95, 6.28)	1.77 (1.05, 2.50)	
Hazard Ratio (95% CI)		0.576 (0.382, 0.868)	
p-value		0.0074	
Geographic region			0.9473
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	20 (66.7%)	29 (85.3%)	
Patients (%) Without Events (Censored)	10 (33.3%)	5 (14.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.99 (0.46, NR)	1.18 (0.72, 2.10)	
Hazard Ratio (95% CI)		0.694 (0.388, 1.243)	
p-value		0.2055	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	67 (71.3%)	80 (90.9%)	
Patients (%) Without Events (Censored)	27 (28.7%)	8 (9.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.77 (0.69, 4.14)	1.15 (0.95, 2.10)	
Hazard Ratio (95% CI)		0.625 (0.446, 0.875)	
p-value		0.0053	
Age group			0.0295
< 65			
Total Patients	98	94	
Patients (%) With Events	66 (67.3%)	84 (89.4%)	
Patients (%) Without Events (Censored)	32 (32.7%)	10 (10.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.37 (0.95, 4.34)	1.02 (0.92, 1.64)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.554 (0.397, 0.774)	
p-value		0.0004	
>= 65			
Total Patients	26	28	
Patients (%) With Events	21 (80.8%)	25 (89.3%)	
Patients (%) Without Events (Censored)	5 (19.2%)	3 (10.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.66 (0.33, 1.71)	1.56 (0.92, 3.81)	
Hazard Ratio (95% CI)		1.083 (0.597, 1.965)	
p-value		0.8076	
Race			0.2782
White			
Total Patients	80	75	
Patients (%) With Events	50 (62.5%)	66 (88.0%)	
Patients (%) Without Events (Censored)	30 (37.5%)	9 (12.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.37 (0.95, 9.86)	1.18 (0.95, 1.84)	
Hazard Ratio (95% CI)		0.546 (0.374, 0.797)	
p-value		0.0014	
Asian			
Total Patients	26	26	
Patients (%) With Events	20 (76.9%)	22 (84.6%)	
Patients (%) Without Events (Censored)	6 (23.1%)	4 (15.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.09 (0.49, 6.28)	1.64 (0.72, 3.02)	
Hazard Ratio (95% CI)		0.766 (0.412, 1.424)	
p-value		0.3828	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Other			
Total Patients	16	21	
Patients (%) With Events	15 (93.8%)	21 (100.0%)	
Patients (%) Without Events (Censored)	1 (6.2%)	0	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.54 (0.30, 1.38)	0.95 (0.72, 2.50)	
Hazard Ratio (95% CI)		0.967 (0.474, 1.973)	
p-value		0.9209	
Baseline ECOG status			0.2795
0			
Total Patients	81	79	
Patients (%) With Events	52 (64.2%)	73 (92.4%)	
Patients (%) Without Events (Censored)	29 (35.8%)	6 (7.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.72, 6.28)	1.25 (0.95, 1.84)	
Hazard Ratio (95% CI)		0.583 (0.405, 0.840)	
p-value		0.0030	
1			
Total Patients	43	43	
Patients (%) With Events	35 (81.4%)	36 (83.7%)	
Patients (%) Without Events (Censored)	8 (18.6%)	7 (16.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.46, 3.81)	0.95 (0.72, 2.63)	
Hazard Ratio (95% CI)		0.759 (0.467, 1.233)	
p-value		0.2585	
History of liver metastasis			0.8780
Yes			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	36	25	
Patients (%) With Events	26 (72.2%)	22 (88.0%)	
Patients (%) Without Events (Censored)	10 (27.8%)	3 (12.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.92 (0.43, 6.28)	0.95 (0.72, 2.33)	
Hazard Ratio (95% CI)		0.677 (0.372, 1.231)	
p-value		0.1866	
No			
Total Patients	88	97	
Patients (%) With Events	61 (69.3%)	87 (89.7%)	
Patients (%) Without Events (Censored)	27 (30.7%)	10 (10.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.69 (0.95, 4.34)	1.25 (0.95, 1.84)	
Hazard Ratio (95% CI)		0.608 (0.434, 0.853)	
p-value		0.0034	
History of brain metastasis			0.3068
Yes			
Total Patients	6	7	
Patients (%) With Events	5 (83.3%)	6 (85.7%)	
Patients (%) Without Events (Censored)	1 (16.7%)	1 (14.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.69 (0.20, NR)	1.64 (0.20, 2.50)	
Hazard Ratio (95% CI)		1.136 (0.338, 3.813)	
p-value		0.8367	
No			
Total Patients	118	115	
Patients (%) With Events	82 (69.5%)	103 (89.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	36 (30.5%)	12 (10.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.61 (0.72, 3.68)	1.15 (0.95, 1.77)	
Hazard Ratio (95% CI)		0.612 (0.453, 0.827)	
p-value		0.0011	
PD-L1 Status			0.6346
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	27 (62.8%)	43 (84.3%)	
Patients (%) Without Events (Censored)	16 (37.2%)	8 (15.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.52 (0.72, 9.86)	1.41 (0.95, 2.27)	
Hazard Ratio (95% CI)		0.583 (0.354, 0.958)	
p-value		0.0298	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	60 (74.1%)	66 (93.0%)	
Patients (%) Without Events (Censored)	21 (25.9%)	5 (7.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.99 (0.69, 2.63)	0.99 (0.89, 1.84)	
Hazard Ratio (95% CI)		0.654 (0.456, 0.939)	
p-value		0.0187	
BRCA 1/2 status			0.0444
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	28 (66.7%)	37 (82.2%)	
Patients (%) Without Events (Censored)	14 (33.3%)	8 (17.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.31 (0.72, 6.28)	0.95 (0.72, 1.35)	
Hazard Ratio (95% CI)		0.597 (0.360, 0.989)	
p-value		0.0427	
Mutant			
Total Patients	9	7	
Patients (%) With Events	8 (88.9%)	7 (100.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	0	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.43 (0.20, 5.39)	2.10 (0.72, 4.63)	
Hazard Ratio (95% CI)		1.930 (0.649, 5.742)	
p-value		0.2379	
Menopausal status			0.8908
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	19 (65.5%)	30 (88.2%)	
Patients (%) Without Events (Censored)	10 (34.5%)	4 (11.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.99 (0.69, 8.05)	0.97 (0.85, 2.27)	
Hazard Ratio (95% CI)		0.646 (0.359, 1.161)	
p-value		0.1353	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	68 (71.6%)	79 (90.8%)	
Patients (%) Without Events (Censored)	27 (28.4%)	8 (9.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.72, 4.14)	1.18 (0.92, 1.77)	
Hazard Ratio (95% CI)		0.613 (0.437, 0.859)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0038	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.9. Table 1.1.9: Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Number of patients at risk	124 (100.0%)	122 (100.0%)
Number of patients with events	5 (4.0%)	23 (18.9%)
Sacituzumab Govitecan	5 (4.0%)	0
Gemcitabine	0	12 (9.8%)
Carboplatin	0	22 (18.0%)
Number of patients censored	119 (96.0%)	99 (81.1%)
Probability of being event-free [a] [95% CI] [b] at:		
Month 3	96.7 [91.4, 98.7]	94.8 [88.9, 97.7]
Month 6	96.7 [91.4, 98.7]	90.5 [83.0, 94.8]
Month 9	96.7 [91.4, 98.7]	81.0 [70.2, 88.2]
Month 12	96.7 [91.4, 98.7]	70.7 [55.0, 81.8]
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	28.32 (14.55, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.163 (0.061, 0.434)
p-value		<0.0001

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[a] Estimated from the Kaplan-Meier method.
[b] Calculated using the log-log transformation (Brookmeyer-Crowley method).
[c] Median 95% CI based on Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties. p-value is from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm in the Safety Analysis Set.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.10. Table 1.1.10: Subgroup Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2654
De novo			
Total Patients	29	26	
Patients (%) With Events	3 (10.3%)	5 (19.2%)	
Patients (%) Without Events (Censored)	26 (89.7%)	21 (80.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (7.16, NR)	
Hazard Ratio (95% CI)		0.440 (0.102, 1.893)	
p-value		0.2601	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	0	3 (10.0%)	
Patients (%) Without Events (Censored)	31 (100.0%)	27 (90.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.73, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0275	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	2 (3.1%)	15 (22.7%)	
Patients (%) Without Events (Censored)	62 (96.9%)	51 (77.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.93, NR)	
Hazard Ratio (95% CI)		0.120 (0.027, 0.530)	
p-value		0.0009	
Geographic region			0.1044
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	0	6 (17.6%)	
Patients (%) Without Events (Censored)	30 (100.0%)	28 (82.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.93, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0077	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	5 (5.3%)	17 (19.3%)	
Patients (%) Without Events (Censored)	89 (94.7%)	71 (80.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (12.06, NR)	
Hazard Ratio (95% CI)		0.216 (0.079, 0.591)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0011	
Age group			0.0634
< 65			
Total Patients	98	94	
Patients (%) With Events	3 (3.1%)	20 (21.3%)	
Patients (%) Without Events (Censored)	95 (96.9%)	74 (78.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (11.93, NR)	
Hazard Ratio (95% CI)		0.098 (0.029, 0.333)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	2 (7.7%)	3 (10.7%)	
Patients (%) Without Events (Censored)	24 (92.3%)	25 (89.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (19.61, NR)	
Hazard Ratio (95% CI)		0.730 (0.117, 4.565)	
p-value		0.7353	
Race			0.0352
White			
Total Patients	80	75	
Patients (%) With Events	2 (2.5%)	18 (24.0%)	
Patients (%) Without Events (Censored)	78 (97.5%)	57 (76.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.73, NR)	
Hazard Ratio (95% CI)		0.082 (0.019, 0.357)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Asian			
Total Patients	26	26	
Patients (%) With Events	3 (11.5%)	2 (7.7%)	
Patients (%) Without Events (Censored)	23 (88.5%)	24 (92.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.07, NR)	
Hazard Ratio (95% CI)		1.167 (0.191, 7.133)	
p-value		0.8669	
Other			
Total Patients	16	21	
Patients (%) With Events	0	3 (14.3%)	
Patients (%) Without Events (Censored)	16 (100.0%)	18 (85.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	14.55 (14.55, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0478	
Baseline ECOG status			0.7855
0			
Total Patients	81	79	
Patients (%) With Events	3 (3.7%)	16 (20.3%)	
Patients (%) Without Events (Censored)	78 (96.3%)	63 (79.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (12.06, NR)	
Hazard Ratio (95% CI)		0.135 (0.039, 0.467)	
p-value		0.0002	
1			
Total Patients	43	43	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	2 (4.7%)	7 (16.3%)	
Patients (%) Without Events (Censored)	41 (95.3%)	36 (83.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (8.48, NR)	
Hazard Ratio (95% CI)		0.212 (0.043, 1.035)	
p-value		0.0357	
History of liver metastasis			0.1006
Yes			
Total Patients	36	25	
Patients (%) With Events	0	3 (12.0%)	
Patients (%) Without Events (Censored)	36 (100.0%)	22 (88.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.44, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0034	
No			
Total Patients	88	97	
Patients (%) With Events	5 (5.7%)	20 (20.6%)	
Patients (%) Without Events (Censored)	83 (94.3%)	77 (79.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.221 (0.082, 0.596)	
p-value		0.0011	
History of brain metastasis			0.4312
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	3 (42.9%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	5 (83.3%)	4 (57.1%)	
Median Time to Discontinuation, months (95% CI)	NR (1.58, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		0.453 (0.047, 4.379)	
p-value		0.4831	
No			
Total Patients	118	115	
Patients (%) With Events	4 (3.4%)	20 (17.4%)	
Patients (%) Without Events (Censored)	114 (96.6%)	95 (82.6%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.143 (0.048, 0.423)	
p-value		0.0001	
PD-L1 Status			0.0042
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	0	15 (29.4%)	
Patients (%) Without Events (Censored)	43 (100.0%)	36 (70.6%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	12.06 (7.16, NR)	
Hazard Ratio (95% CI)		NC	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	5 (6.2%)	8 (11.3%)	
Patients (%) Without Events (Censored)	76 (93.8%)	63 (88.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.455 (0.146, 1.424)	
p-value		0.1664	
BRCA 1/2 status			0.0927
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	0	5 (11.1%)	
Patients (%) Without Events (Censored)	42 (100.0%)	40 (88.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (28.32, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0364	
Mutant			
Total Patients	9	7	
Patients (%) With Events	1 (11.1%)	2 (28.6%)	
Patients (%) Without Events (Censored)	8 (88.9%)	5 (71.4%)	
Median Time to Discontinuation, months (95% CI)	NR (2.33, NR)	19.61 (6.93, NR)	
Hazard Ratio (95% CI)		0.966 (0.059, 15.699)	
p-value		0.9807	
Menopausal status			0.7576
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	1 (3.4%)	5 (14.7%)	
Patients (%) Without Events (Censored)	28 (96.6%)	29 (85.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.214 (0.025, 1.845)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.1231	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	4 (4.2%)	18 (20.7%)	
Patients (%) Without Events (Censored)	91 (95.8%)	69 (79.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.93, NR)	
Hazard Ratio (95% CI)		0.143 (0.048, 0.429)	
p-value		0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. NC = Not Calculable (HR is NC when one treatment arm has zero events; log-rank p-value remains valid).
Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.11. Table 1.1.11: Analysis of Time to First TEAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Blood and lymphatic system disorders		
Total Patients	124	122
Patients (%) With Events	95 (76.6%)	116 (95.1%)
Patients (%) Without Events (Censored)	29 (23.4%)	6 (4.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.72 (0.69, 1.08)	0.69 (0.49, 0.72)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.570 (0.431, 0.754)
p-value		0.0001
Anaemia		
Total Patients	124	122
Patients (%) With Events	46 (37.1%)	83 (68.0%)
Patients (%) Without Events (Censored)	78 (62.9%)	39 (32.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (10.68, NR)	2.10 (1.64, 2.63)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.380 (0.264, 0.548)
p-value		<0.0001
Leukopenia		
Total Patients	124	122
Patients (%) With Events	38 (30.6%)	54 (44.3%)
Patients (%) Without Events (Censored)	86 (69.4%)	68 (55.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	29.90 (23.66, NR)	9.92 (5.78, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.605 (0.399, 0.918)
p-value		0.0168
Lymphopenia		
Total Patients	124	122
Patients (%) With Events	20 (16.1%)	19 (15.6%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	104 (83.9%)	103 (84.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.005 (0.535, 1.887)
p-value		0.9878
Neutropenia		
Total Patients	124	122
Patients (%) With Events	83 (66.9%)	105 (86.1%)
Patients (%) Without Events (Censored)	41 (33.1%)	17 (13.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 3.09)	0.92 (0.72, 0.95)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.618 (0.460, 0.829)
p-value		0.0010
Thrombocytopenia		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	70 (57.4%)
Patients (%) Without Events (Censored)	119 (96.0%)	52 (42.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	4.83 (3.94, 6.18)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.043 (0.017, 0.108)
p-value		<0.0001

	SG (N=124)	TPC (N=122)
Cardiac disorders		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	12 (9.8%)
Patients (%) Without Events (Censored)	115 (92.7%)	110 (90.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.650 (0.273, 1.552)
p-value		0.3285
Ear and labyrinth disorders		
Total Patients	124	122
Patients (%) With Events	4 (3.2%)	6 (4.9%)
Patients (%) Without Events (Censored)	120 (96.8%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.635 (0.179, 2.252)
p-value		0.4778
Eye disorders		
Total Patients	124	122
Patients (%) With Events	23 (18.5%)	6 (4.9%)
Patients (%) Without Events (Censored)	101 (81.5%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (20.76, NR)	NR (26.84, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.539 (1.432, 8.748)
p-value		0.0036
Gastrointestinal disorders		
Total Patients	124	122
Patients (%) With Events	113 (91.1%)	95 (77.9%)
Patients (%) Without Events (Censored)	11 (8.9%)	27 (22.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.23 (0.13, 0.30)	0.72 (0.30, 1.05)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.638 (1.243, 2.160)
p-value		0.0003
Abdominal pain		
Total Patients	124	122
Patients (%) With Events	21 (16.9%)	8 (6.6%)
Patients (%) Without Events (Censored)	103 (83.1%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.641 (1.168, 5.972)
p-value		0.0155
Abdominal pain upper		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	8 (6.6%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	112 (90.3%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.472 (0.601, 3.604)
p-value		0.3946
Constipation		
Total Patients	124	122
Patients (%) With Events	50 (40.3%)	41 (33.6%)
Patients (%) Without Events (Censored)	74 (59.7%)	81 (66.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (5.09, NR)	NR (14.16, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.201 (0.794, 1.816)
p-value		0.3823
Diarrhoea		
Total Patients	124	122
Patients (%) With Events	71 (57.3%)	28 (23.0%)
Patients (%) Without Events (Censored)	53 (42.7%)	94 (77.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	3.52 (1.58, 11.04)	30.42 (20.96, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.339 (2.153, 5.180)
p-value		<0.0001

	SG (N=124)	TPC (N=122)
Dyspepsia		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	6 (4.9%)
Patients (%) Without Events (Censored)	114 (91.9%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.510 (0.545, 4.183)
p-value		0.4249
Gastrooesophageal reflux disease		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	3 (2.5%)
Patients (%) Without Events (Censored)	117 (94.4%)	119 (97.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.191 (0.565, 8.488)
p-value		0.2444
Nausea		
Total Patients	124	122
Patients (%) With Events	80 (64.5%)	58 (47.5%)
Patients (%) Without Events (Censored)	44 (35.5%)	64 (52.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.14 (0.36, 4.47)	9.33 (3.09, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.590 (1.133, 2.232)
p-value		0.0065
Stomatitis		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	6 (4.9%)
Patients (%) Without Events (Censored)	109 (87.9%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.190 (0.846, 5.668)
p-value		0.0976
Vomiting		
Total Patients	124	122
Patients (%) With Events	38 (30.6%)	23 (18.9%)
Patients (%) Without Events (Censored)	86 (69.4%)	99 (81.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (12.68, NR)	33.58 (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.618 (0.963, 2.719)
p-value		0.0660
General disorders and administration site conditions		
Total Patients	124	122
Patients (%) With Events	84 (67.7%)	79 (64.8%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	40 (32.3%)	43 (35.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.91 (1.38, 3.12)	2.92 (1.84, 4.44)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.072 (0.788, 1.459)
p-value		0.6578
Fatigue		
Total Patients	124	122
Patients (%) With Events	61 (49.2%)	63 (51.6%)
Patients (%) Without Events (Censored)	63 (50.8%)	59 (48.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	7.66 (2.53, NR)	6.28 (2.63, 17.51)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.947 (0.666, 1.348)
p-value		0.7622
Malaise		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	3 (2.5%)
Patients (%) Without Events (Censored)	117 (94.4%)	119 (97.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.344 (0.606, 9.067)
p-value		0.2033

	SG (N=124)	TPC (N=122)
Oedema peripheral		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	8 (6.6%)
Patients (%) Without Events (Censored)	109 (87.9%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.727 (0.731, 4.081)
p-value		0.2071
Pyrexia		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	17 (13.9%)
Patients (%) Without Events (Censored)	112 (90.3%)	105 (86.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.618 (0.294, 1.300)
p-value		0.2000
Hepatobiliary disorders		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	8 (6.6%)
Patients (%) Without Events (Censored)	116 (93.5%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (25.56, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.891 (0.333, 2.387)
p-value		0.8186
Immune system disorders		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	5 (4.1%)
Patients (%) Without Events (Censored)	117 (94.4%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.330 (0.422, 4.199)
p-value		0.6252
Infections and infestations		
Total Patients	124	122
Patients (%) With Events	70 (56.5%)	64 (52.5%)
Patients (%) Without Events (Censored)	54 (43.5%)	58 (47.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	7.20 (5.09, 8.48)	5.59 (4.01, 9.46)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.967 (0.686, 1.362)
p-value		0.8492
COVID-19		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	8 (6.6%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	117 (94.4%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.786 (0.284, 2.172)
p-value		0.6415
Influenza		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	6 (4.9%)
Patients (%) Without Events (Censored)	118 (95.2%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.762 (0.242, 2.396)
p-value		0.6407
Nasopharyngitis		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	6 (4.9%)
Patients (%) Without Events (Censored)	115 (92.7%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (22.97, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.103 (0.389, 3.131)
p-value		0.8538

	SG (N=124)	TPC (N=122)
Pneumonia		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	10 (8.2%)
Patients (%) Without Events (Censored)	118 (95.2%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.445 (0.160, 1.237)
p-value		0.1111
Upper respiratory tract infection		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	6 (4.9%)
Patients (%) Without Events (Censored)	109 (87.9%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (26.02, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.254 (0.873, 5.821)
p-value		0.0845
Urinary tract infection		
Total Patients	124	122
Patients (%) With Events	18 (14.5%)	19 (15.6%)
Patients (%) Without Events (Censored)	106 (85.5%)	103 (84.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.85, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.852 (0.446, 1.626)
p-value		0.6271
Injury, poisoning and procedural complications		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	22 (18.0%)
Patients (%) Without Events (Censored)	111 (89.5%)	100 (82.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	33.58 (18.83, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.462 (0.230, 0.928)
p-value		0.0264
Investigations		
Total Patients	124	122
Patients (%) With Events	51 (41.1%)	66 (54.1%)
Patients (%) Without Events (Censored)	73 (58.9%)	56 (45.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (6.93, NR)	3.68 (1.64, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.607 (0.420, 0.875)
p-value		0.0075
Alanine aminotransferase increased		
Total Patients	124	122
Patients (%) With Events	24 (19.4%)	54 (44.3%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	100 (80.6%)	68 (55.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (3.22, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.335 (0.207, 0.544)
p-value		<0.0001
Aspartate aminotransferase increased		
Total Patients	124	122
Patients (%) With Events	23 (18.5%)	43 (35.2%)
Patients (%) Without Events (Censored)	101 (81.5%)	79 (64.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.436 (0.263, 0.725)
p-value		0.0010
Blood alkaline phosphatase increased		
Total Patients	124	122
Patients (%) With Events	18 (14.5%)	10 (8.2%)
Patients (%) Without Events (Censored)	106 (85.5%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.723 (0.794, 3.740)
p-value		0.1638

	SG (N=124)	TPC (N=122)
Gamma-glutamyltransferase increased		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	10 (8.2%)
Patients (%) Without Events (Censored)	117 (94.4%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.639 (0.243, 1.680)
p-value		0.3612
Weight decreased		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	5 (4.1%)
Patients (%) Without Events (Censored)	112 (90.3%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.370 (0.833, 6.742)
p-value		0.0955
Metabolism and nutrition disorders		
Total Patients	124	122
Patients (%) With Events	54 (43.5%)	42 (34.4%)
Patients (%) Without Events (Censored)	70 (56.5%)	80 (65.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	11.43 (6.21, NR)	15.44 (11.20, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.335 (0.892, 1.999)
p-value		0.1597
Decreased appetite		
Total Patients	124	122
Patients (%) With Events	25 (20.2%)	11 (9.0%)
Patients (%) Without Events (Censored)	99 (79.8%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.213 (1.088, 4.501)
p-value		0.0245
Hyperglycaemia		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	11 (9.0%)
Patients (%) Without Events (Censored)	111 (89.5%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.144 (0.511, 2.557)
p-value		0.7468
Hypocalcaemia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	7 (5.7%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	116 (93.5%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (26.48, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.043 (0.376, 2.893)
p-value		0.9337
Hypokalaemia		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	11 (9.0%)
Patients (%) Without Events (Censored)	115 (92.7%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.739 (0.305, 1.792)
p-value		0.5016
Hypomagnesaemia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	10 (8.2%)
Patients (%) Without Events (Censored)	116 (93.5%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.19, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.614 (0.240, 1.571)
p-value		0.3044

	SG (N=124)	TPC (N=122)
Hyponatraemia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	7 (5.7%)
Patients (%) Without Events (Censored)	116 (93.5%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.133 (0.411, 3.123)
p-value		0.8095
Musculoskeletal and connective tissue disorders		
Total Patients	124	122
Patients (%) With Events	47 (37.9%)	44 (36.1%)
Patients (%) Without Events (Censored)	77 (62.1%)	78 (63.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.13 (10.41, NR)	13.50 (11.14, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.925 (0.609, 1.404)
p-value		0.7122
Arthralgia		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	14 (11.5%)
Patients (%) Without Events (Censored)	111 (89.5%)	108 (88.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (22.60, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.766 (0.357, 1.648)
p-value		0.4942
Back pain		
Total Patients	124	122
Patients (%) With Events	11 (8.9%)	13 (10.7%)
Patients (%) Without Events (Censored)	113 (91.1%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	30.36 (19.68, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.709 (0.315, 1.594)
p-value		0.4028
Myalgia		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	11 (9.0%)
Patients (%) Without Events (Censored)	114 (91.9%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.781 (0.329, 1.855)
p-value		0.5743
Pain in extremity		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	11 (9.0%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	119 (96.0%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.383 (0.132, 1.109)
p-value		0.0664
Nervous system disorders		
Total Patients	124	122
Patients (%) With Events	49 (39.5%)	41 (33.6%)
Patients (%) Without Events (Censored)	75 (60.5%)	81 (66.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.29 (7.39, NR)	25.40 (12.58, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.110 (0.731, 1.685)
p-value		0.6198
Dizziness		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	9 (7.4%)
Patients (%) Without Events (Censored)	116 (93.5%)	113 (92.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (25.26, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.809 (0.312, 2.101)
p-value		0.6638

	SG (N=124)	TPC (N=122)
Dysgeusia		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	8 (6.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.203 (0.474, 3.051)
p-value		0.6970
Headache		
Total Patients	124	122
Patients (%) With Events	23 (18.5%)	21 (17.2%)
Patients (%) Without Events (Censored)	101 (81.5%)	101 (82.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	36.86 (21.88, NR)	NR (25.40, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.953 (0.523, 1.737)
p-value		0.8756
Neuropathy peripheral		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	5 (4.1%)
Patients (%) Without Events (Censored)	117 (94.4%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.236 (0.391, 3.902)
p-value		0.7175
Psychiatric disorders		
Total Patients	124	122
Patients (%) With Events	19 (15.3%)	14 (11.5%)
Patients (%) Without Events (Censored)	105 (84.7%)	108 (88.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	37.13 (37.13, NR)	NR (28.32, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.284 (0.637, 2.586)
p-value		0.4830
Anxiety		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	6 (4.9%)
Patients (%) Without Events (Censored)	119 (96.0%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.763 (0.232, 2.503)
p-value		0.6539
Depression		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	2 (1.6%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	115 (92.7%)	120 (98.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.323 (0.933, 20.034)
p-value		0.0411
Insomnia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	4 (3.3%)
Patients (%) Without Events (Censored)	116 (93.5%)	118 (96.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	37.13 (37.13, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.603 (0.466, 5.516)
p-value		0.4505
Renal and urinary disorders		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	7 (5.7%)
Patients (%) Without Events (Censored)	109 (87.9%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.042 (0.831, 5.017)
p-value		0.1122

	SG (N=124)	TPC (N=122)
Reproductive system and breast disorders		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	13 (10.7%)
Patients (%) Without Events (Censored)	112 (90.3%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.837 (0.380, 1.841)
p-value		0.6573
Breast pain		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	10 (8.2%)
Patients (%) Without Events (Censored)	116 (93.5%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.724 (0.285, 1.840)
p-value		0.4950
Respiratory, thoracic and mediastinal disorders		
Total Patients	124	122
Patients (%) With Events	48 (38.7%)	39 (32.0%)
Patients (%) Without Events (Censored)	76 (61.3%)	83 (68.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	15.41 (12.09, NR)	22.05 (10.55, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.186 (0.775, 1.815)
p-value		0.4313
Cough		
Total Patients	124	122
Patients (%) With Events	25 (20.2%)	11 (9.0%)
Patients (%) Without Events (Censored)	99 (79.8%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (18.17, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.102 (1.032, 4.282)
p-value		0.0364
Dyspnoea		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	17 (13.9%)
Patients (%) Without Events (Censored)	111 (89.5%)	105 (86.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (22.05, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.716 (0.347, 1.475)
p-value		0.3615
Oropharyngeal pain		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	4 (3.3%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	118 (95.2%)	118 (96.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.484 (0.419, 5.260)
p-value		0.5381
Pulmonary embolism		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	5 (4.1%)
Patients (%) Without Events (Censored)	118 (95.2%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.188 (0.363, 3.893)
p-value		0.7757
Skin and subcutaneous tissue disorders		
Total Patients	124	122
Patients (%) With Events	85 (68.5%)	45 (36.9%)
Patients (%) Without Events (Censored)	39 (31.5%)	77 (63.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.92 (0.69, 1.15)	23.56 (6.74, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.918 (2.025, 4.206)
p-value		<0.0001

	SG (N=124)	TPC (N=122)
Alopecia		
Total Patients	124	122
Patients (%) With Events	68 (54.8%)	18 (14.8%)
Patients (%) Without Events (Censored)	56 (45.2%)	104 (85.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.38 (0.82, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		5.693 (3.378, 9.596)
p-value		<0.0001
Pruritus		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	4 (3.3%)
Patients (%) Without Events (Censored)	111 (89.5%)	118 (96.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (25.72, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.113 (1.012, 9.580)
p-value		0.0370
Rash		
Total Patients	124	122
Patients (%) With Events	16 (12.9%)	11 (9.0%)
Patients (%) Without Events (Censored)	108 (87.1%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.321 (0.612, 2.854)
p-value		0.4767
Urticaria		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	5 (4.1%)
Patients (%) Without Events (Censored)	119 (96.0%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.742 (0.212, 2.594)
p-value		0.6391
Vascular disorders		
Total Patients	124	122
Patients (%) With Events	22 (17.7%)	20 (16.4%)
Patients (%) Without Events (Censored)	102 (82.3%)	102 (83.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	25.56 (18.73, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.981 (0.534, 1.803)
p-value		0.9527
Hot flush		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	3 (2.5%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	115 (92.7%)	119 (97.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.843 (0.768, 10.522)
p-value		0.1015

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.12. Table 1.1.12.1: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.5632
De novo			
Total Patients	29	26	
Patients (%) With Events	21 (72.4%)	25 (96.2%)	
Patients (%) Without Events (Censored)	8 (27.6%)	1 (3.8%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 1.38)	0.79 (0.26, 0.95)	
Hazard Ratio (95% CI)		0.674 (0.373, 1.219)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.1759	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	26 (83.9%)	28 (93.3%)	
Patients (%) Without Events (Censored)	5 (16.1%)	2 (6.7%)	
Median Time to First TEAE, months (95% CI)	0.69 (0.26, 0.76)	0.69 (0.26, 0.92)	
Hazard Ratio (95% CI)		0.787 (0.458, 1.352)	
p-value		0.3154	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	48 (75.0%)	63 (95.5%)	
Patients (%) Without Events (Censored)	16 (25.0%)	3 (4.5%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.69, 2.30)	0.69 (0.26, 0.72)	
Hazard Ratio (95% CI)		0.468 (0.317, 0.690)	
p-value		0.0001	
Geographic region			0.2910
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	18 (60.0%)	31 (91.2%)	
Patients (%) Without Events (Censored)	12 (40.0%)	3 (8.8%)	
Median Time to First TEAE, months (95% CI)	1.17 (0.66, NR)	0.72 (0.26, 0.95)	
Hazard Ratio (95% CI)		0.458 (0.254, 0.828)	
p-value		0.0069	
Rest of the world			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	94	88	
Patients (%) With Events	77 (81.9%)	85 (96.6%)	
Patients (%) Without Events (Censored)	17 (18.1%)	3 (3.4%)	
Median Time to First TEAE, months (95% CI)	0.71 (0.66, 0.92)	0.69 (0.49, 0.72)	
Hazard Ratio (95% CI)		0.605 (0.440, 0.831)	
p-value		0.0015	
Age group			0.6783
< 65			
Total Patients	98	94	
Patients (%) With Events	77 (78.6%)	90 (95.7%)	
Patients (%) Without Events (Censored)	21 (21.4%)	4 (4.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.72 (0.62, 0.72)	
Hazard Ratio (95% CI)		0.583 (0.427, 0.798)	
p-value		0.0005	
>= 65			
Total Patients	26	28	
Patients (%) With Events	18 (69.2%)	26 (92.9%)	
Patients (%) Without Events (Censored)	8 (30.8%)	2 (7.1%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.30, 10.35)	0.28 (0.26, 0.89)	
Hazard Ratio (95% CI)		0.519 (0.279, 0.963)	
p-value		0.0353	
Race			0.2442
White			
Total Patients	80	75	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	59 (73.8%)	72 (96.0%)	
Patients (%) Without Events (Censored)	21 (26.2%)	3 (4.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.69 (0.49, 0.72)	
Hazard Ratio (95% CI)		0.518 (0.363, 0.738)	
p-value		0.0002	
Asian			
Total Patients	26	26	
Patients (%) With Events	22 (84.6%)	24 (92.3%)	
Patients (%) Without Events (Censored)	4 (15.4%)	2 (7.7%)	
Median Time to First TEAE, months (95% CI)	0.67 (0.26, 2.27)	0.71 (0.26, 1.84)	
Hazard Ratio (95% CI)		0.875 (0.486, 1.575)	
p-value		0.6440	
Other			
Total Patients	16	21	
Patients (%) With Events	13 (81.2%)	20 (95.2%)	
Patients (%) Without Events (Censored)	3 (18.8%)	1 (4.8%)	
Median Time to First TEAE, months (95% CI)	0.80 (0.26, 5.09)	0.89 (0.23, 0.95)	
Hazard Ratio (95% CI)		0.461 (0.212, 1.002)	
p-value		0.0430	
Baseline ECOG status			0.7059
0			
Total Patients	81	79	
Patients (%) With Events	64 (79.0%)	76 (96.2%)	
Patients (%) Without Events (Censored)	17 (21.0%)	3 (3.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 0.92)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.599 (0.426, 0.842)	
p-value		0.0024	
1			
Total Patients	43	43	
Patients (%) With Events	31 (72.1%)	40 (93.0%)	
Patients (%) Without Events (Censored)	12 (27.9%)	3 (7.0%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.43, 2.73)	0.69 (0.26, 0.92)	
Hazard Ratio (95% CI)		0.537 (0.331, 0.872)	
p-value		0.0101	
History of liver metastasis			0.6921
Yes			
Total Patients	36	25	
Patients (%) With Events	29 (80.6%)	23 (92.0%)	
Patients (%) Without Events (Censored)	7 (19.4%)	2 (8.0%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.43, 2.33)	0.69 (0.30, 0.92)	
Hazard Ratio (95% CI)		0.626 (0.355, 1.103)	
p-value		0.0986	
No			
Total Patients	88	97	
Patients (%) With Events	66 (75.0%)	93 (95.9%)	
Patients (%) Without Events (Censored)	22 (25.0%)	4 (4.1%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.549 (0.397, 0.759)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0002	
History of brain metastasis			0.2427
Yes			
Total Patients	6	7	
Patients (%) With Events	5 (83.3%)	6 (85.7%)	
Patients (%) Without Events (Censored)	1 (16.7%)	1 (14.3%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.23, NR)	1.64 (0.26, NR)	
Hazard Ratio (95% CI)		1.415 (0.403, 4.961)	
p-value		0.5860	
No			
Total Patients	118	115	
Patients (%) With Events	90 (76.3%)	110 (95.7%)	
Patients (%) Without Events (Censored)	28 (23.7%)	5 (4.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.08)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.555 (0.416, 0.739)	
p-value		<0.0001	
PD-L1 Status			0.3988
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	33 (76.7%)	46 (90.2%)	
Patients (%) Without Events (Censored)	10 (23.3%)	5 (9.8%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.56, 2.30)	0.72 (0.66, 0.95)	
Hazard Ratio (95% CI)		0.650 (0.409, 1.032)	
p-value		0.0694	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	62 (76.5%)	70 (98.6%)	
Patients (%) Without Events (Censored)	19 (23.5%)	1 (1.4%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.59 (0.26, 0.72)	
Hazard Ratio (95% CI)		0.509 (0.357, 0.725)	
p-value		0.0001	
BRCA 1/2 status			0.1218
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	27 (64.3%)	42 (93.3%)	
Patients (%) Without Events (Censored)	15 (35.7%)	3 (6.7%)	
Median Time to First TEAE, months (95% CI)	1.25 (0.66, 20.34)	0.62 (0.26, 0.72)	
Hazard Ratio (95% CI)		0.416 (0.251, 0.687)	
p-value		0.0004	
Mutant			
Total Patients	9	7	
Patients (%) With Events	8 (88.9%)	7 (100.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	0 (0.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.23, 5.26)	0.95 (0.26, 2.10)	
Hazard Ratio (95% CI)		0.830 (0.287, 2.398)	
p-value		0.7136	
Menopausal status			0.7519
Pre-menopausal			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	29	34	
Patients (%) With Events	20 (69.0%)	33 (97.1%)	
Patients (%) Without Events (Censored)	9 (31.0%)	1 (2.9%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.43, 3.78)	0.72 (0.26, 0.95)	
Hazard Ratio (95% CI)		0.530 (0.302, 0.931)	
p-value		0.0212	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	75 (78.9%)	82 (94.3%)	
Patients (%) Without Events (Censored)	20 (21.1%)	5 (5.7%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.66, 1.08)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.589 (0.426, 0.814)	
p-value		0.0012	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.13. Table 1.1.12.2: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.4977
De novo			
Total Patients	29	26	
Patients (%) With Events	26 (89.7%)	21 (80.8%)	
Patients (%) Without Events (Censored)	3 (10.3%)	5 (19.2%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.36)	0.36 (0.13, 0.76)	
Hazard Ratio (95% CI)		1.371 (0.768, 2.448)	
p-value		0.2673	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	28 (90.3%)	22 (73.3%)	
Patients (%) Without Events (Censored)	3 (9.7%)	8 (26.7%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.13, 0.99)	0.87 (0.26, 3.29)	
Hazard Ratio (95% CI)		1.415 (0.800, 2.501)	
p-value		0.2216	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	59 (92.2%)	52 (78.8%)	
Patients (%) Without Events (Censored)	5 (7.8%)	14 (21.2%)	
Median Time to First TEAE, months (95% CI)	0.21 (0.10, 0.30)	0.89 (0.13, 2.73)	
Hazard Ratio (95% CI)		1.946 (1.322, 2.866)	
p-value		0.0005	
Geographic region			0.4855

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	28 (93.3%)	26 (76.5%)	
Patients (%) Without Events (Censored)	2 (6.7%)	8 (23.5%)	
Median Time to First TEAE, months (95% CI)	0.18 (0.10, 0.26)	0.76 (0.13, 2.37)	
Hazard Ratio (95% CI)		2.064 (1.191, 3.576)	
p-value		0.0089	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	85 (90.4%)	69 (78.4%)	
Patients (%) Without Events (Censored)	9 (9.6%)	19 (21.6%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.72 (0.26, 1.38)	
Hazard Ratio (95% CI)		1.564 (1.133, 2.160)	
p-value		0.0053	
Age group			0.2920
< 65			
Total Patients	98	94	
Patients (%) With Events	89 (90.8%)	72 (76.6%)	
Patients (%) Without Events (Censored)	9 (9.2%)	22 (23.4%)	
Median Time to First TEAE, months (95% CI)	0.18 (0.10, 0.33)	0.72 (0.26, 0.95)	
Hazard Ratio (95% CI)		1.508 (1.103, 2.061)	
p-value		0.0087	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	24 (92.3%)	23 (82.1%)	
Patients (%) Without Events (Censored)	2 (7.7%)	5 (17.9%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.30)	0.90 (0.13, 5.06)	
Hazard Ratio (95% CI)		2.491 (1.317, 4.714)	
p-value		0.0040	
Race			0.2838
White			
Total Patients	80	75	
Patients (%) With Events	73 (91.2%)	54 (72.0%)	
Patients (%) Without Events (Censored)	7 (8.8%)	21 (28.0%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	1.08 (0.69, 3.29)	
Hazard Ratio (95% CI)		1.940 (1.357, 2.772)	
p-value		0.0002	
Asian			
Total Patients	26	26	
Patients (%) With Events	24 (92.3%)	21 (80.8%)	
Patients (%) Without Events (Censored)	2 (7.7%)	5 (19.2%)	
Median Time to First TEAE, months (95% CI)	0.15 (0.10, 0.36)	0.18 (0.07, 5.06)	
Hazard Ratio (95% CI)		1.174 (0.645, 2.137)	
p-value		0.5612	
Other			
Total Patients	16	21	
Patients (%) With Events	14 (87.5%)	20 (95.2%)	
Patients (%) Without Events (Censored)	2 (12.5%)	1 (4.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.23 (0.07, 0.59)	0.30 (0.10, 0.76)	
Hazard Ratio (95% CI)		1.165 (0.583, 2.329)	
p-value		0.6773	
Baseline ECOG status			0.3907
0			
Total Patients	81	79	
Patients (%) With Events	73 (90.1%)	59 (74.7%)	
Patients (%) Without Events (Censored)	8 (9.9%)	20 (25.3%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.33)	0.76 (0.23, 1.87)	
Hazard Ratio (95% CI)		1.718 (1.213, 2.434)	
p-value		0.0018	
1			
Total Patients	43	43	
Patients (%) With Events	40 (93.0%)	36 (83.7%)	
Patients (%) Without Events (Censored)	3 (7.0%)	7 (16.3%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.72 (0.23, 1.05)	
Hazard Ratio (95% CI)		1.497 (0.950, 2.360)	
p-value		0.0792	
History of liver metastasis			0.5881
Yes			
Total Patients	36	25	
Patients (%) With Events	33 (91.7%)	19 (76.0%)	
Patients (%) Without Events (Censored)	3 (8.3%)	6 (24.0%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.10, 0.36)	0.33 (0.07, 3.29)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.356 (0.767, 2.395)	
p-value		0.2703	
No			
Total Patients	88	97	
Patients (%) With Events	80 (90.9%)	76 (78.4%)	
Patients (%) Without Events (Censored)	8 (9.1%)	21 (21.6%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.30)	0.76 (0.30, 1.74)	
Hazard Ratio (95% CI)		1.697 (1.234, 2.334)	
p-value		0.0009	
History of brain metastasis			0.6972
Yes			
Total Patients	6	7	
Patients (%) With Events	6 (100.0%)	6 (85.7%)	
Patients (%) Without Events (Censored)	0 (0.0%)	1 (14.3%)	
Median Time to First TEAE, months (95% CI)	0.28 (0.10, NR)	2.73 (0.10, NR)	
Hazard Ratio (95% CI)		2.940 (0.714, 12.095)	
p-value		0.1121	
No			
Total Patients	118	115	
Patients (%) With Events	107 (90.7%)	89 (77.4%)	
Patients (%) Without Events (Censored)	11 (9.3%)	26 (22.6%)	
Median Time to First TEAE, months (95% CI)	0.21 (0.13, 0.30)	0.72 (0.30, 0.95)	
Hazard Ratio (95% CI)		1.604 (1.208, 2.132)	
p-value		0.0008	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.8970
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	40 (93.0%)	41 (80.4%)	
Patients (%) Without Events (Censored)	3 (7.0%)	10 (19.6%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.33)	0.76 (0.13, 3.12)	
Hazard Ratio (95% CI)		1.699 (1.092, 2.643)	
p-value		0.0169	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	73 (90.1%)	54 (76.1%)	
Patients (%) Without Events (Censored)	8 (9.9%)	17 (23.9%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.30)	0.72 (0.26, 1.05)	
Hazard Ratio (95% CI)		1.637 (1.145, 2.339)	
p-value		0.0054	
BRCA 1/2 status			0.1279
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	40 (95.2%)	34 (75.6%)	
Patients (%) Without Events (Censored)	2 (4.8%)	11 (24.4%)	
Median Time to First TEAE, months (95% CI)	0.31 (0.10, 0.36)	0.95 (0.26, 3.29)	
Hazard Ratio (95% CI)		1.908 (1.191, 3.058)	
p-value		0.0059	
Mutant			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	9	7	
Patients (%) With Events	7 (77.8%)	7 (100.0%)	
Patients (%) Without Events (Censored)	2 (22.2%)	0 (0.0%)	
Median Time to First TEAE, months (95% CI)	0.46 (0.03, 5.39)	0.33 (0.03, 3.52)	
Hazard Ratio (95% CI)		0.803 (0.269, 2.398)	
p-value		0.6960	
Menopausal status			0.9141
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	27 (93.1%)	27 (79.4%)	
Patients (%) Without Events (Censored)	2 (6.9%)	7 (20.6%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.36)	0.34 (0.10, 1.38)	
Hazard Ratio (95% CI)		1.552 (0.899, 2.678)	
p-value		0.1081	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	86 (90.5%)	67 (77.0%)	
Patients (%) Without Events (Censored)	9 (9.5%)	20 (23.0%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.76 (0.33, 2.37)	
Hazard Ratio (95% CI)		1.690 (1.222, 2.337)	
p-value		0.0012	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.14. Table 1.1.12.3: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Injury, poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Age group			0.3581
< 65			
Total Patients	98	94	
Patients (%) With Events	10 (10.2%)	12 (12.8%)	
Patients (%) Without Events (Censored)	88 (89.8%)	82 (87.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		0.683 (0.294, 1.585)	
p-value		0.3713	
>= 65			
Total Patients	26	28	
Patients (%) With Events	3 (11.5%)	10 (35.7%)	
Patients (%) Without Events (Censored)	23 (88.5%)	18 (64.3%)	
Median Time to First TEAE, months (95% CI)	NR (9.95, NR)	18.83 (11.76, NR)	
Hazard Ratio (95% CI)		0.281 (0.075, 1.050)	
p-value		0.0455	
History of brain metastasis			0.5076

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	5 (83.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	NR (1.58, NR)	NR (3.42, NR)	
Hazard Ratio (95% CI)		1.225 (0.077, 19.583)	
p-value		0.8858	
No			
Total Patients	118	115	
Patients (%) With Events	12 (10.2%)	21 (18.3%)	
Patients (%) Without Events (Censored)	106 (89.8%)	94 (81.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.83, NR)	
Hazard Ratio (95% CI)		0.436 (0.212, 0.897)	
p-value		0.0207	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.15. Table 1.1.12.4: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.6722
De novo			
Total Patients	29	26	
Patients (%) With Events	12 (41.4%)	16 (61.5%)	
Patients (%) Without Events (Censored)	17 (58.6%)	10 (38.5%)	
Median Time to First TEAE, months (95% CI)	15.41 (3.71, NR)	1.45 (0.26, NR)	
Hazard Ratio (95% CI)		0.439 (0.203, 0.948)	
p-value		0.0315	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	16 (51.6%)	18 (60.0%)	
Patients (%) Without Events (Censored)	15 (48.4%)	12 (40.0%)	
Median Time to First TEAE, months (95% CI)	11.14 (2.69, NR)	1.49 (0.92, NR)	
Hazard Ratio (95% CI)		0.608 (0.304, 1.216)	
p-value		0.1624	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	23 (35.9%)	32 (48.5%)	
Patients (%) Without Events (Censored)	41 (64.1%)	34 (51.5%)	
Median Time to First TEAE, months (95% CI)	NR (6.93, NR)	7.95 (1.87, NR)	
Hazard Ratio (95% CI)		0.666 (0.390, 1.139)	
p-value		0.1380	
Geographic region			0.2192

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	8 (26.7%)	17 (50.0%)	
Patients (%) Without Events (Censored)	22 (73.3%)	17 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (6.93, NR)	11.76 (0.92, NR)	
Hazard Ratio (95% CI)		0.399 (0.171, 0.933)	
p-value		0.0290	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	43 (45.7%)	49 (55.7%)	
Patients (%) Without Events (Censored)	51 (54.3%)	39 (44.3%)	
Median Time to First TEAE, months (95% CI)	11.14 (4.07, NR)	3.45 (1.35, NR)	
Hazard Ratio (95% CI)		0.679 (0.450, 1.023)	
p-value		0.0658	
Age group			0.2524
< 65			
Total Patients	98	94	
Patients (%) With Events	42 (42.9%)	55 (58.5%)	
Patients (%) Without Events (Censored)	56 (57.1%)	39 (41.5%)	
Median Time to First TEAE, months (95% CI)	15.41 (5.59, NR)	1.64 (0.99, 11.76)	
Hazard Ratio (95% CI)		0.531 (0.355, 0.797)	
p-value		0.0020	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	9 (34.6%)	11 (39.3%)	
Patients (%) Without Events (Censored)	17 (65.4%)	17 (60.7%)	
Median Time to First TEAE, months (95% CI)	NR (1.18, NR)	NR (2.69, NR)	
Hazard Ratio (95% CI)		0.929 (0.384, 2.248)	
p-value		0.8655	
Race			0.6552
White			
Total Patients	80	75	
Patients (%) With Events	32 (40.0%)	39 (52.0%)	
Patients (%) Without Events (Censored)	48 (60.0%)	36 (48.0%)	
Median Time to First TEAE, months (95% CI)	NR (4.07, NR)	4.37 (1.64, NR)	
Hazard Ratio (95% CI)		0.662 (0.414, 1.057)	
p-value		0.0844	
Asian			
Total Patients	26	26	
Patients (%) With Events	9 (34.6%)	12 (46.2%)	
Patients (%) Without Events (Censored)	17 (65.4%)	14 (53.8%)	
Median Time to First TEAE, months (95% CI)	NR (7.85, NR)	NR (0.72, NR)	
Hazard Ratio (95% CI)		0.598 (0.251, 1.423)	
p-value		0.2432	
Other			
Total Patients	16	21	
Patients (%) With Events	8 (50.0%)	15 (71.4%)	
Patients (%) Without Events (Censored)	8 (50.0%)	6 (28.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	15.41 (2.53, NR)	0.95 (0.76, 7.95)	
Hazard Ratio (95% CI)		0.385 (0.158, 0.938)	
p-value		0.0309	
Baseline ECOG status			0.0108
0			
Total Patients	81	79	
Patients (%) With Events	28 (34.6%)	46 (58.2%)	
Patients (%) Without Events (Censored)	53 (65.4%)	33 (41.8%)	
Median Time to First TEAE, months (95% CI)	NR (11.56, NR)	2.30 (1.08, 11.76)	
Hazard Ratio (95% CI)		0.429 (0.268, 0.689)	
p-value		0.0003	
1			
Total Patients	43	43	
Patients (%) With Events	23 (53.5%)	20 (46.5%)	
Patients (%) Without Events (Censored)	20 (46.5%)	23 (53.5%)	
Median Time to First TEAE, months (95% CI)	4.30 (1.61, NR)	7.95 (0.95, NR)	
Hazard Ratio (95% CI)		1.153 (0.632, 2.101)	
p-value		0.6266	
History of liver metastasis			0.9448
Yes			
Total Patients	36	25	
Patients (%) With Events	18 (50.0%)	16 (64.0%)	
Patients (%) Without Events (Censored)	18 (50.0%)	9 (36.0%)	
Median Time to First TEAE, months (95% CI)	4.30 (1.18, NR)	1.08 (0.30, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.590 (0.299, 1.165)	
p-value		0.1255	
No			
Total Patients	88	97	
Patients (%) With Events	33 (37.5%)	50 (51.5%)	
Patients (%) Without Events (Censored)	55 (62.5%)	47 (48.5%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	5.09 (1.64, NR)	
Hazard Ratio (95% CI)		0.567 (0.365, 0.881)	
p-value		0.0113	
History of brain metastasis			0.1299
Yes			
Total Patients	6	7	
Patients (%) With Events	4 (66.7%)	3 (42.9%)	
Patients (%) Without Events (Censored)	2 (33.3%)	4 (57.1%)	
Median Time to First TEAE, months (95% CI)	1.61 (0.76, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		2.036 (0.450, 9.214)	
p-value		0.3463	
No			
Total Patients	118	115	
Patients (%) With Events	47 (39.8%)	63 (54.8%)	
Patients (%) Without Events (Censored)	71 (60.2%)	52 (45.2%)	
Median Time to First TEAE, months (95% CI)	NR (7.85, NR)	3.45 (1.45, 11.76)	
Hazard Ratio (95% CI)		0.570 (0.390, 0.834)	
p-value		0.0035	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.5039
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	19 (44.2%)	27 (52.9%)	
Patients (%) Without Events (Censored)	24 (55.8%)	24 (47.1%)	
Median Time to First TEAE, months (95% CI)	NR (3.06, NR)	7.95 (1.08, NR)	
Hazard Ratio (95% CI)		0.718 (0.399, 1.292)	
p-value		0.2764	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	32 (39.5%)	39 (54.9%)	
Patients (%) Without Events (Censored)	49 (60.5%)	32 (45.1%)	
Median Time to First TEAE, months (95% CI)	15.41 (7.85, NR)	3.45 (0.95, NR)	
Hazard Ratio (95% CI)		0.541 (0.338, 0.867)	
p-value		0.0100	
BRCA 1/2 status			0.4743
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	14 (33.3%)	20 (44.4%)	
Patients (%) Without Events (Censored)	28 (66.7%)	25 (55.6%)	
Median Time to First TEAE, months (95% CI)	NR (5.59, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.594 (0.300, 1.179)	
p-value		0.1371	
Mutant			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	9	7	
Patients (%) With Events	4 (44.4%)	3 (42.9%)	
Patients (%) Without Events (Censored)	5 (55.6%)	4 (57.1%)	
Median Time to First TEAE, months (95% CI)	7.85 (0.23, NR)	NR (0.30, NR)	
Hazard Ratio (95% CI)		1.039 (0.232, 4.649)	
p-value		0.9602	
Menopausal status			0.2385
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	11 (37.9%)	22 (64.7%)	
Patients (%) Without Events (Censored)	18 (62.1%)	12 (35.3%)	
Median Time to First TEAE, months (95% CI)	15.41 (4.30, NR)	1.97 (0.72, 7.16)	
Hazard Ratio (95% CI)		0.408 (0.196, 0.853)	
p-value		0.0142	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	40 (42.1%)	43 (49.4%)	
Patients (%) Without Events (Censored)	55 (57.9%)	44 (50.6%)	
Median Time to First TEAE, months (95% CI)	NR (4.07, NR)	7.95 (1.45, NR)	
Hazard Ratio (95% CI)		0.712 (0.463, 1.097)	
p-value		0.1278	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.16. Table 1.1.12.5: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8231
De novo			
Total Patients	29	26	
Patients (%) With Events	21 (72.4%)	11 (42.3%)	
Patients (%) Without Events (Censored)	8 (27.6%)	15 (57.7%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.49, 1.41)	6.54 (2.43, NR)	
Hazard Ratio (95% CI)		2.650 (1.258, 5.584)	
p-value		0.0083	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	19 (61.3%)	9 (30.0%)	
Patients (%) Without Events (Censored)	12 (38.7%)	21 (70.0%)	
Median Time to First TEAE, months (95% CI)	1.51 (0.72, NR)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.662 (1.199, 5.911)	
p-value		0.0123	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	64	66	
Patients (%) With Events	45 (70.3%)	25 (37.9%)	
Patients (%) Without Events (Censored)	19 (29.7%)	41 (62.1%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.53, 1.12)	NR (5.16, NR)	
Hazard Ratio (95% CI)		3.261 (1.980, 5.373)	
p-value		<0.0001	
Geographic region			0.2751
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	19 (63.3%)	13 (38.2%)	
Patients (%) Without Events (Censored)	11 (36.7%)	21 (61.8%)	
Median Time to First TEAE, months (95% CI)	1.53 (0.76, NR)	6.54 (3.25, NR)	
Hazard Ratio (95% CI)		2.384 (1.170, 4.856)	
p-value		0.0138	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	66 (70.2%)	32 (36.4%)	
Patients (%) Without Events (Censored)	28 (29.8%)	56 (63.6%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.53, 1.12)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		3.174 (2.066, 4.878)	
p-value		<0.0001	
Age group			0.1830
< 65			
Total Patients	98	94	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	71 (72.4%)	32 (34.0%)	
Patients (%) Without Events (Censored)	27 (27.6%)	62 (66.0%)	
Median Time to First TEAE, months (95% CI)	0.84 (0.66, 1.15)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		3.295 (2.160, 5.026)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	14 (53.8%)	13 (46.4%)	
Patients (%) Without Events (Censored)	12 (46.2%)	15 (53.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.46, NR)	17.08 (2.37, NR)	
Hazard Ratio (95% CI)		1.890 (0.876, 4.077)	
p-value		0.1017	
Race			0.9462
White			
Total Patients	80	75	
Patients (%) With Events	53 (66.2%)	24 (32.0%)	
Patients (%) Without Events (Censored)	27 (33.8%)	51 (68.0%)	
Median Time to First TEAE, months (95% CI)	1.05 (0.72, 1.64)	17.08 (17.08, NR)	
Hazard Ratio (95% CI)		3.310 (2.033, 5.388)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	21 (80.8%)	13 (50.0%)	
Patients (%) Without Events (Censored)	5 (19.2%)	13 (50.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.53 (0.39, 0.72)	6.47 (1.74, NR)	
Hazard Ratio (95% CI)		2.659 (1.299, 5.440)	
p-value		0.0062	
Other			
Total Patients	16	21	
Patients (%) With Events	11 (68.8%)	8 (38.1%)	
Patients (%) Without Events (Censored)	5 (31.2%)	13 (61.9%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.46, 15.93)	23.56 (2.37, NR)	
Hazard Ratio (95% CI)		3.123 (1.192, 8.181)	
p-value		0.0151	
Baseline ECOG status			0.9241
0			
Total Patients	81	79	
Patients (%) With Events	58 (71.6%)	31 (39.2%)	
Patients (%) Without Events (Censored)	23 (28.4%)	48 (60.8%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.56, 1.35)	17.08 (6.47, NR)	
Hazard Ratio (95% CI)		2.925 (1.880, 4.550)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	27 (62.8%)	14 (32.6%)	
Patients (%) Without Events (Censored)	16 (37.2%)	29 (67.4%)	
Median Time to First TEAE, months (95% CI)	0.85 (0.66, NR)	NR (3.38, NR)	
Hazard Ratio (95% CI)		2.931 (1.527, 5.628)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0008	
History of liver metastasis			0.6769
Yes			
Total Patients	36	25	
Patients (%) With Events	22 (61.1%)	6 (24.0%)	
Patients (%) Without Events (Censored)	14 (38.9%)	19 (76.0%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.49, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.473 (1.400, 8.611)	
p-value		0.0044	
No			
Total Patients	88	97	
Patients (%) With Events	63 (71.6%)	39 (40.2%)	
Patients (%) Without Events (Censored)	25 (28.4%)	58 (59.8%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 1.15)	17.08 (6.47, NR)	
Hazard Ratio (95% CI)		2.962 (1.975, 4.443)	
p-value		<0.0001	
History of brain metastasis			0.6483
Yes			
Total Patients	6	7	
Patients (%) With Events	3 (50.0%)	2 (28.6%)	
Patients (%) Without Events (Censored)	3 (50.0%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	6.41 (0.13, NR)	NR (0.36, NR)	
Hazard Ratio (95% CI)		1.981 (0.327, 11.999)	
p-value		0.4487	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
No			
Total Patients	118	115	
Patients (%) With Events	82 (69.5%)	43 (37.4%)	
Patients (%) Without Events (Censored)	36 (30.5%)	72 (62.6%)	
Median Time to First TEAE, months (95% CI)	0.85 (0.66, 1.15)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.996 (2.061, 4.355)	
p-value		<0.0001	
PD-L1 Status			0.5146
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	30 (69.8%)	22 (43.1%)	
Patients (%) Without Events (Censored)	13 (30.2%)	29 (56.9%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.43, 1.51)	17.08 (5.09, NR)	
Hazard Ratio (95% CI)		2.485 (1.423, 4.339)	
p-value		0.0010	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	55 (67.9%)	23 (32.4%)	
Patients (%) Without Events (Censored)	26 (32.1%)	48 (67.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.69, 1.41)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.236 (1.978, 5.294)	
p-value		<0.0001	
BRCA 1/2 status			0.5059
Wild-Type			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	42	45	
Patients (%) With Events	29 (69.0%)	17 (37.8%)	
Patients (%) Without Events (Censored)	13 (31.0%)	28 (62.2%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.49, 1.41)	NR (3.48, NR)	
Hazard Ratio (95% CI)		2.711 (1.479, 4.969)	
p-value		0.0009	
Mutant			
Total Patients	9	7	
Patients (%) With Events	6 (66.7%)	5 (71.4%)	
Patients (%) Without Events (Censored)	3 (33.3%)	2 (28.6%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.07, NR)	17.08 (0.07, NR)	
Hazard Ratio (95% CI)		2.356 (0.572, 9.696)	
p-value		0.2182	
Menopausal status			0.4665
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	23 (79.3%)	14 (41.2%)	
Patients (%) Without Events (Censored)	6 (20.7%)	20 (58.8%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.36, 1.41)	23.56 (3.91, NR)	
Hazard Ratio (95% CI)		3.739 (1.851, 7.552)	
p-value		0.0001	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	62 (65.3%)	31 (35.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	33 (34.7%)	56 (64.4%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 1.41)	17.08 (6.54, NR)	
Hazard Ratio (95% CI)		2.780 (1.800, 4.294)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.17. Table 1.1.12.6: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Anaemia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2539
De novo			
Total Patients	29	26	
Patients (%) With Events	11 (37.9%)	16 (61.5%)	
Patients (%) Without Events (Censored)	18 (62.1%)	10 (38.5%)	
Median Time to First TEAE, months (95% CI)	NR (2.86, NR)	2.33 (1.38, 6.47)	
Hazard Ratio (95% CI)		0.468 (0.211, 1.037)	
p-value		0.0553	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	13 (41.9%)	17 (56.7%)	
Patients (%) Without Events (Censored)	18 (58.1%)	13 (43.3%)	
Median Time to First TEAE, months (95% CI)	10.68 (4.90, NR)	4.21 (1.64, NR)	
Hazard Ratio (95% CI)		0.546 (0.262, 1.139)	
p-value		0.1018	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	22 (34.4%)	50 (75.8%)	
Patients (%) Without Events (Censored)	42 (65.6%)	16 (24.2%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.74, NR)	1.87 (0.95, 2.23)	
Hazard Ratio (95% CI)		0.295 (0.177, 0.490)	
p-value		<0.0001	
Geographic region			0.5515
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	7 (23.3%)	19 (55.9%)	
Patients (%) Without Events (Censored)	23 (76.7%)	15 (44.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	3.02 (1.38, NR)	
Hazard Ratio (95% CI)		0.314 (0.131, 0.749)	
p-value		0.0059	
Rest of the world			
Total Patients	94	88	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	39 (41.5%)	64 (72.7%)	
Patients (%) Without Events (Censored)	55 (58.5%)	24 (27.3%)	
Median Time to First TEAE, months (95% CI)	14.49 (9.63, NR)	1.94 (1.61, 2.50)	
Hazard Ratio (95% CI)		0.387 (0.258, 0.581)	
p-value		<0.0001	
Age group			0.2327
< 65			
Total Patients	98	94	
Patients (%) With Events	40 (40.8%)	63 (67.0%)	
Patients (%) Without Events (Censored)	58 (59.2%)	31 (33.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	2.10 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.412 (0.275, 0.616)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	6 (23.1%)	20 (71.4%)	
Patients (%) Without Events (Censored)	20 (76.9%)	8 (28.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	1.68 (0.79, 4.21)	
Hazard Ratio (95% CI)		0.258 (0.103, 0.644)	
p-value		0.0018	
Race			0.6755
White			
Total Patients	80	75	
Patients (%) With Events	31 (38.8%)	52 (69.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	49 (61.2%)	23 (30.7%)	
Median Time to First TEAE, months (95% CI)	NR (5.13, NR)	2.07 (0.95, 2.63)	
Hazard Ratio (95% CI)		0.393 (0.250, 0.616)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	7 (26.9%)	17 (65.4%)	
Patients (%) Without Events (Censored)	19 (73.1%)	9 (34.6%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.10 (1.08, 6.47)	
Hazard Ratio (95% CI)		0.318 (0.130, 0.781)	
p-value		0.0085	
Other			
Total Patients	16	21	
Patients (%) With Events	8 (50.0%)	14 (66.7%)	
Patients (%) Without Events (Censored)	8 (50.0%)	7 (33.3%)	
Median Time to First TEAE, months (95% CI)	10.68 (2.10, NR)	2.27 (1.64, 4.63)	
Hazard Ratio (95% CI)		0.451 (0.185, 1.097)	
p-value		0.0724	
Baseline ECOG status			0.1673
0			
Total Patients	81	79	
Patients (%) With Events	26 (32.1%)	55 (69.6%)	
Patients (%) Without Events (Censored)	55 (67.9%)	24 (30.4%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.10 (1.71, 2.73)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.319 (0.199, 0.510)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	20 (46.5%)	28 (65.1%)	
Patients (%) Without Events (Censored)	23 (53.5%)	15 (34.9%)	
Median Time to First TEAE, months (95% CI)	10.32 (2.33, NR)	2.14 (0.95, 4.21)	
Hazard Ratio (95% CI)		0.461 (0.249, 0.854)	
p-value		0.0119	
History of liver metastasis			0.2212
Yes			
Total Patients	36	25	
Patients (%) With Events	11 (30.6%)	17 (68.0%)	
Patients (%) Without Events (Censored)	25 (69.4%)	8 (32.0%)	
Median Time to First TEAE, months (95% CI)	NR (14.49, NR)	1.63 (0.72, 2.20)	
Hazard Ratio (95% CI)		0.272 (0.123, 0.603)	
p-value		0.0007	
No			
Total Patients	88	97	
Patients (%) With Events	35 (39.8%)	66 (68.0%)	
Patients (%) Without Events (Censored)	53 (60.2%)	31 (32.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (9.63, NR)	2.23 (1.84, 3.02)	
Hazard Ratio (95% CI)		0.420 (0.278, 0.636)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of brain metastasis			0.6888
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	5 (71.4%)	
Patients (%) Without Events (Censored)	4 (66.7%)	2 (28.6%)	
Median Time to First TEAE, months (95% CI)	NR (2.14, NR)	2.10 (0.26, NR)	
Hazard Ratio (95% CI)		0.229 (0.043, 1.235)	
p-value		0.0647	
No			
Total Patients	118	115	
Patients (%) With Events	44 (37.3%)	78 (67.8%)	
Patients (%) Without Events (Censored)	74 (62.7%)	37 (32.2%)	
Median Time to First TEAE, months (95% CI)	NR (10.68, NR)	2.10 (1.64, 2.73)	
Hazard Ratio (95% CI)		0.388 (0.266, 0.564)	
p-value		<0.0001	
PD-L1 Status			0.4088
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	14 (32.6%)	35 (68.6%)	
Patients (%) Without Events (Censored)	29 (67.4%)	16 (31.4%)	
Median Time to First TEAE, months (95% CI)	NR (9.63, NR)	2.10 (0.92, 4.34)	
Hazard Ratio (95% CI)		0.315 (0.168, 0.592)	
p-value		0.0002	
CPS ≥ 1			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	81	71	
Patients (%) With Events	32 (39.5%)	48 (67.6%)	
Patients (%) Without Events (Censored)	49 (60.5%)	23 (32.4%)	
Median Time to First TEAE, months (95% CI)	14.49 (10.32, NR)	2.10 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.424 (0.269, 0.668)	
p-value		0.0001	
Menopausal status			0.9451
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	9 (31.0%)	22 (64.7%)	
Patients (%) Without Events (Censored)	20 (69.0%)	12 (35.3%)	
Median Time to First TEAE, months (95% CI)	NR (3.02, NR)	2.73 (1.64, 6.47)	
Hazard Ratio (95% CI)		0.363 (0.166, 0.790)	
p-value		0.0075	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	37 (38.9%)	60 (69.0%)	
Patients (%) Without Events (Censored)	58 (61.1%)	27 (31.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	2.10 (1.18, 2.50)	
Hazard Ratio (95% CI)		0.388 (0.255, 0.588)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.18. Table 1.1.12.7: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Leukopenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.1055
De novo			
Total Patients	29	26	
Patients (%) With Events	5 (17.2%)	11 (42.3%)	
Patients (%) Without Events (Censored)	24 (82.8%)	15 (57.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	8.18 (4.93, NR)	
Hazard Ratio (95% CI)		0.331 (0.114, 0.961)	
p-value		0.0329	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	14 (45.2%)	10 (33.3%)	
Patients (%) Without Events (Censored)	17 (54.8%)	20 (66.7%)	
Median Time to First TEAE, months (95% CI)	23.66 (0.69, NR)	NR (5.03, NR)	
Hazard Ratio (95% CI)		1.362 (0.604, 3.072)	
p-value		0.4707	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	64	66	
Patients (%) With Events	19 (29.7%)	33 (50.0%)	
Patients (%) Without Events (Censored)	45 (70.3%)	33 (50.0%)	
Median Time to First TEAE, months (95% CI)	29.90 (NR, NR)	7.82 (2.63, NR)	
Hazard Ratio (95% CI)		0.490 (0.276, 0.870)	
p-value		0.0133	
Geographic region			0.2822
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	3 (10.0%)	9 (26.5%)	
Patients (%) Without Events (Censored)	27 (90.0%)	25 (73.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (5.78, NR)	
Hazard Ratio (95% CI)		0.313 (0.084, 1.160)	
p-value		0.0664	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	35 (37.2%)	45 (51.1%)	
Patients (%) Without Events (Censored)	59 (62.8%)	43 (48.9%)	
Median Time to First TEAE, months (95% CI)	29.90 (7.23, NR)	8.18 (3.45, 15.90)	
Hazard Ratio (95% CI)		0.640 (0.409, 1.001)	
p-value		0.0476	
Age group			0.2135
< 65			
Total Patients	98	94	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	29 (29.6%)	44 (46.8%)	
Patients (%) Without Events (Censored)	69 (70.4%)	50 (53.2%)	
Median Time to First TEAE, months (95% CI)	NR (23.66, NR)	8.18 (4.63, NR)	
Hazard Ratio (95% CI)		0.535 (0.334, 0.856)	
p-value		0.0078	
>= 65			
Total Patients	26	28	
Patients (%) With Events	9 (34.6%)	10 (35.7%)	
Patients (%) Without Events (Censored)	17 (65.4%)	18 (64.3%)	
Median Time to First TEAE, months (95% CI)	29.90 (2.92, NR)	12.02 (4.37, NR)	
Hazard Ratio (95% CI)		0.911 (0.358, 2.316)	
p-value		0.8570	
Race			0.8011
White			
Total Patients	80	75	
Patients (%) With Events	23 (28.8%)	35 (46.7%)	
Patients (%) Without Events (Censored)	57 (71.2%)	40 (53.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.47 (3.45, NR)	
Hazard Ratio (95% CI)		0.538 (0.317, 0.912)	
p-value		0.0194	
Asian			
Total Patients	26	26	
Patients (%) With Events	9 (34.6%)	12 (46.2%)	
Patients (%) Without Events (Censored)	17 (65.4%)	14 (53.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (2.27, NR)	9.92 (4.37, NR)	
Hazard Ratio (95% CI)		0.711 (0.299, 1.691)	
p-value		0.4419	
Other			
Total Patients	16	21	
Patients (%) With Events	5 (31.2%)	7 (33.3%)	
Patients (%) Without Events (Censored)	11 (68.8%)	14 (66.7%)	
Median Time to First TEAE, months (95% CI)	23.66 (4.90, NR)	NR (4.93, NR)	
Hazard Ratio (95% CI)		0.619 (0.179, 2.137)	
p-value		0.4478	
Baseline ECOG status			0.7988
0			
Total Patients	81	79	
Patients (%) With Events	26 (32.1%)	38 (48.1%)	
Patients (%) Without Events (Censored)	55 (67.9%)	41 (51.9%)	
Median Time to First TEAE, months (95% CI)	29.90 (29.90, NR)	9.92 (4.93, NR)	
Hazard Ratio (95% CI)		0.583 (0.354, 0.961)	
p-value		0.0322	
1			
Total Patients	43	43	
Patients (%) With Events	12 (27.9%)	16 (37.2%)	
Patients (%) Without Events (Censored)	31 (72.1%)	27 (62.8%)	
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	12.02 (4.37, NR)	
Hazard Ratio (95% CI)		0.643 (0.295, 1.401)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.2576	
History of liver metastasis			0.4176
Yes			
Total Patients	36	25	
Patients (%) With Events	9 (25.0%)	11 (44.0%)	
Patients (%) Without Events (Censored)	27 (75.0%)	14 (56.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	5.03 (1.15, NR)	
Hazard Ratio (95% CI)		0.507 (0.209, 1.231)	
p-value		0.1244	
No			
Total Patients	88	97	
Patients (%) With Events	29 (33.0%)	43 (44.3%)	
Patients (%) Without Events (Censored)	59 (67.0%)	54 (55.7%)	
Median Time to First TEAE, months (95% CI)	29.90 (23.66, NR)	11.47 (6.97, NR)	
Hazard Ratio (95% CI)		0.659 (0.411, 1.056)	
p-value		0.0804	
History of brain metastasis			0.5127
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	4 (57.1%)	
Patients (%) Without Events (Censored)	5 (83.3%)	3 (42.9%)	
Median Time to First TEAE, months (95% CI)	NR (0.23, NR)	3.45 (0.95, NR)	
Hazard Ratio (95% CI)		0.298 (0.033, 2.682)	
p-value		0.2517	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
No			
Total Patients	118	115	
Patients (%) With Events	37 (31.4%)	50 (43.5%)	
Patients (%) Without Events (Censored)	81 (68.6%)	65 (56.5%)	
Median Time to First TEAE, months (95% CI)	29.90 (23.66, NR)	11.47 (6.97, NR)	
Hazard Ratio (95% CI)		0.624 (0.407, 0.956)	
p-value		0.0288	
PD-L1 Status			0.4798
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	10 (23.3%)	21 (41.2%)	
Patients (%) Without Events (Censored)	33 (76.7%)	30 (58.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	15.90 (2.63, NR)	
Hazard Ratio (95% CI)		0.510 (0.240, 1.085)	
p-value		0.0752	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	28 (34.6%)	33 (46.5%)	
Patients (%) Without Events (Censored)	53 (65.4%)	38 (53.5%)	
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	9.92 (5.03, NR)	
Hazard Ratio (95% CI)		0.635 (0.381, 1.058)	
p-value		0.0770	
BRCA 1/2 status			0.4193
Wild-Type			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	42	45	
Patients (%) With Events	10 (23.8%)	13 (28.9%)	
Patients (%) Without Events (Censored)	32 (76.2%)	32 (71.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (9.92, NR)	
Hazard Ratio (95% CI)		0.764 (0.334, 1.746)	
p-value		0.5190	
Mutant			
Total Patients	9	7	
Patients (%) With Events	1 (11.1%)	3 (42.9%)	
Patients (%) Without Events (Censored)	8 (88.9%)	4 (57.1%)	
Median Time to First TEAE, months (95% CI)	NR (0.26, NR)	15.90 (0.76, NR)	
Hazard Ratio (95% CI)		0.348 (0.035, 3.424)	
p-value		0.3448	
Menopausal status			0.0844
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	5 (17.2%)	17 (50.0%)	
Patients (%) Without Events (Censored)	24 (82.8%)	17 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	7.82 (0.95, NR)	
Hazard Ratio (95% CI)		0.294 (0.108, 0.799)	
p-value		0.0108	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	33 (34.7%)	36 (41.4%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	62 (65.3%)	51 (58.6%)	
Median Time to First TEAE, months (95% CI)	29.90 (23.66, NR)	11.47 (5.03, NR)	
Hazard Ratio (95% CI)		0.752 (0.468, 1.208)	
p-value		0.2379	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.19. Table 1.1.12.8: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2733
De novo			
Total Patients	29	26	
Patients (%) With Events	19 (65.5%)	21 (80.8%)	
Patients (%) Without Events (Censored)	10 (34.5%)	5 (19.2%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.43, 7.20)	1.18 (0.85, 2.10)	
Hazard Ratio (95% CI)		0.794 (0.423, 1.491)	
p-value		0.4639	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	25 (80.6%)	26 (86.7%)	
Patients (%) Without Events (Censored)	6 (19.4%)	4 (13.3%)	
Median Time to First TEAE, months (95% CI)	0.69 (0.26, 1.58)	0.79 (0.69, 0.95)	
Hazard Ratio (95% CI)		0.930 (0.531, 1.629)	
p-value		0.7049	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	39 (60.9%)	58 (87.9%)	
Patients (%) Without Events (Censored)	25 (39.1%)	8 (12.1%)	
Median Time to First TEAE, months (95% CI)	2.92 (0.92, 5.09)	0.84 (0.72, 1.15)	
Hazard Ratio (95% CI)		0.481 (0.318, 0.727)	
p-value		0.0004	
Geographic region			0.5495
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	16 (53.3%)	26 (76.5%)	
Patients (%) Without Events (Censored)	14 (46.7%)	8 (23.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.72, NR)	0.94 (0.72, 3.12)	
Hazard Ratio (95% CI)		0.548 (0.290, 1.033)	
p-value		0.0512	
Rest of the world			
Total Patients	94	88	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	67 (71.3%)	79 (89.8%)	
Patients (%) Without Events (Censored)	27 (28.7%)	9 (10.2%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.69, 2.73)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.630 (0.451, 0.880)	
p-value		0.0053	
Age group			0.1660
< 65			
Total Patients	98	94	
Patients (%) With Events	69 (70.4%)	80 (85.1%)	
Patients (%) Without Events (Censored)	29 (29.6%)	14 (14.9%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 2.92)	0.92 (0.72, 1.38)	
Hazard Ratio (95% CI)		0.671 (0.482, 0.935)	
p-value		0.0152	
>= 65			
Total Patients	26	28	
Patients (%) With Events	14 (53.8%)	25 (89.3%)	
Patients (%) Without Events (Censored)	12 (46.2%)	3 (10.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.43, NR)	0.66 (0.26, 0.92)	
Hazard Ratio (95% CI)		0.449 (0.232, 0.867)	
p-value		0.0146	
Race			0.6527
White			
Total Patients	80	75	
Patients (%) With Events	50 (62.5%)	64 (85.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	30 (37.5%)	11 (14.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 4.86)	0.92 (0.72, 1.15)	
Hazard Ratio (95% CI)		0.602 (0.412, 0.879)	
p-value		0.0072	
Asian			
Total Patients	26	26	
Patients (%) With Events	20 (76.9%)	22 (84.6%)	
Patients (%) Without Events (Censored)	6 (23.1%)	4 (15.4%)	
Median Time to First TEAE, months (95% CI)	2.04 (0.56, 4.14)	0.79 (0.26, 1.87)	
Hazard Ratio (95% CI)		0.756 (0.407, 1.403)	
p-value		0.3636	
Other			
Total Patients	16	21	
Patients (%) With Events	12 (75.0%)	19 (90.5%)	
Patients (%) Without Events (Censored)	4 (25.0%)	2 (9.5%)	
Median Time to First TEAE, months (95% CI)	0.80 (0.26, 5.09)	0.95 (0.30, 1.97)	
Hazard Ratio (95% CI)		0.566 (0.257, 1.246)	
p-value		0.1445	
Baseline ECOG status			0.9322
0			
Total Patients	81	79	
Patients (%) With Events	56 (69.1%)	71 (89.9%)	
Patients (%) Without Events (Censored)	25 (30.9%)	8 (10.1%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.69, 3.09)	0.92 (0.72, 0.95)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.613 (0.427, 0.878)	
p-value		0.0058	
1			
Total Patients	43	43	
Patients (%) With Events	27 (62.8%)	34 (79.1%)	
Patients (%) Without Events (Censored)	16 (37.2%)	9 (20.9%)	
Median Time to First TEAE, months (95% CI)	2.60 (0.66, 5.09)	0.92 (0.62, 1.87)	
Hazard Ratio (95% CI)		0.656 (0.394, 1.093)	
p-value		0.0980	
History of liver metastasis			0.3490
Yes			
Total Patients	36	25	
Patients (%) With Events	26 (72.2%)	20 (80.0%)	
Patients (%) Without Events (Censored)	10 (27.8%)	5 (20.0%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.66, 3.09)	0.92 (0.69, 1.64)	
Hazard Ratio (95% CI)		0.775 (0.426, 1.411)	
p-value		0.3993	
No			
Total Patients	88	97	
Patients (%) With Events	57 (64.8%)	85 (87.6%)	
Patients (%) Without Events (Censored)	31 (35.2%)	12 (12.4%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.69, 4.14)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.573 (0.407, 0.807)	
p-value		0.0010	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of brain metastasis			0.9099
Yes			
Total Patients	6	7	
Patients (%) With Events	3 (50.0%)	6 (85.7%)	
Patients (%) Without Events (Censored)	3 (50.0%)	1 (14.3%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.23, NR)	1.64 (0.66, NR)	
Hazard Ratio (95% CI)		0.571 (0.140, 2.335)	
p-value		0.4304	
No			
Total Patients	118	115	
Patients (%) With Events	80 (67.8%)	99 (86.1%)	
Patients (%) Without Events (Censored)	38 (32.2%)	16 (13.9%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 3.09)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.620 (0.459, 0.838)	
p-value		0.0014	
PD-L1 Status			0.3735
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	27 (62.8%)	39 (76.5%)	
Patients (%) Without Events (Censored)	16 (37.2%)	12 (23.5%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.66, 20.34)	0.95 (0.72, 2.07)	
Hazard Ratio (95% CI)		0.718 (0.429, 1.200)	
p-value		0.2016	
CPS ≥ 1			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	81	71	
Patients (%) With Events	56 (69.1%)	66 (93.0%)	
Patients (%) Without Events (Censored)	25 (30.9%)	5 (7.0%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.79)	0.72 (0.62, 0.92)	
Hazard Ratio (95% CI)		0.535 (0.372, 0.770)	
p-value		0.0004	
BRCA 1/2 status			0.2962
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	24 (57.1%)	36 (80.0%)	
Patients (%) Without Events (Censored)	18 (42.9%)	9 (20.0%)	
Median Time to First TEAE, months (95% CI)	2.60 (0.69, NR)	0.89 (0.69, 1.87)	
Hazard Ratio (95% CI)		0.551 (0.324, 0.936)	
p-value		0.0234	
Mutant			
Total Patients	9	7	
Patients (%) With Events	8 (88.9%)	7 (100.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	0 (0.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.23, 5.26)	0.95 (0.26, 2.10)	
Hazard Ratio (95% CI)		0.855 (0.295, 2.477)	
p-value		0.7574	
Menopausal status			0.5335
Pre-menopausal			
Total Patients	29	34	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	19 (65.5%)	28 (82.4%)	
Patients (%) Without Events (Censored)	10 (34.5%)	6 (17.6%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.66, 8.54)	0.95 (0.85, 2.10)	
Hazard Ratio (95% CI)		0.732 (0.406, 1.321)	
p-value		0.2844	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	64 (67.4%)	76 (87.4%)	
Patients (%) Without Events (Censored)	31 (32.6%)	11 (12.6%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.92)	0.76 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.588 (0.418, 0.827)	
p-value		0.0018	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.20. Table 1.1.12.9: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Diarrhoea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.0150
De novo			
Total Patients	29	26	
Patients (%) With Events	16 (55.2%)	8 (30.8%)	
Patients (%) Without Events (Censored)	13 (44.8%)	18 (69.2%)	
Median Time to First TEAE, months (95% CI)	1.74 (0.49, NR)	NR (4.40, NR)	
Hazard Ratio (95% CI)		2.322 (0.987, 5.461)	
p-value		0.0470	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	14 (45.2%)	9 (30.0%)	
Patients (%) Without Events (Censored)	17 (54.8%)	21 (70.0%)	
Median Time to First TEAE, months (95% CI)	NR (1.97, NR)	23.56 (NR, NR)	
Hazard Ratio (95% CI)		1.525 (0.659, 3.531)	
p-value		0.3232	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	41 (64.1%)	11 (16.7%)	
Patients (%) Without Events (Censored)	23 (35.9%)	55 (83.3%)	
Median Time to First TEAE, months (95% CI)	2.50 (0.36, 6.54)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		6.695 (3.331, 13.456)	
p-value		<0.0001	
Geographic region			0.6704

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	21 (70.0%)	8 (23.5%)	
Patients (%) Without Events (Censored)	9 (30.0%)	26 (76.5%)	
Median Time to First TEAE, months (95% CI)	1.97 (0.36, 7.33)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.818 (1.684, 8.657)	
p-value		0.0006	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	50 (53.2%)	20 (22.7%)	
Patients (%) Without Events (Censored)	44 (46.8%)	68 (77.3%)	
Median Time to First TEAE, months (95% CI)	4.90 (1.58, NR)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.160 (1.878, 5.317)	
p-value		<0.0001	
Age group			0.3654
< 65			
Total Patients	98	94	
Patients (%) With Events	55 (56.1%)	21 (22.3%)	
Patients (%) Without Events (Censored)	43 (43.9%)	73 (77.7%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.97, 16.82)	23.56 (20.96, NR)	
Hazard Ratio (95% CI)		3.084 (1.864, 5.105)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	16 (61.5%)	7 (25.0%)	
Patients (%) Without Events (Censored)	10 (38.5%)	21 (75.0%)	
Median Time to First TEAE, months (95% CI)	0.44 (0.30, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.884 (1.933, 12.343)	
p-value		0.0003	
Race			0.5475
White			
Total Patients	80	75	
Patients (%) With Events	46 (57.5%)	14 (18.7%)	
Patients (%) Without Events (Censored)	34 (42.5%)	61 (81.3%)	
Median Time to First TEAE, months (95% CI)	4.70 (1.58, 11.56)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		4.210 (2.272, 7.801)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	12 (46.2%)	7 (26.9%)	
Patients (%) Without Events (Censored)	14 (53.8%)	19 (73.1%)	
Median Time to First TEAE, months (95% CI)	5.39 (0.36, NR)	NR (6.21, NR)	
Hazard Ratio (95% CI)		2.250 (0.880, 5.754)	
p-value		0.0828	
Other			
Total Patients	16	21	
Patients (%) With Events	11 (68.8%)	7 (33.3%)	
Patients (%) Without Events (Censored)	5 (31.2%)	14 (66.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	1.25 (0.26, NR)	23.56 (3.29, NR)	
Hazard Ratio (95% CI)		3.734 (1.368, 10.193)	
p-value		0.0060	
Baseline ECOG status			0.4228
0			
Total Patients	81	79	
Patients (%) With Events	44 (54.3%)	15 (19.0%)	
Patients (%) Without Events (Censored)	37 (45.7%)	64 (81.0%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.25, NR)	30.42 (23.56, NR)	
Hazard Ratio (95% CI)		3.766 (2.091, 6.783)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	27 (62.8%)	13 (30.2%)	
Patients (%) Without Events (Censored)	16 (37.2%)	30 (69.8%)	
Median Time to First TEAE, months (95% CI)	3.25 (0.49, 6.54)	20.96 (NR, NR)	
Hazard Ratio (95% CI)		2.824 (1.453, 5.489)	
p-value		0.0014	
History of liver metastasis			0.6964
Yes			
Total Patients	36	25	
Patients (%) With Events	21 (58.3%)	6 (24.0%)	
Patients (%) Without Events (Censored)	15 (41.7%)	19 (76.0%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.36, NR)	NR (NR, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.844 (1.144, 7.073)	
p-value		0.0187	
No			
Total Patients	88	97	
Patients (%) With Events	50 (56.8%)	22 (22.7%)	
Patients (%) Without Events (Censored)	38 (43.2%)	75 (77.3%)	
Median Time to First TEAE, months (95% CI)	4.57 (2.33, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.673 (2.201, 6.130)	
p-value		<0.0001	
History of brain metastasis			0.5501
Yes			
Total Patients	6	7	
Patients (%) With Events	4 (66.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	2 (33.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	1.61 (0.36, NR)	NR (2.50, NR)	
Hazard Ratio (95% CI)		7.487 (0.821, 68.274)	
p-value		0.0375	
No			
Total Patients	118	115	
Patients (%) With Events	67 (56.8%)	27 (23.5%)	
Patients (%) Without Events (Censored)	51 (43.2%)	88 (76.5%)	
Median Time to First TEAE, months (95% CI)	3.52 (1.25, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.220 (2.056, 5.042)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.5738
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	25 (58.1%)	10 (19.6%)	
Patients (%) Without Events (Censored)	18 (41.9%)	41 (80.4%)	
Median Time to First TEAE, months (95% CI)	3.52 (0.43, NR)	NR (23.56, NR)	
Hazard Ratio (95% CI)		4.014 (1.922, 8.381)	
p-value		0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	46 (56.8%)	18 (25.4%)	
Patients (%) Without Events (Censored)	35 (43.2%)	53 (74.6%)	
Median Time to First TEAE, months (95% CI)	4.53 (1.05, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.099 (1.772, 5.421)	
p-value		<0.0001	
Menopausal status			0.4213
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	15 (51.7%)	9 (26.5%)	
Patients (%) Without Events (Censored)	14 (48.3%)	25 (73.5%)	
Median Time to First TEAE, months (95% CI)	4.53 (0.89, NR)	23.56 (23.56, NR)	
Hazard Ratio (95% CI)		2.664 (1.126, 6.304)	
p-value		0.0202	
Post-menopausal			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	95	87	
Patients (%) With Events	56 (58.9%)	18 (20.7%)	
Patients (%) Without Events (Censored)	39 (41.1%)	69 (79.3%)	
Median Time to First TEAE, months (95% CI)	3.32 (1.02, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.856 (2.263, 6.570)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.21. Table 1.1.12.10: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Nausea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.4748
De novo			
Total Patients	29	26	
Patients (%) With Events	21 (72.4%)	16 (61.5%)	
Patients (%) Without Events (Censored)	8 (27.6%)	10 (38.5%)	
Median Time to First TEAE, months (95% CI)	3.06 (0.13, 4.17)	1.46 (0.30, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.137 (0.588, 2.200)	
p-value		0.6955	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	16 (51.6%)	10 (33.3%)	
Patients (%) Without Events (Censored)	15 (48.4%)	20 (66.7%)	
Median Time to First TEAE, months (95% CI)	9.43 (0.33, NR)	NR (3.25, NR)	
Hazard Ratio (95% CI)		1.709 (0.773, 3.778)	
p-value		0.1771	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	43 (67.2%)	32 (48.5%)	
Patients (%) Without Events (Censored)	21 (32.8%)	34 (51.5%)	
Median Time to First TEAE, months (95% CI)	0.59 (0.26, 5.59)	9.33 (2.04, NR)	
Hazard Ratio (95% CI)		1.910 (1.203, 3.033)	
p-value		0.0051	
Geographic region			0.5423
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	24 (80.0%)	18 (52.9%)	
Patients (%) Without Events (Censored)	6 (20.0%)	16 (47.1%)	
Median Time to First TEAE, months (95% CI)	0.48 (0.16, 4.17)	3.09 (0.95, NR)	
Hazard Ratio (95% CI)		1.832 (0.987, 3.400)	
p-value		0.0509	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	56 (59.6%)	40 (45.5%)	
Patients (%) Without Events (Censored)	38 (40.4%)	48 (54.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.49, 6.47)	9.82 (3.25, NR)	
Hazard Ratio (95% CI)		1.494 (0.994, 2.246)	
p-value		0.0492	
Age group			0.7685
< 65			
Total Patients	98	94	
Patients (%) With Events	65 (66.3%)	46 (48.9%)	
Patients (%) Without Events (Censored)	33 (33.7%)	48 (51.1%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.30, 5.39)	9.23 (2.10, NR)	
Hazard Ratio (95% CI)		1.530 (1.048, 2.234)	
p-value		0.0257	
>= 65			
Total Patients	26	28	
Patients (%) With Events	15 (57.7%)	12 (42.9%)	
Patients (%) Without Events (Censored)	11 (42.3%)	16 (57.1%)	
Median Time to First TEAE, months (95% CI)	2.99 (0.36, NR)	9.82 (3.25, NR)	
Hazard Ratio (95% CI)		1.980 (0.910, 4.311)	
p-value		0.0773	
Race			0.8764
White			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	80	75	
Patients (%) With Events	52 (65.0%)	34 (45.3%)	
Patients (%) Without Events (Censored)	28 (35.0%)	41 (54.7%)	
Median Time to First TEAE, months (95% CI)	2.99 (0.33, 7.20)	9.82 (3.09, NR)	
Hazard Ratio (95% CI)		1.703 (1.104, 2.626)	
p-value		0.0147	
Asian			
Total Patients	26	26	
Patients (%) With Events	14 (53.8%)	11 (42.3%)	
Patients (%) Without Events (Censored)	12 (46.2%)	15 (57.7%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.10, NR)	9.33 (0.10, NR)	
Hazard Ratio (95% CI)		1.282 (0.580, 2.834)	
p-value		0.5232	
Other			
Total Patients	16	21	
Patients (%) With Events	12 (75.0%)	13 (61.9%)	
Patients (%) Without Events (Censored)	4 (25.0%)	8 (38.1%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.13, 5.59)	1.74 (0.13, NR)	
Hazard Ratio (95% CI)		1.430 (0.649, 3.154)	
p-value		0.3680	
Baseline ECOG status			0.2767
0			
Total Patients	81	79	
Patients (%) With Events	52 (64.2%)	35 (44.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	29 (35.8%)	44 (55.7%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.33, 6.47)	15.54 (3.09, NR)	
Hazard Ratio (95% CI)		1.813 (1.180, 2.787)	
p-value		0.0059	
1			
Total Patients	43	43	
Patients (%) With Events	28 (65.1%)	23 (53.5%)	
Patients (%) Without Events (Censored)	15 (34.9%)	20 (46.5%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.30, 7.20)	5.19 (0.76, NR)	
Hazard Ratio (95% CI)		1.241 (0.712, 2.161)	
p-value		0.4295	
History of liver metastasis			0.4680
Yes			
Total Patients	36	25	
Patients (%) With Events	26 (72.2%)	11 (44.0%)	
Patients (%) Without Events (Censored)	10 (27.8%)	14 (56.0%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.10, 3.48)	9.23 (0.33, NR)	
Hazard Ratio (95% CI)		1.957 (0.961, 3.987)	
p-value		0.0574	
No			
Total Patients	88	97	
Patients (%) With Events	54 (61.4%)	47 (48.5%)	
Patients (%) Without Events (Censored)	34 (38.6%)	50 (51.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.99, 7.20)	9.82 (2.73, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.454 (0.982, 2.153)	
p-value		0.0579	
History of brain metastasis			0.1849
Yes			
Total Patients	6	7	
Patients (%) With Events	5 (83.3%)	2 (28.6%)	
Patients (%) Without Events (Censored)	1 (16.7%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	0.31 (0.10, NR)	NR (0.10, NR)	
Hazard Ratio (95% CI)		3.527 (0.610, 20.402)	
p-value		0.1316	
No			
Total Patients	118	115	
Patients (%) With Events	75 (63.6%)	56 (48.7%)	
Patients (%) Without Events (Censored)	43 (36.4%)	59 (51.3%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.36, 5.39)	9.33 (2.43, NR)	
Hazard Ratio (95% CI)		1.511 (1.068, 2.138)	
p-value		0.0181	
PD-L1 Status			0.9273
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	26 (60.5%)	23 (45.1%)	
Patients (%) Without Events (Censored)	17 (39.5%)	28 (54.9%)	
Median Time to First TEAE, months (95% CI)	3.98 (0.20, 18.20)	15.54 (1.08, NR)	
Hazard Ratio (95% CI)		1.511 (0.860, 2.655)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.1516	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	54 (66.7%)	35 (49.3%)	
Patients (%) Without Events (Censored)	27 (33.3%)	36 (50.7%)	
Median Time to First TEAE, months (95% CI)	1.48 (0.33, 4.47)	9.33 (2.10, NR)	
Hazard Ratio (95% CI)		1.624 (1.059, 2.490)	
p-value		0.0227	
BRCA 1/2 status			0.9060
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	25 (59.5%)	21 (46.7%)	
Patients (%) Without Events (Censored)	17 (40.5%)	24 (53.3%)	
Median Time to First TEAE, months (95% CI)	4.17 (0.36, 7.23)	9.33 (2.37, NR)	
Hazard Ratio (95% CI)		1.508 (0.842, 2.702)	
p-value		0.1656	
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	4 (57.1%)	
Patients (%) Without Events (Censored)	4 (44.4%)	3 (42.9%)	
Median Time to First TEAE, months (95% CI)	5.39 (0.03, NR)	15.54 (0.03, NR)	
Hazard Ratio (95% CI)		1.582 (0.370, 6.760)	
p-value		0.5270	
Menopausal status			0.8197

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	22 (75.9%)	20 (58.8%)	
Patients (%) Without Events (Censored)	7 (24.1%)	14 (41.2%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.13, 3.06)	2.10 (0.13, NR)	
Hazard Ratio (95% CI)		1.525 (0.828, 2.808)	
p-value		0.1595	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	58 (61.1%)	37 (42.5%)	
Patients (%) Without Events (Censored)	37 (38.9%)	50 (57.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.49, 7.20)	15.54 (5.19, NR)	
Hazard Ratio (95% CI)		1.694 (1.120, 2.561)	
p-value		0.0116	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.22. Table 1.1.12.11: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alanine aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.6864
De novo			
Total Patients	29	26	
Patients (%) With Events	6 (20.7%)	14 (53.8%)	
Patients (%) Without Events (Censored)	23 (79.3%)	12 (46.2%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	4.14 (0.62, NR)	
Hazard Ratio (95% CI)		0.188 (0.062, 0.573)	
p-value		0.0010	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	7 (22.6%)	15 (50.0%)	
Patients (%) Without Events (Censored)	24 (77.4%)	15 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	7.16 (1.61, NR)	
Hazard Ratio (95% CI)		0.273 (0.106, 0.705)	
p-value		0.0047	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	11 (17.2%)	25 (37.9%)	
Patients (%) Without Events (Censored)	53 (82.8%)	41 (62.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.397 (0.195, 0.808)	
p-value		0.0083	
Geographic region			0.0738

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	2 (6.7%)	14 (41.2%)	
Patients (%) Without Events (Censored)	28 (93.3%)	20 (58.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (1.45, NR)	
Hazard Ratio (95% CI)		0.124 (0.028, 0.556)	
p-value		0.0013	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	22 (23.4%)	40 (45.5%)	
Patients (%) Without Events (Censored)	72 (76.6%)	48 (54.5%)	
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	NR (2.40, NR)	
Hazard Ratio (95% CI)		0.406 (0.241, 0.685)	
p-value		0.0005	
Age group			0.3281
< 65			
Total Patients	98	94	
Patients (%) With Events	23 (23.5%)	46 (48.9%)	
Patients (%) Without Events (Censored)	75 (76.5%)	48 (51.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	7.16 (1.64, NR)	
Hazard Ratio (95% CI)		0.339 (0.204, 0.562)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	1 (3.8%)	8 (28.6%)	
Patients (%) Without Events (Censored)	25 (96.2%)	20 (71.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (2.69, NR)	
Hazard Ratio (95% CI)		0.129 (0.016, 1.032)	
p-value		0.0224	
Race			0.3762
White			
Total Patients	80	75	
Patients (%) With Events	15 (18.8%)	32 (42.7%)	
Patients (%) Without Events (Censored)	65 (81.2%)	43 (57.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.349 (0.189, 0.646)	
p-value		0.0005	
Asian			
Total Patients	26	26	
Patients (%) With Events	6 (23.1%)	10 (38.5%)	
Patients (%) Without Events (Censored)	20 (76.9%)	16 (61.5%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.450 (0.161, 1.256)	
p-value		0.1189	
Other			
Total Patients	16	21	
Patients (%) With Events	2 (12.5%)	12 (57.1%)	
Patients (%) Without Events (Censored)	14 (87.5%)	9 (42.9%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	4.14 (0.92, NR)	
Hazard Ratio (95% CI)		0.130 (0.028, 0.600)	
p-value		0.0025	
Baseline ECOG status			0.1576
0			
Total Patients	81	79	
Patients (%) With Events	15 (18.5%)	40 (50.6%)	
Patients (%) Without Events (Censored)	66 (81.5%)	39 (49.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	7.16 (1.64, NR)	
Hazard Ratio (95% CI)		0.265 (0.146, 0.481)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	9 (20.9%)	14 (32.6%)	
Patients (%) Without Events (Censored)	34 (79.1%)	29 (67.4%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (4.14, NR)	
Hazard Ratio (95% CI)		0.566 (0.244, 1.309)	
p-value		0.1797	
History of liver metastasis			0.8812
Yes			
Total Patients	36	25	
Patients (%) With Events	10 (27.8%)	14 (56.0%)	
Patients (%) Without Events (Censored)	26 (72.2%)	11 (44.0%)	
Median Time to First TEAE, months (95% CI)	NR (5.49, NR)	1.61 (0.33, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.314 (0.137, 0.724)	
p-value		0.0042	
No			
Total Patients	88	97	
Patients (%) With Events	14 (15.9%)	40 (41.2%)	
Patients (%) Without Events (Censored)	74 (84.1%)	57 (58.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.300 (0.163, 0.554)	
p-value		<0.0001	
History of brain metastasis			0.0607
Yes			
Total Patients	6	7	
Patients (%) With Events	3 (50.0%)	2 (28.6%)	
Patients (%) Without Events (Censored)	3 (50.0%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	4.58 (3.48, NR)	NR (0.95, NR)	
Hazard Ratio (95% CI)		1.653 (0.273, 10.030)	
p-value		0.5808	
No			
Total Patients	118	115	
Patients (%) With Events	21 (17.8%)	52 (45.2%)	
Patients (%) Without Events (Censored)	97 (82.2%)	63 (54.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (3.22, NR)	
Hazard Ratio (95% CI)		0.300 (0.180, 0.499)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.2709
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	11 (25.6%)	22 (43.1%)	
Patients (%) Without Events (Censored)	32 (74.4%)	29 (56.9%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	11.76 (1.64, NR)	
Hazard Ratio (95% CI)		0.461 (0.223, 0.955)	
p-value		0.0337	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	13 (16.0%)	32 (45.1%)	
Patients (%) Without Events (Censored)	68 (84.0%)	39 (54.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (2.33, NR)	
Hazard Ratio (95% CI)		0.271 (0.141, 0.519)	
p-value		<0.0001	
Menopausal status			0.9517
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	7 (24.1%)	18 (52.9%)	
Patients (%) Without Events (Censored)	22 (75.9%)	16 (47.1%)	
Median Time to First TEAE, months (95% CI)	15.41 (11.14, NR)	6.01 (1.02, NR)	
Hazard Ratio (95% CI)		0.282 (0.113, 0.704)	
p-value		0.0043	
Post-menopausal			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	95	87	
Patients (%) With Events	17 (17.9%)	35 (40.2%)	
Patients (%) Without Events (Censored)	78 (82.1%)	52 (59.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.354 (0.198, 0.633)	
p-value		0.0003	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.23. Table 1.1.12.12: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Aspartate aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Geographic region			0.4060
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	2 (6.7%)	8 (23.5%)	
Patients (%) Without Events (Censored)	28 (93.3%)	26 (76.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.265 (0.056, 1.251)	
p-value		0.0716	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	21 (22.3%)	35 (39.8%)	
Patients (%) Without Events (Censored)	73 (77.7%)	53 (60.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.458 (0.267, 0.788)	
p-value		0.0040	
Age group			0.3857
< 65			
Total Patients	98	94	
Patients (%) With Events	22 (22.4%)	37 (39.4%)	
Patients (%) Without Events (Censored)	76 (77.6%)	57 (60.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.444 (0.261, 0.754)	
p-value		0.0021	
>= 65			
Total Patients	26	28	
Patients (%) With Events	1 (3.8%)	6 (21.4%)	
Patients (%) Without Events (Censored)	25 (96.2%)	22 (78.6%)	
Median Time to First TEAE, months (95% CI)	NR (7.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.175 (0.021, 1.453)	
p-value		0.0678	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Race			0.6507
White			
Total Patients	80	75	
Patients (%) With Events	15 (18.8%)	23 (30.7%)	
Patients (%) Without Events (Censored)	65 (81.2%)	52 (69.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.516 (0.269, 0.990)	
p-value		0.0432	
Asian			
Total Patients	26	26	
Patients (%) With Events	4 (15.4%)	10 (38.5%)	
Patients (%) Without Events (Censored)	22 (84.6%)	16 (61.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.58, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.299 (0.093, 0.963)	
p-value		0.0324	
Other			
Total Patients	16	21	
Patients (%) With Events	3 (18.8%)	10 (47.6%)	
Patients (%) Without Events (Censored)	13 (81.2%)	11 (52.4%)	
Median Time to First TEAE, months (95% CI)	NR (3.71, NR)	NR (0.99, NR)	
Hazard Ratio (95% CI)		0.320 (0.088, 1.167)	
p-value		0.0686	
Baseline ECOG status			0.1670
0			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	81	79	
Patients (%) With Events	14 (17.3%)	32 (40.5%)	
Patients (%) Without Events (Censored)	67 (82.7%)	47 (59.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (3.48, NR)	
Hazard Ratio (95% CI)		0.345 (0.184, 0.648)	
p-value		0.0005	
1			
Total Patients	43	43	
Patients (%) With Events	9 (20.9%)	11 (25.6%)	
Patients (%) Without Events (Censored)	34 (79.1%)	32 (74.4%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.672 (0.276, 1.637)	
p-value		0.3840	
History of liver metastasis			0.7356
Yes			
Total Patients	36	25	
Patients (%) With Events	9 (25.0%)	12 (48.0%)	
Patients (%) Without Events (Censored)	27 (75.0%)	13 (52.0%)	
Median Time to First TEAE, months (95% CI)	NR (7.72, NR)	NR (0.33, NR)	
Hazard Ratio (95% CI)		0.310 (0.125, 0.765)	
p-value		0.0079	
No			
Total Patients	88	97	
Patients (%) With Events	14 (15.9%)	31 (32.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	74 (84.1%)	66 (68.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.429 (0.228, 0.808)	
p-value		0.0070	
History of brain metastasis			0.1381
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	1 (14.3%)	
Patients (%) Without Events (Censored)	4 (66.7%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	7.97 (3.68, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		2.345 (0.212, 25.955)	
p-value		0.4741	
No			
Total Patients	118	115	
Patients (%) With Events	21 (17.8%)	42 (36.5%)	
Patients (%) Without Events (Censored)	97 (82.2%)	73 (63.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.401 (0.237, 0.677)	
p-value		0.0004	
PD-L1 Status			0.5105
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	10 (23.3%)	18 (35.3%)	
Patients (%) Without Events (Censored)	33 (76.7%)	33 (64.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (3.09, NR)	
Hazard Ratio (95% CI)		0.546 (0.251, 1.184)	
p-value		0.1222	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	13 (16.0%)	25 (35.2%)	
Patients (%) Without Events (Censored)	68 (84.0%)	46 (64.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (7.16, NR)	
Hazard Ratio (95% CI)		0.385 (0.197, 0.754)	
p-value		0.0039	
Menopausal status			0.1786
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	5 (17.2%)	17 (50.0%)	
Patients (%) Without Events (Censored)	24 (82.8%)	17 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (12.58, NR)	7.16 (1.02, NR)	
Hazard Ratio (95% CI)		0.250 (0.091, 0.689)	
p-value		0.0040	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	18 (18.9%)	25 (28.7%)	
Patients (%) Without Events (Censored)	77 (81.1%)	62 (71.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.567 (0.309, 1.041)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0641	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.24. Table 1.1.12.13: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Decreased appetite (SOC: Metabolism and nutrition disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of brain metastasis			0.9999
Yes			
Total Patients	6	7	
Patients (%) With Events	0 (0.0%)	0 (0.0%)	
Patients (%) Without Events (Censored)	6 (100.0%)	7 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		1.0000	
No			
Total Patients	118	115	
Patients (%) With Events	25 (21.2%)	11 (9.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	93 (78.8%)	104 (90.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.189 (1.076, 4.453)	
p-value		0.0266	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.25. Table 1.1.12.14: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Cough (SOC: Respiratory, thoracic and mediastinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Baseline ECOG status			0.9948
0			
Total Patients	81	79	
Patients (%) With Events	22 (27.2%)	10 (12.7%)	
Patients (%) Without Events (Censored)	59 (72.8%)	69 (87.3%)	
Median Time to First TEAE, months (95% CI)	NR (14.23, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.215 (1.046, 4.687)	
p-value		0.0329	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
1			
Total Patients	43	43	
Patients (%) With Events	3 (7.0%)	1 (2.3%)	
Patients (%) Without Events (Censored)	40 (93.0%)	42 (97.7%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.720 (0.169, 17.476)	
p-value		0.6430	
History of brain metastasis			0.8540
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	5 (83.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	NR (2.99, NR)	NR (7.59, NR)	
Hazard Ratio (95% CI)		1.732 (0.108, 27.890)	
p-value		0.6949	
No			
Total Patients	118	115	
Patients (%) With Events	24 (20.3%)	10 (8.7%)	
Patients (%) Without Events (Censored)	94 (79.7%)	105 (91.3%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.170 (1.035, 4.549)	
p-value		0.0355	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.26. Table 1.1.12.15: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alopecia (SOC: Skin and subcutaneous tissue disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8243
De novo			
Total Patients	29	26	
Patients (%) With Events	17 (58.6%)	3 (11.5%)	
Patients (%) Without Events (Censored)	12 (41.4%)	23 (88.5%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.49, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		7.854 (2.286, 26.988)	
p-value		0.0001	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	15 (48.4%)	4 (13.3%)	
Patients (%) Without Events (Censored)	16 (51.6%)	26 (86.7%)	
Median Time to First TEAE, months (95% CI)	NR (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.910 (1.626, 14.831)	
p-value		0.0018	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	36 (56.2%)	11 (16.7%)	
Patients (%) Without Events (Censored)	28 (43.8%)	55 (83.3%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.420 (2.747, 10.695)	
p-value		<0.0001	
Geographic region			0.1477
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	15 (50.0%)	7 (20.6%)	
Patients (%) Without Events (Censored)	15 (50.0%)	27 (79.4%)	
Median Time to First TEAE, months (95% CI)	5.06 (0.85, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.342 (1.358, 8.227)	
p-value		0.0055	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	53 (56.4%)	11 (12.5%)	
Patients (%) Without Events (Censored)	41 (43.6%)	77 (87.5%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		7.043 (3.666, 13.529)	
p-value		<0.0001	
Age group			0.0233
< 65			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	98	94	
Patients (%) With Events	57 (58.2%)	10 (10.6%)	
Patients (%) Without Events (Censored)	41 (41.8%)	84 (89.4%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		8.303 (4.230, 16.299)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	11 (42.3%)	8 (28.6%)	
Patients (%) Without Events (Censored)	15 (57.7%)	20 (71.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.76, NR)	NR (5.45, NR)	
Hazard Ratio (95% CI)		2.452 (0.972, 6.187)	
p-value		0.0513	
Race			0.6344
White			
Total Patients	80	75	
Patients (%) With Events	42 (52.5%)	10 (13.3%)	
Patients (%) Without Events (Censored)	38 (47.5%)	65 (86.7%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.952 (2.978, 11.897)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	18 (69.2%)	4 (15.4%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	8 (30.8%)	22 (84.6%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.49, 1.51)	NR (NR, NR)	
Hazard Ratio (95% CI)		8.111 (2.709, 24.284)	
p-value		<0.0001	
Other			
Total Patients	16	21	
Patients (%) With Events	8 (50.0%)	4 (19.0%)	
Patients (%) Without Events (Censored)	8 (50.0%)	17 (81.0%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.53, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.602 (1.080, 12.015)	
p-value		0.0262	
Baseline ECOG status			0.9691
0			
Total Patients	81	79	
Patients (%) With Events	45 (55.6%)	12 (15.2%)	
Patients (%) Without Events (Censored)	36 (44.4%)	67 (84.8%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.541 (2.923, 10.504)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	23 (53.5%)	6 (14.0%)	
Patients (%) Without Events (Censored)	20 (46.5%)	37 (86.0%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.79, NR)	NR (NR, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		5.909 (2.392, 14.594)	
p-value		<0.0001	
History of liver metastasis			0.1472
Yes			
Total Patients	36	25	
Patients (%) With Events	18 (50.0%)	1 (4.0%)	
Patients (%) Without Events (Censored)	18 (50.0%)	24 (96.0%)	
Median Time to First TEAE, months (95% CI)	5.06 (0.56, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		17.149 (2.285, 128.697)	
p-value		0.0002	
No			
Total Patients	88	97	
Patients (%) With Events	50 (56.8%)	17 (17.5%)	
Patients (%) Without Events (Censored)	38 (43.2%)	80 (82.5%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.79, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.103 (2.932, 8.880)	
p-value		<0.0001	
History of brain metastasis			0.2770
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	5 (83.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	NR (5.06, NR)	NR (2.30, NR)	
Hazard Ratio (95% CI)		1.095 (0.068, 17.564)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.9486	
No			
Total Patients	118	115	
Patients (%) With Events	67 (56.8%)	17 (14.8%)	
Patients (%) Without Events (Censored)	51 (43.2%)	98 (85.2%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.011 (3.520, 10.264)	
p-value		<0.0001	
PD-L1 Status			0.7763
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	28 (65.1%)	10 (19.6%)	
Patients (%) Without Events (Censored)	15 (34.9%)	41 (80.4%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.49, 5.06)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.466 (2.642, 11.310)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	40 (49.4%)	8 (11.3%)	
Patients (%) Without Events (Censored)	41 (50.6%)	63 (88.7%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.268 (2.927, 13.424)	
p-value		<0.0001	
Menopausal status			0.0986

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	19 (65.5%)	3 (8.8%)	
Patients (%) Without Events (Censored)	10 (34.5%)	31 (91.2%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.49, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		12.145 (3.565, 41.377)	
p-value		<0.0001	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	49 (51.6%)	15 (17.2%)	
Patients (%) Without Events (Censored)	46 (48.4%)	72 (82.8%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.437 (2.482, 7.931)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.27. Table 1.1.13: Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Blood and lymphatic system disorders		
Total Patients	124	122
Patients (%) With Events	61 (49.2%)	103 (84.4%)
Patients (%) Without Events (Censored)	63 (50.8%)	19 (15.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	11.17 (2.56, NR)	1.64 (1.05, 2.30)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.449 (0.324, 0.622)
p-value		<0.0001
Anaemia		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	35 (28.7%)
Patients (%) Without Events (Censored)	119 (96.0%)	87 (71.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (11.37, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.119 (0.046, 0.303)
p-value		<0.0001
Leukopenia		
Total Patients	124	122
Patients (%) With Events	11 (8.9%)	31 (25.4%)
Patients (%) Without Events (Censored)	113 (91.1%)	91 (74.6%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (13.63, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.305 (0.153, 0.611)
p-value		0.0004
Neutropenia		
Total Patients	124	122
Patients (%) With Events	54 (43.5%)	89 (73.0%)
Patients (%) Without Events (Censored)	70 (56.5%)	33 (27.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	21.39 (5.09, NR)	2.10 (1.41, 3.02)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.480 (0.340, 0.678)
p-value		<0.0001
Thrombocytopenia		
Total Patients	124	122
Patients (%) With Events	2 (1.6%)	35 (28.7%)
Patients (%) Without Events (Censored)	122 (98.4%)	87 (71.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	17.31 (10.64, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.043 (0.010, 0.178)
p-value		<0.0001
Gastrointestinal disorders		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	23 (18.5%)	6 (4.9%)
Patients (%) Without Events (Censored)	101 (81.5%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (26.97, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.007 (1.629, 9.855)
p-value		0.0011
Diarrhoea		
Total Patients	124	122
Patients (%) With Events	14 (11.3%)	3 (2.5%)
Patients (%) Without Events (Censored)	110 (88.7%)	119 (97.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (26.97, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.837 (1.387, 16.870)
p-value		0.0063
General disorders and administration site conditions		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	8 (6.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		1.062 (0.414, 2.719)
p-value		0.8998
Fatigue		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	6 (4.9%)
Patients (%) Without Events (Censored)	118 (95.2%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.830 (0.264, 2.606)
p-value		0.7496
Infections and infestations		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	12 (9.8%)
Patients (%) Without Events (Censored)	109 (87.9%)	110 (90.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (28.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.173 (0.548, 2.512)
p-value		0.6819
Investigations		
Total Patients	124	122
Patients (%) With Events	4 (3.2%)	17 (13.9%)
Patients (%) Without Events (Censored)	120 (96.8%)	105 (86.1%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.218 (0.073, 0.647)
p-value		0.0026
Alanine aminotransferase increased		
Total Patients	124	122
Patients (%) With Events	3 (2.4%)	13 (10.7%)
Patients (%) Without Events (Censored)	121 (97.6%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.213 (0.061, 0.748)
p-value		0.0079
Metabolism and nutrition disorders		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	6 (4.9%)
Patients (%) Without Events (Censored)	116 (93.5%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.092 (0.376, 3.173)
p-value		0.8713
Respiratory, thoracic and mediastinal disorders		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	7 (5.7%)
Patients (%) Without Events (Censored)	115 (92.7%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.216 (0.452, 3.270)
p-value		0.6979

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.28. Table 1.1.14.1: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.4034
De novo			
Total Patients	29	26	
Patients (%) With Events	15 (51.7%)	22 (84.6%)	
Patients (%) Without Events (Censored)	14 (48.3%)	4 (15.4%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (0.49, NR)	1.84 (0.85, 3.09)	
Hazard Ratio (95% CI)		0.529 (0.269, 1.038)	
p-value		0.0576	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	20 (64.5%)	27 (90.0%)	
Patients (%) Without Events (Censored)	11 (35.5%)	3 (10.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.49, 23.66)	1.07 (0.92, 1.87)	
Hazard Ratio (95% CI)		0.663 (0.364, 1.207)	
p-value		0.1597	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	26 (40.6%)	54 (81.8%)	
Patients (%) Without Events (Censored)	38 (59.4%)	12 (18.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (5.09, NR)	2.10 (1.25, 3.02)	
Hazard Ratio (95% CI)		0.334 (0.206, 0.541)	
p-value		<0.0001	
Geographic region			0.9998
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	13 (43.3%)	26 (76.5%)	
Patients (%) Without Events (Censored)	17 (56.7%)	8 (23.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (0.95, NR)	1.76 (0.92, 3.12)	
Hazard Ratio (95% CI)		0.474 (0.242, 0.928)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0235	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	48 (51.1%)	77 (87.5%)	
Patients (%) Without Events (Censored)	46 (48.9%)	11 (12.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (1.71, NR)	1.64 (0.95, 2.30)	
Hazard Ratio (95% CI)		0.445 (0.306, 0.647)	
p-value		<0.0001	
Age group			0.0793
< 65			
Total Patients	98	94	
Patients (%) With Events	46 (46.9%)	80 (85.1%)	
Patients (%) Without Events (Censored)	52 (53.1%)	14 (14.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (2.92, NR)	1.64 (0.95, 2.27)	
Hazard Ratio (95% CI)		0.394 (0.270, 0.574)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	15 (57.7%)	23 (82.1%)	
Patients (%) Without Events (Censored)	11 (42.3%)	5 (17.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.49, NR)	2.40 (0.92, 4.27)	
Hazard Ratio (95% CI)		0.759 (0.395, 1.460)	
p-value		0.3964	
Race			0.0572

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
White			
Total Patients	80	75	
Patients (%) With Events	31 (38.8%)	62 (82.7%)	
Patients (%) Without Events (Censored)	49 (61.2%)	13 (17.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.17, NR)	1.61 (0.95, 2.33)	
Hazard Ratio (95% CI)		0.349 (0.225, 0.542)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	18 (69.2%)	21 (80.8%)	
Patients (%) Without Events (Censored)	8 (30.8%)	5 (19.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.92 (0.49, 11.24)	1.87 (0.92, 3.45)	
Hazard Ratio (95% CI)		0.779 (0.408, 1.488)	
p-value		0.4255	
Other			
Total Patients	16	21	
Patients (%) With Events	11 (68.8%)	20 (95.2%)	
Patients (%) Without Events (Censored)	5 (31.2%)	1 (4.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.03 (0.30, NR)	0.99 (0.85, 4.27)	
Hazard Ratio (95% CI)		0.582 (0.266, 1.276)	
p-value		0.1673	
Baseline ECOG status			0.8155
0			
Total Patients	81	79	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	41 (50.6%)	70 (88.6%)	
Patients (%) Without Events (Censored)	40 (49.4%)	9 (11.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (0.99, NR)	1.84 (1.05, 2.37)	
Hazard Ratio (95% CI)		0.468 (0.316, 0.695)	
p-value		0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	20 (46.5%)	33 (76.7%)	
Patients (%) Without Events (Censored)	23 (53.5%)	10 (23.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (2.56, NR)	1.64 (0.92, 3.02)	
Hazard Ratio (95% CI)		0.406 (0.223, 0.738)	
p-value		0.0021	
History of liver metastasis			0.7823
Yes			
Total Patients	36	25	
Patients (%) With Events	18 (50.0%)	21 (84.0%)	
Patients (%) Without Events (Censored)	18 (50.0%)	4 (16.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (0.89, NR)	1.41 (0.92, 2.33)	
Hazard Ratio (95% CI)		0.455 (0.236, 0.876)	
p-value		0.0155	
No			
Total Patients	88	97	
Patients (%) With Events	43 (48.9%)	82 (84.5%)	
Patients (%) Without Events (Censored)	45 (51.1%)	15 (15.5%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (2.56, NR)	1.87 (1.15, 2.50)	
Hazard Ratio (95% CI)		0.439 (0.300, 0.642)	
p-value		<0.0001	
History of brain metastasis			0.9417
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	5 (71.4%)	
Patients (%) Without Events (Censored)	4 (66.7%)	2 (28.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.43, NR)	2.10 (0.66, NR)	
Hazard Ratio (95% CI)		0.462 (0.088, 2.412)	
p-value		0.3481	
No			
Total Patients	118	115	
Patients (%) With Events	59 (50.0%)	98 (85.2%)	
Patients (%) Without Events (Censored)	59 (50.0%)	17 (14.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (1.77, NR)	1.64 (0.95, 2.30)	
Hazard Ratio (95% CI)		0.450 (0.322, 0.627)	
p-value		<0.0001	
PD-L1 Status			0.5393
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	19 (44.2%)	37 (72.5%)	
Patients (%) Without Events (Censored)	24 (55.8%)	14 (27.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.95, NR)	2.17 (1.18, 3.48)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.553 (0.316, 0.970)	
p-value		0.0349	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	42 (51.9%)	66 (93.0%)	
Patients (%) Without Events (Censored)	39 (48.1%)	5 (7.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (1.71, 23.66)	1.64 (0.92, 2.10)	
Hazard Ratio (95% CI)		0.381 (0.254, 0.571)	
p-value		<0.0001	
BRCA 1/2 status			0.6461
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	21 (50.0%)	35 (77.8%)	
Patients (%) Without Events (Censored)	21 (50.0%)	10 (22.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (0.89, NR)	1.18 (0.72, 2.10)	
Hazard Ratio (95% CI)		0.490 (0.282, 0.854)	
p-value		0.0094	
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	7 (100.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	0 (0.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (0.23, NR)	2.33 (0.95, 4.63)	
Hazard Ratio (95% CI)		0.487 (0.141, 1.690)	
p-value		0.2549	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Menopausal status			0.5772
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	12 (41.4%)	30 (88.2%)	
Patients (%) Without Events (Censored)	17 (58.6%)	4 (11.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.69, NR)	1.84 (0.92, 3.02)	
Hazard Ratio (95% CI)		0.401 (0.202, 0.793)	
p-value		0.0058	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	49 (51.6%)	73 (83.9%)	
Patients (%) Without Events (Censored)	46 (48.4%)	14 (16.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (1.77, 23.66)	1.64 (0.95, 2.50)	
Hazard Ratio (95% CI)		0.458 (0.315, 0.665)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.29. Table 1.1.14.2: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Leukopenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of brain metastasis			0.3136
Yes			
Total Patients	6	7	
Patients (%) With Events	0 (0.0%)	2 (28.6%)	
Patients (%) Without Events (Censored)	6 (100.0%)	5 (71.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.1761	
No			
Total Patients	118	115	
Patients (%) With Events	11 (9.3%)	29 (25.2%)	
Patients (%) Without Events (Censored)	107 (90.7%)	86 (74.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (13.63, NR)	
Hazard Ratio (95% CI)		0.323 (0.160, 0.650)	
p-value		0.0009	
Menopausal status			0.1746
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	1 (3.4%)	10 (29.4%)	
Patients (%) Without Events (Censored)	28 (96.6%)	24 (70.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (15.08, NR)	NR (7.66, NR)	
Hazard Ratio (95% CI)		0.085 (0.011, 0.675)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0034	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	10 (10.5%)	21 (24.1%)	
Patients (%) Without Events (Censored)	85 (89.5%)	66 (75.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (28.25, NR)	
Hazard Ratio (95% CI)		0.399 (0.187, 0.852)	
p-value		0.0140	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.30. Table 1.1.14.3: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.3538
De novo			
Total Patients	29	26	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	13 (44.8%)	17 (65.4%)	
Patients (%) Without Events (Censored)	16 (55.2%)	9 (34.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (0.69, NR)	2.33 (0.95, 4.63)	
Hazard Ratio (95% CI)		0.671 (0.324, 1.391)	
p-value		0.2713	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	18 (58.1%)	23 (76.7%)	
Patients (%) Without Events (Censored)	13 (41.9%)	7 (23.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.69, NR)	1.07 (0.92, 2.37)	
Hazard Ratio (95% CI)		0.683 (0.362, 1.289)	
p-value		0.2211	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	23 (35.9%)	49 (74.2%)	
Patients (%) Without Events (Censored)	41 (64.1%)	17 (25.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (6.28, NR)	2.50 (1.61, 3.22)	
Hazard Ratio (95% CI)		0.348 (0.210, 0.576)	
p-value		<0.0001	
Geographic region			0.7510
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	11 (36.7%)	22 (64.7%)	
Patients (%) Without Events (Censored)	19 (63.3%)	12 (35.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (1.38, NR)	2.10 (0.92, 5.82)	
Hazard Ratio (95% CI)		0.455 (0.219, 0.944)	
p-value		0.0269	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	43 (45.7%)	67 (76.1%)	
Patients (%) Without Events (Censored)	51 (54.3%)	21 (23.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.34, NR)	2.10 (1.25, 3.02)	
Hazard Ratio (95% CI)		0.490 (0.331, 0.726)	
p-value		0.0003	
Age group			0.1168
< 65			
Total Patients	98	94	
Patients (%) With Events	41 (41.8%)	69 (73.4%)	
Patients (%) Without Events (Censored)	57 (58.2%)	25 (26.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	23.66 (6.28, NR)	2.10 (1.15, 3.02)	
Hazard Ratio (95% CI)		0.422 (0.283, 0.628)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	13 (50.0%)	20 (71.4%)	
Patients (%) Without Events (Censored)	13 (50.0%)	8 (28.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	5.09 (0.66, NR)	2.66 (1.05, 8.48)	
Hazard Ratio (95% CI)		0.795 (0.394, 1.603)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.5109	
Race			0.0604
White			
Total Patients	80	75	
Patients (%) With Events	27 (33.8%)	54 (72.0%)	
Patients (%) Without Events (Censored)	53 (66.2%)	21 (28.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (11.17, NR)	1.87 (1.15, 2.99)	
Hazard Ratio (95% CI)		0.361 (0.226, 0.578)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	16 (61.5%)	18 (69.2%)	
Patients (%) Without Events (Censored)	10 (38.5%)	8 (30.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	4.34 (0.56, 11.24)	3.02 (1.64, 5.78)	
Hazard Ratio (95% CI)		0.846 (0.425, 1.685)	
p-value		0.6196	
Other			
Total Patients	16	21	
Patients (%) With Events	10 (62.5%)	17 (81.0%)	
Patients (%) Without Events (Censored)	6 (37.5%)	4 (19.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.24 (0.43, NR)	2.30 (0.89, 4.93)	
Hazard Ratio (95% CI)		0.692 (0.306, 1.568)	
p-value		0.3698	
Baseline ECOG status			0.9495

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
0			
Total Patients	81	79	
Patients (%) With Events	36 (44.4%)	61 (77.2%)	
Patients (%) Without Events (Censored)	45 (55.6%)	18 (22.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (4.14, NR)	2.30 (1.18, 3.02)	
Hazard Ratio (95% CI)		0.485 (0.320, 0.737)	
p-value		0.0005	
1			
Total Patients	43	43	
Patients (%) With Events	18 (41.9%)	28 (65.1%)	
Patients (%) Without Events (Censored)	25 (58.1%)	15 (34.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.86, NR)	2.10 (0.95, 4.27)	
Hazard Ratio (95% CI)		0.467 (0.250, 0.874)	
p-value		0.0141	
History of liver metastasis			0.9741
Yes			
Total Patients	36	25	
Patients (%) With Events	15 (41.7%)	16 (64.0%)	
Patients (%) Without Events (Censored)	21 (58.3%)	9 (36.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.61, NR)	1.86 (0.92, 3.12)	
Hazard Ratio (95% CI)		0.537 (0.262, 1.102)	
p-value		0.0856	
No			
Total Patients	88	97	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	39 (44.3%)	73 (75.3%)	
Patients (%) Without Events (Censored)	49 (55.7%)	24 (24.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.86, NR)	2.27 (1.25, 3.22)	
Hazard Ratio (95% CI)		0.470 (0.316, 0.698)	
p-value		0.0001	
History of brain metastasis			0.3220
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	5 (71.4%)	
Patients (%) Without Events (Censored)	5 (83.3%)	2 (28.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.58, NR)	2.50 (0.66, NR)	
Hazard Ratio (95% CI)		0.187 (0.022, 1.609)	
p-value		0.0877	
No			
Total Patients	118	115	
Patients (%) With Events	53 (44.9%)	84 (73.0%)	
Patients (%) Without Events (Censored)	65 (55.1%)	31 (27.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.86, NR)	2.10 (1.18, 3.02)	
Hazard Ratio (95% CI)		0.499 (0.351, 0.709)	
p-value		0.0001	
PD-L1 Status			0.4986
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	17 (39.5%)	32 (62.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	26 (60.5%)	19 (37.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.61, NR)	2.99 (1.61, 5.78)	
Hazard Ratio (95% CI)		0.589 (0.324, 1.071)	
p-value		0.0777	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	37 (45.7%)	57 (80.3%)	
Patients (%) Without Events (Censored)	44 (54.3%)	14 (19.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.86, NR)	1.87 (0.95, 2.53)	
Hazard Ratio (95% CI)		0.414 (0.270, 0.635)	
p-value		<0.0001	
BRCA 1/2 status			0.7854
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	19 (45.2%)	31 (68.9%)	
Patients (%) Without Events (Censored)	23 (54.8%)	14 (31.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.95, NR)	1.87 (0.92, 3.48)	
Hazard Ratio (95% CI)		0.539 (0.302, 0.960)	
p-value		0.0313	
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	7 (100.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	0 (0.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (0.23, NR)	2.33 (0.95, 4.63)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.487 (0.141, 1.690)	
p-value		0.2549	
Menopausal status			0.6940
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	12 (41.4%)	24 (70.6%)	
Patients (%) Without Events (Censored)	17 (58.6%)	10 (29.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.69, NR)	2.30 (0.95, 4.40)	
Hazard Ratio (95% CI)		0.602 (0.299, 1.209)	
p-value		0.1397	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	42 (44.2%)	65 (74.7%)	
Patients (%) Without Events (Censored)	53 (55.8%)	22 (25.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (5.09, NR)	1.87 (1.15, 3.02)	
Hazard Ratio (95% CI)		0.446 (0.300, 0.662)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.31. Table 1.1.15: Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Blood and lymphatic system disorders		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	20 (16.4%)
Patients (%) Without Events (Censored)	114 (91.9%)	102 (83.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	31.47 (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.476 (0.223, 1.019)
p-value		0.0500
Neutropenia		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	8 (6.6%)
Patients (%) Without Events (Censored)	119 (96.0%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.616 (0.201, 1.882)
p-value		0.3893
Thrombocytopenia		
Total Patients	124	122
Patients (%) With Events	0 (0.0%)	10 (8.2%)
Patients (%) Without Events (Censored)	124 (100.0%)	112 (91.8%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0012
Gastrointestinal disorders		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	2 (1.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	120 (98.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.799 (1.050, 21.933)
p-value		0.0254
Infections and infestations		
Total Patients	124	122
Patients (%) With Events	16 (12.9%)	12 (9.8%)
Patients (%) Without Events (Censored)	108 (87.1%)	110 (90.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (28.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.264 (0.597, 2.679)
p-value		0.5400
Respiratory, thoracic and mediastinal disorders		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	5 (4.1%)
Patients (%) Without Events (Censored)	117 (94.4%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.316 (0.417, 4.155)
p-value		0.6391

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.32. Table 1.1.16: Subgroup Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

No Eligible Subgroups

6.33. Table 1.1.17: Incidence of TEAE leading to Study Drug Discontinuation by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Number (%) of Participants with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	5 (4.0%)	23 (18.9%)
Blood and lymphatic system disorders	1 (0.8%)	14 (11.5%)

	SG (N=124)	TPC (N=122)
Thrombocytopenia	0	9 (7.4%)
Neutropenia	0	3 (2.5%)
Anaemia	0	2 (1.6%)
Febrile neutropenia	1 (0.8%)	0
Cardiac disorders	0	1 (0.8%)
Cardiac failure congestive	0	1 (0.8%)
Gastrointestinal disorders	1 (0.8%)	0
Neutropenic colitis	1 (0.8%)	0
General disorders and administration site conditions	0	1 (0.8%)
Fatigue	0	1 (0.8%)
Hepatobiliary disorders	0	1 (0.8%)
Hypertransaminasaemia	0	1 (0.8%)
Immune system disorders	0	2 (1.6%)
Hypersensitivity	0	2 (1.6%)
Injury, poisoning and procedural complications	1 (0.8%)	2 (1.6%)
Infusion related reaction	1 (0.8%)	2 (1.6%)
Psychiatric disorders	0	1 (0.8%)
Panic attack	0	1 (0.8%)
Respiratory, thoracic and mediastinal disorders	2 (1.6%)	1 (0.8%)
Interstitial lung disease	1 (0.8%)	0
Pneumonitis	1 (0.8%)	0

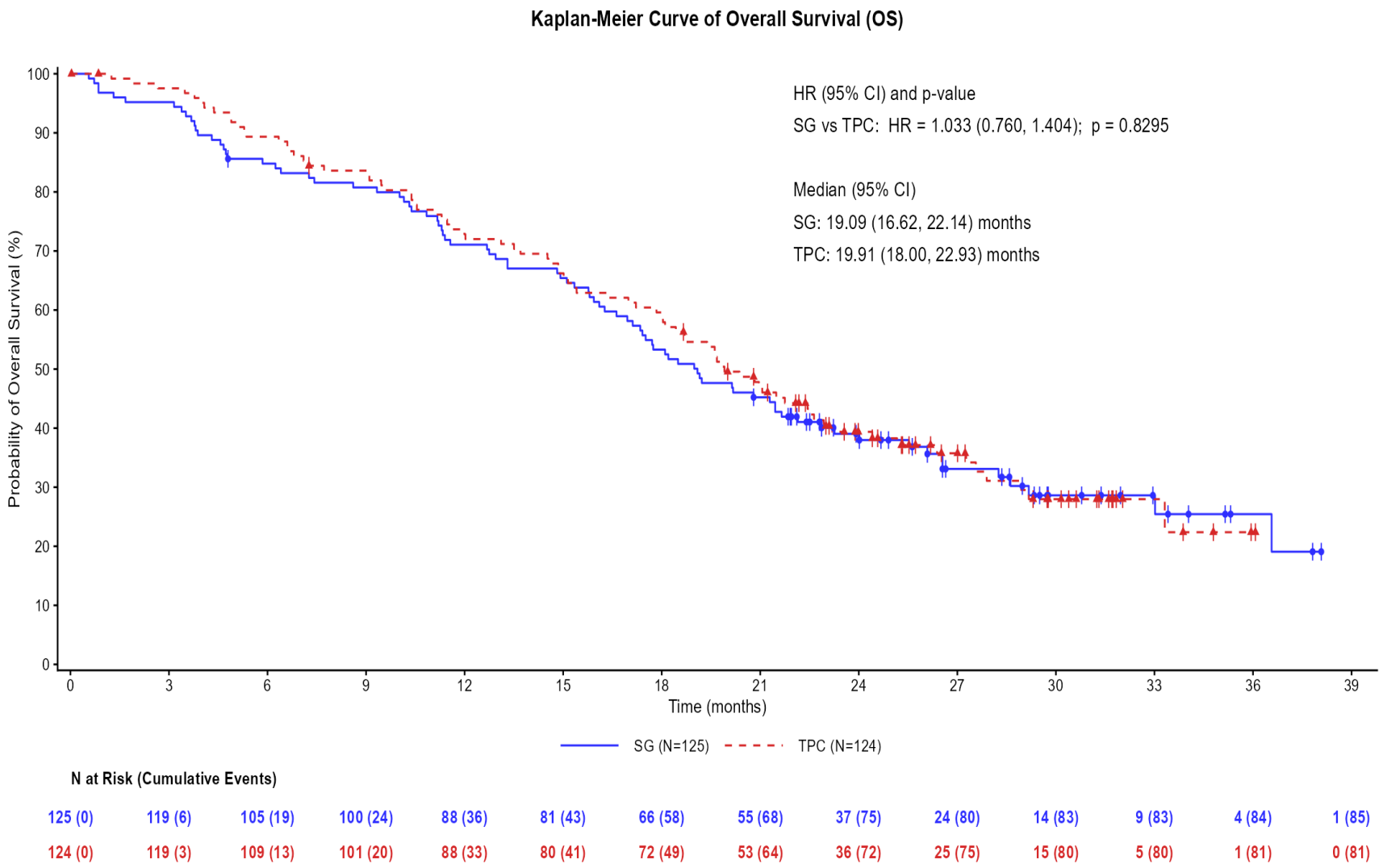
	SG (N=124)	TPC (N=122)
Pulmonary embolism	0	1 (0.8%)
Skin and subcutaneous tissue disorders	0	1 (0.8%)
Eczema	0	1 (0.8%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Adverse events were coded according to MedDRA Version 27.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

7. KM FIGURES — Efficacy

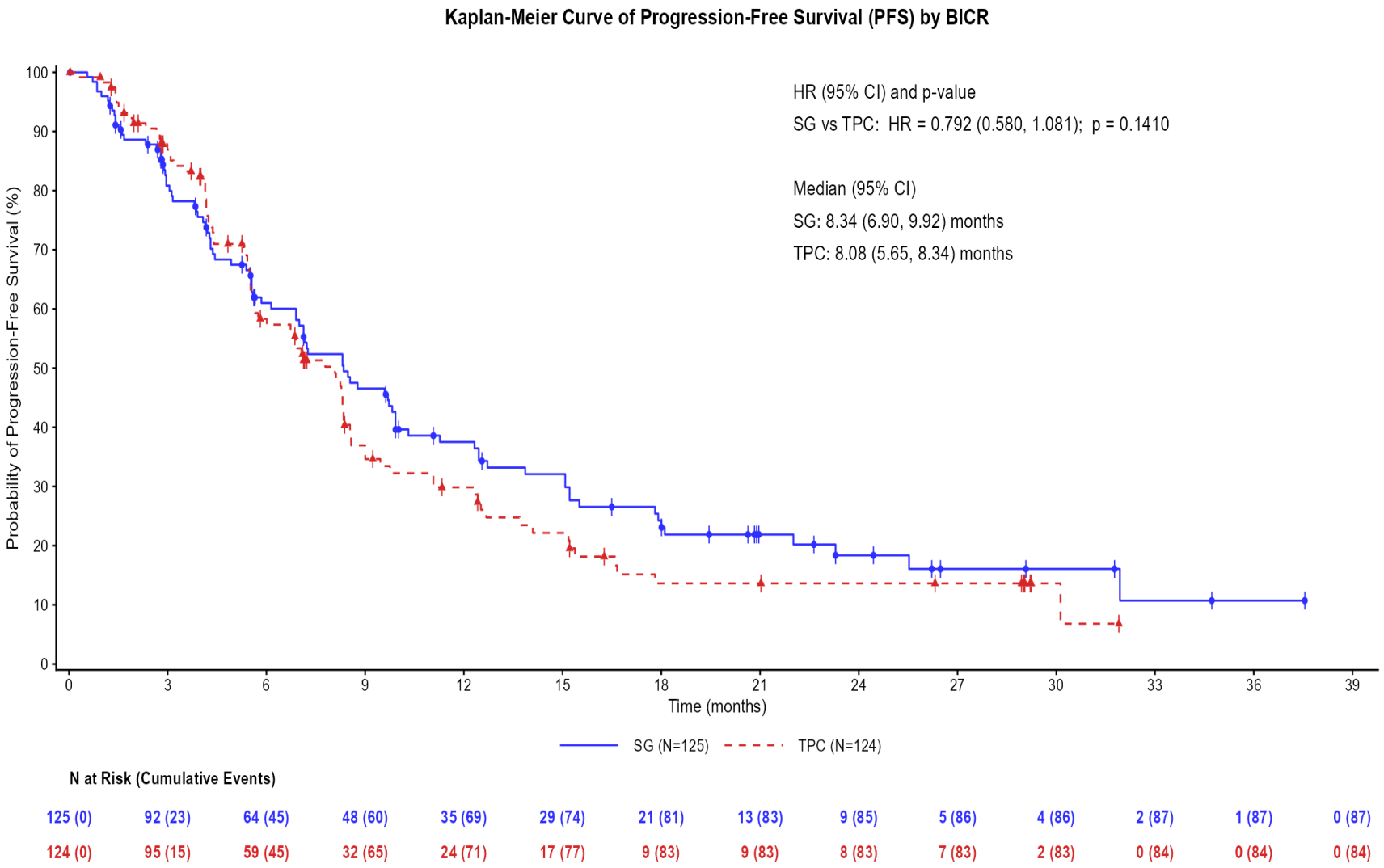
7.1. mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

7.2. Figure 1.1.1: Kaplan-Meier Curve of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



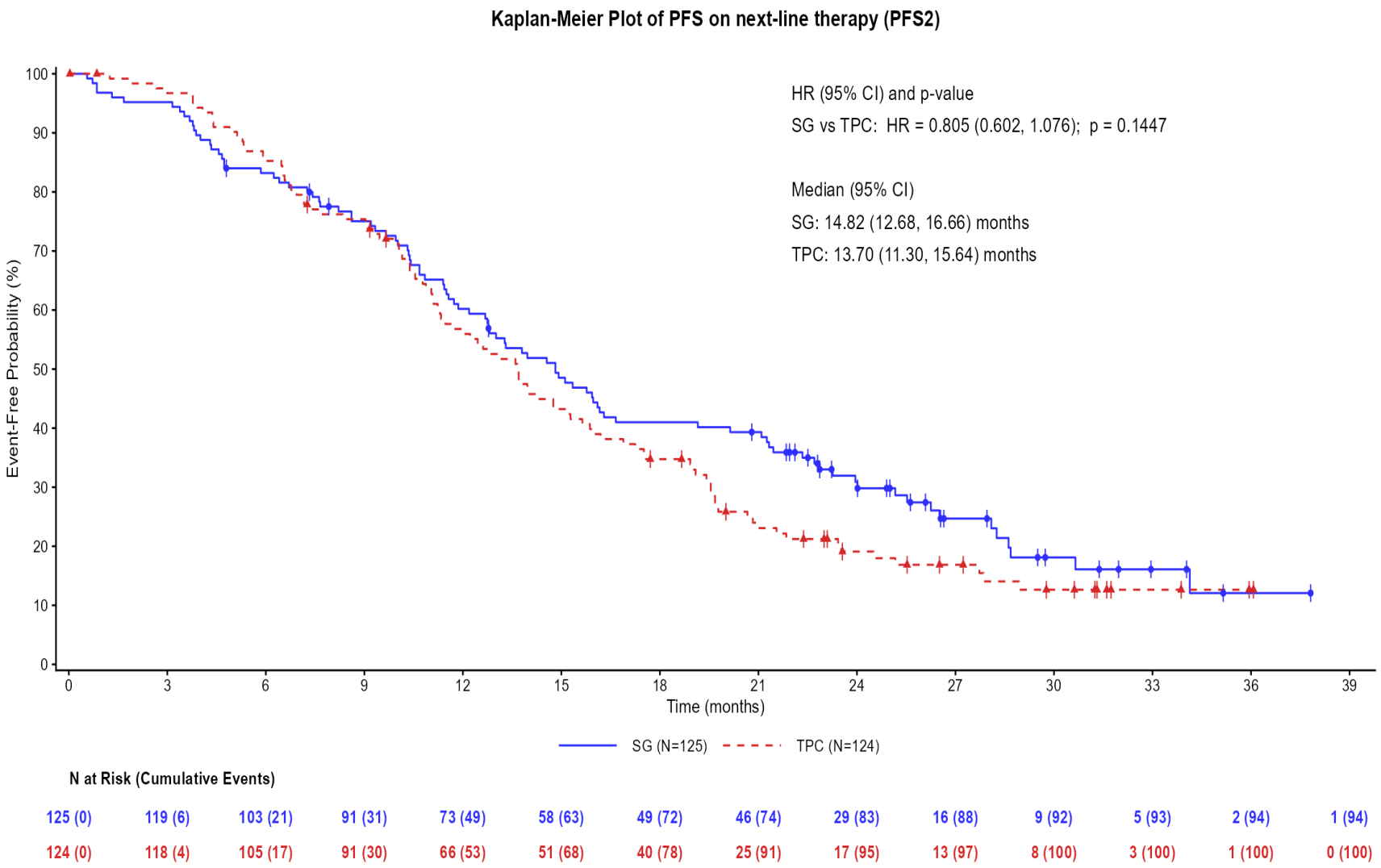
Two-sided p-value from the log-rank test stratified by the randomization stratification factors (STRAT1, STRAT2) from IWRS; hazard ratio from a Cox model adjusted for the same factors as covariates. SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.3. Figure 1.1.2: Kaplan-Meier Curve of Progression-Free Survival (PFS) by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



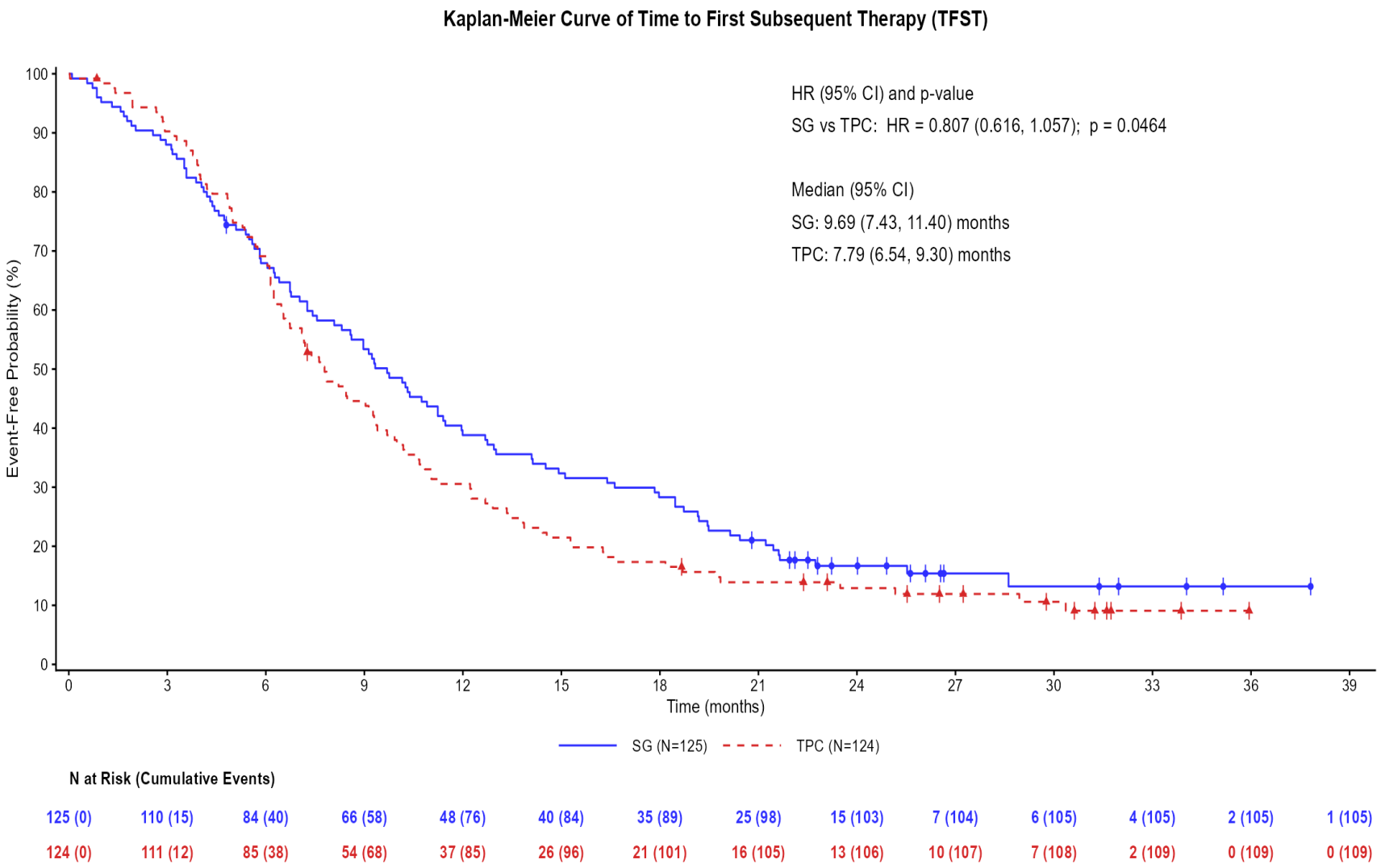
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.4. Figure 1.1.3: Kaplan-Meier Plot of PFS on next-line therapy (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.5. Figure 1.1.4: Kaplan-Meier Curve of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

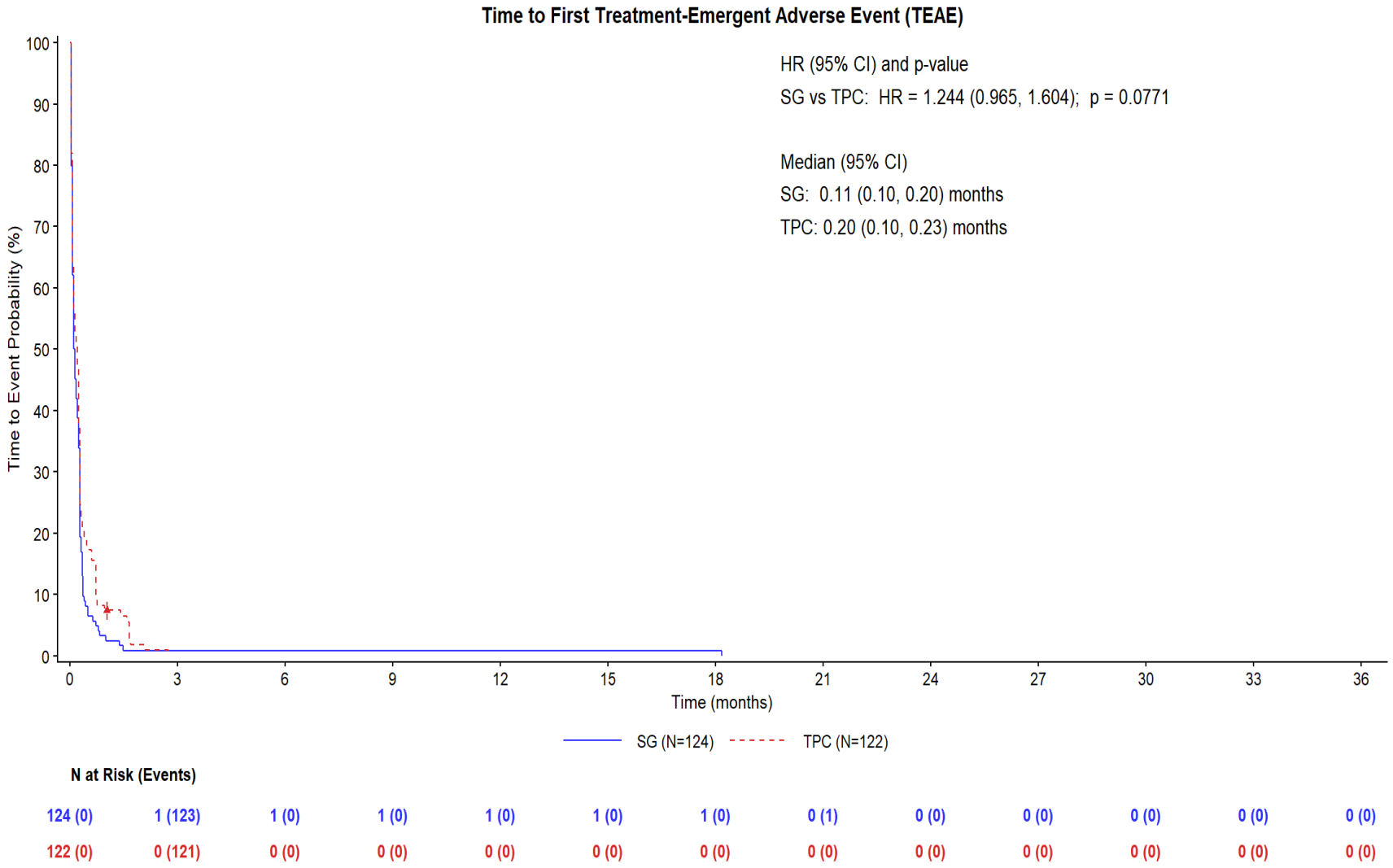


Two-sided p-value from the log-rank test stratified by the randomization stratification factors (STRAT1, STRAT2) from IWRS; hazard ratio from a Cox model adjusted for the same factors as covariates. SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

8. KM FIGURES — Safety

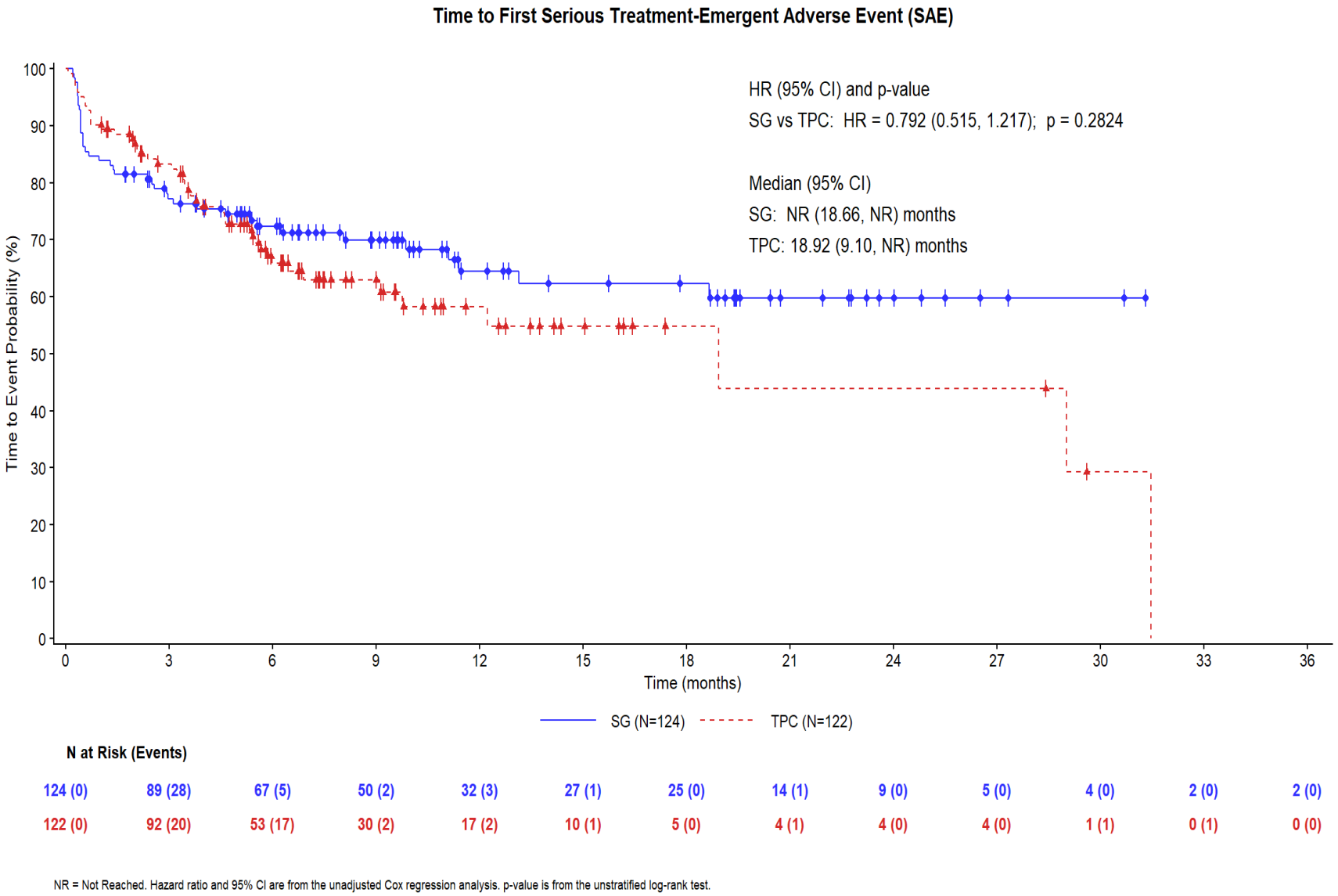
8.1. mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

8.2. Figure 1.1.1: Kaplan Meier Plot of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



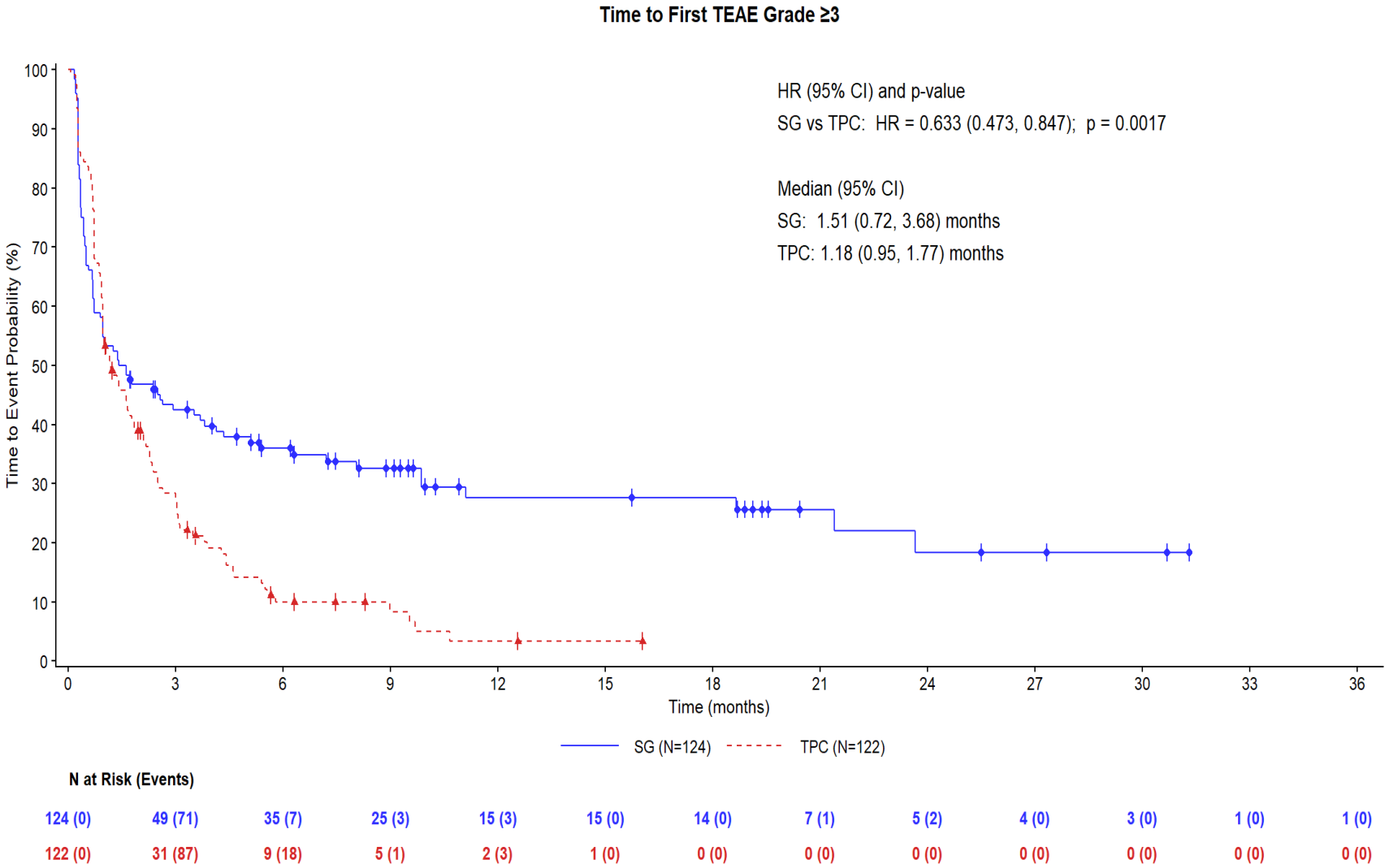
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.3. Figure 1.1.2: Kaplan Meier Plot of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



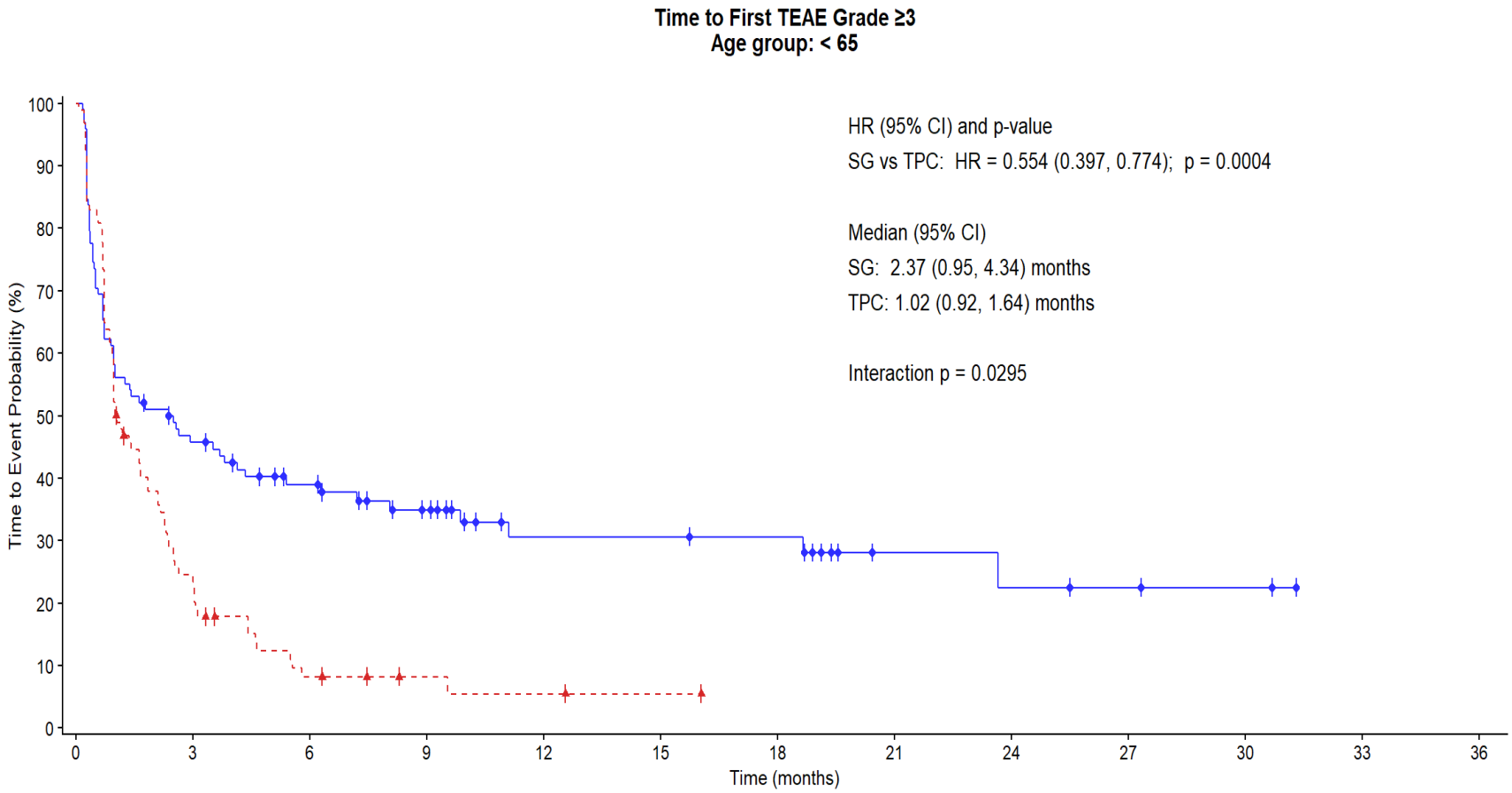
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.4. Figure 1.1.3: Kaplan Meier Plot of Time to First TEAE Grade 3 or higher — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



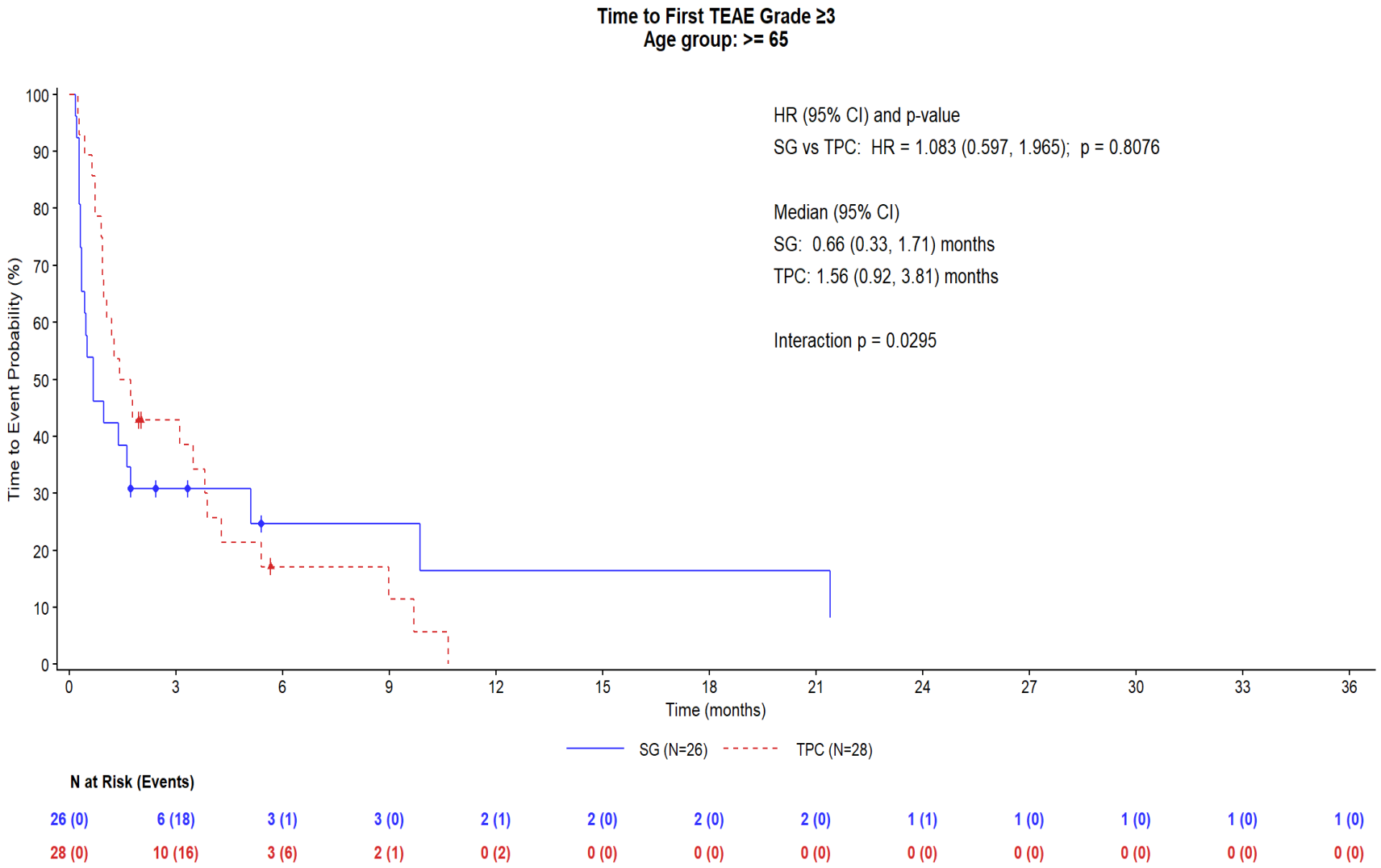
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.5. Figure 1.1.4: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



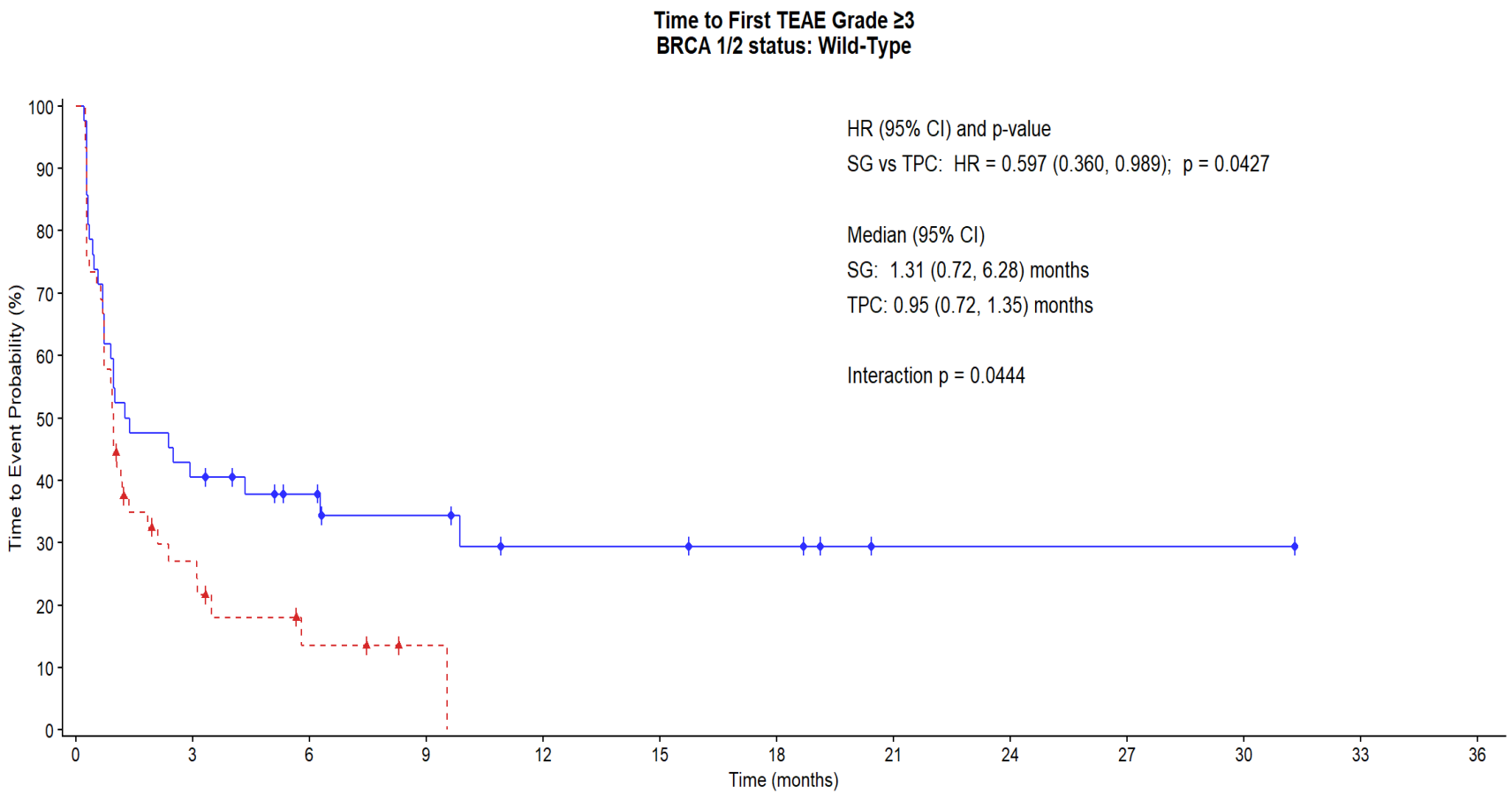
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.6. Figure 1.1.5: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



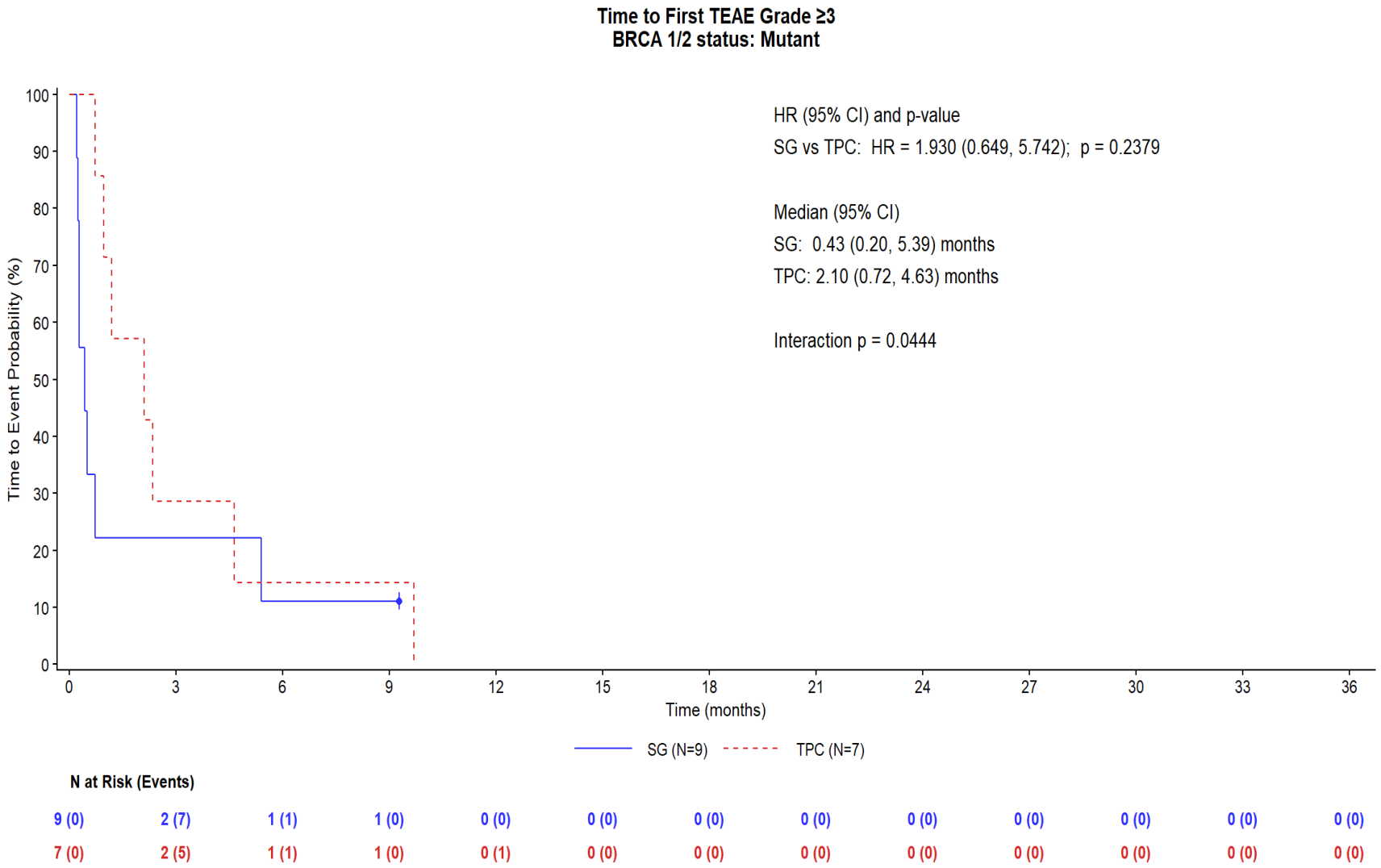
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.7. Figure 1.1.6: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



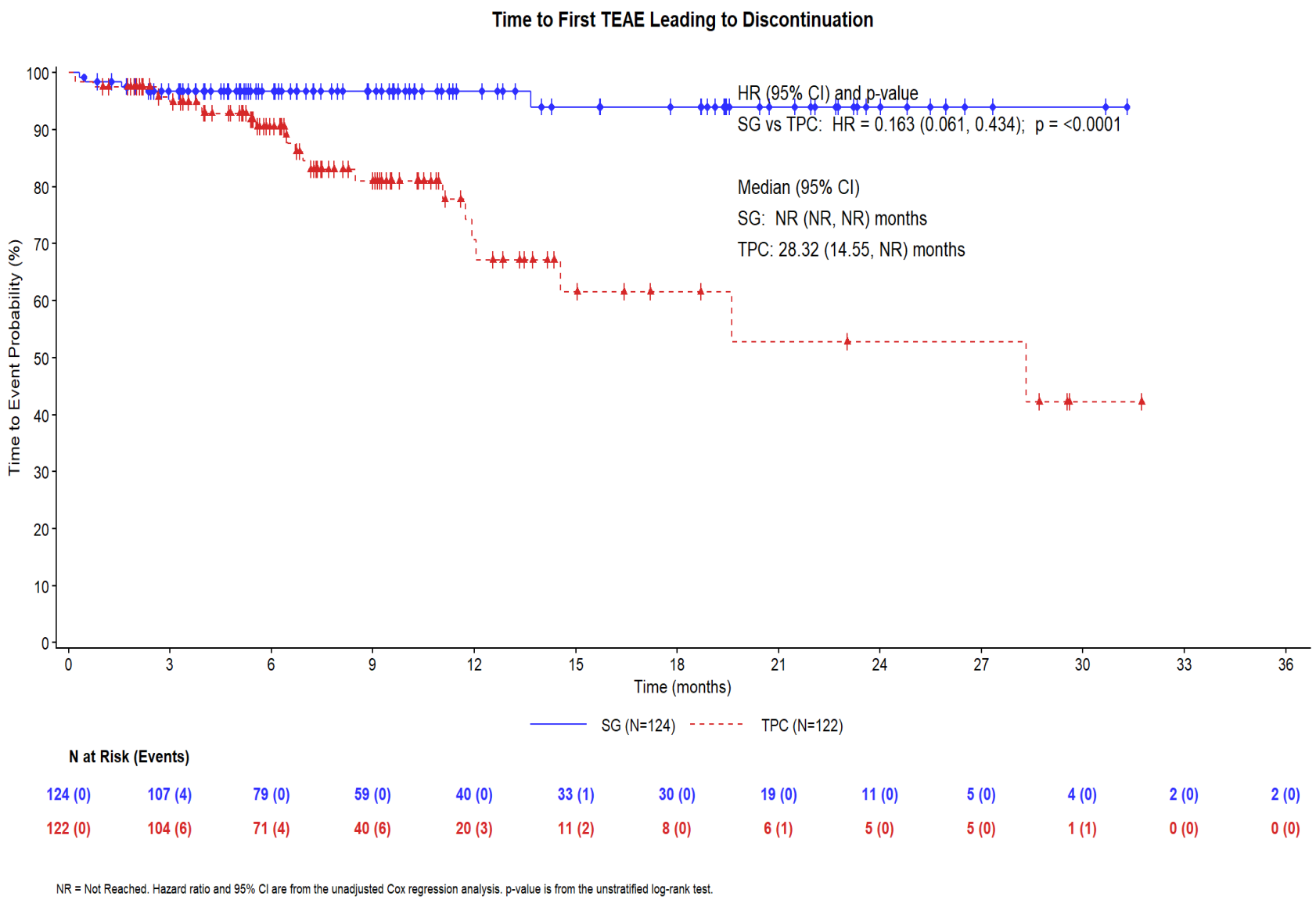
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.8. Figure 1.1.7: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



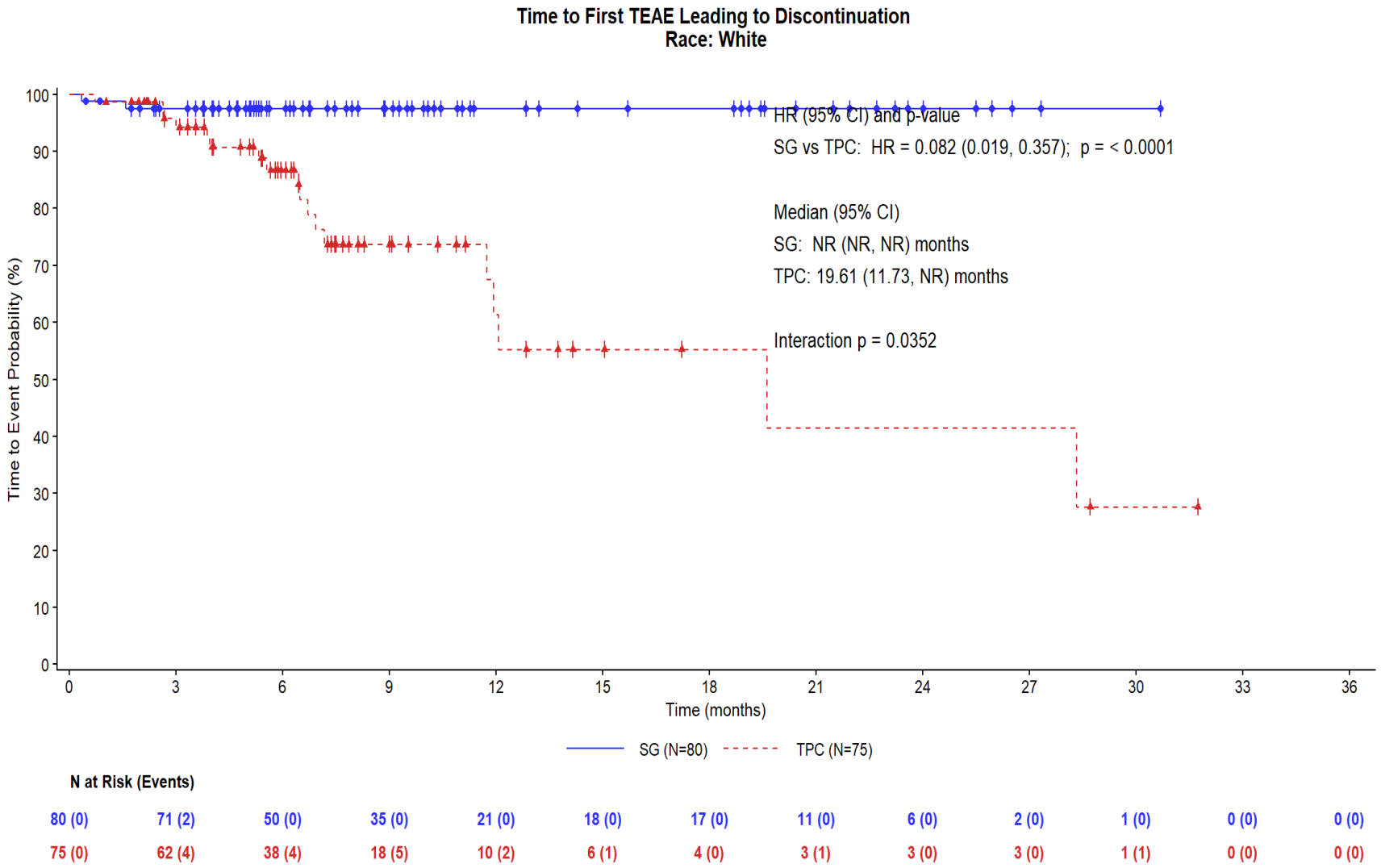
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.9. Figure 1.1.8: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



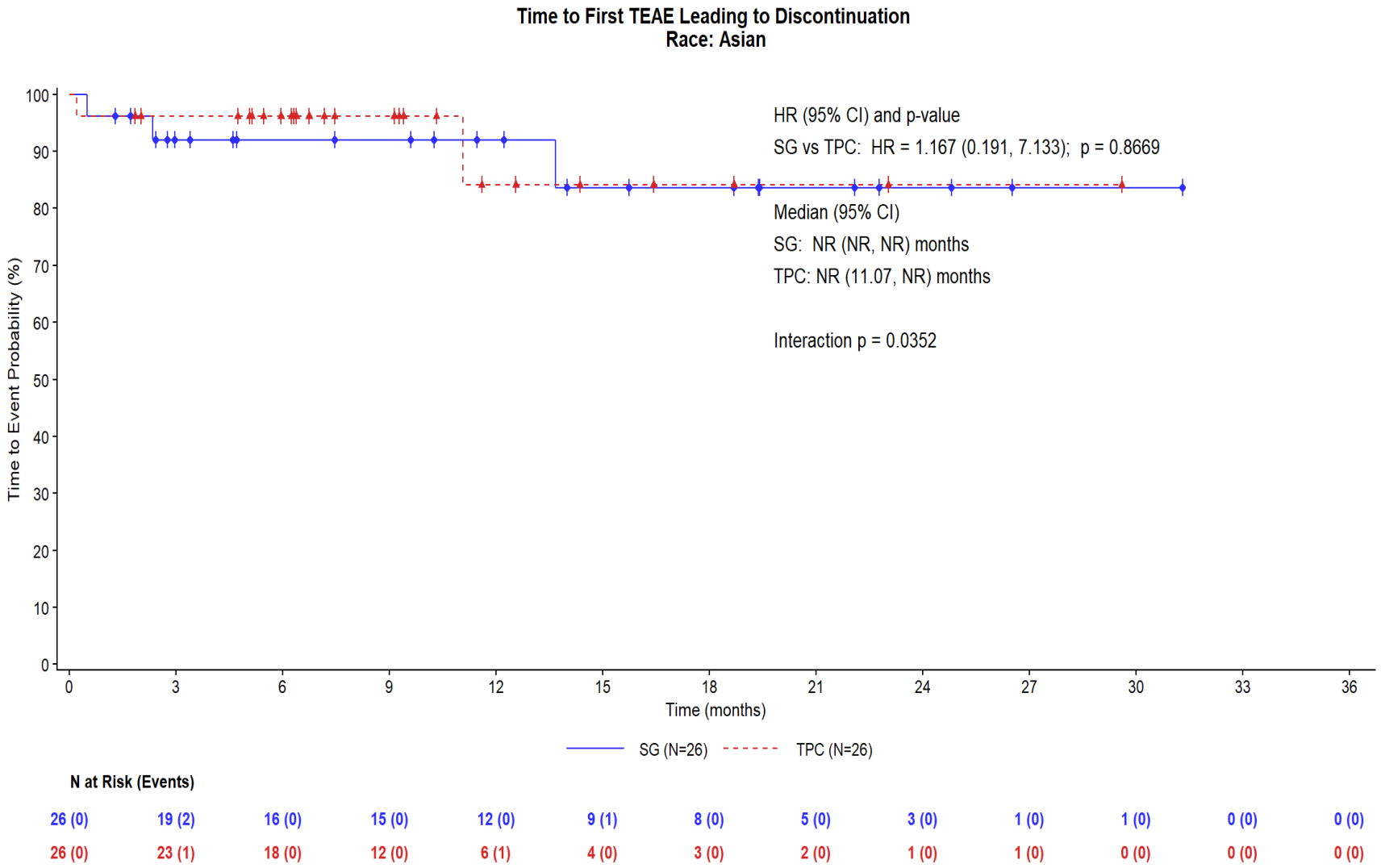
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.10. Figure 1.1.9: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



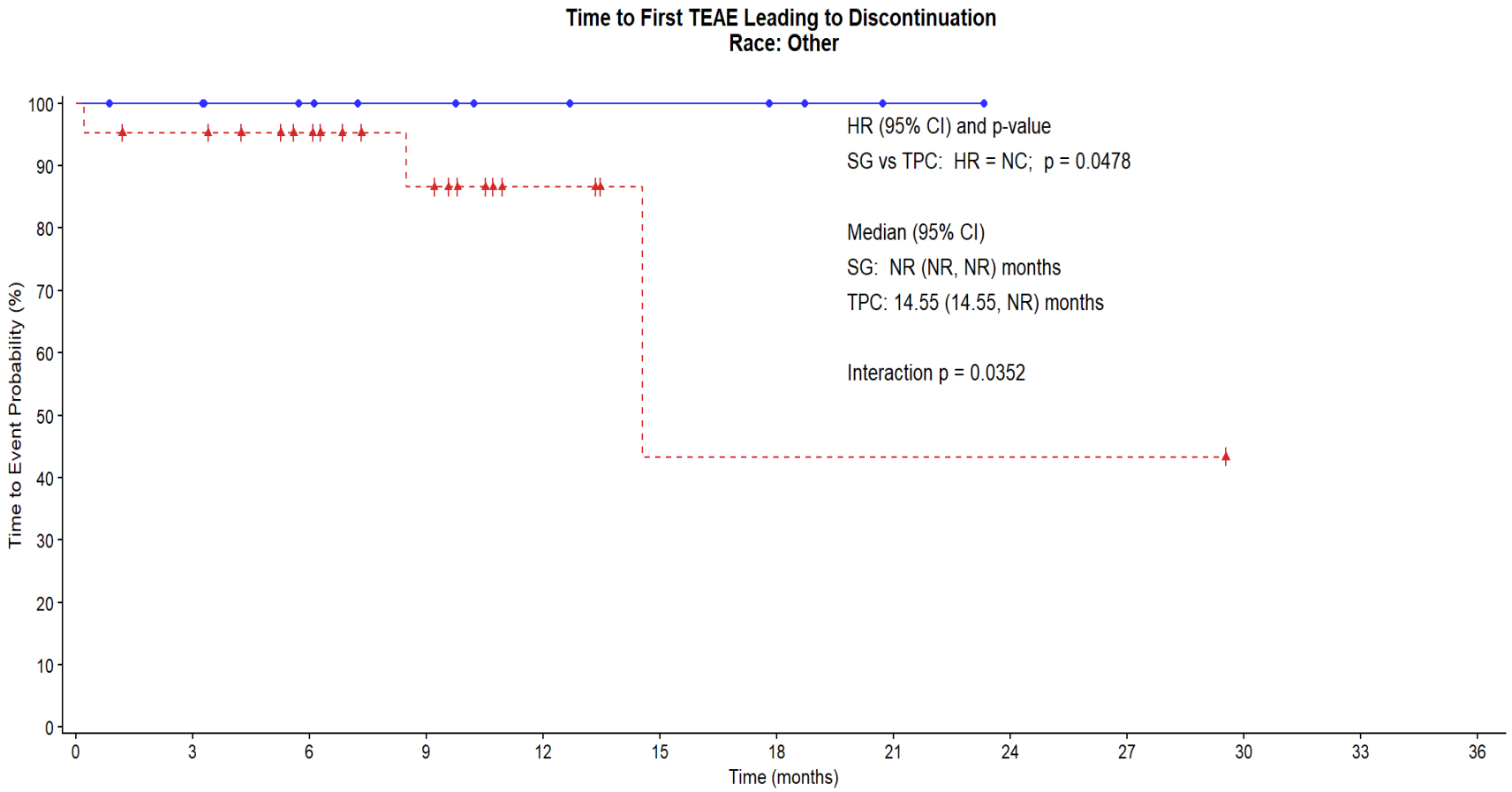
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.11. Figure 1.1.10: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Race Asian — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



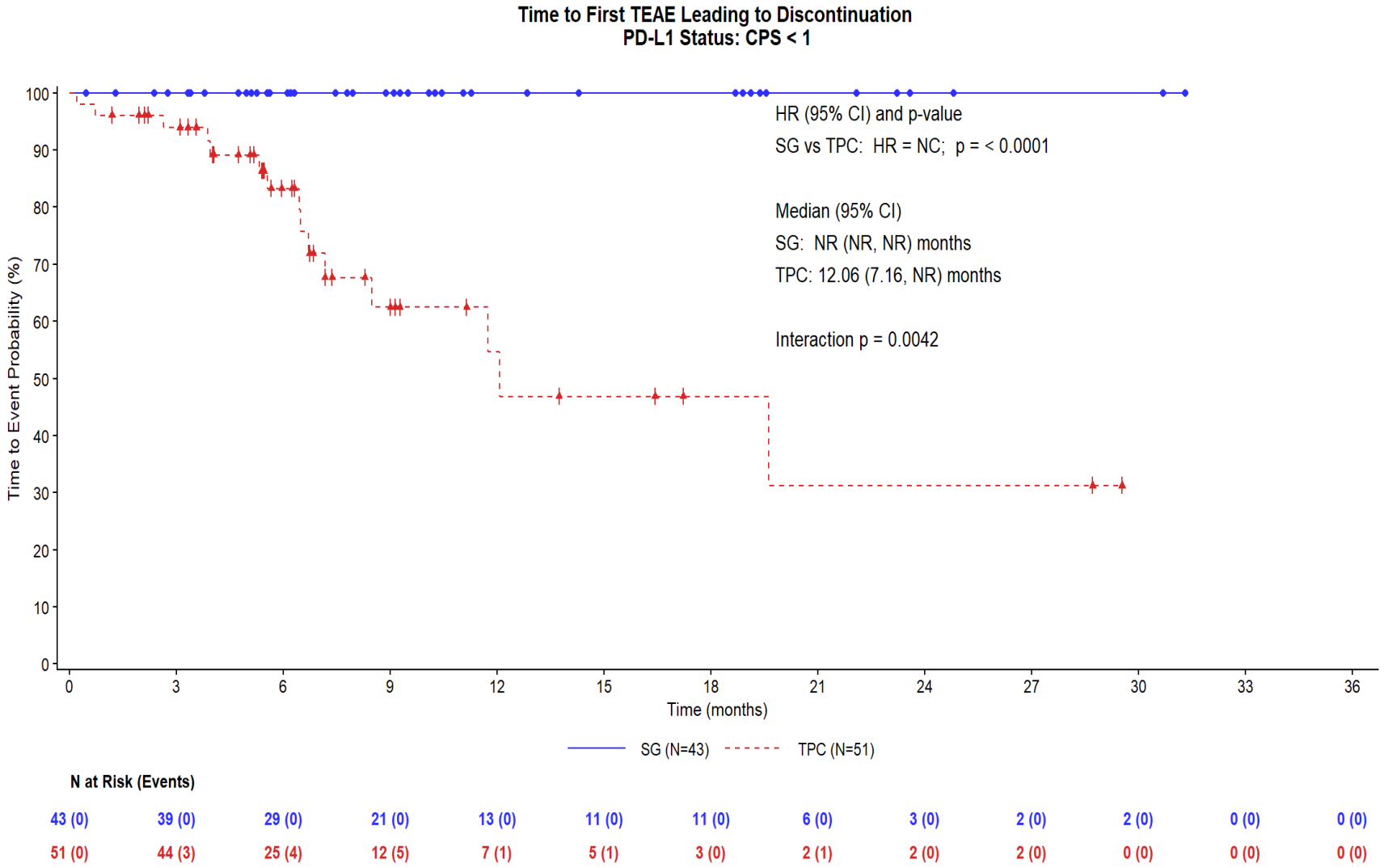
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.12. Figure 1.1.11: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



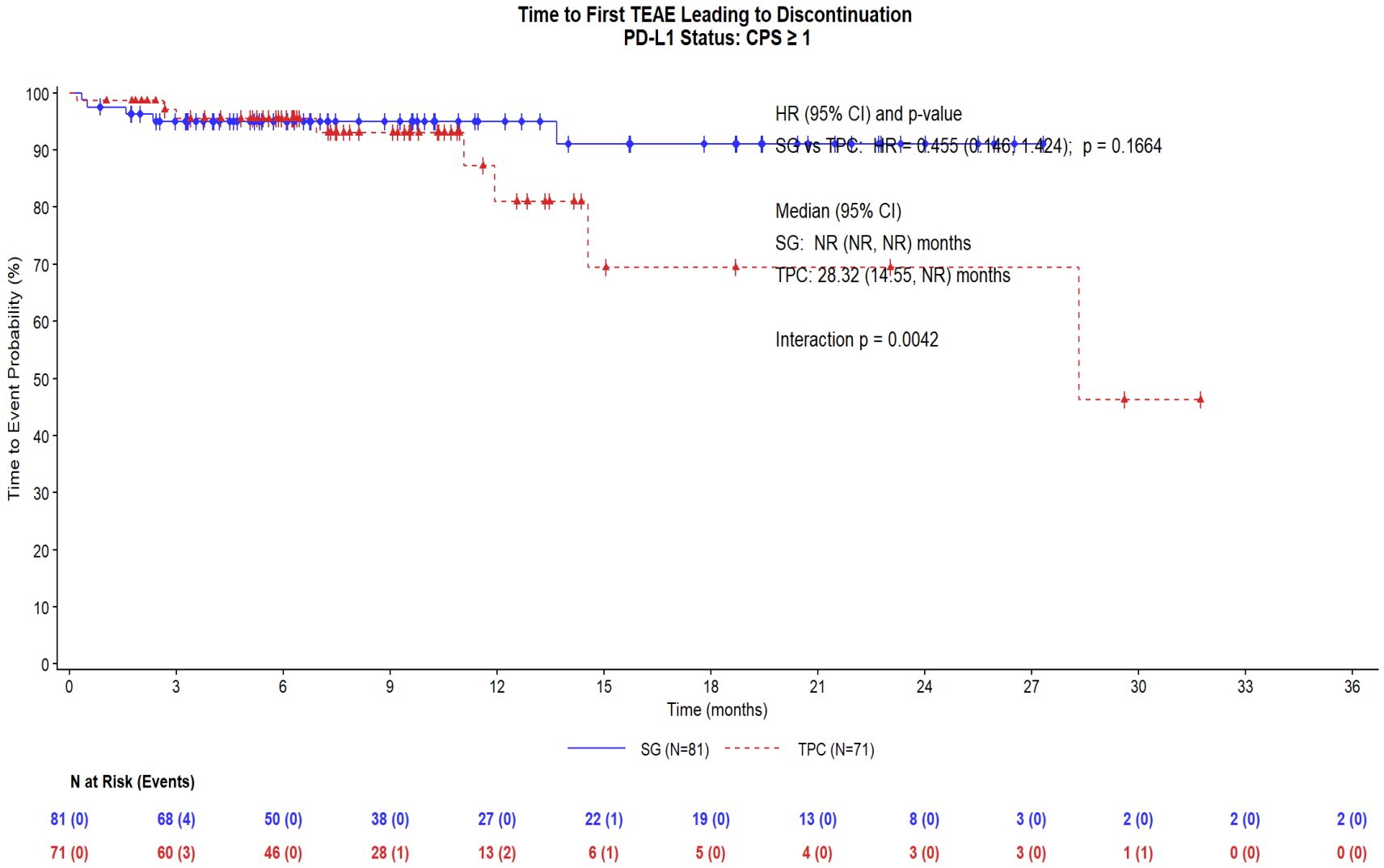
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.13. Figure 1.1.12: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



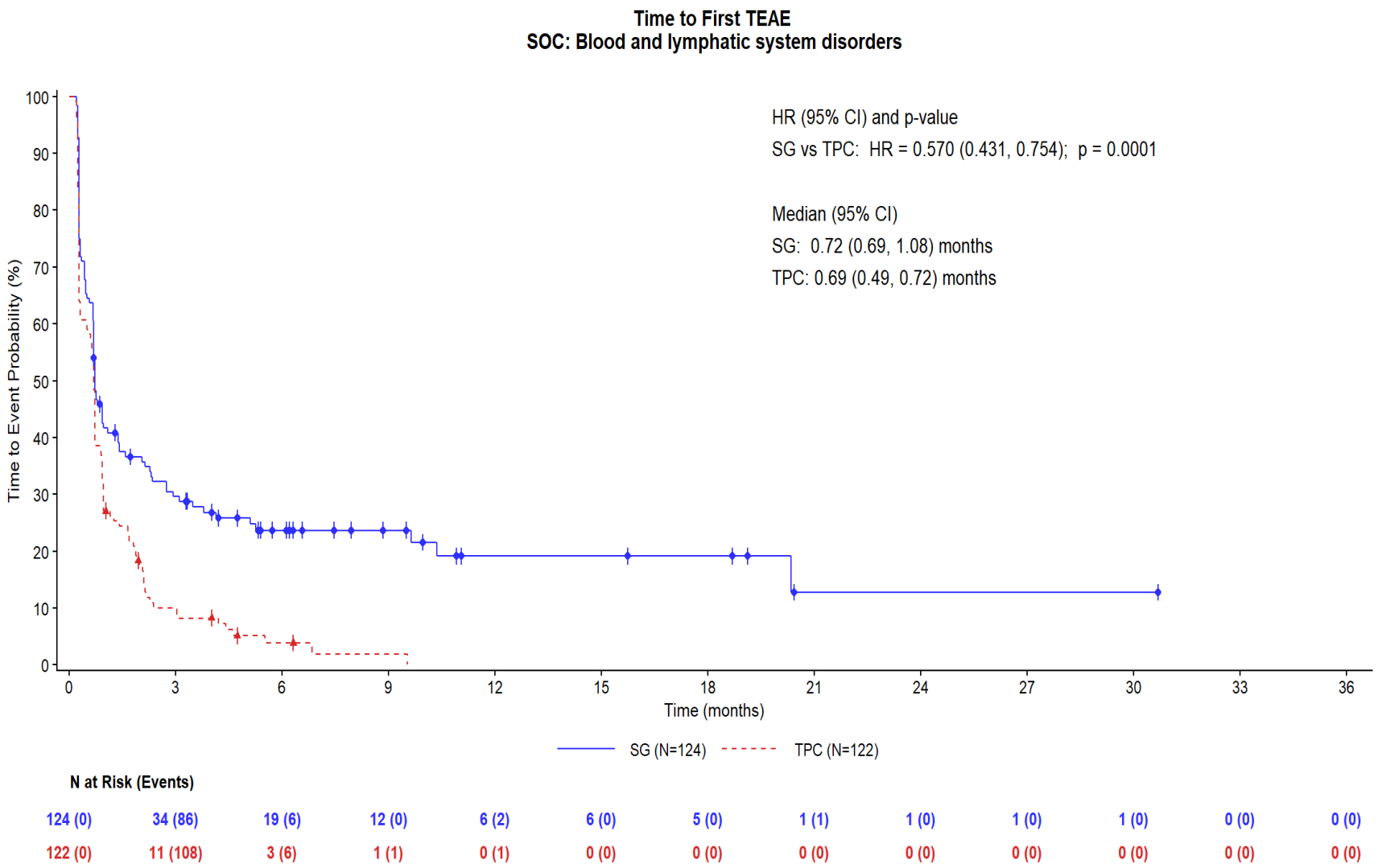
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.14. Figure 1.1.13: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



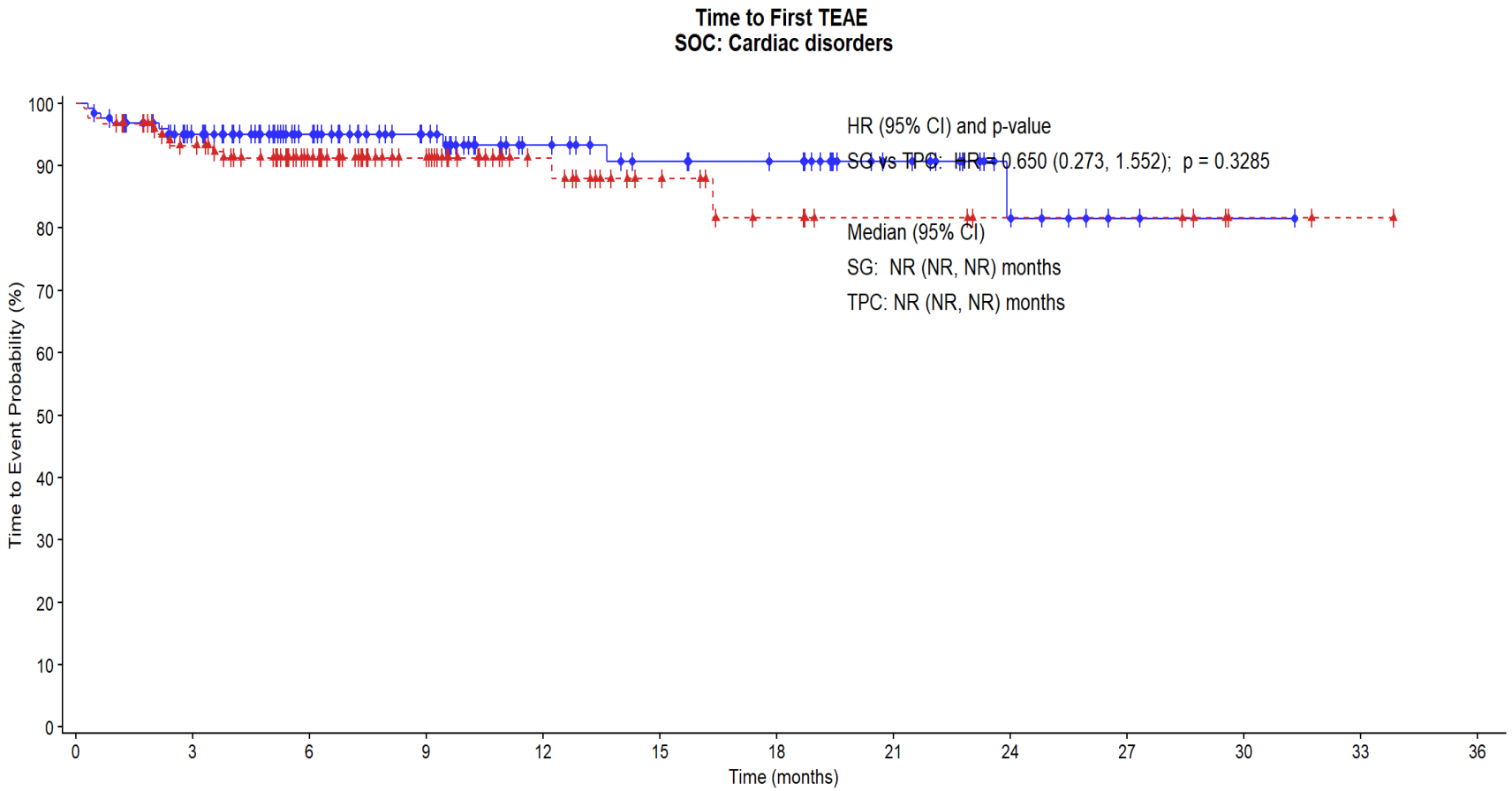
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.15. Figure 1.1.14: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



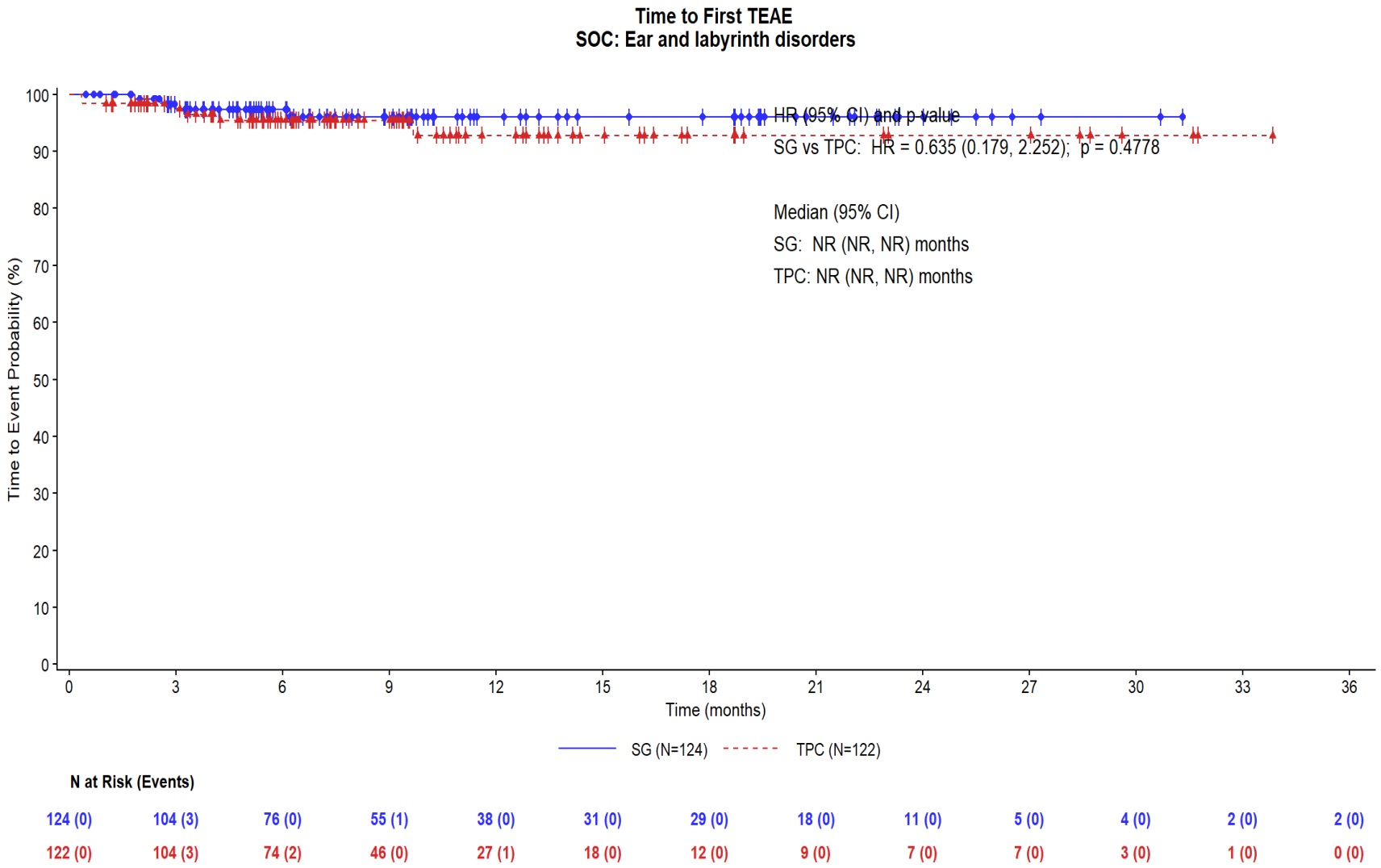
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.16. Figure 1.1.15: Kaplan Meier Plot of Time to First TEAE by SOC Cardiac disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



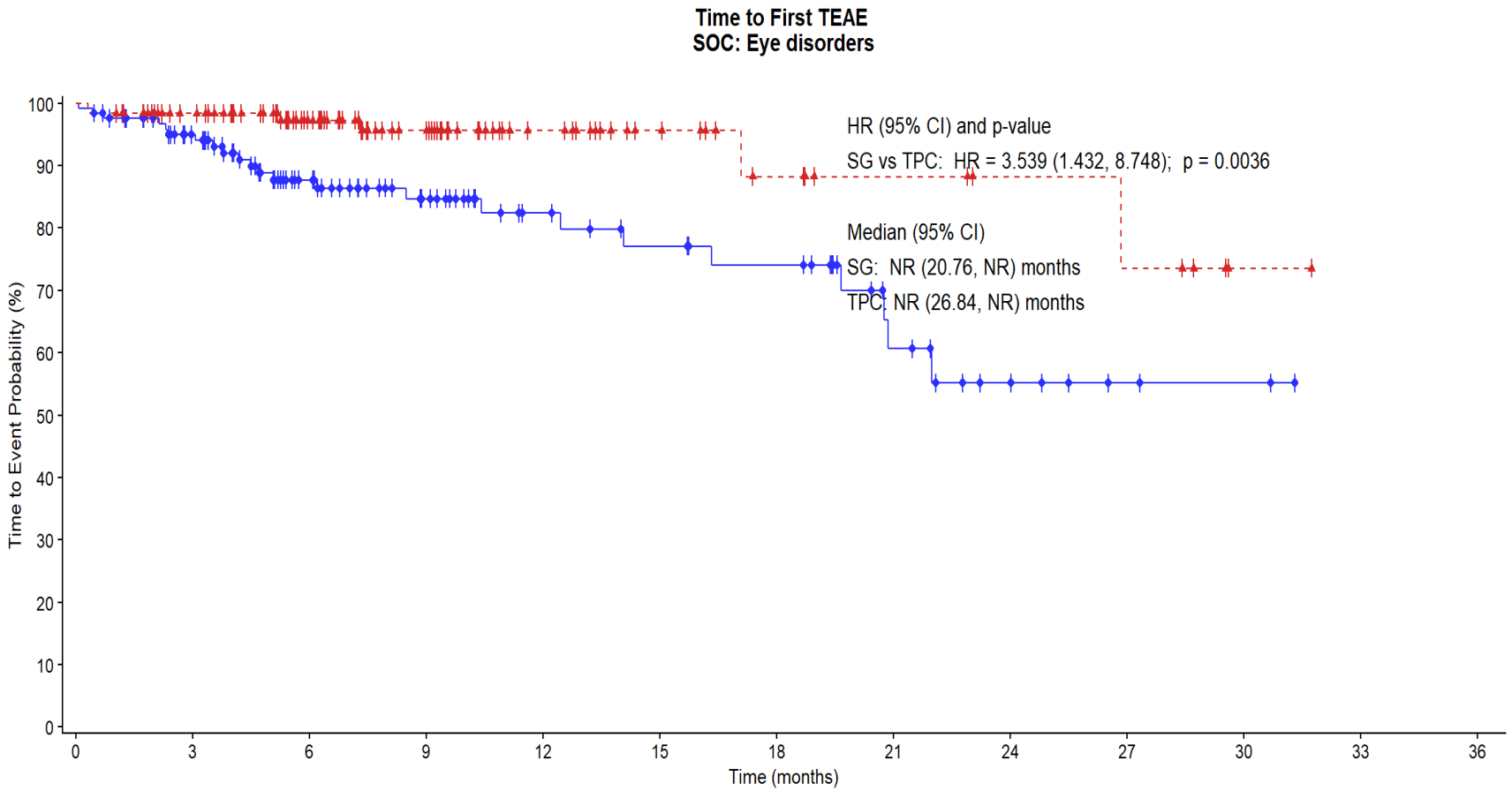
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.17. Figure 1.1.16: Kaplan Meier Plot of Time to First TEAE by SOC Ear and labyrinth disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



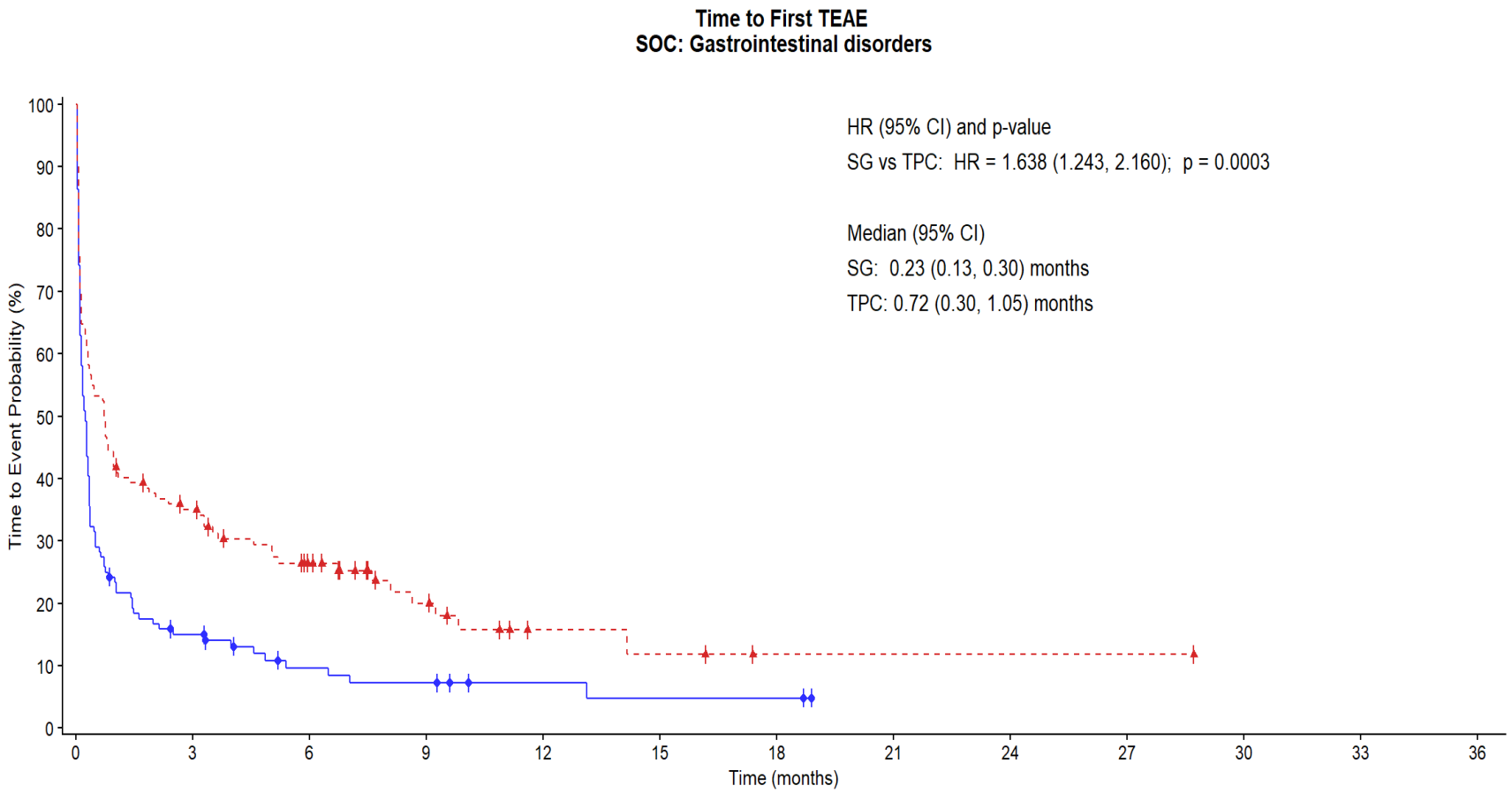
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.18. Figure 1.1.17: Kaplan Meier Plot of Time to First TEAE by SOC Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



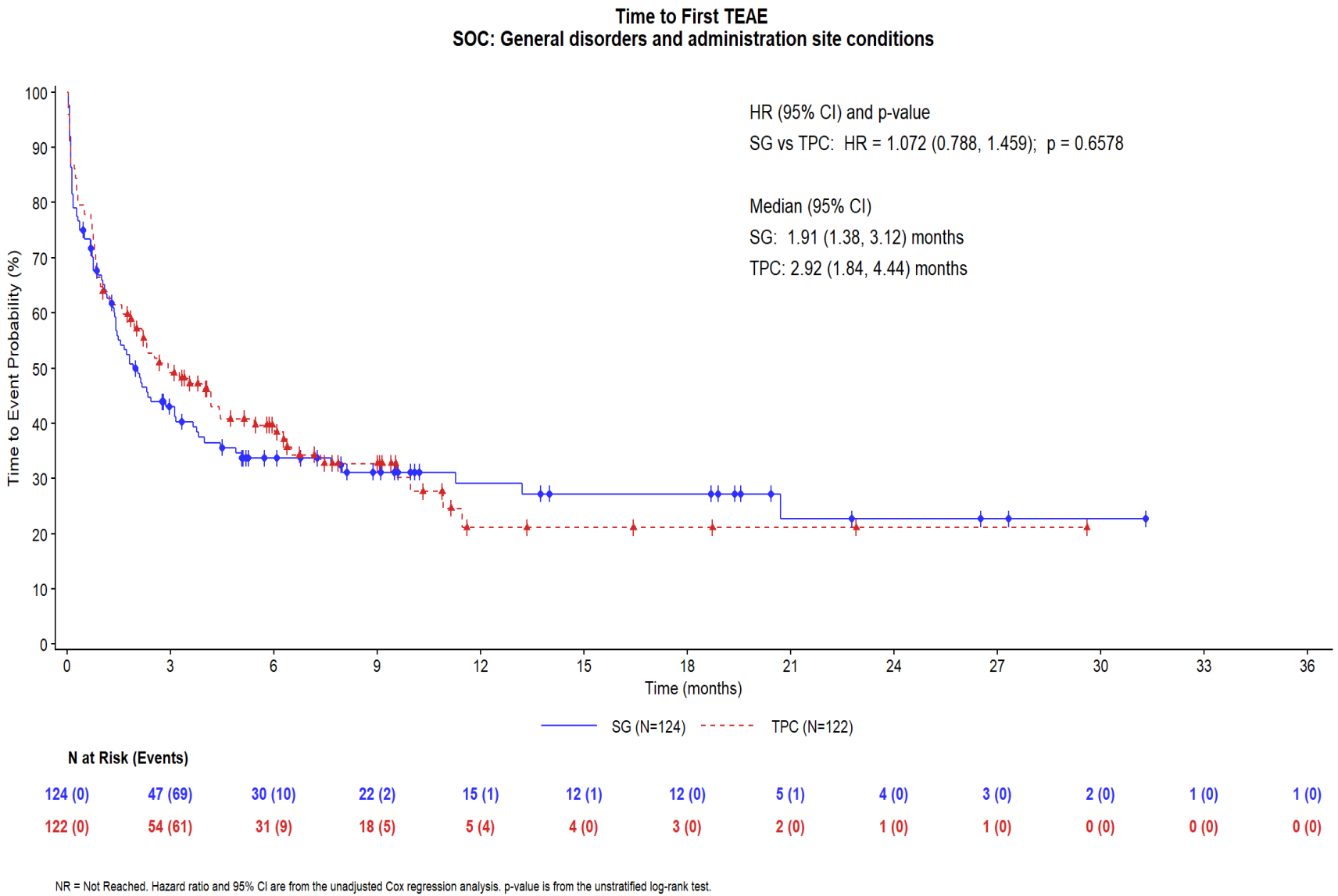
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.19. Figure 1.1.18: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



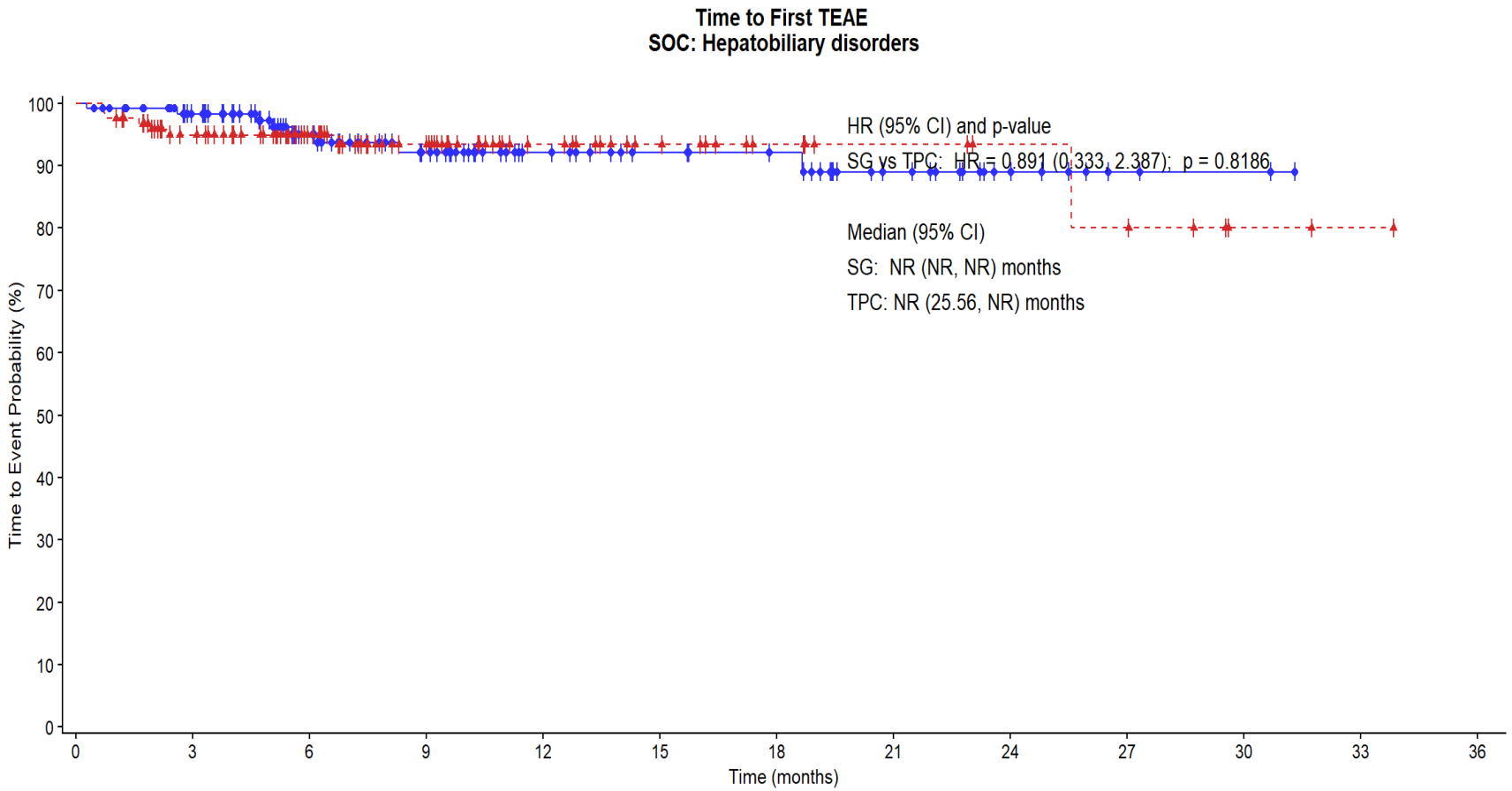
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.20. Figure 1.1.19: Kaplan Meier Plot of Time to First TEAE by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



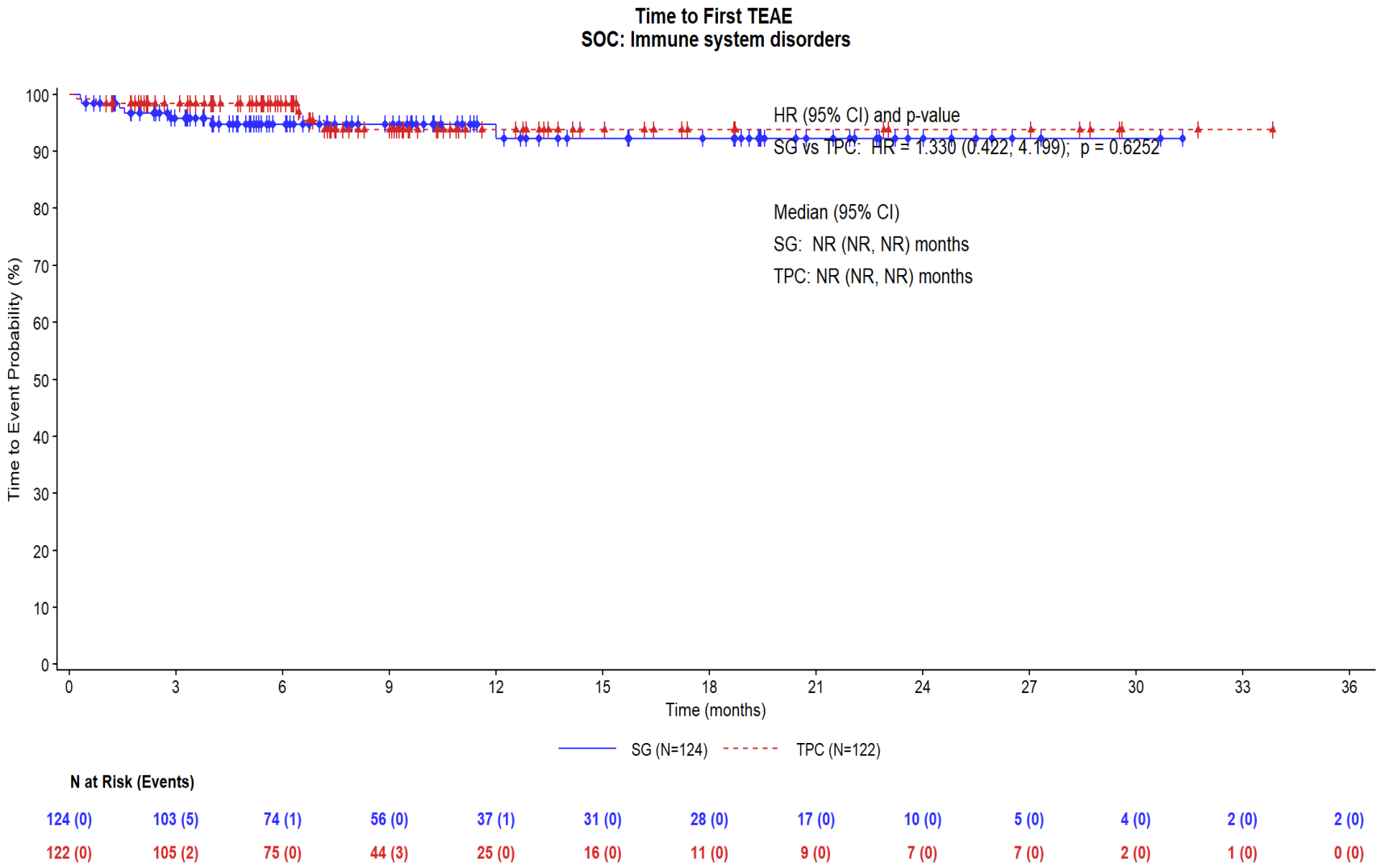
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.21. Figure 1.1.20: Kaplan Meier Plot of Time to First TEAE by SOC Hepatobiliary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



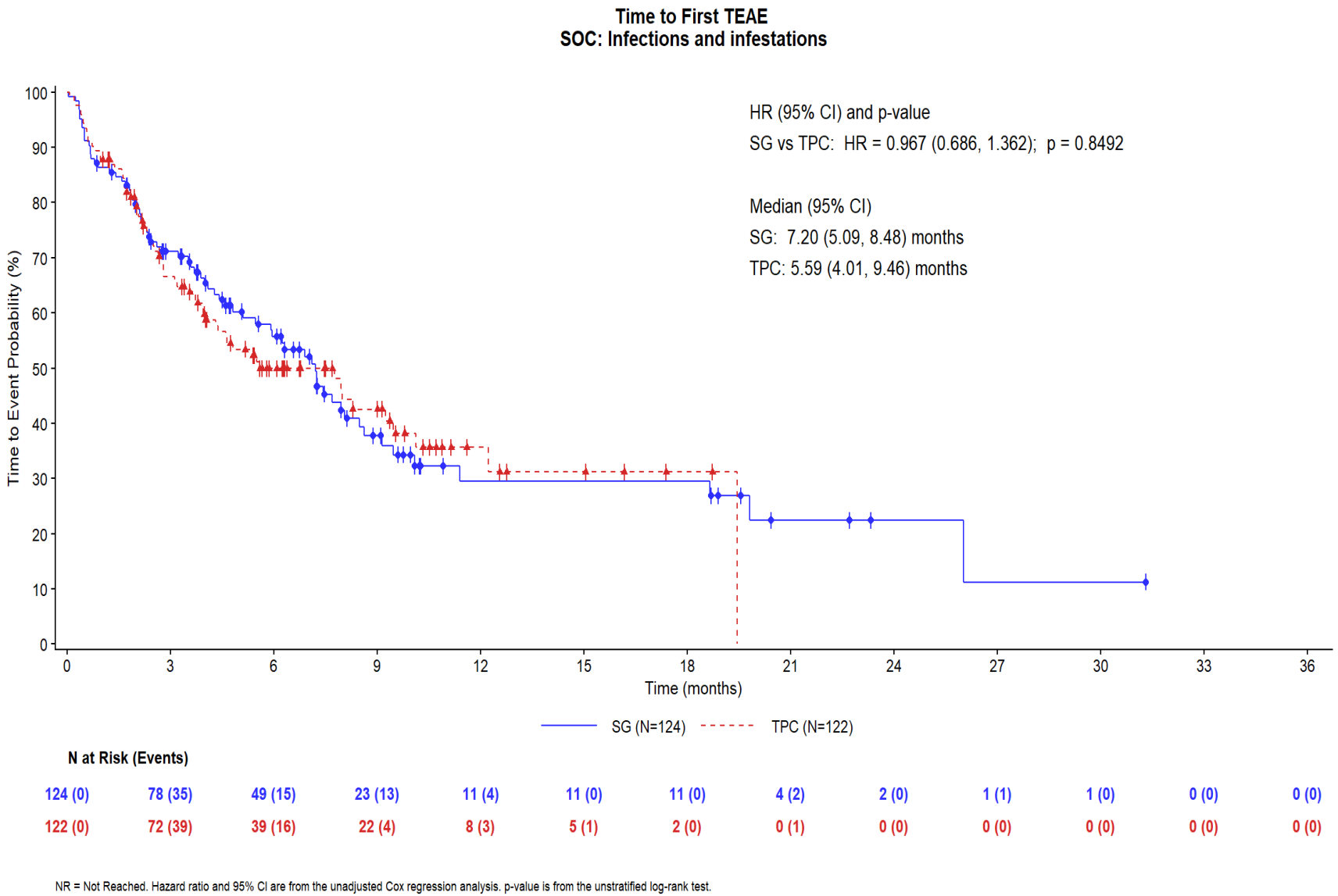
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.22. Figure 1.1.21: Kaplan Meier Plot of Time to First TEAE by SOC Immune system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



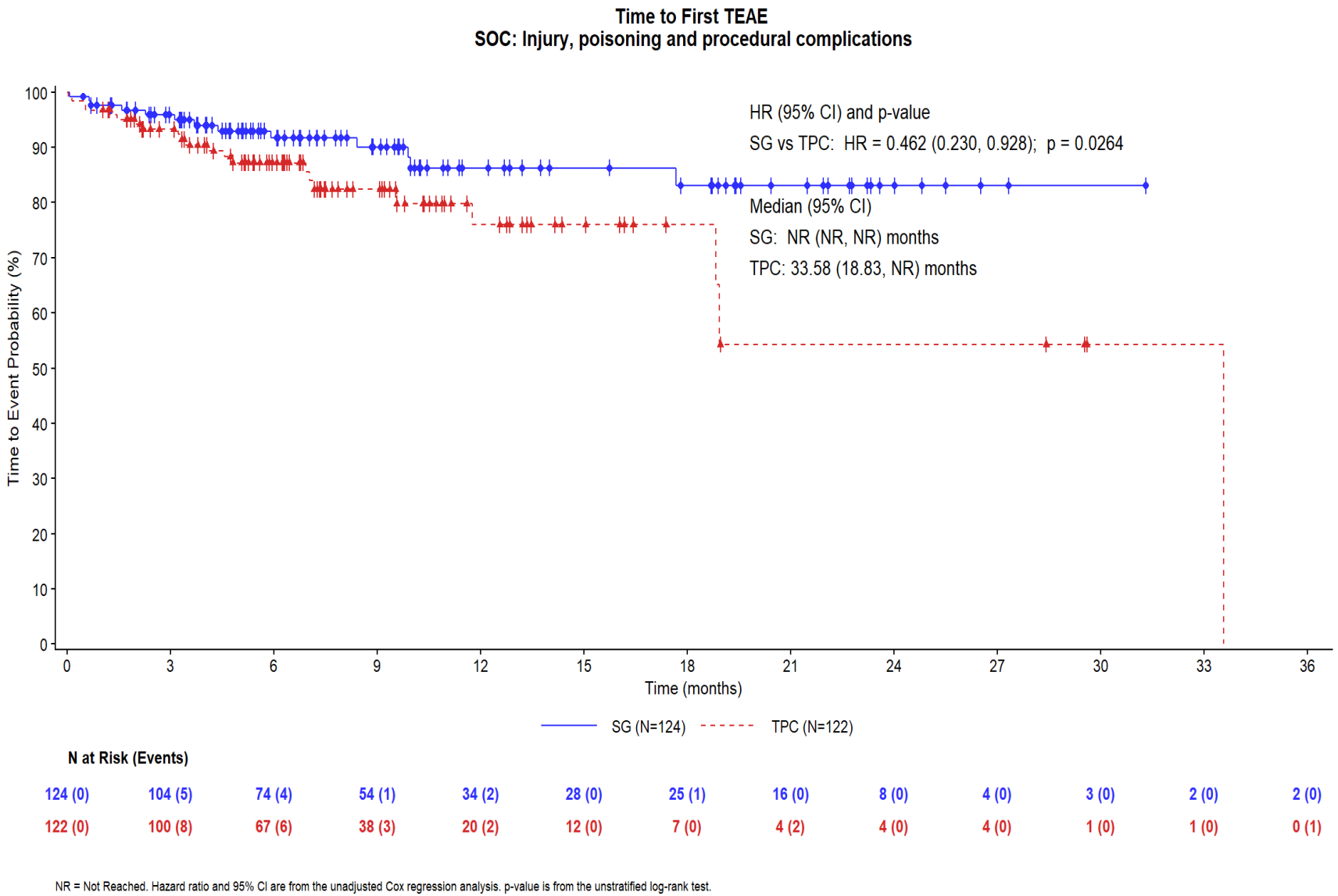
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.23. Figure 1.1.22: Kaplan Meier Plot of Time to First TEAE by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



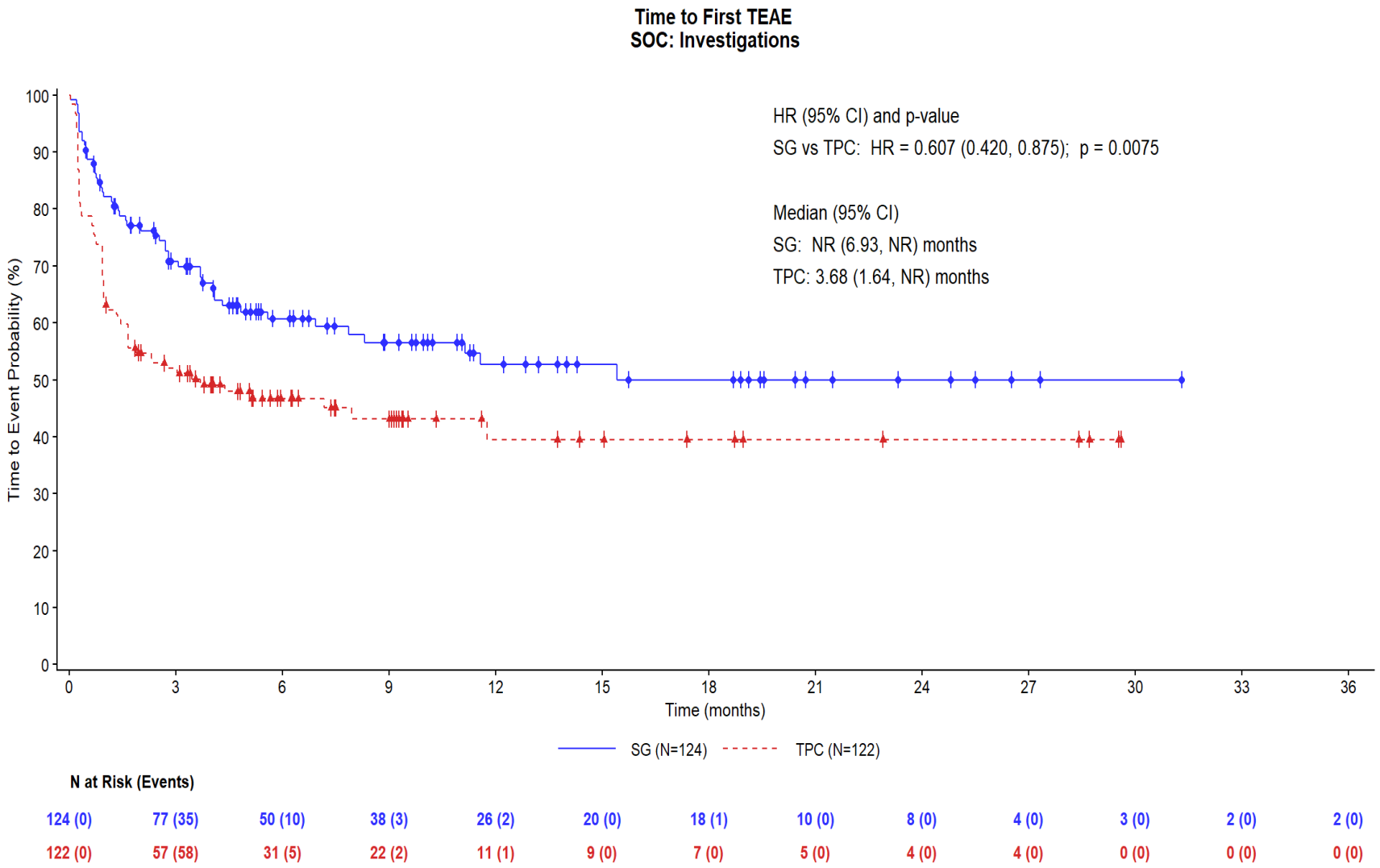
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.24. Figure 1.1.23: Kaplan Meier Plot of Time to First TEAE by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



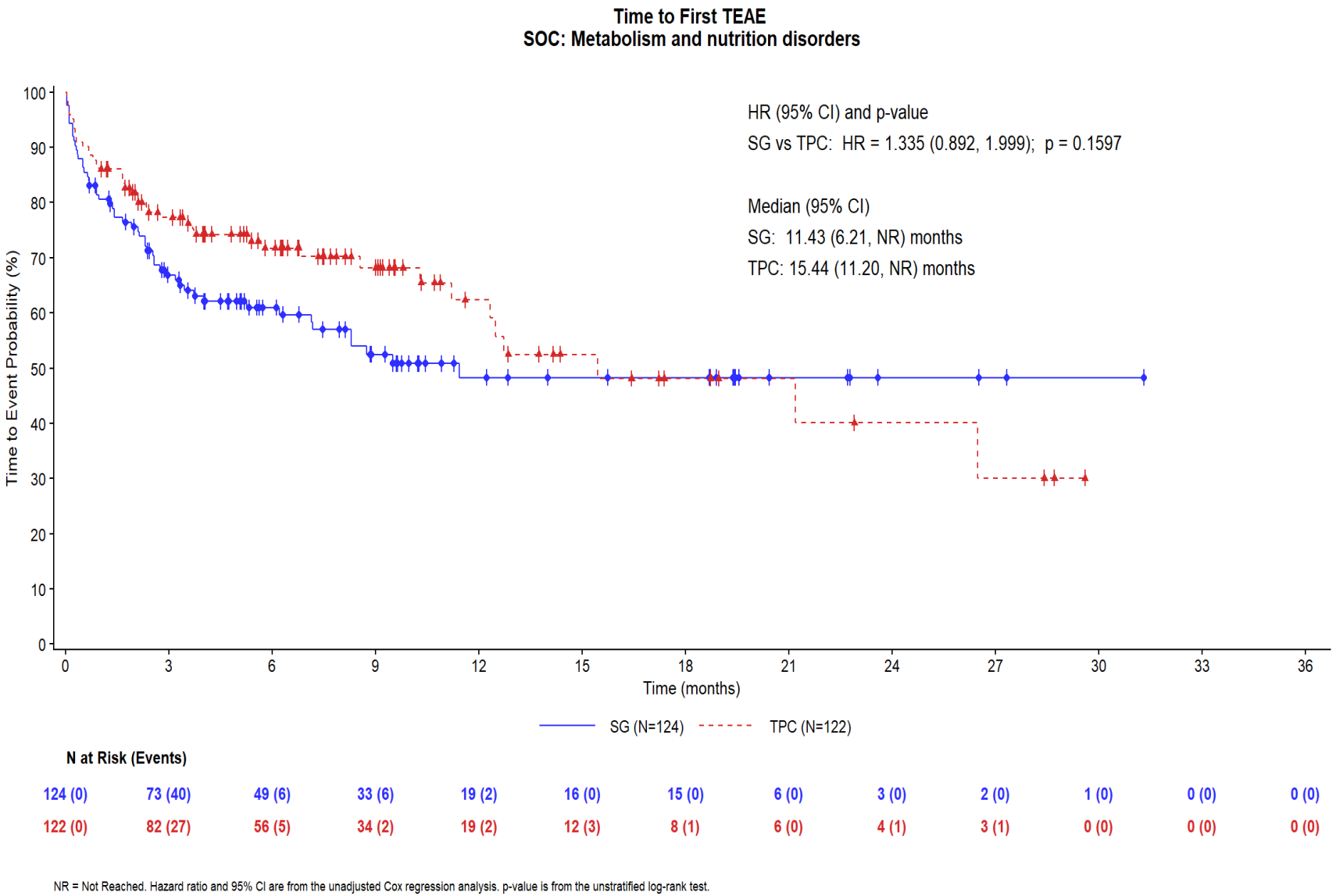
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.25. Figure 1.1.24: Kaplan Meier Plot of Time to First TEAE by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



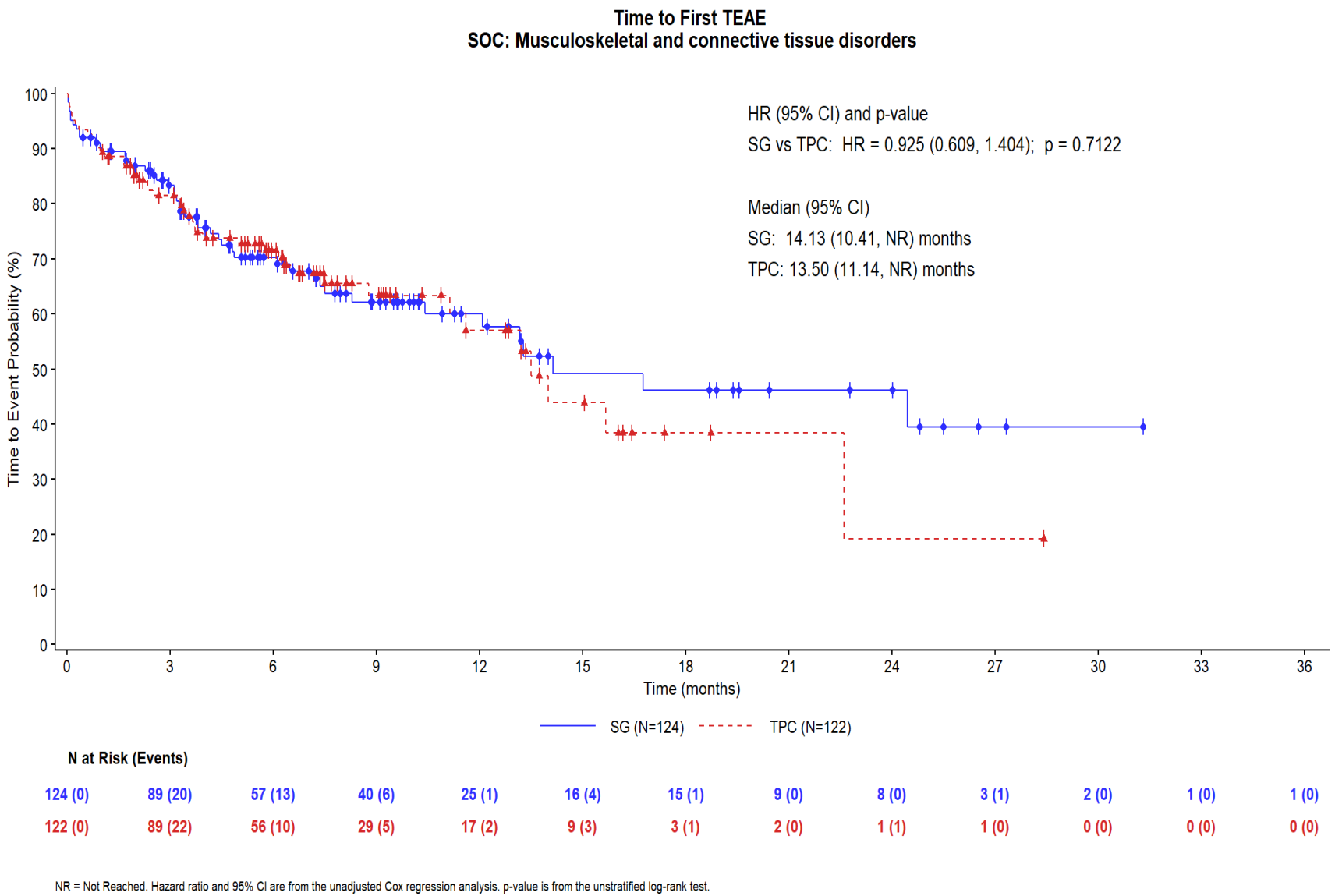
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.26. Figure 1.1.25: Kaplan Meier Plot of Time to First TEAE by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



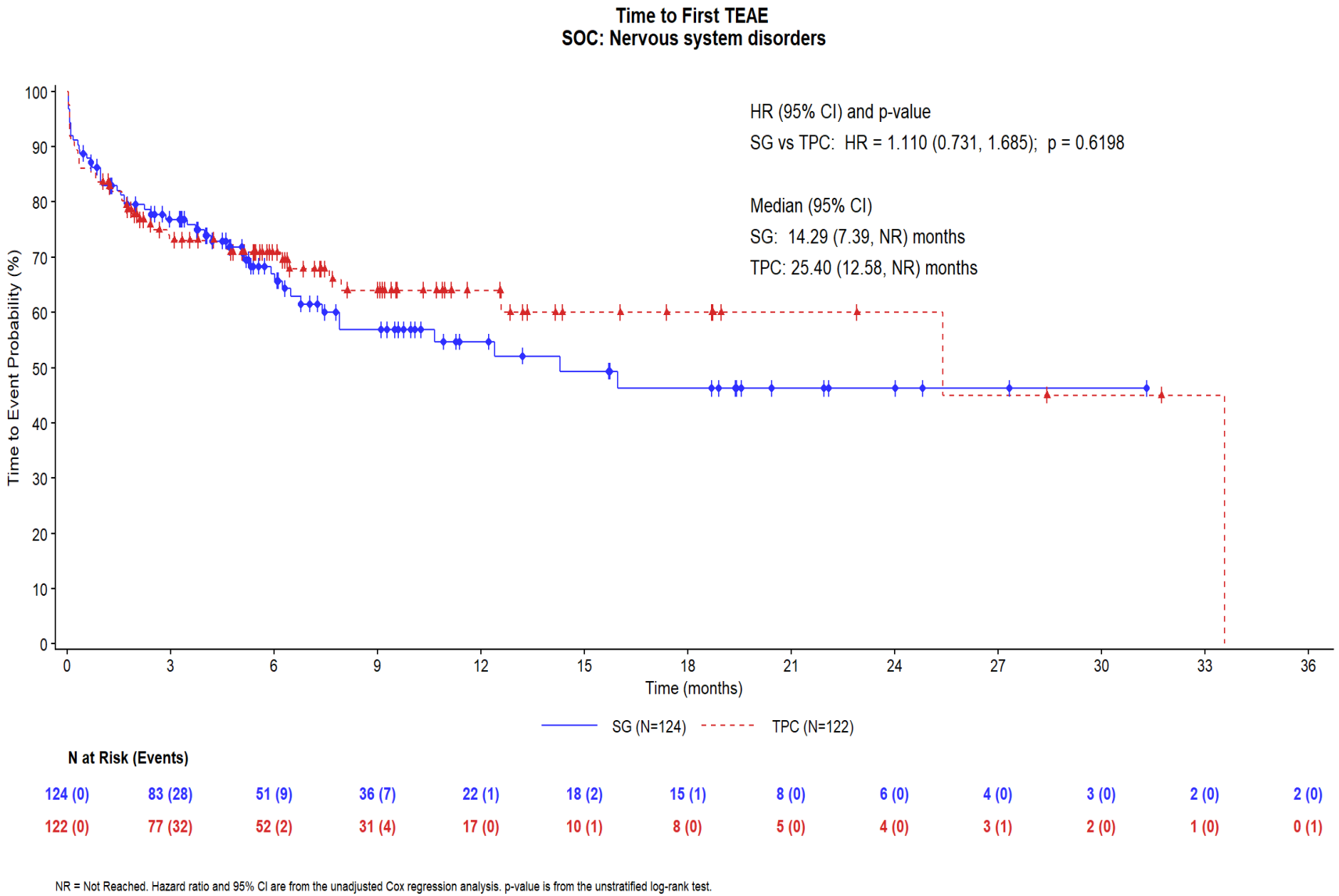
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.27. Figure 1.1.26: Kaplan Meier Plot of Time to First TEAE by SOC Musculoskeletal and connective tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



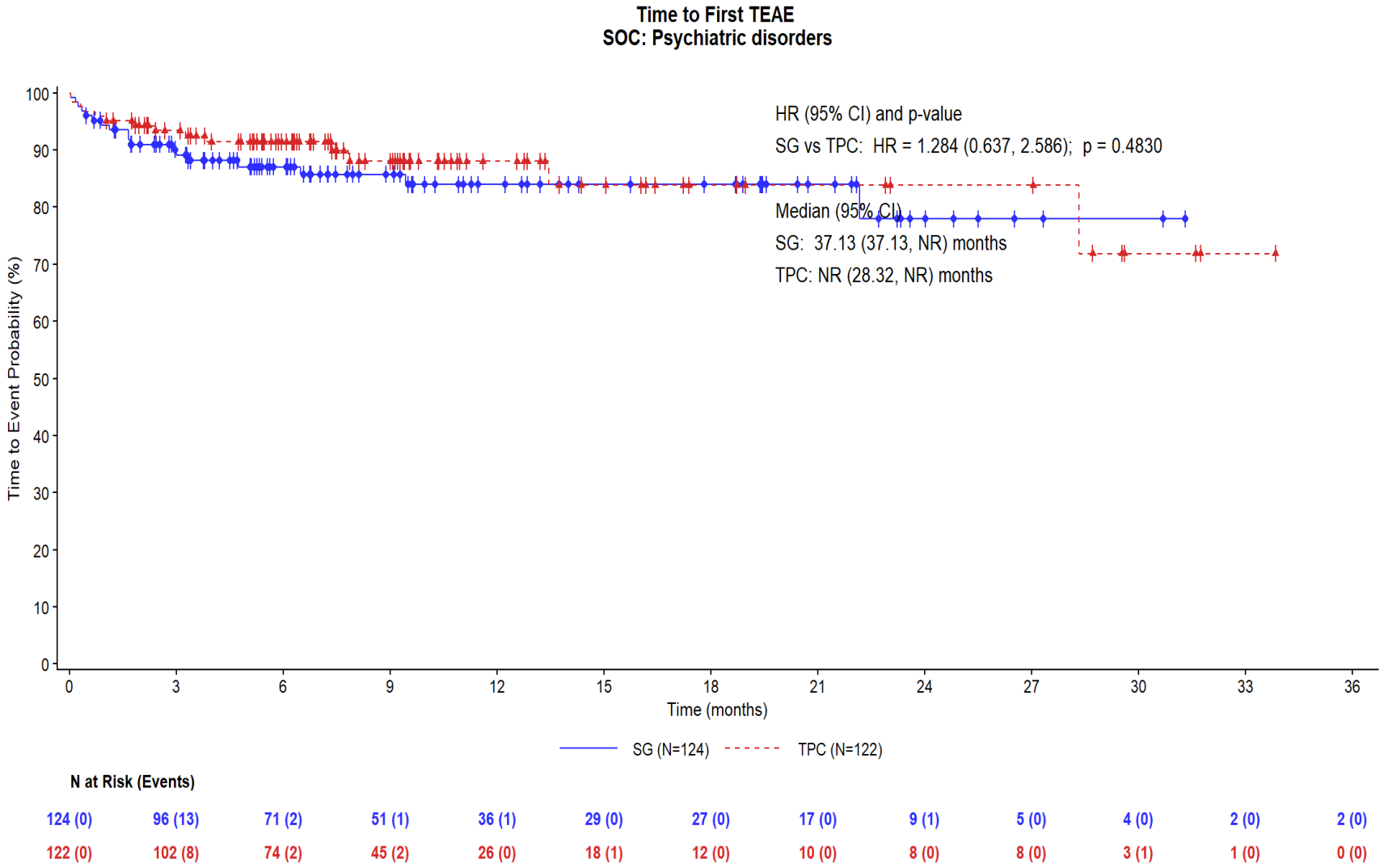
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.28. Figure 1.1.27: Kaplan Meier Plot of Time to First TEAE by SOC Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



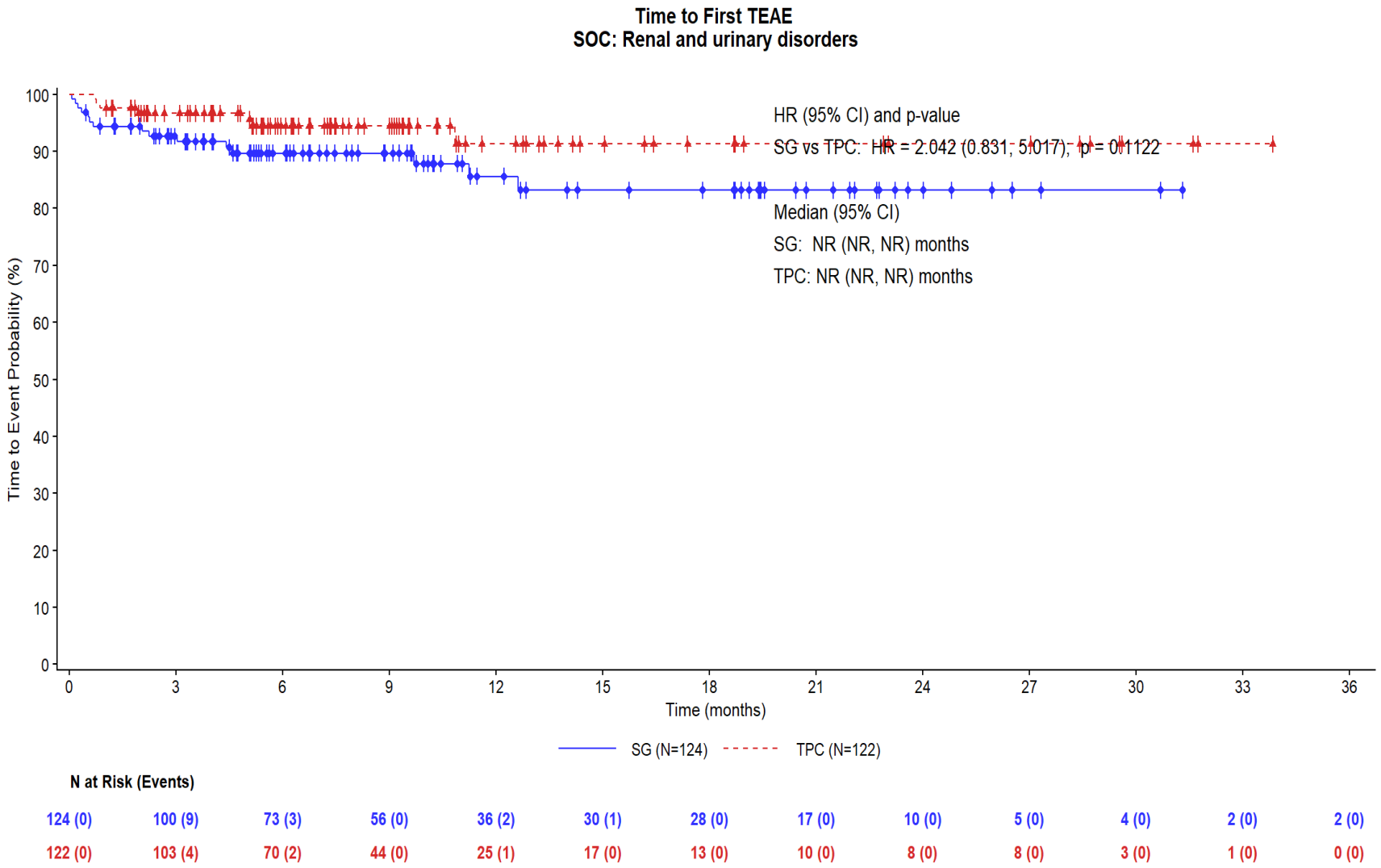
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.29. Figure 1.1.28: Kaplan Meier Plot of Time to First TEAE by SOC Psychiatric disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



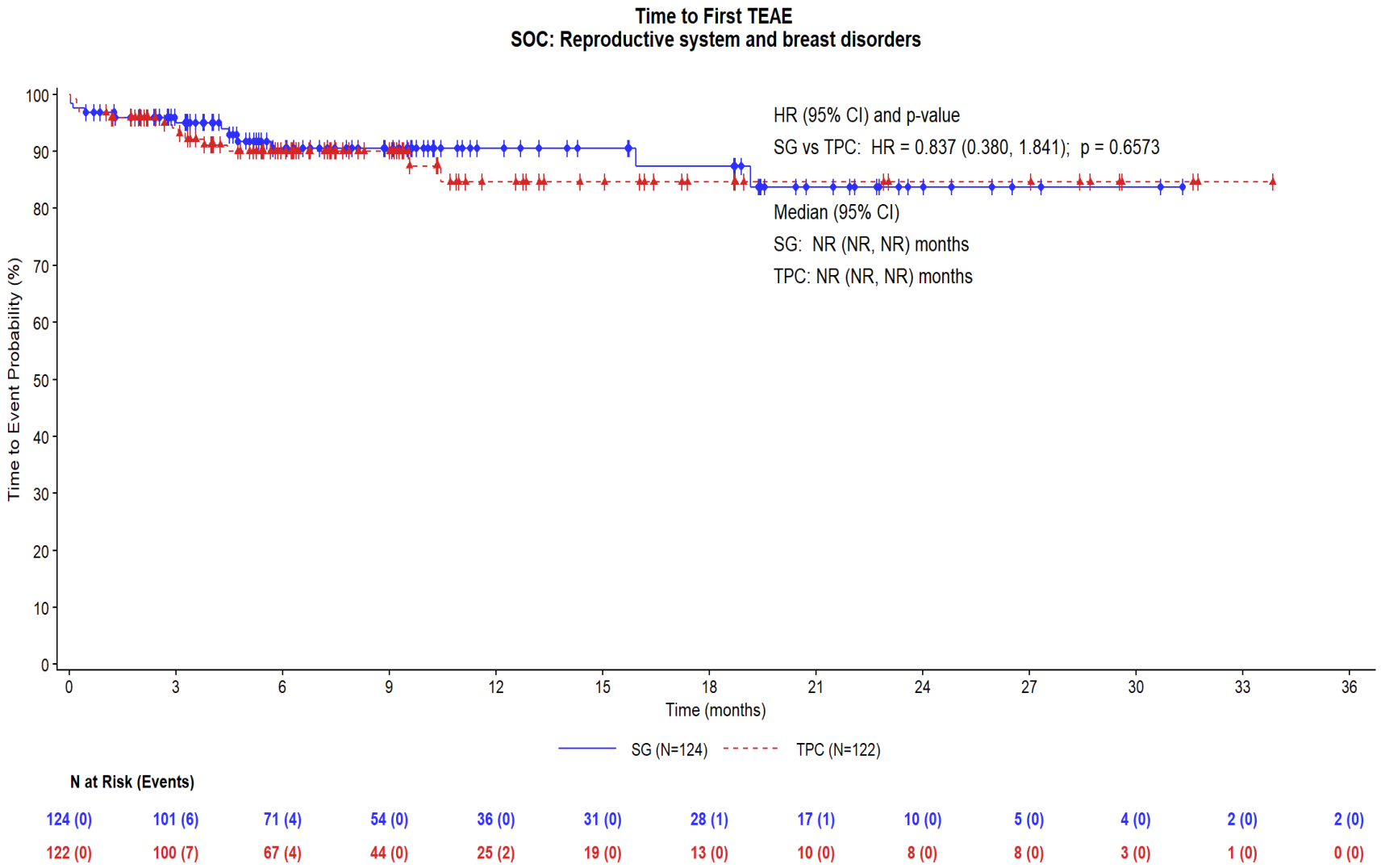
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.30. Figure 1.1.29: Kaplan Meier Plot of Time to First TEAE by SOC Renal and urinary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



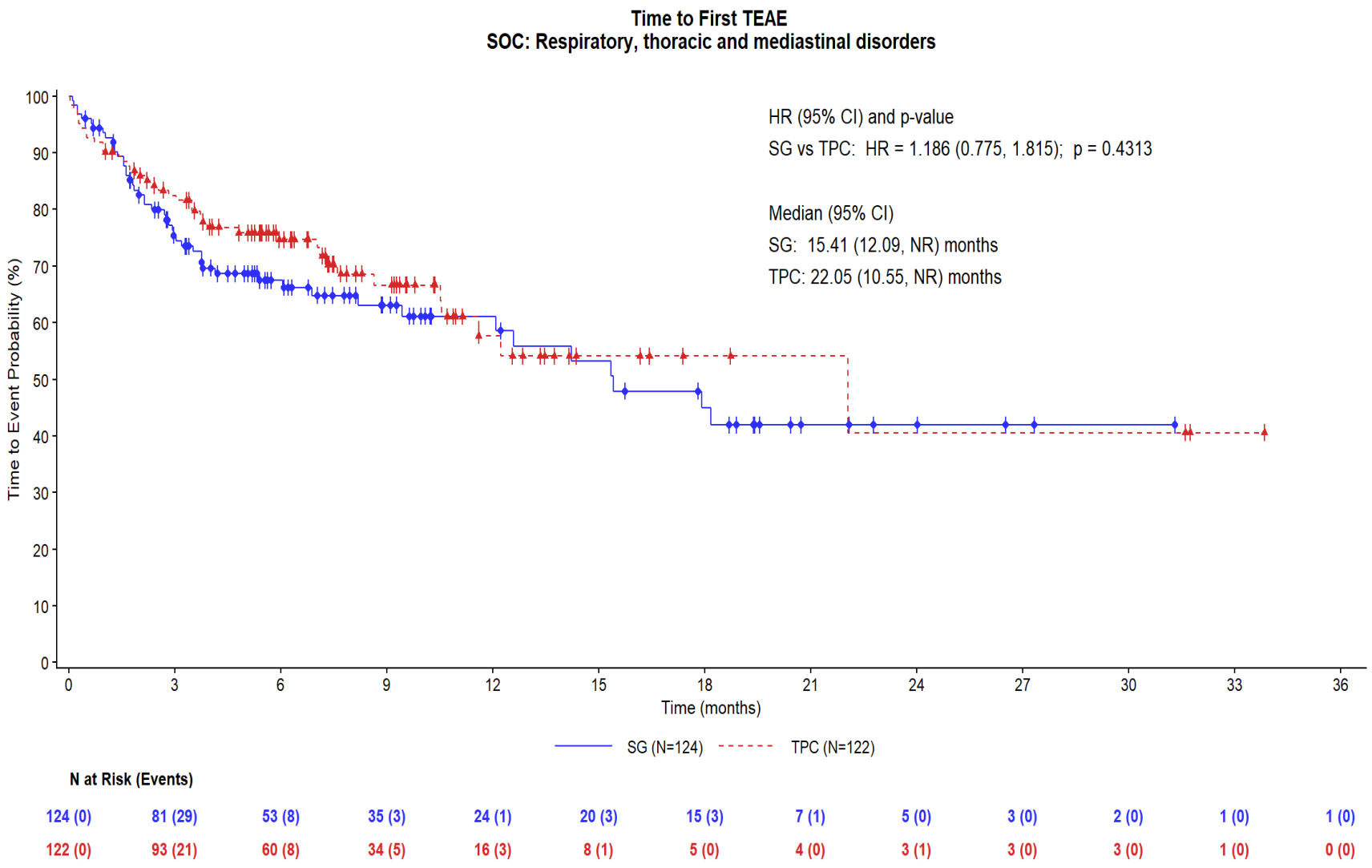
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.31. Figure 1.1.30: Kaplan Meier Plot of Time to First TEAE by SOC Reproductive system and breast disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



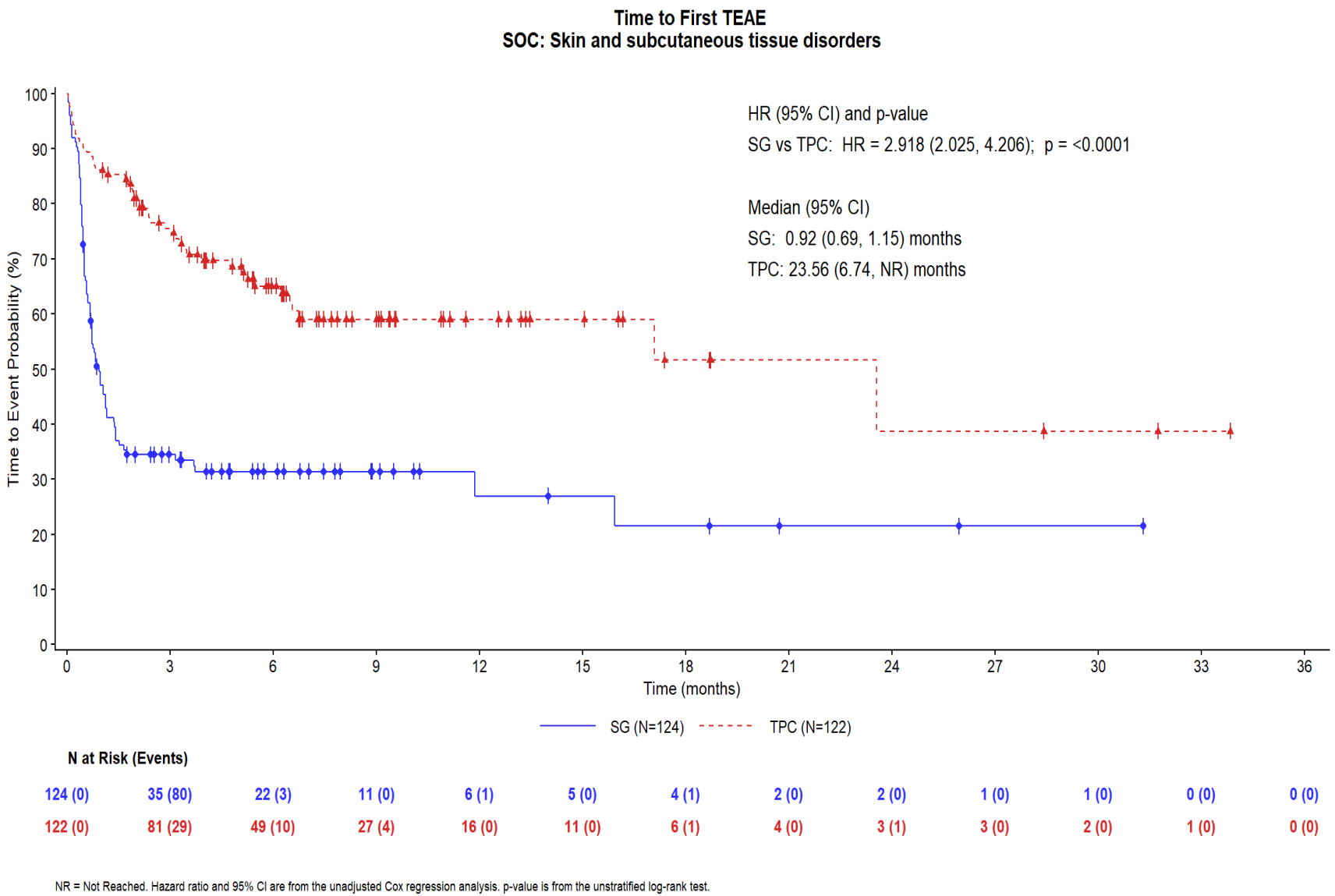
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.32. Figure 1.1.31: Kaplan Meier Plot of Time to First TEAE by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



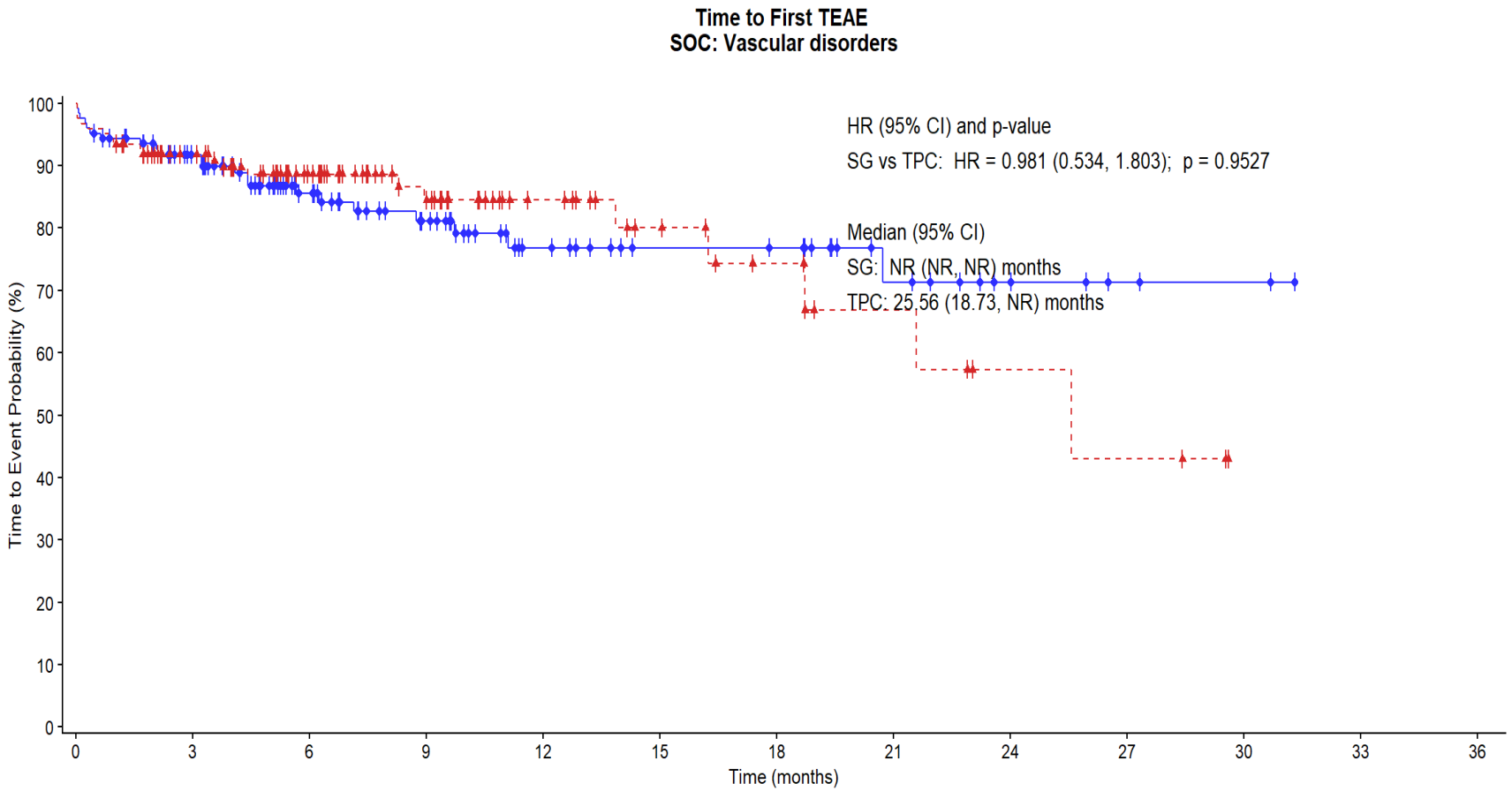
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.33. Figure 1.1.32: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



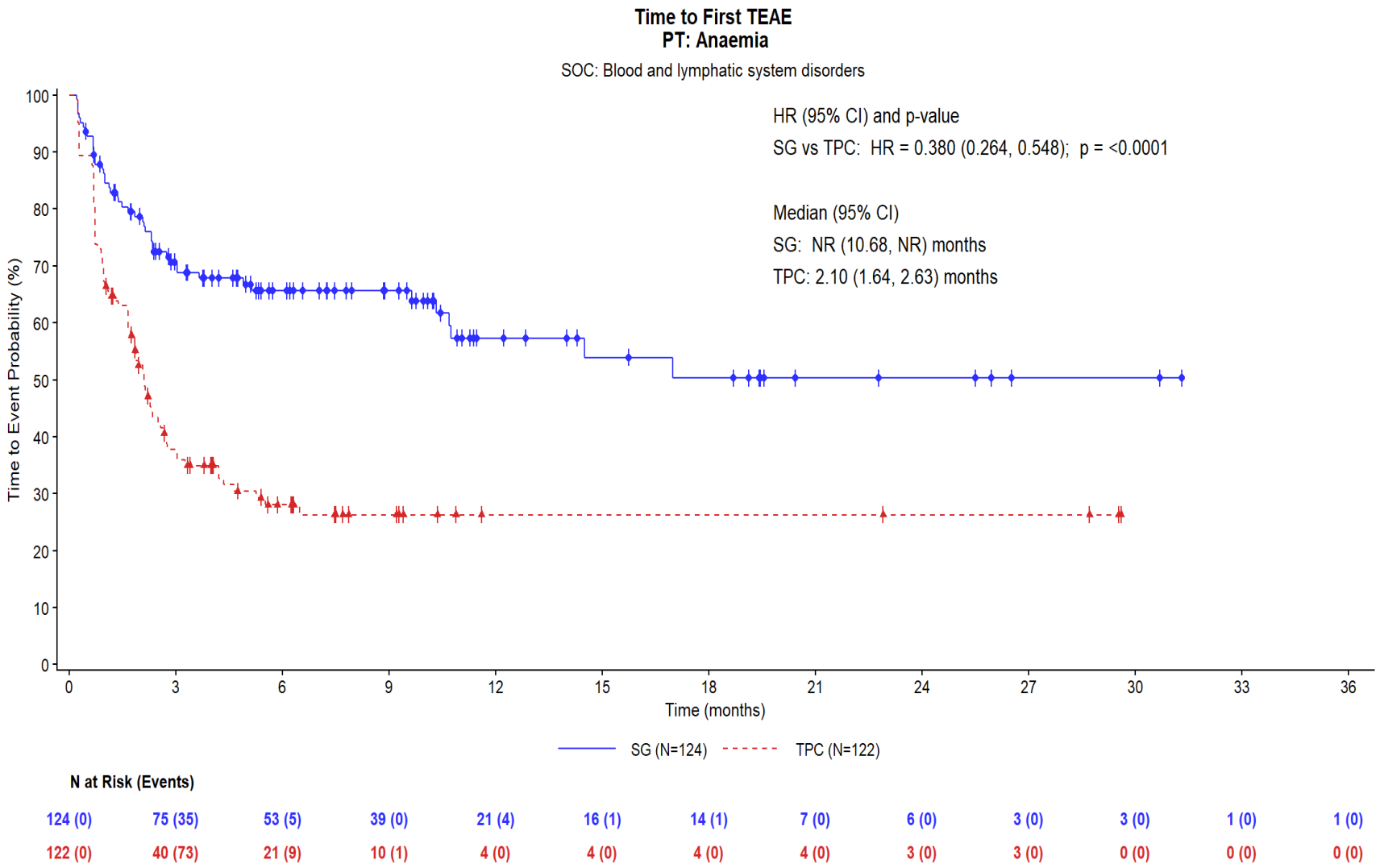
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.34. Figure 1.1.33: Kaplan Meier Plot of Time to First TEAE by SOC Vascular disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



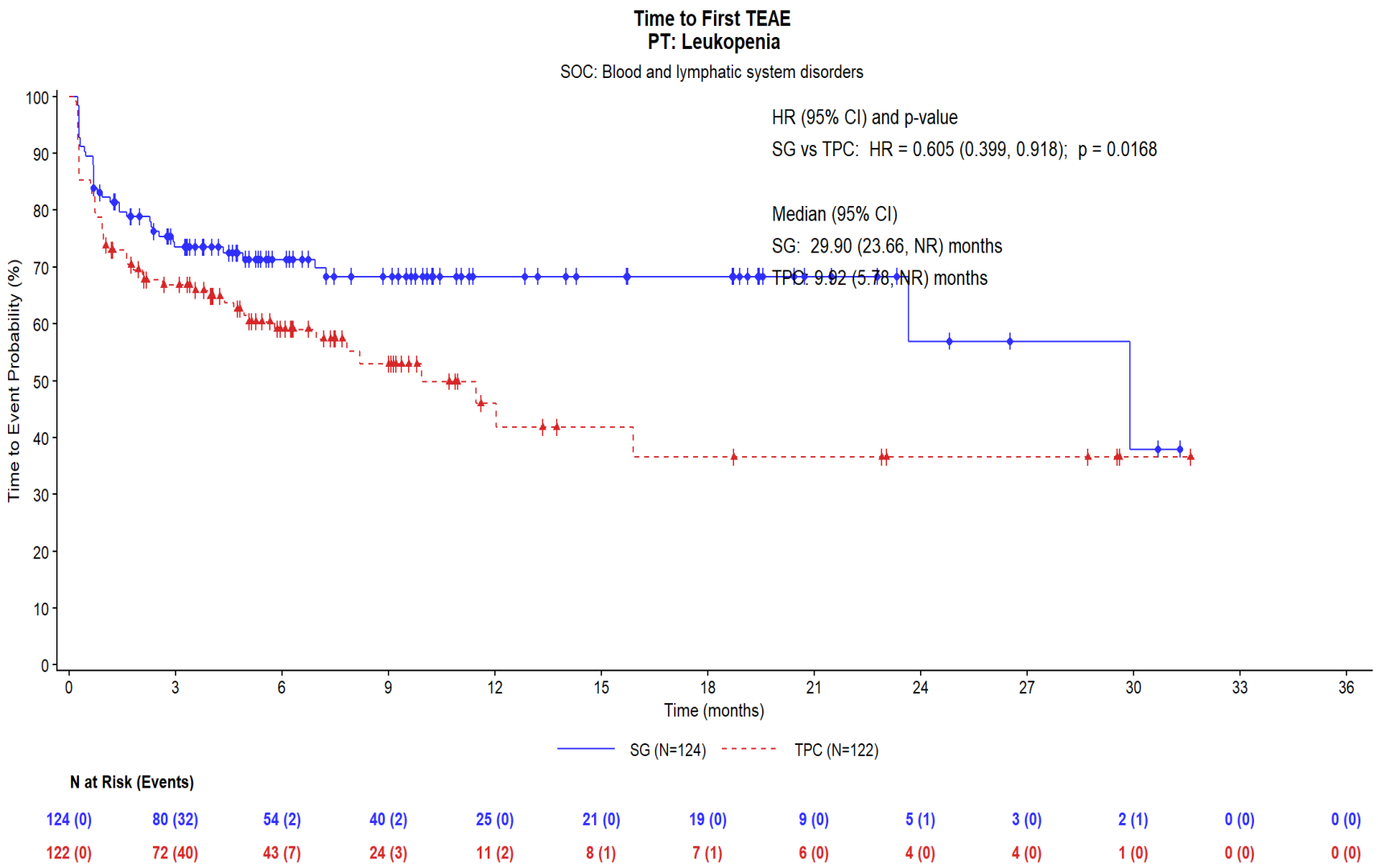
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.35. Figure 1.1.34: Kaplan Meier Plot of Time to First TEAE by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



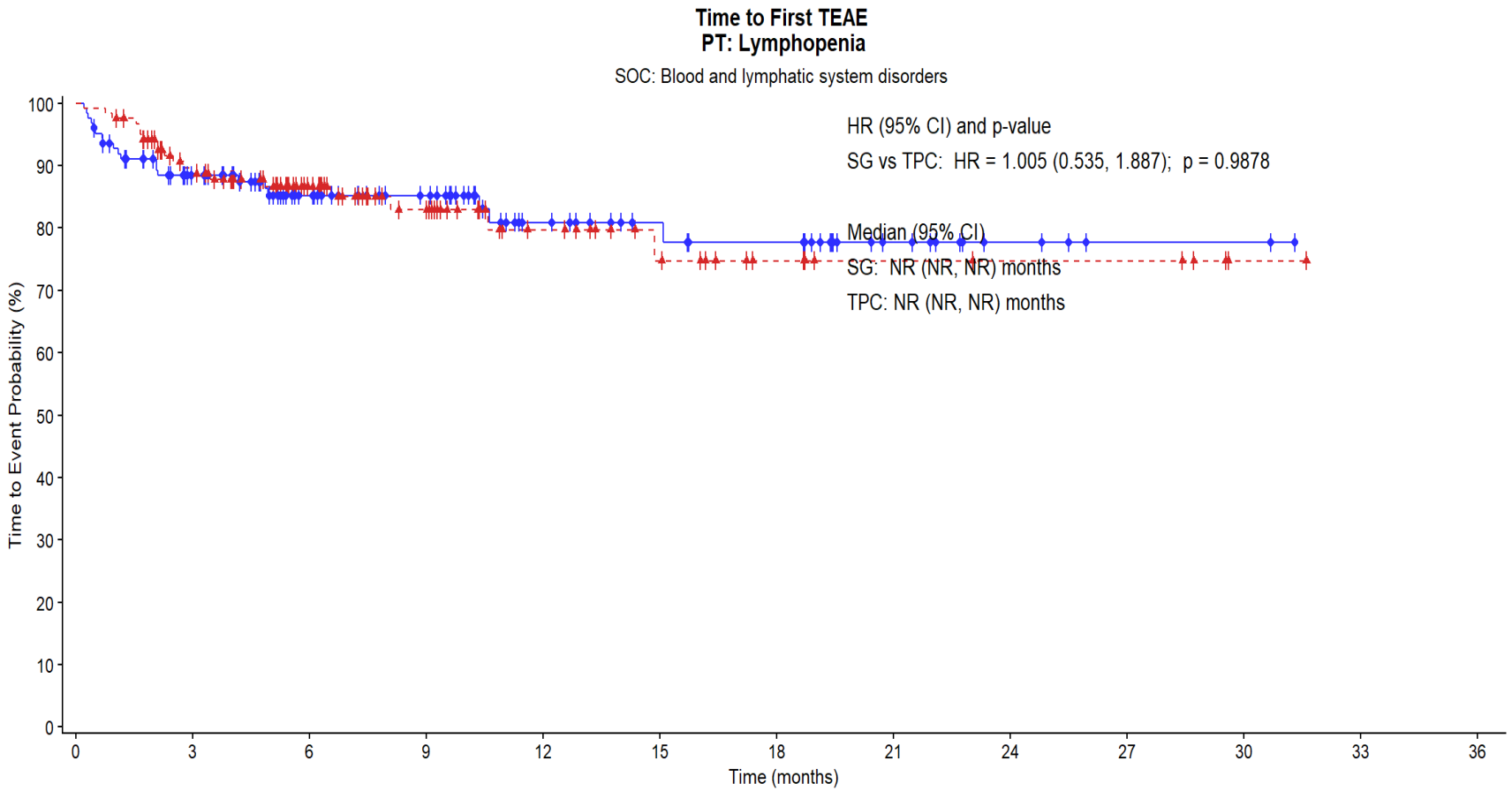
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.36. Figure 1.1.35: Kaplan Meier Plot of Time to First TEAE by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



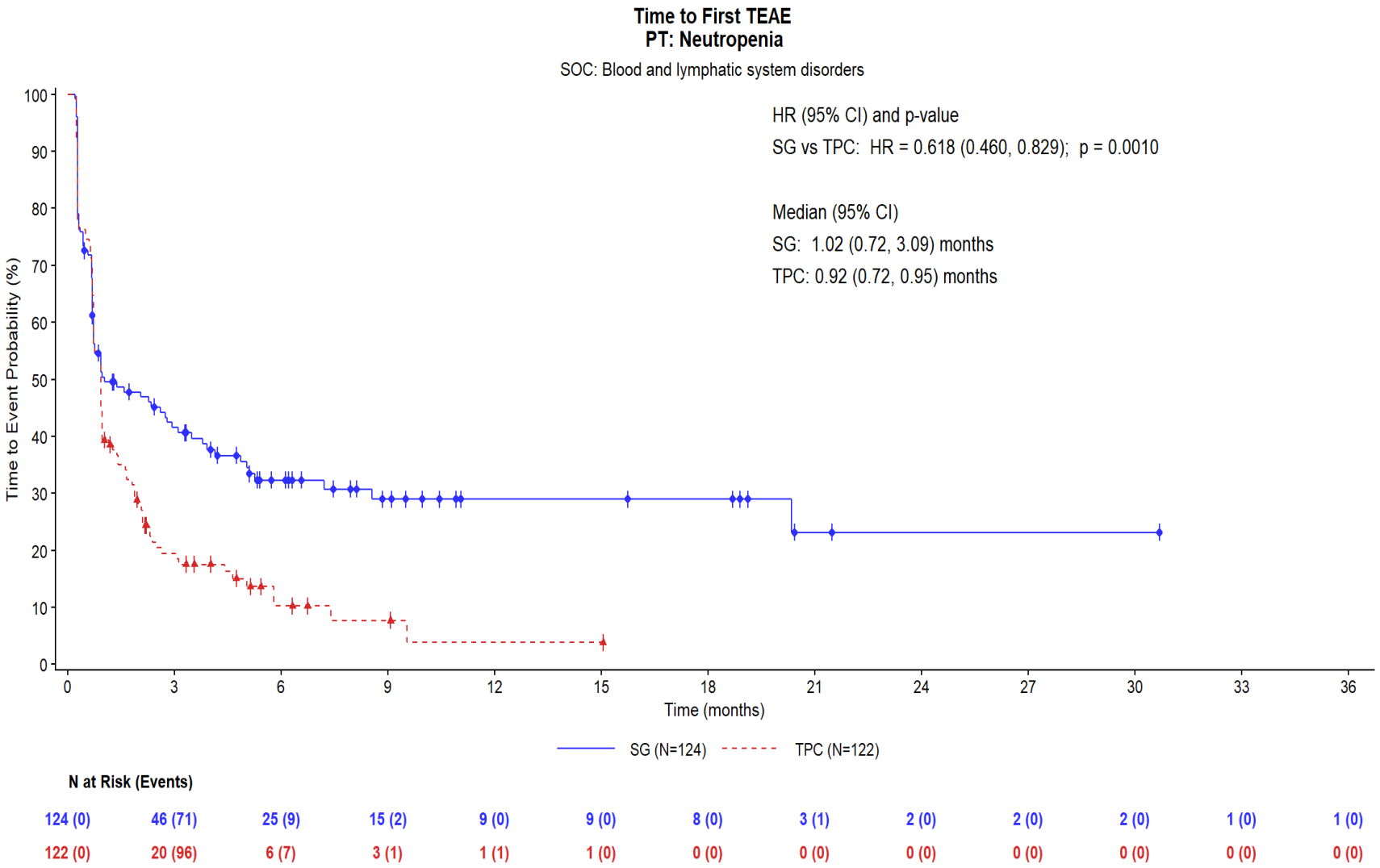
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.37. Figure 1.1.36: Kaplan Meier Plot of Time to First TEAE by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



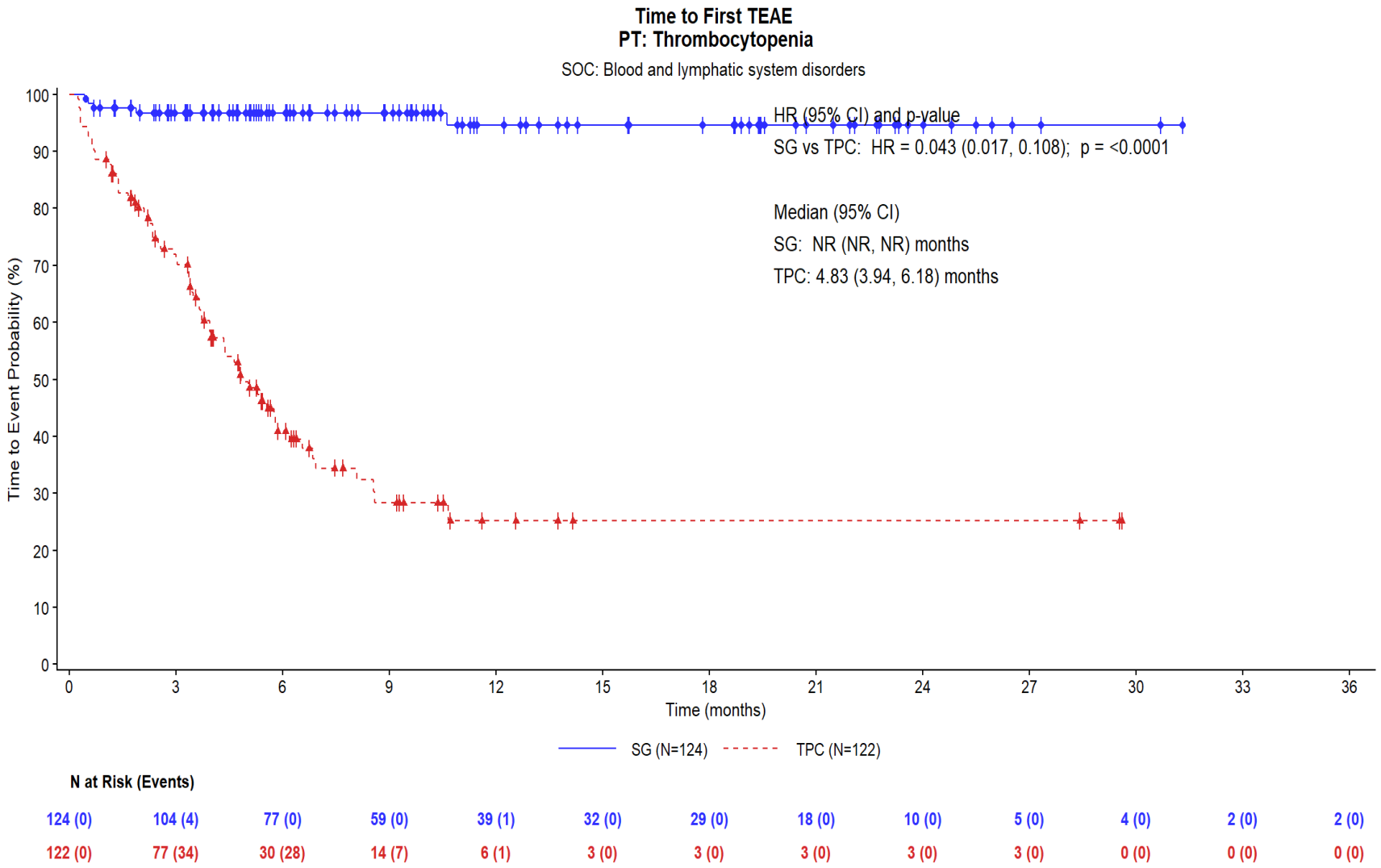
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.38. Figure 1.1.37: Kaplan Meier Plot of Time to First TEAE by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



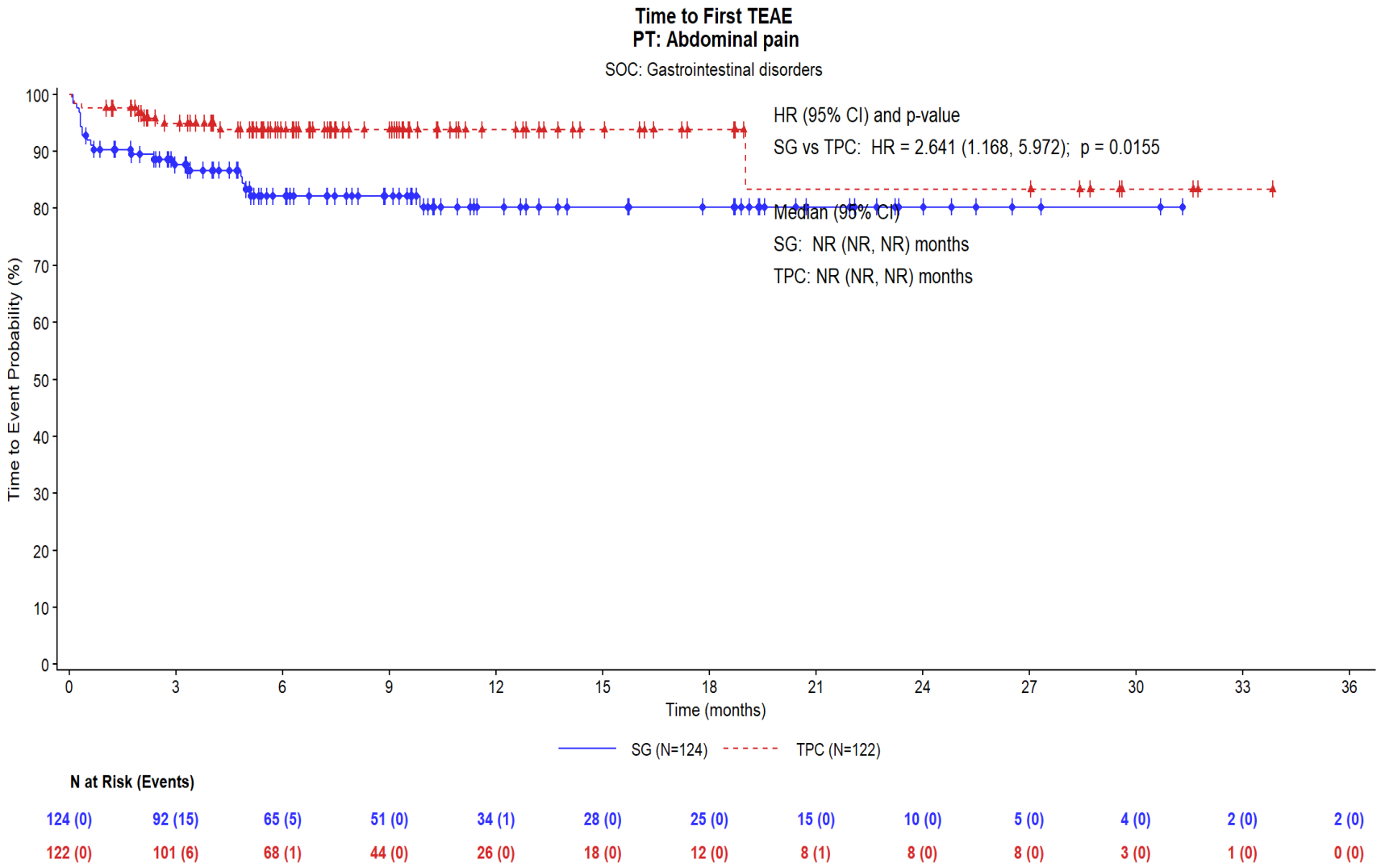
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.39. Figure 1.1.38: Kaplan Meier Plot of Time to First TEAE by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



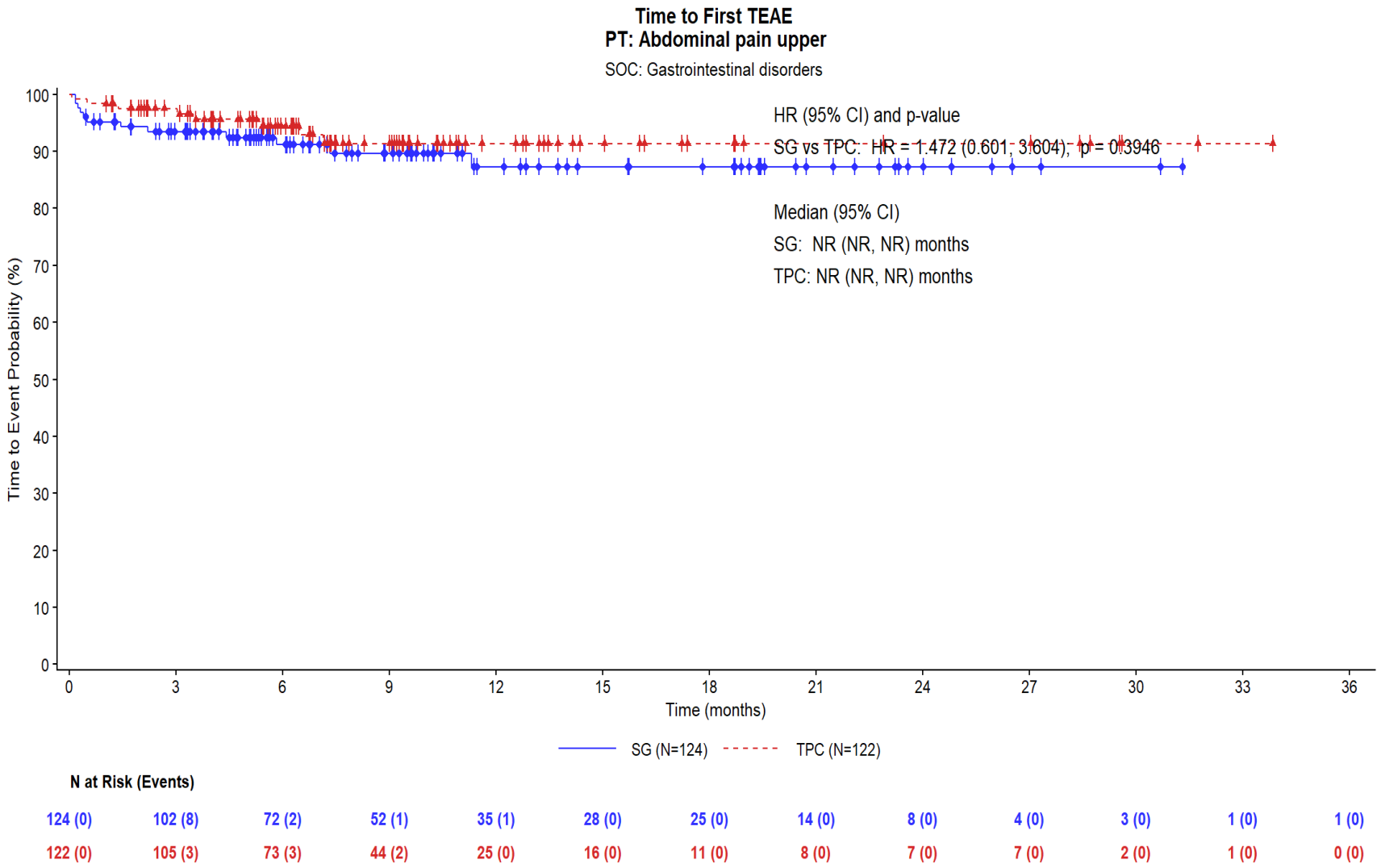
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.40. Figure 1.1.39: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



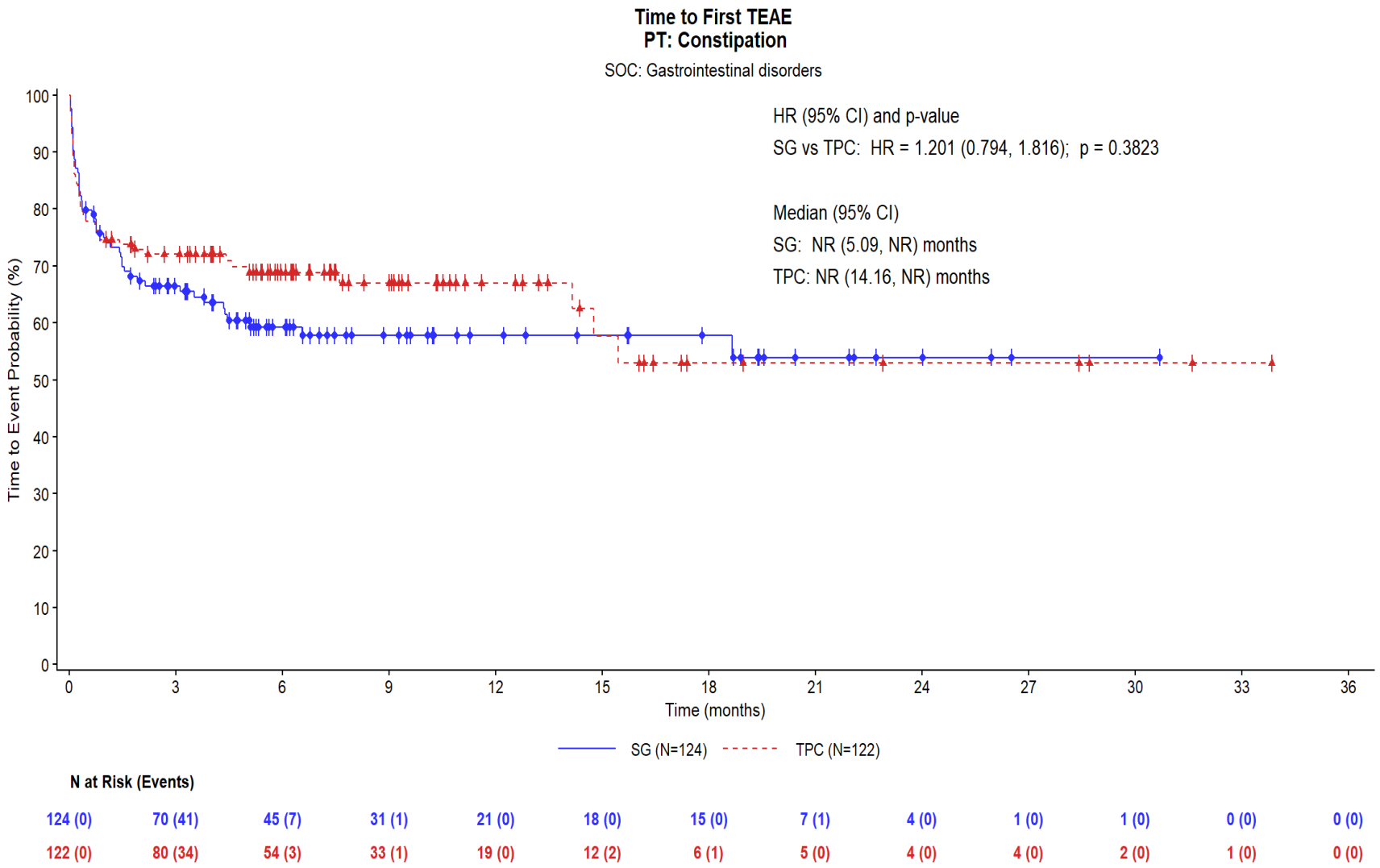
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.41. Figure 1.1.40: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain upper — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



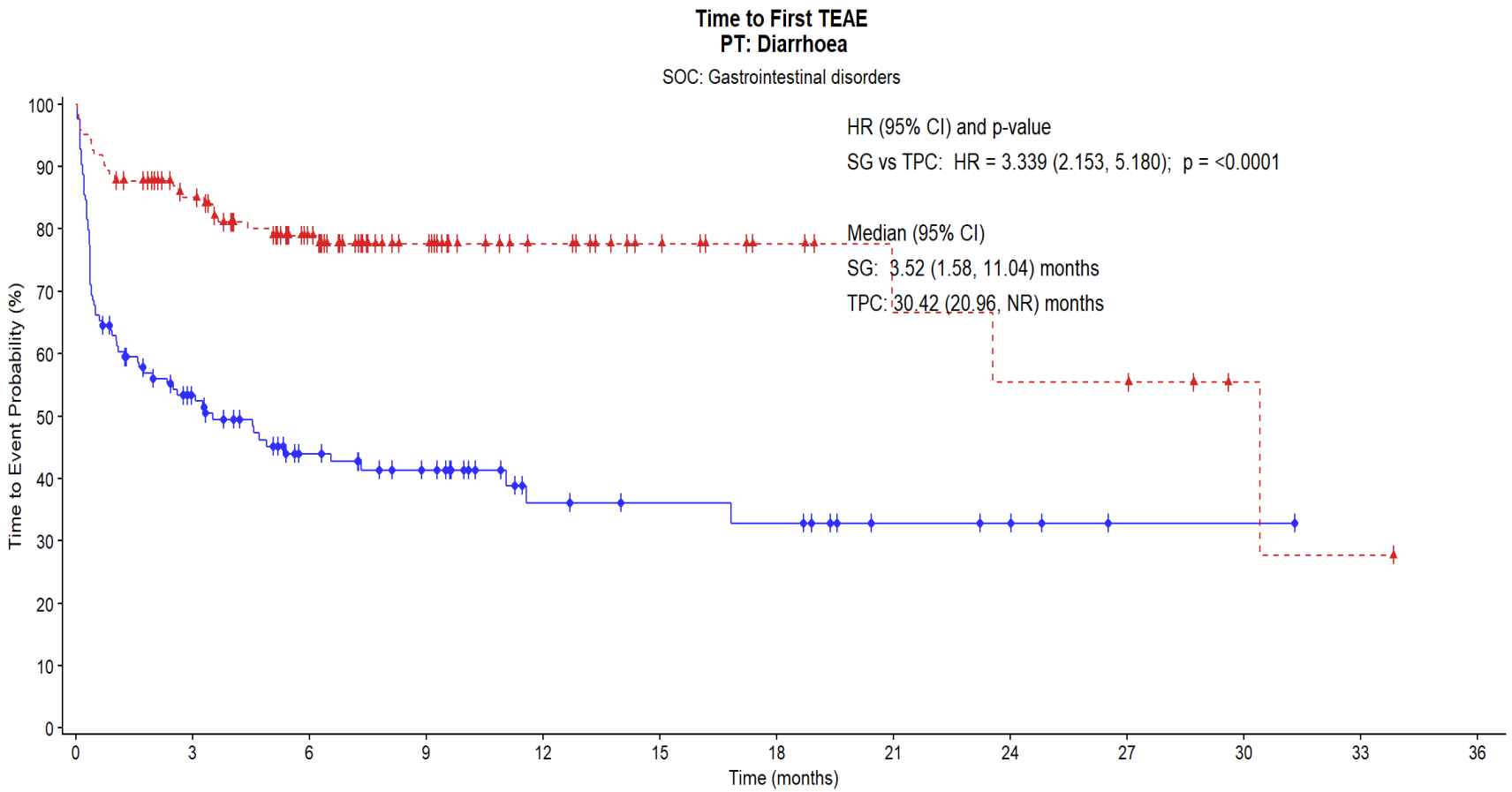
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.42. Figure 1.1.41: Kaplan Meier Plot of Time to First TEAE by PT Constipation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



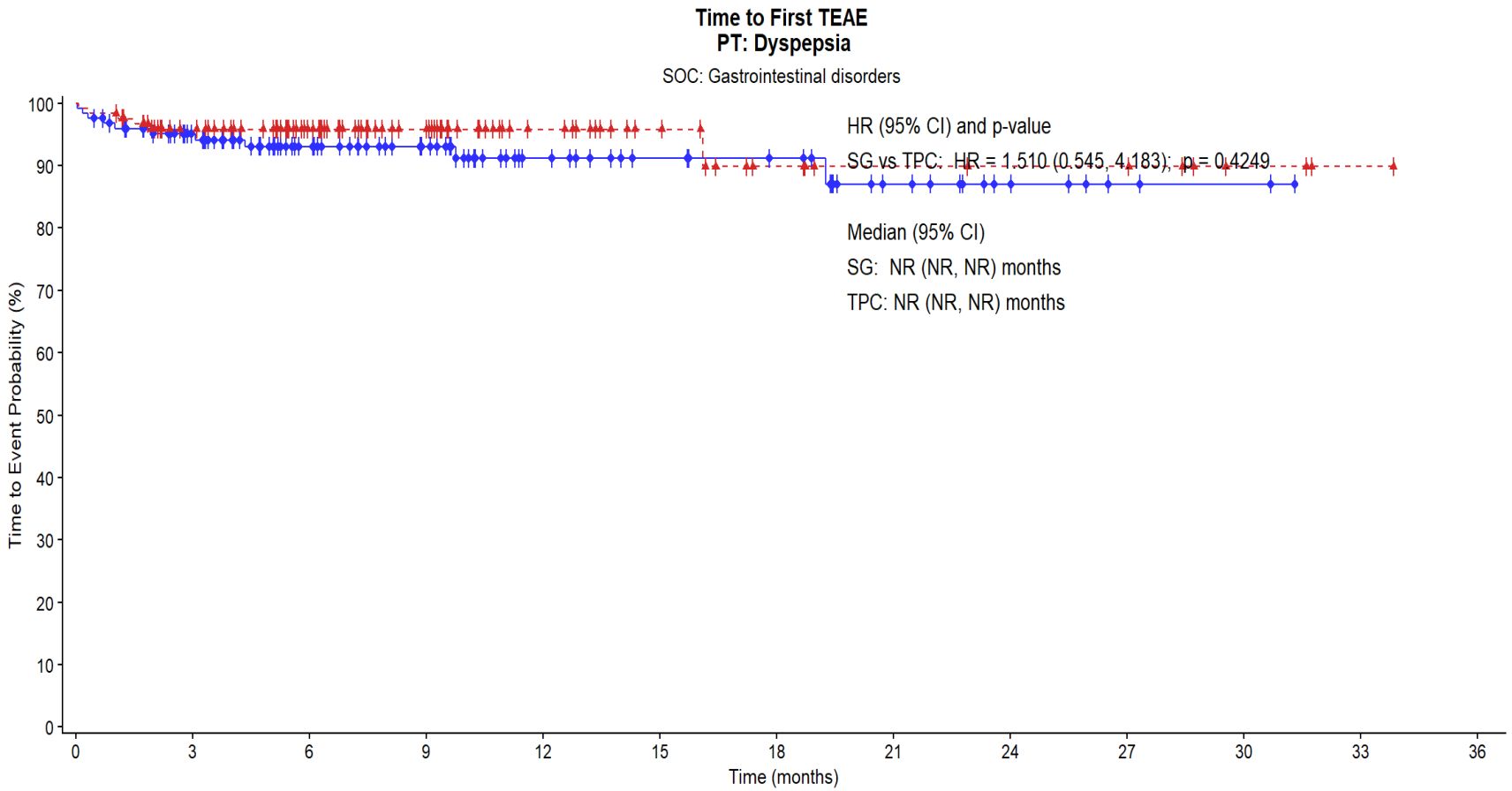
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.43. Figure 1.1.42: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



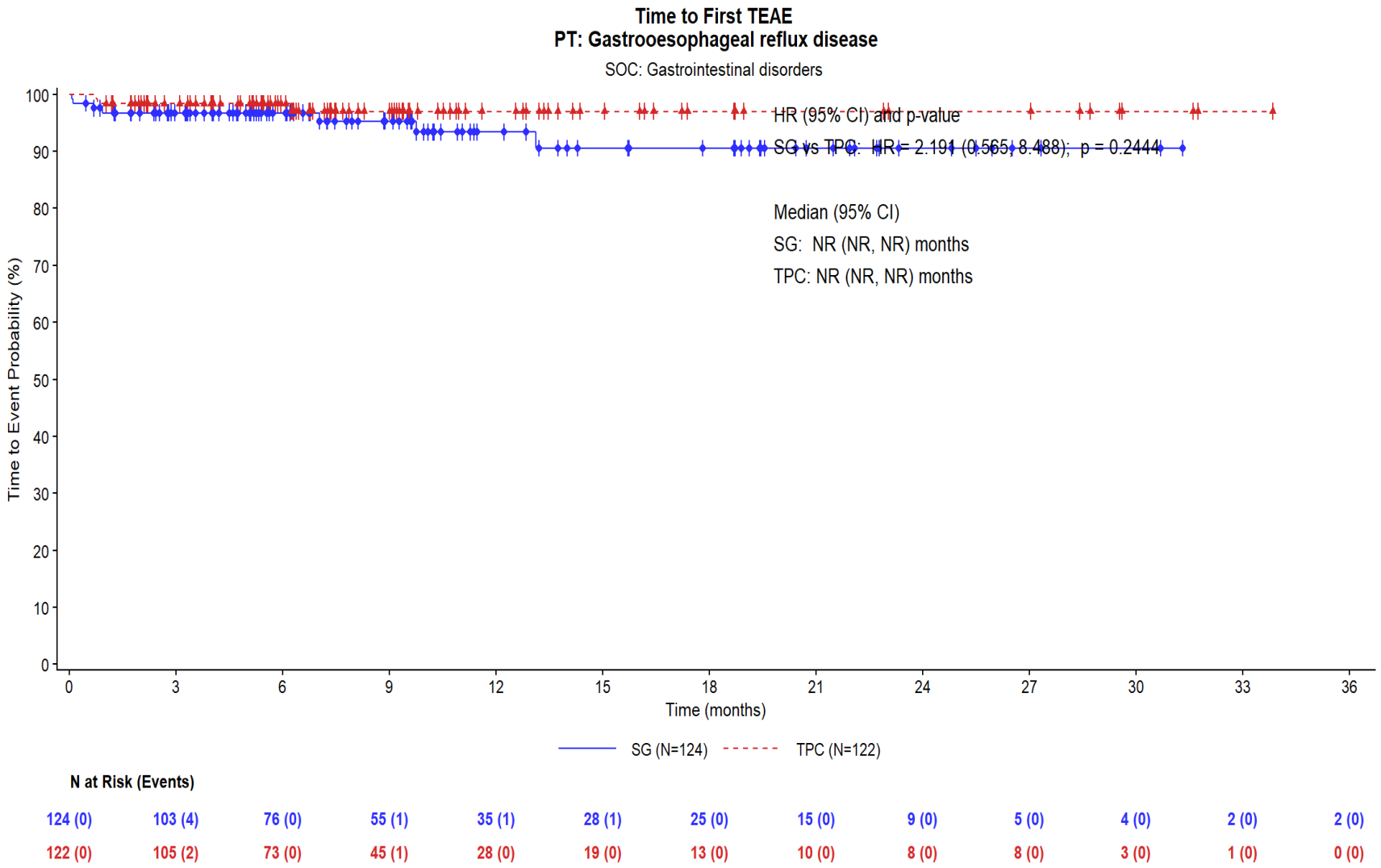
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.44. Figure 1.1.43: Kaplan Meier Plot of Time to First TEAE by PT Dyspepsia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



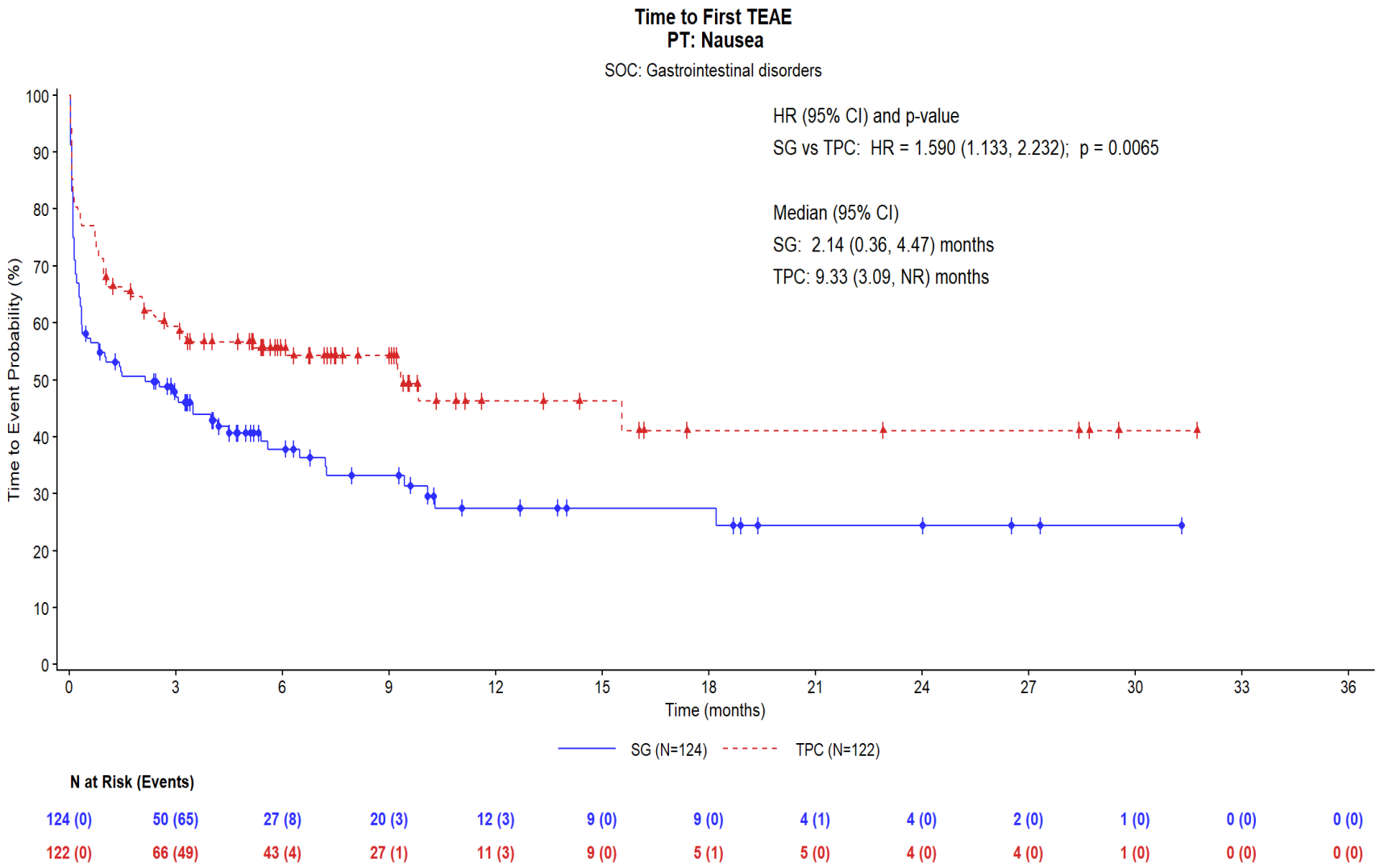
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.45. Figure 1.1.44: Kaplan Meier Plot of Time to First TEAE by PT Gastrooesophageal reflux disease — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



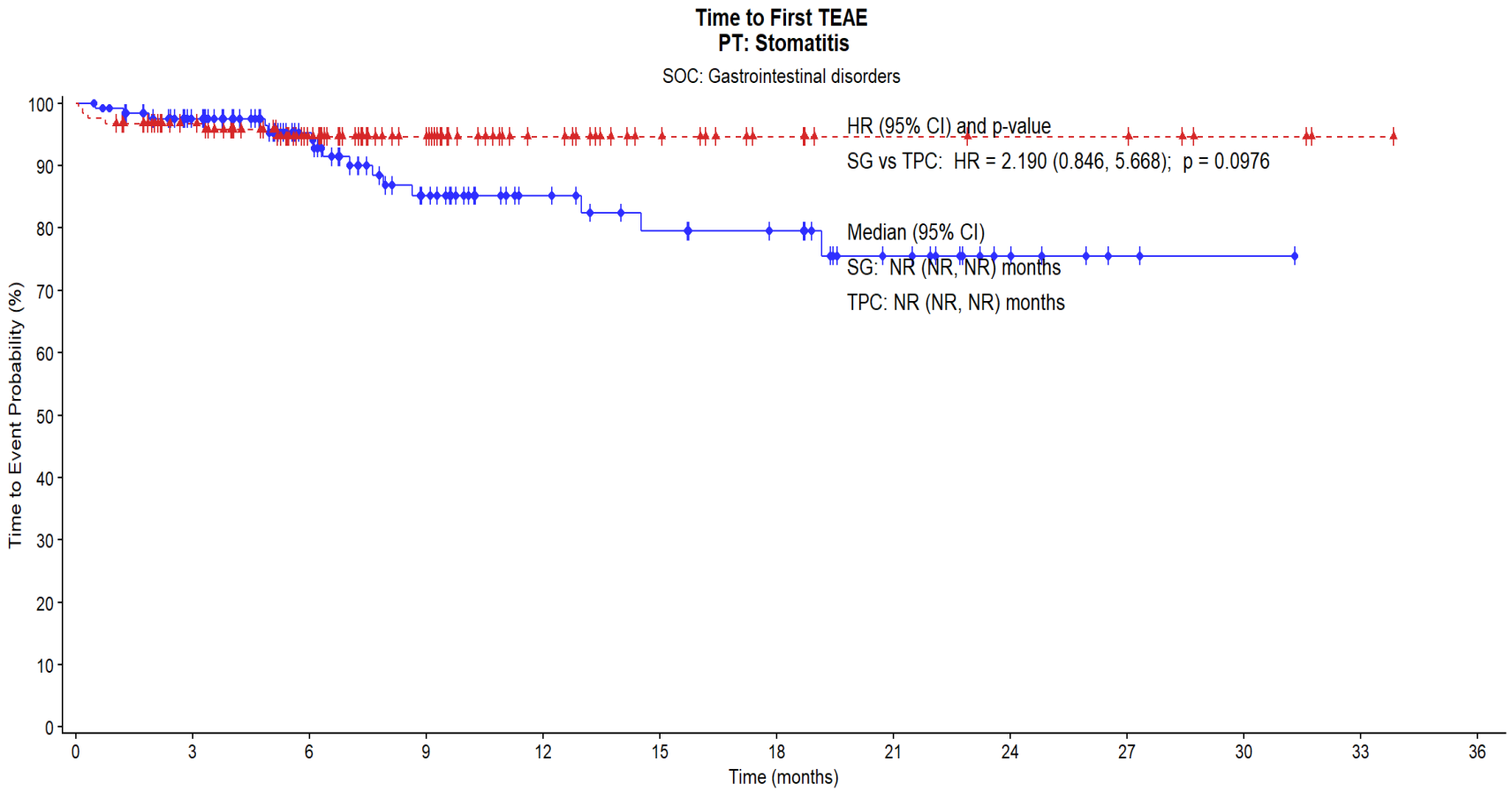
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.46. Figure 1.1.45: Kaplan Meier Plot of Time to First TEAE by PT Nausea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



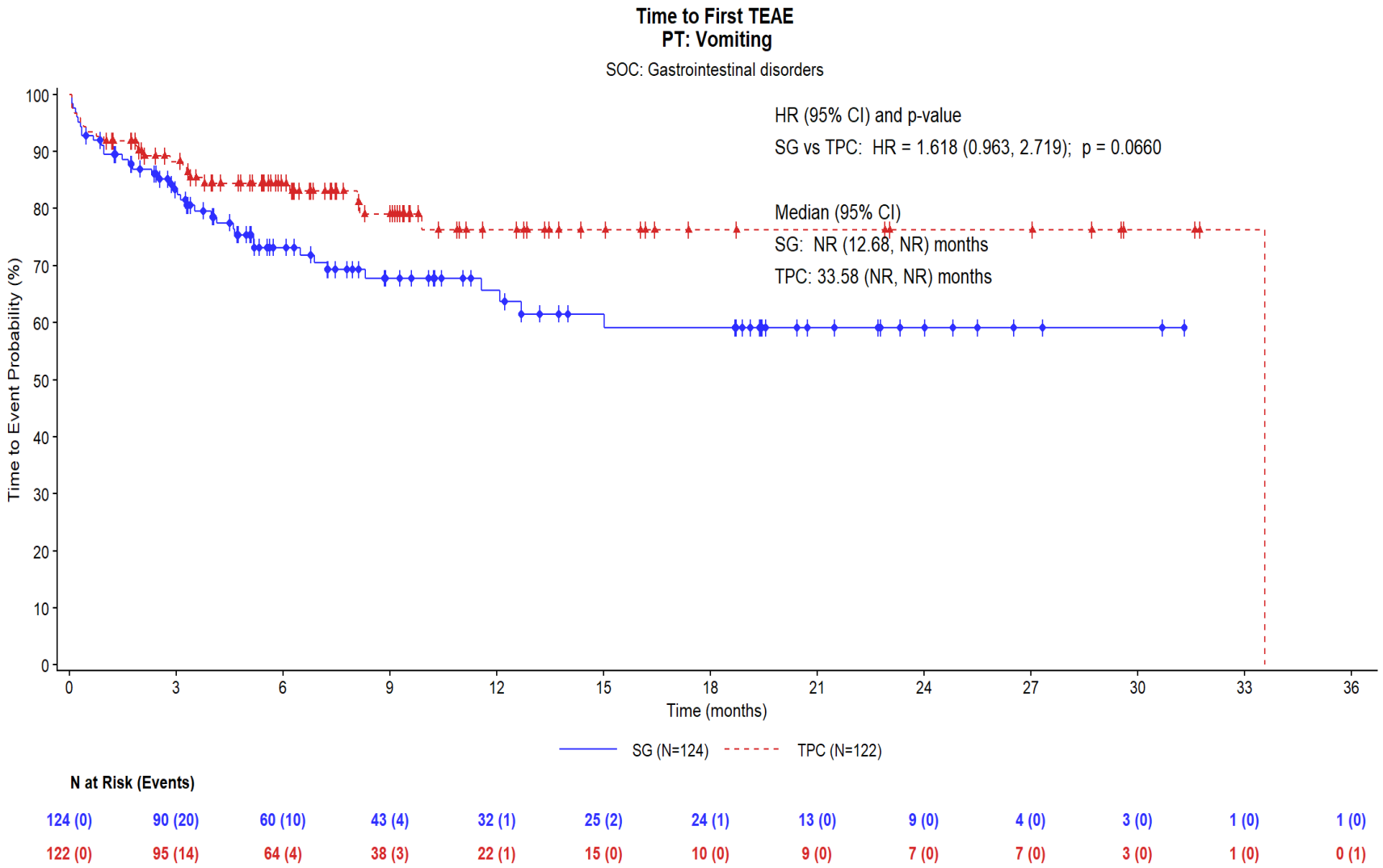
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.47. Figure 1.1.46: Kaplan Meier Plot of Time to First TEAE by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



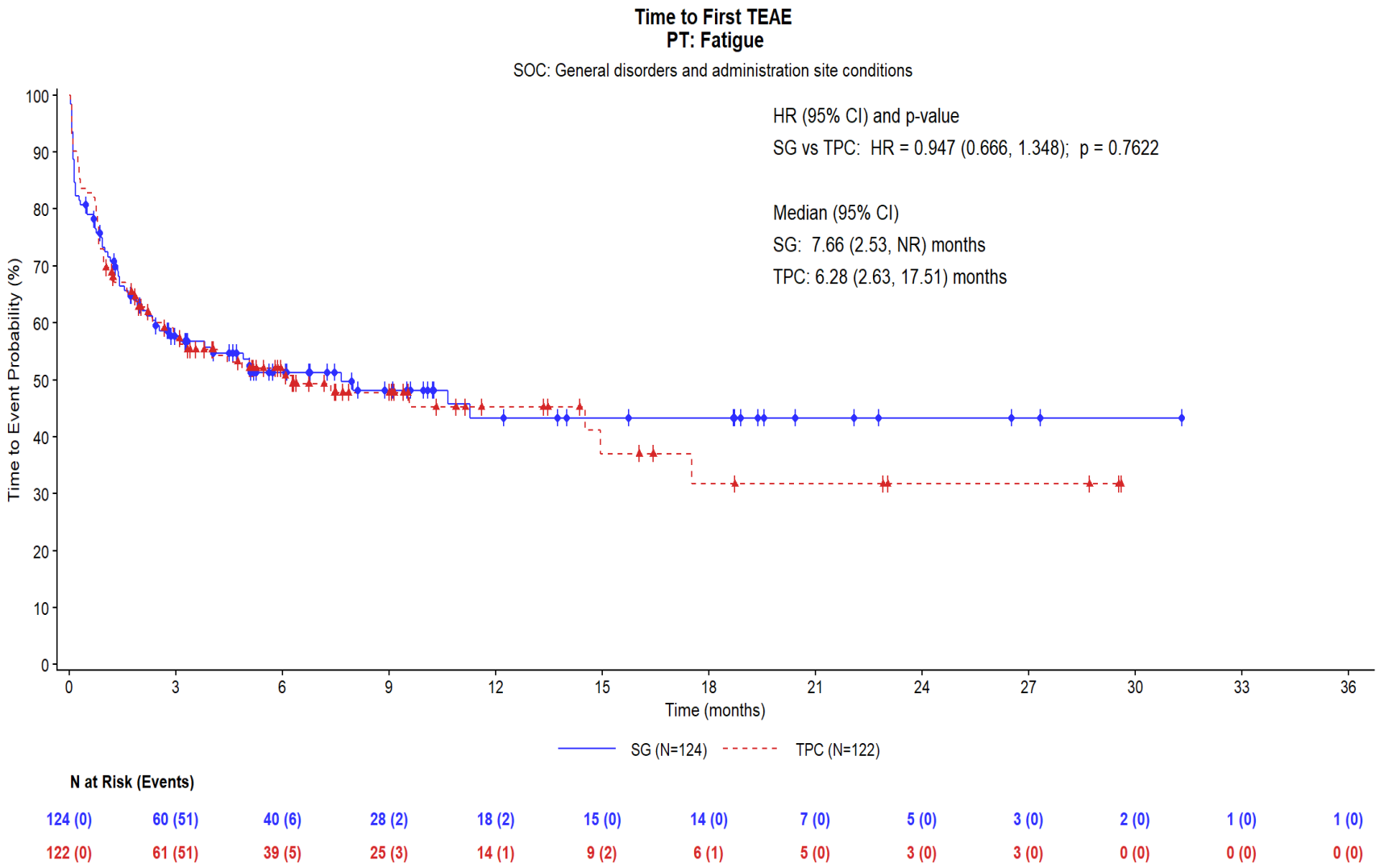
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.48. Figure 1.1.47: Kaplan Meier Plot of Time to First TEAE by PT Vomiting — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



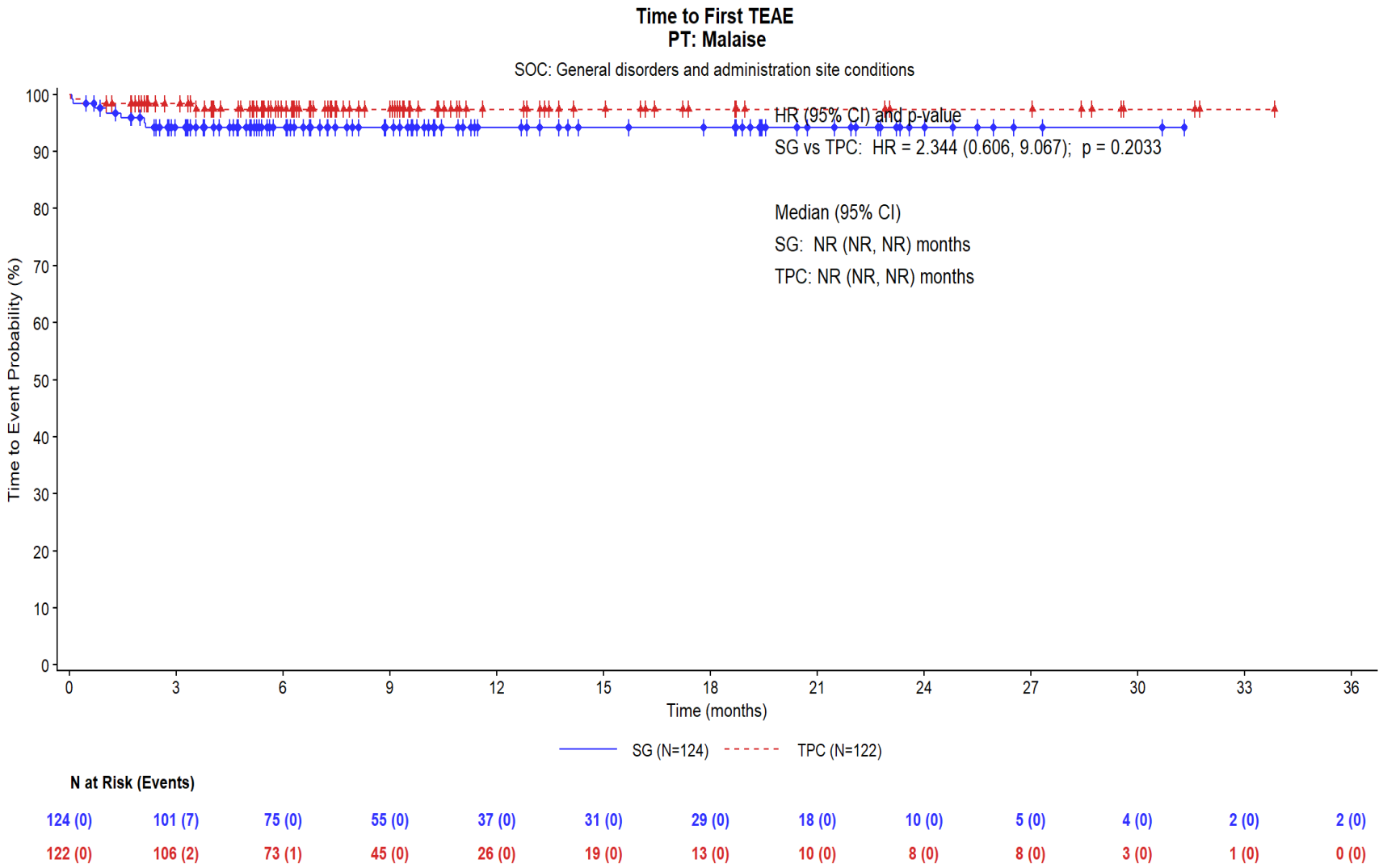
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.49. Figure 1.1.48: Kaplan Meier Plot of Time to First TEAE by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



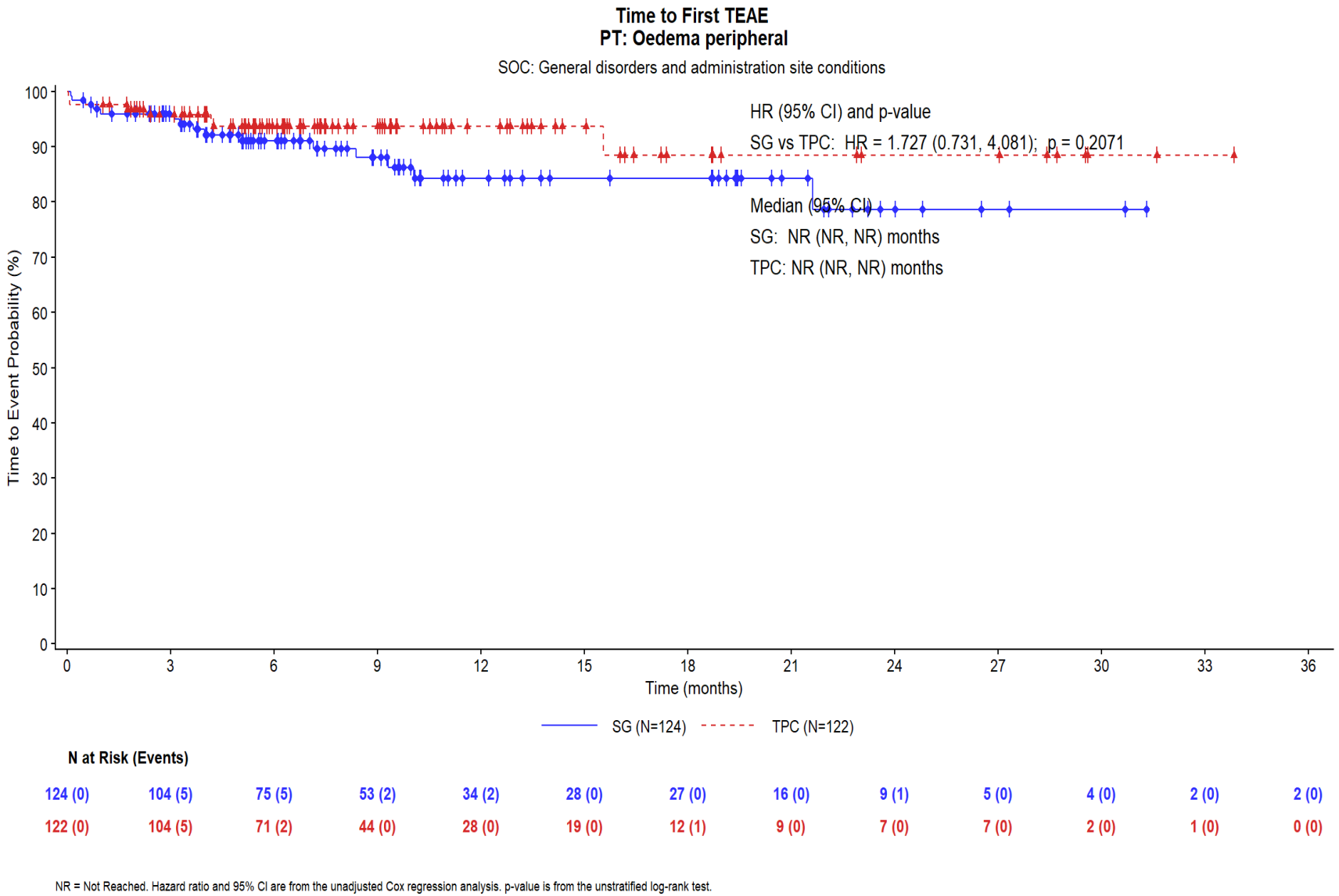
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.50. Figure 1.1.49: Kaplan Meier Plot of Time to First TEAE by PT Malaise — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



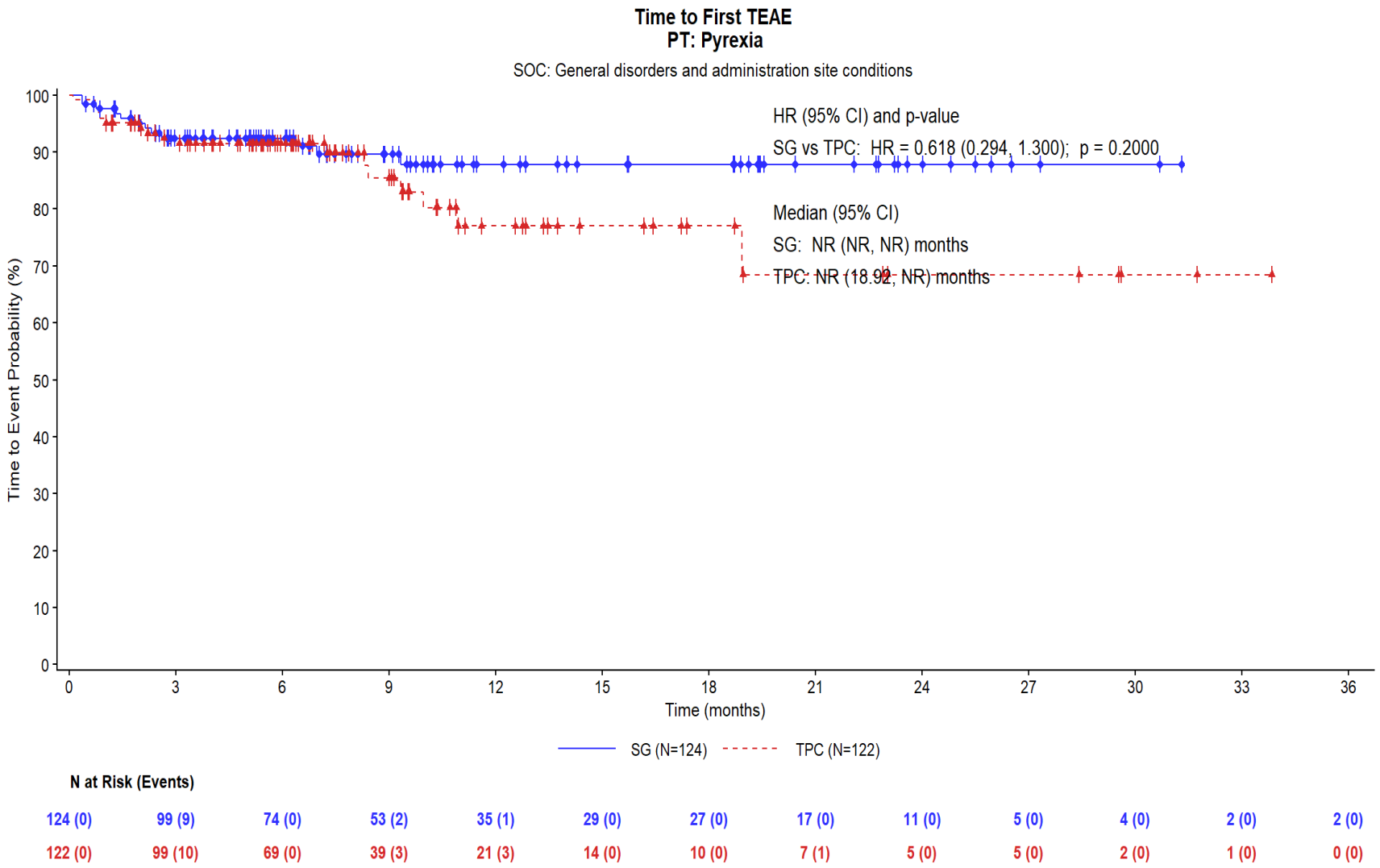
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.51. Figure 1.1.50: Kaplan Meier Plot of Time to First TEAE by PT Oedema peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



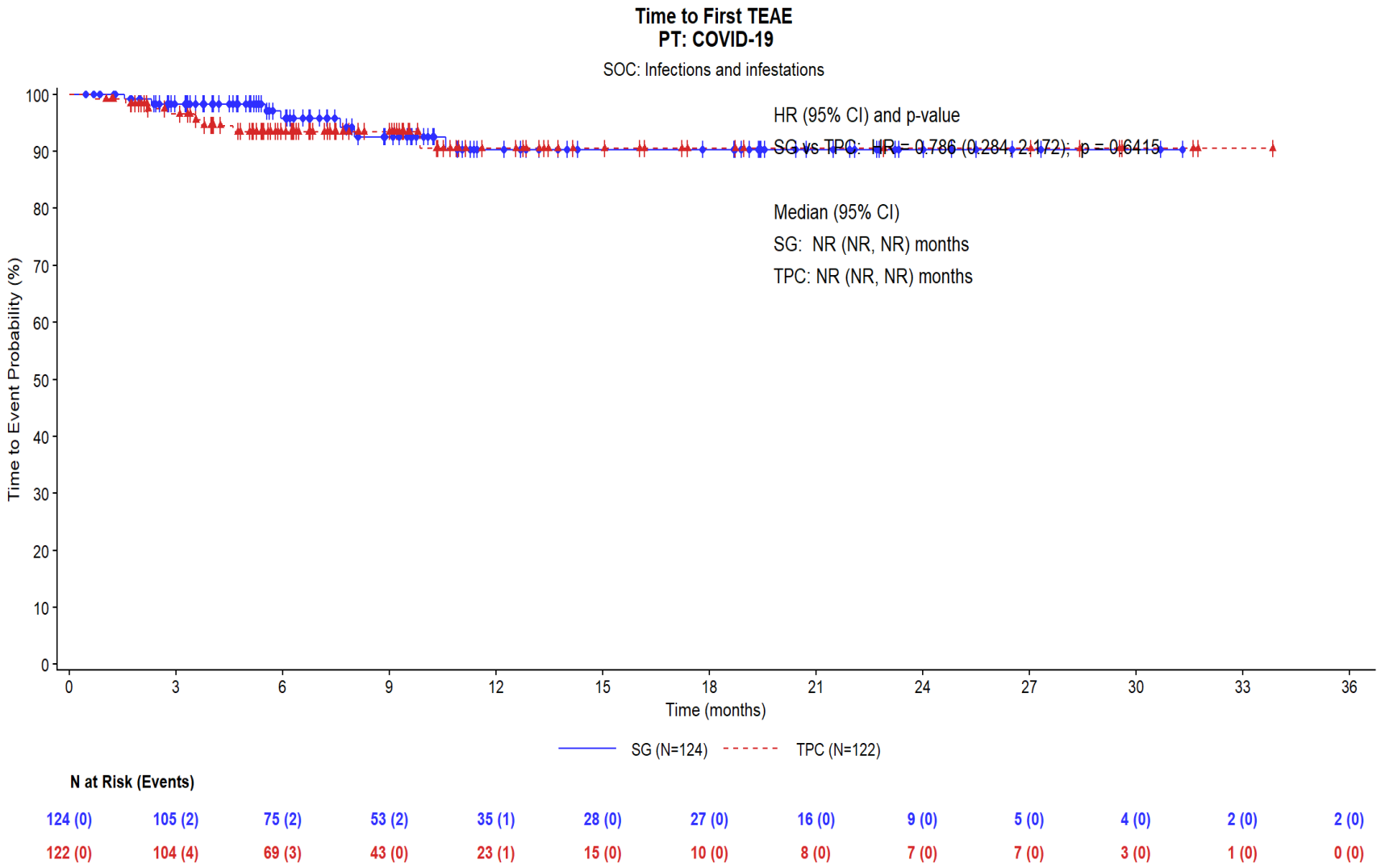
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.52. Figure 1.1.51: Kaplan Meier Plot of Time to First TEAE by PT Pyrexia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



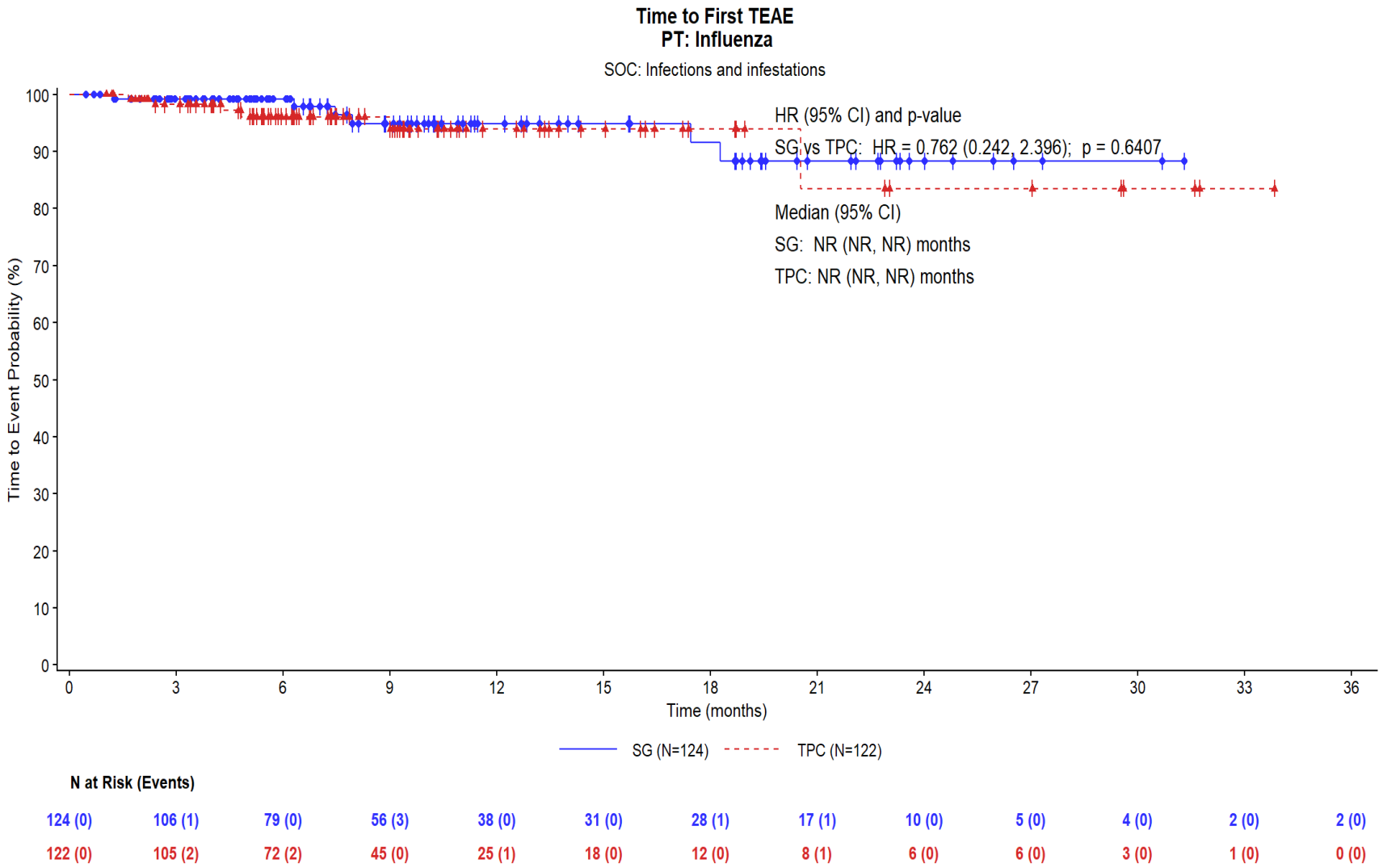
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.53. Figure 1.1.52: Kaplan Meier Plot of Time to First TEAE by PT COVID 19 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



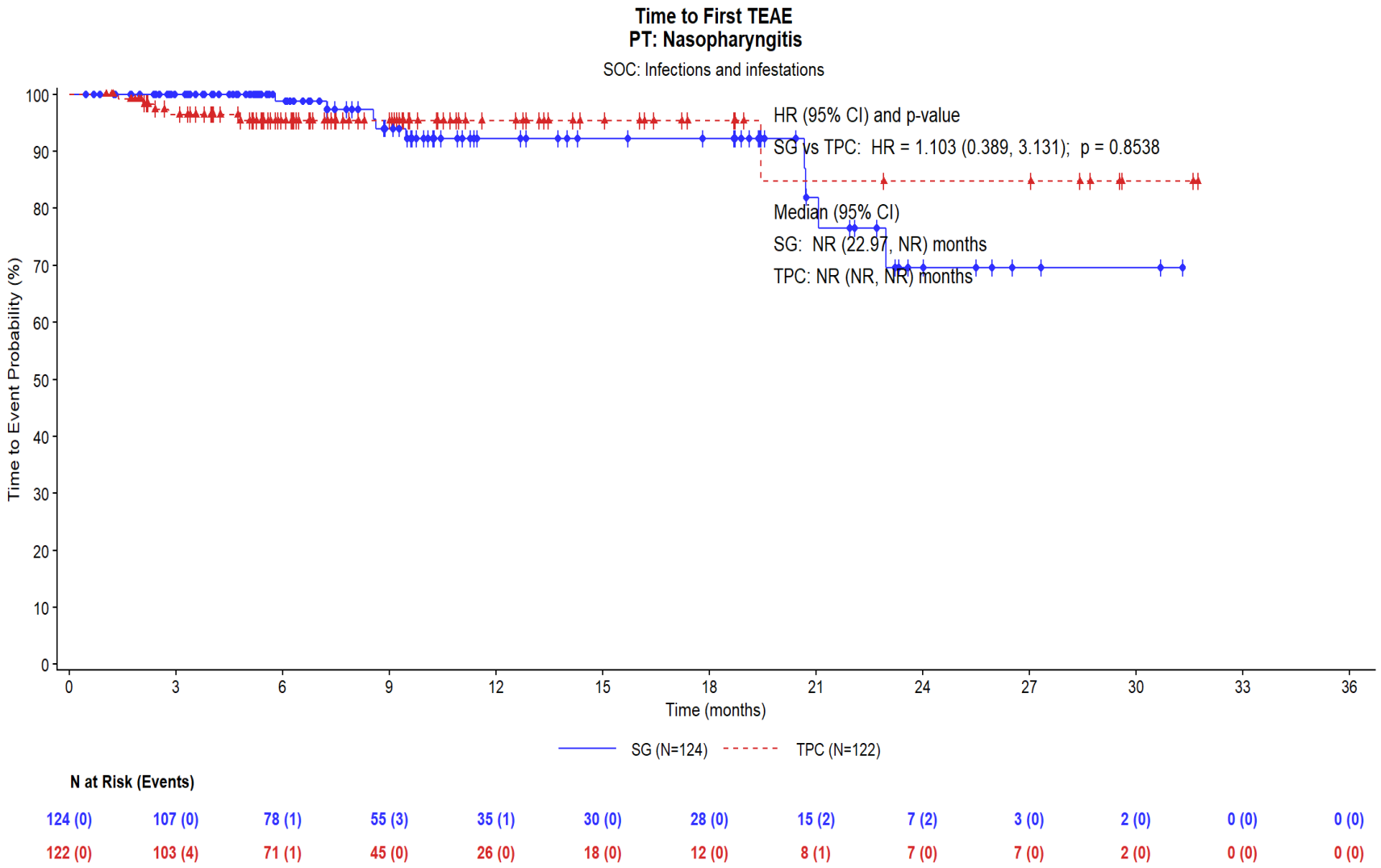
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.54. Figure 1.1.53: Kaplan Meier Plot of Time to First TEAE by PT Influenza — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



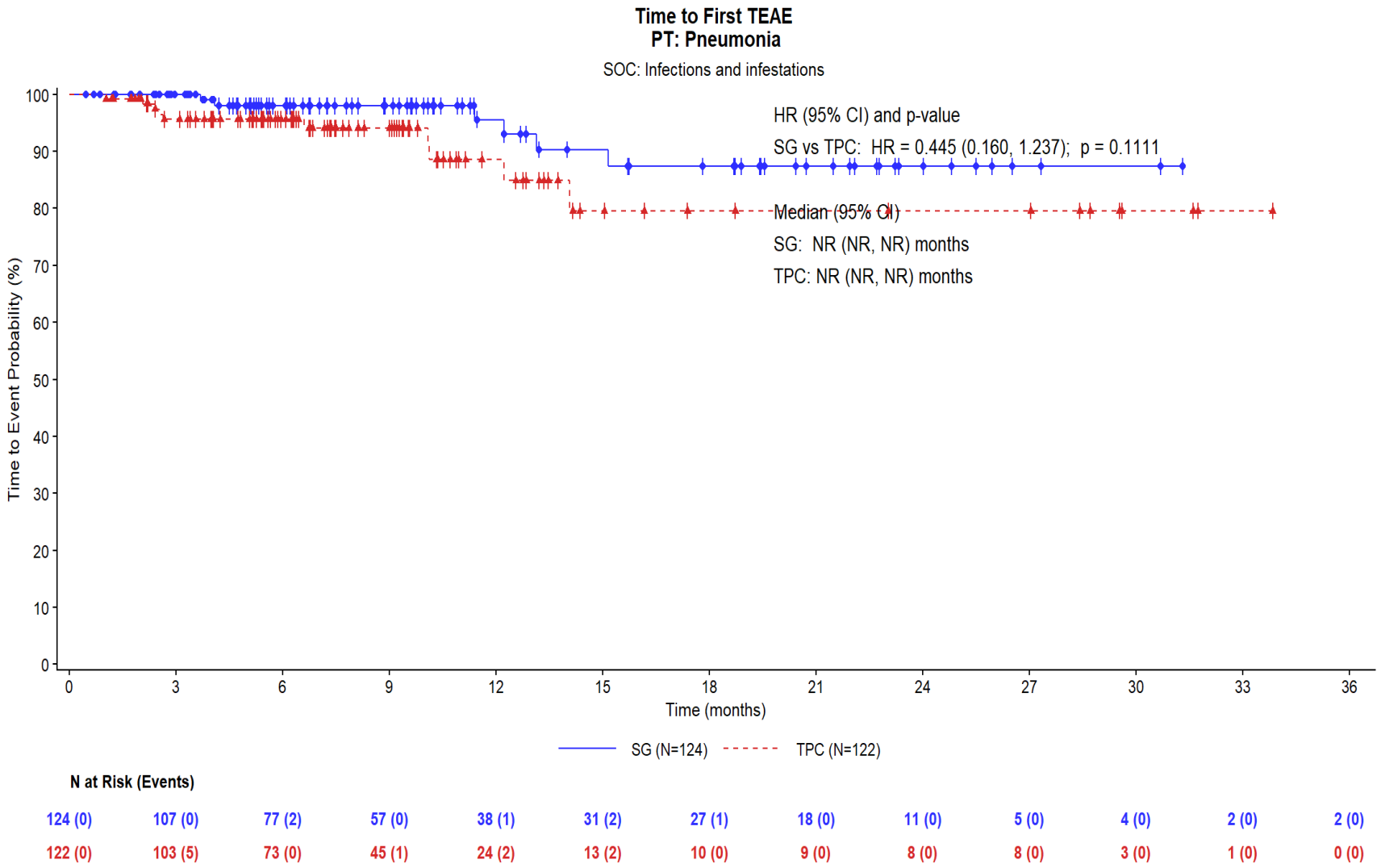
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.55. Figure 1.1.54: Kaplan Meier Plot of Time to First TEAE by PT Nasopharyngitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



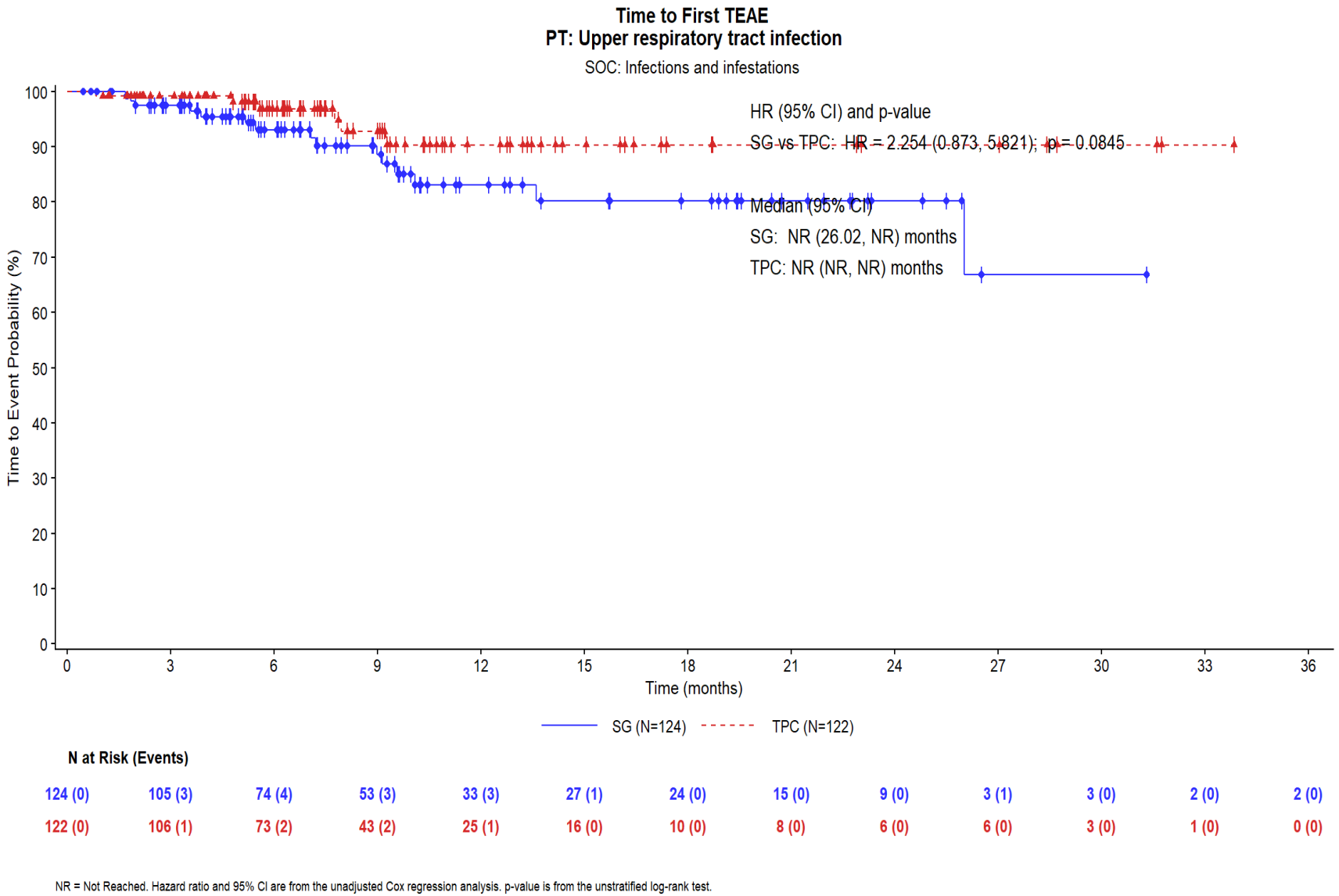
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.56. Figure 1.1.55: Kaplan Meier Plot of Time to First TEAE by PT Pneumonia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



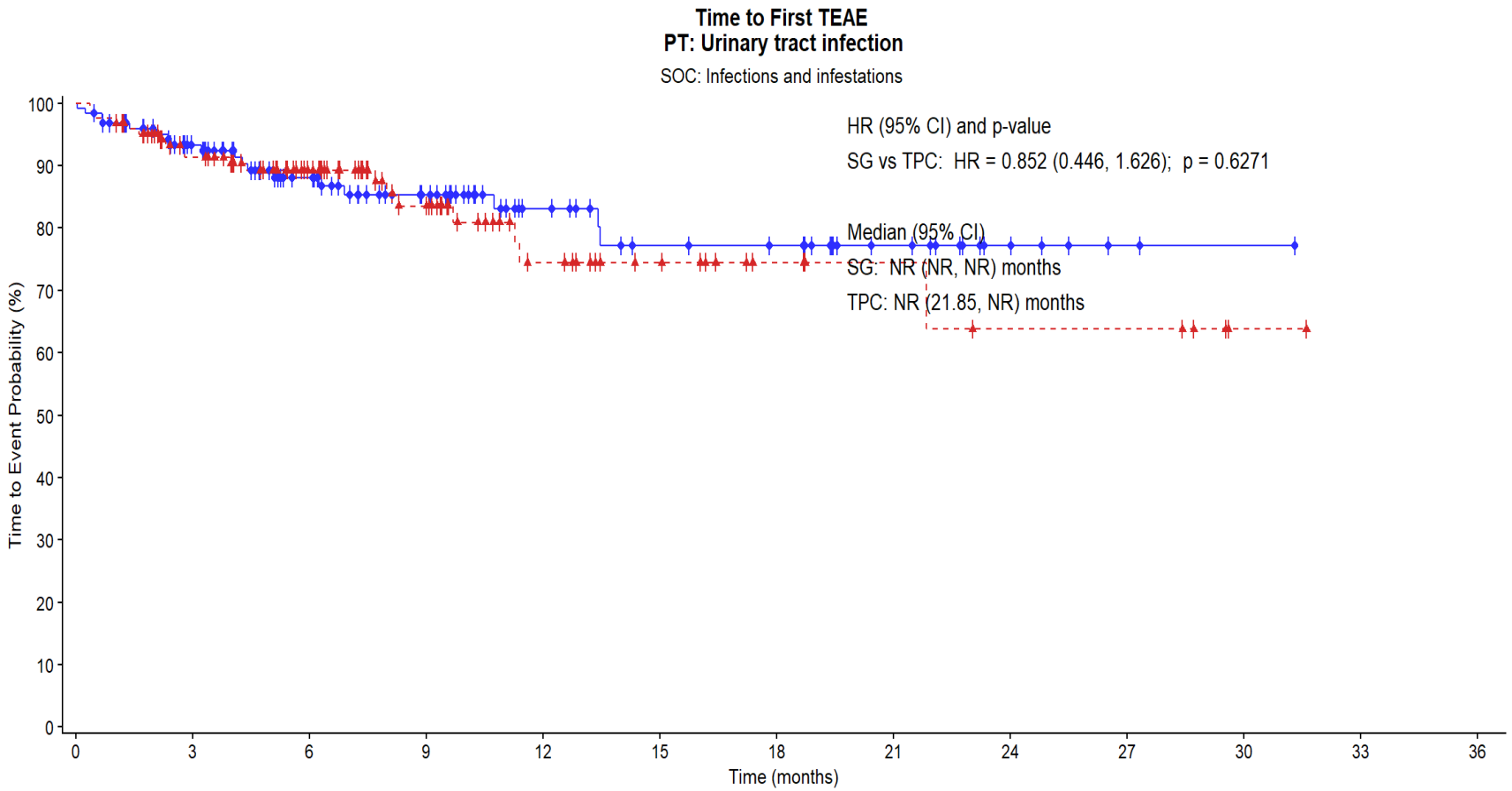
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.57. Figure 1.1.56: Kaplan Meier Plot of Time to First TEAE by PT Upper respiratory tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



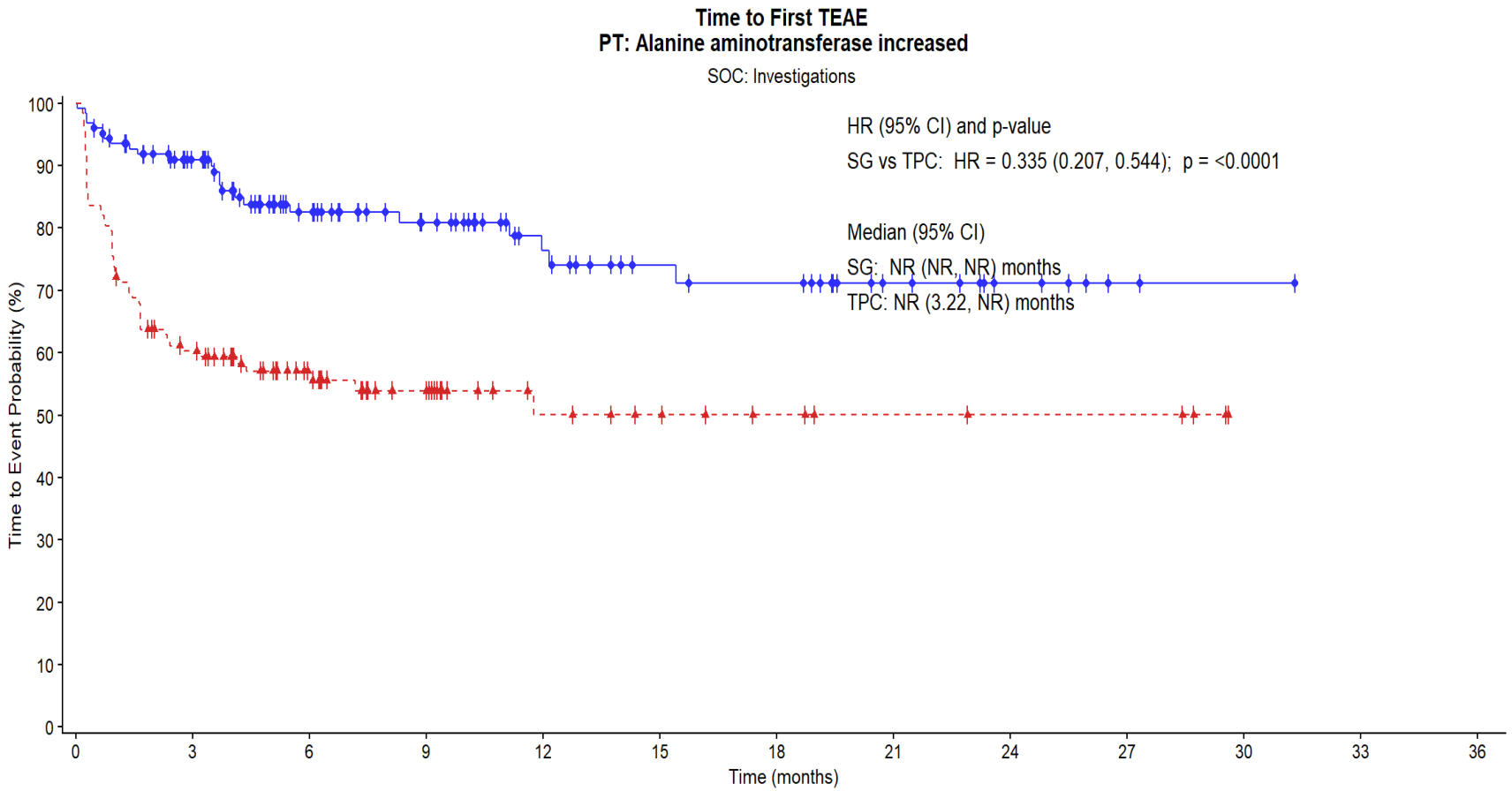
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.58. Figure 1.1.57: Kaplan Meier Plot of Time to First TEAE by PT Urinary tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



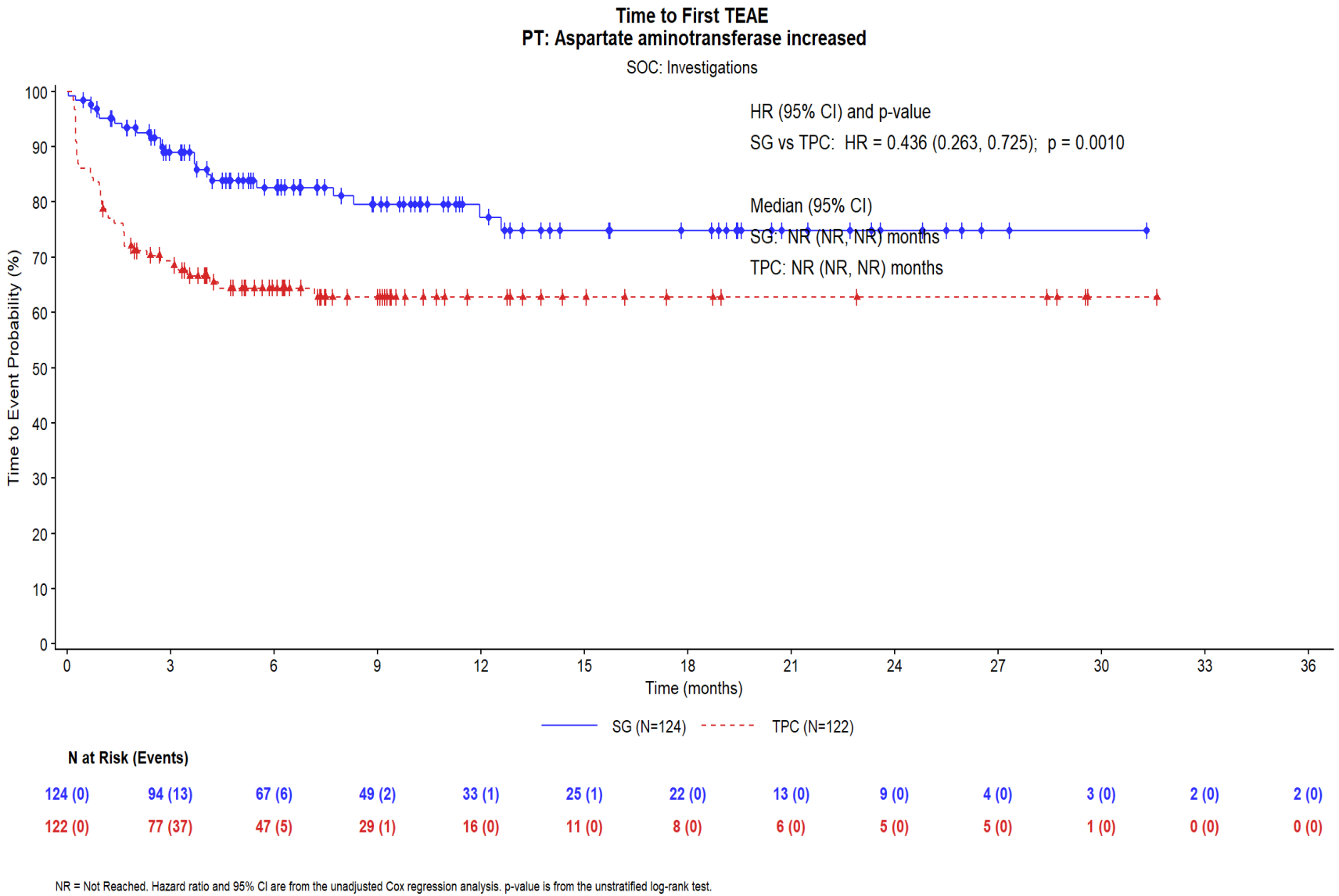
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.59. Figure 1.1.58: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



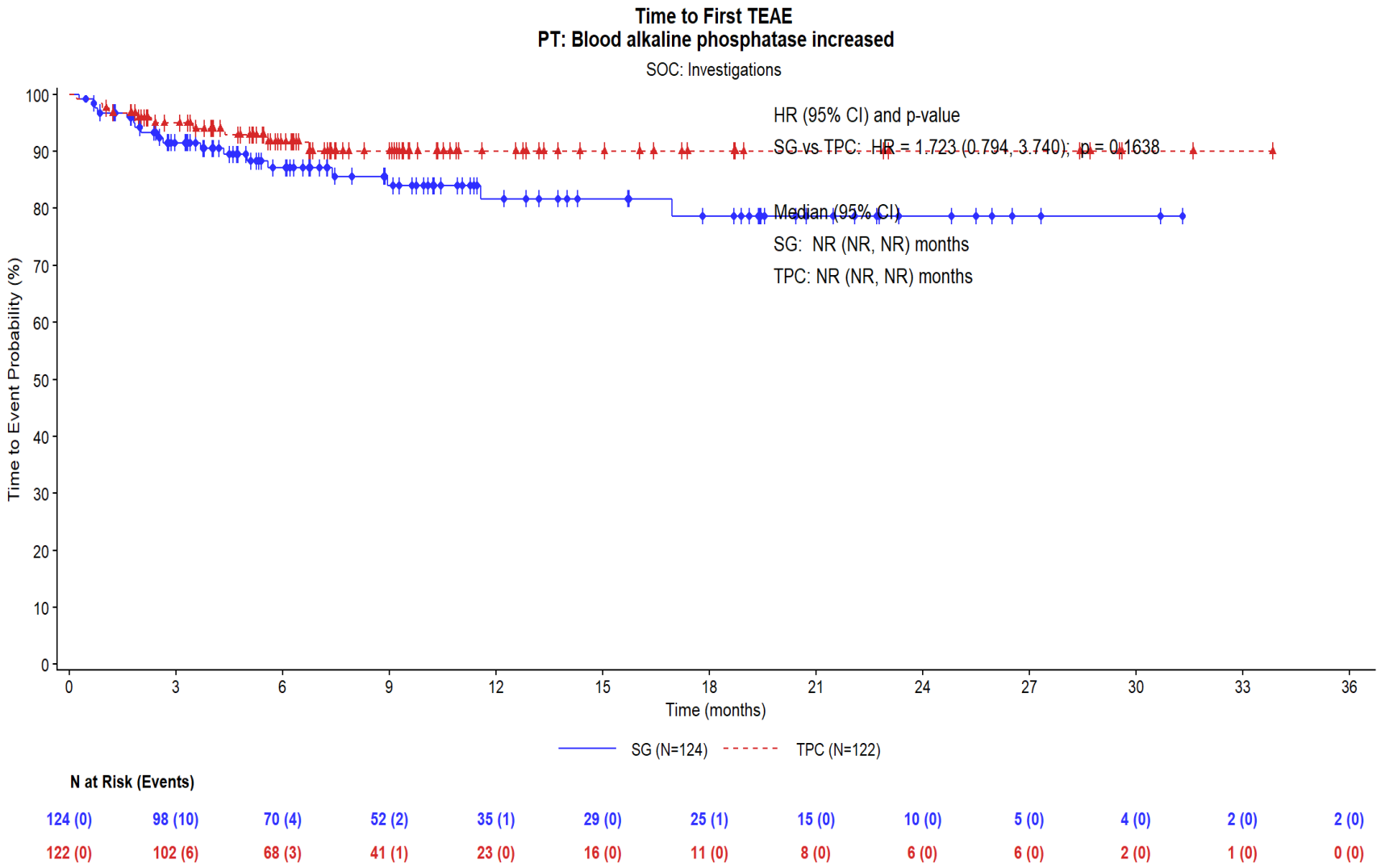
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.60. Figure 1.1.59: Kaplan Meier Plot of Time to First TEAE by PT Aspartate aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



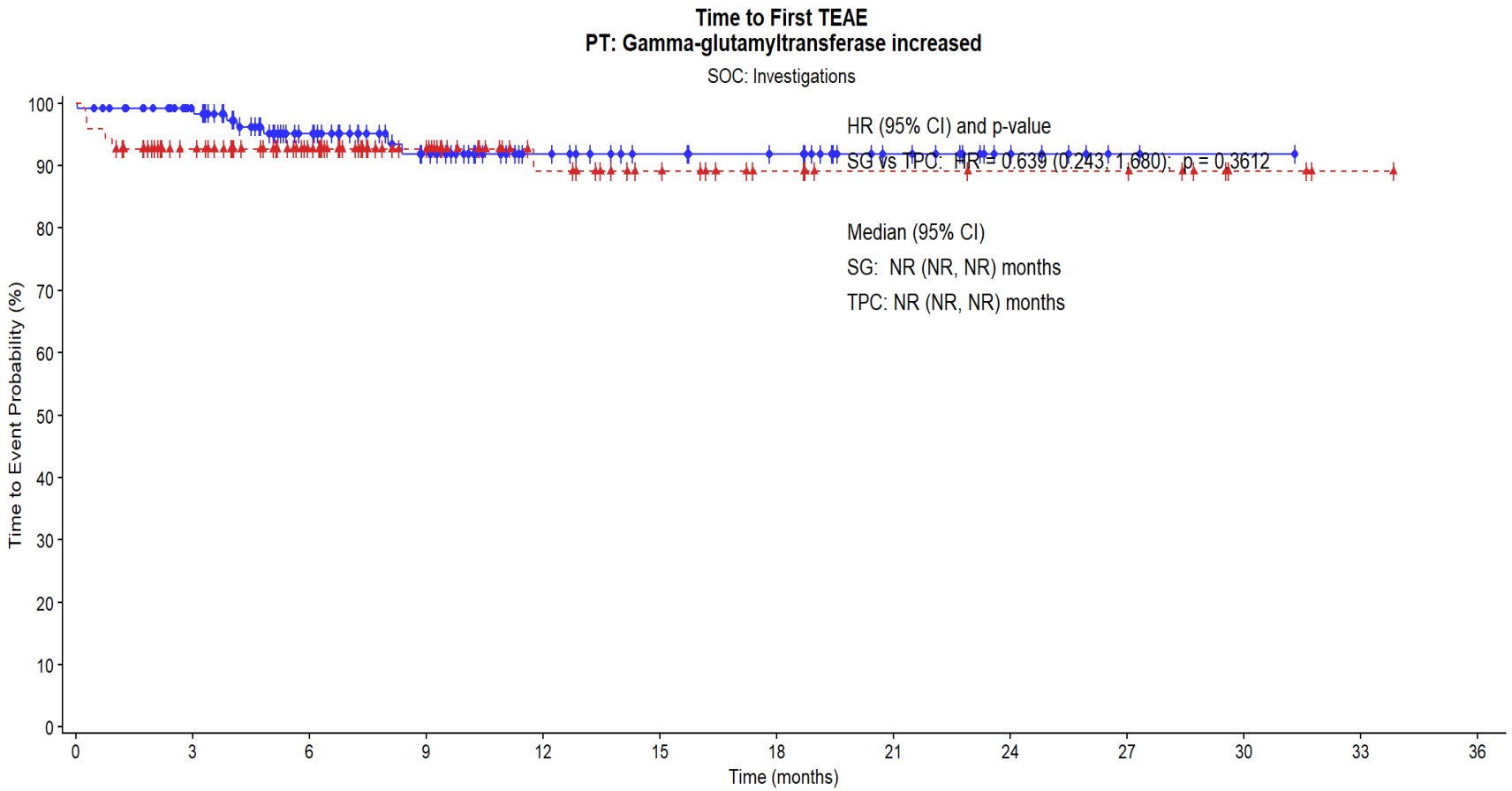
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.61. Figure 1.1.60: Kaplan Meier Plot of Time to First TEAE by PT Blood alkaline phosphatase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



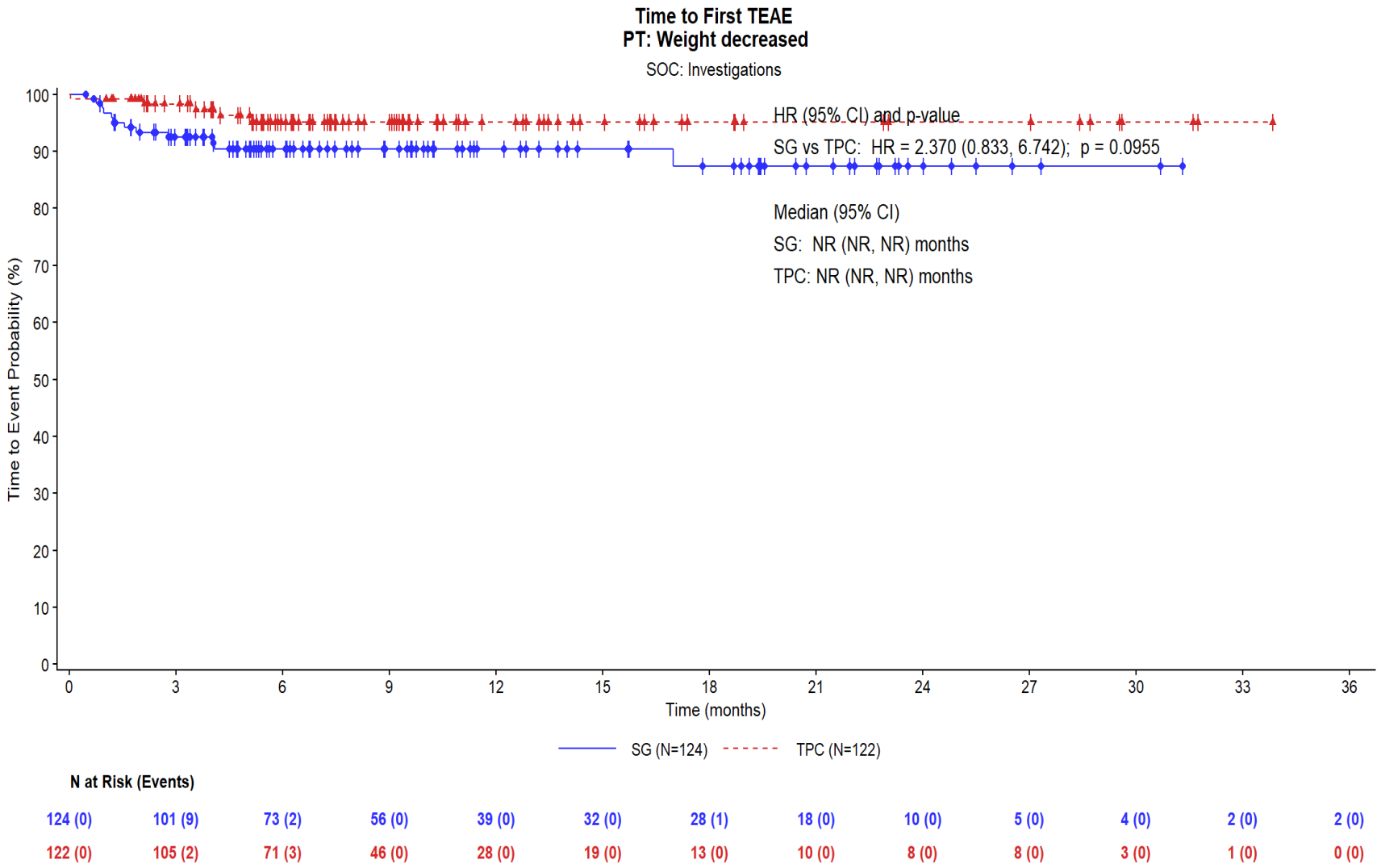
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.62. Figure 1.1.61: Kaplan Meier Plot of Time to First TEAE by PT Gamma glutamyltransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



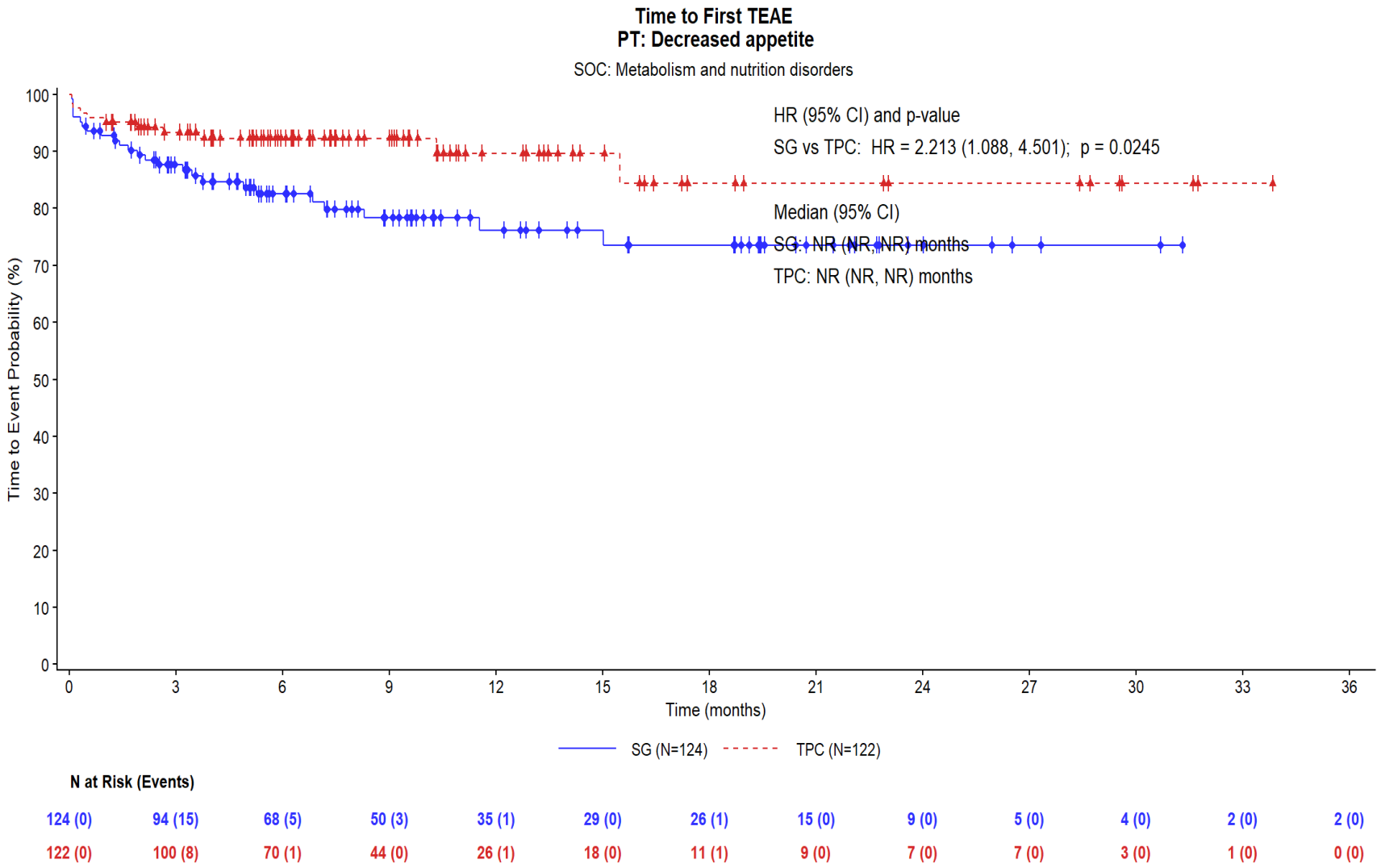
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.63. Figure 1.1.62: Kaplan Meier Plot of Time to First TEAE by PT Weight decreased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



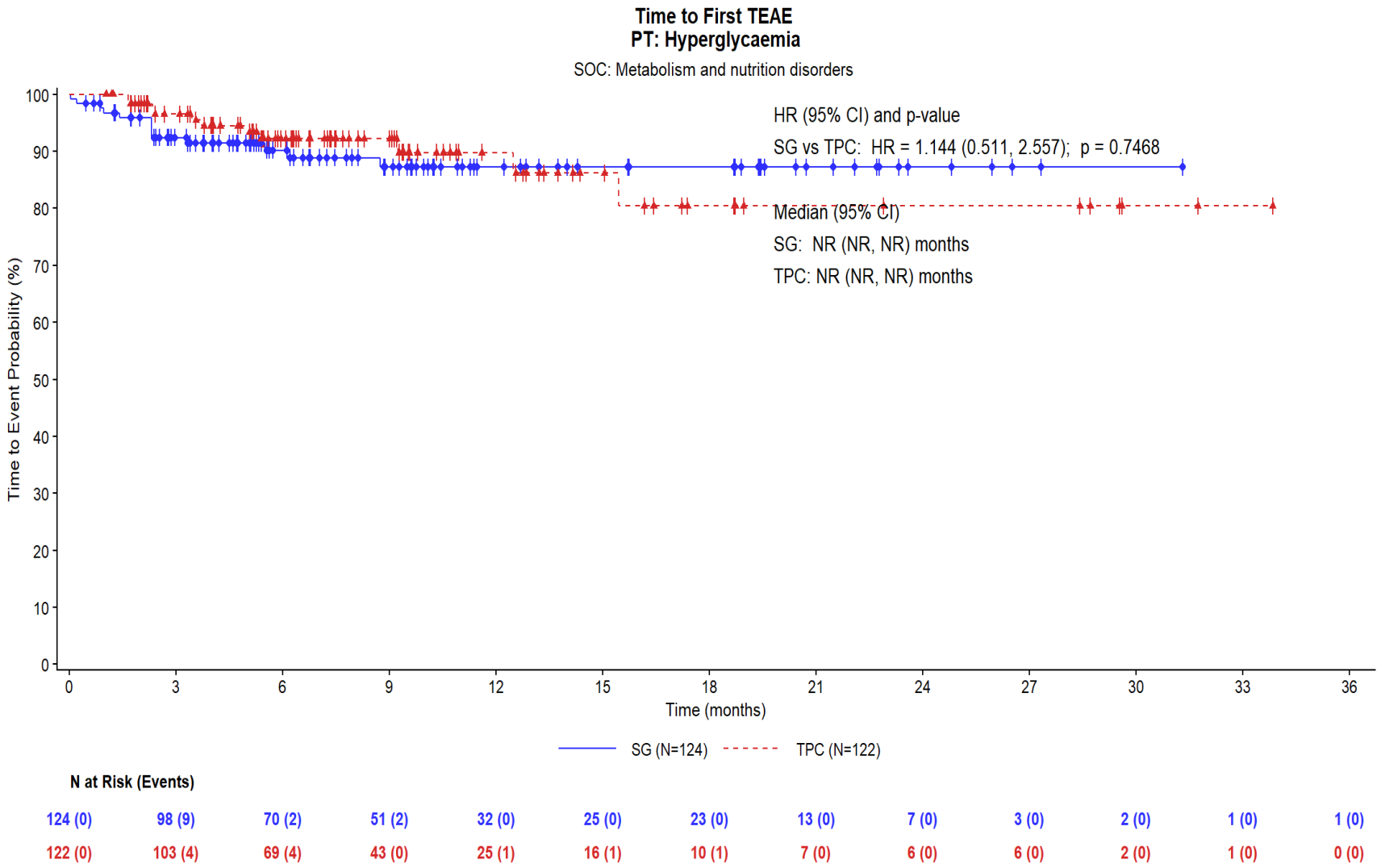
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.64. Figure 1.1.63: Kaplan Meier Plot of Time to First TEAE by PT Decreased appetite — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



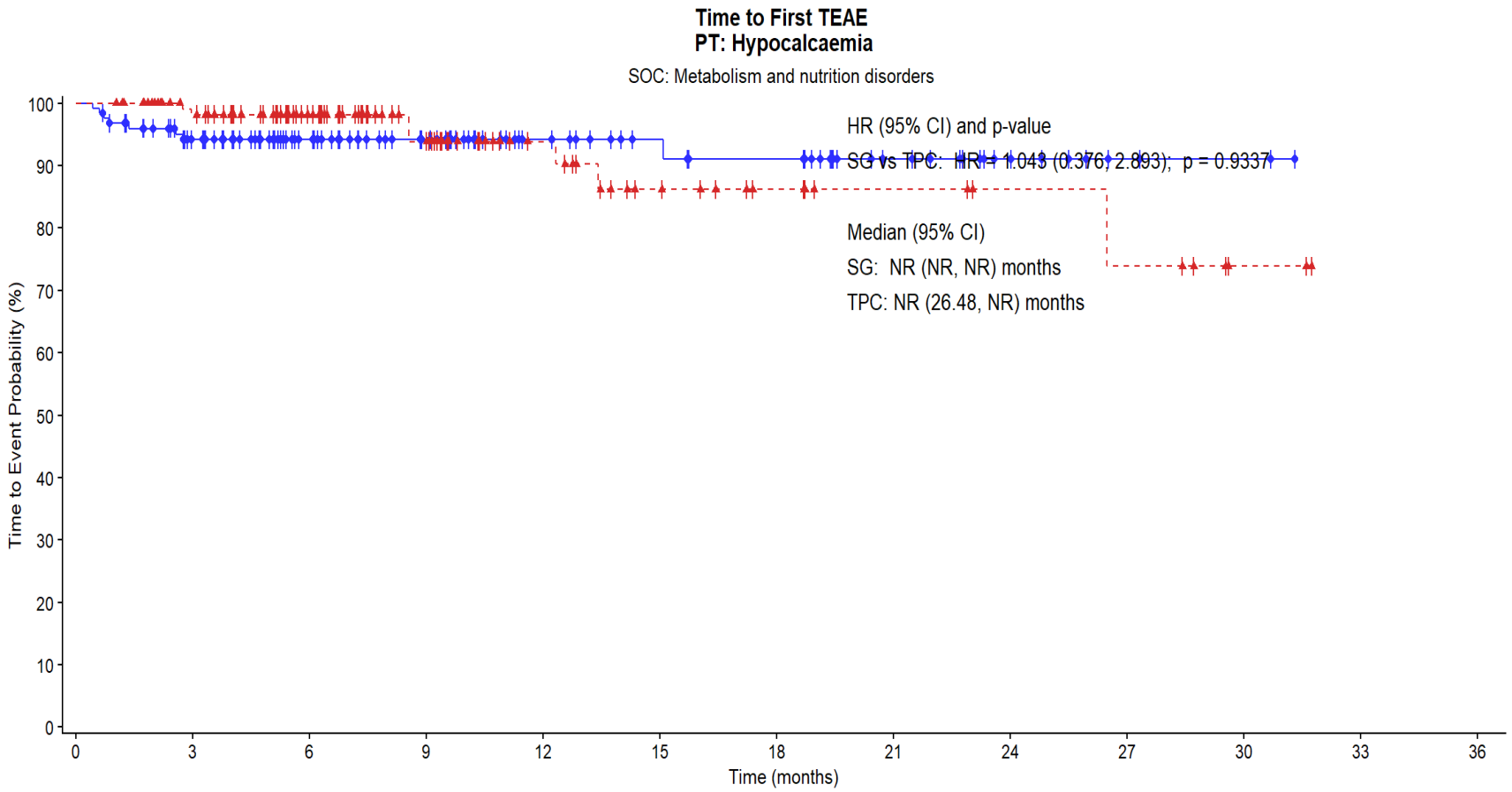
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.65. Figure 1.1.64: Kaplan Meier Plot of Time to First TEAE by PT Hyperglycaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



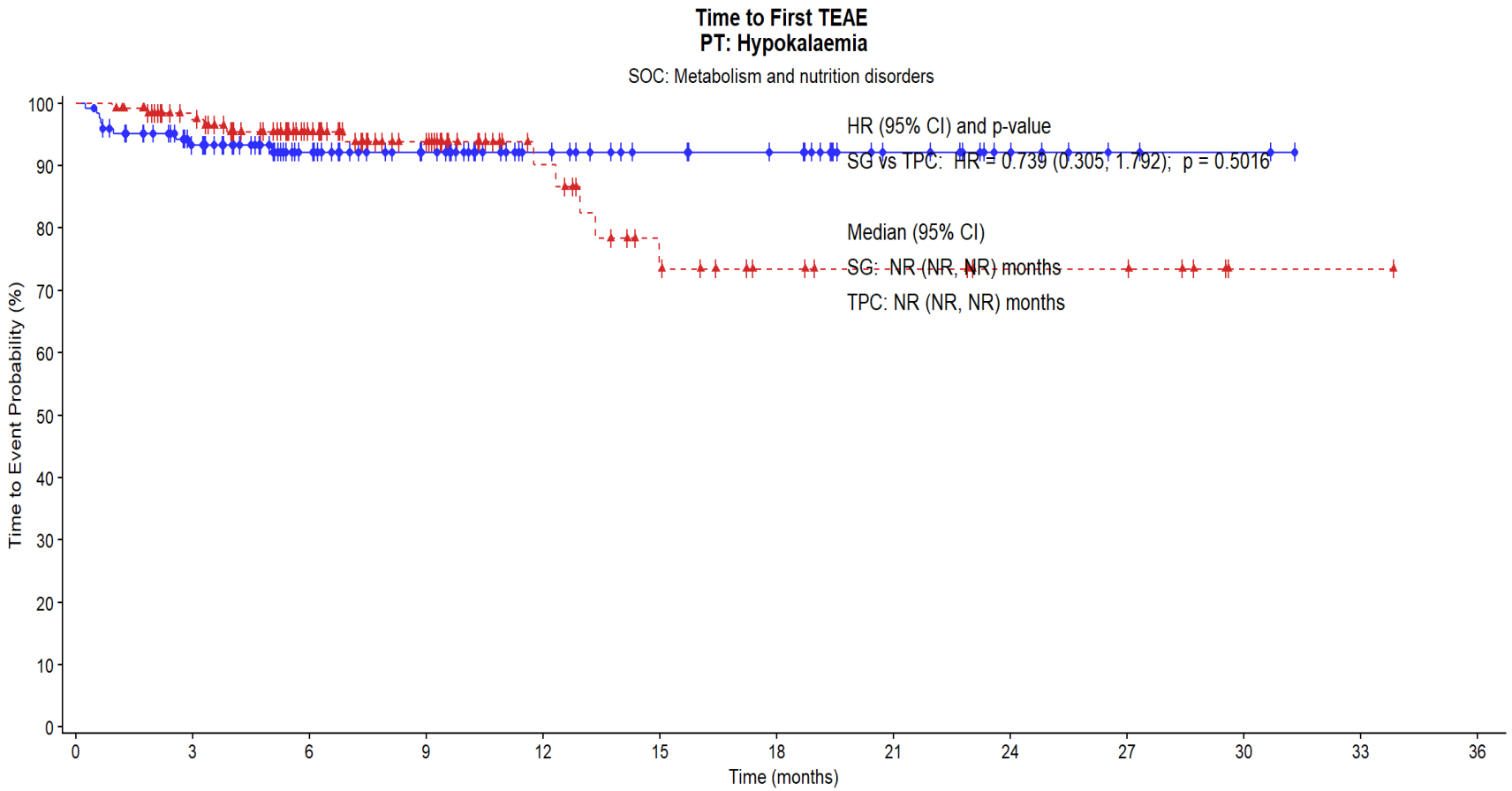
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.66. Figure 1.1.65: Kaplan Meier Plot of Time to First TEAE by PT Hypocalcaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



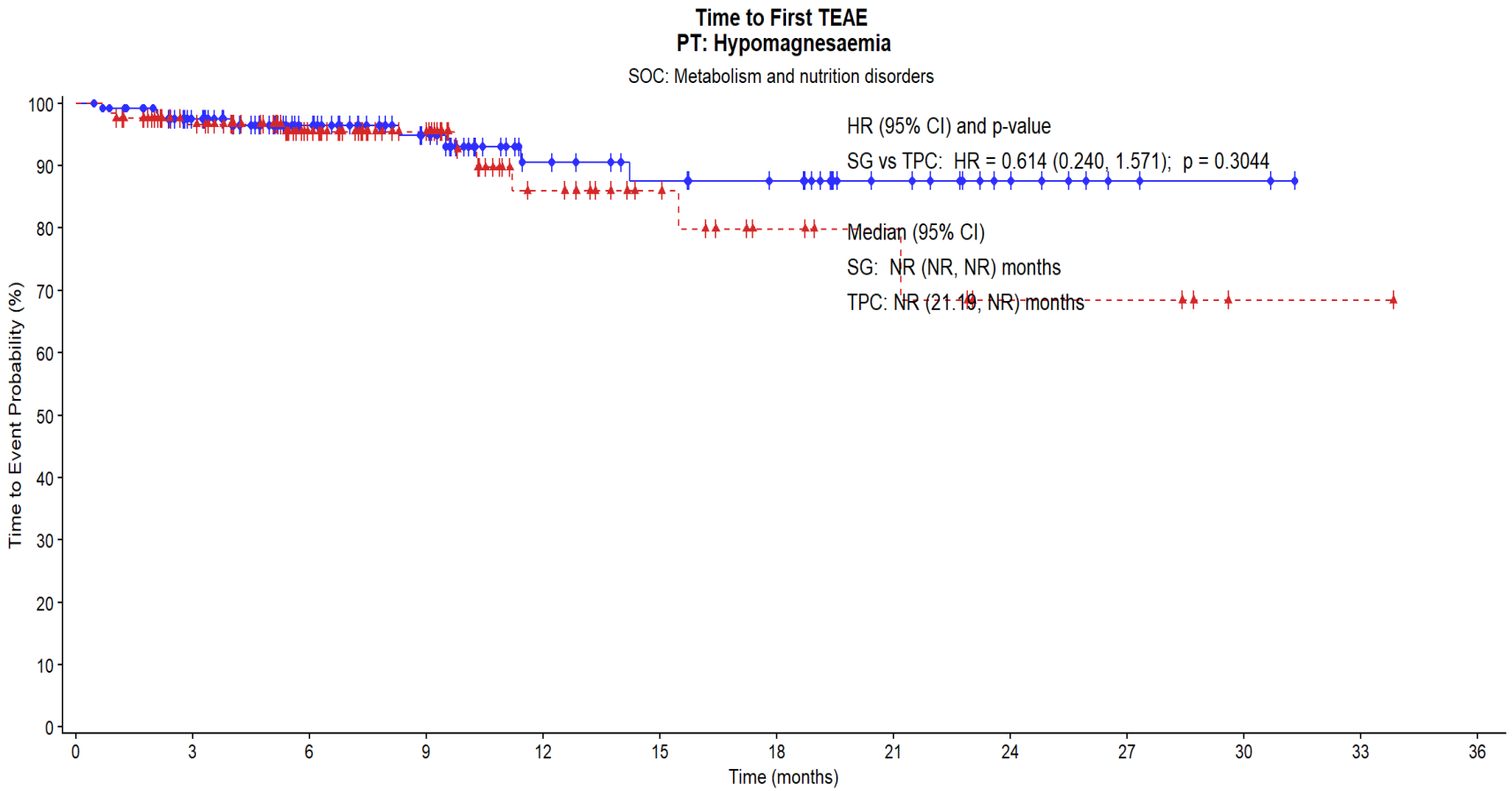
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.67. Figure 1.1.66: Kaplan Meier Plot of Time to First TEAE by PT Hypokalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



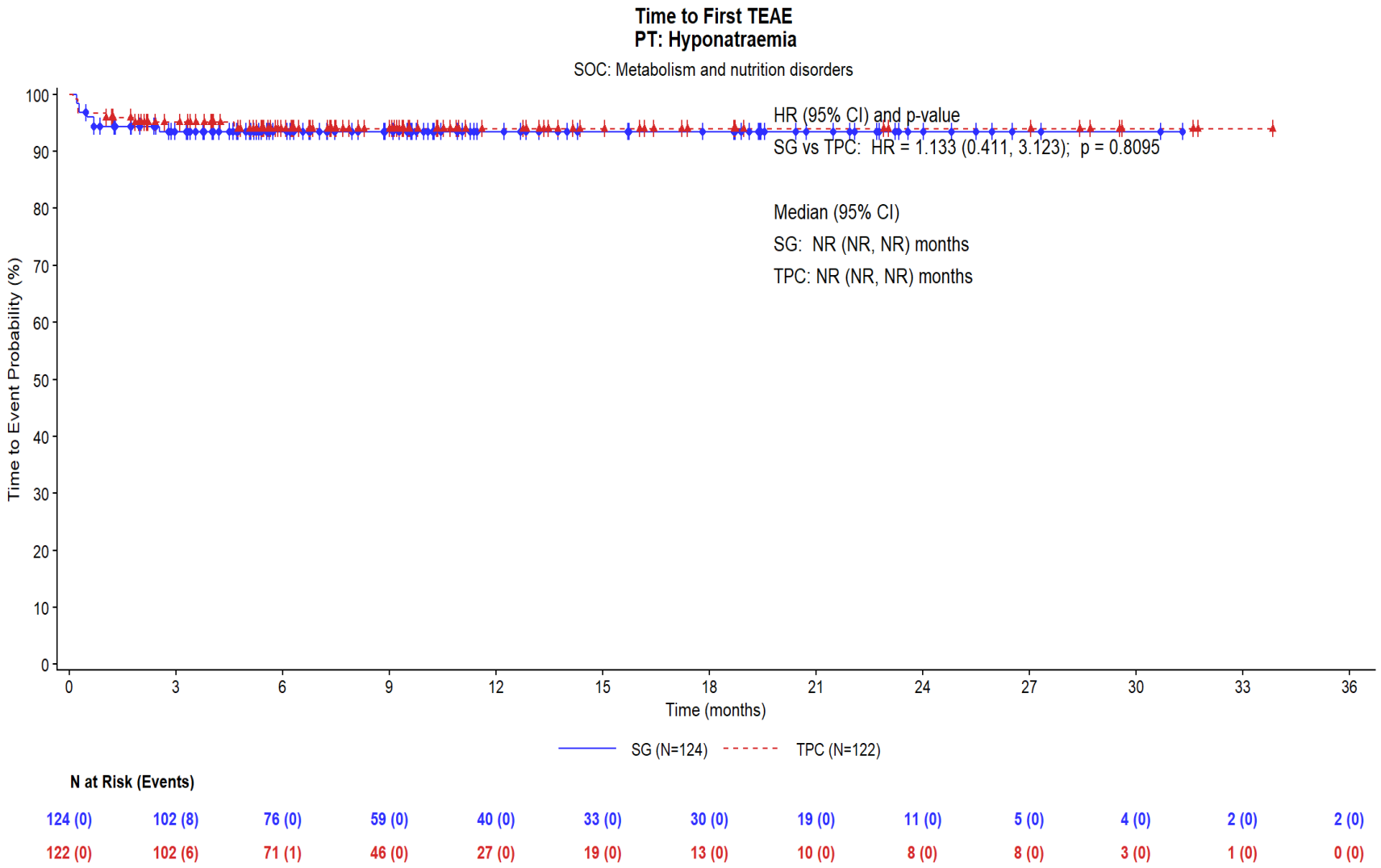
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.68. Figure 1.1.67: Kaplan Meier Plot of Time to First TEAE by PT Hypomagnesaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



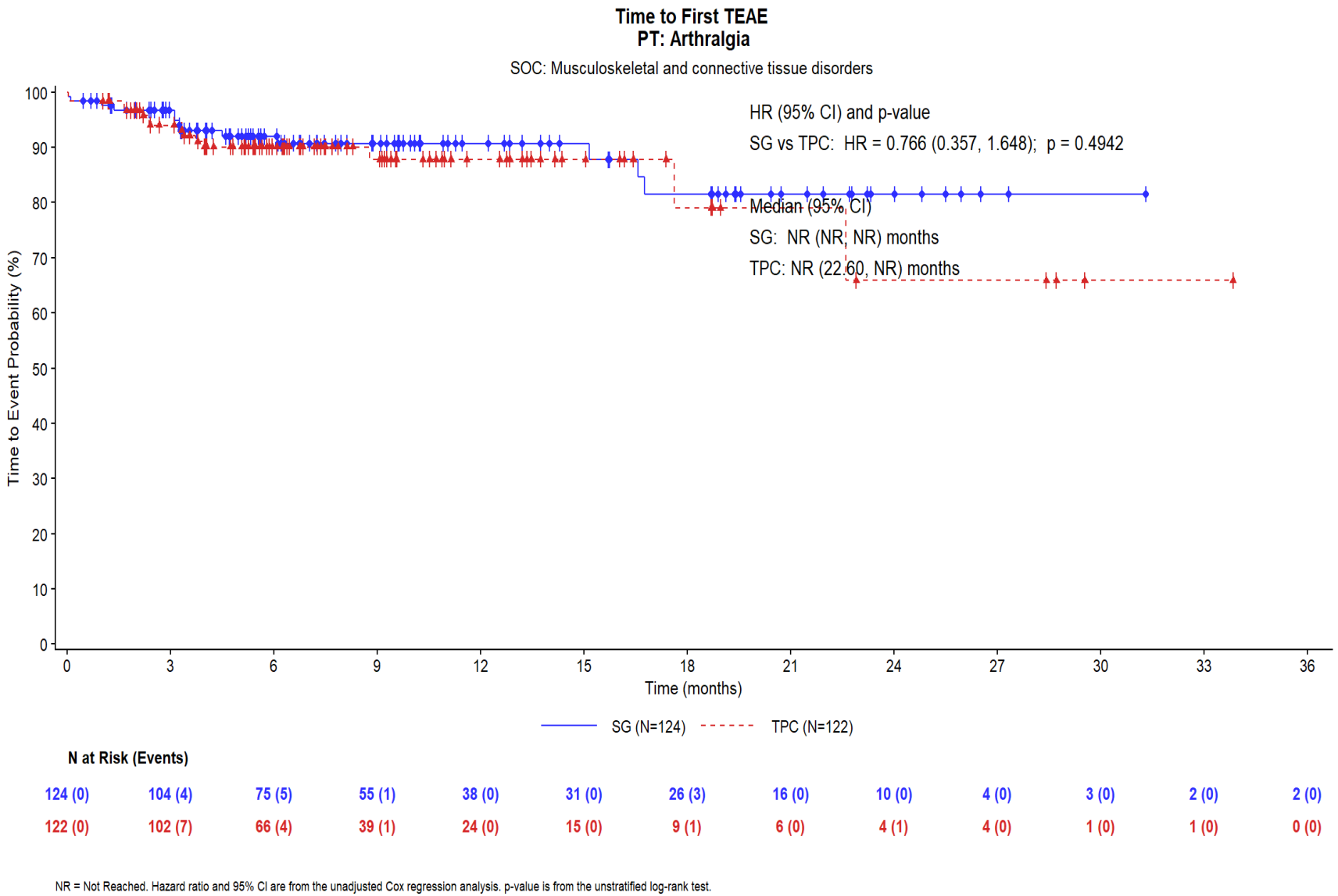
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.69. Figure 1.1.68: Kaplan Meier Plot of Time to First TEAE by PT Hyponatraemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



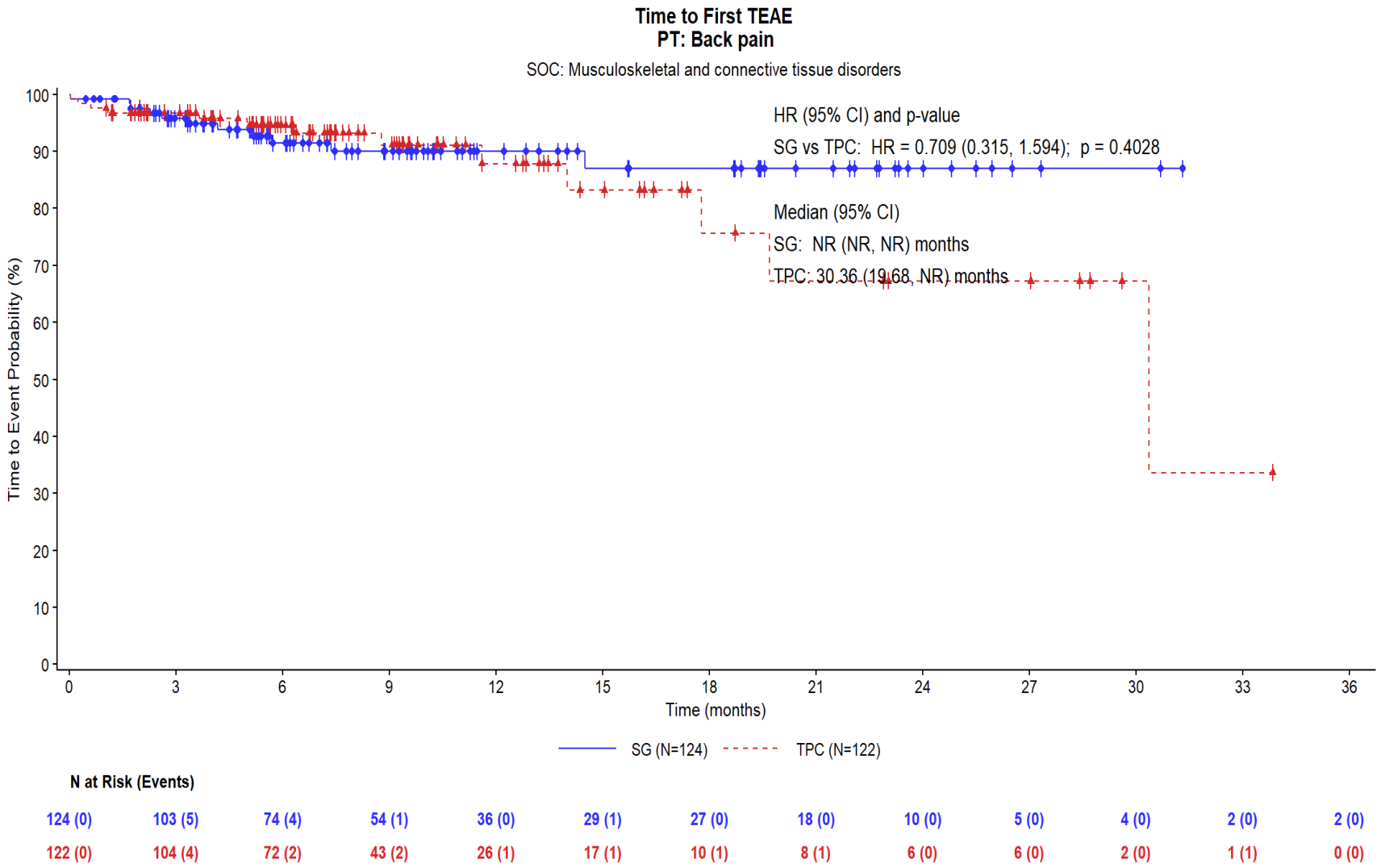
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.70. Figure 1.1.69: Kaplan Meier Plot of Time to First TEAE by PT Arthralgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



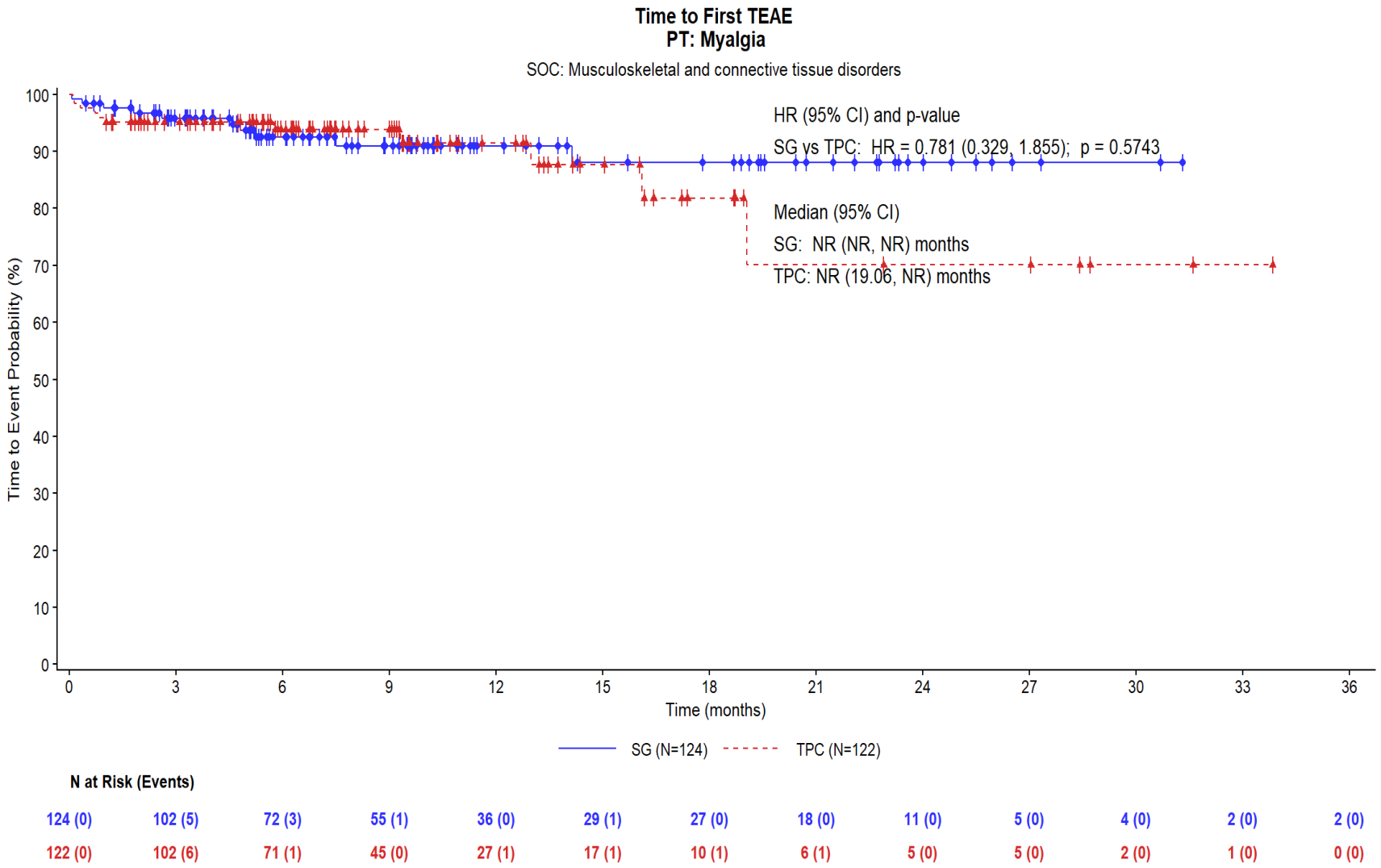
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.71. Figure 1.1.70: Kaplan Meier Plot of Time to First TEAE by PT Back pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



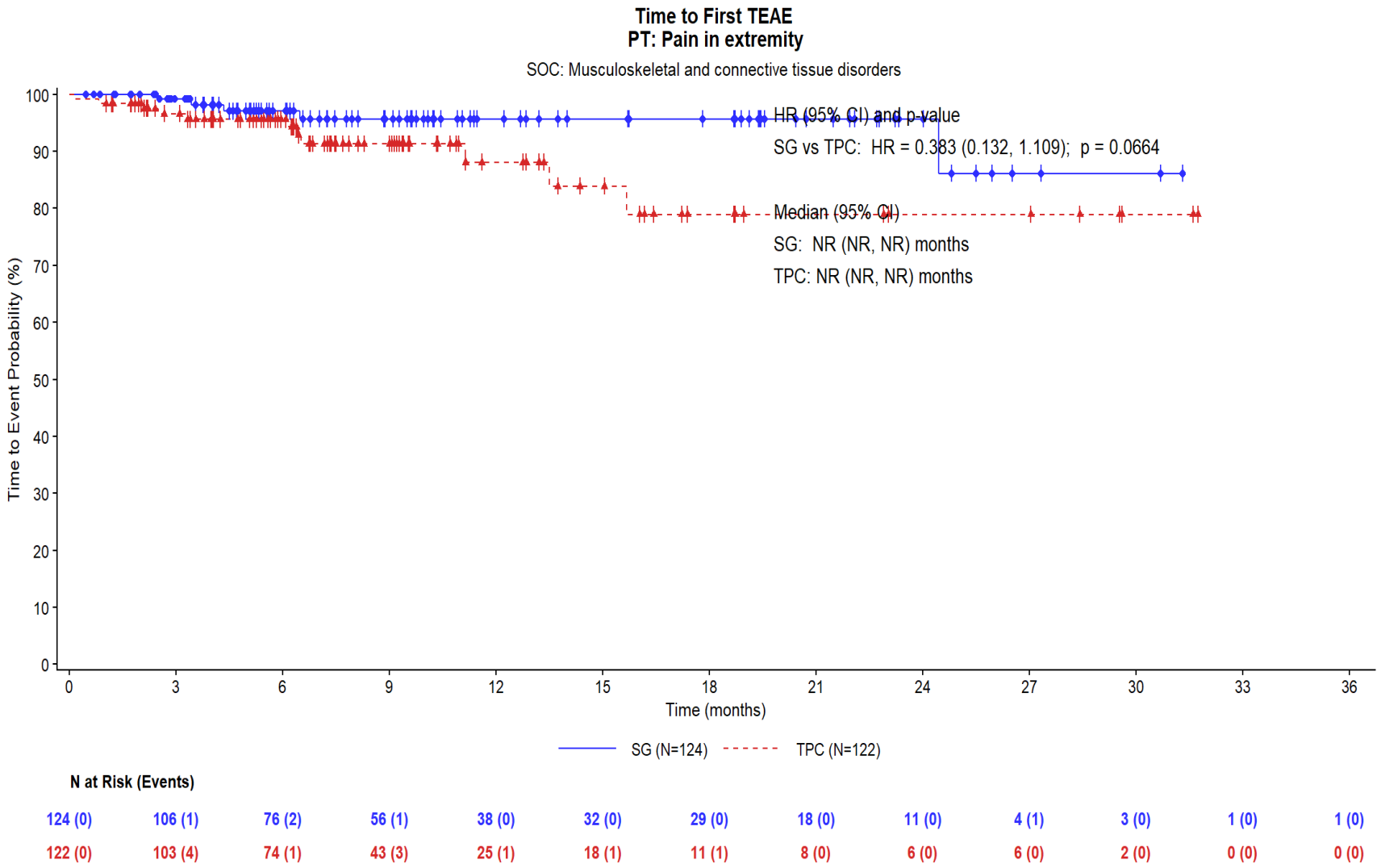
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.72. Figure 1.1.71: Kaplan Meier Plot of Time to First TEAE by PT Myalgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



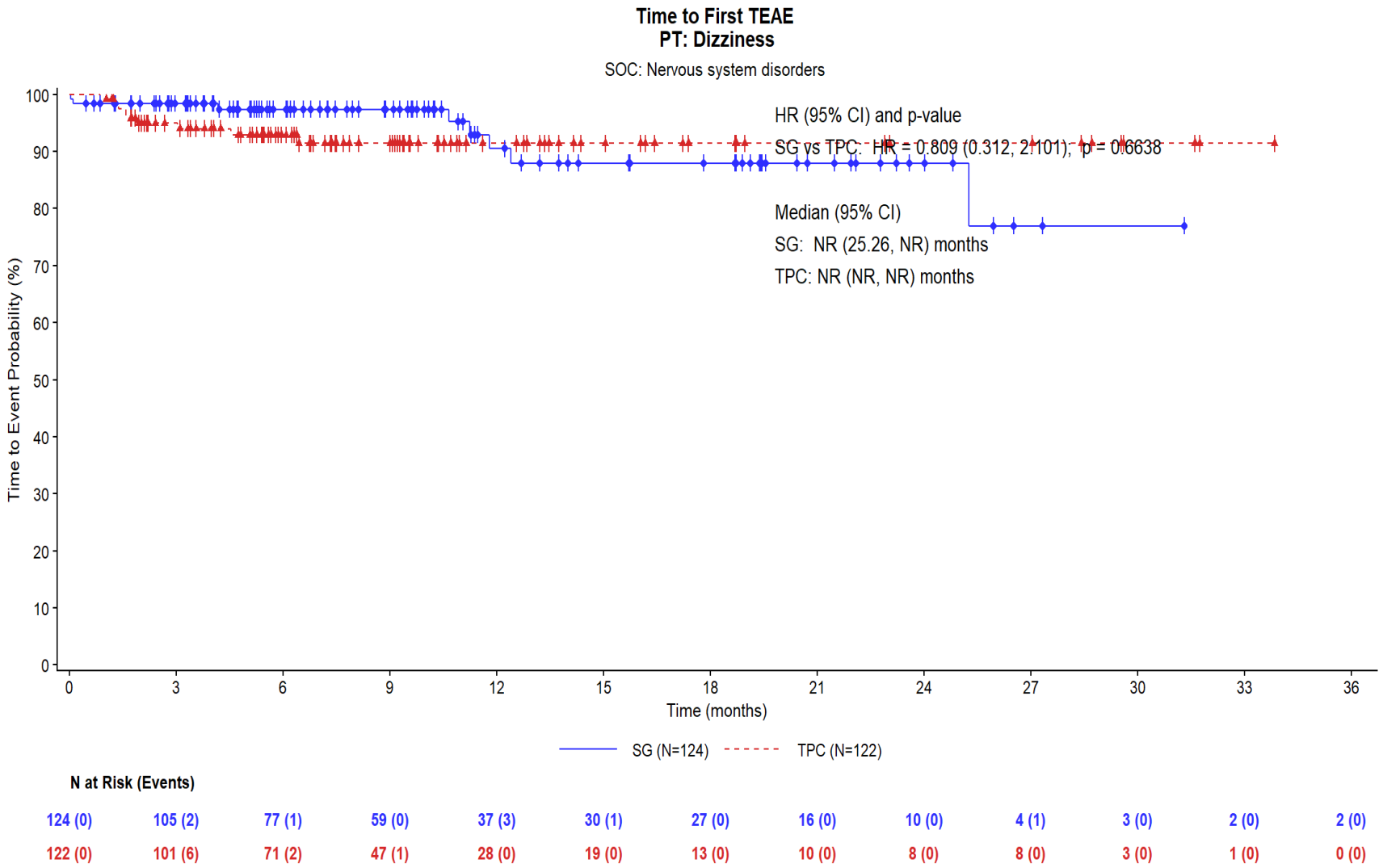
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.73. Figure 1.1.72: Kaplan Meier Plot of Time to First TEAE by PT Pain in extremity — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



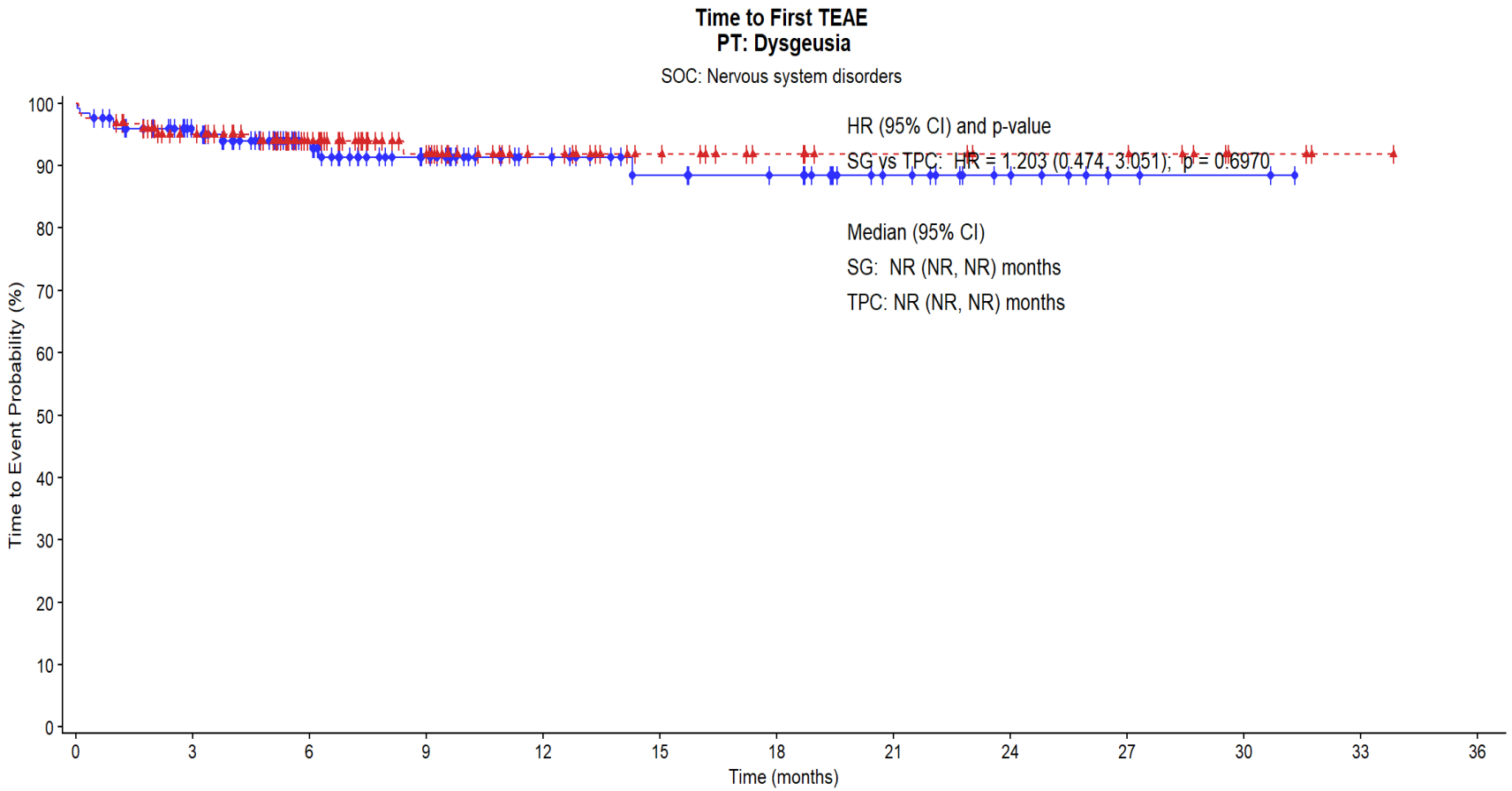
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.74. Figure 1.1.73: Kaplan Meier Plot of Time to First TEAE by PT Dizziness — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



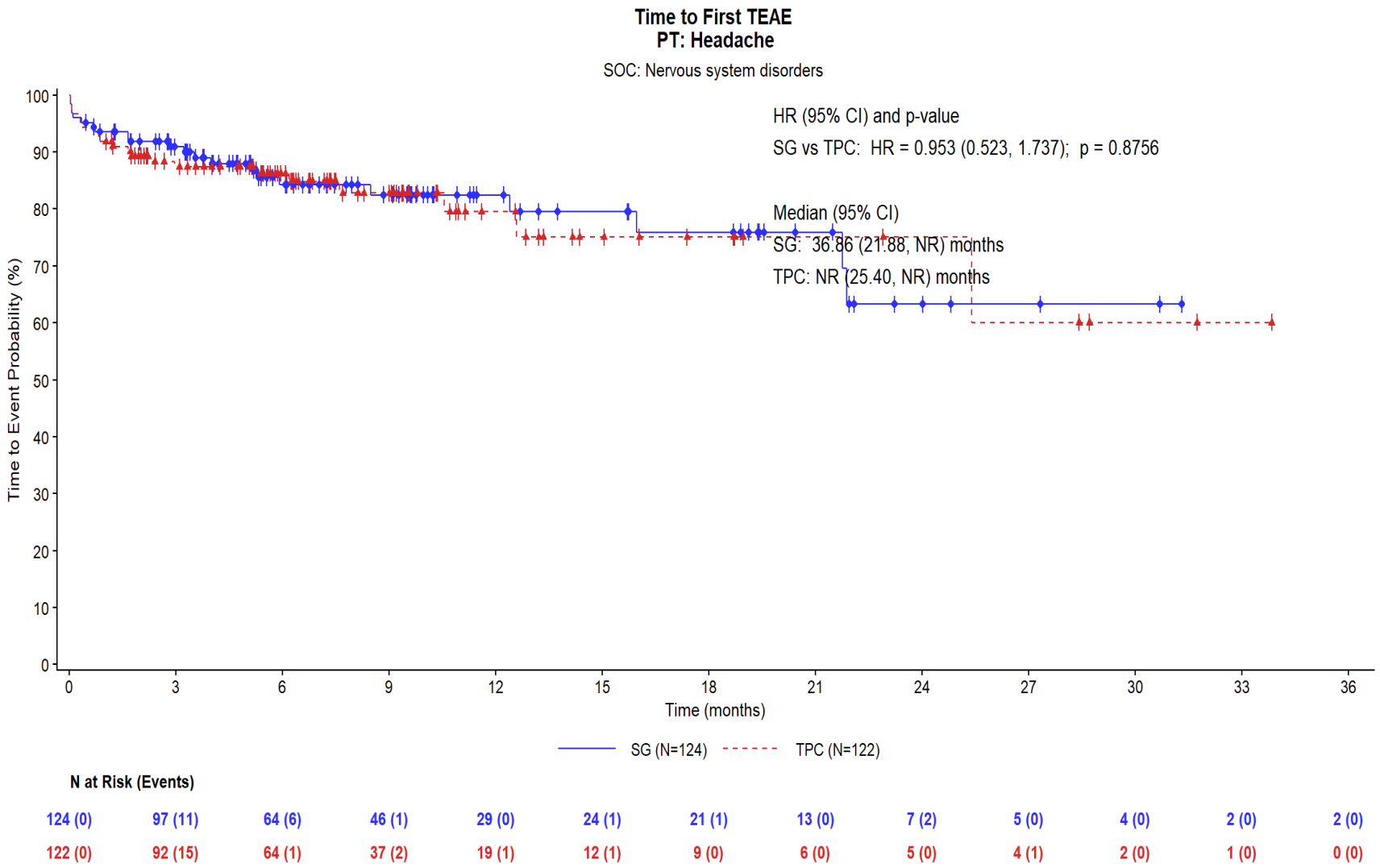
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.75. Figure 1.1.74: Kaplan Meier Plot of Time to First TEAE by PT Dysgeusia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



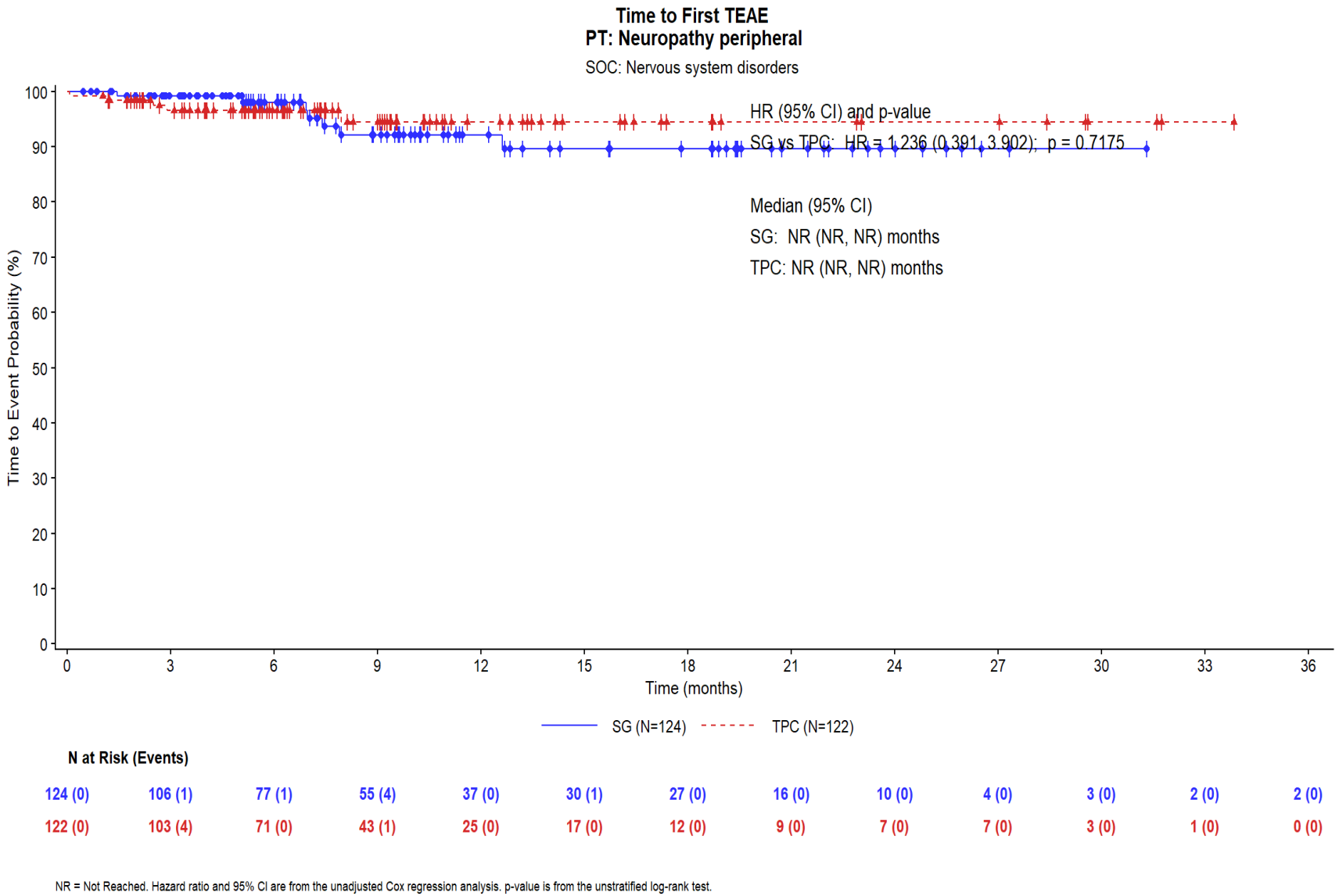
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.76. Figure 1.1.75: Kaplan Meier Plot of Time to First TEAE by PT Headache — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



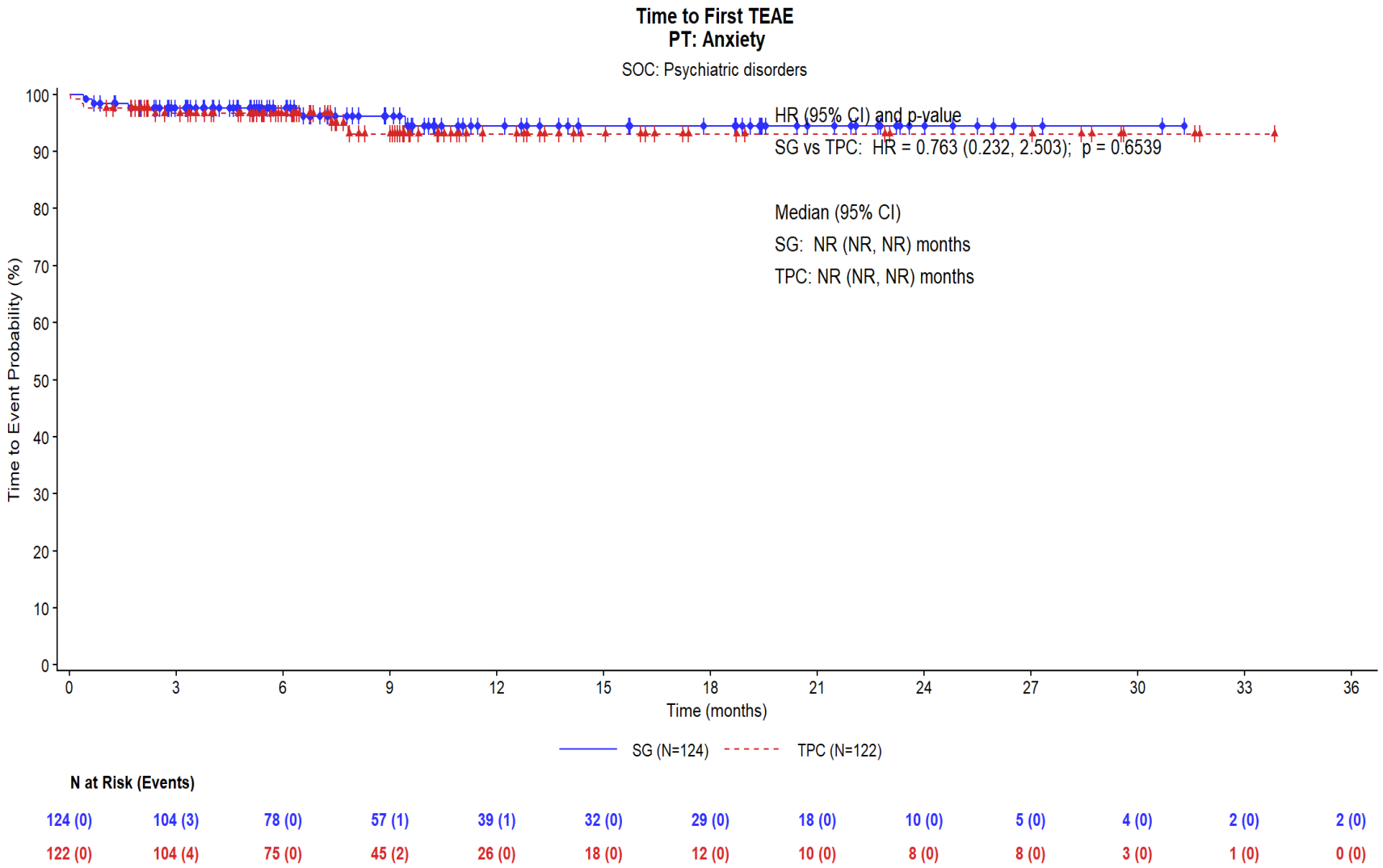
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.77. Figure 1.1.76: Kaplan Meier Plot of Time to First TEAE by PT Neuropathy peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



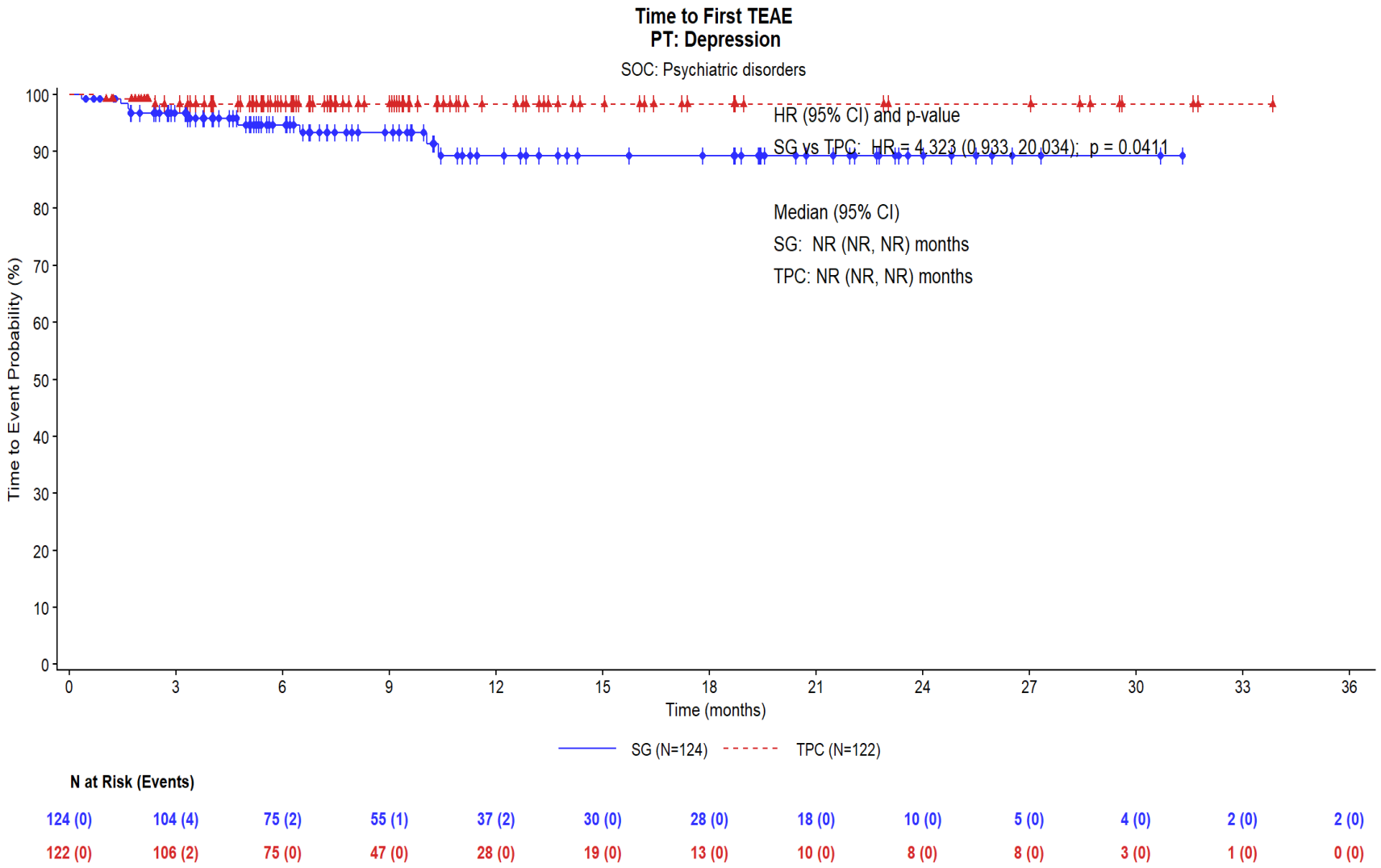
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.78. Figure 1.1.77: Kaplan Meier Plot of Time to First TEAE by PT Anxiety — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



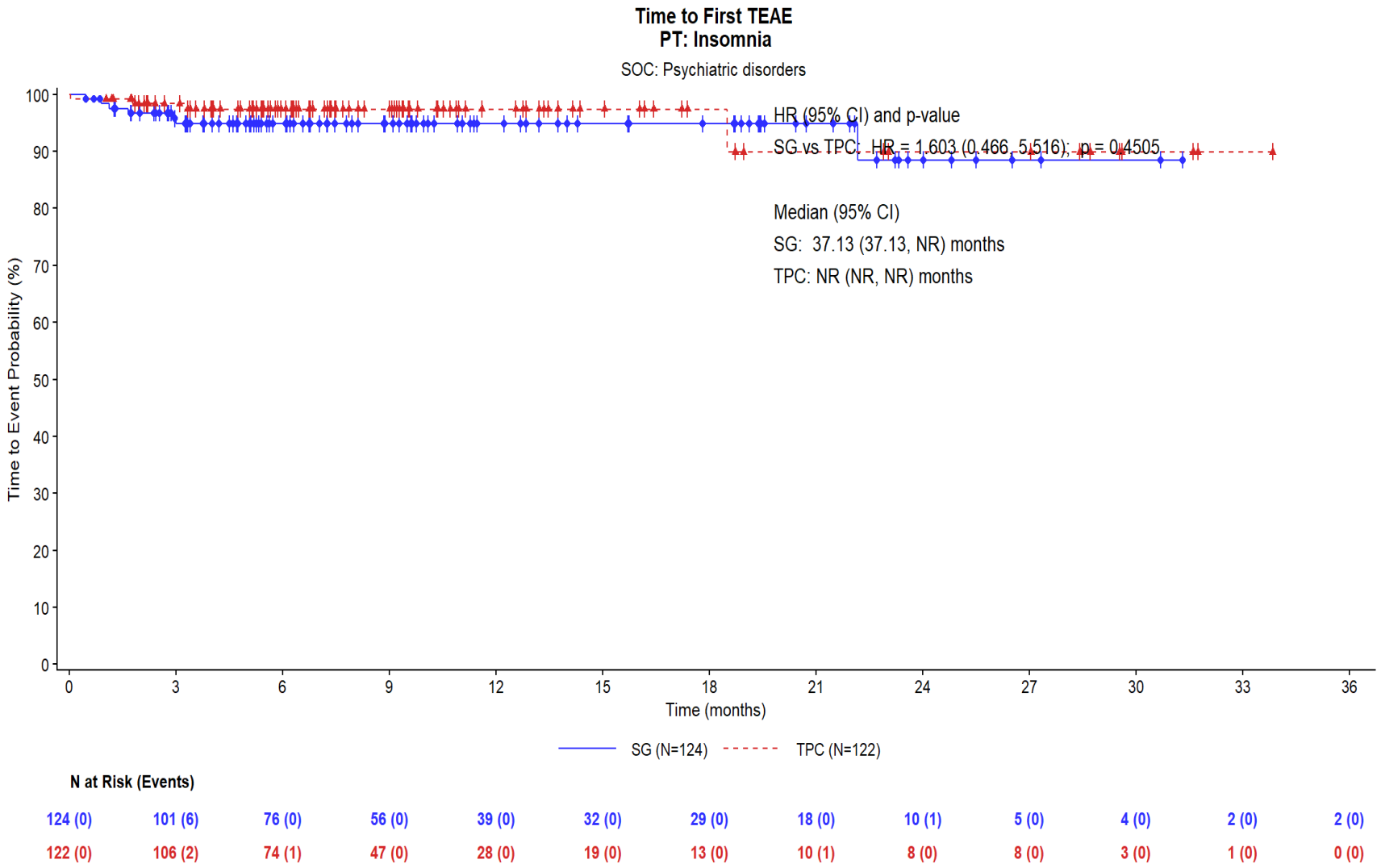
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.79. Figure 1.1.78: Kaplan Meier Plot of Time to First TEAE by PT Depression — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



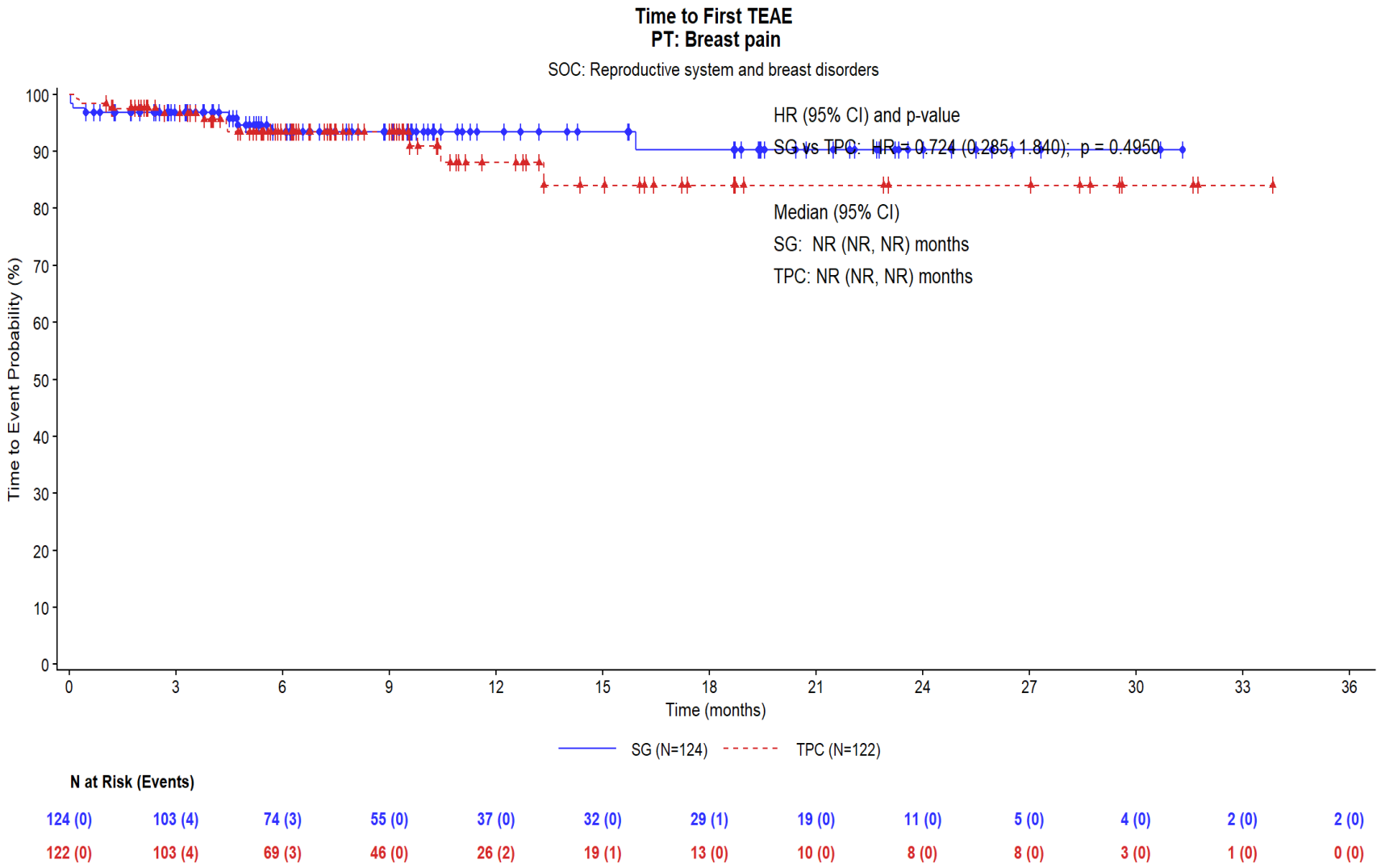
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.80. Figure 1.1.79: Kaplan Meier Plot of Time to First TEAE by PT Insomnia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



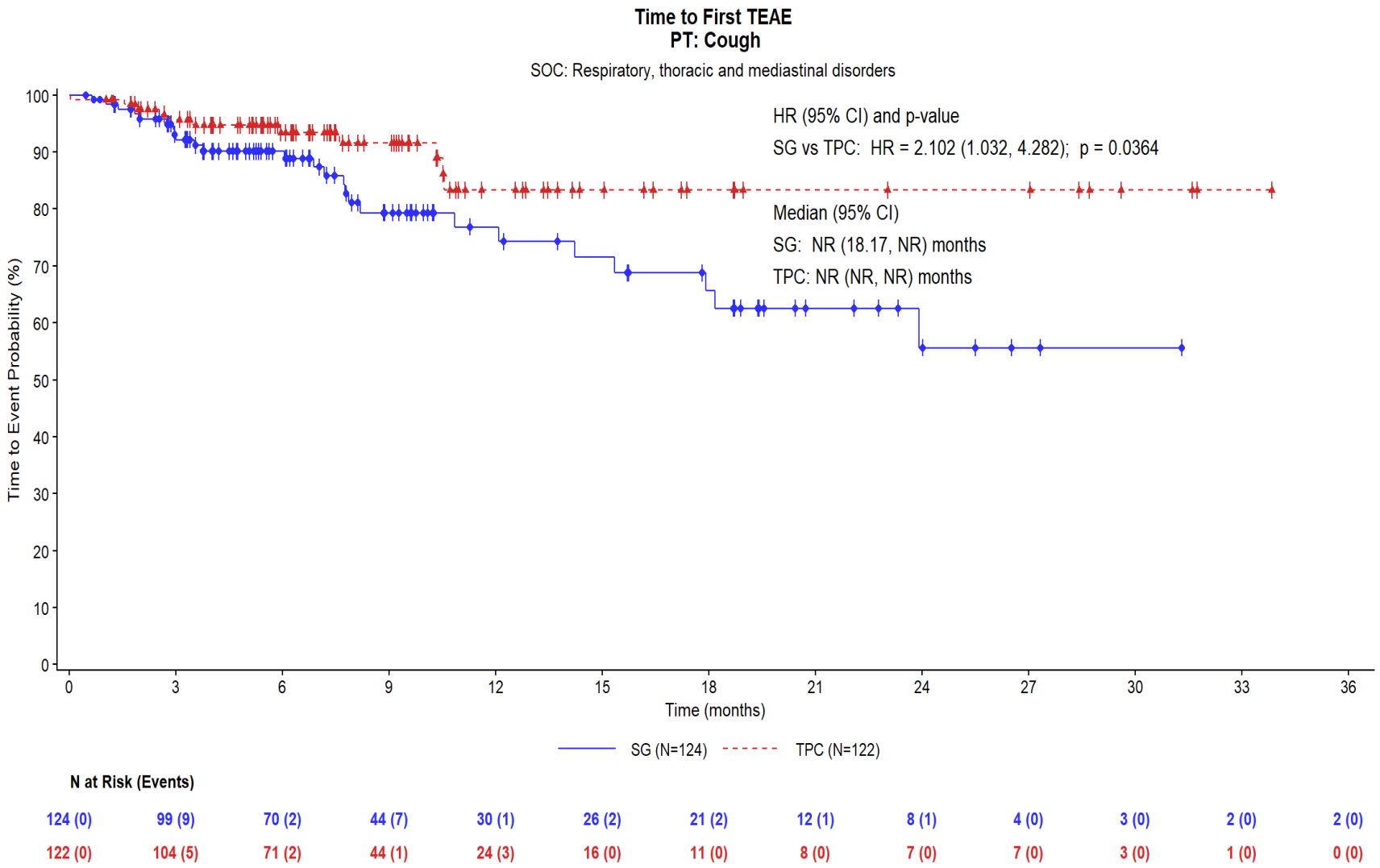
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.81. Figure 1.1.80: Kaplan Meier Plot of Time to First TEAE by PT Breast pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



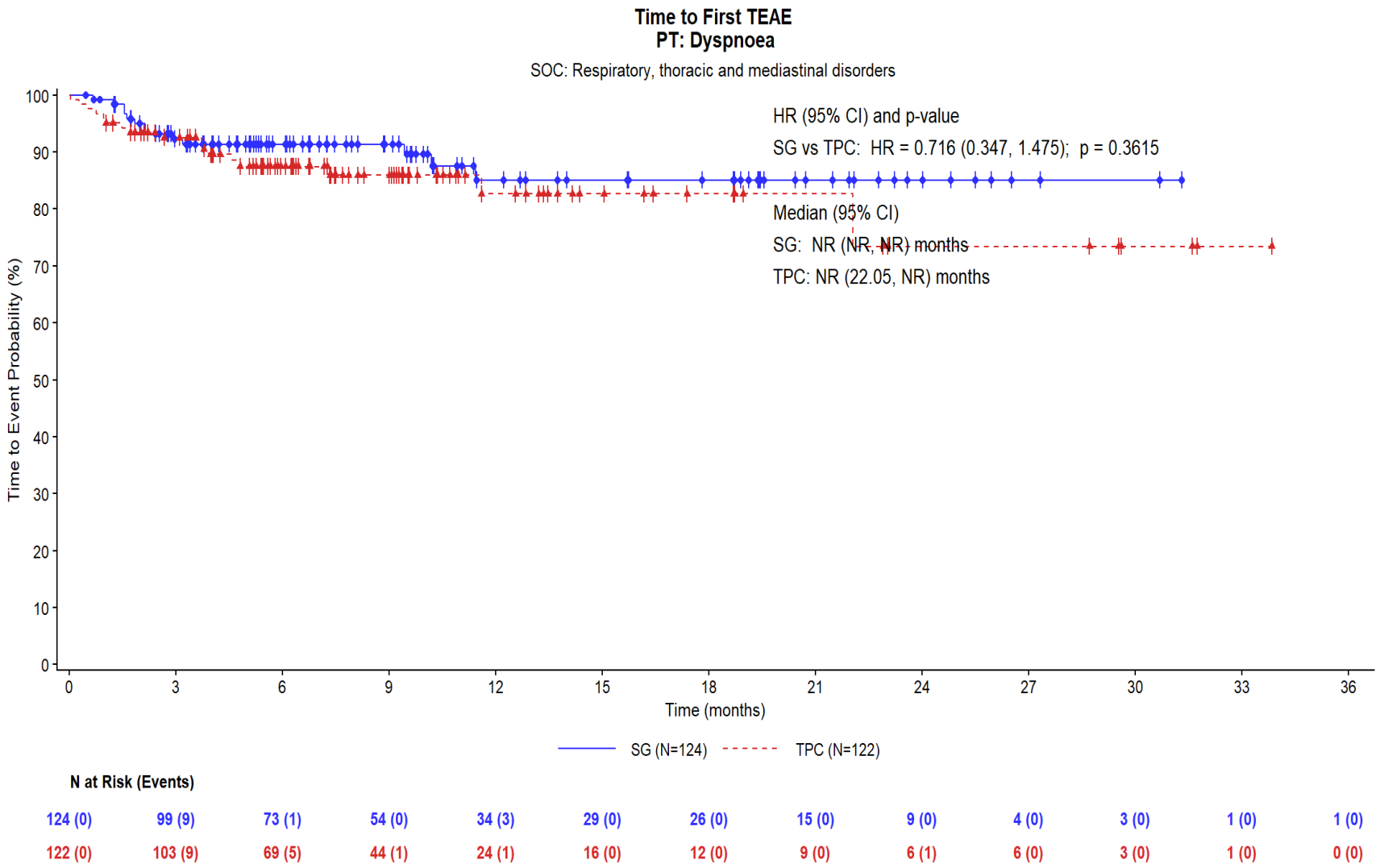
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.82. Figure 1.1.81: Kaplan Meier Plot of Time to First TEAE by PT Cough — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



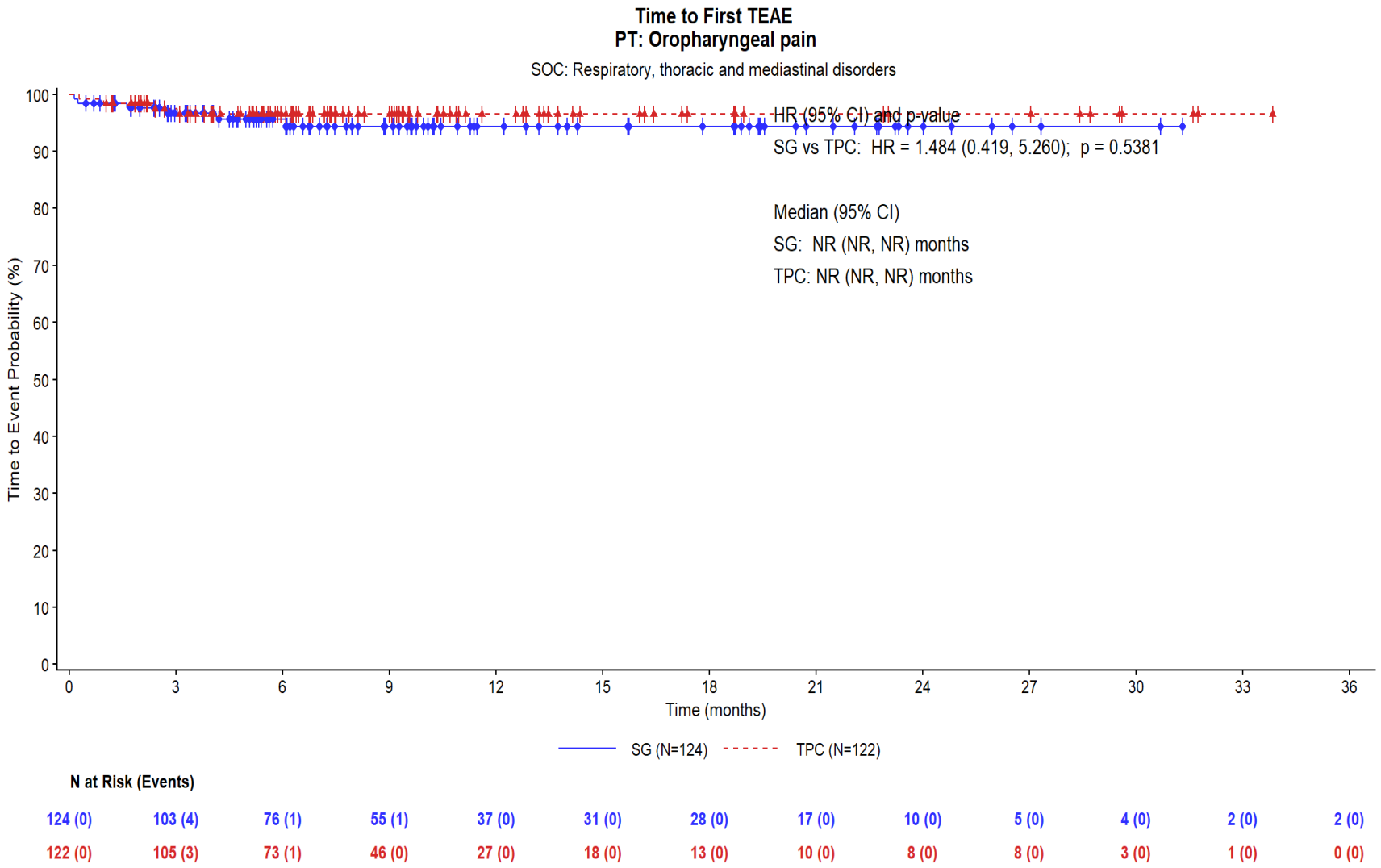
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.83. Figure 1.1.82: Kaplan Meier Plot of Time to First TEAE by PT Dyspnoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



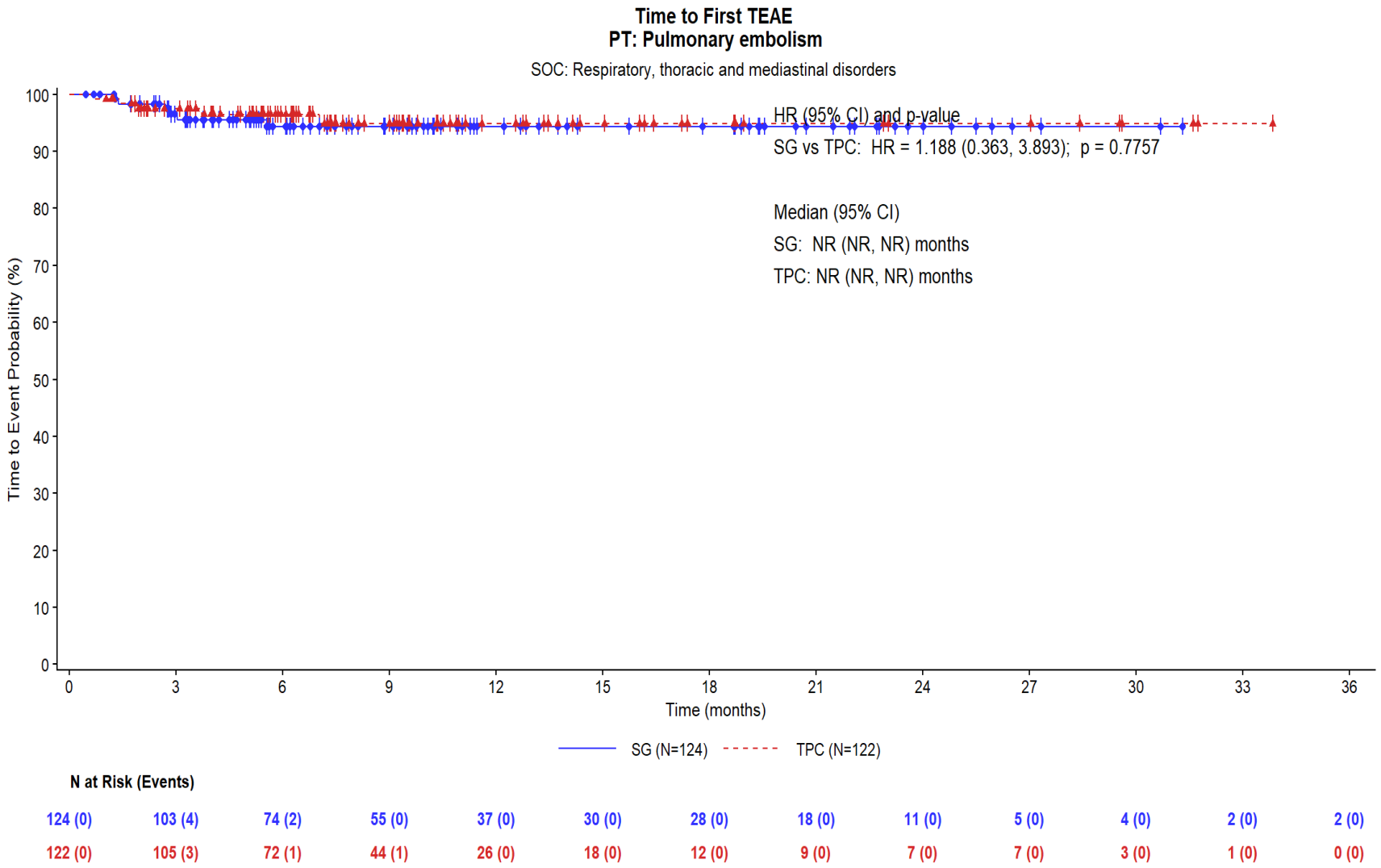
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.84. Figure 1.1.83: Kaplan Meier Plot of Time to First TEAE by PT Oropharyngeal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



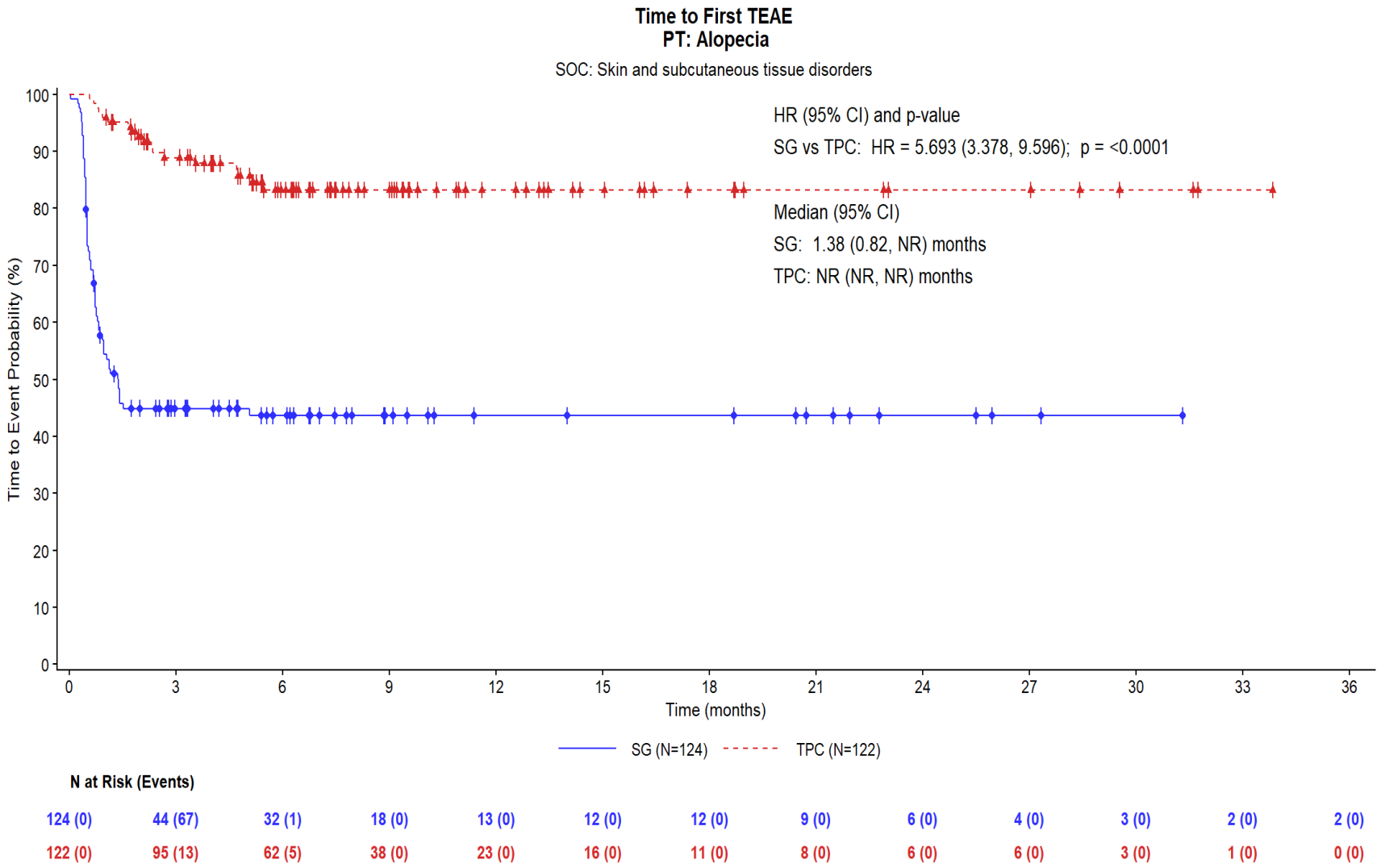
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.85. Figure 1.1.84: Kaplan Meier Plot of Time to First TEAE by PT Pulmonary embolism — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



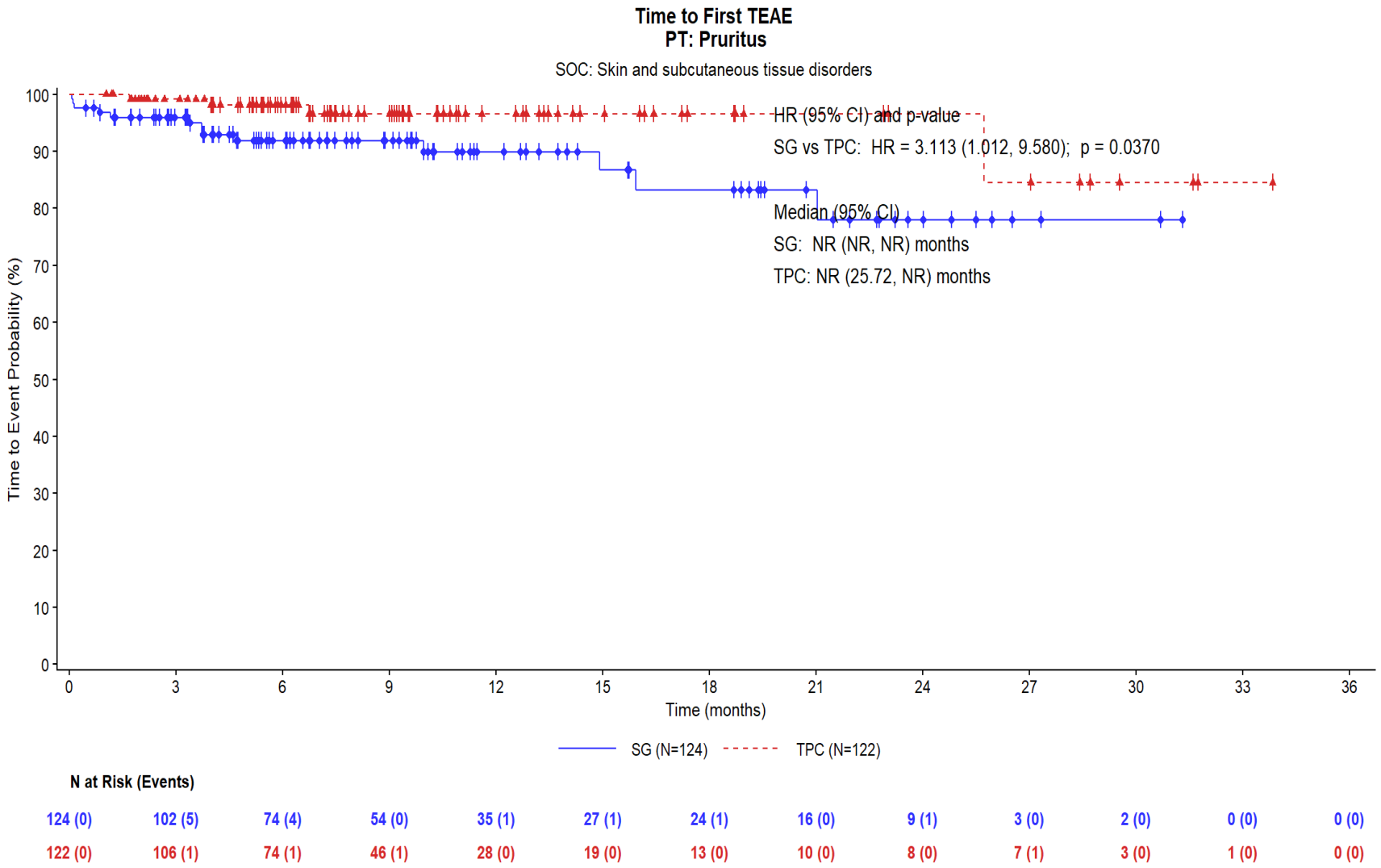
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.86. Figure 1.1.85: Kaplan Meier Plot of Time to First TEAE by PT Alopecia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



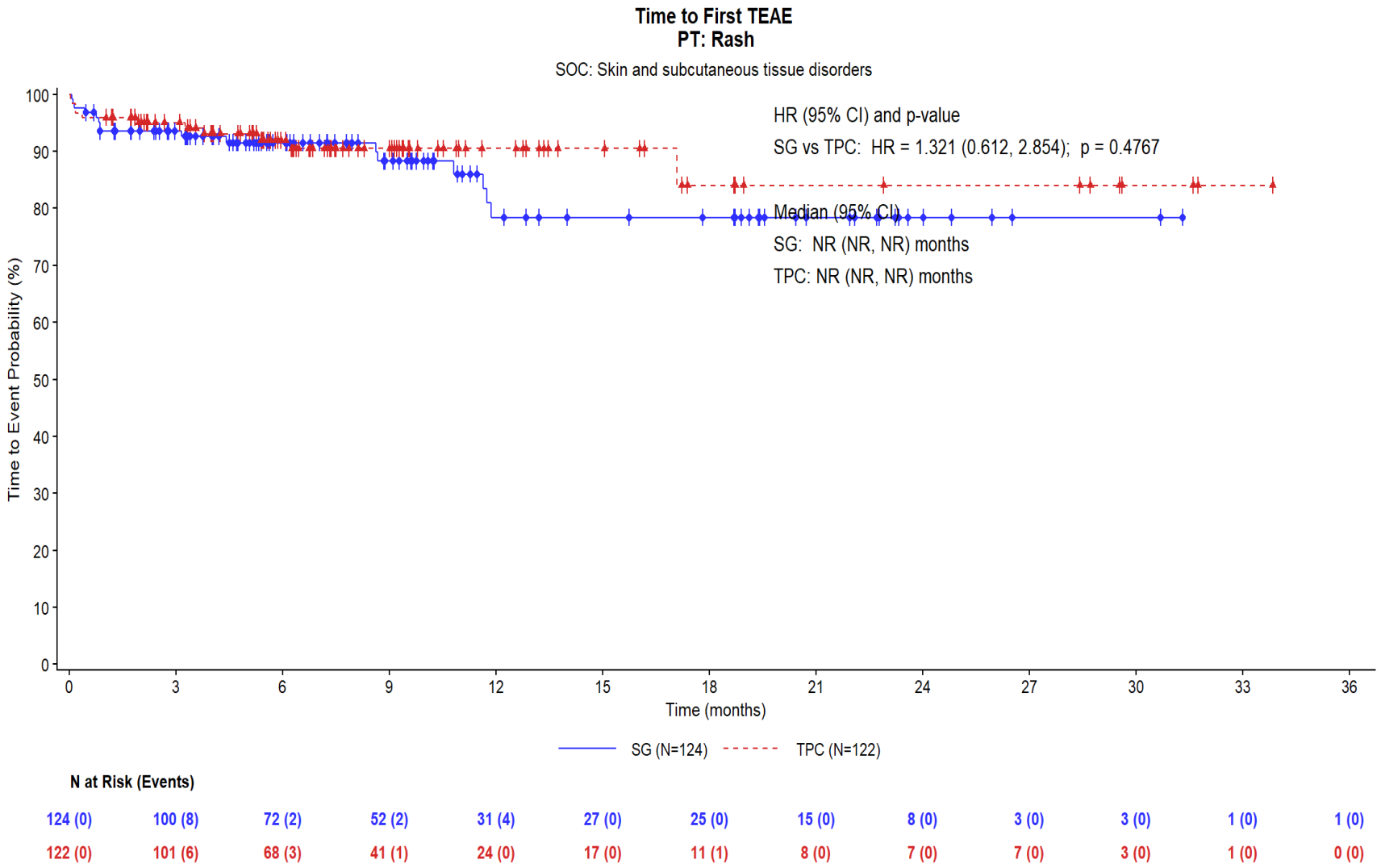
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.87. Figure 1.1.86: Kaplan Meier Plot of Time to First TEAE by PT Pruritus — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



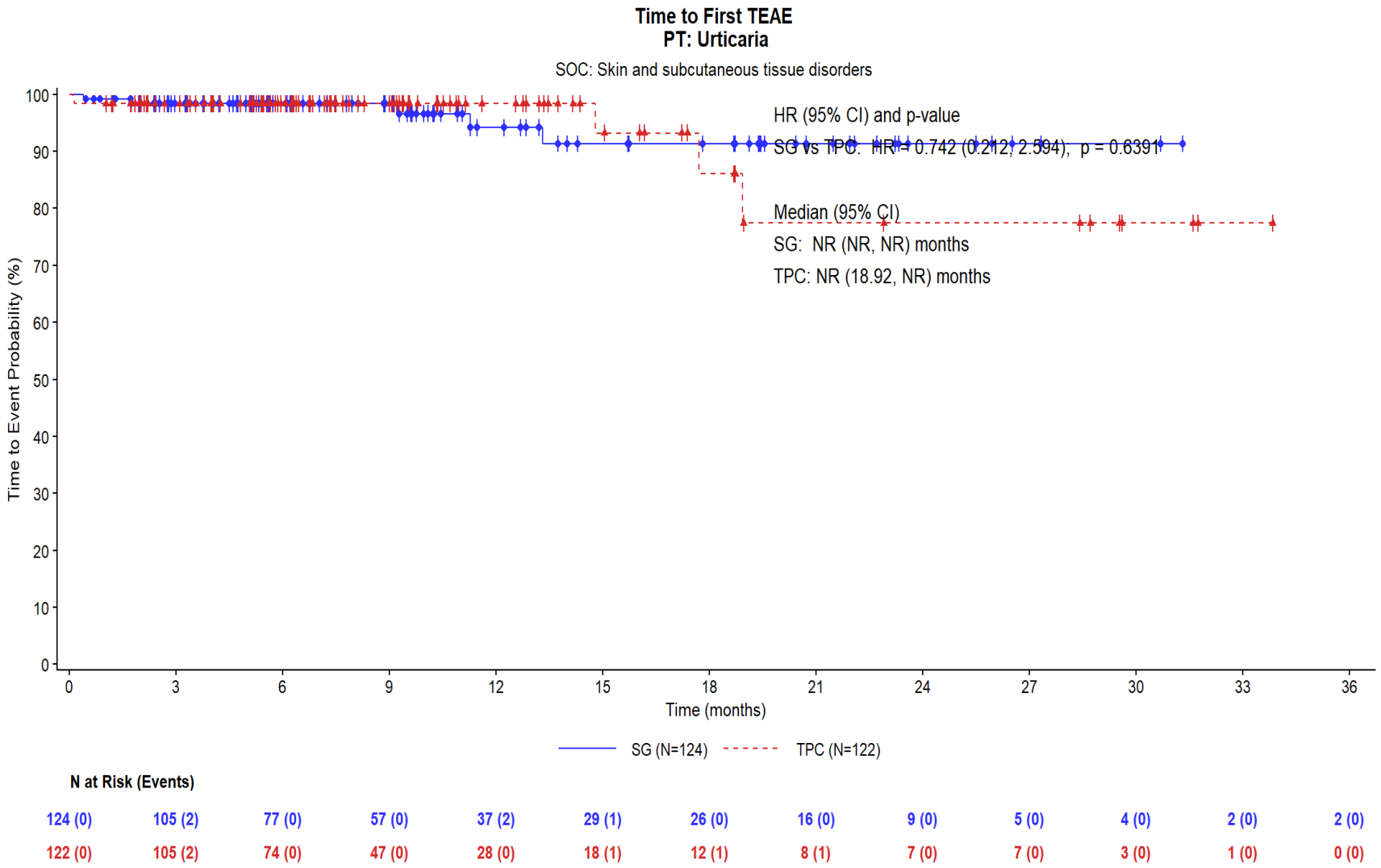
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.88. Figure 1.1.87: Kaplan Meier Plot of Time to First TEAE by PT Rash — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



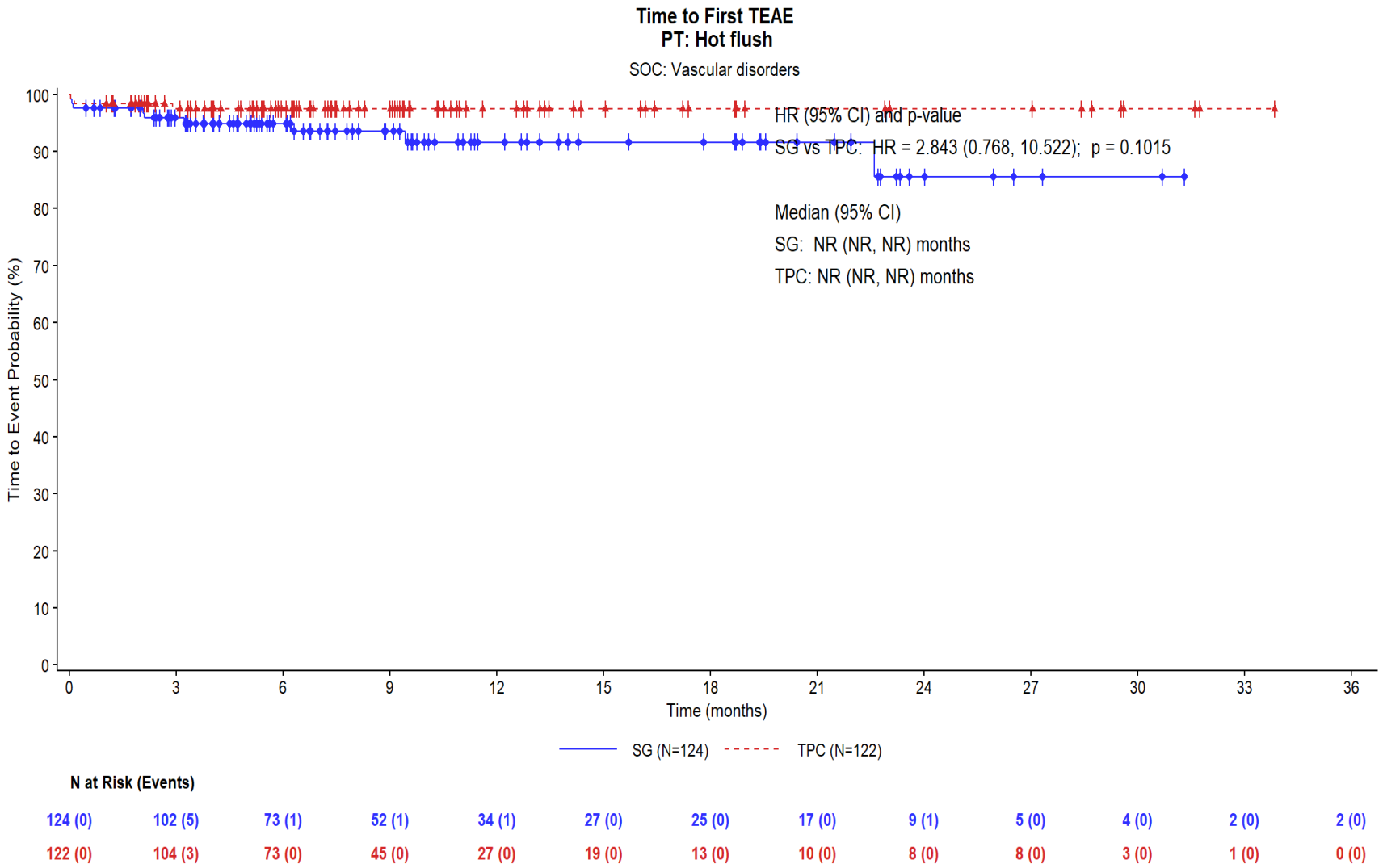
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.89. Figure 1.1.88: Kaplan Meier Plot of Time to First TEAE by PT Urticaria — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



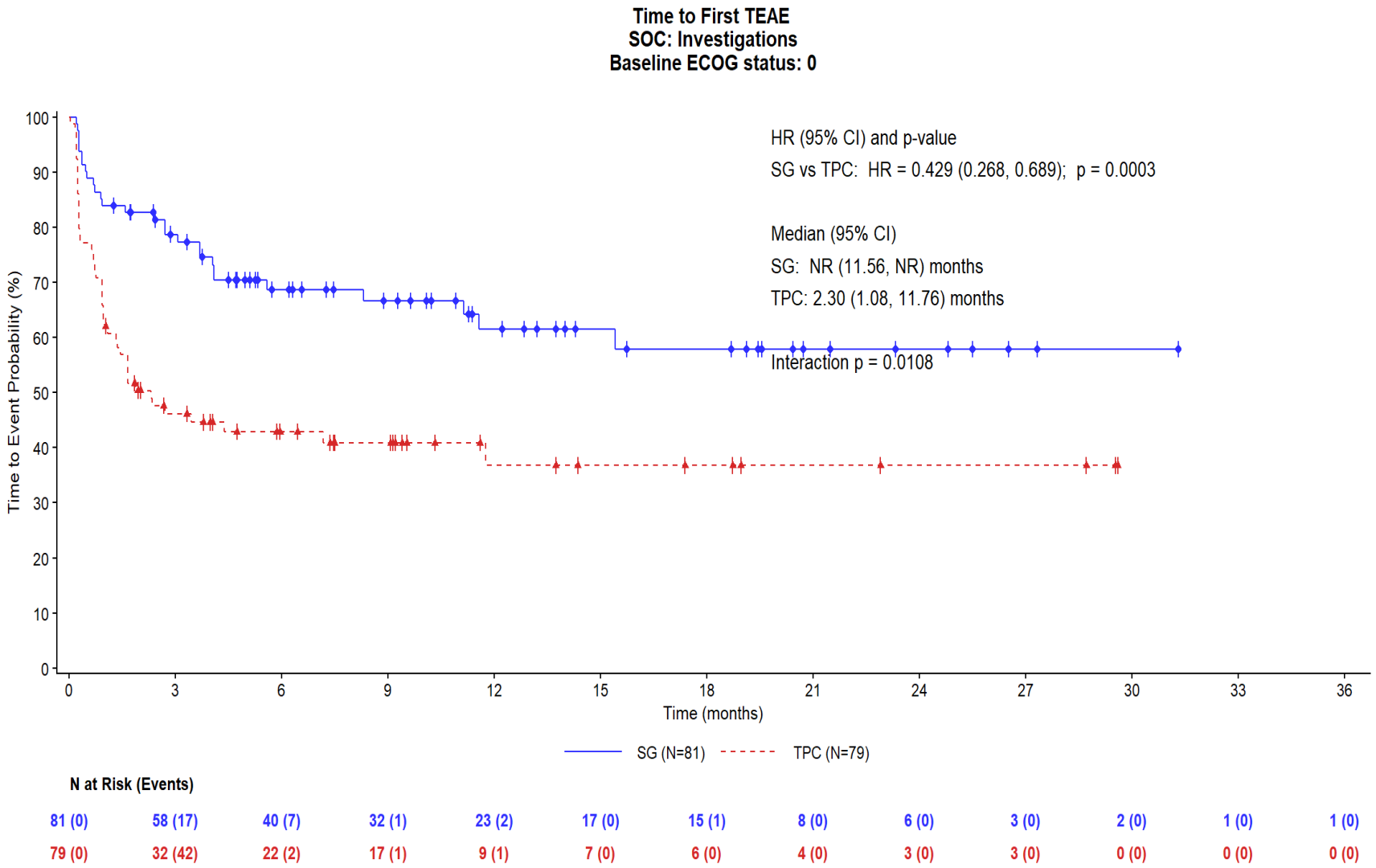
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.90. Figure 1.1.89: Kaplan Meier Plot of Time to First TEAE by PT Hot flush — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



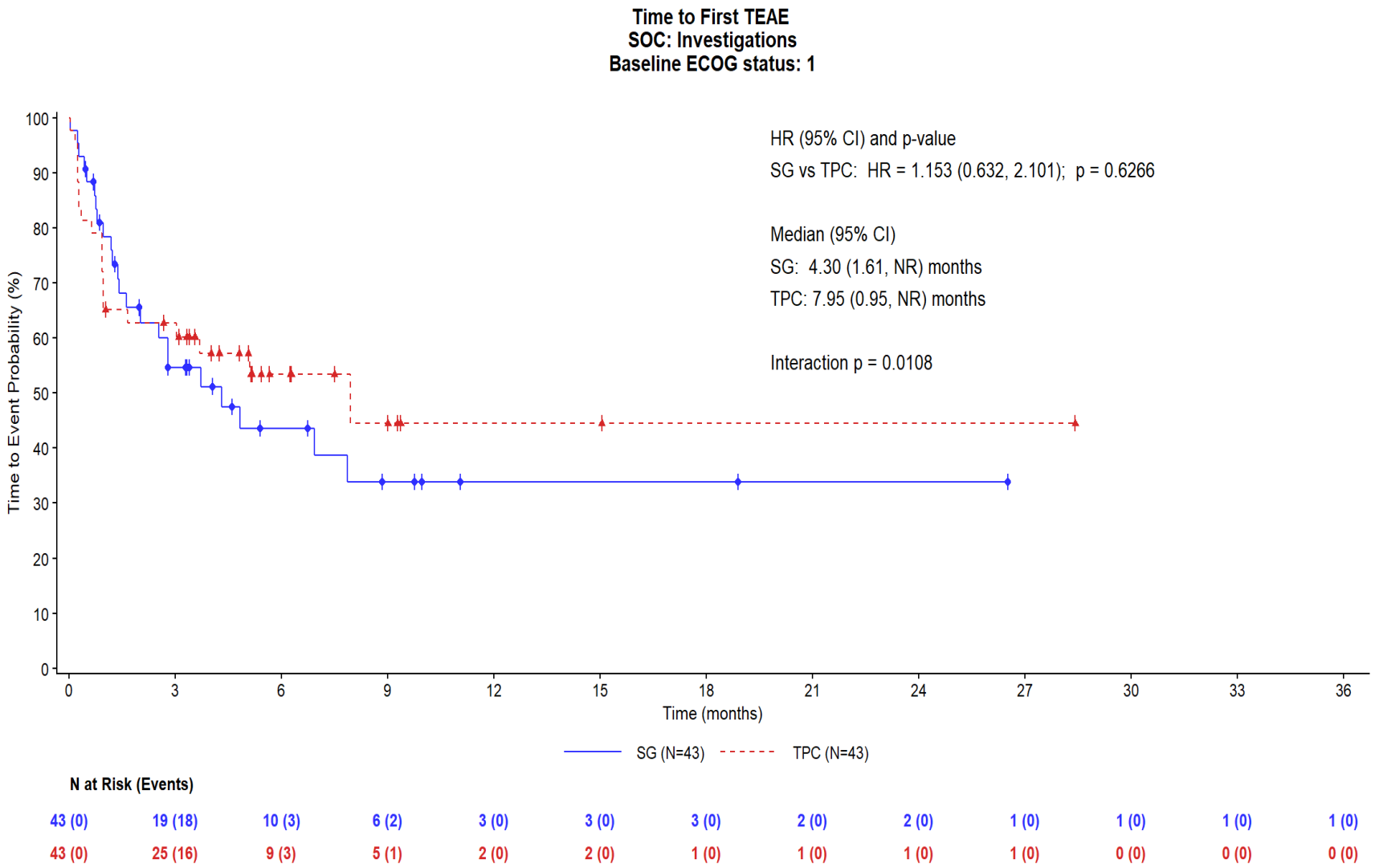
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.91. Figure 1.1.90: Kaplan Meier Plot of Time to First TEAE by SOC Investigations Baseline ECOG status 0 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



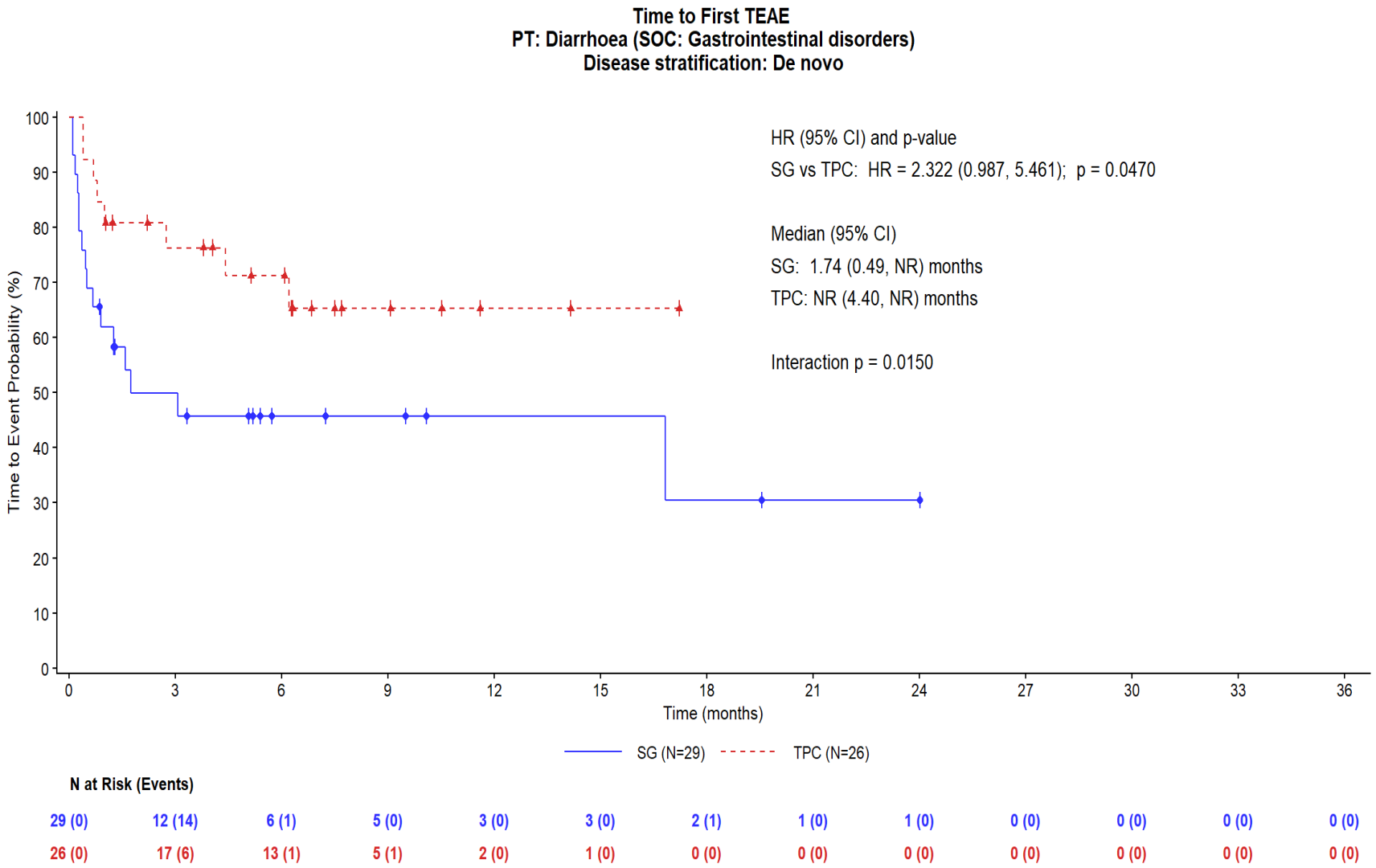
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.92. Figure 1.1.91: Kaplan Meier Plot of Time to First TEAE by SOC Investigations Baseline ECOG status 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



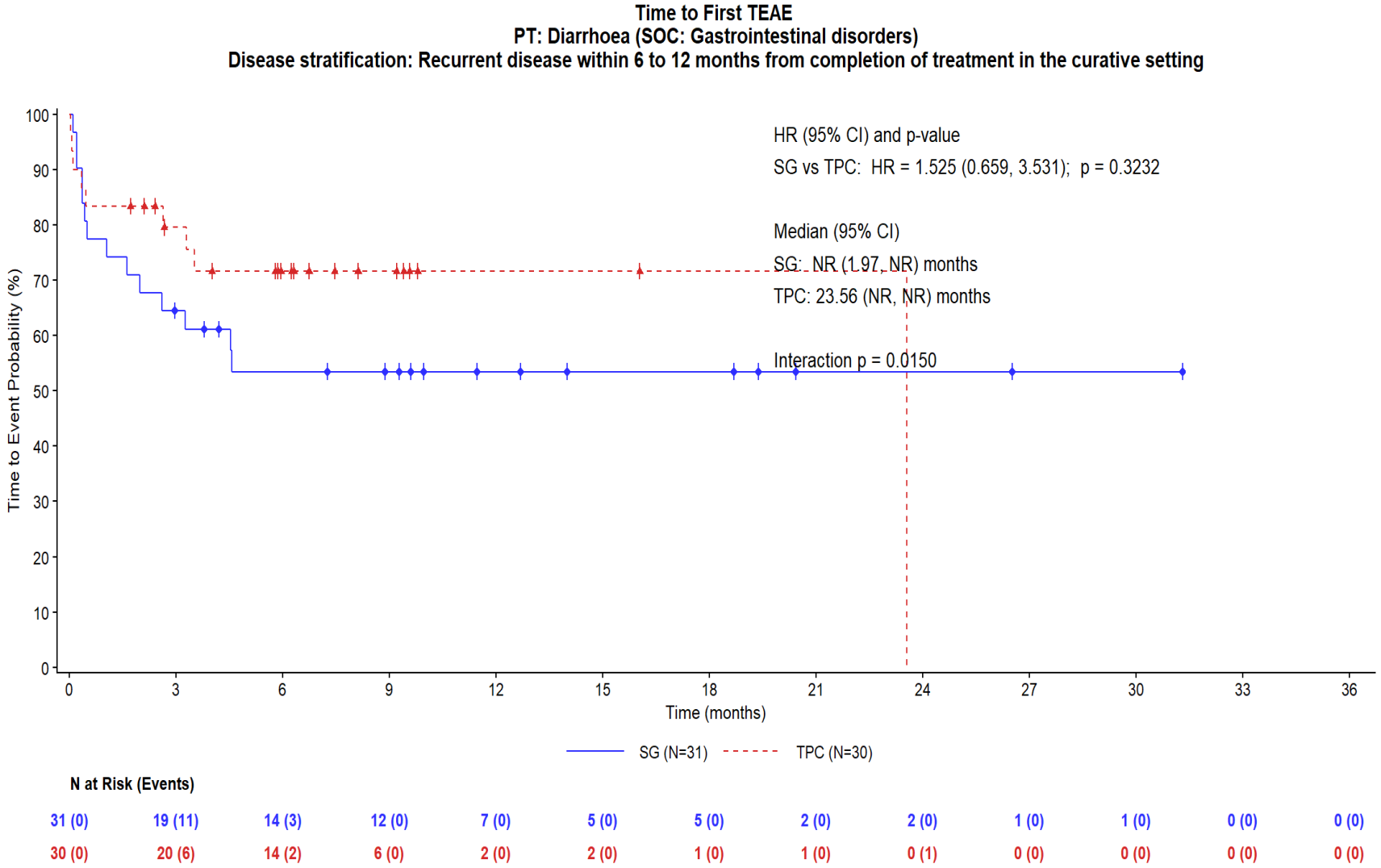
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.93. Figure 1.1.92: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification De novo — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



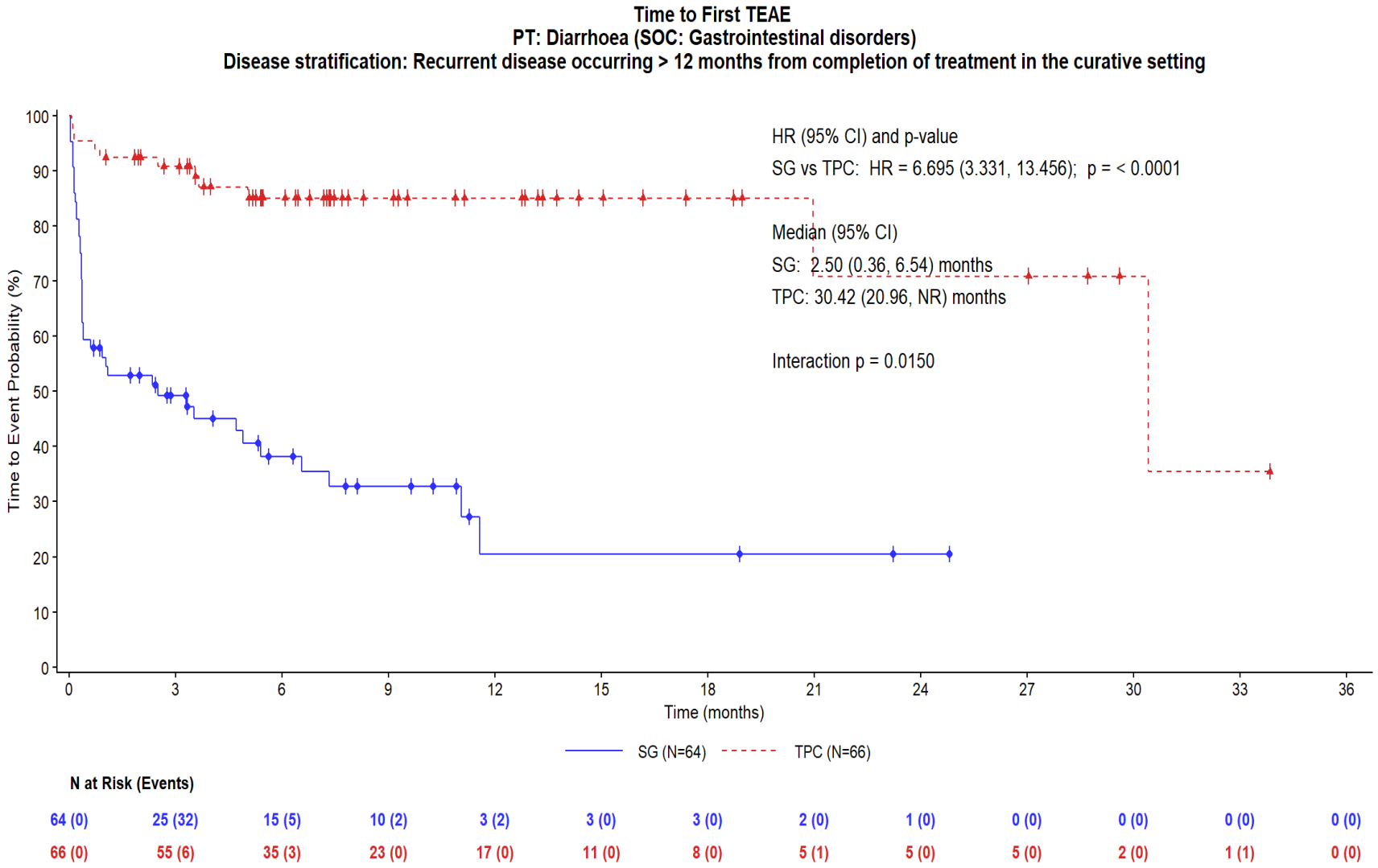
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.94. Figure 1.1.93: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease within 6 to 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



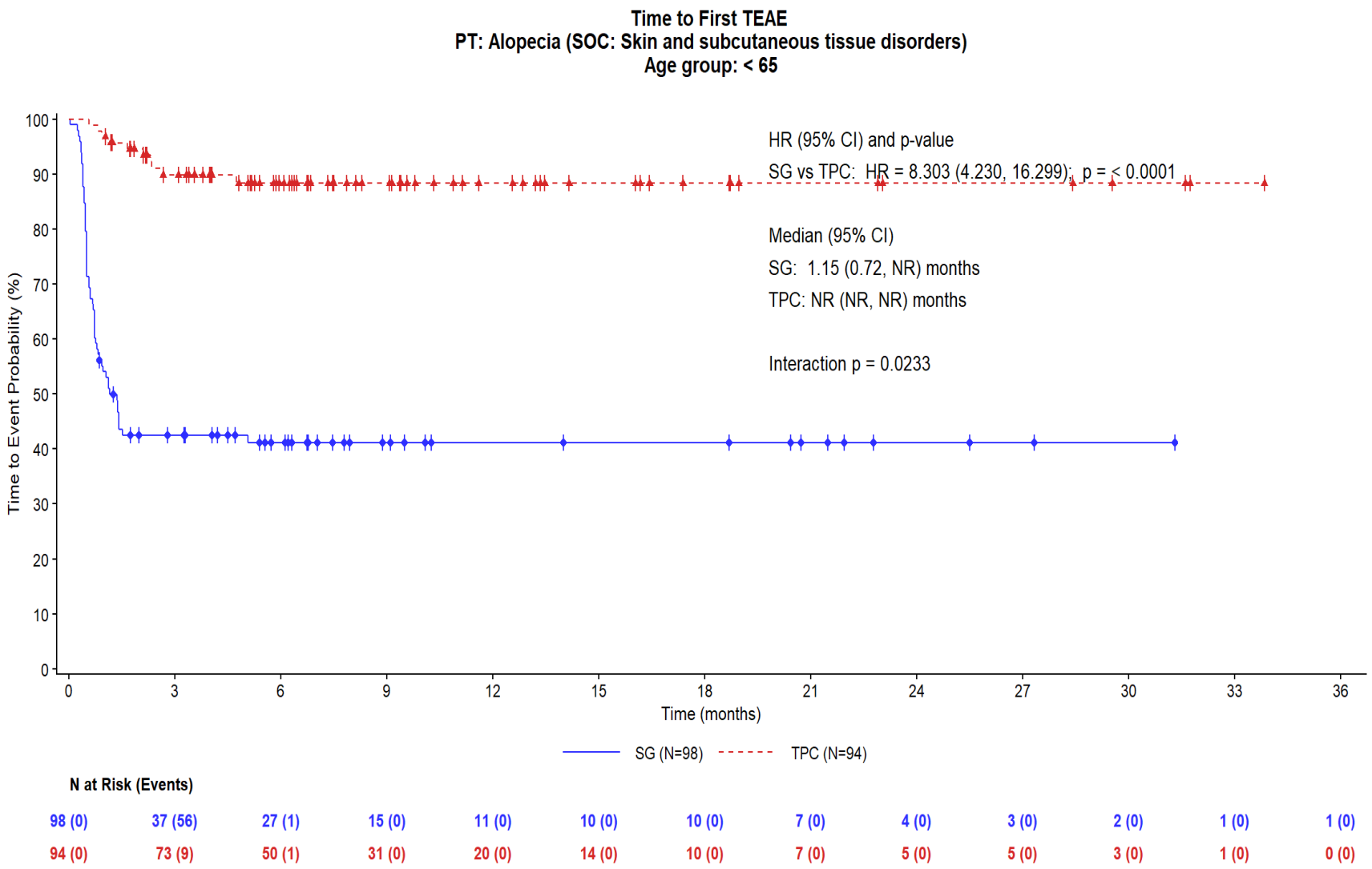
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.95. Figure 1.1.94: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease occurring greater than 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



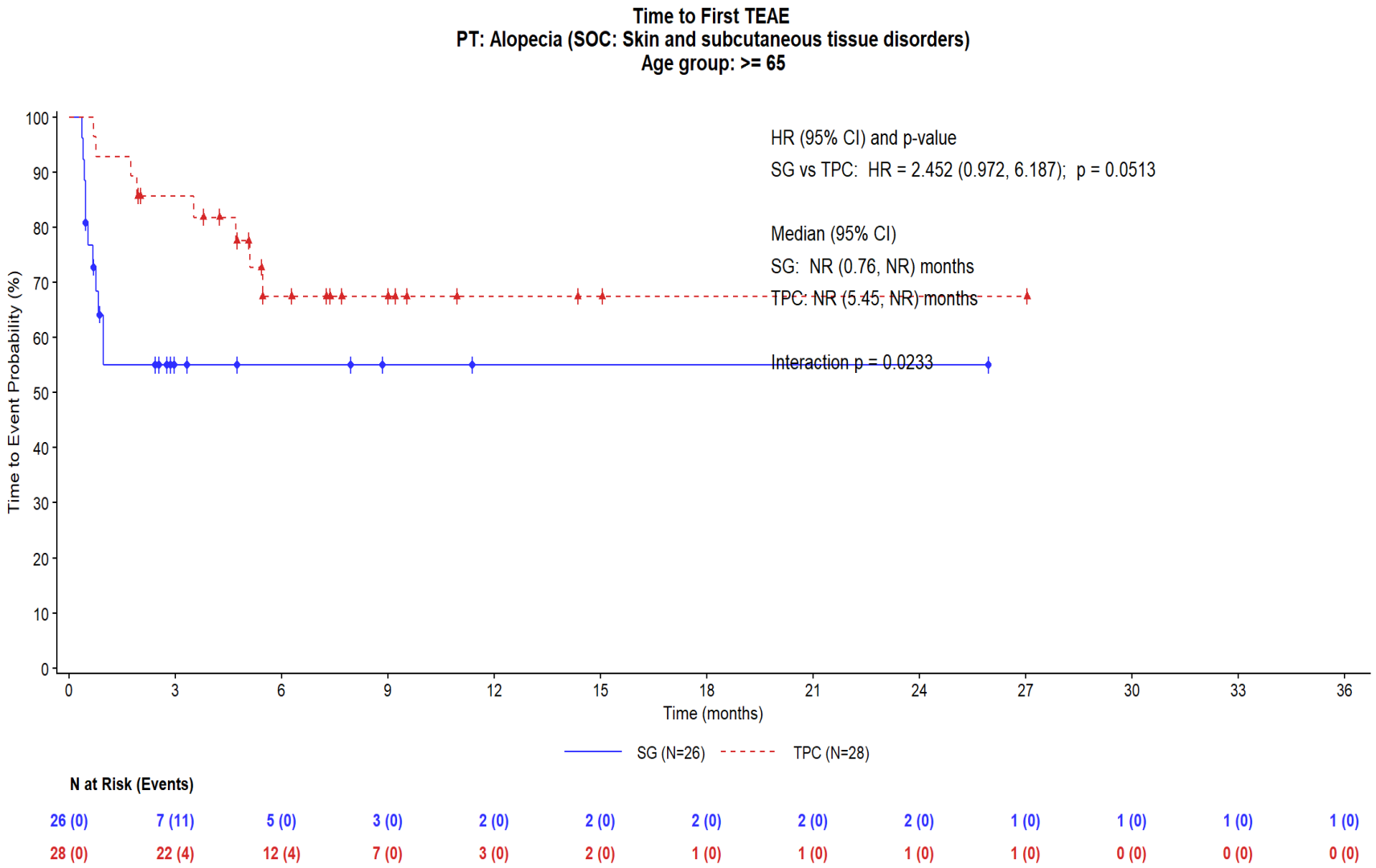
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.96. Figure 1.1.95: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



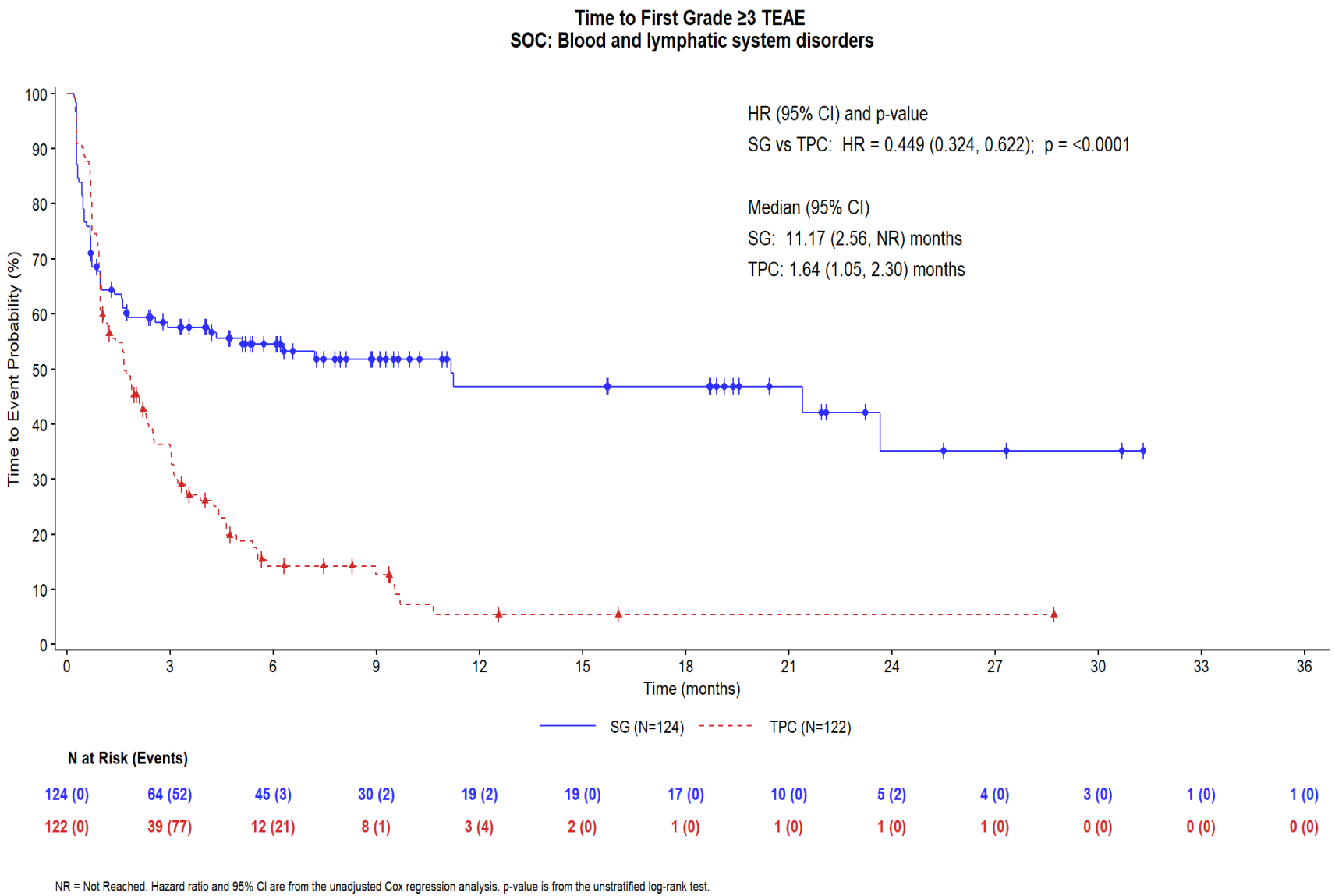
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.97. Figure 1.1.96: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



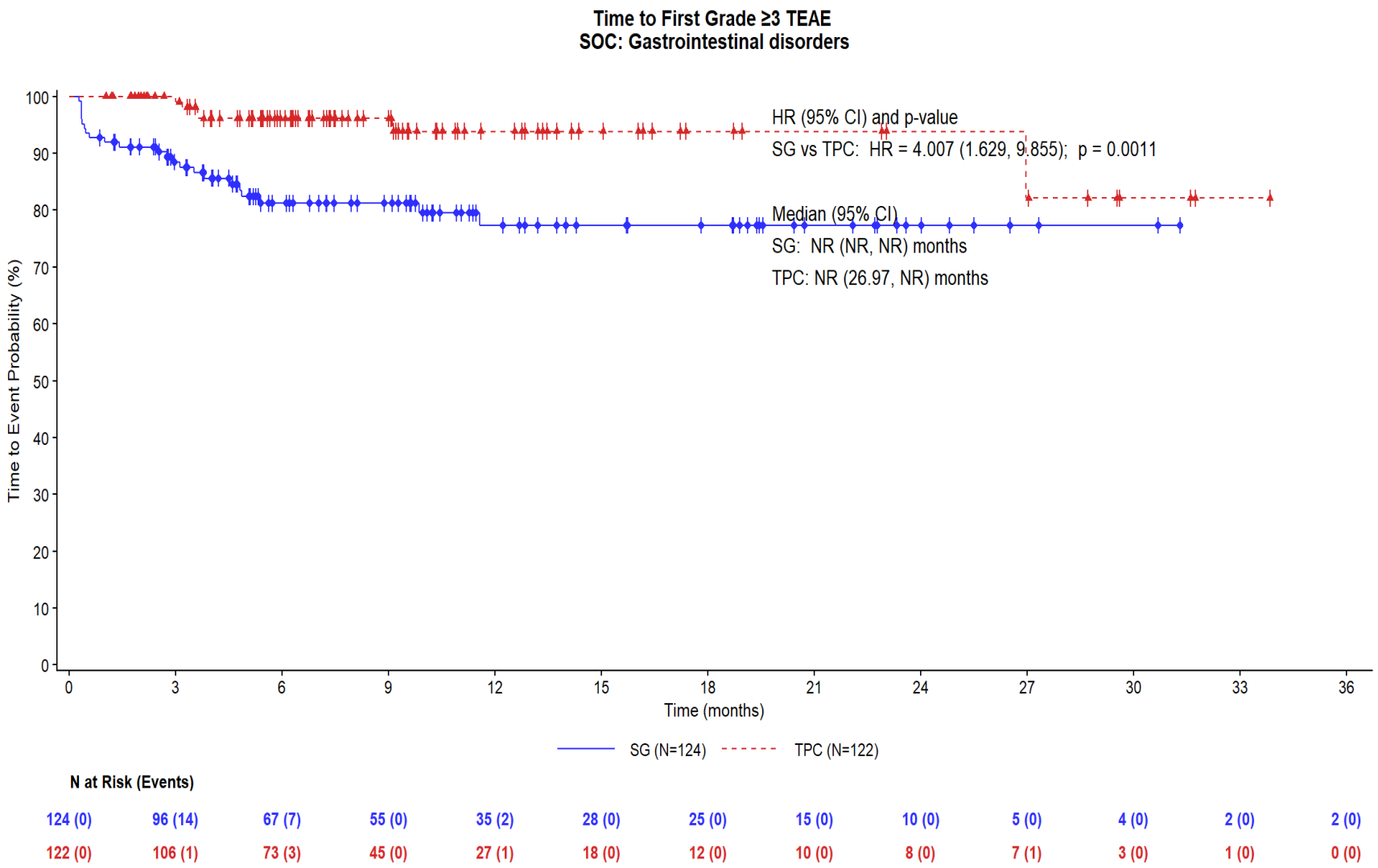
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.98. Figure 1.1.97: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



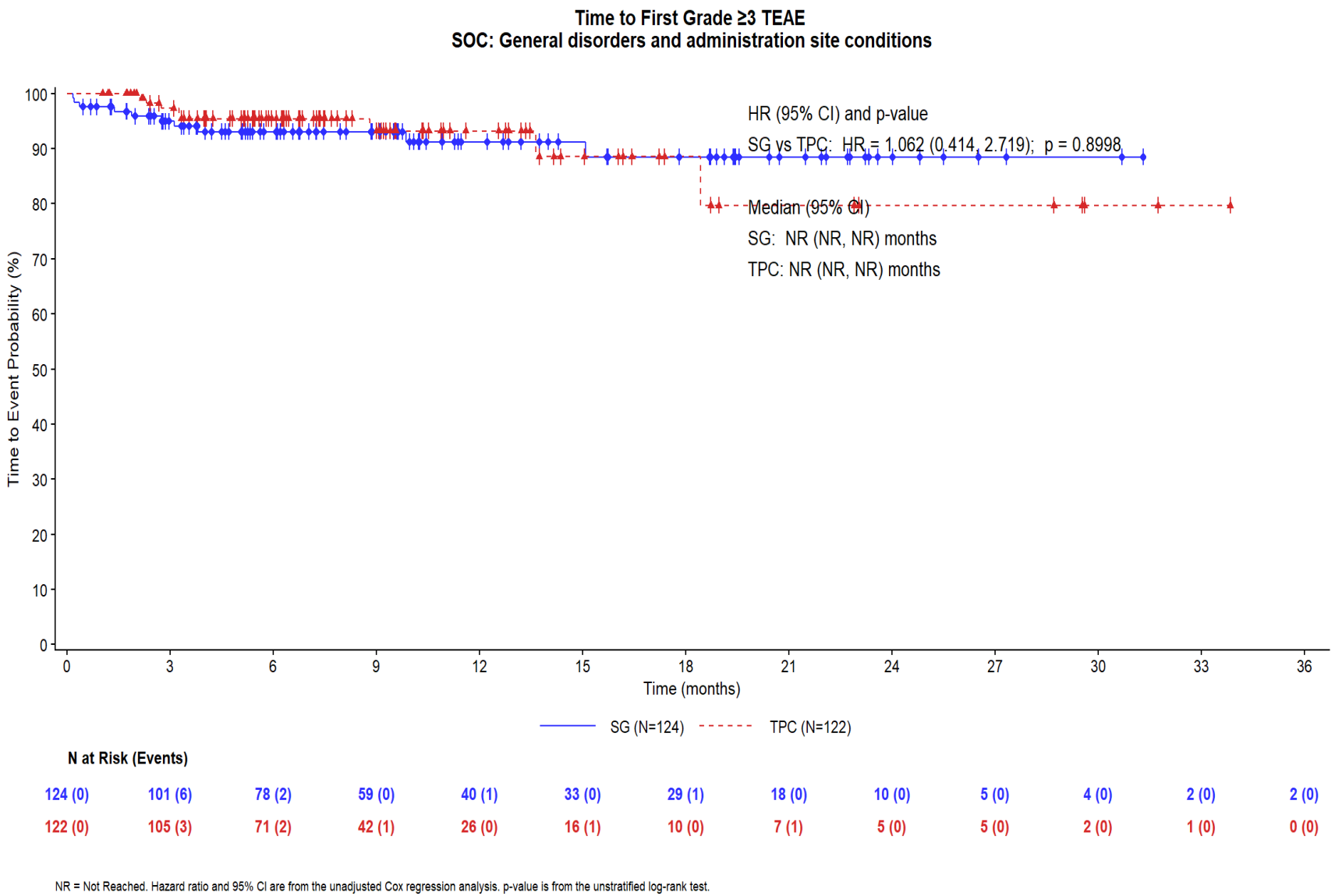
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.99. Figure 1.1.98: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



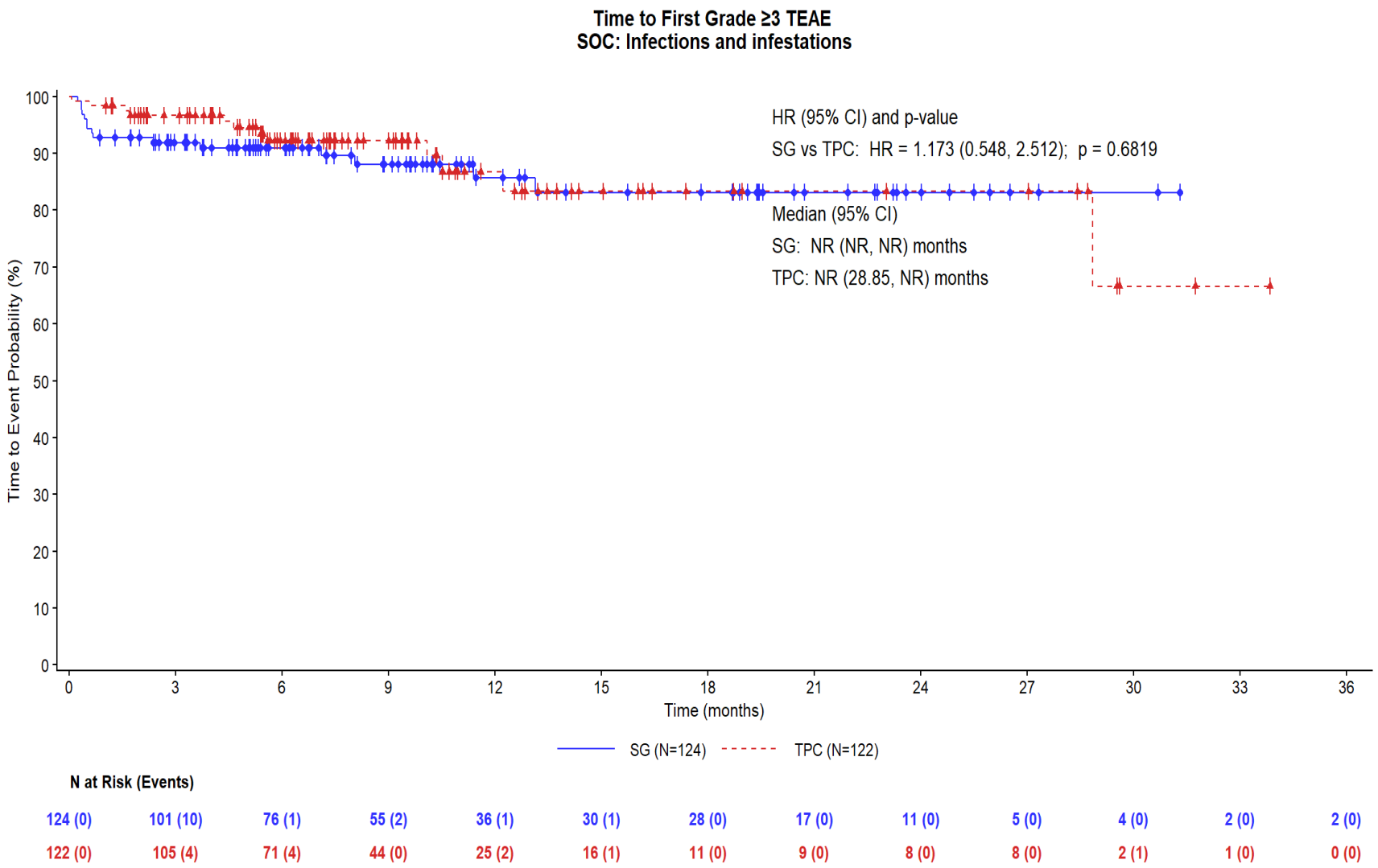
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.100. Figure 1.1.99: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



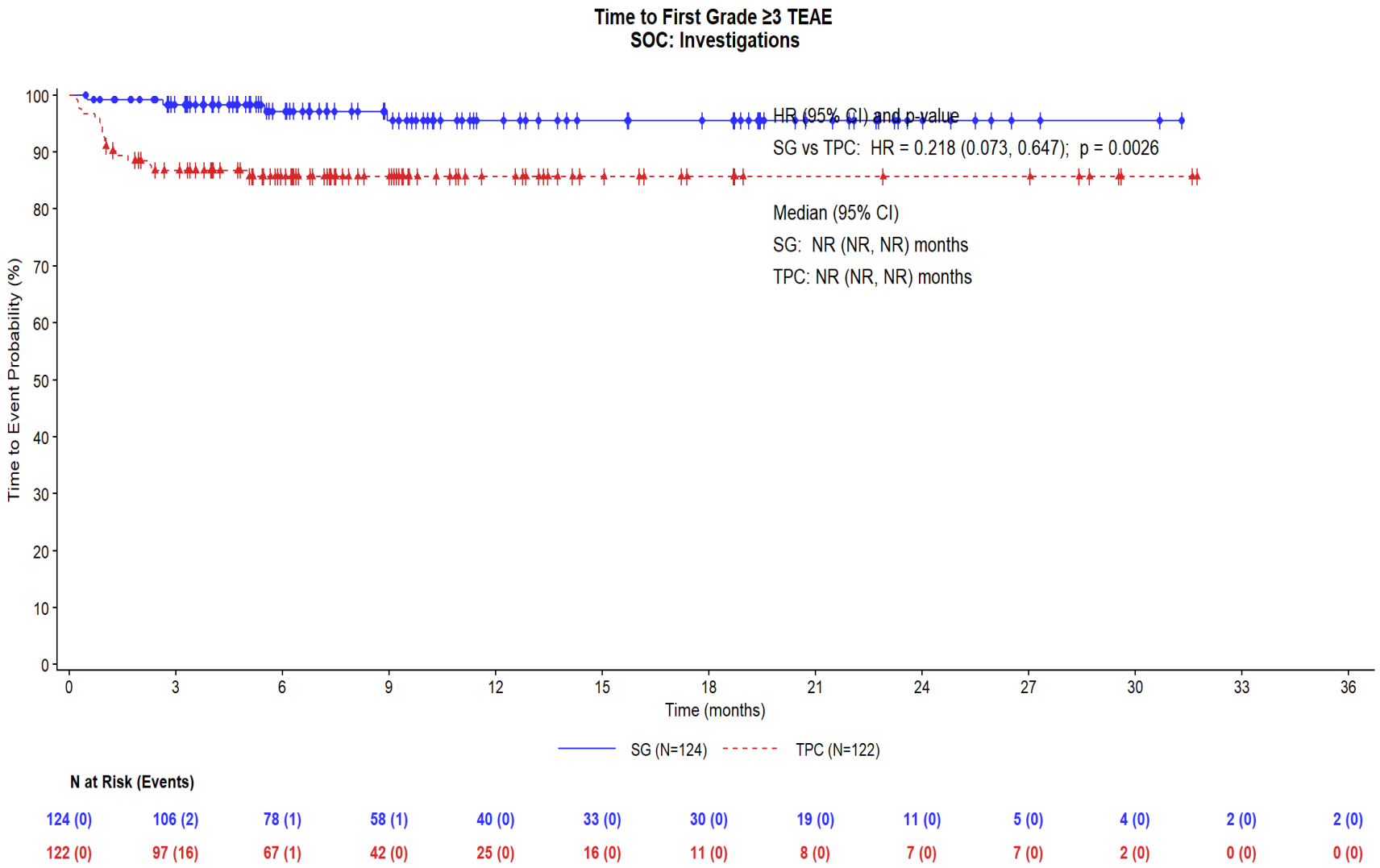
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.101. Figure 1.1.100: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



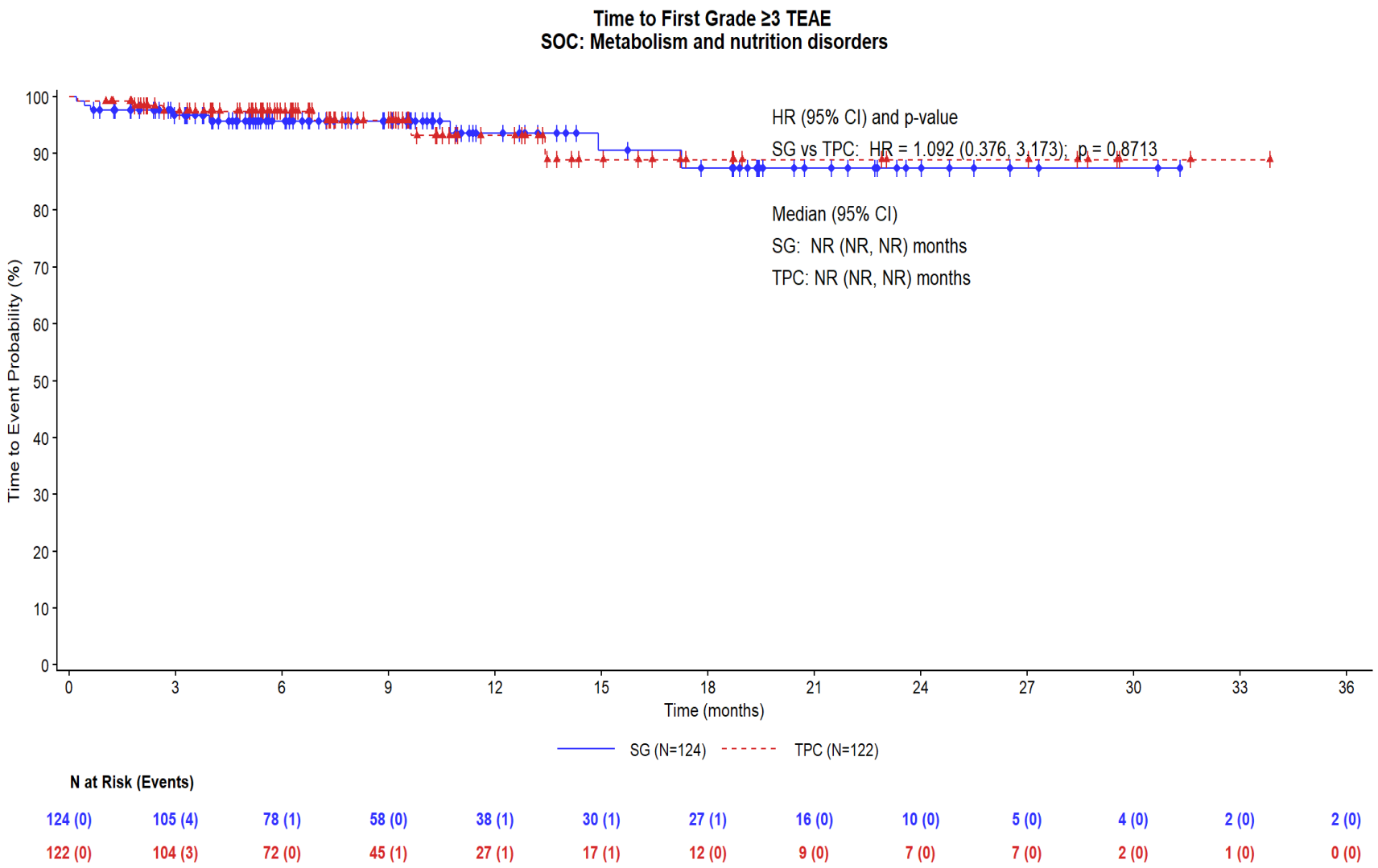
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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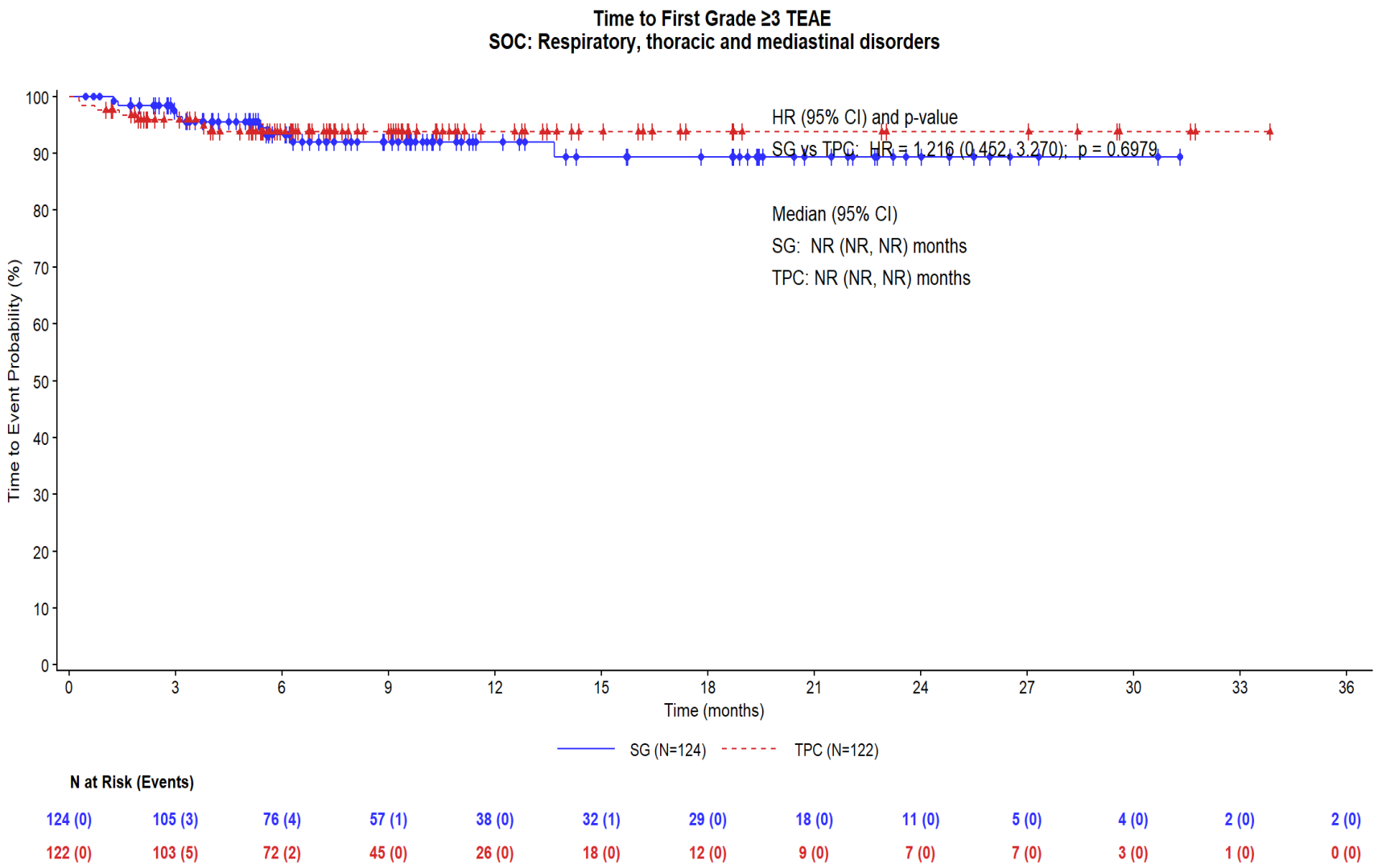
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

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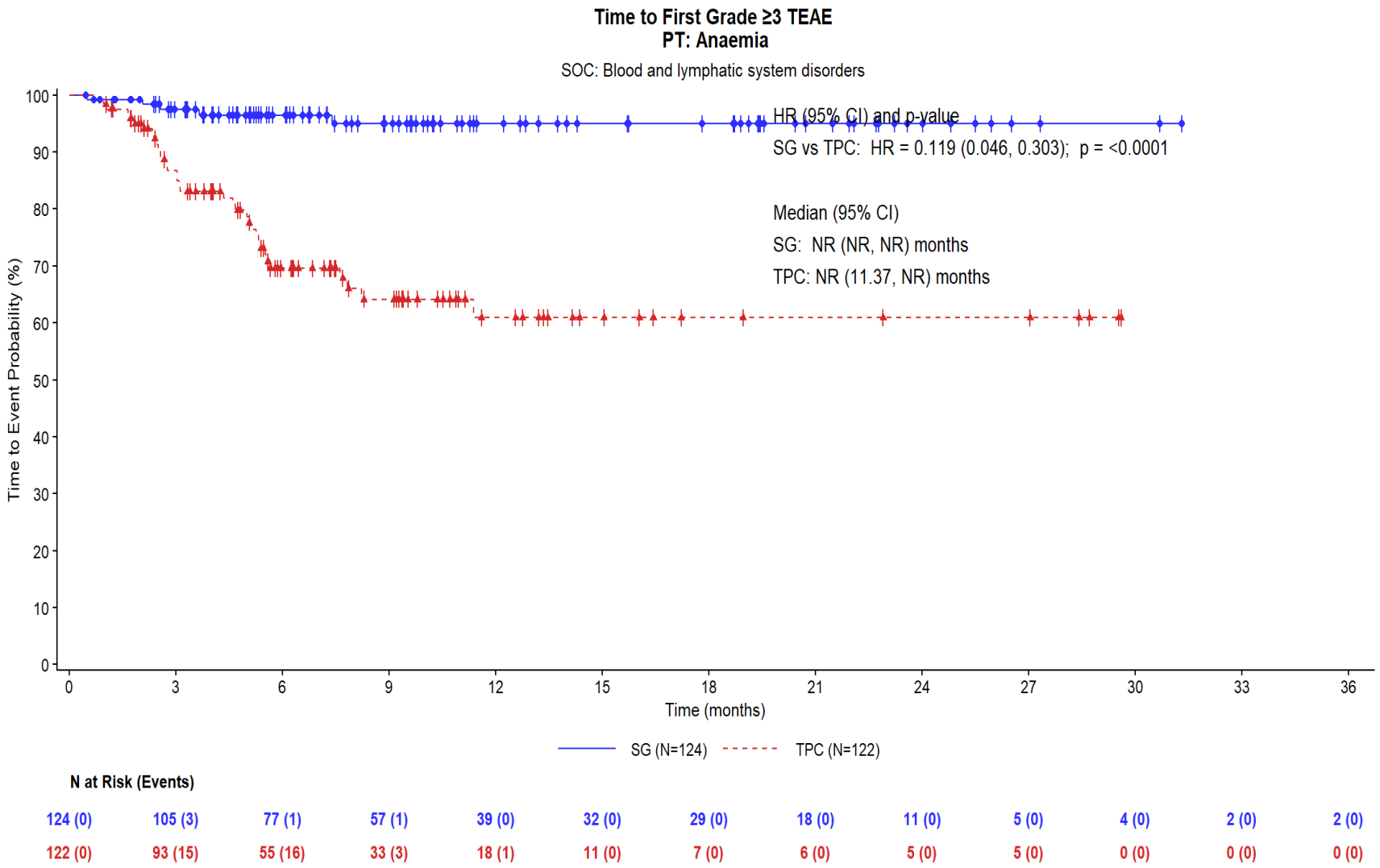
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.104. Figure 1.1.103: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



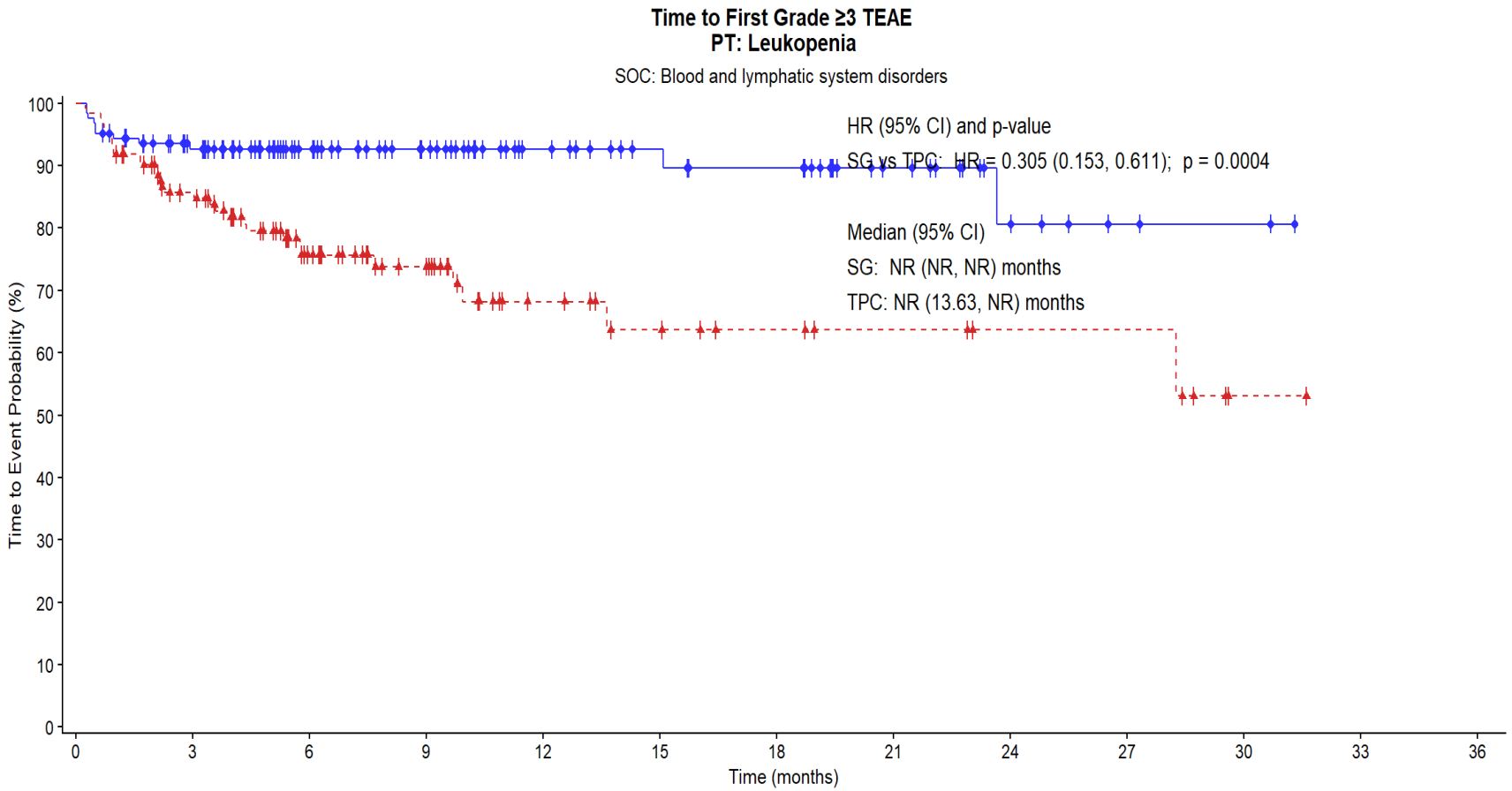
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.105. Figure 1.1.104: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



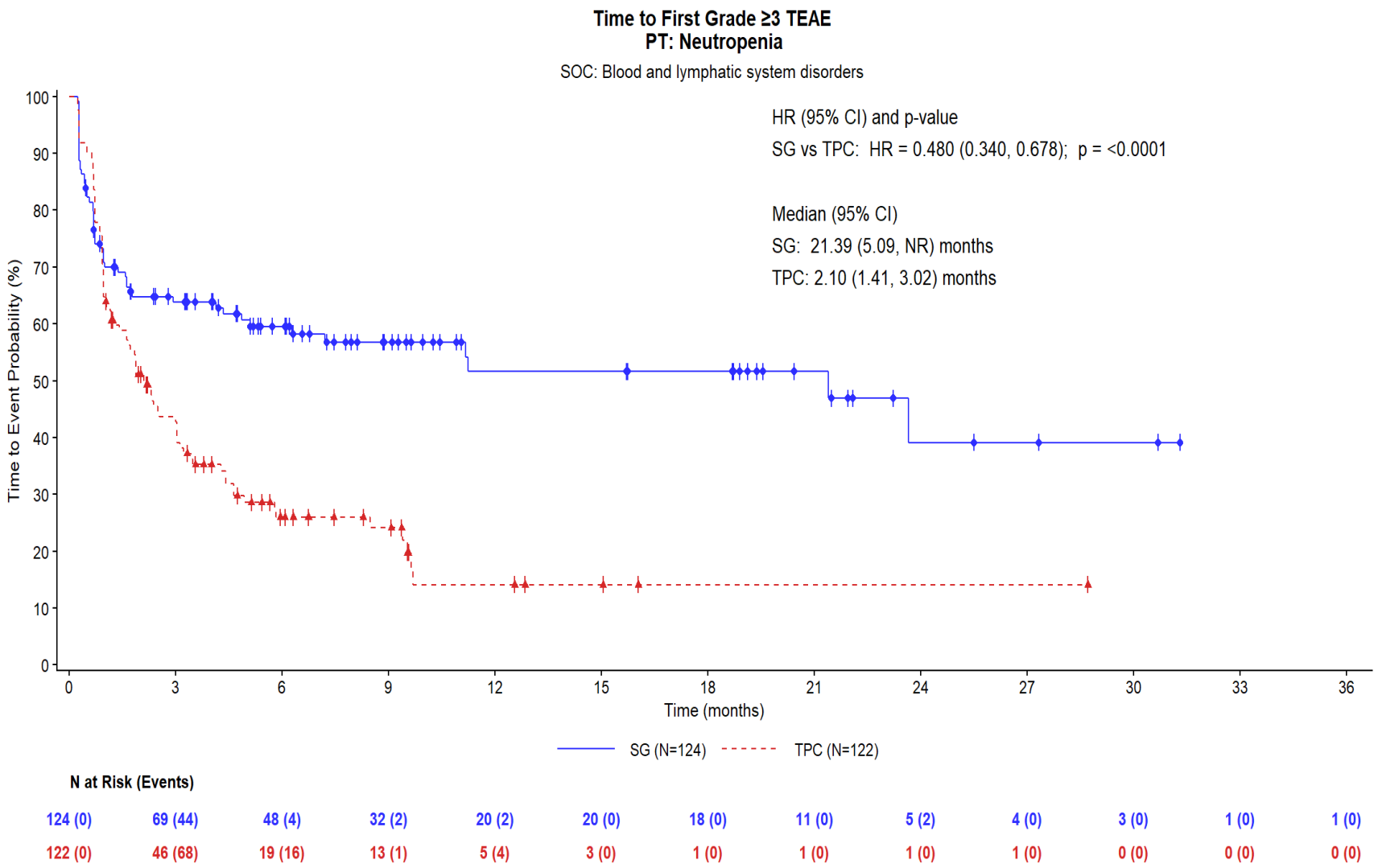
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.106. Figure 1.1.105: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



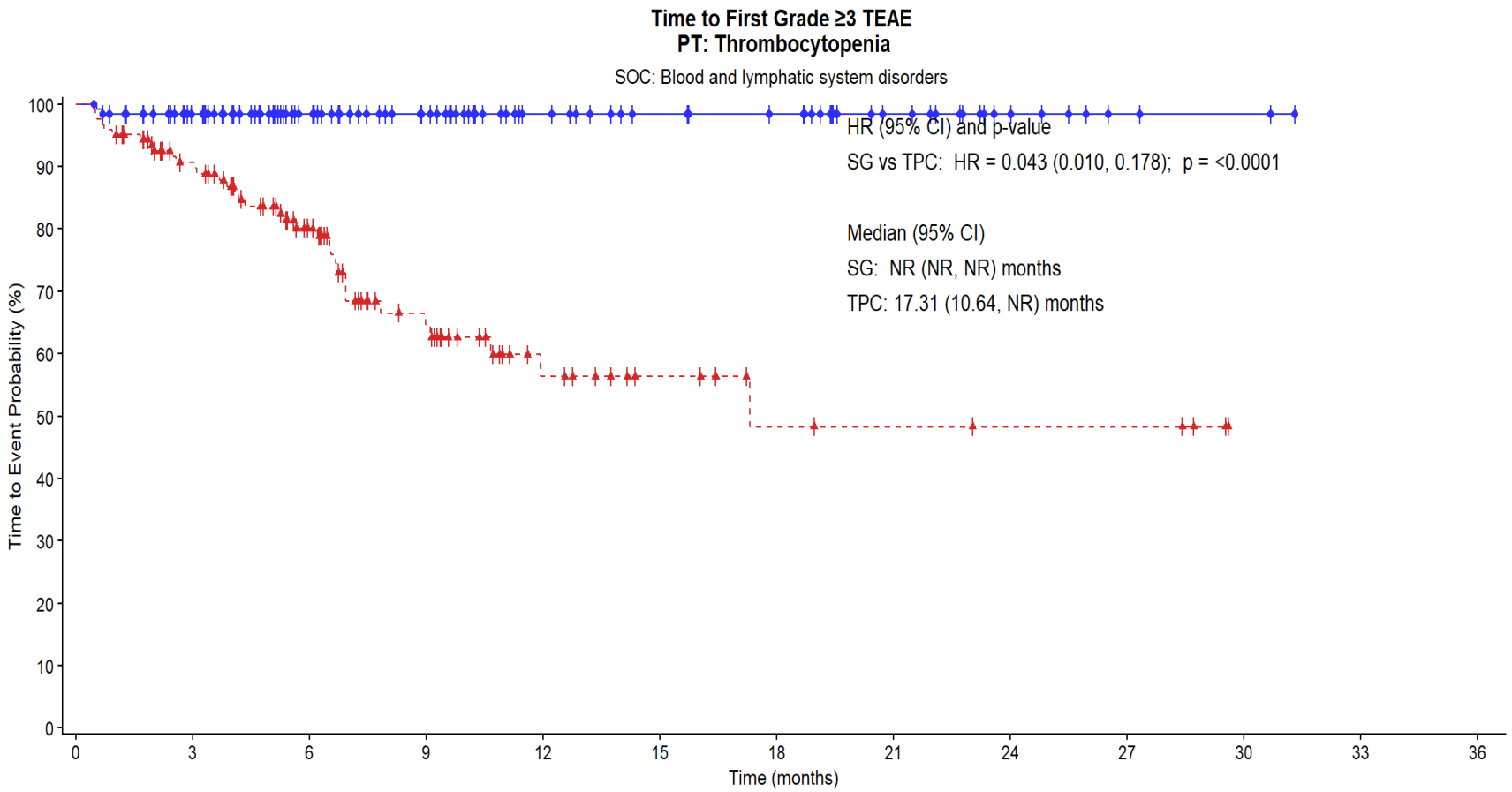
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.107. Figure 1.1.106: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



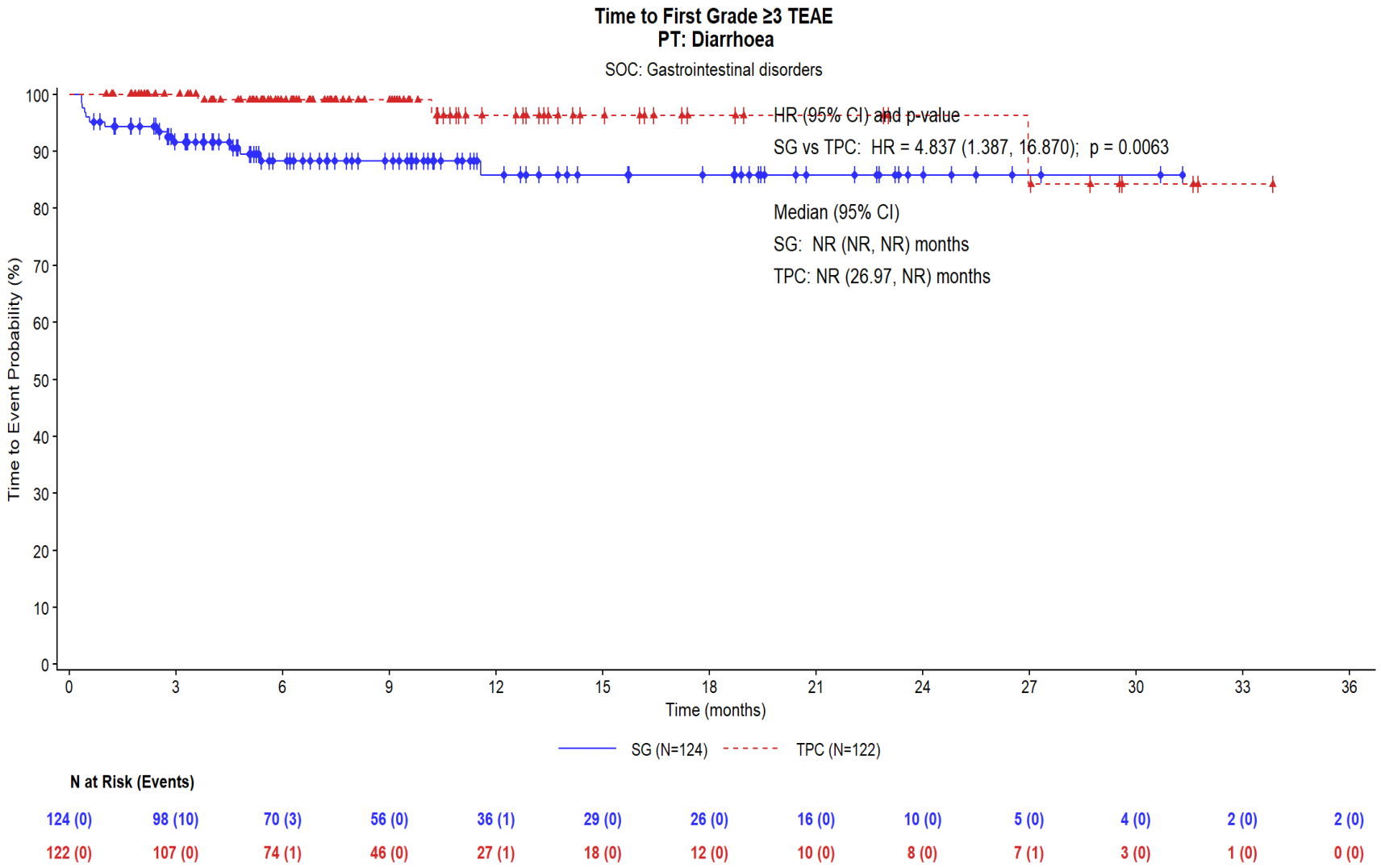
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.108. Figure 1.1.107: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



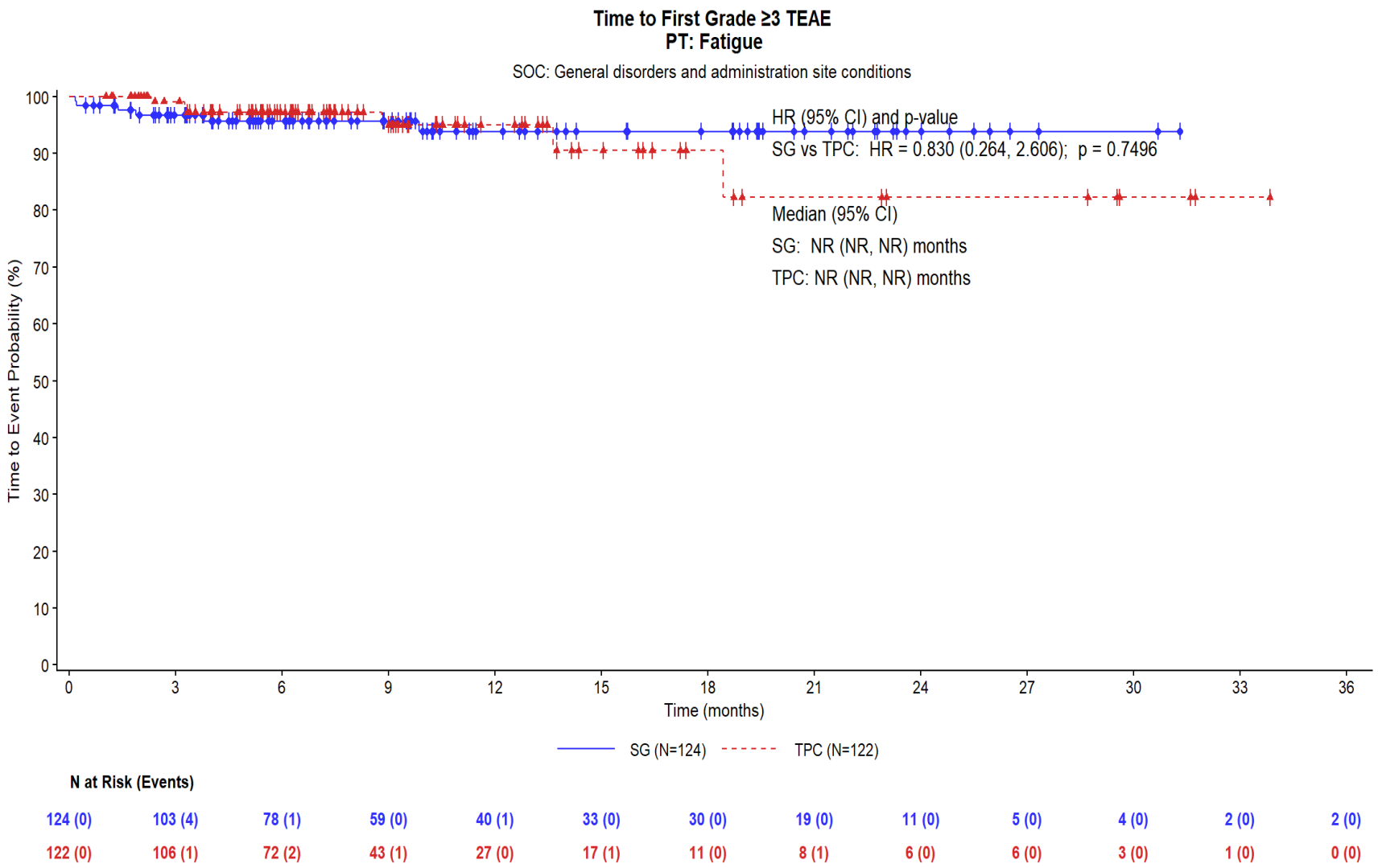
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.109. Figure 1.1.108: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



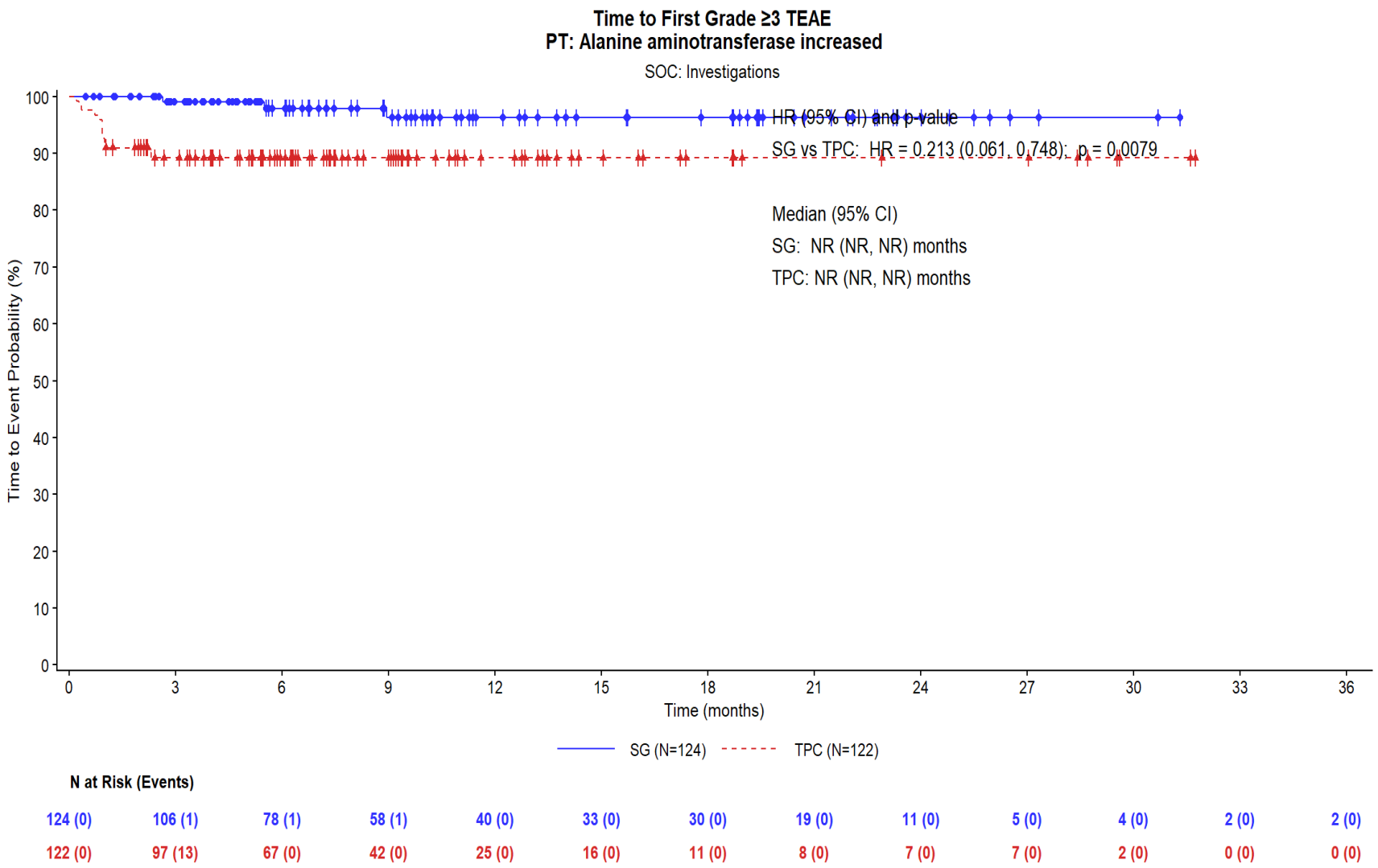
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.110. Figure 1.1.109: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



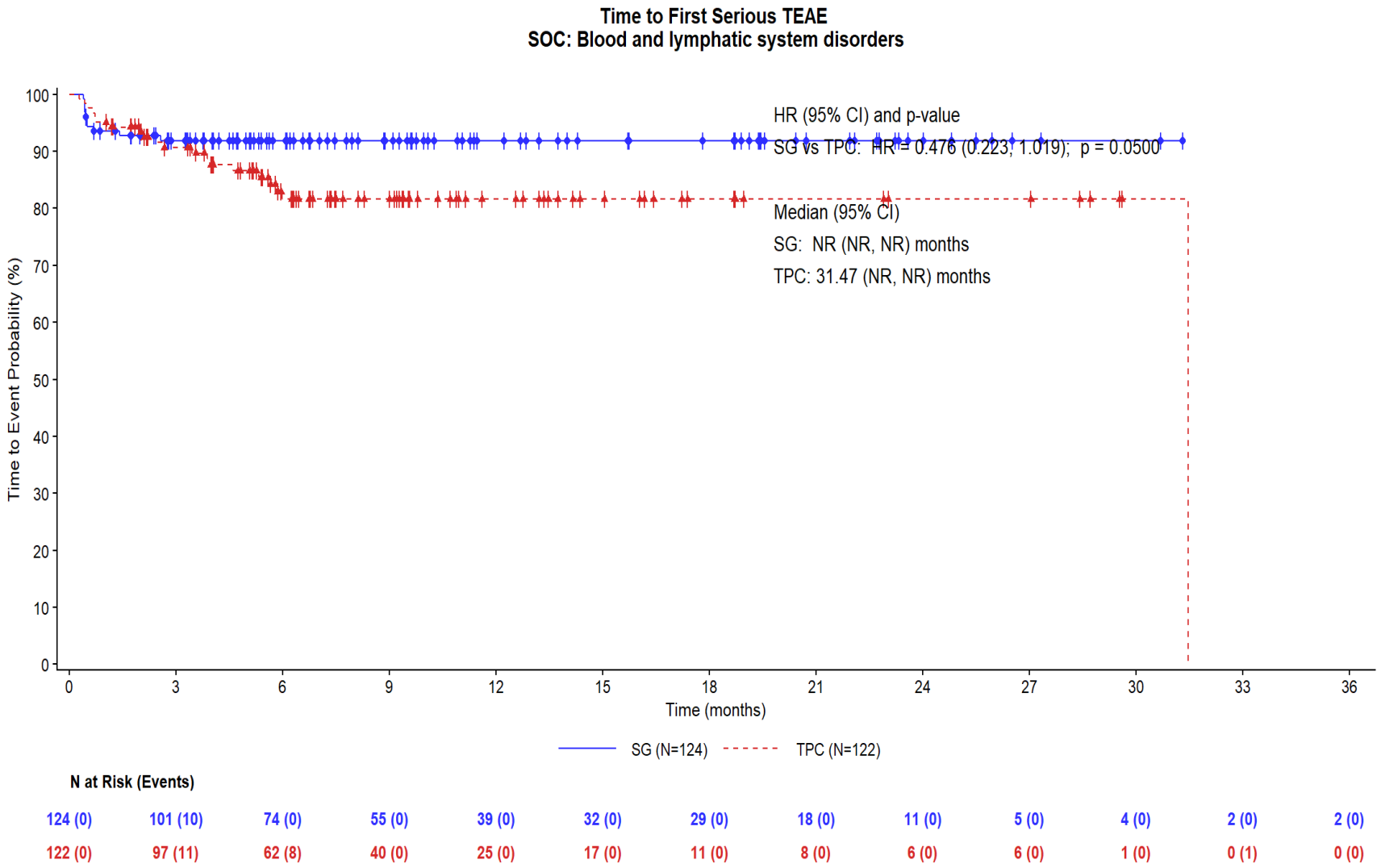
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.111. Figure 1.1.110: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



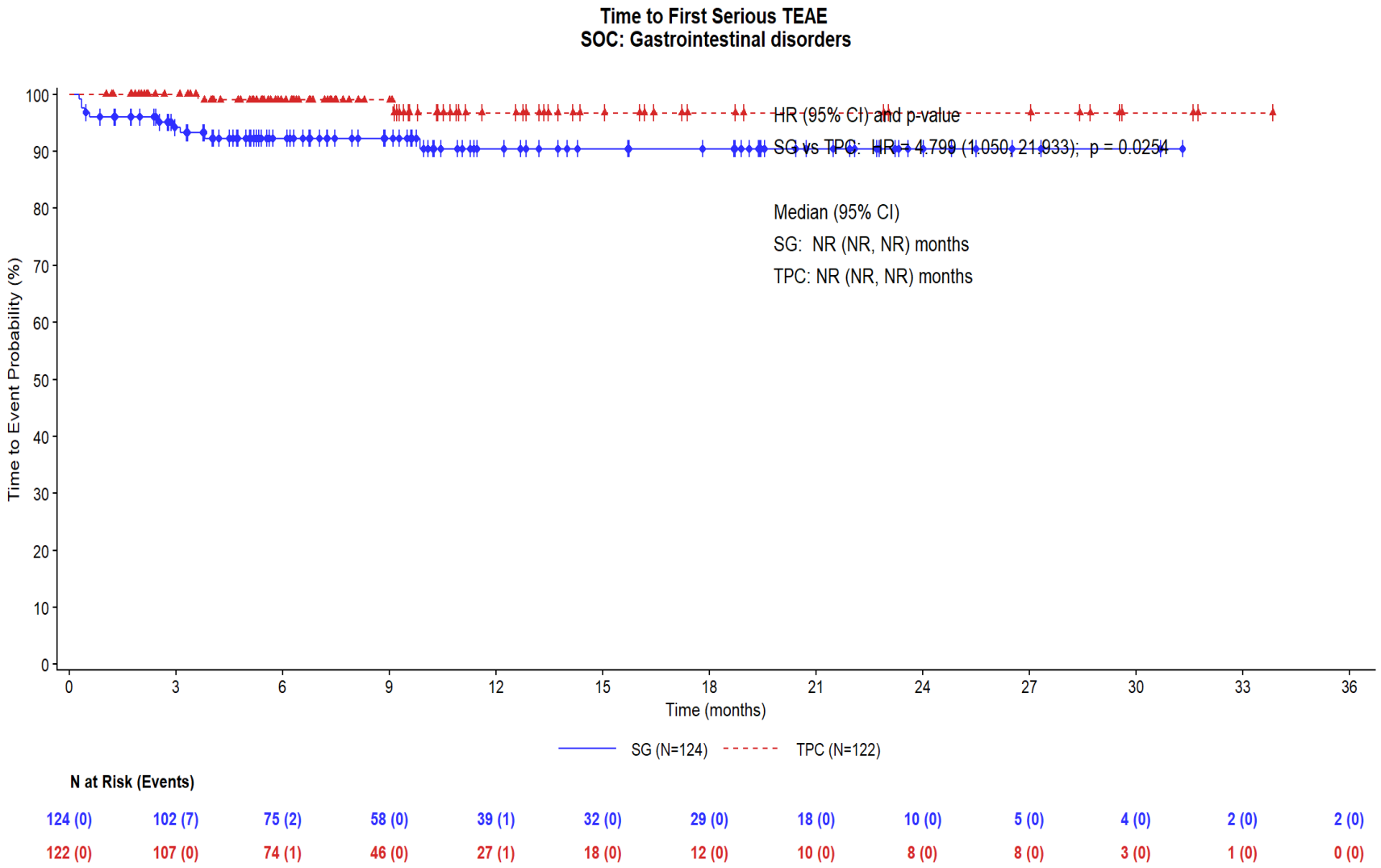
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.112. Figure 1.1.111: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



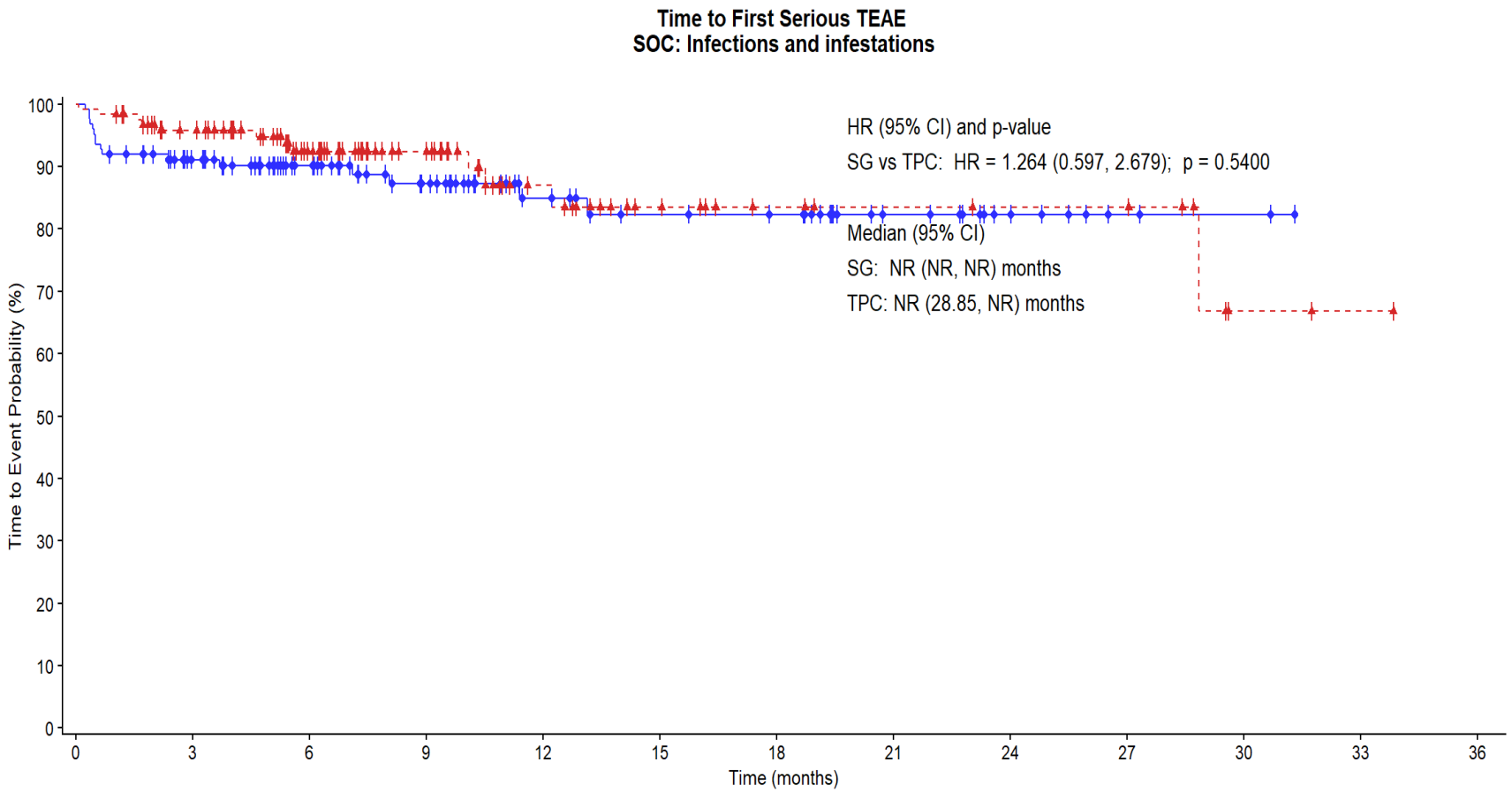
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.113. Figure 1.1.112: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



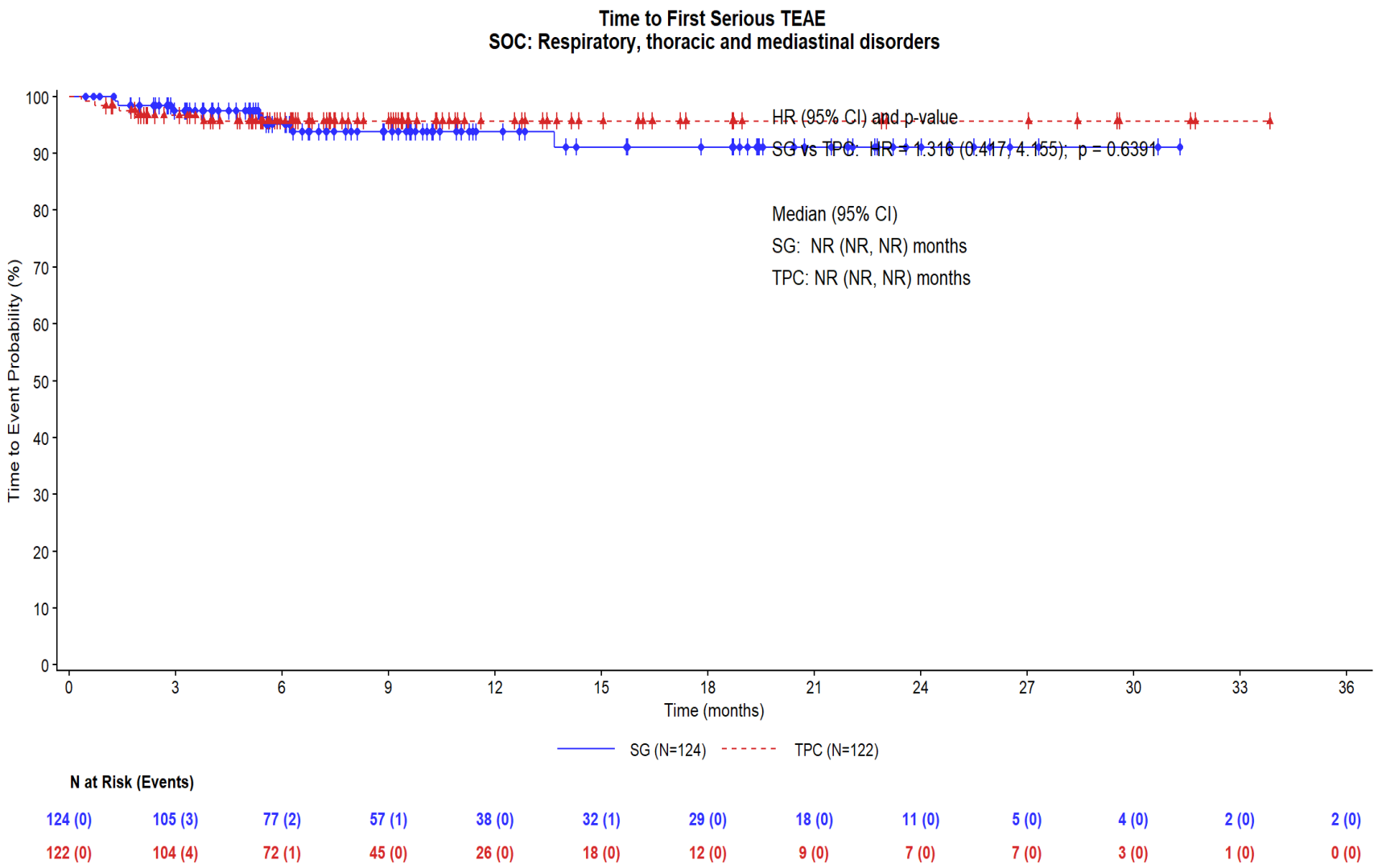
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.114. Figure 1.1.113: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



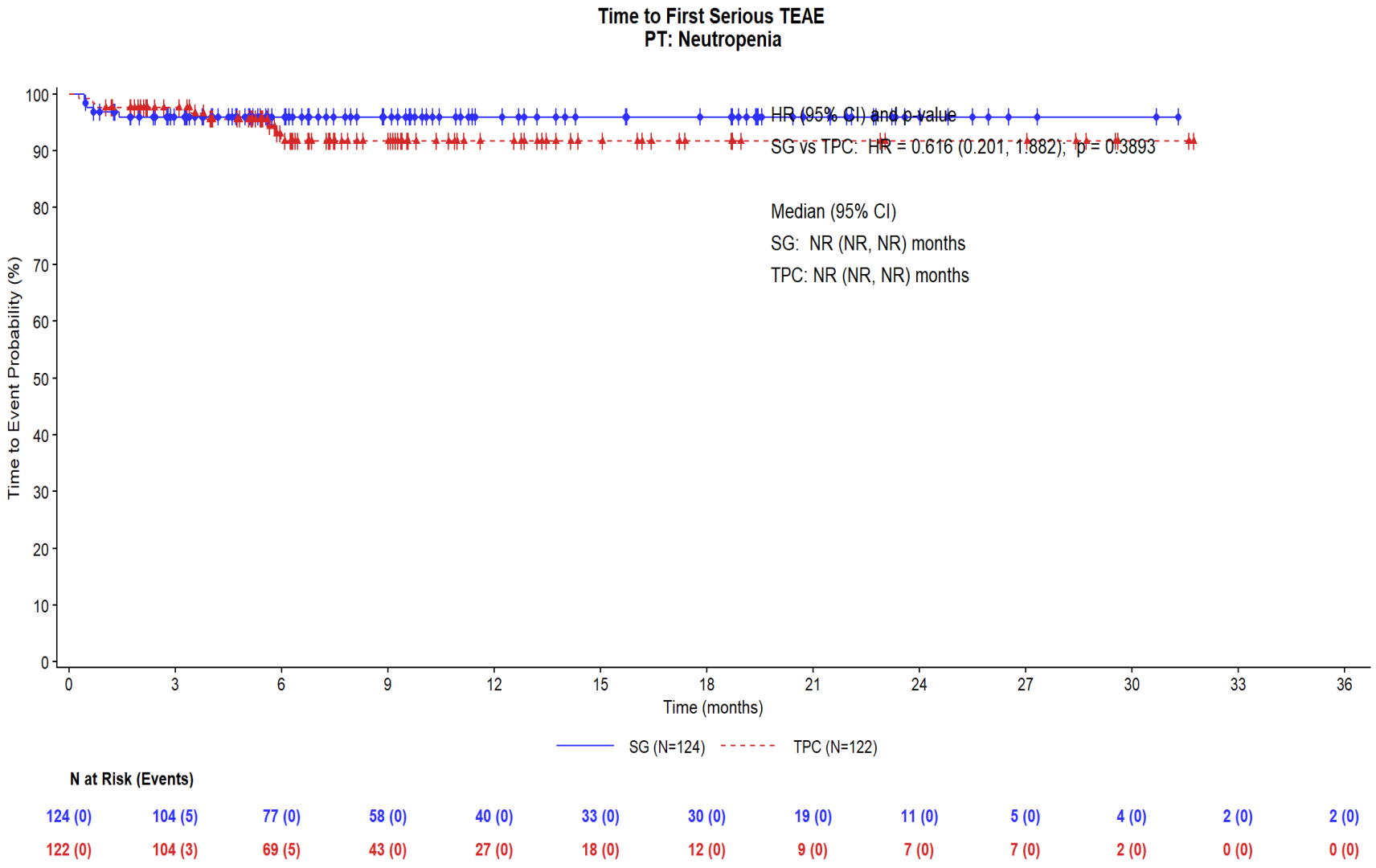
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.115. Figure 1.1.114: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



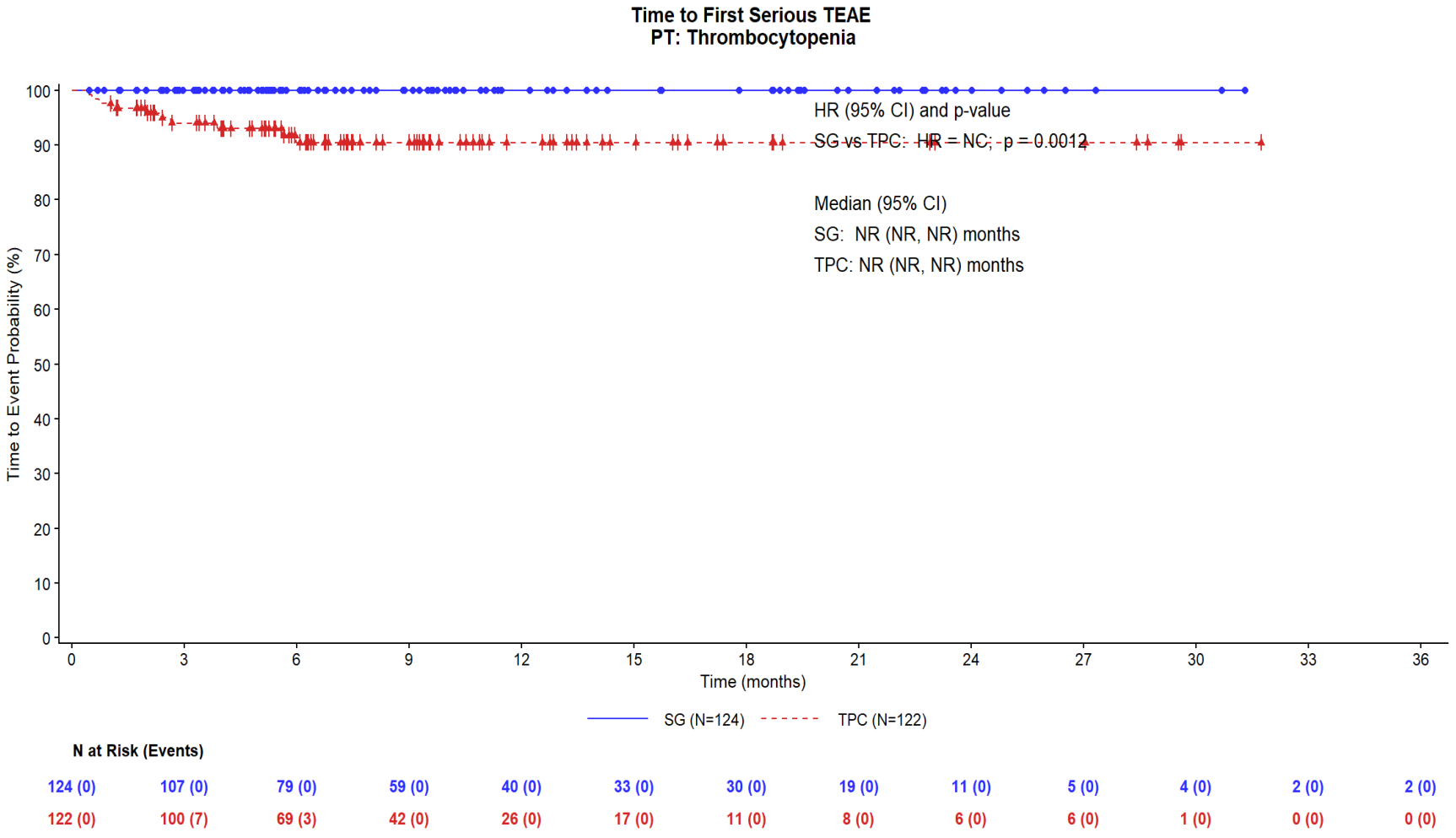
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.116. Figure 1.1.115: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.117. Figure 1.1.116: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

Table. Recurrence of diarrhoea TEAE — mSAF3: Excluding patients preselected to nab-paclitaxel or paclitaxel

	SG (N=124)			TPC (N=122)		
Incidence of diarrhoea TEAE	**1 event**	**2 events**	**>2 events**	**1 event**	**2 events**	**>2 events**
Grade 1	29 (23.4%)	11 (8.9%)	14 (11.3%)	21 (17.2%)	2 (1.6%)	2 (1.6%)
Grade 2	28 (22.6%)	8 (6.5%)	5 (4.0%)	8 (6.6%)	1 (0.8%)	0
Grade ≥3	14 (11.3%)	0	0	3 (2.5%)	0	0
Grade 3	14 (11.3%)	0	0	3 (2.5%)	0	0
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

n = number of events per patient; Data cut off:- 22 APR 2026

Descriptive Analysis of G-CSF Use Prior to First Febrile Neutropenia AE

	Febrile Neutropenia CTCAE Grade ≥3[1]			Febrile Neutropenia Serious Adverse Event (SAE)[2]		
Parameter	**SG (N=124)**	**TPC (N=122)**	**Overall (N=246)**	**SG (N=124)**	**TPC (N=122)**	**Overall (N=246)**
Total Patients in Safety Analysis Set	**124**	**122**	**246**	**124**	**122**	**246**
Patients with Febrile Neutropenia, n (%)	**5 (4.0%)**	**3 (2.5%)**	**8 (3.3%)**	**4 (3.2%)**	**2 (1.6%)**	**6 (2.4%)**
G-CSF Prophylaxis Prior to AE						
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	5 (100.0%)	3 (100.0%)	8 (100.0%)	4 (100.0%)	2 (100.0%)	6 (100.0%)
Patients Without Febrile Neutropenia, n (%)	**119 (96.0%)**	**119 (97.5%)**	**238 (96.7%)**	**120 (96.8%)**	**120 (98.4%)**	**240 (97.6%)**

n (%) = number of subjects and percentage of the relevant denominator.
Denominator for Total Patients, Patients with Febrile Neutropenia, and Patients without Febrile Neutropenia rows = total number of patients in each treatment arm (or overall) in the Safety Analysis Set.
Denominator for G-CSF Prophylaxis Yes/No rows = number of patients who experienced a febrile neutropenia event in the respective treatment arm or overall.
[a] Observation period is the time from first dose until the earliest of: the data cut-off (DCO) date; the date of study treatment discontinuation plus 30 days; or death; whichever occurs first and stops the collection of endpoint data. The same observation period applies to any adverse event and any serious adverse event, so the adverse-event and serious-adverse-event windows coincide. Only febrile neutropenia events with an onset date within this period are counted.
Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 28.1.

[1] Febrile neutropenia with CTCAE Grade ≥3: includes only febrile neutropenia events with a toxicity grade of 3 or higher and an onset date within the adverse-event observation period defined in footnote [a]. [2] Febrile neutropenia classified as a Serious Adverse Event (SAE): includes only febrile neutropenia events that met at least one seriousness criterion and had an onset date within the serious-adverse-event observation period defined in footnote [a].

1. Statistical Analysis for German Submission of ASCENT-03

2. Study : ASCENT-03

Population: Triple-Negative Breast Cancer (mTNBC)

Sub-Population:
- mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Data Cut Date: 27 October 2025
Report Date: 1 May 2026

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4. Disposition - mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

4.1. Table 1.1.1: Participant Disposition — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Screened			249
mITT (Excluding patients preselected to receive nab-paclitaxel or paclitaxel)	125	124	249
Randomized but not Treated	1	2	3
Safety Analysis Set	124	122	246
Study Treatment Completion Status (Randomized Phase)			
Continuing Study Treatment	19 (15.2%)	8 (6.5%)	27 (10.8%)
Discontinued Study Treatment	106 (84.8%)	116 (93.5%)	222 (89.2%)
Adverse Event	5 (4.0%)	10 (8.1%)	15 (6.0%)
Pregnancy	0	0	0
Investigator's Discretion	6 (4.8%)	5 (4.0%)	11 (4.4%)
Non-Compliance with Study Drug	0	0	0
Subject Decision	6 (4.8%)	10 (8.1%)	16 (6.4%)
Study Terminated by Sponsor	0	0	0
Progressive Disease	85 (68.0%)	91 (73.4%)	176 (70.7%)
Lost to Follow-Up	0	0	0
Death	4 (3.2%)	0	4 (1.6%)
Received Study Treatment in Crossover Phase		52 (41.9%)	
Study Completion Status			

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Continuing Study	52 (41.6%)	48 (38.7%)	100 (40.2%)
Discontinued Study	73 (58.4%)	76 (61.3%)	149 (59.8%)
Death	70 (56.0%)	65 (52.4%)	135 (54.2%)
Withdrew Consent	3 (2.4%)	11 (8.9%)	14 (5.6%)
Lost to Follow-Up	0	0	0
Study Terminated by Sponsor	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Screened Population: Participants who have signed an informed consent and participated in the screening procedures at site to assess eligibility.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug.
Denominator of percentages is the number of participants in each treatment group.
Randomized Phase excludes crossover phase when participants in TPC arm started to receive SG.
Data Cut Date: 27 October 2025.

Source: mITT3/Table1.Disposition of participants.R

4.2. Table 1.1.2: Demographic and Baseline Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Age (years)			
N	125	124	249
Mean (Sd)	54.8 (11.7)	53.3 (12.0)	54.0 (11.8)
Median	53.0	52.0	53.0
Q1, Q3	47.0, 62.0	44.8, 62.2	46.0, 62.0
Min, Max	28.0, 81.0	28.0, 77.0	28.0, 81.0

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Age Group			
< 65	98 (78.4%)	96 (77.4%)	194 (77.9%)
>= 65	27 (21.6%)	28 (22.6%)	55 (22.1%)
Sex at Birth			
F	125 (100.0%)	123 (99.2%)	248 (99.6%)
M	0	1 (0.8%)	1 (0.4%)
Race			
AMERICAN INDIAN OR ALASKA NATIVE	6 (4.8%)	10 (8.1%)	16 (6.4%)
ASIAN	26 (20.8%)	26 (21.0%)	52 (20.9%)
BLACK OR AFRICAN AMERICAN	4 (3.2%)	4 (3.2%)	8 (3.2%)
NOT REPORTED	2 (1.6%)	0	2 (0.8%)
OTHER	6 (4.8%)	7 (5.6%)	13 (5.2%)
WHITE	81 (64.8%)	77 (62.1%)	158 (63.5%)
Ethnicity			
HISPANIC OR LATINO	37 (29.6%)	43 (34.7%)	80 (32.1%)
NOT HISPANIC OR LATINO	87 (69.6%)	81 (65.3%)	168 (67.5%)
NOT REPORTED	1 (0.8%)	0	1 (0.4%)
Region			
Rest of the World	95 (76.0%)	89 (71.8%)	184 (73.9%)
US/Canada/Western Europe	30 (24.0%)	35 (28.2%)	65 (26.1%)
Country			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Argentina	8 (6.4%)	10 (8.1%)	18 (7.2%)
Australia	4 (3.2%)	0	4 (1.6%)
Belgium	1 (0.8%)	3 (2.4%)	4 (1.6%)
Brazil	17 (13.6%)	14 (11.3%)	31 (12.4%)
Canada	3 (2.4%)	1 (0.8%)	4 (1.6%)
Chile	1 (0.8%)	4 (3.2%)	5 (2.0%)
China	2 (1.6%)	5 (4.0%)	7 (2.8%)
Czech Republic	1 (0.8%)	2 (1.6%)	3 (1.2%)
France	3 (2.4%)	1 (0.8%)	4 (1.6%)
Germany	3 (2.4%)	1 (0.8%)	4 (1.6%)
Hong Kong	1 (0.8%)	1 (0.8%)	2 (0.8%)
Hungary	2 (1.6%)	2 (1.6%)	4 (1.6%)
Israel	7 (5.6%)	1 (0.8%)	8 (3.2%)
Italy	8 (6.4%)	10 (8.1%)	18 (7.2%)
Japan	10 (8.0%)	7 (5.6%)	17 (6.8%)
Korea, Republic of	10 (8.0%)	6 (4.8%)	16 (6.4%)
Malaysia	3 (2.4%)	3 (2.4%)	6 (2.4%)
Mexico	10 (8.0%)	14 (11.3%)	24 (9.6%)
Netherlands	2 (1.6%)	1 (0.8%)	3 (1.2%)
Poland	1 (0.8%)	0	1 (0.4%)
South Africa	4 (3.2%)	5 (4.0%)	9 (3.6%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Spain	3 (2.4%)	7 (5.6%)	10 (4.0%)
Turkey	14 (11.2%)	10 (8.1%)	24 (9.6%)
United States	7 (5.6%)	10 (8.1%)	17 (6.8%)
Romania	0	1 (0.8%)	1 (0.4%)
Slovakia	0	2 (1.6%)	2 (0.8%)
Taiwan	0	2 (1.6%)	2 (0.8%)
United Kingdom	0	1 (0.8%)	1 (0.4%)
Weight (kg)			
N	125	124	249
Mean (Sd)	70.5 (15.8)	69.3 (14.4)	69.9 (15.1)
Median	68.8	68.5	68.8
Q1, Q3	59.0, 81.0	56.9, 80.1	58.0, 80.6
Min, Max	38.1, 131.4	44.8, 113.0	38.1, 131.4
Height (cm)			
N	125	124	249
Mean (Sd)	160.6 (7.6)	160.5 (7.3)	160.6 (7.5)
Median	161.0	160.0	160.0
Q1, Q3	155.8, 166.0	155.0, 166.0	155.0, 166.0
Min, Max	140.0, 178.0	145.0, 183.0	140.0, 183.0
BMI (kg/m2)			
N	125	124	249

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Mean (Sd)	27.3 (5.8)	26.9 (5.3)	27.1 (5.6)
Median	26.5	26.2	26.3
Q1, Q3	23.5, 31.0	22.7, 30.2	22.9, 30.8
Min, Max	14.1, 54.8	17.5, 44.1	14.1, 54.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Age (in years) was collected on the date of first study drug administration (Day 1) if dosed, or randomization if not dosed.
Not Permitted = local regulators did not allow collection of race or ethnicity information or participant refused to provide information.
*Body Mass Index (BMI) (kg/m^2) = [Weight (kg) / Height (cm)^2]*10,000*
Data Cut Date: 27 October 2025.

Source: mITT3/Table2.Demographic and Baseline Characteristics.R

4.3. Table 1.1.3: Other Baseline Disease Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Baseline ECOG Score			
0	81 (64.8%)	80 (64.5%)	161 (64.7%)
1	44 (35.2%)	44 (35.5%)	88 (35.3%)
UGT1A1 Genotype			
*1/*1	51 (40.8%)	55 (44.4%)	106 (42.6%)
*1/*28	49 (39.2%)	39 (31.5%)	88 (35.3%)
*1/*6	7 (5.6%)	7 (5.6%)	14 (5.6%)
*28/*28	11 (8.8%)	14 (11.3%)	25 (10.0%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
*28/*37	2 (1.6%)	0 (0.0%)	2 (0.8%)
*6/*28	1 (0.8%)	1 (0.8%)	2 (0.8%)
Missing/Not Done	4 (3.2%)	6 (4.8%)	10 (4.0%)
*1/*37	0 (0.0%)	1 (0.8%)	1 (0.4%)
*27/*28	0 (0.0%)	1 (0.8%)	1 (0.4%)
Menopausal Status (Females Only)			
Post-menopausal	96 (76.8%)	88 (71.5%)	184 (74.2%)
Pre-menopausal	29 (23.2%)	35 (28.5%)	64 (25.8%)
BRCA1 Mutation Status (Local testing)			
Mutant	8 (6.4%)	6 (4.8%)	14 (5.6%)
Unknown	74 (59.2%)	71 (57.3%)	145 (58.2%)
Wild Type	43 (34.4%)	47 (37.9%)	90 (36.1%)
BRCA2 Mutation Status (Local testing)			
Mutant	2 (1.6%)	2 (1.6%)	4 (1.6%)
Unknown	74 (59.2%)	75 (60.5%)	149 (59.8%)
Wild Type	49 (39.2%)	47 (37.9%)	96 (38.6%)
BRCA1/2 Mutation Status (Local testing)			
Mutant	9 (7.2%)	7 (5.6%)	16 (6.4%)
Unknown	74 (59.2%)	71 (57.3%)	145 (58.2%)
Wild Type	42 (33.6%)	46 (37.1%)	88 (35.3%)
BRCA1 Genotype (BRCA Central Testing)			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Mutant	13 (10.4%)	11 (8.9%)	24 (9.6%)
Unknown	26 (20.8%)	35 (28.2%)	61 (24.5%)
Wild Type	86 (68.8%)	78 (62.9%)	164 (65.9%)
BRCA2 Genotype (BRCA Central Testing)			
Mutant	9 (7.2%)	5 (4.0%)	14 (5.6%)
Unknown	26 (20.8%)	35 (28.2%)	61 (24.5%)
Wild Type	90 (72.0%)	84 (67.7%)	174 (69.9%)
BRCA1/BRCA2 Mutation Category (BRCA Central Testing)			
Mutant	18 (14.4%)	15 (12.1%)	33 (13.3%)
Unknown	26 (20.8%)	35 (28.2%)	61 (24.5%)
Wild Type	81 (64.8%)	74 (59.7%)	155 (62.2%)
BRCA1/2 Mutation Category (Central or local testing)			
Mutant	22 (17.6%)	18 (14.5%)	40 (16.1%)
Wild-type	85 (68.0%)	80 (64.5%)	165 (66.3%)
Unknown	18 (14.4%)	26 (21.0%)	44 (17.7%)
BRCA1 Genotype (Central or local testing)			
Mutant	17 (13.6%)	14 (11.3%)	31 (12.4%)
Wild-type	90 (72.0%)	84 (67.7%)	174 (69.9%)
Unknown	18 (14.4%)	26 (21.0%)	44 (17.7%)
BRCA2 Genotype (Central or local testing)			
Mutant	10 (8.0%)	6 (4.8%)	16 (6.4%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Wild-type	97 (77.6%)	91 (73.4%)	188 (75.5%)
Unknown	18 (14.4%)	27 (21.8%)	45 (18.1%)
PD-L1 CPS			
1 to <10	80 (64.0%)	72 (58.1%)	152 (61.0%)
<1	44 (35.2%)	52 (41.9%)	96 (38.6%)
>=10	1 (0.8%)	0 (0.0%)	1 (0.4%)
Estrogen Receptor Status			
Positive (>= 1%)	1 (0.8%)	0 (0.0%)	1 (0.4%)
Negative (< 1%)	124 (99.2%)	124 (100.0%)	248 (99.6%)
Progesterone Receptor Status			
Negative (< 1%)	125 (100.0%)	124 (100.0%)	249 (100.0%)
HER2 Status			
Negative	125 (100.0%)	124 (100.0%)	249 (100.0%)
Disease Stratification			
De novo	29 (23.2%)	26 (21.0%)	55 (22.1%)
Recurrent disease occurring > 12 months	65 (52.0%)	67 (54.0%)	132 (53.0%)
Recurrent disease within 6 to 12 months	31 (24.8%)	31 (25.0%)	62 (24.9%)
Pre-selected TPC Prior to Randomization			
Gemcitabine/Carboplatin	125 (100.0%)	124 (100.0%)	249 (100.0%)
Breast Cancer Stage at Initial Diagnosis			
STAGE 1	18 (14.4%)	16 (12.9%)	34 (13.7%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
STAGE 2	49 (39.2%)	48 (38.7%)	97 (39.0%)
STAGE 3	31 (24.8%)	37 (29.8%)	68 (27.3%)
STAGE 4	27 (21.6%)	23 (18.5%)	50 (20.1%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subtype of Cancer at Initial Diagnosis			
HR+/HER2+	1 (0.8%)	3 (2.4%)	4 (1.6%)
HR+/HER2-	17 (13.6%)	15 (12.1%)	32 (12.9%)
HR-/HER2+	2 (1.6%)	0 (0.0%)	2 (0.8%)
HR-/HER2- (TNBC)	105 (84.0%)	105 (84.7%)	210 (84.3%)
Missing	0 (0.0%)	1 (0.8%)	1 (0.4%)
Disease Status at Screening			
Locally advanced and Inoperable	3 (2.4%)	5 (4.0%)	8 (3.2%)
Metastatic	122 (97.6%)	119 (96.0%)	241 (96.8%)
Site of Metastasis at Screening			
Bone	46 (36.8%)	32 (25.8%)	78 (31.3%)
Brain	6 (4.8%)	7 (5.6%)	13 (5.2%)
Liver	36 (28.8%)	26 (21.0%)	62 (24.9%)
Lung	78 (62.4%)	81 (65.3%)	159 (63.9%)
Lymph Node	83 (66.4%)	77 (62.1%)	160 (64.3%)
Other	40 (32.0%)	44 (35.5%)	84 (33.7%)
Time from Locally Advanced and Inoperable or Metastatic Disease to Randomization (months) [a]			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
N	124	124	248
Mean (StD)	2.2 (1.69)	2.4 (2.07)	2.3 (1.89)
Median	1.8	1.8	1.8
Q1, Q3	1.4, 2.5	1.2, 2.9	1.3, 2.7
Min, Max	0.5, 14.3	0.1, 13.1	0.1, 14.3

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages for other baseline characteristics is the number of participants in each treatment group.
[a] Mutant denotes participant is either BRCA1 or BRCA2 mutant, or both mutant. Wild type denotes participant is both BRCA1 and BRCA2 wild type. Unknown denotes participant is BRCA1 unknown and BRCA2 wild type or unknown, or participant is BRCA1 wild type or unknown and BRCA2 unknown.
PD-L1 CPS (combined positive score) and TNBC status were collected centrally.
Data Cut Date: 27 October 2025.

Source: mITT3/Table3.Other Baseline Disease Characteristics.R

4.4. Table 1.1.4: Medical History by System Organ Class and Preferred Term — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Number (%) of Participants with Any Medical History	113 (90.4%)	112 (90.3%)	225 (90.4%)
Blood and lymphatic system disorders	9 (7.2%)	13 (10.5%)	22 (8.8%)
Anaemia	8 (6.4%)	10 (8.1%)	18 (7.2%)
Lymphopenia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Coagulopathy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Increased tendency to bruise	1 (0.8%)	0 (0.0%)	1 (7.2%)
Leukopenia	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Neutropenia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Thrombocytosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cardiac disorders	9 (7.2%)	11 (8.9%)	20 (8.8%)
Tachycardia	3 (2.4%)	1 (0.8%)	4 (7.2%)
Atrial fibrillation	2 (1.6%)	1 (0.8%)	3 (7.2%)
Ventricular extrasystoles	0 (0.0%)	3 (2.4%)	3 (7.2%)
Arrhythmia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Cardiomyopathy	1 (0.8%)	1 (0.8%)	2 (7.2%)
Sinus tachycardia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Angina pectoris	0 (0.0%)	1 (0.8%)	1 (7.2%)
Arrhythmia supraventricular	1 (0.8%)	0 (0.0%)	1 (7.2%)
Arteriosclerosis coronary artery	0 (0.0%)	1 (0.8%)	1 (7.2%)
Bradycardia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pericardial effusion	0 (0.0%)	1 (0.8%)	1 (7.2%)
Sinus bradycardia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Supraventricular extrasystoles	0 (0.0%)	1 (0.8%)	1 (7.2%)
Congenital, familial and genetic disorders	1 (0.8%)	4 (3.2%)	5 (8.8%)
Coarctation of the aorta	0 (0.0%)	1 (0.8%)	1 (7.2%)
Congenital musculoskeletal disorder of limbs	0 (0.0%)	1 (0.8%)	1 (7.2%)
Congenital neuropathy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Kidney duplex	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Venous angioma of brain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Ear and labyrinth disorders	3 (2.4%)	3 (2.4%)	6 (8.8%)
Vertigo	0 (0.0%)	2 (1.6%)	2 (7.2%)
Deafness	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hypoacusis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Meniere's disease	0 (0.0%)	1 (0.8%)	1 (7.2%)
Sudden hearing loss	1 (0.8%)	0 (0.0%)	1 (7.2%)
Endocrine disorders	15 (12.0%)	18 (14.5%)	33 (8.8%)
Hypothyroidism	10 (8.0%)	13 (10.5%)	23 (7.2%)
Hyperthyroidism	2 (1.6%)	4 (3.2%)	6 (7.2%)
Thyroid mass	2 (1.6%)	0 (0.0%)	2 (7.2%)
Autoimmune hypothyroidism	1 (0.8%)	0 (0.0%)	1 (7.2%)
Autoimmune thyroiditis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Goitre	0 (0.0%)	1 (0.8%)	1 (7.2%)
Eye disorders	11 (8.8%)	5 (4.0%)	16 (8.8%)
Myopia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Presbyopia	2 (1.6%)	1 (0.8%)	3 (7.2%)
Astigmatism	0 (0.0%)	2 (1.6%)	2 (7.2%)
Glaucoma	0 (0.0%)	2 (1.6%)	2 (7.2%)
Cataract	1 (0.8%)	0 (0.0%)	1 (7.2%)
Conjunctivitis allergic	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Dry eye	0 (0.0%)	1 (0.8%)	1 (7.2%)
Eye pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Fuchs' syndrome	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hypermetropia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Macular degeneration	1 (0.8%)	0 (0.0%)	1 (7.2%)
Macular oedema	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pterygium	1 (0.8%)	0 (0.0%)	1 (7.2%)
Retinal vein occlusion	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vision blurred	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gastrointestinal disorders	30 (24.0%)	36 (29.0%)	66 (8.8%)
Constipation	6 (4.8%)	12 (9.7%)	18 (7.2%)
Gastrooesophageal reflux disease	5 (4.0%)	6 (4.8%)	11 (7.2%)
Nausea	2 (1.6%)	6 (4.8%)	8 (7.2%)
Abdominal pain upper	3 (2.4%)	3 (2.4%)	6 (7.2%)
Diarrhoea	2 (1.6%)	2 (1.6%)	4 (7.2%)
Hiatus hernia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Irritable bowel syndrome	2 (1.6%)	2 (1.6%)	4 (7.2%)
Gastritis	1 (0.8%)	2 (1.6%)	3 (7.2%)
Tooth loss	2 (1.6%)	1 (0.8%)	3 (7.2%)
Abdominal pain	1 (0.8%)	1 (0.8%)	2 (7.2%)
Colitis ulcerative	1 (0.8%)	1 (0.8%)	2 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Dyspepsia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Dysphagia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Gastric ulcer	1 (0.8%)	1 (0.8%)	2 (7.2%)
Umbilical hernia	0 (0.0%)	2 (1.6%)	2 (7.2%)
Abdominal discomfort	0 (0.0%)	1 (0.8%)	1 (7.2%)
Ascites	1 (0.8%)	0 (0.0%)	1 (7.2%)
Chronic gastritis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Coeliac disease	1 (0.8%)	0 (0.0%)	1 (7.2%)
Crohn's disease	0 (0.0%)	1 (0.8%)	1 (7.2%)
Diverticulum	0 (0.0%)	1 (0.8%)	1 (7.2%)
Diverticulum intestinal	1 (0.8%)	0 (0.0%)	1 (7.2%)
Food poisoning	0 (0.0%)	1 (0.8%)	1 (7.2%)
Gastrointestinal disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Haemorrhoidal haemorrhage	1 (0.8%)	0 (0.0%)	1 (7.2%)
Haemorrhoids	0 (0.0%)	1 (0.8%)	1 (7.2%)
Inguinal hernia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Large intestine polyp	1 (0.8%)	0 (0.0%)	1 (7.2%)
Lumbar hernia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pancreatitis chronic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tongue pigmentation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vomiting	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
General disorders and administration site conditions	18 (14.4%)	15 (12.1%)	33 (8.8%)
Fatigue	5 (4.0%)	3 (2.4%)	8 (7.2%)
Pain	3 (2.4%)	4 (3.2%)	7 (7.2%)
Chest pain	2 (1.6%)	4 (3.2%)	6 (7.2%)
Asthenia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Oedema peripheral	3 (2.4%)	1 (0.8%)	4 (7.2%)
Peripheral swelling	1 (0.8%)	1 (0.8%)	2 (7.2%)
Pyrexia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Axillary pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Drug intolerance	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gait disturbance	0 (0.0%)	1 (0.8%)	1 (7.2%)
Non-cardiac chest pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Oedema	0 (0.0%)	1 (0.8%)	1 (7.2%)
Supraclavicular fossa pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hepatobiliary disorders	11 (8.8%)	6 (4.8%)	17 (8.8%)
Cholelithiasis	4 (3.2%)	4 (3.2%)	8 (7.2%)
Hepatic function abnormal	3 (2.4%)	0 (0.0%)	3 (7.2%)
Hepatic steatosis	2 (1.6%)	1 (0.8%)	3 (7.2%)
Cholecystitis chronic	2 (1.6%)	0 (0.0%)	2 (7.2%)
Hyperbilirubinaemia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Autoimmune hepatitis	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Jaundice cholestatic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Immune system disorders	10 (8.0%)	18 (14.5%)	28 (8.8%)
Drug hypersensitivity	3 (2.4%)	9 (7.3%)	12 (7.2%)
Seasonal allergy	2 (1.6%)	7 (5.6%)	9 (7.2%)
Contrast media allergy	2 (1.6%)	1 (0.8%)	3 (7.2%)
Hypersensitivity	1 (0.8%)	1 (0.8%)	2 (7.2%)
Allergy to arthropod sting	1 (0.8%)	0 (0.0%)	1 (7.2%)
Food allergy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Immunodeficiency	0 (0.0%)	1 (0.8%)	1 (7.2%)
Infections and infestations	16 (12.8%)	14 (11.3%)	30 (8.8%)
COVID-19	5 (4.0%)	1 (0.8%)	6 (7.2%)
Urinary tract infection	1 (0.8%)	4 (3.2%)	5 (7.2%)
Appendicitis	2 (1.6%)	0 (0.0%)	2 (7.2%)
Empyema	1 (0.8%)	1 (0.8%)	2 (7.2%)
Labyrinthitis	2 (1.6%)	0 (0.0%)	2 (7.2%)
American trypanosomiasis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Anal abscess	0 (0.0%)	1 (0.8%)	1 (7.2%)
Conjunctivitis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Dengue fever	0 (0.0%)	1 (0.8%)	1 (7.2%)
Erysipelas	1 (0.8%)	0 (0.0%)	1 (7.2%)
Furuncle	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Genital herpes	0 (0.0%)	1 (0.8%)	1 (7.2%)
Gingivitis	1 (0.8%)	0 (0.0%)	1 (7.2%)
HIV infection	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hepatitis B	0 (0.0%)	1 (0.8%)	1 (7.2%)
Herpes zoster	1 (0.8%)	0 (0.0%)	1 (7.2%)
Nosocomial infection	1 (0.8%)	0 (0.0%)	1 (7.2%)
Periodontitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pneumonia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pyelonephritis acute	1 (0.8%)	0 (0.0%)	1 (7.2%)
Rash pustular	0 (0.0%)	1 (0.8%)	1 (7.2%)
Rhinitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Skin candida	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tonsillitis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tuberculosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Upper respiratory tract infection	0 (0.0%)	1 (0.8%)	1 (7.2%)
Injury, poisoning and procedural complications	6 (4.8%)	1 (0.8%)	7 (8.8%)
Pelvic fracture	2 (1.6%)	0 (0.0%)	2 (7.2%)
Ankle fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Compression fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Foot fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Humerus fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Joint dislocation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Postoperative ileus	1 (0.8%)	0 (0.0%)	1 (7.2%)
Procedural pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Upper limb fracture	1 (0.8%)	0 (0.0%)	1 (7.2%)
Wound complication	1 (0.8%)	0 (0.0%)	1 (7.2%)
Investigations	16 (12.8%)	19 (15.3%)	35 (8.8%)
Aspartate aminotransferase increased	5 (4.0%)	5 (4.0%)	10 (7.2%)
Blood cholesterol increased	3 (2.4%)	5 (4.0%)	8 (7.2%)
Blood alkaline phosphatase increased	4 (3.2%)	2 (1.6%)	6 (7.2%)
Blood lactate dehydrogenase increased	2 (1.6%)	3 (2.4%)	5 (7.2%)
Alanine aminotransferase increased	3 (2.4%)	1 (0.8%)	4 (7.2%)
Arthroscopy	1 (0.8%)	1 (0.8%)	2 (7.2%)
Blood uric acid increased	0 (0.0%)	2 (1.6%)	2 (7.2%)
Gamma-glutamyltransferase increased	1 (0.8%)	1 (0.8%)	2 (7.2%)
Bile acids increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Biopsy breast	1 (0.8%)	0 (0.0%)	1 (7.2%)
Biopsy liver	1 (0.8%)	0 (0.0%)	1 (7.2%)
Biopsy lung	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood bilirubin increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood chloride increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood glucose abnormal	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Blood glucose increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood potassium increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood pressure increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood sodium increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood triglycerides increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Blood urea increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cardiac murmur functional	0 (0.0%)	1 (0.8%)	1 (7.2%)
Ejection fraction decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hepatic enzyme increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hepatitis B core antibody positive	1 (0.8%)	0 (0.0%)	1 (7.2%)
Low density lipoprotein increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lymph node palpable	1 (0.8%)	0 (0.0%)	1 (7.2%)
Lymphocyte count decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
Platelet count decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
Transaminases increased	0 (0.0%)	1 (0.8%)	1 (7.2%)
Weight decreased	1 (0.8%)	0 (0.0%)	1 (7.2%)
White blood cells urine positive	0 (0.0%)	1 (0.8%)	1 (7.2%)
Metabolism and nutrition disorders	39 (31.2%)	33 (26.6%)	72 (8.8%)
Diabetes mellitus	14 (11.2%)	5 (4.0%)	19 (7.2%)
Dyslipidaemia	10 (8.0%)	5 (4.0%)	15 (7.2%)
Hypercholesterolaemia	10 (8.0%)	4 (3.2%)	14 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Type 2 diabetes mellitus	3 (2.4%)	4 (3.2%)	7 (7.2%)
Hyperglycaemia	3 (2.4%)	3 (2.4%)	6 (7.2%)
Hyperlipidaemia	2 (1.6%)	4 (3.2%)	6 (7.2%)
Hypertriglyceridaemia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Hyponatraemia	2 (1.6%)	2 (1.6%)	4 (7.2%)
Obesity	2 (1.6%)	2 (1.6%)	4 (7.2%)
Decreased appetite	0 (0.0%)	3 (2.4%)	3 (7.2%)
Hypoalbuminaemia	1 (0.8%)	2 (1.6%)	3 (7.2%)
Vitamin D deficiency	1 (0.8%)	2 (1.6%)	3 (7.2%)
Hypercalcaemia	0 (0.0%)	2 (1.6%)	2 (7.2%)
Hypomagnesaemia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Insulin resistance	2 (1.6%)	0 (0.0%)	2 (7.2%)
Food intolerance	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gout	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hyperuricaemia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hypocalcaemia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hypoglycaemia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lactose intolerance	1 (0.8%)	0 (0.0%)	1 (7.2%)
Malnutrition	0 (0.0%)	1 (0.8%)	1 (7.2%)
Tetany	0 (0.0%)	1 (0.8%)	1 (7.2%)
Vitamin B12 deficiency	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Musculoskeletal and connective tissue disorders	35 (28.0%)	33 (26.6%)	68 (8.8%)
Back pain	8 (6.4%)	10 (8.1%)	18 (7.2%)
Arthralgia	7 (5.6%)	8 (6.5%)	15 (7.2%)
Osteoarthritis	2 (1.6%)	7 (5.6%)	9 (7.2%)
Osteoporosis	6 (4.8%)	2 (1.6%)	8 (7.2%)
Pain in extremity	5 (4.0%)	3 (2.4%)	8 (7.2%)
Musculoskeletal chest pain	0 (0.0%)	5 (4.0%)	5 (7.2%)
Arthritis	1 (0.8%)	2 (1.6%)	3 (7.2%)
Bone pain	2 (1.6%)	1 (0.8%)	3 (7.2%)
Intervertebral disc protrusion	2 (1.6%)	1 (0.8%)	3 (7.2%)
Osteopenia	1 (0.8%)	2 (1.6%)	3 (7.2%)
Fibromyalgia	2 (1.6%)	0 (0.0%)	2 (7.2%)
Muscle spasms	1 (0.8%)	1 (0.8%)	2 (7.2%)
Axillary mass	1 (0.8%)	0 (0.0%)	1 (7.2%)
Foot deformity	1 (0.8%)	0 (0.0%)	1 (7.2%)
Groin pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Intervertebral disc compression	1 (0.8%)	0 (0.0%)	1 (7.2%)
Intervertebral disc degeneration	0 (0.0%)	1 (0.8%)	1 (7.2%)
Joint contracture	0 (0.0%)	1 (0.8%)	1 (7.2%)
Muscular weakness	0 (0.0%)	1 (0.8%)	1 (7.2%)
Myalgia	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Neck pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Rheumatic disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Rheumatoid arthritis	1 (0.8%)	0 (0.0%)	1 (7.2%)
Sacral pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Spinal osteoarthritis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Trigger finger	0 (0.0%)	1 (0.8%)	1 (7.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	19 (15.2%)	23 (18.5%)	42 (8.8%)
Cancer pain	11 (8.8%)	7 (5.6%)	18 (7.2%)
Uterine leiomyoma	2 (1.6%)	4 (3.2%)	6 (7.2%)
Breast cancer	2 (1.6%)	2 (1.6%)	4 (7.2%)
Tumour pain	2 (1.6%)	2 (1.6%)	4 (7.2%)
Basal cell carcinoma	2 (1.6%)	0 (0.0%)	2 (7.2%)
Tumour ulceration	2 (1.6%)	0 (0.0%)	2 (7.2%)
Cervix carcinoma	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dysplastic naevus	0 (0.0%)	1 (0.8%)	1 (7.2%)
Haemangioma of liver	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hormone receptor positive breast cancer	0 (0.0%)	1 (0.8%)	1 (7.2%)
Infected neoplasm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Intraductal papillary mucinous neoplasm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lymphangiosis carcinomatosa	0 (0.0%)	1 (0.8%)	1 (7.2%)
Mediastinum neoplasm	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Ovarian cancer	1 (0.8%)	0 (0.0%)	1 (7.2%)
Ovarian cancer recurrent	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pituitary tumour benign	0 (0.0%)	1 (0.8%)	1 (7.2%)
Squamous cell carcinoma of skin	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tumour exudation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Tumour inflammation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Tumour thrombosis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nervous system disorders	18 (14.4%)	30 (24.2%)	48 (8.8%)
Peripheral sensory neuropathy	4 (3.2%)	5 (4.0%)	9 (7.2%)
Migraine	3 (2.4%)	4 (3.2%)	7 (7.2%)
Neuropathy peripheral	4 (3.2%)	3 (2.4%)	7 (7.2%)
Headache	3 (2.4%)	3 (2.4%)	6 (7.2%)
Polyneuropathy	1 (0.8%)	2 (1.6%)	3 (7.2%)
Cerebrovascular accident	2 (1.6%)	0 (0.0%)	2 (7.2%)
Cervicobrachial syndrome	1 (0.8%)	1 (0.8%)	2 (7.2%)
Epilepsy	1 (0.8%)	1 (0.8%)	2 (7.2%)
Paraesthesia	1 (0.8%)	1 (0.8%)	2 (7.2%)
Sciatica	0 (0.0%)	2 (1.6%)	2 (7.2%)
Amnesia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Brain fog	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cerebral small vessel ischaemic disease	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Complex regional pain syndrome	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hypoaesthesia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nervous system disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Neurotoxicity	0 (0.0%)	1 (0.8%)	1 (7.2%)
Peripheral motor neuropathy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Petit mal epilepsy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Restless legs syndrome	0 (0.0%)	1 (0.8%)	1 (7.2%)
Spinal cord compression	0 (0.0%)	1 (0.8%)	1 (7.2%)
Taste disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Trigeminal neuropathy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Psychiatric disorders	27 (21.6%)	24 (19.4%)	51 (8.8%)
Anxiety	11 (8.8%)	9 (7.3%)	20 (7.2%)
Depression	9 (7.2%)	11 (8.9%)	20 (7.2%)
Insomnia	11 (8.8%)	9 (7.3%)	20 (7.2%)
Burnout syndrome	0 (0.0%)	2 (1.6%)	2 (7.2%)
Affective disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Anxiety disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Attention deficit hyperactivity disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Bipolar disorder	1 (0.8%)	0 (0.0%)	1 (7.2%)
Generalised anxiety disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Irritability	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Schizophrenia	1 (0.8%)	0 (0.0%)	1 (7.2%)
Sleep disorder due to general medical condition, insomnia type	0 (0.0%)	1 (0.8%)	1 (7.2%)
Suicidal ideation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Renal and urinary disorders	5 (4.0%)	4 (3.2%)	9 (8.8%)
Stress urinary incontinence	1 (0.8%)	1 (0.8%)	2 (7.2%)
Calculus bladder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Chronic kidney disease	1 (0.8%)	0 (0.0%)	1 (7.2%)
Haematuria	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hydronephrosis	1 (0.8%)	0 (0.0%)	1 (7.2%)
IgA nephropathy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Renal colic	0 (0.0%)	1 (0.8%)	1 (7.2%)
Urge incontinence	1 (0.8%)	0 (0.0%)	1 (7.2%)
Urinary incontinence	1 (0.8%)	0 (0.0%)	1 (7.2%)
Reproductive system and breast disorders	10 (8.0%)	14 (11.3%)	24 (8.8%)
Breast pain	8 (6.4%)	6 (4.8%)	14 (7.2%)
Amenorrhoea	1 (0.8%)	0 (0.0%)	1 (7.2%)
Breast discomfort	1 (0.8%)	0 (0.0%)	1 (7.2%)
Breast mass	0 (0.0%)	1 (0.8%)	1 (7.2%)
Breast ulceration	0 (0.0%)	1 (0.8%)	1 (7.2%)
Cervical dysplasia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Endometriosis	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Menopausal symptoms	0 (0.0%)	1 (0.8%)	1 (7.2%)
Menstrual disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Premenstrual dysphoric disorder	0 (0.0%)	1 (0.8%)	1 (7.2%)
Vaginal prolapse	0 (0.0%)	1 (0.8%)	1 (7.2%)
Respiratory, thoracic and mediastinal disorders	32 (25.6%)	30 (24.2%)	62 (8.8%)
Cough	16 (12.8%)	16 (12.9%)	32 (7.2%)
Dyspnoea	7 (5.6%)	7 (5.6%)	14 (7.2%)
Rhinitis allergic	6 (4.8%)	4 (3.2%)	10 (7.2%)
Asthma	6 (4.8%)	2 (1.6%)	8 (7.2%)
Pleural effusion	1 (0.8%)	5 (4.0%)	6 (7.2%)
Sleep apnoea syndrome	1 (0.8%)	1 (0.8%)	2 (7.2%)
Bronchial hyperreactivity	1 (0.8%)	0 (0.0%)	1 (7.2%)
Bronchospasm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dysphonia	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dyspnoea exertional	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hyperventilation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nasal septum deviation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Oropharyngeal pain	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pleuritic pain	1 (0.8%)	0 (0.0%)	1 (7.2%)
Productive cough	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pulmonary arterial hypertension	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Pulmonary embolism	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pulmonary hypertension	0 (0.0%)	1 (0.8%)	1 (7.2%)
Pulmonary mass	1 (0.8%)	0 (0.0%)	1 (7.2%)
Skin and subcutaneous tissue disorders	10 (8.0%)	6 (4.8%)	16 (8.8%)
Dermatitis atopic	2 (1.6%)	1 (0.8%)	3 (7.2%)
Dry skin	1 (0.8%)	2 (1.6%)	3 (7.2%)
Eczema	1 (0.8%)	1 (0.8%)	2 (7.2%)
Dermatitis	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dermatitis acneiform	0 (0.0%)	1 (0.8%)	1 (7.2%)
Dermatitis allergic	1 (0.8%)	0 (0.0%)	1 (7.2%)
Henoch-Schonlein purpura	0 (0.0%)	1 (0.8%)	1 (7.2%)
Nail bed bleeding	1 (0.8%)	0 (0.0%)	1 (7.2%)
Pruritus	1 (0.8%)	0 (0.0%)	1 (7.2%)
Rash erythematous	1 (0.8%)	0 (0.0%)	1 (7.2%)
Skin ulcer	1 (0.8%)	0 (0.0%)	1 (7.2%)
Xeroderma	1 (0.8%)	0 (0.0%)	1 (7.2%)
Social circumstances	2 (1.6%)	4 (3.2%)	6 (8.8%)
Edentulous	2 (1.6%)	0 (0.0%)	2 (7.2%)
Postmenopause	0 (0.0%)	2 (1.6%)	2 (7.2%)
Menopause	0 (0.0%)	1 (0.8%)	1 (7.2%)
Orthodontic appliance user	0 (0.0%)	1 (0.8%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Surgical and medical procedures	33 (26.4%)	22 (17.7%)	55 (8.8%)
Hysterectomy	10 (8.0%)	5 (4.0%)	15 (7.2%)
Cholecystectomy	9 (7.2%)	3 (2.4%)	12 (7.2%)
Caesarean section	5 (4.0%)	3 (2.4%)	8 (7.2%)
Female sterilisation	3 (2.4%)	4 (3.2%)	7 (7.2%)
Tonsillectomy	1 (0.8%)	3 (2.4%)	4 (7.2%)
Appendicectomy	3 (2.4%)	0 (0.0%)	3 (7.2%)
Breast conserving surgery	2 (1.6%)	1 (0.8%)	3 (7.2%)
Hysterosalpingo-oophorectomy	3 (2.4%)	0 (0.0%)	3 (7.2%)
Mastectomy	3 (2.4%)	0 (0.0%)	3 (7.2%)
Salpingo-oophorectomy bilateral	1 (0.8%)	2 (1.6%)	3 (7.2%)
Central venous catheterisation	2 (1.6%)	0 (0.0%)	2 (7.2%)
Fracture treatment	1 (0.8%)	1 (0.8%)	2 (7.2%)
Axillary lymphadenectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Breast reconstruction	0 (0.0%)	1 (0.8%)	1 (7.2%)
Corneal operation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Corneal transplant	1 (0.8%)	0 (0.0%)	1 (7.2%)
Gastric ulcer surgery	1 (0.8%)	0 (0.0%)	1 (7.2%)
Hernia repair	1 (0.8%)	0 (0.0%)	1 (7.2%)
Knee operation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Lung operation	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Mammoplasty	0 (0.0%)	1 (0.8%)	1 (7.2%)
Metabolic surgery	1 (0.8%)	0 (0.0%)	1 (7.2%)
Myomectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Myopia correction	1 (0.8%)	0 (0.0%)	1 (7.2%)
Nasal septal operation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Oophorectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Ovarian operation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Peptic ulcer repair	1 (0.8%)	0 (0.0%)	1 (7.2%)
Red blood cell transfusion	1 (0.8%)	0 (0.0%)	1 (7.2%)
Salpingo-oophorectomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Salpingo-oophorectomy unilateral	0 (0.0%)	1 (0.8%)	1 (7.2%)
Skin graft	1 (0.8%)	0 (0.0%)	1 (7.2%)
Sterilisation	0 (0.0%)	1 (0.8%)	1 (7.2%)
Surgery	1 (0.8%)	0 (0.0%)	1 (7.2%)
Synovectomy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Thyroid nodule removal	0 (0.0%)	1 (0.8%)	1 (7.2%)
Thyroidectomy	0 (0.0%)	1 (0.8%)	1 (7.2%)
Tracheostomy	1 (0.8%)	0 (0.0%)	1 (7.2%)
Transfusion	1 (0.8%)	0 (0.0%)	1 (7.2%)
Varicose vein operation	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vascular access placement	1 (0.8%)	0 (0.0%)	1 (7.2%)

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Wisdom teeth removal	1 (0.8%)	0 (0.0%)	1 (7.2%)
Vascular disorders	46 (36.8%)	37 (29.8%)	83 (8.8%)
Hypertension	38 (30.4%)	33 (26.6%)	71 (7.2%)
Lymphoedema	3 (2.4%)	4 (3.2%)	7 (7.2%)
Deep vein thrombosis	4 (3.2%)	1 (0.8%)	5 (7.2%)
Varicose vein	3 (2.4%)	1 (0.8%)	4 (7.2%)
Aneurysm	0 (0.0%)	1 (0.8%)	1 (7.2%)
Hot flush	1 (0.8%)	0 (0.0%)	1 (7.2%)
Peripheral venous disease	1 (0.8%)	0 (0.0%)	1 (7.2%)
Raynaud's phenomenon	1 (0.8%)	0 (0.0%)	1 (7.2%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Medical history was coded according to MedDRA Version 27.1.
Participants may report >=1 medical history per system organ class or preferred term. At each level of summarization, a participant was counted once if the participant reported 1 or more medical history.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
Data Cut Date: 27 October 2025.

Source: mITT3/Table4.Summary of Medical History.R

4.5. Table 1.1.5: Summary of Prior Systemic Therapy — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
Patients with Prior Systemic Therapy	92 (73.6%)	99 (79.8%)	191 (76.7%)
Number of Prior Regimens			

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)
1	45 (36.0%)	53 (42.7%)	98 (39.4%)
2	34 (27.2%)	32 (25.8%)	66 (26.5%)
3	12 (9.6%)	10 (8.1%)	22 (8.8%)
4	1 (0.8%)	4 (3.2%)	5 (2.0%)
Regimen Setting			
ADJUVANT	65 (52.0%)	58 (46.8%)	123 (49.4%)
NEO-ADJUVANT	27 (21.6%)	40 (32.3%)	67 (26.9%)
METASTATIC	0 (0.0%)	1 (0.8%)	1 (0.4%)
Best Response to Prior Therapy			
Complete Remission	14 (11.2%)	15 (12.1%)	29 (11.6%)
Partial Remission	11 (8.8%)	14 (11.3%)	25 (10.0%)
Stable Disease	5 (4.0%)	10 (8.1%)	15 (6.0%)
Progressive Disease	6 (4.8%)	10 (8.1%)	16 (6.4%)
Unevaluable	6 (4.8%)	5 (4.0%)	11 (4.4%)
Not Available	29 (23.2%)	23 (18.5%)	52 (20.9%)
Unknown	21 (16.8%)	22 (17.7%)	43 (17.3%)
Progression After Prior Therapy			
Yes	75 (60.0%)	79 (63.7%)	154 (61.8%)
No	17 (13.6%)	20 (16.1%)	37 (14.9%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Data Cut Date: 27 October 2025.

Characteristic	SG (N=125)	TPC (N=124)	Total (N=249)

Source: mITT3/Table5.Summary of Prior Systemic Therapy.R

4.6. Table 1.1.6: Prior Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Participants with Any Prior Anti-Cancer Therapy, n (%)	92 (73.6%)	99 (79.8%)	191 (76.7%)
Prior Neoadjuvant or Adjuvant Anti-cancer Therapy [a]			
Yes	92 (73.6%)	98 (79.0%)	190 (76.3%)
Taxanes	83 (66.4%)	88 (71.0%)	171 (68.7%)
Anthracyclines	75 (60.0%)	84 (67.7%)	159 (63.9%)
Platinum	17 (13.6%)	17 (13.7%)	34 (13.7%)
Anti-PD-1/PD-L1 agents	7 (5.6%)	5 (4.0%)	12 (4.8%)
Capecitabine	27 (21.6%)	28 (22.6%)	55 (22.1%)
PARP inhibitors	1 (0.8%)	0	1 (0.4%)
Other	86 (68.8%)	86 (69.4%)	172 (69.1%)
No	0	1 (0.8%)	1 (0.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
[a] Participants can receive multiple categories of prior neoadjuvant or adjuvant anti-cancer therapy. Participants who received any prior neoadjuvant or adjuvant anti-cancer therapy will be summarized as "Yes". Participants who received prior anti-cancer therapy but did not receive any prior neoadjuvant/adjuvant anti-cancer therapy will be summarized as "No".
Data Cut Date: 27 October 2025.

Source: mITT3/Table6.Prior Anti-Cancer Therapy.R

4.7. Table 1.1.7: Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Participants with Any Subsequent Anti Cancer Therapy, n (%)	74 (59.2%)	89 (71.8%)	163 (65.5%)
Taxanes	26 (20.8%)	17 (13.7%)	43 (17.3%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.8%)	1 (0.4%)
DOCETAXEL	3 (2.4%)	3 (2.4%)	6 (2.4%)
PACLITAXEL	20 (16.0%)	12 (9.7%)	32 (12.9%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	4 (3.2%)	1 (0.8%)	5 (2.0%)
Anthracyclines	14 (11.2%)	7 (5.6%)	21 (8.4%)
DOXORUBICIN	5 (4.0%)	2 (1.6%)	7 (2.8%)
DOXORUBICIN HYDROCHLORIDE	1 (0.8%)	3 (2.4%)	4 (1.6%)
EPIRUBICIN	2 (1.6%)	2 (1.6%)	4 (1.6%)
LIPOSOMAL DOXORUBICIN	2 (1.6%)	0	2 (0.8%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	5 (4.0%)	0	5 (2.0%)
Platinum	38 (30.4%)	9 (7.3%)	47 (18.9%)
CARBOPLATIN	32 (25.6%)	8 (6.5%)	40 (16.1%)
CISPLATIN	6 (4.8%)	1 (0.8%)	7 (2.8%)
Anti-PD-1/PD-L1 agents	5 (4.0%)	6 (4.8%)	11 (4.4%)
ATEZOLIZUMAB	0	1 (0.8%)	1 (0.4%)
PEMBROLIZUMAB	5 (4.0%)	3 (2.4%)	8 (3.2%)
SINTILIMAB	0	1 (0.8%)	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
TISLELIZUMAB	0	1 (0.8%)	1 (0.4%)
PARP inhibitors	3 (2.4%)	2 (1.6%)	5 (2.0%)
OLAPARIB	3 (2.4%)	1 (0.8%)	4 (1.6%)
TALAZOPARIB	0	1 (0.8%)	1 (0.4%)
ADC	15 (12.0%)	77 (62.1%)	92 (36.9%)
SACITUZUMAB GOVITECAN	1 (0.8%)	76 (61.3%)	77 (30.9%)
TRASTUZUMAB DERUXTECAN	13 (10.4%)	13 (10.5%)	26 (10.4%)
TRASTUZUMAB DERUXTECAN NXKI	1 (0.8%)	0	1 (0.4%)
Other	54 (43.2%)	46 (37.1%)	100 (40.2%)
ABBV 400	1 (0.8%)	0	1 (0.4%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.8%)	0	1 (0.4%)
BEVACIZUMAB	5 (4.0%)	3 (2.4%)	8 (3.2%)
CAPECITABINE	19 (15.2%)	20 (16.1%)	39 (15.7%)
CATEQUENTINIB HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
CHLORINE DIOXIDE	0	1 (0.8%)	1 (0.4%)
CYCLOPHOSPHAMIDE	6 (4.8%)	7 (5.6%)	13 (5.2%)
ERIBULIN	15 (12.0%)	10 (8.1%)	25 (10.0%)
ERIBULIN MESILATE	5 (4.0%)	7 (5.6%)	12 (4.8%)
ETOPOSIDE	0	1 (0.8%)	1 (0.4%)
FLUOROURACIL	3 (2.4%)	2 (1.6%)	5 (2.0%)
GEMCITABINE	21 (16.8%)	1 (0.8%)	22 (8.8%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
GEMCITABINE HYDROCHLORIDE	5 (4.0%)	2 (1.6%)	7 (2.8%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (0.8%)	0	1 (0.4%)
INVESTIGATIONAL DRUG	1 (0.8%)	0	1 (0.4%)
IXABEPILONE	0	1 (0.8%)	1 (0.4%)
LAROTRECTINIB	0	1 (0.8%)	1 (0.4%)
METHOTREXATE	2 (1.6%)	2 (1.6%)	4 (1.6%)
NADUNOLIMAB	1 (0.8%)	0	1 (0.4%)
NATURAL KILLER CELLS	1 (0.8%)	0	1 (0.4%)
NIVOLUMAB	0	3 (2.4%)	3 (1.2%)
ONDANSETRON	1 (0.8%)	0	1 (0.4%)
RADIOTHERAPY	1 (0.8%)	0	1 (0.4%)
REPOTRECTINIB	0	1 (0.8%)	1 (0.4%)
TUMOR-INFILTRATING LYMPHOCYTES	0	1 (0.8%)	1 (0.4%)
VINORELBINE	6 (4.8%)	3 (2.4%)	9 (3.6%)
VINORELBINE TARTRATE	3 (2.4%)	4 (3.2%)	7 (2.8%)
XMT 1660	1 (0.8%)	0	1 (0.4%)
ZEN 3694	0	1 (0.8%)	1 (0.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 27 October 2025.

Source: mITT3/Table10.Subsequent Anti cancer by preferred drug name.R

4.8. Table 1.1.8: First Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Category	SG (N=125)	TPC (N=124)	Total (N=249)
Participants with First Subsequent Anti-Cancer Therapy, n (%)	74 (59.2%)	88 (71.0%)	162 (65.1%)
Taxanes	22 (17.6%)	4 (3.2%)	26 (10.4%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.8%)	1 (0.4%)
DOCETAXEL	1 (0.8%)	1 (0.8%)	2 (0.8%)
PACLITAXEL	17 (13.6%)	2 (1.6%)	19 (7.6%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	4 (3.2%)	0	4 (1.6%)
Anthracyclines	5 (4.0%)	1 (0.8%)	6 (2.4%)
DOXORUBICIN	1 (0.8%)	0	1 (0.4%)
EPIRUBICIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
LIPOSOMAL DOXORUBICIN	1 (0.8%)	0	1 (0.4%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	2 (1.6%)	0	2 (0.8%)
Platinum	31 (24.8%)	2 (1.6%)	33 (13.3%)
CARBOPLATIN	25 (20.0%)	2 (1.6%)	27 (10.8%)
CISPLATIN	6 (4.8%)	0	6 (2.4%)
Anti-PD-1/PD-L1 agents	3 (2.4%)	2 (1.6%)	5 (2.0%)
ATEZOLIZUMAB	0	1 (0.8%)	1 (0.4%)
PEMBROLIZUMAB	3 (2.4%)	0	3 (1.2%)
SINTILIMAB	0	1 (0.8%)	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
PARP inhibitors	2 (1.6%)	2 (1.6%)	4 (1.6%)
OLAPARIB	2 (1.6%)	1 (0.8%)	3 (1.2%)
TALAZOPARIB	0	1 (0.8%)	1 (0.4%)
ADC	7 (5.6%)	70 (56.5%)	77 (30.9%)
SACITUZUMAB GOVITECAN	0	68 (54.8%)	68 (27.3%)
TRASTUZUMAB DERUXTECAN	6 (4.8%)	2 (1.6%)	8 (3.2%)
TRASTUZUMAB DERUXTECAN NXKI	1 (0.8%)	0	1 (0.4%)
Other	48 (38.4%)	13 (10.5%)	61 (24.5%)
ABBV 400	1 (0.8%)	0	1 (0.4%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.8%)	0	1 (0.4%)
BEVACIZUMAB	5 (4.0%)	0	5 (2.0%)
CAPECITABINE	12 (9.6%)	8 (6.5%)	20 (8.0%)
CYCLOPHOSPHAMIDE	2 (1.6%)	1 (0.8%)	3 (1.2%)
ERIBULIN	10 (8.0%)	1 (0.8%)	11 (4.4%)
ERIBULIN MESILATE	1 (0.8%)	0	1 (0.4%)
GEMCITABINE	18 (14.4%)	1 (0.8%)	19 (7.6%)
GEMCITABINE HYDROCHLORIDE	2 (1.6%)	1 (0.8%)	3 (1.2%)
INVESTIGATIONAL DRUG	1 (0.8%)	0	1 (0.4%)
LAROTRECTINIB	0	1 (0.8%)	1 (0.4%)
NADUNOLIMAB	1 (0.8%)	0	1 (0.4%)
NATURAL KILLER CELLS	1 (0.8%)	0	1 (0.4%)

Category	SG (N=125)	TPC (N=124)	Total (N=249)
VINORELBINE	2 (1.6%)	0	2 (0.8%)
VINORELBINE TARTRATE	1 (0.8%)	0	1 (0.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name. Participants may be counted in more than one drug category if they received multiple drugs as part of their first subsequent anti-cancer therapy. The total number of participants with any subsequent anti-cancer therapy differs by 1 from the first subsequent therapy count because one patient in the TPC arm has a missing first subsequent therapy record but has two entries recorded for the fourth subsequent therapy. This patient is therefore counted in "Participants with any subsequent anti-cancer therapy" but not in "First subsequent anti-cancer therapy"
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 27 October 2025.

Source: mITT3/Table11.First Subsequent Anti cancer therapy by Preferred drug name.R

5. Efficacy - mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

5.1. Table 1.1.1: Observation Period (Months) for Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	SG (N=125)	TPC (N=124)	Total (N=249)
Observation Period (months)			
N	125	124	249
Mean (SD)	16.2 (8)	16.4 (7.4)	16.3 (7.7)
Median	17.1	18	17.3
Q1, Q3	11.2, 21.5	10.5, 21.8	10.8, 21.7
Min, Max	0.6, 35	0, 30.3	0, 35

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Observation period is defined as time from randomisation to death date or the last date known alive.
Data Cut Date: 27 OCT 2025.

5.2. Table 1.1.2: Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events (Death)	72 (57.6%)	69 (55.6%)
Number (%) of Participants Censored	53 (42.4%)	55 (44.4%)
Ongoing [a]	52 (41.6%)	48 (38.7%)
Discontinued Study	1 (0.8%)	7 (5.6%)
Kaplan-Meier Estimate of OS (Months) (95% CI) [b]		
Q1	11.20 (7.26, 13.31)	11.47 (9.10, 14.85)
Median	18.50 (16.62, 22.14)	19.68 (17.84, 22.93)

Parameter	SG (N=125)	TPC (N=124)
Q3	NR (26.55, NR)	NR (26.38, NR)
Absolute Difference in Median OS, SG vs TPC (Months)	-1.18	
Kaplan-Meier Estimate of OS Rate (95% CI) [b]		
At 12 Months	0.711 (0.622, 0.782)	0.728 (0.639, 0.798)
At 18 Months	0.520 (0.427, 0.606)	0.590 (0.496, 0.672)
At 24 Months	0.384 (0.287, 0.479)	0.385 (0.286, 0.484)
At 30 Months	0.289 (0.175, 0.413)	0.268 (0.143, 0.410)
At 36 Months	NR (NR, NR)	NR (NR, NR)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.6413	
Hazard Ratio of SG vs TPC (95% CI) [d]	1.083 (0.775, 1.513)	
Duration of OS Follow-up (Months) [e]		
N	125	124
Mean (StD)	16.24 (8.018)	16.41 (7.445)
Median	17.05	18.02
Q1, Q3	11.17, 21.45	10.54, 21.77
Min, Max	0.56, 34.99	0.03, 30.26
>=12 Months	88 (70.4%)	87 (70.2%)
>=18 Months	52 (41.6%)	63 (50.8%)
>=24 Months	19 (15.2%)	20 (16.1%)
>=30 Months	4 (3.2%)	2 (1.6%)
>=36 Months	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice; NR = Not Reached; IWRS = Interactive Web Response System.
[a] Ongoing participants are those who have not discontinued participation in the study by the data cutoff date.
[b] OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Based on Kaplan-Meier estimates with 95% CI using the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test, adjusted for randomization stratification factors (IWRS).
[d] Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).

Parameter	SG (N=125)	TPC (N=124)

[e] Duration of OS follow-up (months) = (date of death or censoring - date of randomization + 1) / 30.4375.
Data Cut Date: 27 OCT 2025.

5.3. Table 1.1.3: Subgroup Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

label	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.3114
Number (%) of Participants with Events (Death)	15 (51.7%)	17 (65.4%)	
Number (%) of Participants Censored	14 (48.3%)	9 (34.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (12.94, NR)	19.38 (11.10, 25.17)	
Log-Rank Test p-value (unstratified)	0.3774		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.728 (0.358, 1.478)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Death)	19 (61.3%)	20 (64.5%)	
Number (%) of Participants Censored	12 (38.7%)	11 (35.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.51 (14.82, NR)	16.99 (13.70, 22.44)	
Log-Rank Test p-value (unstratified)	0.7572		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.906 (0.483, 1.698)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Death)	38 (58.5%)	32 (47.8%)	
Number (%) of Participants Censored	27 (41.5%)	35 (52.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

label	SG (N=125)	TPC (N=124)	Interaction
Median	19.22 (15.34, 25.53)	22.93 (18.04, NR)	
Log-Rank Test p-value (unstratified)	0.2107		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.350 (0.843, 2.162)		
Geographic region			
US/Canada/Western Europe	30	35	0.3838
Number (%) of Participants with Events (Death)	16 (53.3%)	21 (60.0%)	
Number (%) of Participants Censored	14 (46.7%)	14 (40.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (15.93, NR)	20.37 (11.53, 26.38)	
Log-Rank Test p-value (unstratified)	0.5829		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.833 (0.434, 1.599)		
Rest of the world	95	89	
Number (%) of Participants with Events (Death)	56 (58.9%)	48 (53.9%)	
Number (%) of Participants Censored	39 (41.1%)	41 (46.1%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.50 (15.80, 21.65)	19.68 (16.99, 27.27)	
Log-Rank Test p-value (unstratified)	0.4861		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.148 (0.779, 1.690)		
Age group			
< 65	98	96	0.7714
Number (%) of Participants with Events (Death)	55 (56.1%)	51 (53.1%)	
Number (%) of Participants Censored	43 (43.9%)	45 (46.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.15 (17.35, 25.53)	19.68 (17.22, 27.27)	

label	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.8626		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.034 (0.706, 1.515)		
>= 65	27	28	
Number (%) of Participants with Events (Death)	17 (63.0%)	18 (64.3%)	
Number (%) of Participants Censored	10 (37.0%)	10 (35.7%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.34 (3.88, NR)	21.75 (13.11, 25.17)	
Log-Rank Test p-value (unstratified)	0.6588		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.162 (0.596, 2.264)		
Race			
White	81	77	0.3290
Number (%) of Participants with Events (Death)	49 (60.5%)	46 (59.7%)	
Number (%) of Participants Censored	32 (39.5%)	31 (40.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.41 (15.77, 22.14)	18.73 (15.41, 22.51)	
Log-Rank Test p-value (unstratified)	0.8276		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.046 (0.699, 1.564)		
Asian	26	26	
Number (%) of Participants with Events (Death)	12 (46.2%)	9 (34.6%)	
Number (%) of Participants Censored	14 (53.8%)	17 (65.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.99 (14.82, NR)	27.27 (17.22, NR)	
Log-Rank Test p-value (unstratified)	0.3438		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.512 (0.635, 3.599)		

label	SG (N=125)	TPC (N=124)	Interaction
Other	16	21	
Number (%) of Participants with Events (Death)	9 (56.2%)	14 (66.7%)	
Number (%) of Participants Censored	7 (43.8%)	7 (33.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	26.55 (7.43, NR)	18.00 (11.30, 21.75)	
Log-Rank Test p-value (unstratified)	0.2797		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.616 (0.253, 1.495)		
Baseline ECOG status			
0	81	80	0.9689
Number (%) of Participants with Events (Death)	40 (49.4%)	38 (47.5%)	
Number (%) of Participants Censored	41 (50.6%)	42 (52.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (17.71, NR)	22.51 (19.38, NR)	
Log-Rank Test p-value (unstratified)	0.8151		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.055 (0.676, 1.646)		
1	44	44	
Number (%) of Participants with Events (Death)	32 (72.7%)	31 (70.5%)	
Number (%) of Participants Censored	12 (27.3%)	13 (29.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.80 (9.33, 19.15)	15.15 (10.38, 18.73)	
Log-Rank Test p-value (unstratified)	0.7421		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.087 (0.662, 1.783)		
History of liver metastasis			
Yes	36	26	0.2325

label	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Death)	26 (72.2%)	20 (76.9%)	
Number (%) of Participants Censored	10 (27.8%)	6 (23.1%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.31 (10.02, 18.20)	11.47 (6.67, 16.99)	
Log-Rank Test p-value (unstratified)	0.2767		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.721 (0.399, 1.303)		
No	89	98	
Number (%) of Participants with Events (Death)	46 (51.7%)	49 (50.0%)	
Number (%) of Participants Censored	43 (48.3%)	49 (50.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.35, 26.55)	22.44 (18.73, 27.27)	
Log-Rank Test p-value (unstratified)	0.6767		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.090 (0.728, 1.631)		
History of brain metastasis			
Yes	6	7	0.8304
Number (%) of Participants with Events (Death)	5 (83.3%)	5 (71.4%)	
Number (%) of Participants Censored	1 (16.7%)	2 (28.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.48 (0.85, NR)	13.50 (2.66, NR)	
Log-Rank Test p-value (unstratified)	0.5660		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.658 (0.156, 2.777)		
No	119	117	
Number (%) of Participants with Events (Death)	67 (56.3%)	64 (54.7%)	
Number (%) of Participants Censored	52 (43.7%)	53 (45.3%)	

label	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.50 (16.62, 25.53)	20.37 (18.00, 23.20)	
Log-Rank Test p-value (unstratified)	0.7275		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.063 (0.754, 1.499)		
PD-L1 Status			
CPS < 1	44	52	0.4531
Number (%) of Participants with Events (Death)	25 (56.8%)	32 (61.5%)	
Number (%) of Participants Censored	19 (43.2%)	20 (38.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.35 (12.75, NR)	19.38 (11.99, 23.20)	
Log-Rank Test p-value (unstratified)	0.6491		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.886 (0.524, 1.496)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Death)	47 (58.0%)	37 (51.4%)	
Number (%) of Participants Censored	34 (42.0%)	35 (48.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.99 (16.95, 22.87)	19.68 (17.22, NR)	
Log-Rank Test p-value (unstratified)	0.4587		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.177 (0.764, 1.814)		
BRCA 1/2 status			
Wild-Type	42	46	0.4491
Number (%) of Participants with Events (Death)	27 (64.3%)	26 (56.5%)	
Number (%) of Participants Censored	15 (35.7%)	20 (43.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

label	SG (N=125)	TPC (N=124)	Interaction
Median	17.12 (12.75, 20.14)	18.43 (11.53, NR)	
Log-Rank Test p-value (unstratified)	0.6512		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.133 (0.659, 1.947)		
Mutant	9	7	
Number (%) of Participants with Events (Death)	5 (55.6%)	2 (28.6%)	
Number (%) of Participants Censored	4 (44.4%)	5 (71.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.37 (3.15, NR)	NR (7.72, NR)	
Log-Rank Test p-value (unstratified)	0.3934		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.020 (0.389, 10.489)		
Menopausal status			
Pre-menopausal	29	35	0.3951
Number (%) of Participants with Events (Death)	19 (65.5%)	20 (57.1%)	
Number (%) of Participants Censored	10 (34.5%)	15 (42.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.50 (10.15, 22.87)	19.68 (14.85, 27.27)	
Log-Rank Test p-value (unstratified)	0.3292		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.365 (0.726, 2.566)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Death)	53 (55.2%)	49 (55.7%)	
Number (%) of Participants Censored	43 (44.8%)	39 (44.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.15 (16.95, 25.53)	19.91 (16.99, 25.17)	
Log-Rank Test p-value (unstratified)	0.9156		

label	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.980 (0.663, 1.447)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Median OS from Kaplan-Meier estimate. 95% CI based on log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
Log-rank test is unstratified.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Participants with unknown BRCA 1/2 status were excluded from that subgroup.
Disease stratification and geographic region are collected from IWRS.
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.4. Table 1.1.4: Follow-up Duration (Months) for PFS and Tumor Response by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	SG (N=125)	TPC (N=124)	Total (N=249)
Follow-up duration (months) for Progression-Free Survival by Blinded Independent Central Review (BICR) [a]			
N	125	124	249
Mean (SD)	8.6 (6.9)	7.4 (6)	8 (6.5)
Median	6.9	5.7	5.8
Q1, Q3	3, 12.7	3.2, 9	3.1, 11.1
Min, Max	0, 31.9	0, 26.4	0, 31.9
Tumor Response by Blinded Independent Central Review (BICR), n (%)			
CR	14 (11.2%)	9 (7.3%)	23 (9.2%)
PR	60 (48.0%)	55 (44.4%)	115 (46.2%)
SD	34 (27.2%)	41 (33.1%)	75 (30.1%)
PD	11 (8.8%)	12 (9.7%)	23 (9.2%)
NE	0 (0.0%)	1 (0.8%)	1 (0.4%)
NON-CR/NON-PD	0 (0.0%)	1 (0.8%)	1 (0.4%)
Missing/NE	6 (4.8%)	5 (4.0%)	11 (4.4%)

Statistic	SG (N=125)	TPC (N=124)	Total (N=249)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; BICR = blinded independent central review; IWRS = Interactive Web Response System; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE = not evaluable; NON-CR/NON-PD = non-complete response/non-progressive disease (applicable to non-measurable disease).
[a] Observation period for PFS is defined as time from randomisation to the event or censoring date of progression-free survival.
Tumour response assessed by BICR per RECIST v1.1; confirmed responses only.
Data Cut Date: 27 OCT 2025.

5.5. Table 1.1.5: Analysis of PFS by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events	84 (67.2%)	82 (66.1%)
Disease Progression (PD)	73 (58.4%)	79 (63.7%)
Death	11 (8.8%)	3 (2.4%)
Number (%) of Participants Censored	41 (32.8%)	42 (33.9%)
PD after Starting New Anti-Cancer Therapy	0	1 (0.8%)
PD right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	1 (0.8%)	2 (1.6%)
Death after Starting New Anti-Cancer Therapy	14 (11.2%)	10 (8.1%)
Death right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	0	2 (1.6%)
No PD and No Death without New Anti-Cancer Therapy	19 (15.2%)	14 (11.3%)
No PD and No Death with New Anti-Cancer Therapy	7 (5.6%)	10 (8.1%)
No Baseline or Postbaseline Evaluable Assessment [a]	0	3 (2.4%)
Kaplan-Meier Estimate of PFS (Months) (95% CI) [b]		
Q1	4.07 (2.92, 5.39)	4.24 (3.98, 5.49)
Median	8.34 (6.90, 9.92)	8.08 (5.65, 8.34)
Q3	18.00 (13.86, 25.53)	12.68 (9.46, 17.81)
Absolute Difference in Median PFS, SG vs TPC (Months)	0.26	
Kaplan-Meier Estimate of PFS Rate (95% CI) [c]		
At 3 Months	0.808 (0.726, 0.868)	0.869 (0.792, 0.919)

Parameter	SG (N=125)	TPC (N=124)
At 6 Months	0.610 (0.514, 0.693)	0.583 (0.484, 0.670)
At 9 Months	0.466 (0.370, 0.556)	0.369 (0.275, 0.464)
At 12 Months	0.375 (0.284, 0.466)	0.299 (0.210, 0.393)
At 18 Months	0.251 (0.167, 0.343)	0.146 (0.079, 0.234)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [d]	0.1487	
Stratified Hazard Ratio of SG vs TPC (95% CI) [e]	0.793 (0.578, 1.087)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
[a] Censoring due to no baseline or no postbaseline evaluable assessment does not include death events before the second scheduled postbaseline visit.
[b] PFS (months) = (date of event or censoring − date of randomisation + 1) / 30.4375. The 95% CI is based on the log-log transformation.
[c] PFS rate is the proportion of participants alive without progressive disease (PD). The 95% CI is based on the log-log transformation.
[d] The two-sided p-value is from stratified log-rank test.
[e] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 27 OCT 2025.

5.6. Table 1.1.6: Analysis of PFS by BICR – Subgroup — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

label	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.6291
Number (%) of Participants with Events	21 (72.4%)	21 (80.8%)	
Disease Progression (PD)	17 (58.6%)	20 (76.9%)	
Death	4 (13.8%)	1 (3.8%)	
Number (%) of Participants Censored	8 (27.6%)	5 (19.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (4.30, 15.21)	5.75 (4.40, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.687 (0.367, 1.286)		

label	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.2384		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events	24 (77.4%)	22 (71.0%)	
Disease Progression (PD)	23 (74.2%)	22 (71.0%)	
Death	1 (3.2%)	0	
Number (%) of Participants Censored	7 (22.6%)	9 (29.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.44, 9.92)	6.74 (5.42, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.724 (0.401, 1.307)		
p-value (Log-Rank Test, Unstratified)	0.2826		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events	39 (60.0%)	39 (58.2%)	
Disease Progression (PD)	33 (50.8%)	37 (55.2%)	
Death	6 (9.2%)	2 (3.0%)	
Number (%) of Participants Censored	26 (40.0%)	28 (41.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.59 (6.90, 15.08)	8.34 (5.59, 13.70)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.998 (0.640, 1.557)		
p-value (Log-Rank Test, Unstratified)	0.9913		
Geographic region			
US/Canada/Western Europe	30	35	0.6775
Number (%) of Participants with Events	20 (66.7%)	19 (54.3%)	
Disease Progression (PD)	19 (63.3%)	19 (54.3%)	
Death	1 (3.3%)	0	

label	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	10 (33.3%)	16 (45.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (6.14, 15.51)	7.06 (5.49, 9.76)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.738 (0.391, 1.394)		
p-value (Log-Rank Test, Unstratified)	0.3464		
Rest of the world	95	89	
Number (%) of Participants with Events	64 (67.4%)	63 (70.8%)	
Disease Progression (PD)	54 (56.8%)	60 (67.4%)	
Death	10 (10.5%)	3 (3.4%)	
Number (%) of Participants Censored	31 (32.6%)	26 (29.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.23 (5.55, 9.92)	8.08 (5.59, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.903 (0.637, 1.280)		
p-value (Log-Rank Test, Unstratified)	0.5641		
Age group			
< 65	98	96	0.0476
Number (%) of Participants with Events	65 (66.3%)	66 (68.8%)	
Disease Progression (PD)	58 (59.2%)	64 (66.7%)	
Death	7 (7.1%)	2 (2.1%)	
Number (%) of Participants Censored	33 (33.7%)	30 (31.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.90, 10.32)	7.13 (5.52, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.740 (0.524, 1.044)		
p-value (Log-Rank Test, Unstratified)	0.0843		

label	SG (N=125)	TPC (N=124)	Interaction
>= 65	27	28	
Number (%) of Participants with Events	19 (70.4%)	16 (57.1%)	
Disease Progression (PD)	15 (55.6%)	15 (53.6%)	
Death	4 (14.8%)	1 (3.6%)	
Number (%) of Participants Censored	8 (29.6%)	12 (42.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (2.79, 13.86)	8.54 (5.49, 15.21)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.493 (0.764, 2.918)		
p-value (Log-Rank Test, Unstratified)	0.2369		
Race			
White	81	77	0.6174
Number (%) of Participants with Events	55 (67.9%)	46 (59.7%)	
Disease Progression (PD)	49 (60.5%)	44 (57.1%)	
Death	6 (7.4%)	2 (2.6%)	
Number (%) of Participants Censored	26 (32.1%)	31 (40.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (5.55, 9.92)	7.79 (5.49, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.959 (0.647, 1.422)		
p-value (Log-Rank Test, Unstratified)	0.8330		
Asian	26	26	
Number (%) of Participants with Events	16 (61.5%)	20 (76.9%)	
Disease Progression (PD)	13 (50.0%)	20 (76.9%)	
Death	3 (11.5%)	0	
Number (%) of Participants Censored	10 (38.5%)	6 (23.1%)	

label	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.82 (3.88, NR)	8.08 (5.49, 11.07)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.649 (0.333, 1.264)		
p-value (Log-Rank Test, Unstratified)	0.2003		
Other	16	21	
Number (%) of Participants with Events	11 (68.8%)	16 (76.2%)	
Disease Progression (PD)	10 (62.5%)	15 (71.4%)	
Death	1 (6.2%)	1 (4.8%)	
Number (%) of Participants Censored	5 (31.2%)	5 (23.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (5.52, 18.00)	8.31 (5.39, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.752 (0.345, 1.643)		
p-value (Log-Rank Test, Unstratified)	0.4786		
Baseline ECOG status			
0	81	80	0.8297
Number (%) of Participants with Events	53 (65.4%)	52 (65.0%)	
Disease Progression (PD)	48 (59.3%)	50 (62.5%)	
Death	5 (6.2%)	2 (2.5%)	
Number (%) of Participants Censored	28 (34.6%)	28 (35.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.92 (8.31, 12.71)	8.31 (7.13, 9.76)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.854 (0.582, 1.255)		
p-value (Log-Rank Test, Unstratified)	0.4218		
1	44	44	

label	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events	31 (70.5%)	30 (68.2%)	
Disease Progression (PD)	25 (56.8%)	29 (65.9%)	
Death	6 (13.6%)	1 (2.3%)	
Number (%) of Participants Censored	13 (29.5%)	14 (31.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.21, 7.26)	5.52 (4.17, 7.06)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.872 (0.525, 1.448)		
p-value (Log-Rank Test, Unstratified)	0.5987		
History of liver metastasis			
Yes	36	26	0.4358
Number (%) of Participants with Events	29 (80.6%)	17 (65.4%)	
Disease Progression (PD)	26 (72.2%)	15 (57.7%)	
Death	3 (8.3%)	2 (7.7%)	
Number (%) of Participants Censored	7 (19.4%)	9 (34.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.16 (2.96, 9.59)	4.21 (2.79, 5.49)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.689 (0.371, 1.279)		
p-value (Log-Rank Test, Unstratified)	0.2383		
No	89	98	
Number (%) of Participants with Events	55 (61.8%)	65 (66.3%)	
Disease Progression (PD)	47 (52.8%)	64 (65.3%)	
Death	8 (9.0%)	1 (1.0%)	
Number (%) of Participants Censored	34 (38.2%)	33 (33.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=125)	TPC (N=124)	Interaction
Median	9.69 (6.90, 13.86)	8.31 (6.93, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.835 (0.582, 1.198)		
p-value (Log-Rank Test, Unstratified)	0.3268		
History of brain metastasis			
Yes	6	7	0.5292
Number (%) of Participants with Events	5 (83.3%)	5 (71.4%)	
Disease Progression (PD)	4 (66.7%)	5 (71.4%)	
Death	1 (16.7%)	0	
Number (%) of Participants Censored	1 (16.7%)	2 (28.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (0.85, NR)	8.08 (0.30, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.704 (0.448, 6.484)		
p-value (Log-Rank Test, Unstratified)	0.4296		
No	119	117	
Number (%) of Participants with Events	79 (66.4%)	77 (65.8%)	
Disease Progression (PD)	69 (58.0%)	74 (63.2%)	
Death	10 (8.4%)	3 (2.6%)	
Number (%) of Participants Censored	40 (33.6%)	40 (34.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.90, 10.32)	7.79 (5.65, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.858 (0.626, 1.177)		
p-value (Log-Rank Test, Unstratified)	0.3419		
PD-L1 Status			
CPS < 1	44	52	0.4558

label	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events	31 (70.5%)	30 (57.7%)	
Disease Progression (PD)	26 (59.1%)	29 (55.8%)	
Death	5 (11.4%)	1 (1.9%)	
Number (%) of Participants Censored	13 (29.5%)	22 (42.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (6.14, 12.45)	8.28 (5.42, 12.52)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.009 (0.607, 1.675)		
p-value (Log-Rank Test, Unstratified)	0.9774		
CPS ≥ 1	81	72	
Number (%) of Participants with Events	53 (65.4%)	52 (72.2%)	
Disease Progression (PD)	47 (58.0%)	50 (69.4%)	
Death	6 (7.4%)	2 (2.8%)	
Number (%) of Participants Censored	28 (34.6%)	20 (27.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.77 (5.55, 11.27)	7.79 (5.65, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.790 (0.537, 1.162)		
p-value (Log-Rank Test, Unstratified)	0.2305		
BRCA 1/2 status			
Wild-Type	42	46	0.1603
Number (%) of Participants with Events	29 (69.0%)	30 (65.2%)	
Disease Progression (PD)	25 (59.5%)	29 (63.0%)	
Death	4 (9.5%)	1 (2.2%)	
Number (%) of Participants Censored	13 (31.0%)	16 (34.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=125)	TPC (N=124)	Interaction
Median	6.14 (4.21, 12.45)	6.87 (4.40, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.863 (0.516, 1.443)		
p-value (Log-Rank Test, Unstratified)	0.5668		
Mutant	9	7	
Number (%) of Participants with Events	6 (66.7%)	3 (42.9%)	
Disease Progression (PD)	5 (55.6%)	3 (42.9%)	
Death	1 (11.1%)	0	
Number (%) of Participants Censored	3 (33.3%)	4 (57.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (1.51, NR)	14.09 (4.21, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.615 (0.629, 10.870)		
p-value (Log-Rank Test, Unstratified)	0.1722		
Menopausal status			
Pre-menopausal	29	35	0.9927
Number (%) of Participants with Events	18 (62.1%)	25 (71.4%)	
Disease Progression (PD)	16 (55.2%)	24 (68.6%)	
Death	2 (6.9%)	1 (2.9%)	
Number (%) of Participants Censored	11 (37.9%)	10 (28.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.14 (4.27, 12.45)	6.74 (4.40, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.482, 1.624)		
p-value (Log-Rank Test, Unstratified)	0.7002		
Post-menopausal	96	88	
Number (%) of Participants with Events	66 (68.8%)	56 (63.6%)	

label	SG (N=125)	TPC (N=124)	Interaction
Disease Progression (PD)	57 (59.4%)	54 (61.4%)	
Death	9 (9.4%)	2 (2.3%)	
Number (%) of Participants Censored	30 (31.2%)	32 (36.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.54 (7.00, 10.32)	8.28 (5.65, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.860 (0.601, 1.233)		
p-value (Log-Rank Test, Unstratified)	0.4112		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Intent-to-treat (ITT) Analysis Set includes all participants who were randomised in the study.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS (months) = (date of events or censoring − date of randomisation + 1) / 30.4375. 95% CI based on log-log transformation. Median PFS from Kaplan-Meier estimate.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
[a] Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.7. Table 1.1.7: Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events	81 (64.8%)	91 (73.4%)
Disease Progression (PD)	39 (31.2%)	67 (54.0%)
Death	42 (33.6%)	24 (19.4%)
Number (%) of Participants Censored	44 (35.2%)	33 (26.6%)
Alive Without PFS2 Event and Without Second Next-Line Therapy	16 (12.8%)	11 (8.9%)
Alive Without PFS2 Event and With Second Next-Line Therapy	4 (3.2%)	3 (2.4%)
Discontinued Study	0	0

Parameter	SG (N=125)	TPC (N=124)
No Baseline or Postbaseline Evaluable Assessment	0	0
Kaplan-Meier Estimate of PFS2 (Months) (95% CI) [a]		
Q1	9.20 (6.24, 10.68)	9.03 (6.54, 10.38)
Median	14.82 (12.68, 16.66)	13.67 (11.30, 15.28)
Q3	29.17 (23.95, NR)	19.68 (18.92, NR)
Absolute Difference in Median PFS2, SG vs TPC (Months)	1.15	
Kaplan-Meier Estimate of PFS2 Rate (95% CI) [b]		
At 3 Months	0.952 (0.896, 0.978)	0.967 (0.915, 0.988)
At 6 Months	0.832 (0.754, 0.887)	0.861 (0.785, 0.911)
At 9 Months	0.750 (0.664, 0.817)	0.754 (0.667, 0.821)
At 12 Months	0.602 (0.510, 0.682)	0.558 (0.464, 0.642)
At 18 Months	0.407 (0.319, 0.494)	0.339 (0.255, 0.425)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [c]	0.1262	
Stratified Hazard Ratio of SG vs TPC (95% CI) [d]	0.786 (0.579, 1.067)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first. Next line therapy is defined as the first new systemic anti-cancer therapy (including crossover treatment) initiated after discontinuation of study treatment regardless of end of treatment reason.
[a] Quantile of PFS2 is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
Data Cut Date: 27 OCT 2025.

5.8. Table 1.1.8: Subgroup Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

label	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			

label	SG (N=125)	TPC (N=124)	Interaction
De novo	29	26	0.2957
Number (%) of Participants with Events	26 (89.7%)	24 (92.3%)	
Disease Progression (PD)	22 (75.9%)	23 (88.5%)	
Death	4 (13.8%)	1 (3.8%)	
Number (%) of Participants Censored	3 (10.3%)	2 (7.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (2.92, 12.45)	5.70 (4.21, 8.25)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.772 (0.436, 1.368)		
p-value (Log-Rank Test, Unstratified)	0.3744		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events	25 (80.6%)	27 (87.1%)	
Disease Progression (PD)	24 (77.4%)	27 (87.1%)	
Death	1 (3.2%)	0	
Number (%) of Participants Censored	6 (19.4%)	4 (12.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.37, 9.82)	5.63 (4.40, 7.13)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.557 (0.317, 0.977)		
p-value (Log-Rank Test, Unstratified)	0.0390		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events	56 (86.2%)	58 (86.6%)	
Disease Progression (PD)	50 (76.9%)	56 (83.6%)	
Death	6 (9.2%)	2 (3.0%)	
Number (%) of Participants Censored	9 (13.8%)	9 (13.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=125)	TPC (N=124)	Interaction
Median	6.90 (4.07, 8.77)	6.06 (4.34, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.009 (0.697, 1.460)		
p-value (Log-Rank Test, Unstratified)	0.9643		
Geographic region			
US/Canada/Western Europe	30	35	0.4943
Number (%) of Participants with Events	28 (93.3%)	31 (88.6%)	
Disease Progression (PD)	27 (90.0%)	31 (88.6%)	
Death	1 (3.3%)	0	
Number (%) of Participants Censored	2 (6.7%)	4 (11.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.11 (5.36, 9.92)	5.62 (3.02, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.700 (0.415, 1.179)		
p-value (Log-Rank Test, Unstratified)	0.1781		
Rest of the world	95	89	
Number (%) of Participants with Events	79 (83.2%)	78 (87.6%)	
Disease Progression (PD)	69 (72.6%)	75 (84.3%)	
Death	10 (10.5%)	3 (3.4%)	
Number (%) of Participants Censored	16 (16.8%)	11 (12.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.30, 8.31)	6.01 (5.32, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.886 (0.647, 1.213)		
p-value (Log-Rank Test, Unstratified)	0.4491		
Age group			
< 65	98	96	0.0414

label	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events	81 (82.7%)	84 (87.5%)	
Disease Progression (PD)	74 (75.5%)	82 (85.4%)	
Death	7 (7.1%)	2 (2.1%)	
Number (%) of Participants Censored	17 (17.3%)	12 (12.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.06 (5.36, 8.77)	5.62 (4.40, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.726 (0.534, 0.986)		
p-value (Log-Rank Test, Unstratified)	0.0394		
>= 65	27	28	
Number (%) of Participants with Events	26 (96.3%)	25 (89.3%)	
Disease Progression (PD)	22 (81.5%)	24 (85.7%)	
Death	4 (14.8%)	1 (3.6%)	
Number (%) of Participants Censored	1 (3.7%)	3 (10.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	3.15 (1.91, 7.92)	6.41 (4.53, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.374 (0.786, 2.403)		
p-value (Log-Rank Test, Unstratified)	0.2601		
Race			
White	81	77	0.7345
Number (%) of Participants with Events	72 (88.9%)	66 (85.7%)	
Disease Progression (PD)	66 (81.5%)	64 (83.1%)	
Death	6 (7.4%)	2 (2.6%)	
Number (%) of Participants Censored	9 (11.1%)	11 (14.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=125)	TPC (N=124)	Interaction
Median	5.55 (4.30, 8.31)	5.62 (4.34, 6.87)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.891 (0.637, 1.247)		
p-value (Log-Rank Test, Unstratified)	0.5013		
Asian	26	26	
Number (%) of Participants with Events	19 (73.1%)	24 (92.3%)	
Disease Progression (PD)	16 (61.5%)	24 (92.3%)	
Death	3 (11.5%)	0	
Number (%) of Participants Censored	7 (26.9%)	2 (7.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.95 (1.91, 15.08)	6.16 (4.14, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.664 (0.361, 1.221)		
p-value (Log-Rank Test, Unstratified)	0.1848		
Other	16	21	
Number (%) of Participants with Events	14 (87.5%)	19 (90.5%)	
Disease Progression (PD)	13 (81.2%)	18 (85.7%)	
Death	1 (6.2%)	1 (4.8%)	
Number (%) of Participants Censored	2 (12.5%)	2 (9.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.36 (2.33, 17.81)	6.34 (4.40, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.804 (0.398, 1.623)		
p-value (Log-Rank Test, Unstratified)	0.5472		
Baseline ECOG status			
0	81	80	0.6513
Number (%) of Participants with Events	68 (84.0%)	70 (87.5%)	

label	SG (N=125)	TPC (N=124)	Interaction
Disease Progression (PD)	63 (77.8%)	68 (85.0%)	
Death	5 (6.2%)	2 (2.5%)	
Number (%) of Participants Censored	13 (16.0%)	10 (12.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (5.32, 9.82)	6.93 (5.49, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.854 (0.610, 1.195)		
p-value (Log-Rank Test, Unstratified)	0.3575		
1	44	44	
Number (%) of Participants with Events	39 (88.6%)	39 (88.6%)	
Disease Progression (PD)	33 (75.0%)	38 (86.4%)	
Death	6 (13.6%)	1 (2.3%)	
Number (%) of Participants Censored	5 (11.4%)	5 (11.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.47 (3.12, 7.13)	4.53 (4.14, 5.65)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.799 (0.510, 1.252)		
p-value (Log-Rank Test, Unstratified)	0.3265		
History of liver metastasis			
Yes	36	26	0.1523
Number (%) of Participants with Events	33 (91.7%)	23 (88.5%)	
Disease Progression (PD)	30 (83.3%)	21 (80.8%)	
Death	3 (8.3%)	2 (7.7%)	
Number (%) of Participants Censored	3 (8.3%)	3 (11.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.83 (2.89, 8.31)	4.14 (1.87, 4.34)	

label	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.608 (0.350, 1.054)		
p-value (Log-Rank Test, Unstratified)	0.0739		
No	89	98	
Number (%) of Participants with Events	74 (83.1%)	86 (87.8%)	
Disease Progression (PD)	66 (74.2%)	85 (86.7%)	
Death	8 (9.0%)	1 (1.0%)	
Number (%) of Participants Censored	15 (16.9%)	12 (12.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (5.36, 9.26)	6.80 (5.62, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.623, 1.164)		
p-value (Log-Rank Test, Unstratified)	0.3127		
History of brain metastasis			
Yes	6	7	0.6765
Number (%) of Participants with Events	6 (100.0%)	7 (100.0%)	
Disease Progression (PD)	5 (83.3%)	7 (100.0%)	
Death	1 (16.7%)	0	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.72 (0.85, NR)	5.78 (0.30, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.329 (0.423, 4.176)		
p-value (Log-Rank Test, Unstratified)	0.6257		
No	119	117	
Number (%) of Participants with Events	101 (84.9%)	102 (87.2%)	
Disease Progression (PD)	91 (76.5%)	99 (84.6%)	

label	SG (N=125)	TPC (N=124)	Interaction
Death	10 (8.4%)	3 (2.6%)	
Number (%) of Participants Censored	18 (15.1%)	15 (12.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.90 (5.22, 8.48)	5.65 (5.32, 6.90)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.834 (0.633, 1.099)		
p-value (Log-Rank Test, Unstratified)	0.1967		
PD-L1 Status			
CPS < 1	44	52	0.9570
Number (%) of Participants with Events	38 (86.4%)	45 (86.5%)	
Disease Progression (PD)	33 (75.0%)	44 (84.6%)	
Death	5 (11.4%)	1 (1.9%)	
Number (%) of Participants Censored	6 (13.6%)	7 (13.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.08 (4.44, 9.72)	5.49 (4.17, 7.06)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.858 (0.555, 1.325)		
p-value (Log-Rank Test, Unstratified)	0.4853		
CPS ≥ 1	81	72	
Number (%) of Participants with Events	69 (85.2%)	64 (88.9%)	
Disease Progression (PD)	63 (77.8%)	62 (86.1%)	
Death	6 (7.4%)	2 (2.8%)	
Number (%) of Participants Censored	12 (14.8%)	8 (11.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.59 (4.30, 8.74)	6.34 (5.39, 7.20)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.832 (0.590, 1.172)		

label	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.2911		
BRCA 1/2 status			
Wild-Type	42	46	0.1276
Number (%) of Participants with Events	38 (90.5%)	40 (87.0%)	
Disease Progression (PD)	34 (81.0%)	39 (84.8%)	
Death	4 (9.5%)	1 (2.2%)	
Number (%) of Participants Censored	4 (9.5%)	6 (13.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.34 (4.01, 7.13)	5.40 (3.09, 6.70)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.874 (0.559, 1.367)		
p-value (Log-Rank Test, Unstratified)	0.5523		
Mutant	9	7	
Number (%) of Participants with Events	8 (88.9%)	4 (57.1%)	
Disease Progression (PD)	7 (77.8%)	4 (57.1%)	
Death	1 (11.1%)	0	
Number (%) of Participants Censored	1 (11.1%)	3 (42.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.26 (1.51, 9.30)	11.55 (4.21, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.341 (0.688, 7.969)		
p-value (Log-Rank Test, Unstratified)	0.1624		
Menopausal status			
Pre-menopausal	29	35	0.5196
Number (%) of Participants with Events	25 (86.2%)	31 (88.6%)	
Disease Progression (PD)	23 (79.3%)	30 (85.7%)	

label	SG (N=125)	TPC (N=124)	Interaction
Death	2 (6.9%)	1 (2.9%)	
Number (%) of Participants Censored	4 (13.8%)	4 (11.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.52 (2.92, 7.23)	5.45 (4.14, 7.06)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.943 (0.555, 1.600)		
p-value (Log-Rank Test, Unstratified)	0.8354		
Post-menopausal	96	88	
Number (%) of Participants with Events	82 (85.4%)	77 (87.5%)	
Disease Progression (PD)	73 (76.0%)	75 (85.2%)	
Death	9 (9.4%)	2 (2.3%)	
Number (%) of Participants Censored	14 (14.6%)	11 (12.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.15 (4.44, 9.26)	6.01 (5.32, 8.08)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.799 (0.584, 1.092)		
p-value (Log-Rank Test, Unstratified)	0.1567		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from an unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.9. Table 1.1.9: Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Parameter	SG (N=125)	TPC (N=124)
Number (%) of Participants with Events	101 (80.8%)	105 (84.7%)
First Subsequent Therapy	74 (59.2%)	89 (71.8%)
Death	27 (21.6%)	16 (12.9%)
Number (%) of Participants Censored	24 (19.2%)	19 (15.3%)
Kaplan-Meier Estimate of TFST (Months) (95% CI) [a]		
Q1	4.80 (3.58, 6.05)	4.99 (4.01, 6.05)
Median	9.69 (7.43, 11.40)	7.79 (6.54, 9.30)
Q3	19.15 (14.92, 21.45)	13.37 (10.84, 16.62)
Absolute Difference in Median TFST, SG vs TPC (Months)	1.91	
Kaplan-Meier Estimate of TFST Rate (95% CI) [b]		
At 3 Months	0.880 (0.809, 0.926)	0.902 (0.835, 0.943)
At 6 Months	0.679 (0.590, 0.753)	0.691 (0.601, 0.765)
At 9 Months	0.534 (0.442, 0.617)	0.446 (0.357, 0.531)
At 12 Months	0.388 (0.303, 0.473)	0.306 (0.226, 0.388)
At 18 Months	0.278 (0.201, 0.360)	0.173 (0.112, 0.245)
At 24 Months	0.136 (0.073, 0.219)	0.144 (0.088, 0.214)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.0684	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.770 (0.581, 1.020)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomization to the start date of the first subsequent anti-cancer therapy after discontinuation of randomized treatment, or death due to any cause.
[a] Quantile of TFST is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] TFST rate is the proportion of participants alive without any subsequent therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors from Interactive Web Response System (IWRS).
Data Cut Date: 27 OCT 2025.

5.10. Table 1.1.10: Subgroup Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

label	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.421
Number (%) of Participants with Events	23 (79.3%)	25 (96.2%)	
First Subsequent Therapy	16 (55.2%)	19 (73.1%)	
Death	7 (24.1%)	6 (23.1%)	
Number (%) of Participants Censored	6 (20.7%)	1 (3.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.32 (5.82, 17.97)	7.11 (4.99, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.660 (0.371, 1.172)		
p-value (Log-Rank Test, Unstratified)	0.154		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events	26 (83.9%)	27 (87.1%)	
First Subsequent Therapy	20 (64.5%)	23 (74.2%)	
Death	6 (19.4%)	4 (12.9%)	
Number (%) of Participants Censored	5 (16.1%)	4 (12.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.33 (6.74, 12.94)	7.24 (6.11, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.657 (0.381, 1.131)		
p-value (Log-Rank Test, Unstratified)	0.122		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events	52 (80.0%)	53 (79.1%)	
First Subsequent Therapy	38 (58.5%)	47 (70.1%)	

label	SG (N=125)	TPC (N=124)	Interaction
Death	14 (21.5%)	6 (9.0%)	
Number (%) of Participants Censored	13 (20.0%)	14 (20.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.97 (6.05, 11.96)	8.48 (6.24, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.994 (0.678, 1.459)		
p-value (Log-Rank Test, Unstratified)	0.977		
Geographic region			
US/Canada/Western Europe	30	35	0.208
Number (%) of Participants with Events	26 (86.7%)	33 (94.3%)	
First Subsequent Therapy	22 (73.3%)	29 (82.9%)	
Death	4 (13.3%)	4 (11.4%)	
Number (%) of Participants Censored	4 (13.3%)	2 (5.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.46 (6.74, 12.94)	6.24 (5.36, 8.21)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.611 (0.363, 1.029)		
p-value (Log-Rank Test, Unstratified)	0.061		
Rest of the world	95	89	
Number (%) of Participants with Events	75 (78.9%)	72 (80.9%)	
First Subsequent Therapy	52 (54.7%)	60 (67.4%)	
Death	23 (24.2%)	12 (13.5%)	
Number (%) of Participants Censored	20 (21.1%)	17 (19.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.76 (7.26, 12.68)	8.48 (6.74, 10.84)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.931 (0.673, 1.287)		

label	SG (N=125)	TPC (N=124)	Interaction
p-value (Log-Rank Test, Unstratified)	0.664		
Age group			
< 65	98	96	0.253
Number (%) of Participants with Events	77 (78.6%)	79 (82.3%)	
First Subsequent Therapy	59 (60.2%)	70 (72.9%)	
Death	18 (18.4%)	9 (9.4%)	
Number (%) of Participants Censored	21 (21.4%)	17 (17.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.32 (8.57, 12.75)	7.39 (6.21, 9.92)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.778 (0.568, 1.065)		
p-value (Log-Rank Test, Unstratified)	0.117		
>= 65	27	28	
Number (%) of Participants with Events	24 (88.9%)	26 (92.9%)	
First Subsequent Therapy	15 (55.6%)	19 (67.9%)	
Death	9 (33.3%)	7 (25.0%)	
Number (%) of Participants Censored	3 (11.1%)	2 (7.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	4.73 (3.15, 10.91)	8.33 (6.47, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.115 (0.637, 1.953)		
p-value (Log-Rank Test, Unstratified)	0.700		
Race			
White	81	77	0.479
Number (%) of Participants with Events	70 (86.4%)	64 (83.1%)	
First Subsequent Therapy	51 (63.0%)	53 (68.8%)	

label	SG (N=125)	TPC (N=124)	Interaction
Death	19 (23.5%)	11 (14.3%)	
Number (%) of Participants Censored	11 (13.6%)	13 (16.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.23 (6.77, 11.24)	7.62 (6.01, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.934 (0.665, 1.312)		
p-value (Log-Rank Test, Unstratified)	0.694		
Asian	26	26	
Number (%) of Participants with Events	18 (69.2%)	23 (88.5%)	
First Subsequent Therapy	15 (57.7%)	23 (88.5%)	
Death	3 (11.5%)	0	
Number (%) of Participants Censored	8 (30.8%)	3 (11.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.86 (4.11, 18.46)	8.13 (6.14, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.694 (0.372, 1.296)		
p-value (Log-Rank Test, Unstratified)	0.252		
Other	16	21	
Number (%) of Participants with Events	11 (68.8%)	18 (85.7%)	
First Subsequent Therapy	7 (43.8%)	13 (61.9%)	
Death	4 (25.0%)	5 (23.8%)	
Number (%) of Participants Censored	5 (31.2%)	3 (14.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.52 (7.26, 19.15)	10.18 (6.47, 12.22)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.515 (0.238, 1.115)		
p-value (Log-Rank Test, Unstratified)	0.087		

label	SG (N=125)	TPC (N=124)	Interaction
Baseline ECOG status			
0	81	80	0.829
Number (%) of Participants with Events	63 (77.8%)	65 (81.2%)	
First Subsequent Therapy	51 (63.0%)	58 (72.5%)	
Death	12 (14.8%)	7 (8.8%)	
Number (%) of Participants Censored	18 (22.2%)	15 (18.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.47 (8.97, 14.52)	9.36 (7.39, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.836 (0.591, 1.184)		
p-value (Log-Rank Test, Unstratified)	0.313		
1	44	44	
Number (%) of Participants with Events	38 (86.4%)	40 (90.9%)	
First Subsequent Therapy	23 (52.3%)	31 (70.5%)	
Death	15 (34.1%)	9 (20.5%)	
Number (%) of Participants Censored	6 (13.6%)	4 (9.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.26 (4.30, 9.33)	6.23 (5.29, 7.79)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.832 (0.532, 1.303)		
p-value (Log-Rank Test, Unstratified)	0.421		
History of liver metastasis			
Yes	36	26	0.274
Number (%) of Participants with Events	32 (88.9%)	24 (92.3%)	
First Subsequent Therapy	22 (61.1%)	19 (73.1%)	
Death	10 (27.8%)	5 (19.2%)	

label	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	4 (11.1%)	2 (7.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.44 (4.73, 9.76)	4.99 (3.91, 6.01)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.648 (0.377, 1.114)		
p-value (Log-Rank Test, Unstratified)	0.114		
No	89	98	
Number (%) of Participants with Events	69 (77.5%)	81 (82.7%)	
First Subsequent Therapy	52 (58.4%)	70 (71.4%)	
Death	17 (19.1%)	11 (11.2%)	
Number (%) of Participants Censored	20 (22.5%)	17 (17.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.74 (7.26, 12.94)	9.03 (7.39, 10.55)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.843 (0.611, 1.164)		
p-value (Log-Rank Test, Unstratified)	0.299		
History of brain metastasis			
Yes	6	7	0.491
Number (%) of Participants with Events	6 (100.0%)	7 (100.0%)	
First Subsequent Therapy	5 (83.3%)	5 (71.4%)	
Death	1 (16.7%)	2 (28.6%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	6.85 (0.85, NR)	8.38 (2.66, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.562 (0.498, 4.896)		
p-value (Log-Rank Test, Unstratified)	0.440		

label	SG (N=125)	TPC (N=124)	Interaction
No	119	117	
Number (%) of Participants with Events	95 (79.8%)	98 (83.8%)	
First Subsequent Therapy	69 (58.0%)	84 (71.8%)	
Death	26 (21.8%)	14 (12.0%)	
Number (%) of Participants Censored	24 (20.2%)	19 (16.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.15 (7.56, 11.99)	7.66 (6.47, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.831 (0.626, 1.103)		
p-value (Log-Rank Test, Unstratified)	0.200		
PD-L1 Status			
CPS < 1	44	52	0.995
Number (%) of Participants with Events	38 (86.4%)	44 (84.6%)	
First Subsequent Therapy	29 (65.9%)	36 (69.2%)	
Death	9 (20.5%)	8 (15.4%)	
Number (%) of Participants Censored	6 (13.6%)	8 (15.4%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.49 (6.24, 12.75)	6.93 (5.36, 8.48)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.839 (0.542, 1.297)		
p-value (Log-Rank Test, Unstratified)	0.427		
CPS ≥ 1	81	72	
Number (%) of Participants with Events	63 (77.8%)	61 (84.7%)	
First Subsequent Therapy	45 (55.6%)	53 (73.6%)	
Death	18 (22.2%)	8 (11.1%)	
Number (%) of Participants Censored	18 (22.2%)	11 (15.3%)	

label	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.76 (6.77, 12.68)	9.03 (6.60, 10.68)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.829 (0.582, 1.181)		
p-value (Log-Rank Test, Unstratified)	0.298		
BRCA 1/2 status			
Wild-Type	42	46	0.050
Number (%) of Participants with Events	37 (88.1%)	42 (91.3%)	
First Subsequent Therapy	27 (64.3%)	35 (76.1%)	
Death	10 (23.8%)	7 (15.2%)	
Number (%) of Participants Censored	5 (11.9%)	4 (8.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.69 (5.82, 11.99)	6.23 (4.99, 7.85)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.740 (0.474, 1.155)		
p-value (Log-Rank Test, Unstratified)	0.185		
Mutant	9	7	
Number (%) of Participants with Events	8 (88.9%)	5 (71.4%)	
First Subsequent Therapy	6 (66.7%)	4 (57.1%)	
Death	2 (22.2%)	1 (14.3%)	
Number (%) of Participants Censored	1 (11.1%)	2 (28.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.08 (3.15, NR)	16.33 (4.99, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.042 (0.889, 10.411)		
p-value (Log-Rank Test, Unstratified)	0.064		
Menopausal status			

label	SG (N=125)	TPC (N=124)	Interaction
Pre-menopausal	29	35	0.395
Number (%) of Participants with Events	23 (79.3%)	29 (82.9%)	
First Subsequent Therapy	20 (69.0%)	27 (77.1%)	
Death	3 (10.3%)	2 (5.7%)	
Number (%) of Participants Censored	6 (20.7%)	6 (17.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.03 (4.44, 12.68)	7.39 (6.24, 9.92)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.029 (0.593, 1.784)		
p-value (Log-Rank Test, Unstratified)	0.912		
Post-menopausal	96	88	
Number (%) of Participants with Events	78 (81.2%)	75 (85.2%)	
First Subsequent Therapy	54 (56.2%)	61 (69.3%)	
Death	24 (25.0%)	14 (15.9%)	
Number (%) of Participants Censored	18 (18.8%)	13 (14.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.25 (8.31, 11.99)	7.85 (6.11, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.779 (0.567, 1.071)		
p-value (Log-Rank Test, Unstratified)	0.123		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomisation to the start date of the first subsequent anti-cancer therapy after discontinuation of randomised treatment, or death due to any cause.
TFST rate is the proportion of participants alive without any subsequent therapy.
Hazard ratio and 95% CIs calculated using unstratified Cox proportional hazards model. Efron method used to handle ties. Reference arm = TPC.
Log-rank p-value is from an unstratified log-rank test.
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Data Cut Date: 27 OCT 2025.

6. Safety - mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

6.1. Table 1.1.1: Summary of Treatment Exposure - Treatment Duration (months) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	Gemcitabine (N=122)	Carboplatin (N=122)	Gem/Carbo (N=122)	Any TPC (N=122)
Total Duration of Exposure to Study Drug					
Duration (months)					
N	124	122	122	122	122
Mean (StD)	9.33 (7.442)	7.82 (6.426)	7.10 (5.533)	7.01 (5.499)	7.01 (5.499)
Median	7.05	6.09	5.77	5.77	5.77
Q1, Q3	3.69, 14.76	3.76, 9.68	3.50, 9.49	3.50, 9.20	3.50, 9.20
Min, Max	0.20, 34.76	0.03, 27.86	0.03, 27.73	0.03, 27.73	0.03, 27.73
Cumulative Number (%) of Participants					
Exposed to Study Drug					
>= 3 months, n, (%)	98 (79.0%)	95 (77.9%)	95 (77.9%)	95 (77.9%)	95 (77.9%)
>= 6 months, n, (%)	70 (56.5%)	62 (50.8%)	58 (47.5%)	58 (47.5%)	58 (47.5%)
>= 12 months, n, (%)	37 (29.8%)	24 (19.7%)	18 (14.8%)	17 (13.9%)	17 (13.9%)
>= 24 months, n, (%)	5 (4.0%)	6 (4.9%)	4 (3.3%)	4 (3.3%)	4 (3.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, Gem = gemcitabine, Carbo = carboplatin.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug. Taxane includes participants who have received Paclitaxel. TPC column includes participants who have received any of Gem, Carbo or Paclitaxel.
Duration of exposure to study drug (months) = (last dosing date − first dosing date + 1)/30.4375.

6.2. Table 1.1.2: Observation Period (Months) for Safety — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Total (N=246)
Observation Period (months) for Safety [a]			
N	124	122	246
Mean (StD)	10.16 (7.281)	8.84 (6.325)	9.51 (6.841)
Median	8.03	7.21	7.46
Q1, Q3	4.67, 15.71	4.75, 10.92	4.70, 13.12
Min, Max	0.46, 34.96	1.02, 28.71	0.46, 34.96

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
[a] Observation period is defined as the time from first dose until Data cutoff date, study treatment discontinuation +30 days for any AE and any serious AE, or death, whichever comes first and stops the collection of endpoint data.

6.3. Table 1.1.3: Analysis of Time to First Treatment-Emergent Adverse Event (TEAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	124 (100.0%)	121 (99.2%)
Patients (%) Without Events (Censored)	0 (0.0%)	1 (0.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.11 (0.10, 0.20)	0.20 (0.10, 0.23)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.244 (0.965, 1.604)
p-value		0.0771

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=124)	TPC (N=122)

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.4. Table 1.1.4: Subgroup Analysis of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8681
De novo			
Total Patients	29	26	
Patients (%) With Events	29 (100.0%)	26 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.15 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.287 (0.747, 2.216)	
p-value		0.3427	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	31 (100.0%)	30 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.26)	0.21 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.124 (0.673, 1.876)	
p-value		0.6618	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	64 (100.0%)	65 (98.5%)	
Patients (%) Without Events (Censored)	0	1 (1.5%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.335 (0.938, 1.900)	
p-value		0.0931	
Geographic region			0.8760
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	30 (100.0%)	34 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.08 (0.03, 0.16)	0.20 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.453 (0.881, 2.396)	
p-value		0.1614	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	94 (100.0%)	87 (98.9%)	
Patients (%) Without Events (Censored)	0	1 (1.1%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.285 (0.950, 1.738)	
p-value		0.0890	
Age group			0.6162
< 65			
Total Patients	98	94	
Patients (%) With Events	98 (100.0%)	93 (98.9%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	0	1 (1.1%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.16)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.279 (0.959, 1.706)	
p-value		0.0849	
>= 65			
Total Patients	26	28	
Patients (%) With Events	26 (100.0%)	28 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.18 (0.07, 0.26)	0.15 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.106 (0.639, 1.913)	
p-value		0.6673	
Race			0.9294
White			
Total Patients	80	75	
Patients (%) With Events	80 (100.0%)	74 (98.7%)	
Patients (%) Without Events (Censored)	0	1 (1.3%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.23 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.203 (0.875, 1.654)	
p-value		0.2223	
Asian			
Total Patients	26	26	
Patients (%) With Events	26 (100.0%)	26 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.26)	0.08 (0.07, 0.23)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.239 (0.692, 2.216)	
p-value		0.5134	
Other			
Total Patients	16	21	
Patients (%) With Events	16 (100.0%)	21 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.03, 0.26)	0.13 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.197 (0.609, 2.354)	
p-value		0.5819	
Baseline ECOG status			0.3260
0			
Total Patients	81	79	
Patients (%) With Events	81 (100.0%)	79 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.16)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.346 (0.980, 1.849)	
p-value		0.0612	
1			
Total Patients	43	43	
Patients (%) With Events	43 (100.0%)	42 (97.7%)	
Patients (%) Without Events (Censored)	0	1 (2.3%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.26)	0.23 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.070 (0.697, 1.643)	
p-value		0.7049	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of liver metastasis			0.7864
Yes			
Total Patients	36	25	
Patients (%) With Events	36 (100.0%)	24 (96.0%)	
Patients (%) Without Events (Censored)	0	1 (4.0%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.10 (0.03, 0.26)	
Hazard Ratio (95% CI)		1.130 (0.671, 1.903)	
p-value		0.5845	
No			
Total Patients	88	97	
Patients (%) With Events	88 (100.0%)	97 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.243 (0.927, 1.666)	
p-value		0.1271	
History of brain metastasis			0.2536
Yes			
Total Patients	6	7	
Patients (%) With Events	6 (100.0%)	7 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.03, NR)	0.20 (0.10, 1.64)	
Hazard Ratio (95% CI)		2.107 (0.639, 6.949)	
p-value		0.2119	
No			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	118	115	
Patients (%) With Events	118 (100.0%)	114 (99.1%)	
Patients (%) Without Events (Censored)	0	1 (0.9%)	
Median Time to First TEAE, months (95% CI)	0.11 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.197 (0.923, 1.553)	
p-value		0.1488	
PD-L1 Status			0.8052
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	43 (100.0%)	51 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.13)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.330 (0.874, 2.023)	
p-value		0.1542	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	81 (100.0%)	70 (98.6%)	
Patients (%) Without Events (Censored)	0	1 (1.4%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.23)	0.20 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.236 (0.894, 1.709)	
p-value		0.1952	
BRCA 1/2 status			0.4905
Wild-Type			
Total Patients	42	45	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	42 (100.0%)	44 (97.8%)	
Patients (%) Without Events (Censored)	0	1 (2.2%)	
Median Time to First TEAE, months (95% CI)	0.11 (0.10, 0.26)	0.26 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.176 (0.768, 1.803)	
p-value		0.4078	
Mutant			
Total Patients	9	7	
Patients (%) With Events	9 (100.0%)	7 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.03, NR)	0.10 (0.03, 0.33)	
Hazard Ratio (95% CI)		1.991 (0.651, 6.090)	
p-value		0.2488	
Menopausal status			0.0940
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	29 (100.0%)	34 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.07 (0.07, 0.16)	0.16 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.798 (1.047, 3.085)	
p-value		0.0291	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	95 (100.0%)	86 (98.9%)	
Patients (%) Without Events (Censored)	0	1 (1.1%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.123 (0.837, 1.506)	
p-value		0.3939	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.5. Table 1.1.5: Analysis of Time to First Serious Treatment-Emergent Adverse Event (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	40 (32.3%)	42 (34.4%)
Patients (%) Without Events (Censored)	84 (67.7%)	80 (65.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (18.66, NR)	18.92 (9.76, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.864 (0.559, 1.337)
p-value		0.5072

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.

	SG (N=124)	TPC (N=122)

Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.6. Table 1.1.6: Subgroup Analysis of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8417
De novo			
Total Patients	29	26	
Patients (%) With Events	12 (41.4%)	11 (42.3%)	
Patients (%) Without Events (Censored)	17 (58.6%)	15 (57.7%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (3.12, NR)	12.22 (3.06, NR)	
Hazard Ratio (95% CI)		0.802 (0.345, 1.867)	
p-value		0.6057	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	8 (25.8%)	6 (20.0%)	
Patients (%) Without Events (Censored)	23 (74.2%)	24 (80.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.10, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.173 (0.403, 3.412)	
p-value		0.7660	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	20 (31.2%)	25 (37.9%)	
Patients (%) Without Events (Censored)	44 (68.8%)	41 (62.1%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (11.40, NR)	18.92 (5.62, NR)	
Hazard Ratio (95% CI)		0.787 (0.436, 1.422)	
p-value		0.4229	
Geographic region			0.8977
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	10 (33.3%)	11 (32.4%)	
Patients (%) Without Events (Censored)	20 (66.7%)	23 (67.6%)	
Median Time to First Serious TEAE, months (95% CI)	NR (5.55, NR)	12.22 (5.32, NR)	
Hazard Ratio (95% CI)		0.936 (0.394, 2.223)	
p-value		0.8772	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	30 (31.9%)	31 (35.2%)	
Patients (%) Without Events (Censored)	64 (68.1%)	57 (64.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	18.92 (9.10, NR)	
Hazard Ratio (95% CI)		0.850 (0.513, 1.409)	
p-value		0.5257	
Age group			0.0922
< 65			
Total Patients	98	94	
Patients (%) With Events	30 (30.6%)	34 (36.2%)	
Patients (%) Without Events (Censored)	68 (69.4%)	60 (63.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	NR (6.47, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.715 (0.436, 1.175)	
p-value		0.1823	
>= 65			
Total Patients	26	28	
Patients (%) With Events	10 (38.5%)	8 (28.6%)	
Patients (%) Without Events (Censored)	16 (61.5%)	20 (71.4%)	
Median Time to First Serious TEAE, months (95% CI)	11.40 (1.38, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		1.667 (0.652, 4.263)	
p-value		0.2822	
Race			0.1920
White			
Total Patients	80	75	
Patients (%) With Events	22 (27.5%)	27 (36.0%)	
Patients (%) Without Events (Censored)	58 (72.5%)	48 (64.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.40, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.695 (0.395, 1.224)	
p-value		0.2025	
Asian			
Total Patients	26	26	
Patients (%) With Events	8 (30.8%)	9 (34.6%)	
Patients (%) Without Events (Censored)	18 (69.2%)	17 (65.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (8.05, NR)	NR (5.42, NR)	
Hazard Ratio (95% CI)		0.800 (0.303, 2.107)	
p-value		0.6497	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Other			
Total Patients	16	21	
Patients (%) With Events	9 (56.2%)	6 (28.6%)	
Patients (%) Without Events (Censored)	7 (43.8%)	15 (71.4%)	
Median Time to First Serious TEAE, months (95% CI)	12.11 (0.66, NR)	NR (5.62, NR)	
Hazard Ratio (95% CI)		2.096 (0.737, 5.958)	
p-value		0.1562	
Baseline ECOG status			0.1229
0			
Total Patients	81	79	
Patients (%) With Events	20 (24.7%)	27 (34.2%)	
Patients (%) Without Events (Censored)	61 (75.3%)	52 (65.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.646 (0.361, 1.155)	
p-value		0.1370	
1			
Total Patients	43	43	
Patients (%) With Events	20 (46.5%)	15 (34.9%)	
Patients (%) Without Events (Censored)	23 (53.5%)	28 (65.1%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (2.50, NR)	12.22 (4.63, NR)	
Hazard Ratio (95% CI)		1.330 (0.676, 2.619)	
p-value		0.4122	
History of liver metastasis			0.7536
Yes			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	36	25	
Patients (%) With Events	15 (41.7%)	9 (36.0%)	
Patients (%) Without Events (Censored)	21 (58.3%)	16 (64.0%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (3.81, NR)	12.22 (3.06, NR)	
Hazard Ratio (95% CI)		0.895 (0.379, 2.118)	
p-value		0.7811	
No			
Total Patients	88	97	
Patients (%) With Events	25 (28.4%)	33 (34.0%)	
Patients (%) Without Events (Censored)	63 (71.6%)	64 (66.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.790 (0.469, 1.331)	
p-value		0.3750	
History of brain metastasis			0.2255
Yes			
Total Patients	6	7	
Patients (%) With Events	4 (66.7%)	3 (42.9%)	
Patients (%) Without Events (Censored)	2 (33.3%)	4 (57.1%)	
Median Time to First Serious TEAE, months (95% CI)	2.38 (0.26, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		1.718 (0.383, 7.712)	
p-value		0.4745	
No			
Total Patients	118	115	
Patients (%) With Events	36 (30.5%)	39 (33.9%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	82 (69.5%)	76 (66.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.811 (0.514, 1.281)	
p-value		0.3653	
PD-L1 Status			0.0778
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	12 (27.9%)	22 (43.1%)	
Patients (%) Without Events (Censored)	31 (72.1%)	29 (56.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.40, NR)	12.22 (4.63, NR)	
Hazard Ratio (95% CI)		0.525 (0.257, 1.069)	
p-value		0.0682	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	28 (34.6%)	20 (28.2%)	
Patients (%) Without Events (Censored)	53 (65.4%)	51 (71.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (13.14, NR)	NR (9.10, NR)	
Hazard Ratio (95% CI)		1.239 (0.696, 2.206)	
p-value		0.4689	
BRCA 1/2 status			0.0218
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	11 (26.2%)	12 (26.7%)	
Patients (%) Without Events (Censored)	31 (73.8%)	33 (73.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (12.22, NR)	
Hazard Ratio (95% CI)		0.856 (0.376, 1.949)	
p-value		0.7108	
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	1 (14.3%)	
Patients (%) Without Events (Censored)	4 (44.4%)	6 (85.7%)	
Median Time to First Serious TEAE, months (95% CI)	1.41 (0.23, NR)	21.42 (18.92, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0227	
Menopausal status			0.9619
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	8 (27.6%)	11 (32.4%)	
Patients (%) Without Events (Censored)	21 (72.4%)	23 (67.6%)	
Median Time to First Serious TEAE, months (95% CI)	NR (8.05, NR)	9.10 (5.98, NR)	
Hazard Ratio (95% CI)		0.815 (0.325, 2.044)	
p-value		0.6590	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	32 (33.7%)	31 (35.6%)	
Patients (%) Without Events (Censored)	63 (66.3%)	56 (64.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (13.14, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.854 (0.519, 1.406)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.5321	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
NC = Not Calculable: the hazard ratio and 95% CI are not estimable by the Cox model.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.7. Table 1.1.7: Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	87 (70.2%)	109 (89.3%)
Patients (%) Without Events (Censored)	37 (29.8%)	13 (10.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.51 (0.72, 3.68)	1.18 (0.95, 1.77)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.632 (0.472, 0.847)
p-value		0.0017

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.8. Table 1.1.8: Subgroup Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.9739
De novo			
Total Patients	29	26	
Patients (%) With Events	22 (75.9%)	24 (92.3%)	
Patients (%) Without Events (Censored)	7 (24.1%)	2 (7.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.25 (0.43, 2.63)	0.94 (0.72, 2.10)	
Hazard Ratio (95% CI)		0.702 (0.387, 1.273)	
p-value		0.2431	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	22 (71.0%)	28 (93.3%)	
Patients (%) Without Events (Censored)	9 (29.0%)	2 (6.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.69 (0.43, 11.10)	0.95 (0.72, 1.64)	
Hazard Ratio (95% CI)		0.706 (0.397, 1.257)	
p-value		0.2158	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	43 (67.2%)	57 (86.4%)	
Patients (%) Without Events (Censored)	21 (32.8%)	9 (13.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.52 (0.95, 6.28)	1.77 (1.05, 2.50)	
Hazard Ratio (95% CI)		0.576 (0.382, 0.868)	
p-value		0.0073	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Geographic region			0.9567
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	20 (66.7%)	29 (85.3%)	
Patients (%) Without Events (Censored)	10 (33.3%)	5 (14.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.99 (0.46, NR)	1.18 (0.72, 2.10)	
Hazard Ratio (95% CI)		0.694 (0.388, 1.243)	
p-value		0.2055	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	67 (71.3%)	80 (90.9%)	
Patients (%) Without Events (Censored)	27 (28.7%)	8 (9.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.77 (0.69, 4.14)	1.15 (0.95, 2.10)	
Hazard Ratio (95% CI)		0.625 (0.446, 0.875)	
p-value		0.0053	
Age group			0.0317
< 65			
Total Patients	98	94	
Patients (%) With Events	66 (67.3%)	84 (89.4%)	
Patients (%) Without Events (Censored)	32 (32.7%)	10 (10.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.37 (0.95, 4.34)	1.02 (0.92, 1.64)	
Hazard Ratio (95% CI)		0.554 (0.397, 0.774)	
p-value		0.0004	
>= 65			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	26	28	
Patients (%) With Events	21 (80.8%)	25 (89.3%)	
Patients (%) Without Events (Censored)	5 (19.2%)	3 (10.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.66 (0.33, 1.71)	1.56 (0.92, 3.81)	
Hazard Ratio (95% CI)		1.082 (0.596, 1.963)	
p-value		0.8099	
Race			0.2944
White			
Total Patients	80	75	
Patients (%) With Events	50 (62.5%)	66 (88.0%)	
Patients (%) Without Events (Censored)	30 (37.5%)	9 (12.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.37 (0.95, 9.86)	1.18 (0.95, 1.84)	
Hazard Ratio (95% CI)		0.546 (0.374, 0.797)	
p-value		0.0014	
Asian			
Total Patients	26	26	
Patients (%) With Events	20 (76.9%)	22 (84.6%)	
Patients (%) Without Events (Censored)	6 (23.1%)	4 (15.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.09 (0.49, 6.28)	1.64 (0.72, 3.02)	
Hazard Ratio (95% CI)		0.765 (0.411, 1.422)	
p-value		0.3809	
Other			
Total Patients	16	21	
Patients (%) With Events	15 (93.8%)	21 (100.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	1 (6.2%)	0	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.54 (0.30, 1.38)	0.95 (0.72, 2.50)	
Hazard Ratio (95% CI)		0.967 (0.474, 1.973)	
p-value		0.9209	
Baseline ECOG status			0.2955
0			
Total Patients	81	79	
Patients (%) With Events	52 (64.2%)	73 (92.4%)	
Patients (%) Without Events (Censored)	29 (35.8%)	6 (7.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.72, 6.28)	1.25 (0.95, 1.84)	
Hazard Ratio (95% CI)		0.583 (0.405, 0.840)	
p-value		0.0030	
1			
Total Patients	43	43	
Patients (%) With Events	35 (81.4%)	36 (83.7%)	
Patients (%) Without Events (Censored)	8 (18.6%)	7 (16.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.46, 3.81)	0.95 (0.72, 2.63)	
Hazard Ratio (95% CI)		0.758 (0.466, 1.232)	
p-value		0.2556	
History of liver metastasis			0.8948
Yes			
Total Patients	36	25	
Patients (%) With Events	26 (72.2%)	22 (88.0%)	
Patients (%) Without Events (Censored)	10 (27.8%)	3 (12.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.92 (0.43, 6.28)	0.95 (0.72, 2.33)	
Hazard Ratio (95% CI)		0.676 (0.371, 1.230)	
p-value		0.1866	
No			
Total Patients	88	97	
Patients (%) With Events	61 (69.3%)	87 (89.7%)	
Patients (%) Without Events (Censored)	27 (30.7%)	10 (10.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.69 (0.95, 4.34)	1.25 (0.95, 1.84)	
Hazard Ratio (95% CI)		0.608 (0.434, 0.853)	
p-value		0.0034	
History of brain metastasis			0.3065
Yes			
Total Patients	6	7	
Patients (%) With Events	5 (83.3%)	6 (85.7%)	
Patients (%) Without Events (Censored)	1 (16.7%)	1 (14.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.69 (0.20, NR)	1.64 (0.20, 2.50)	
Hazard Ratio (95% CI)		1.136 (0.338, 3.813)	
p-value		0.8367	
No			
Total Patients	118	115	
Patients (%) With Events	82 (69.5%)	103 (89.6%)	
Patients (%) Without Events (Censored)	36 (30.5%)	12 (10.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.61 (0.72, 3.68)	1.15 (0.95, 1.77)	
Hazard Ratio (95% CI)		0.612 (0.453, 0.827)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0011	
PD-L1 Status			0.6218
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	27 (62.8%)	43 (84.3%)	
Patients (%) Without Events (Censored)	16 (37.2%)	8 (15.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.52 (0.72, 9.86)	1.41 (0.95, 2.27)	
Hazard Ratio (95% CI)		0.582 (0.354, 0.957)	
p-value		0.0296	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	60 (74.1%)	66 (93.0%)	
Patients (%) Without Events (Censored)	21 (25.9%)	5 (7.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.99 (0.69, 2.63)	0.99 (0.89, 1.84)	
Hazard Ratio (95% CI)		0.654 (0.456, 0.939)	
p-value		0.0187	
BRCA 1/2 status			0.0451
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	28 (66.7%)	37 (82.2%)	
Patients (%) Without Events (Censored)	14 (33.3%)	8 (17.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.31 (0.72, 6.28)	0.95 (0.72, 1.35)	
Hazard Ratio (95% CI)		0.597 (0.360, 0.989)	
p-value		0.0427	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Mutant			
Total Patients	9	7	
Patients (%) With Events	8 (88.9%)	7 (100.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	0	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.43 (0.23, 5.39)	2.10 (0.72, 4.63)	
Hazard Ratio (95% CI)		1.930 (0.649, 5.742)	
p-value		0.2418	
Menopausal status			0.9005
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	19 (65.5%)	30 (88.2%)	
Patients (%) Without Events (Censored)	10 (34.5%)	4 (11.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.99 (0.69, 8.05)	0.97 (0.85, 2.27)	
Hazard Ratio (95% CI)		0.646 (0.359, 1.161)	
p-value		0.1353	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	68 (71.6%)	79 (90.8%)	
Patients (%) Without Events (Censored)	27 (28.4%)	8 (9.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.72, 4.14)	1.18 (0.92, 1.77)	
Hazard Ratio (95% CI)		0.613 (0.437, 0.859)	
p-value		0.0037	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.9. Table 1.1.9: Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Number of patients at risk	124 (100.0%)	122 (100.0%)
Number of patients with events	5 (4.0%)	22 (18.0%)
Sacituzumab Govitecan	5 (4.0%)	0
Gemcitabine	0	11 (9.0%)
Carboplatin	0	21 (17.2%)
Number of patients censored	119 (96.0%)	100 (82.0%)
Probability of being event-free [a] [95% CI] [b] at:		
Month 3	96.7 [91.4, 98.7]	94.8 [88.9, 97.7]
Month 6	96.7 [91.4, 98.7]	90.5 [83.0, 94.8]
Month 9	96.7 [91.4, 98.7]	81.0 [70.2, 88.2]
Month 12	96.7 [91.4, 98.7]	70.7 [55.0, 81.8]
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (14.55, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.170 (0.064, 0.454)
p-value		0.0001

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.

	SG (N=124)	TPC (N=122)

[a] Estimated from the Kaplan-Meier method.
[b] Calculated using the log-log transformation (Brookmeyer-Crowley method).
[c] Median 95% CI based on Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties. p-value is from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm in the Safety Analysis Set.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.10. Table 1.1.10: Subgroup Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2680
De novo			
Total Patients	29	26	
Patients (%) With Events	3 (10.3%)	5 (19.2%)	
Patients (%) Without Events (Censored)	26 (89.7%)	21 (80.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (7.16, NR)	
Hazard Ratio (95% CI)		0.440 (0.102, 1.893)	
p-value		0.2601	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	0	3 (10.0%)	
Patients (%) Without Events (Censored)	31 (100.0%)	27 (90.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.73, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0275	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	64	66	
Patients (%) With Events	2 (3.1%)	14 (21.2%)	
Patients (%) Without Events (Censored)	62 (96.9%)	52 (78.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.93, NR)	
Hazard Ratio (95% CI)		0.126 (0.029, 0.556)	
p-value		0.0012	
Geographic region			0.0896
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	0	6 (17.6%)	
Patients (%) Without Events (Censored)	30 (100.0%)	28 (82.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.93, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0077	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	5 (5.3%)	16 (18.2%)	
Patients (%) Without Events (Censored)	89 (94.7%)	72 (81.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (12.06, NR)	
Hazard Ratio (95% CI)		0.231 (0.084, 0.637)	
p-value		0.0021	
Age group			0.0661
< 65			
Total Patients	98	94	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	3 (3.1%)	19 (20.2%)	
Patients (%) Without Events (Censored)	95 (96.9%)	75 (79.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.93, NR)	
Hazard Ratio (95% CI)		0.100 (0.029, 0.343)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	2 (7.7%)	3 (10.7%)	
Patients (%) Without Events (Censored)	24 (92.3%)	25 (89.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (19.61, NR)	
Hazard Ratio (95% CI)		0.776 (0.126, 4.767)	
p-value		0.7834	
Race			0.0373
White			
Total Patients	80	75	
Patients (%) With Events	2 (2.5%)	17 (22.7%)	
Patients (%) Without Events (Censored)	78 (97.5%)	58 (77.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.73, NR)	
Hazard Ratio (95% CI)		0.085 (0.020, 0.371)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	3 (11.5%)	2 (7.7%)	
Patients (%) Without Events (Censored)	23 (88.5%)	24 (92.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.07, NR)	
Hazard Ratio (95% CI)		1.167 (0.191, 7.133)	
p-value		0.8669	
Other			
Total Patients	16	21	
Patients (%) With Events	0	3 (14.3%)	
Patients (%) Without Events (Censored)	16 (100.0%)	18 (85.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	14.55 (14.55, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0478	
Baseline ECOG status			0.6486
0			
Total Patients	81	79	
Patients (%) With Events	3 (3.7%)	16 (20.3%)	
Patients (%) Without Events (Censored)	78 (96.3%)	63 (79.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (12.06, NR)	
Hazard Ratio (95% CI)		0.137 (0.039, 0.474)	
p-value		0.0003	
1			
Total Patients	43	43	
Patients (%) With Events	2 (4.7%)	6 (14.0%)	
Patients (%) Without Events (Censored)	41 (95.3%)	37 (86.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (8.48, NR)	
Hazard Ratio (95% CI)		0.262 (0.052, 1.321)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0822	
History of liver metastasis			0.1037
Yes			
Total Patients	36	25	
Patients (%) With Events	0	3 (12.0%)	
Patients (%) Without Events (Censored)	36 (100.0%)	22 (88.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.44, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0034	
No			
Total Patients	88	97	
Patients (%) With Events	5 (5.7%)	19 (19.6%)	
Patients (%) Without Events (Censored)	83 (94.3%)	78 (80.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.230 (0.085, 0.621)	
p-value		0.0016	
History of brain metastasis			0.4507
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	3 (42.9%)	
Patients (%) Without Events (Censored)	5 (83.3%)	4 (57.1%)	
Median Time to Discontinuation, months (95% CI)	NR (1.58, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		0.453 (0.047, 4.379)	
p-value		0.4831	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
No			
Total Patients	118	115	
Patients (%) With Events	4 (3.4%)	19 (16.5%)	
Patients (%) Without Events (Censored)	114 (96.6%)	96 (83.5%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.150 (0.051, 0.445)	
p-value		0.0001	
PD-L1 Status			0.0034
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	0	15 (29.4%)	
Patients (%) Without Events (Censored)	43 (100.0%)	36 (70.6%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	12.06 (7.16, NR)	
Hazard Ratio (95% CI)		NC	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	5 (6.2%)	7 (9.9%)	
Patients (%) Without Events (Censored)	76 (93.8%)	64 (90.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.495 (0.154, 1.590)	
p-value		0.2288	
BRCA 1/2 status			0.1311
Wild-Type			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	42	45	
Patients (%) With Events	0	4 (8.9%)	
Patients (%) Without Events (Censored)	42 (100.0%)	41 (91.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0477	
Mutant			
Total Patients	9	7	
Patients (%) With Events	1 (11.1%)	2 (28.6%)	
Patients (%) Without Events (Censored)	8 (88.9%)	5 (71.4%)	
Median Time to Discontinuation, months (95% CI)	NR (2.33, NR)	19.61 (6.93, NR)	
Hazard Ratio (95% CI)		0.966 (0.059, 15.699)	
p-value		0.9807	
Menopausal status			0.7835
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	1 (3.4%)	5 (14.7%)	
Patients (%) Without Events (Censored)	28 (96.6%)	29 (85.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.214 (0.025, 1.845)	
p-value		0.1231	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	4 (4.2%)	17 (19.5%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	91 (95.8%)	70 (80.5%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.93, NR)	
Hazard Ratio (95% CI)		0.152 (0.050, 0.456)	
p-value		0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. NC = Not Calculable (HR is NC when one treatment arm has zero events; log-rank p-value remains valid).
Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.11. Table 1.1.11: Analysis of Time to First TEAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Blood and lymphatic system disorders		
Total Patients	124	122
Patients (%) With Events	95 (76.6%)	116 (95.1%)
Patients (%) Without Events (Censored)	29 (23.4%)	6 (4.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.72 (0.69, 1.08)	0.69 (0.49, 0.72)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.570 (0.431, 0.754)
p-value		0.0001
Anaemia		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	46 (37.1%)	83 (68.0%)
Patients (%) Without Events (Censored)	78 (62.9%)	39 (32.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	16.99 (10.68, NR)	2.10 (1.71, 2.73)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.381 (0.265, 0.549)
p-value		<0.0001
Leukopenia		
Total Patients	124	122
Patients (%) With Events	38 (30.6%)	54 (44.3%)
Patients (%) Without Events (Censored)	86 (69.4%)	68 (55.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	29.90 (23.66, NR)	9.92 (5.78, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.598 (0.393, 0.910)
p-value		0.0151
Lymphopenia		
Total Patients	124	122
Patients (%) With Events	20 (16.1%)	19 (15.6%)
Patients (%) Without Events (Censored)	104 (83.9%)	103 (84.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		1.006 (0.536, 1.889)
p-value		0.9854
Neutropenia		
Total Patients	124	122
Patients (%) With Events	83 (66.9%)	105 (86.1%)
Patients (%) Without Events (Censored)	41 (33.1%)	17 (13.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 3.09)	0.92 (0.72, 0.95)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.618 (0.460, 0.829)
p-value		0.0010
Thrombocytopenia		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	70 (57.4%)
Patients (%) Without Events (Censored)	119 (96.0%)	52 (42.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	4.83 (3.94, 6.18)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.043 (0.017, 0.108)
p-value		<0.0001
Cardiac disorders		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	12 (9.8%)
Patients (%) Without Events (Censored)	115 (92.7%)	110 (90.2%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (23.92, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.676 (0.284, 1.611)
p-value		0.3735
Ear and labyrinth disorders		
Total Patients	124	122
Patients (%) With Events	4 (3.2%)	6 (4.9%)
Patients (%) Without Events (Censored)	120 (96.8%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.635 (0.179, 2.252)
p-value		0.4778
Eye disorders		
Total Patients	124	122
Patients (%) With Events	21 (16.9%)	5 (4.1%)
Patients (%) Without Events (Censored)	103 (83.1%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (19.65, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.057 (1.526, 10.786)
p-value		0.0024
Gastrointestinal disorders		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	113 (91.1%)	95 (77.9%)
Patients (%) Without Events (Censored)	11 (8.9%)	27 (22.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.23 (0.13, 0.30)	0.72 (0.30, 1.05)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.638 (1.243, 2.160)
p-value		0.0003
Abdominal pain		
Total Patients	124	122
Patients (%) With Events	21 (16.9%)	8 (6.6%)
Patients (%) Without Events (Censored)	103 (83.1%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.672 (1.183, 6.036)
p-value		0.0140
Abdominal pain upper		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	8 (6.6%)
Patients (%) Without Events (Censored)	112 (90.3%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		1.472 (0.601, 3.604)
p-value		0.3946
Constipation		
Total Patients	124	122
Patients (%) With Events	50 (40.3%)	41 (33.6%)
Patients (%) Without Events (Censored)	74 (59.7%)	81 (66.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (5.09, NR)	NR (14.16, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.205 (0.797, 1.822)
p-value		0.3724
Diarrhoea		
Total Patients	124	122
Patients (%) With Events	71 (57.3%)	27 (22.1%)
Patients (%) Without Events (Censored)	53 (42.7%)	95 (77.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	3.52 (1.58, 11.04)	NR (20.96, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.576 (2.286, 5.594)
p-value		<0.0001
Dyspepsia		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	6 (4.9%)
Patients (%) Without Events (Censored)	114 (91.9%)	116 (95.1%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.539 (0.557, 4.252)
p-value		0.4020
Nausea		
Total Patients	124	122
Patients (%) With Events	80 (64.5%)	58 (47.5%)
Patients (%) Without Events (Censored)	44 (35.5%)	64 (52.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.14 (0.36, 4.47)	9.33 (3.09, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.591 (1.134, 2.234)
p-value		0.0064
Stomatitis		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	6 (4.9%)
Patients (%) Without Events (Censored)	109 (87.9%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.221 (0.859, 5.738)
p-value		0.0909
Vomiting		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	38 (30.6%)	22 (18.0%)
Patients (%) Without Events (Censored)	86 (69.4%)	100 (82.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (12.68, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.693 (1.000, 2.864)
p-value		0.0471
General disorders and administration site conditions		
Total Patients	124	122
Patients (%) With Events	83 (66.9%)	79 (64.8%)
Patients (%) Without Events (Censored)	41 (33.1%)	43 (35.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.91 (1.38, 3.12)	2.92 (1.84, 4.44)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.066 (0.782, 1.451)
p-value		0.6860
Fatigue		
Total Patients	124	122
Patients (%) With Events	61 (49.2%)	63 (51.6%)
Patients (%) Without Events (Censored)	63 (50.8%)	59 (48.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	7.66 (2.53, NR)	6.28 (2.63, 17.51)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		0.949 (0.667, 1.350)
p-value		0.7680
Malaise		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	3 (2.5%)
Patients (%) Without Events (Censored)	117 (94.4%)	119 (97.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.344 (0.606, 9.067)
p-value		0.2033
Oedema peripheral		
Total Patients	124	122
Patients (%) With Events	14 (11.3%)	8 (6.6%)
Patients (%) Without Events (Censored)	110 (88.7%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.643 (0.689, 3.921)
p-value		0.2578
Pyrexia		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	17 (13.9%)
Patients (%) Without Events (Censored)	112 (90.3%)	105 (86.1%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.624 (0.297, 1.309)
p-value		0.2075
Hepatobiliary disorders		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	7 (5.7%)
Patients (%) Without Events (Censored)	116 (93.5%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.034 (0.374, 2.862)
p-value		0.9482
Immune system disorders		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	5 (4.1%)
Patients (%) Without Events (Censored)	117 (94.4%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.330 (0.422, 4.199)
p-value		0.6252
Infections and infestations		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	67 (54.0%)	64 (52.5%)
Patients (%) Without Events (Censored)	57 (46.0%)	58 (47.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	7.20 (5.09, 8.48)	5.59 (4.01, 9.46)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.964 (0.684, 1.358)
p-value		0.8335
COVID-19		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	8 (6.6%)
Patients (%) Without Events (Censored)	117 (94.4%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.786 (0.284, 2.172)
p-value		0.6415
Influenza		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	6 (4.9%)
Patients (%) Without Events (Censored)	119 (96.0%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (20.53, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		0.711 (0.216, 2.340)
p-value		0.5724
Nasopharyngitis		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	6 (4.9%)
Patients (%) Without Events (Censored)	117 (94.4%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (22.97, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.015 (0.340, 3.026)
p-value		0.9794
Pneumonia		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	10 (8.2%)
Patients (%) Without Events (Censored)	118 (95.2%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.446 (0.161, 1.239)
p-value		0.1120
Upper respiratory tract infection		
Total Patients	124	122
Patients (%) With Events	14 (11.3%)	6 (4.9%)
Patients (%) Without Events (Censored)	110 (88.7%)	116 (95.1%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.092 (0.802, 5.455)
p-value		0.1226
Urinary tract infection		
Total Patients	124	122
Patients (%) With Events	18 (14.5%)	19 (15.6%)
Patients (%) Without Events (Censored)	106 (85.5%)	103 (84.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.874 (0.458, 1.668)
p-value		0.6824
Injury, poisoning and procedural complications		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	21 (17.2%)
Patients (%) Without Events (Censored)	111 (89.5%)	101 (82.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.83, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.508 (0.253, 1.021)
p-value		0.0528
Investigations		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	51 (41.1%)	66 (54.1%)
Patients (%) Without Events (Censored)	73 (58.9%)	56 (45.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	15.41 (6.93, NR)	3.68 (1.64, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.607 (0.421, 0.876)
p-value		0.0075
Alanine aminotransferase increased		
Total Patients	124	122
Patients (%) With Events	24 (19.4%)	54 (44.3%)
Patients (%) Without Events (Censored)	100 (80.6%)	68 (55.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (3.22, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.335 (0.207, 0.544)
p-value		<0.0001
Aspartate aminotransferase increased		
Total Patients	124	122
Patients (%) With Events	23 (18.5%)	43 (35.2%)
Patients (%) Without Events (Censored)	101 (81.5%)	79 (64.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		0.436 (0.263, 0.725)
p-value		0.0010
Blood alkaline phosphatase increased		
Total Patients	124	122
Patients (%) With Events	18 (14.5%)	10 (8.2%)
Patients (%) Without Events (Censored)	106 (85.5%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.733 (0.799, 3.759)
p-value		0.1589
Gamma-glutamyltransferase increased		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	10 (8.2%)
Patients (%) Without Events (Censored)	117 (94.4%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.639 (0.243, 1.680)
p-value		0.3612
Weight decreased		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	5 (4.1%)
Patients (%) Without Events (Censored)	112 (90.3%)	117 (95.9%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.393 (0.842, 6.800)
p-value		0.0912
Metabolism and nutrition disorders		
Total Patients	124	122
Patients (%) With Events	54 (43.5%)	42 (34.4%)
Patients (%) Without Events (Censored)	70 (56.5%)	80 (65.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	11.43 (6.21, NR)	15.44 (11.20, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.370 (0.912, 2.056)
p-value		0.1281
Decreased appetite		
Total Patients	124	122
Patients (%) With Events	25 (20.2%)	11 (9.0%)
Patients (%) Without Events (Censored)	99 (79.8%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.216 (1.089, 4.508)
p-value		0.0241
Hyperglycaemia		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	11 (9.0%)
Patients (%) Without Events (Censored)	111 (89.5%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.145 (0.512, 2.561)
p-value		0.7439
Hypocalcaemia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	7 (5.7%)
Patients (%) Without Events (Censored)	116 (93.5%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	26.48 (26.48, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.069 (0.384, 2.976)
p-value		0.8959
Hypokalaemia		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	11 (9.0%)
Patients (%) Without Events (Censored)	115 (92.7%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		0.740 (0.305, 1.795)
p-value		0.5040
Hypomagnesaemia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	10 (8.2%)
Patients (%) Without Events (Censored)	116 (93.5%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.19, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.640 (0.251, 1.633)
p-value		0.3467
Hyponatraemia		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	7 (5.7%)
Patients (%) Without Events (Censored)	116 (93.5%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.134 (0.411, 3.128)
p-value		0.8061
Musculoskeletal and connective tissue disorders		
Total Patients	124	122
Patients (%) With Events	46 (37.1%)	43 (35.2%)
Patients (%) Without Events (Censored)	78 (62.9%)	79 (64.8%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.13 (10.41, NR)	13.50 (11.14, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.964 (0.634, 1.464)
p-value		0.8620
Arthralgia		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	13 (10.7%)
Patients (%) Without Events (Censored)	111 (89.5%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.864 (0.398, 1.876)
p-value		0.7112
Back pain		
Total Patients	124	122
Patients (%) With Events	11 (8.9%)	12 (9.8%)
Patients (%) Without Events (Censored)	113 (91.1%)	110 (90.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.68, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.800 (0.351, 1.823)
p-value		0.5951
Myalgia		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	11 (9.0%)
Patients (%) Without Events (Censored)	114 (91.9%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.795 (0.336, 1.884)
p-value		0.6021
Pain in extremity		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	11 (9.0%)
Patients (%) Without Events (Censored)	119 (96.0%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (24.44, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.392 (0.136, 1.132)
p-value		0.0728
Nervous system disorders		
Total Patients	124	122
Patients (%) With Events	48 (38.7%)	39 (32.0%)
Patients (%) Without Events (Censored)	76 (61.3%)	83 (68.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.29 (7.39, NR)	NR (12.58, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		1.174 (0.769, 1.793)
p-value		0.4514
Dizziness		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	9 (7.4%)
Patients (%) Without Events (Censored)	116 (93.5%)	113 (92.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (25.26, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.809 (0.312, 2.101)
p-value		0.6638
Dysgeusia		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	8 (6.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.203 (0.474, 3.051)
p-value		0.6970
Headache		
Total Patients	124	122
Patients (%) With Events	20 (16.1%)	20 (16.4%)
Patients (%) Without Events (Censored)	104 (83.9%)	102 (83.6%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.932 (0.501, 1.735)
p-value		0.8249
Neuropathy peripheral		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	5 (4.1%)
Patients (%) Without Events (Censored)	116 (93.5%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.370 (0.447, 4.202)
p-value		0.5802
Psychiatric disorders		
Total Patients	124	122
Patients (%) With Events	17 (13.7%)	13 (10.7%)
Patients (%) Without Events (Censored)	107 (86.3%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.295 (0.629, 2.669)
p-value		0.4814
Anxiety		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	6 (4.9%)
Patients (%) Without Events (Censored)	119 (96.0%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.763 (0.232, 2.503)
p-value		0.6539
Depression		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	2 (1.6%)
Patients (%) Without Events (Censored)	115 (92.7%)	120 (98.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.323 (0.933, 20.034)
p-value		0.0411
Insomnia		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	4 (3.3%)
Patients (%) Without Events (Censored)	118 (95.2%)	118 (96.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		1.442 (0.405, 5.129)
p-value		0.5700
Renal and urinary disorders		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	7 (5.7%)
Patients (%) Without Events (Censored)	109 (87.9%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.042 (0.831, 5.017)
p-value		0.1122
Reproductive system and breast disorders		
Total Patients	124	122
Patients (%) With Events	12 (9.7%)	13 (10.7%)
Patients (%) Without Events (Censored)	112 (90.3%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.847 (0.386, 1.861)
p-value		0.6796
Breast pain		
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	10 (8.2%)
Patients (%) Without Events (Censored)	116 (93.5%)	112 (91.8%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.725 (0.286, 1.843)
p-value		0.4975
Respiratory, thoracic and mediastinal disorders		
Total Patients	124	122
Patients (%) With Events	47 (37.9%)	39 (32.0%)
Patients (%) Without Events (Censored)	77 (62.1%)	83 (68.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	15.41 (12.09, NR)	22.05 (10.55, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.193 (0.779, 1.827)
p-value		0.4176
Cough		
Total Patients	124	122
Patients (%) With Events	24 (19.4%)	11 (9.0%)
Patients (%) Without Events (Censored)	100 (80.6%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (18.17, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.088 (1.021, 4.268)
p-value		0.0391
Dyspnoea		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	17 (13.9%)
Patients (%) Without Events (Censored)	111 (89.5%)	105 (86.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (22.05, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.735 (0.357, 1.517)
p-value		0.4024
Oropharyngeal pain		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	4 (3.3%)
Patients (%) Without Events (Censored)	118 (95.2%)	118 (96.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.484 (0.419, 5.260)
p-value		0.5381
Pulmonary embolism		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	5 (4.1%)
Patients (%) Without Events (Censored)	118 (95.2%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=124)	TPC (N=122)
Hazard Ratio (95% CI)		1.188 (0.363, 3.893)
p-value		0.7757
Skin and subcutaneous tissue disorders		
Total Patients	124	122
Patients (%) With Events	85 (68.5%)	45 (36.9%)
Patients (%) Without Events (Censored)	39 (31.5%)	77 (63.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.92 (0.69, 1.15)	23.56 (6.74, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.949 (2.045, 4.252)
p-value		<0.0001
Alopecia		
Total Patients	124	122
Patients (%) With Events	68 (54.8%)	18 (14.8%)
Patients (%) Without Events (Censored)	56 (45.2%)	104 (85.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.38 (0.82, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		5.651 (3.353, 9.523)
p-value		<0.0001
Pruritus		
Total Patients	124	122
Patients (%) With Events	13 (10.5%)	3 (2.5%)
Patients (%) Without Events (Censored)	111 (89.5%)	119 (97.5%)

	SG (N=124)	TPC (N=122)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (21.03, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.253 (1.209, 14.955)
p-value		0.0141
Rash		
Total Patients	124	122
Patients (%) With Events	16 (12.9%)	11 (9.0%)
Patients (%) Without Events (Censored)	108 (87.1%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.334 (0.618, 2.879)
p-value		0.4616
Vascular disorders		
Total Patients	124	122
Patients (%) With Events	21 (16.9%)	19 (15.6%)
Patients (%) Without Events (Censored)	103 (83.1%)	103 (84.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	25.56 (18.73, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.013 (0.544, 1.887)
p-value		0.9672
Hot flush		

	SG (N=124)	TPC (N=122)
Total Patients	124	122
Patients (%) With Events	8 (6.5%)	3 (2.5%)
Patients (%) Without Events (Censored)	116 (93.5%)	119 (97.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.601 (0.690, 9.813)
p-value		0.1426

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.12. Table 1.1.12.1: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.5541
De novo			
Total Patients	29	26	
Patients (%) With Events	21 (72.4%)	25 (96.2%)	
Patients (%) Without Events (Censored)	8 (27.6%)	1 (3.8%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.26, 1.38)	0.79 (0.26, 0.95)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.674 (0.373, 1.219)	
p-value		0.1759	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	26 (83.9%)	28 (93.3%)	
Patients (%) Without Events (Censored)	5 (16.1%)	2 (6.7%)	
Median Time to First TEAE, months (95% CI)	0.69 (0.26, 0.76)	0.69 (0.26, 0.92)	
Hazard Ratio (95% CI)		0.787 (0.458, 1.352)	
p-value		0.3154	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	48 (75.0%)	63 (95.5%)	
Patients (%) Without Events (Censored)	16 (25.0%)	3 (4.5%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.69, 2.30)	0.69 (0.26, 0.72)	
Hazard Ratio (95% CI)		0.468 (0.317, 0.690)	
p-value		0.0001	
Geographic region			0.2910
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	18 (60.0%)	31 (91.2%)	
Patients (%) Without Events (Censored)	12 (40.0%)	3 (8.8%)	
Median Time to First TEAE, months (95% CI)	1.17 (0.66, NR)	0.72 (0.26, 0.95)	
Hazard Ratio (95% CI)		0.458 (0.254, 0.828)	
p-value		0.0069	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	77 (81.9%)	85 (96.6%)	
Patients (%) Without Events (Censored)	17 (18.1%)	3 (3.4%)	
Median Time to First TEAE, months (95% CI)	0.71 (0.66, 0.92)	0.69 (0.49, 0.72)	
Hazard Ratio (95% CI)		0.605 (0.440, 0.831)	
p-value		0.0015	
Age group			0.6783
< 65			
Total Patients	98	94	
Patients (%) With Events	77 (78.6%)	90 (95.7%)	
Patients (%) Without Events (Censored)	21 (21.4%)	4 (4.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.72 (0.62, 0.72)	
Hazard Ratio (95% CI)		0.583 (0.427, 0.798)	
p-value		0.0005	
>= 65			
Total Patients	26	28	
Patients (%) With Events	18 (69.2%)	26 (92.9%)	
Patients (%) Without Events (Censored)	8 (30.8%)	2 (7.1%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.30, 10.35)	0.28 (0.26, 0.89)	
Hazard Ratio (95% CI)		0.519 (0.279, 0.963)	
p-value		0.0353	
Race			0.2578
White			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	80	75	
Patients (%) With Events	59 (73.8%)	72 (96.0%)	
Patients (%) Without Events (Censored)	21 (26.2%)	3 (4.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.69 (0.49, 0.72)	
Hazard Ratio (95% CI)		0.518 (0.363, 0.738)	
p-value		0.0002	
Asian			
Total Patients	26	26	
Patients (%) With Events	22 (84.6%)	24 (92.3%)	
Patients (%) Without Events (Censored)	4 (15.4%)	2 (7.7%)	
Median Time to First TEAE, months (95% CI)	0.67 (0.26, 2.27)	0.71 (0.26, 1.84)	
Hazard Ratio (95% CI)		0.875 (0.486, 1.575)	
p-value		0.6440	
Other			
Total Patients	16	21	
Patients (%) With Events	13 (81.2%)	20 (95.2%)	
Patients (%) Without Events (Censored)	3 (18.8%)	1 (4.8%)	
Median Time to First TEAE, months (95% CI)	0.80 (0.26, 5.09)	0.89 (0.23, 0.95)	
Hazard Ratio (95% CI)		0.461 (0.212, 1.002)	
p-value		0.0430	
Baseline ECOG status			0.6862
0			
Total Patients	81	79	
Patients (%) With Events	64 (79.0%)	76 (96.2%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	17 (21.0%)	3 (3.8%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 0.92)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.599 (0.426, 0.842)	
p-value		0.0024	
1			
Total Patients	43	43	
Patients (%) With Events	31 (72.1%)	40 (93.0%)	
Patients (%) Without Events (Censored)	12 (27.9%)	3 (7.0%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.43, 2.73)	0.69 (0.26, 0.92)	
Hazard Ratio (95% CI)		0.537 (0.331, 0.872)	
p-value		0.0101	
History of liver metastasis			0.7117
Yes			
Total Patients	36	25	
Patients (%) With Events	29 (80.6%)	23 (92.0%)	
Patients (%) Without Events (Censored)	7 (19.4%)	2 (8.0%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.43, 2.33)	0.69 (0.30, 0.92)	
Hazard Ratio (95% CI)		0.626 (0.355, 1.103)	
p-value		0.0986	
No			
Total Patients	88	97	
Patients (%) With Events	66 (75.0%)	93 (95.9%)	
Patients (%) Without Events (Censored)	22 (25.0%)	4 (4.1%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.69 (0.30, 0.72)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.549 (0.397, 0.759)	
p-value		0.0002	
History of brain metastasis			0.2427
Yes			
Total Patients	6	7	
Patients (%) With Events	5 (83.3%)	6 (85.7%)	
Patients (%) Without Events (Censored)	1 (16.7%)	1 (14.3%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.23, NR)	1.64 (0.26, NR)	
Hazard Ratio (95% CI)		1.415 (0.403, 4.961)	
p-value		0.5860	
No			
Total Patients	118	115	
Patients (%) With Events	90 (76.3%)	110 (95.7%)	
Patients (%) Without Events (Censored)	28 (23.7%)	5 (4.3%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.08)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.555 (0.416, 0.739)	
p-value		<0.0001	
PD-L1 Status			0.4344
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	33 (76.7%)	46 (90.2%)	
Patients (%) Without Events (Censored)	10 (23.3%)	5 (9.8%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.56, 2.30)	0.72 (0.66, 0.95)	
Hazard Ratio (95% CI)		0.650 (0.409, 1.032)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0694	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	62 (76.5%)	70 (98.6%)	
Patients (%) Without Events (Censored)	19 (23.5%)	1 (1.4%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.69, 1.38)	0.59 (0.26, 0.72)	
Hazard Ratio (95% CI)		0.509 (0.357, 0.725)	
p-value		0.0001	
BRCA 1/2 status			0.1218
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	27 (64.3%)	42 (93.3%)	
Patients (%) Without Events (Censored)	15 (35.7%)	3 (6.7%)	
Median Time to First TEAE, months (95% CI)	1.25 (0.66, NR)	0.62 (0.26, 0.72)	
Hazard Ratio (95% CI)		0.416 (0.251, 0.687)	
p-value		0.0004	
Mutant			
Total Patients	9	7	
Patients (%) With Events	8 (88.9%)	7 (100.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	0 (0.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.23, 5.26)	0.95 (0.26, 2.10)	
Hazard Ratio (95% CI)		0.830 (0.287, 2.398)	
p-value		0.7136	
Menopausal status			0.7519

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	20 (69.0%)	33 (97.1%)	
Patients (%) Without Events (Censored)	9 (31.0%)	1 (2.9%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.43, 3.78)	0.72 (0.26, 0.95)	
Hazard Ratio (95% CI)		0.530 (0.302, 0.931)	
p-value		0.0212	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	75 (78.9%)	82 (94.3%)	
Patients (%) Without Events (Censored)	20 (21.1%)	5 (5.7%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.66, 1.08)	0.69 (0.30, 0.72)	
Hazard Ratio (95% CI)		0.589 (0.426, 0.814)	
p-value		0.0012	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.13. Table 1.1.12.2: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.4977
De novo			
Total Patients	29	26	
Patients (%) With Events	26 (89.7%)	21 (80.8%)	
Patients (%) Without Events (Censored)	3 (10.3%)	5 (19.2%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.36)	0.36 (0.13, 0.76)	
Hazard Ratio (95% CI)		1.371 (0.768, 2.448)	
p-value		0.2673	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	28 (90.3%)	22 (73.3%)	
Patients (%) Without Events (Censored)	3 (9.7%)	8 (26.7%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.13, 0.99)	0.87 (0.26, 3.29)	
Hazard Ratio (95% CI)		1.415 (0.800, 2.501)	
p-value		0.2216	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	59 (92.2%)	52 (78.8%)	
Patients (%) Without Events (Censored)	5 (7.8%)	14 (21.2%)	
Median Time to First TEAE, months (95% CI)	0.21 (0.10, 0.30)	0.89 (0.13, 2.73)	
Hazard Ratio (95% CI)		1.946 (1.322, 2.866)	
p-value		0.0005	
Geographic region			0.4855

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	28 (93.3%)	26 (76.5%)	
Patients (%) Without Events (Censored)	2 (6.7%)	8 (23.5%)	
Median Time to First TEAE, months (95% CI)	0.18 (0.10, 0.26)	0.76 (0.13, 2.37)	
Hazard Ratio (95% CI)		2.064 (1.191, 3.576)	
p-value		0.0089	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	85 (90.4%)	69 (78.4%)	
Patients (%) Without Events (Censored)	9 (9.6%)	19 (21.6%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.72 (0.26, 1.38)	
Hazard Ratio (95% CI)		1.564 (1.133, 2.160)	
p-value		0.0053	
Age group			0.2920
< 65			
Total Patients	98	94	
Patients (%) With Events	89 (90.8%)	72 (76.6%)	
Patients (%) Without Events (Censored)	9 (9.2%)	22 (23.4%)	
Median Time to First TEAE, months (95% CI)	0.18 (0.10, 0.33)	0.72 (0.26, 0.95)	
Hazard Ratio (95% CI)		1.508 (1.103, 2.061)	
p-value		0.0087	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	24 (92.3%)	23 (82.1%)	
Patients (%) Without Events (Censored)	2 (7.7%)	5 (17.9%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.30)	0.90 (0.13, 5.06)	
Hazard Ratio (95% CI)		2.491 (1.317, 4.714)	
p-value		0.0040	
Race			0.2838
White			
Total Patients	80	75	
Patients (%) With Events	73 (91.2%)	54 (72.0%)	
Patients (%) Without Events (Censored)	7 (8.8%)	21 (28.0%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	1.08 (0.69, 3.29)	
Hazard Ratio (95% CI)		1.940 (1.357, 2.772)	
p-value		0.0002	
Asian			
Total Patients	26	26	
Patients (%) With Events	24 (92.3%)	21 (80.8%)	
Patients (%) Without Events (Censored)	2 (7.7%)	5 (19.2%)	
Median Time to First TEAE, months (95% CI)	0.15 (0.10, 0.36)	0.18 (0.07, 5.06)	
Hazard Ratio (95% CI)		1.174 (0.645, 2.137)	
p-value		0.5612	
Other			
Total Patients	16	21	
Patients (%) With Events	14 (87.5%)	20 (95.2%)	
Patients (%) Without Events (Censored)	2 (12.5%)	1 (4.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.23 (0.07, 0.59)	0.30 (0.10, 0.76)	
Hazard Ratio (95% CI)		1.165 (0.583, 2.329)	
p-value		0.6773	
Baseline ECOG status			0.3907
0			
Total Patients	81	79	
Patients (%) With Events	73 (90.1%)	59 (74.7%)	
Patients (%) Without Events (Censored)	8 (9.9%)	20 (25.3%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.33)	0.76 (0.23, 1.87)	
Hazard Ratio (95% CI)		1.718 (1.213, 2.434)	
p-value		0.0018	
1			
Total Patients	43	43	
Patients (%) With Events	40 (93.0%)	36 (83.7%)	
Patients (%) Without Events (Censored)	3 (7.0%)	7 (16.3%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.72 (0.23, 1.05)	
Hazard Ratio (95% CI)		1.497 (0.950, 2.360)	
p-value		0.0792	
History of liver metastasis			0.5881
Yes			
Total Patients	36	25	
Patients (%) With Events	33 (91.7%)	19 (76.0%)	
Patients (%) Without Events (Censored)	3 (8.3%)	6 (24.0%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.10, 0.36)	0.33 (0.07, 3.29)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.356 (0.767, 2.395)	
p-value		0.2703	
No			
Total Patients	88	97	
Patients (%) With Events	80 (90.9%)	76 (78.4%)	
Patients (%) Without Events (Censored)	8 (9.1%)	21 (21.6%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.30)	0.76 (0.30, 1.74)	
Hazard Ratio (95% CI)		1.697 (1.234, 2.334)	
p-value		0.0009	
History of brain metastasis			0.6972
Yes			
Total Patients	6	7	
Patients (%) With Events	6 (100.0%)	6 (85.7%)	
Patients (%) Without Events (Censored)	0 (0.0%)	1 (14.3%)	
Median Time to First TEAE, months (95% CI)	0.28 (0.10, NR)	2.73 (0.10, NR)	
Hazard Ratio (95% CI)		2.940 (0.714, 12.095)	
p-value		0.1121	
No			
Total Patients	118	115	
Patients (%) With Events	107 (90.7%)	89 (77.4%)	
Patients (%) Without Events (Censored)	11 (9.3%)	26 (22.6%)	
Median Time to First TEAE, months (95% CI)	0.21 (0.13, 0.30)	0.72 (0.30, 0.95)	
Hazard Ratio (95% CI)		1.604 (1.208, 2.132)	
p-value		0.0008	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.8970
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	40 (93.0%)	41 (80.4%)	
Patients (%) Without Events (Censored)	3 (7.0%)	10 (19.6%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.33)	0.76 (0.13, 3.12)	
Hazard Ratio (95% CI)		1.699 (1.092, 2.643)	
p-value		0.0169	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	73 (90.1%)	54 (76.1%)	
Patients (%) Without Events (Censored)	8 (9.9%)	17 (23.9%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.30)	0.72 (0.26, 1.05)	
Hazard Ratio (95% CI)		1.637 (1.145, 2.339)	
p-value		0.0054	
BRCA 1/2 status			0.1279
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	40 (95.2%)	34 (75.6%)	
Patients (%) Without Events (Censored)	2 (4.8%)	11 (24.4%)	
Median Time to First TEAE, months (95% CI)	0.31 (0.10, 0.36)	0.95 (0.26, 3.29)	
Hazard Ratio (95% CI)		1.908 (1.191, 3.058)	
p-value		0.0059	
Mutant			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	9	7	
Patients (%) With Events	7 (77.8%)	7 (100.0%)	
Patients (%) Without Events (Censored)	2 (22.2%)	0 (0.0%)	
Median Time to First TEAE, months (95% CI)	0.46 (0.03, 5.39)	0.33 (0.03, 3.52)	
Hazard Ratio (95% CI)		0.803 (0.269, 2.398)	
p-value		0.6960	
Menopausal status			0.9141
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	27 (93.1%)	27 (79.4%)	
Patients (%) Without Events (Censored)	2 (6.9%)	7 (20.6%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.36)	0.34 (0.10, 1.38)	
Hazard Ratio (95% CI)		1.552 (0.899, 2.678)	
p-value		0.1081	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	86 (90.5%)	67 (77.0%)	
Patients (%) Without Events (Censored)	9 (9.5%)	20 (23.0%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.76 (0.33, 2.37)	
Hazard Ratio (95% CI)		1.690 (1.222, 2.337)	
p-value		0.0012	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.14. Table 1.1.12.3: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.6704
De novo			
Total Patients	29	26	
Patients (%) With Events	12 (41.4%)	16 (61.5%)	
Patients (%) Without Events (Censored)	17 (58.6%)	10 (38.5%)	
Median Time to First TEAE, months (95% CI)	15.41 (3.71, NR)	1.45 (0.26, NR)	
Hazard Ratio (95% CI)		0.439 (0.203, 0.948)	
p-value		0.0315	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	16 (51.6%)	18 (60.0%)	
Patients (%) Without Events (Censored)	15 (48.4%)	12 (40.0%)	
Median Time to First TEAE, months (95% CI)	11.14 (2.69, NR)	1.49 (0.92, NR)	
Hazard Ratio (95% CI)		0.608 (0.304, 1.216)	
p-value		0.1624	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	23 (35.9%)	32 (48.5%)	
Patients (%) Without Events (Censored)	41 (64.1%)	34 (51.5%)	
Median Time to First TEAE, months (95% CI)	NR (6.93, NR)	7.95 (1.87, NR)	
Hazard Ratio (95% CI)		0.666 (0.390, 1.139)	
p-value		0.1380	
Geographic region			0.2185
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	8 (26.7%)	17 (50.0%)	
Patients (%) Without Events (Censored)	22 (73.3%)	17 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (6.93, NR)	11.76 (0.92, NR)	
Hazard Ratio (95% CI)		0.399 (0.171, 0.933)	
p-value		0.0290	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	43 (45.7%)	49 (55.7%)	
Patients (%) Without Events (Censored)	51 (54.3%)	39 (44.3%)	
Median Time to First TEAE, months (95% CI)	11.14 (4.07, NR)	3.45 (1.35, NR)	
Hazard Ratio (95% CI)		0.679 (0.451, 1.024)	
p-value		0.0663	
Age group			0.2529
< 65			
Total Patients	98	94	
Patients (%) With Events	42 (42.9%)	55 (58.5%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	56 (57.1%)	39 (41.5%)	
Median Time to First TEAE, months (95% CI)	15.41 (5.59, NR)	1.64 (0.99, 11.76)	
Hazard Ratio (95% CI)		0.532 (0.355, 0.797)	
p-value		0.0021	
>= 65			
Total Patients	26	28	
Patients (%) With Events	9 (34.6%)	11 (39.3%)	
Patients (%) Without Events (Censored)	17 (65.4%)	17 (60.7%)	
Median Time to First TEAE, months (95% CI)	NR (1.18, NR)	NR (2.69, NR)	
Hazard Ratio (95% CI)		0.929 (0.384, 2.248)	
p-value		0.8655	
Race			0.6601
White			
Total Patients	80	75	
Patients (%) With Events	32 (40.0%)	39 (52.0%)	
Patients (%) Without Events (Censored)	48 (60.0%)	36 (48.0%)	
Median Time to First TEAE, months (95% CI)	NR (4.07, NR)	4.37 (1.64, NR)	
Hazard Ratio (95% CI)		0.662 (0.414, 1.057)	
p-value		0.0844	
Asian			
Total Patients	26	26	
Patients (%) With Events	9 (34.6%)	12 (46.2%)	
Patients (%) Without Events (Censored)	17 (65.4%)	14 (53.8%)	
Median Time to First TEAE, months (95% CI)	NR (7.85, NR)	NR (0.72, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.598 (0.251, 1.423)	
p-value		0.2432	
Other			
Total Patients	16	21	
Patients (%) With Events	8 (50.0%)	15 (71.4%)	
Patients (%) Without Events (Censored)	8 (50.0%)	6 (28.6%)	
Median Time to First TEAE, months (95% CI)	15.41 (2.53, NR)	0.95 (0.76, 7.95)	
Hazard Ratio (95% CI)		0.389 (0.160, 0.945)	
p-value		0.0324	
Baseline ECOG status			0.0108
0			
Total Patients	81	79	
Patients (%) With Events	28 (34.6%)	46 (58.2%)	
Patients (%) Without Events (Censored)	53 (65.4%)	33 (41.8%)	
Median Time to First TEAE, months (95% CI)	NR (11.56, NR)	2.30 (1.08, 11.76)	
Hazard Ratio (95% CI)		0.430 (0.268, 0.689)	
p-value		0.0003	
1			
Total Patients	43	43	
Patients (%) With Events	23 (53.5%)	20 (46.5%)	
Patients (%) Without Events (Censored)	20 (46.5%)	23 (53.5%)	
Median Time to First TEAE, months (95% CI)	4.30 (1.61, NR)	7.95 (0.95, NR)	
Hazard Ratio (95% CI)		1.153 (0.632, 2.101)	
p-value		0.6266	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of liver metastasis			0.9466
Yes			
Total Patients	36	25	
Patients (%) With Events	18 (50.0%)	16 (64.0%)	
Patients (%) Without Events (Censored)	18 (50.0%)	9 (36.0%)	
Median Time to First TEAE, months (95% CI)	4.30 (1.18, NR)	1.08 (0.30, NR)	
Hazard Ratio (95% CI)		0.590 (0.299, 1.165)	
p-value		0.1255	
No			
Total Patients	88	97	
Patients (%) With Events	33 (37.5%)	50 (51.5%)	
Patients (%) Without Events (Censored)	55 (62.5%)	47 (48.5%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	5.09 (1.64, NR)	
Hazard Ratio (95% CI)		0.567 (0.365, 0.882)	
p-value		0.0114	
History of brain metastasis			0.1300
Yes			
Total Patients	6	7	
Patients (%) With Events	4 (66.7%)	3 (42.9%)	
Patients (%) Without Events (Censored)	2 (33.3%)	4 (57.1%)	
Median Time to First TEAE, months (95% CI)	1.61 (0.76, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		2.036 (0.450, 9.214)	
p-value		0.3463	
No			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	118	115	
Patients (%) With Events	47 (39.8%)	63 (54.8%)	
Patients (%) Without Events (Censored)	71 (60.2%)	52 (45.2%)	
Median Time to First TEAE, months (95% CI)	NR (7.85, NR)	3.45 (1.45, 11.76)	
Hazard Ratio (95% CI)		0.571 (0.391, 0.834)	
p-value		0.0036	
PD-L1 Status			0.5051
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	19 (44.2%)	27 (52.9%)	
Patients (%) Without Events (Censored)	24 (55.8%)	24 (47.1%)	
Median Time to First TEAE, months (95% CI)	NR (3.06, NR)	7.95 (1.08, NR)	
Hazard Ratio (95% CI)		0.718 (0.399, 1.292)	
p-value		0.2764	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	32 (39.5%)	39 (54.9%)	
Patients (%) Without Events (Censored)	49 (60.5%)	32 (45.1%)	
Median Time to First TEAE, months (95% CI)	15.41 (7.85, NR)	3.45 (0.95, NR)	
Hazard Ratio (95% CI)		0.542 (0.338, 0.867)	
p-value		0.0101	
BRCA 1/2 status			0.4743
Wild-Type			
Total Patients	42	45	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	14 (33.3%)	20 (44.4%)	
Patients (%) Without Events (Censored)	28 (66.7%)	25 (55.6%)	
Median Time to First TEAE, months (95% CI)	NR (5.59, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.594 (0.300, 1.179)	
p-value		0.1371	
Mutant			
Total Patients	9	7	
Patients (%) With Events	4 (44.4%)	3 (42.9%)	
Patients (%) Without Events (Censored)	5 (55.6%)	4 (57.1%)	
Median Time to First TEAE, months (95% CI)	7.85 (0.23, NR)	NR (0.30, NR)	
Hazard Ratio (95% CI)		1.039 (0.232, 4.649)	
p-value		0.9602	
Menopausal status			0.2410
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	11 (37.9%)	22 (64.7%)	
Patients (%) Without Events (Censored)	18 (62.1%)	12 (35.3%)	
Median Time to First TEAE, months (95% CI)	15.41 (4.30, NR)	1.97 (0.72, 7.16)	
Hazard Ratio (95% CI)		0.412 (0.198, 0.860)	
p-value		0.0151	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	40 (42.1%)	43 (49.4%)	
Patients (%) Without Events (Censored)	55 (57.9%)	44 (50.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (4.07, NR)	7.95 (1.45, NR)	
Hazard Ratio (95% CI)		0.712 (0.463, 1.097)	
p-value		0.1278	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.15. Table 1.1.12.4: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8069
De novo			
Total Patients	29	26	
Patients (%) With Events	21 (72.4%)	11 (42.3%)	
Patients (%) Without Events (Censored)	8 (27.6%)	15 (57.7%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.49, 1.41)	6.54 (2.43, NR)	
Hazard Ratio (95% CI)		2.650 (1.258, 5.584)	
p-value		0.0083	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	19 (61.3%)	9 (30.0%)	
Patients (%) Without Events (Censored)	12 (38.7%)	21 (70.0%)	
Median Time to First TEAE, months (95% CI)	1.51 (0.72, NR)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.662 (1.199, 5.911)	
p-value		0.0123	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	45 (70.3%)	25 (37.9%)	
Patients (%) Without Events (Censored)	19 (29.7%)	41 (62.1%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.53, 1.12)	NR (5.16, NR)	
Hazard Ratio (95% CI)		3.331 (2.012, 5.514)	
p-value		<0.0001	
Geographic region			0.2731
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	19 (63.3%)	13 (38.2%)	
Patients (%) Without Events (Censored)	11 (36.7%)	21 (61.8%)	
Median Time to First TEAE, months (95% CI)	1.53 (0.76, NR)	6.54 (3.25, NR)	
Hazard Ratio (95% CI)		2.384 (1.170, 4.856)	
p-value		0.0138	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	66 (70.2%)	32 (36.4%)	
Patients (%) Without Events (Censored)	28 (29.8%)	56 (63.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.72 (0.53, 1.12)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		3.214 (2.089, 4.946)	
p-value		<0.0001	
Age group			0.1892
< 65			
Total Patients	98	94	
Patients (%) With Events	71 (72.4%)	32 (34.0%)	
Patients (%) Without Events (Censored)	27 (27.6%)	62 (66.0%)	
Median Time to First TEAE, months (95% CI)	0.84 (0.66, 1.15)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		3.305 (2.166, 5.043)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	14 (53.8%)	13 (46.4%)	
Patients (%) Without Events (Censored)	12 (46.2%)	15 (53.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.46, NR)	17.08 (2.37, NR)	
Hazard Ratio (95% CI)		1.890 (0.876, 4.077)	
p-value		0.1017	
Race			0.9461
White			
Total Patients	80	75	
Patients (%) With Events	53 (66.2%)	24 (32.0%)	
Patients (%) Without Events (Censored)	27 (33.8%)	51 (68.0%)	
Median Time to First TEAE, months (95% CI)	1.05 (0.72, 1.64)	17.08 (17.08, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		3.310 (2.033, 5.388)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	21 (80.8%)	13 (50.0%)	
Patients (%) Without Events (Censored)	5 (19.2%)	13 (50.0%)	
Median Time to First TEAE, months (95% CI)	0.53 (0.39, 0.72)	6.47 (1.74, NR)	
Hazard Ratio (95% CI)		2.659 (1.299, 5.440)	
p-value		0.0062	
Other			
Total Patients	16	21	
Patients (%) With Events	11 (68.8%)	8 (38.1%)	
Patients (%) Without Events (Censored)	5 (31.2%)	13 (61.9%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.46, NR)	23.56 (2.37, NR)	
Hazard Ratio (95% CI)		3.235 (1.238, 8.452)	
p-value		0.0116	
Baseline ECOG status			0.9063
0			
Total Patients	81	79	
Patients (%) With Events	58 (71.6%)	31 (39.2%)	
Patients (%) Without Events (Censored)	23 (28.4%)	48 (60.8%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.56, 1.35)	17.08 (6.47, NR)	
Hazard Ratio (95% CI)		2.960 (1.902, 4.606)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
1			
Total Patients	43	43	
Patients (%) With Events	27 (62.8%)	14 (32.6%)	
Patients (%) Without Events (Censored)	16 (37.2%)	29 (67.4%)	
Median Time to First TEAE, months (95% CI)	0.85 (0.66, NR)	NR (3.38, NR)	
Hazard Ratio (95% CI)		2.931 (1.527, 5.628)	
p-value		0.0008	
History of liver metastasis			0.7124
Yes			
Total Patients	36	25	
Patients (%) With Events	22 (61.1%)	6 (24.0%)	
Patients (%) Without Events (Censored)	14 (38.9%)	19 (76.0%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.49, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.473 (1.400, 8.611)	
p-value		0.0044	
No			
Total Patients	88	97	
Patients (%) With Events	63 (71.6%)	39 (40.2%)	
Patients (%) Without Events (Censored)	25 (28.4%)	58 (59.8%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 1.15)	17.08 (6.47, NR)	
Hazard Ratio (95% CI)		3.040 (2.020, 4.576)	
p-value		<0.0001	
History of brain metastasis			0.6403
Yes			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	6	7	
Patients (%) With Events	3 (50.0%)	2 (28.6%)	
Patients (%) Without Events (Censored)	3 (50.0%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	6.41 (0.13, NR)	NR (0.36, NR)	
Hazard Ratio (95% CI)		1.981 (0.327, 11.999)	
p-value		0.4487	
No			
Total Patients	118	115	
Patients (%) With Events	82 (69.5%)	43 (37.4%)	
Patients (%) Without Events (Censored)	36 (30.5%)	72 (62.6%)	
Median Time to First TEAE, months (95% CI)	0.85 (0.66, 1.15)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		3.029 (2.083, 4.404)	
p-value		<0.0001	
PD-L1 Status			0.4864
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	30 (69.8%)	22 (43.1%)	
Patients (%) Without Events (Censored)	13 (30.2%)	29 (56.9%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.43, 1.51)	17.08 (5.09, NR)	
Hazard Ratio (95% CI)		2.485 (1.423, 4.339)	
p-value		0.0010	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	55 (67.9%)	23 (32.4%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	26 (32.1%)	48 (67.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.69, 1.41)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.249 (1.986, 5.316)	
p-value		<0.0001	
BRCA 1/2 status			0.5059
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	29 (69.0%)	17 (37.8%)	
Patients (%) Without Events (Censored)	13 (31.0%)	28 (62.2%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.49, 1.41)	NR (3.48, NR)	
Hazard Ratio (95% CI)		2.711 (1.479, 4.969)	
p-value		0.0009	
Mutant			
Total Patients	9	7	
Patients (%) With Events	6 (66.7%)	5 (71.4%)	
Patients (%) Without Events (Censored)	3 (33.3%)	2 (28.6%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.07, NR)	17.08 (0.07, NR)	
Hazard Ratio (95% CI)		2.356 (0.572, 9.696)	
p-value		0.2182	
Menopausal status			0.4339
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	23 (79.3%)	14 (41.2%)	
Patients (%) Without Events (Censored)	6 (20.7%)	20 (58.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.72 (0.36, 1.41)	23.56 (3.91, NR)	
Hazard Ratio (95% CI)		3.739 (1.851, 7.552)	
p-value		0.0001	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	62 (65.3%)	31 (35.6%)	
Patients (%) Without Events (Censored)	33 (34.7%)	56 (64.4%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 1.41)	17.08 (6.54, NR)	
Hazard Ratio (95% CI)		2.780 (1.800, 4.294)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.16. Table 1.1.12.5: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Anaemia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2708
De novo			
Total Patients	29	26	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	11 (37.9%)	16 (61.5%)	
Patients (%) Without Events (Censored)	18 (62.1%)	10 (38.5%)	
Median Time to First TEAE, months (95% CI)	NR (2.86, NR)	2.33 (1.38, 6.47)	
Hazard Ratio (95% CI)		0.468 (0.211, 1.037)	
p-value		0.0553	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	13 (41.9%)	17 (56.7%)	
Patients (%) Without Events (Censored)	18 (58.1%)	13 (43.3%)	
Median Time to First TEAE, months (95% CI)	10.68 (4.90, NR)	4.21 (1.64, NR)	
Hazard Ratio (95% CI)		0.546 (0.262, 1.139)	
p-value		0.1018	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	22 (34.4%)	50 (75.8%)	
Patients (%) Without Events (Censored)	42 (65.6%)	16 (24.2%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.74, NR)	1.87 (0.95, 2.27)	
Hazard Ratio (95% CI)		0.298 (0.179, 0.495)	
p-value		<0.0001	
Geographic region			0.5337
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	7 (23.3%)	19 (55.9%)	
Patients (%) Without Events (Censored)	23 (76.7%)	15 (44.1%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	3.02 (1.38, NR)	
Hazard Ratio (95% CI)		0.314 (0.131, 0.749)	
p-value		0.0059	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	39 (41.5%)	64 (72.7%)	
Patients (%) Without Events (Censored)	55 (58.5%)	24 (27.3%)	
Median Time to First TEAE, months (95% CI)	14.49 (9.63, NR)	1.94 (1.64, 2.50)	
Hazard Ratio (95% CI)		0.390 (0.260, 0.584)	
p-value		<0.0001	
Age group			0.2625
< 65			
Total Patients	98	94	
Patients (%) With Events	40 (40.8%)	63 (67.0%)	
Patients (%) Without Events (Censored)	58 (59.2%)	31 (33.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	2.10 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.413 (0.276, 0.617)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	6 (23.1%)	20 (71.4%)	
Patients (%) Without Events (Censored)	20 (76.9%)	8 (28.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	2.10 (0.89, 4.21)	
Hazard Ratio (95% CI)		0.261 (0.105, 0.651)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0019	
Race			0.7114
White			
Total Patients	80	75	
Patients (%) With Events	31 (38.8%)	52 (69.3%)	
Patients (%) Without Events (Censored)	49 (61.2%)	23 (30.7%)	
Median Time to First TEAE, months (95% CI)	NR (5.13, NR)	2.07 (0.95, 2.63)	
Hazard Ratio (95% CI)		0.393 (0.250, 0.616)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	7 (26.9%)	17 (65.4%)	
Patients (%) Without Events (Censored)	19 (73.1%)	9 (34.6%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.76 (1.25, 6.47)	
Hazard Ratio (95% CI)		0.326 (0.134, 0.794)	
p-value		0.0096	
Other			
Total Patients	16	21	
Patients (%) With Events	8 (50.0%)	14 (66.7%)	
Patients (%) Without Events (Censored)	8 (50.0%)	7 (33.3%)	
Median Time to First TEAE, months (95% CI)	10.68 (2.10, NR)	2.27 (1.64, 4.63)	
Hazard Ratio (95% CI)		0.451 (0.185, 1.097)	
p-value		0.0724	
Baseline ECOG status			0.1485

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
0			
Total Patients	81	79	
Patients (%) With Events	26 (32.1%)	55 (69.6%)	
Patients (%) Without Events (Censored)	55 (67.9%)	24 (30.4%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.10 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.319 (0.199, 0.512)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	20 (46.5%)	28 (65.1%)	
Patients (%) Without Events (Censored)	23 (53.5%)	15 (34.9%)	
Median Time to First TEAE, months (95% CI)	10.32 (2.33, NR)	2.20 (0.95, 4.21)	
Hazard Ratio (95% CI)		0.464 (0.251, 0.860)	
p-value		0.0127	
History of liver metastasis			0.1973
Yes			
Total Patients	36	25	
Patients (%) With Events	11 (30.6%)	17 (68.0%)	
Patients (%) Without Events (Censored)	25 (69.4%)	8 (32.0%)	
Median Time to First TEAE, months (95% CI)	NR (14.49, NR)	1.63 (0.72, 2.20)	
Hazard Ratio (95% CI)		0.265 (0.120, 0.587)	
p-value		0.0005	
No			
Total Patients	88	97	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	35 (39.8%)	66 (68.0%)	
Patients (%) Without Events (Censored)	53 (60.2%)	31 (32.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (9.63, NR)	2.27 (1.87, 3.02)	
Hazard Ratio (95% CI)		0.424 (0.280, 0.642)	
p-value		<0.0001	
History of brain metastasis			0.6775
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	5 (71.4%)	
Patients (%) Without Events (Censored)	4 (66.7%)	2 (28.6%)	
Median Time to First TEAE, months (95% CI)	NR (2.14, NR)	2.10 (0.26, NR)	
Hazard Ratio (95% CI)		0.229 (0.043, 1.235)	
p-value		0.0647	
No			
Total Patients	118	115	
Patients (%) With Events	44 (37.3%)	78 (67.8%)	
Patients (%) Without Events (Censored)	74 (62.7%)	37 (32.2%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.68, NR)	2.14 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.389 (0.267, 0.566)	
p-value		<0.0001	
PD-L1 Status			0.4262
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	14 (32.6%)	35 (68.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	29 (67.4%)	16 (31.4%)	
Median Time to First TEAE, months (95% CI)	NR (9.63, NR)	2.23 (0.95, 4.21)	
Hazard Ratio (95% CI)		0.313 (0.167, 0.587)	
p-value		0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	32 (39.5%)	48 (67.6%)	
Patients (%) Without Events (Censored)	49 (60.5%)	23 (32.4%)	
Median Time to First TEAE, months (95% CI)	14.49 (10.32, NR)	2.10 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.424 (0.269, 0.668)	
p-value		0.0001	
Menopausal status			0.9290
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	9 (31.0%)	22 (64.7%)	
Patients (%) Without Events (Censored)	20 (69.0%)	12 (35.3%)	
Median Time to First TEAE, months (95% CI)	NR (3.02, NR)	2.73 (1.64, 6.47)	
Hazard Ratio (95% CI)		0.363 (0.166, 0.790)	
p-value		0.0075	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	37 (38.9%)	60 (69.0%)	
Patients (%) Without Events (Censored)	58 (61.1%)	27 (31.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	2.10 (1.25, 2.56)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.389 (0.256, 0.590)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.17. Table 1.1.12.6: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Leukopenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.0886
De novo			
Total Patients	29	26	
Patients (%) With Events	5 (17.2%)	11 (42.3%)	
Patients (%) Without Events (Censored)	24 (82.8%)	15 (57.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	8.18 (4.93, NR)	
Hazard Ratio (95% CI)		0.331 (0.114, 0.961)	
p-value		0.0329	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	14 (45.2%)	10 (33.3%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	17 (54.8%)	20 (66.7%)	
Median Time to First TEAE, months (95% CI)	23.66 (0.69, NR)	NR (5.03, NR)	
Hazard Ratio (95% CI)		1.362 (0.604, 3.072)	
p-value		0.4707	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	19 (29.7%)	33 (50.0%)	
Patients (%) Without Events (Censored)	45 (70.3%)	33 (50.0%)	
Median Time to First TEAE, months (95% CI)	29.90 (NR, NR)	7.82 (2.63, NR)	
Hazard Ratio (95% CI)		0.490 (0.276, 0.870)	
p-value		0.0133	
Geographic region			0.2691
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	3 (10.0%)	9 (26.5%)	
Patients (%) Without Events (Censored)	27 (90.0%)	25 (73.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (5.78, NR)	
Hazard Ratio (95% CI)		0.313 (0.084, 1.160)	
p-value		0.0664	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	35 (37.2%)	45 (51.1%)	
Patients (%) Without Events (Censored)	59 (62.8%)	43 (48.9%)	
Median Time to First TEAE, months (95% CI)	23.66 (7.23, NR)	8.18 (3.45, 15.90)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.644 (0.412, 1.006)	
p-value		0.0504	
Age group			0.3053
< 65			
Total Patients	98	94	
Patients (%) With Events	29 (29.6%)	44 (46.8%)	
Patients (%) Without Events (Censored)	69 (70.4%)	50 (53.2%)	
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	8.18 (4.63, NR)	
Hazard Ratio (95% CI)		0.539 (0.337, 0.863)	
p-value		0.0086	
>= 65			
Total Patients	26	28	
Patients (%) With Events	9 (34.6%)	10 (35.7%)	
Patients (%) Without Events (Censored)	17 (65.4%)	18 (64.3%)	
Median Time to First TEAE, months (95% CI)	29.90 (2.92, NR)	12.02 (4.37, NR)	
Hazard Ratio (95% CI)		0.911 (0.358, 2.316)	
p-value		0.8570	
Race			0.8054
White			
Total Patients	80	75	
Patients (%) With Events	23 (28.8%)	35 (46.7%)	
Patients (%) Without Events (Censored)	57 (71.2%)	40 (53.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.47 (3.45, NR)	
Hazard Ratio (95% CI)		0.538 (0.317, 0.912)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0194	
Asian			
Total Patients	26	26	
Patients (%) With Events	9 (34.6%)	12 (46.2%)	
Patients (%) Without Events (Censored)	17 (65.4%)	14 (53.8%)	
Median Time to First TEAE, months (95% CI)	NR (2.27, NR)	9.92 (4.37, NR)	
Hazard Ratio (95% CI)		0.711 (0.299, 1.691)	
p-value		0.4419	
Other			
Total Patients	16	21	
Patients (%) With Events	5 (31.2%)	7 (33.3%)	
Patients (%) Without Events (Censored)	11 (68.8%)	14 (66.7%)	
Median Time to First TEAE, months (95% CI)	23.66 (4.90, NR)	NR (4.93, NR)	
Hazard Ratio (95% CI)		0.619 (0.179, 2.137)	
p-value		0.4478	
Baseline ECOG status			0.7224
0			
Total Patients	81	79	
Patients (%) With Events	26 (32.1%)	38 (48.1%)	
Patients (%) Without Events (Censored)	55 (67.9%)	41 (51.9%)	
Median Time to First TEAE, months (95% CI)	29.90 (NR, NR)	9.92 (4.93, NR)	
Hazard Ratio (95% CI)		0.566 (0.342, 0.938)	
p-value		0.0252	
1			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	43	43	
Patients (%) With Events	12 (27.9%)	16 (37.2%)	
Patients (%) Without Events (Censored)	31 (72.1%)	27 (62.8%)	
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	12.02 (4.37, NR)	
Hazard Ratio (95% CI)		0.643 (0.295, 1.401)	
p-value		0.2576	
History of liver metastasis			0.4632
Yes			
Total Patients	36	25	
Patients (%) With Events	9 (25.0%)	11 (44.0%)	
Patients (%) Without Events (Censored)	27 (75.0%)	14 (56.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	5.03 (1.15, NR)	
Hazard Ratio (95% CI)		0.507 (0.209, 1.231)	
p-value		0.1244	
No			
Total Patients	88	97	
Patients (%) With Events	29 (33.0%)	43 (44.3%)	
Patients (%) Without Events (Censored)	59 (67.0%)	54 (55.7%)	
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	11.47 (6.97, NR)	
Hazard Ratio (95% CI)		0.647 (0.402, 1.043)	
p-value		0.0711	
History of brain metastasis			0.5200
Yes			
Total Patients	6	7	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	1 (16.7%)	4 (57.1%)	
Patients (%) Without Events (Censored)	5 (83.3%)	3 (42.9%)	
Median Time to First TEAE, months (95% CI)	NR (0.23, NR)	3.45 (0.95, NR)	
Hazard Ratio (95% CI)		0.298 (0.033, 2.682)	
p-value		0.2517	
No			
Total Patients	118	115	
Patients (%) With Events	37 (31.4%)	50 (43.5%)	
Patients (%) Without Events (Censored)	81 (68.6%)	65 (56.5%)	
Median Time to First TEAE, months (95% CI)	29.90 (23.66, NR)	11.47 (6.97, NR)	
Hazard Ratio (95% CI)		0.617 (0.401, 0.948)	
p-value		0.0260	
PD-L1 Status			0.5473
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	10 (23.3%)	21 (41.2%)	
Patients (%) Without Events (Censored)	33 (76.7%)	30 (58.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	15.90 (2.63, NR)	
Hazard Ratio (95% CI)		0.510 (0.240, 1.085)	
p-value		0.0752	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	28 (34.6%)	33 (46.5%)	
Patients (%) Without Events (Censored)	53 (65.4%)	38 (53.5%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	9.92 (5.03, NR)	
Hazard Ratio (95% CI)		0.639 (0.383, 1.064)	
p-value		0.0811	
BRCA 1/2 status			0.4193
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	10 (23.8%)	13 (28.9%)	
Patients (%) Without Events (Censored)	32 (76.2%)	32 (71.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (9.92, NR)	
Hazard Ratio (95% CI)		0.764 (0.334, 1.746)	
p-value		0.5190	
Mutant			
Total Patients	9	7	
Patients (%) With Events	1 (11.1%)	3 (42.9%)	
Patients (%) Without Events (Censored)	8 (88.9%)	4 (57.1%)	
Median Time to First TEAE, months (95% CI)	NR (0.26, NR)	15.90 (0.76, NR)	
Hazard Ratio (95% CI)		0.348 (0.035, 3.424)	
p-value		0.3448	
Menopausal status			0.0917
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	5 (17.2%)	17 (50.0%)	
Patients (%) Without Events (Censored)	24 (82.8%)	17 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	7.82 (0.95, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.300 (0.110, 0.816)	
p-value		0.0125	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	33 (34.7%)	36 (41.4%)	
Patients (%) Without Events (Censored)	62 (65.3%)	51 (58.6%)	
Median Time to First TEAE, months (95% CI)	23.66 (23.66, NR)	11.47 (5.03, NR)	
Hazard Ratio (95% CI)		0.742 (0.460, 1.197)	
p-value		0.2208	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.18. Table 1.1.12.7: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2641
De novo			
Total Patients	29	26	
Patients (%) With Events	19 (65.5%)	21 (80.8%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	10 (34.5%)	5 (19.2%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.43, 7.20)	1.18 (0.85, 2.10)	
Hazard Ratio (95% CI)		0.794 (0.423, 1.491)	
p-value		0.4639	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	25 (80.6%)	26 (86.7%)	
Patients (%) Without Events (Censored)	6 (19.4%)	4 (13.3%)	
Median Time to First TEAE, months (95% CI)	0.69 (0.26, 1.58)	0.79 (0.69, 0.95)	
Hazard Ratio (95% CI)		0.930 (0.531, 1.629)	
p-value		0.7049	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	39 (60.9%)	58 (87.9%)	
Patients (%) Without Events (Censored)	25 (39.1%)	8 (12.1%)	
Median Time to First TEAE, months (95% CI)	2.92 (0.92, 5.09)	0.84 (0.72, 1.15)	
Hazard Ratio (95% CI)		0.481 (0.318, 0.727)	
p-value		0.0004	
Geographic region			0.5442
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	16 (53.3%)	26 (76.5%)	
Patients (%) Without Events (Censored)	14 (46.7%)	8 (23.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.72, NR)	0.94 (0.72, 3.12)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.548 (0.290, 1.033)	
p-value		0.0512	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	67 (71.3%)	79 (89.8%)	
Patients (%) Without Events (Censored)	27 (28.7%)	9 (10.2%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.69, 2.73)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.630 (0.451, 0.880)	
p-value		0.0053	
Age group			0.1628
< 65			
Total Patients	98	94	
Patients (%) With Events	69 (70.4%)	80 (85.1%)	
Patients (%) Without Events (Censored)	29 (29.6%)	14 (14.9%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 2.92)	0.92 (0.72, 1.38)	
Hazard Ratio (95% CI)		0.671 (0.482, 0.935)	
p-value		0.0152	
>= 65			
Total Patients	26	28	
Patients (%) With Events	14 (53.8%)	25 (89.3%)	
Patients (%) Without Events (Censored)	12 (46.2%)	3 (10.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.43, NR)	0.66 (0.26, 0.92)	
Hazard Ratio (95% CI)		0.449 (0.232, 0.867)	
p-value		0.0146	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Race			0.6611
White			
Total Patients	80	75	
Patients (%) With Events	50 (62.5%)	64 (85.3%)	
Patients (%) Without Events (Censored)	30 (37.5%)	11 (14.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 4.86)	0.92 (0.72, 1.15)	
Hazard Ratio (95% CI)		0.602 (0.412, 0.879)	
p-value		0.0072	
Asian			
Total Patients	26	26	
Patients (%) With Events	20 (76.9%)	22 (84.6%)	
Patients (%) Without Events (Censored)	6 (23.1%)	4 (15.4%)	
Median Time to First TEAE, months (95% CI)	2.04 (0.56, 4.14)	0.79 (0.26, 1.87)	
Hazard Ratio (95% CI)		0.756 (0.407, 1.403)	
p-value		0.3636	
Other			
Total Patients	16	21	
Patients (%) With Events	12 (75.0%)	19 (90.5%)	
Patients (%) Without Events (Censored)	4 (25.0%)	2 (9.5%)	
Median Time to First TEAE, months (95% CI)	0.80 (0.26, 5.09)	0.95 (0.30, 1.97)	
Hazard Ratio (95% CI)		0.566 (0.257, 1.246)	
p-value		0.1445	
Baseline ECOG status			0.9388
0			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	81	79	
Patients (%) With Events	56 (69.1%)	71 (89.9%)	
Patients (%) Without Events (Censored)	25 (30.9%)	8 (10.1%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.69, 3.09)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.613 (0.427, 0.878)	
p-value		0.0058	
1			
Total Patients	43	43	
Patients (%) With Events	27 (62.8%)	34 (79.1%)	
Patients (%) Without Events (Censored)	16 (37.2%)	9 (20.9%)	
Median Time to First TEAE, months (95% CI)	2.60 (0.66, 5.09)	0.92 (0.62, 1.87)	
Hazard Ratio (95% CI)		0.656 (0.394, 1.093)	
p-value		0.0980	
History of liver metastasis			0.3537
Yes			
Total Patients	36	25	
Patients (%) With Events	26 (72.2%)	20 (80.0%)	
Patients (%) Without Events (Censored)	10 (27.8%)	5 (20.0%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.66, 3.09)	0.92 (0.69, 1.64)	
Hazard Ratio (95% CI)		0.775 (0.426, 1.411)	
p-value		0.3993	
No			
Total Patients	88	97	
Patients (%) With Events	57 (64.8%)	85 (87.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	31 (35.2%)	12 (12.4%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.69, 4.14)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.573 (0.407, 0.807)	
p-value		0.0010	
History of brain metastasis			0.9099
Yes			
Total Patients	6	7	
Patients (%) With Events	3 (50.0%)	6 (85.7%)	
Patients (%) Without Events (Censored)	3 (50.0%)	1 (14.3%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.23, NR)	1.64 (0.66, NR)	
Hazard Ratio (95% CI)		0.571 (0.140, 2.335)	
p-value		0.4304	
No			
Total Patients	118	115	
Patients (%) With Events	80 (67.8%)	99 (86.1%)	
Patients (%) Without Events (Censored)	38 (32.2%)	16 (13.9%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 3.09)	0.92 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.620 (0.459, 0.838)	
p-value		0.0014	
PD-L1 Status			0.3829
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	27 (62.8%)	39 (76.5%)	
Patients (%) Without Events (Censored)	16 (37.2%)	12 (23.5%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	1.58 (0.66, 20.34)	0.95 (0.72, 2.07)	
Hazard Ratio (95% CI)		0.718 (0.429, 1.200)	
p-value		0.2016	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	56 (69.1%)	66 (93.0%)	
Patients (%) Without Events (Censored)	25 (30.9%)	5 (7.0%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.79)	0.72 (0.62, 0.92)	
Hazard Ratio (95% CI)		0.535 (0.372, 0.770)	
p-value		0.0004	
BRCA 1/2 status			0.2962
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	24 (57.1%)	36 (80.0%)	
Patients (%) Without Events (Censored)	18 (42.9%)	9 (20.0%)	
Median Time to First TEAE, months (95% CI)	2.60 (0.69, NR)	0.89 (0.69, 1.87)	
Hazard Ratio (95% CI)		0.551 (0.324, 0.936)	
p-value		0.0234	
Mutant			
Total Patients	9	7	
Patients (%) With Events	8 (88.9%)	7 (100.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	0 (0.0%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.23, 5.26)	0.95 (0.26, 2.10)	
Hazard Ratio (95% CI)		0.855 (0.295, 2.477)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.7574	
Menopausal status			0.5335
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	19 (65.5%)	28 (82.4%)	
Patients (%) Without Events (Censored)	10 (34.5%)	6 (17.6%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.66, 8.54)	0.95 (0.85, 2.10)	
Hazard Ratio (95% CI)		0.732 (0.406, 1.321)	
p-value		0.2844	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	64 (67.4%)	76 (87.4%)	
Patients (%) Without Events (Censored)	31 (32.6%)	11 (12.6%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.92)	0.76 (0.72, 0.95)	
Hazard Ratio (95% CI)		0.588 (0.418, 0.827)	
p-value		0.0018	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.19. Table 1.1.12.8: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Diarrhoea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.0102
De novo			
Total Patients	29	26	
Patients (%) With Events	16 (55.2%)	8 (30.8%)	
Patients (%) Without Events (Censored)	13 (44.8%)	18 (69.2%)	
Median Time to First TEAE, months (95% CI)	1.74 (0.49, NR)	NR (4.40, NR)	
Hazard Ratio (95% CI)		2.322 (0.987, 5.461)	
p-value		0.0470	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	14 (45.2%)	9 (30.0%)	
Patients (%) Without Events (Censored)	17 (54.8%)	21 (70.0%)	
Median Time to First TEAE, months (95% CI)	NR (1.97, NR)	23.56 (NR, NR)	
Hazard Ratio (95% CI)		1.567 (0.678, 3.623)	
p-value		0.2913	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	41 (64.1%)	10 (15.2%)	
Patients (%) Without Events (Censored)	23 (35.9%)	56 (84.8%)	
Median Time to First TEAE, months (95% CI)	2.50 (0.36, 6.54)	NR (20.96, NR)	
Hazard Ratio (95% CI)		7.344 (3.547, 15.207)	
p-value		<0.0001	
Geographic region			0.7799

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	21 (70.0%)	8 (23.5%)	
Patients (%) Without Events (Censored)	9 (30.0%)	26 (76.5%)	
Median Time to First TEAE, months (95% CI)	1.97 (0.36, 7.33)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.818 (1.684, 8.657)	
p-value		0.0006	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	50 (53.2%)	19 (21.6%)	
Patients (%) Without Events (Censored)	44 (46.8%)	69 (78.4%)	
Median Time to First TEAE, months (95% CI)	4.90 (1.58, NR)	23.56 (20.96, NR)	
Hazard Ratio (95% CI)		3.465 (2.032, 5.909)	
p-value		<0.0001	
Age group			0.3923
< 65			
Total Patients	98	94	
Patients (%) With Events	55 (56.1%)	20 (21.3%)	
Patients (%) Without Events (Censored)	43 (43.9%)	74 (78.7%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.97, 16.82)	23.56 (20.96, NR)	
Hazard Ratio (95% CI)		3.355 (2.003, 5.621)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	16 (61.5%)	7 (25.0%)	
Patients (%) Without Events (Censored)	10 (38.5%)	21 (75.0%)	
Median Time to First TEAE, months (95% CI)	0.44 (0.30, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.884 (1.933, 12.343)	
p-value		0.0003	
Race			0.5212
White			
Total Patients	80	75	
Patients (%) With Events	46 (57.5%)	13 (17.3%)	
Patients (%) Without Events (Censored)	34 (42.5%)	62 (82.7%)	
Median Time to First TEAE, months (95% CI)	4.70 (1.58, 11.56)	NR (20.96, NR)	
Hazard Ratio (95% CI)		4.562 (2.414, 8.621)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	12 (46.2%)	7 (26.9%)	
Patients (%) Without Events (Censored)	14 (53.8%)	19 (73.1%)	
Median Time to First TEAE, months (95% CI)	5.39 (0.36, NR)	NR (6.21, NR)	
Hazard Ratio (95% CI)		2.250 (0.880, 5.754)	
p-value		0.0828	
Other			
Total Patients	16	21	
Patients (%) With Events	11 (68.8%)	7 (33.3%)	
Patients (%) Without Events (Censored)	5 (31.2%)	14 (66.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	1.25 (0.26, NR)	23.56 (3.29, NR)	
Hazard Ratio (95% CI)		3.734 (1.368, 10.193)	
p-value		0.0060	
Baseline ECOG status			0.3224
0			
Total Patients	81	79	
Patients (%) With Events	44 (54.3%)	14 (17.7%)	
Patients (%) Without Events (Censored)	37 (45.7%)	65 (82.3%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.25, NR)	NR (23.56, NR)	
Hazard Ratio (95% CI)		4.105 (2.239, 7.525)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	27 (62.8%)	13 (30.2%)	
Patients (%) Without Events (Censored)	16 (37.2%)	30 (69.8%)	
Median Time to First TEAE, months (95% CI)	3.25 (0.49, 6.54)	20.96 (NR, NR)	
Hazard Ratio (95% CI)		3.084 (1.558, 6.105)	
p-value		0.0007	
History of liver metastasis			0.6243
Yes			
Total Patients	36	25	
Patients (%) With Events	21 (58.3%)	6 (24.0%)	
Patients (%) Without Events (Censored)	15 (41.7%)	19 (76.0%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.36, NR)	NR (NR, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.844 (1.144, 7.073)	
p-value		0.0187	
No			
Total Patients	88	97	
Patients (%) With Events	50 (56.8%)	21 (21.6%)	
Patients (%) Without Events (Censored)	38 (43.2%)	76 (78.4%)	
Median Time to First TEAE, months (95% CI)	4.57 (2.33, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.993 (2.350, 6.786)	
p-value		<0.0001	
History of brain metastasis			0.5970
Yes			
Total Patients	6	7	
Patients (%) With Events	4 (66.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	2 (33.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	1.61 (0.36, NR)	NR (2.50, NR)	
Hazard Ratio (95% CI)		7.487 (0.821, 68.274)	
p-value		0.0375	
No			
Total Patients	118	115	
Patients (%) With Events	67 (56.8%)	26 (22.6%)	
Patients (%) Without Events (Censored)	51 (43.2%)	89 (77.4%)	
Median Time to First TEAE, months (95% CI)	3.52 (1.25, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.457 (2.188, 5.463)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.6197
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	25 (58.1%)	10 (19.6%)	
Patients (%) Without Events (Censored)	18 (41.9%)	41 (80.4%)	
Median Time to First TEAE, months (95% CI)	3.52 (0.43, NR)	23.56 (23.56, NR)	
Hazard Ratio (95% CI)		4.061 (1.945, 8.479)	
p-value		0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	46 (56.8%)	17 (23.9%)	
Patients (%) Without Events (Censored)	35 (43.2%)	54 (76.1%)	
Median Time to First TEAE, months (95% CI)	4.53 (1.05, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.261 (1.842, 5.775)	
p-value		<0.0001	
Menopausal status			0.3483
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	15 (51.7%)	9 (26.5%)	
Patients (%) Without Events (Censored)	14 (48.3%)	25 (73.5%)	
Median Time to First TEAE, months (95% CI)	4.53 (0.89, NR)	23.56 (23.56, NR)	
Hazard Ratio (95% CI)		2.664 (1.126, 6.304)	
p-value		0.0202	
Post-menopausal			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	95	87	
Patients (%) With Events	56 (58.9%)	17 (19.5%)	
Patients (%) Without Events (Censored)	39 (41.1%)	70 (80.5%)	
Median Time to First TEAE, months (95% CI)	3.32 (1.02, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		4.204 (2.434, 7.262)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.20. Table 1.1.12.9: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Nausea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.4736
De novo			
Total Patients	29	26	
Patients (%) With Events	21 (72.4%)	16 (61.5%)	
Patients (%) Without Events (Censored)	8 (27.6%)	10 (38.5%)	
Median Time to First TEAE, months (95% CI)	3.06 (0.13, 4.17)	1.46 (0.30, NR)	
Hazard Ratio (95% CI)		1.137 (0.588, 2.200)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.6955	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	16 (51.6%)	10 (33.3%)	
Patients (%) Without Events (Censored)	15 (48.4%)	20 (66.7%)	
Median Time to First TEAE, months (95% CI)	9.43 (0.33, NR)	NR (3.25, NR)	
Hazard Ratio (95% CI)		1.709 (0.773, 3.778)	
p-value		0.1771	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	43 (67.2%)	32 (48.5%)	
Patients (%) Without Events (Censored)	21 (32.8%)	34 (51.5%)	
Median Time to First TEAE, months (95% CI)	0.59 (0.26, 5.59)	9.33 (2.04, NR)	
Hazard Ratio (95% CI)		1.910 (1.203, 3.033)	
p-value		0.0051	
Geographic region			0.5443
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	24 (80.0%)	18 (52.9%)	
Patients (%) Without Events (Censored)	6 (20.0%)	16 (47.1%)	
Median Time to First TEAE, months (95% CI)	0.48 (0.16, 4.17)	3.09 (0.95, NR)	
Hazard Ratio (95% CI)		1.832 (0.987, 3.400)	
p-value		0.0509	
Rest of the world			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	94	88	
Patients (%) With Events	56 (59.6%)	40 (45.5%)	
Patients (%) Without Events (Censored)	38 (40.4%)	48 (54.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.49, 6.47)	9.82 (3.25, NR)	
Hazard Ratio (95% CI)		1.496 (0.996, 2.248)	
p-value		0.0486	
Age group			0.7703
< 65			
Total Patients	98	94	
Patients (%) With Events	65 (66.3%)	46 (48.9%)	
Patients (%) Without Events (Censored)	33 (33.7%)	48 (51.1%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.30, 5.39)	9.23 (2.10, NR)	
Hazard Ratio (95% CI)		1.532 (1.049, 2.236)	
p-value		0.0254	
>= 65			
Total Patients	26	28	
Patients (%) With Events	15 (57.7%)	12 (42.9%)	
Patients (%) Without Events (Censored)	11 (42.3%)	16 (57.1%)	
Median Time to First TEAE, months (95% CI)	2.99 (0.36, NR)	9.82 (3.25, NR)	
Hazard Ratio (95% CI)		1.980 (0.910, 4.311)	
p-value		0.0773	
Race			0.8800
White			
Total Patients	80	75	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	52 (65.0%)	34 (45.3%)	
Patients (%) Without Events (Censored)	28 (35.0%)	41 (54.7%)	
Median Time to First TEAE, months (95% CI)	2.99 (0.33, 7.20)	9.82 (3.09, NR)	
Hazard Ratio (95% CI)		1.703 (1.104, 2.626)	
p-value		0.0147	
Asian			
Total Patients	26	26	
Patients (%) With Events	14 (53.8%)	11 (42.3%)	
Patients (%) Without Events (Censored)	12 (46.2%)	15 (57.7%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.10, NR)	9.33 (0.10, NR)	
Hazard Ratio (95% CI)		1.282 (0.580, 2.834)	
p-value		0.5232	
Other			
Total Patients	16	21	
Patients (%) With Events	12 (75.0%)	13 (61.9%)	
Patients (%) Without Events (Censored)	4 (25.0%)	8 (38.1%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.13, 5.59)	1.74 (0.13, NR)	
Hazard Ratio (95% CI)		1.430 (0.649, 3.154)	
p-value		0.3680	
Baseline ECOG status			0.2744
0			
Total Patients	81	79	
Patients (%) With Events	52 (64.2%)	35 (44.3%)	
Patients (%) Without Events (Censored)	29 (35.8%)	44 (55.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	2.53 (0.33, 6.47)	15.54 (3.09, NR)	
Hazard Ratio (95% CI)		1.813 (1.180, 2.787)	
p-value		0.0059	
1			
Total Patients	43	43	
Patients (%) With Events	28 (65.1%)	23 (53.5%)	
Patients (%) Without Events (Censored)	15 (34.9%)	20 (46.5%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.30, 7.20)	5.19 (0.76, NR)	
Hazard Ratio (95% CI)		1.241 (0.712, 2.161)	
p-value		0.4295	
History of liver metastasis			0.4708
Yes			
Total Patients	36	25	
Patients (%) With Events	26 (72.2%)	11 (44.0%)	
Patients (%) Without Events (Censored)	10 (27.8%)	14 (56.0%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.10, 3.48)	9.23 (0.33, NR)	
Hazard Ratio (95% CI)		1.957 (0.961, 3.987)	
p-value		0.0574	
No			
Total Patients	88	97	
Patients (%) With Events	54 (61.4%)	47 (48.5%)	
Patients (%) Without Events (Censored)	34 (38.6%)	50 (51.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.99, 7.20)	9.82 (2.73, NR)	
Hazard Ratio (95% CI)		1.456 (0.984, 2.155)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0569	
History of brain metastasis			0.1852
Yes			
Total Patients	6	7	
Patients (%) With Events	5 (83.3%)	2 (28.6%)	
Patients (%) Without Events (Censored)	1 (16.7%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	0.31 (0.10, NR)	NR (0.10, NR)	
Hazard Ratio (95% CI)		3.527 (0.610, 20.402)	
p-value		0.1316	
No			
Total Patients	118	115	
Patients (%) With Events	75 (63.6%)	56 (48.7%)	
Patients (%) Without Events (Censored)	43 (36.4%)	59 (51.3%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.36, 5.39)	9.33 (2.43, NR)	
Hazard Ratio (95% CI)		1.512 (1.069, 2.140)	
p-value		0.0179	
PD-L1 Status			0.9335
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	26 (60.5%)	23 (45.1%)	
Patients (%) Without Events (Censored)	17 (39.5%)	28 (54.9%)	
Median Time to First TEAE, months (95% CI)	3.98 (0.20, 18.20)	15.54 (1.08, NR)	
Hazard Ratio (95% CI)		1.517 (0.864, 2.664)	
p-value		0.1473	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	54 (66.7%)	35 (49.3%)	
Patients (%) Without Events (Censored)	27 (33.3%)	36 (50.7%)	
Median Time to First TEAE, months (95% CI)	1.48 (0.33, 4.47)	9.33 (2.10, NR)	
Hazard Ratio (95% CI)		1.624 (1.059, 2.490)	
p-value		0.0227	
BRCA 1/2 status			0.9060
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	25 (59.5%)	21 (46.7%)	
Patients (%) Without Events (Censored)	17 (40.5%)	24 (53.3%)	
Median Time to First TEAE, months (95% CI)	4.17 (0.36, 7.23)	9.33 (2.37, NR)	
Hazard Ratio (95% CI)		1.508 (0.842, 2.702)	
p-value		0.1656	
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	4 (57.1%)	
Patients (%) Without Events (Censored)	4 (44.4%)	3 (42.9%)	
Median Time to First TEAE, months (95% CI)	5.39 (0.03, NR)	15.54 (0.03, NR)	
Hazard Ratio (95% CI)		1.582 (0.370, 6.760)	
p-value		0.5270	
Menopausal status			0.8346
Pre-menopausal			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	29	34	
Patients (%) With Events	22 (75.9%)	20 (58.8%)	
Patients (%) Without Events (Censored)	7 (24.1%)	14 (41.2%)	
Median Time to First TEAE, months (95% CI)	0.33 (0.13, 3.06)	2.10 (0.13, NR)	
Hazard Ratio (95% CI)		1.525 (0.828, 2.808)	
p-value		0.1595	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	58 (61.1%)	37 (42.5%)	
Patients (%) Without Events (Censored)	37 (38.9%)	50 (57.5%)	
Median Time to First TEAE, months (95% CI)	3.48 (0.49, 7.20)	15.54 (5.19, NR)	
Hazard Ratio (95% CI)		1.694 (1.120, 2.561)	
p-value		0.0116	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.21. Table 1.1.12.10: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Vomiting (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.2152
De novo			
Total Patients	29	26	
Patients (%) With Events	9 (31.0%)	7 (26.9%)	
Patients (%) Without Events (Censored)	20 (69.0%)	19 (73.1%)	
Median Time to First TEAE, months (95% CI)	NR (3.98, NR)	NR (6.18, NR)	
Hazard Ratio (95% CI)		1.077 (0.396, 2.927)	
p-value		0.8844	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	10 (32.3%)	2 (6.7%)	
Patients (%) Without Events (Censored)	21 (67.7%)	28 (93.3%)	
Median Time to First TEAE, months (95% CI)	NR (5.16, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.057 (1.107, 23.107)	
p-value		0.0200	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	19 (29.7%)	13 (19.7%)	
Patients (%) Without Events (Censored)	45 (70.3%)	53 (80.3%)	
Median Time to First TEAE, months (95% CI)	NR (11.56, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.562 (0.771, 3.165)	
p-value		0.2107	
Geographic region			0.6970

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	11 (36.7%)	6 (17.6%)	
Patients (%) Without Events (Censored)	19 (63.3%)	28 (82.4%)	
Median Time to First TEAE, months (95% CI)	NR (4.60, NR)	NR (9.89, NR)	
Hazard Ratio (95% CI)		2.050 (0.756, 5.561)	
p-value		0.1500	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	27 (28.7%)	16 (18.2%)	
Patients (%) Without Events (Censored)	67 (71.3%)	72 (81.8%)	
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.585 (0.854, 2.944)	
p-value		0.1400	
Age group			0.0798
< 65			
Total Patients	98	94	
Patients (%) With Events	31 (31.6%)	20 (21.3%)	
Patients (%) Without Events (Censored)	67 (68.4%)	74 (78.7%)	
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.338 (0.761, 2.351)	
p-value		0.3094	
>= 65			
Total Patients	26	28	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	7 (26.9%)	2 (7.1%)	
Patients (%) Without Events (Censored)	19 (73.1%)	26 (92.9%)	
Median Time to First TEAE, months (95% CI)	NR (2.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.824 (0.997, 23.348)	
p-value		0.0309	
Race			0.9174
White			
Total Patients	80	75	
Patients (%) With Events	26 (32.5%)	16 (21.3%)	
Patients (%) Without Events (Censored)	54 (67.5%)	59 (78.7%)	
Median Time to First TEAE, months (95% CI)	NR (11.56, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.502 (0.805, 2.802)	
p-value		0.1978	
Asian			
Total Patients	26	26	
Patients (%) With Events	5 (19.2%)	3 (11.5%)	
Patients (%) Without Events (Censored)	21 (80.8%)	23 (88.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.683 (0.402, 7.055)	
p-value		0.4735	
Other			
Total Patients	16	21	
Patients (%) With Events	5 (31.2%)	3 (14.3%)	
Patients (%) Without Events (Censored)	11 (68.8%)	18 (85.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (4.63, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.963 (0.462, 8.334)	
p-value		0.3518	
Baseline ECOG status			0.3748
0			
Total Patients	81	79	
Patients (%) With Events	22 (27.2%)	15 (19.0%)	
Patients (%) Without Events (Censored)	59 (72.8%)	64 (81.0%)	
Median Time to First TEAE, months (95% CI)	NR (15.01, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.413 (0.733, 2.725)	
p-value		0.2990	
1			
Total Patients	43	43	
Patients (%) With Events	16 (37.2%)	7 (16.3%)	
Patients (%) Without Events (Censored)	27 (62.8%)	36 (83.7%)	
Median Time to First TEAE, months (95% CI)	12.09 (4.63, NR)	NR (8.08, NR)	
Hazard Ratio (95% CI)		2.278 (0.929, 5.586)	
p-value		0.0643	
History of liver metastasis			0.3666
Yes			
Total Patients	36	25	
Patients (%) With Events	11 (30.6%)	6 (24.0%)	
Patients (%) Without Events (Censored)	25 (69.4%)	19 (76.0%)	
Median Time to First TEAE, months (95% CI)	NR (3.12, NR)	9.89 (3.29, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.175 (0.426, 3.243)	
p-value		0.7543	
No			
Total Patients	88	97	
Patients (%) With Events	27 (30.7%)	16 (16.5%)	
Patients (%) Without Events (Censored)	61 (69.3%)	81 (83.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.877 (1.011, 3.485)	
p-value		0.0424	
History of brain metastasis			0.8452
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	2 (28.6%)	
Patients (%) Without Events (Censored)	4 (66.7%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.30, NR)	NR (0.20, NR)	
Hazard Ratio (95% CI)		1.235 (0.173, 8.845)	
p-value		0.8329	
No			
Total Patients	118	115	
Patients (%) With Events	36 (30.5%)	20 (17.4%)	
Patients (%) Without Events (Censored)	82 (69.5%)	95 (82.6%)	
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.734 (1.003, 2.997)	
p-value		0.0460	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
PD-L1 Status			0.5631
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	12 (27.9%)	10 (19.6%)	
Patients (%) Without Events (Censored)	31 (72.1%)	41 (80.4%)	
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.383 (0.597, 3.204)	
p-value		0.4482	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	26 (32.1%)	12 (16.9%)	
Patients (%) Without Events (Censored)	55 (67.9%)	59 (83.1%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.894 (0.954, 3.762)	
p-value		0.0633	
Menopausal status			0.5130
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	15 (51.7%)	9 (26.5%)	
Patients (%) Without Events (Censored)	14 (48.3%)	25 (73.5%)	
Median Time to First TEAE, months (95% CI)	6.87 (2.79, NR)	NR (8.15, NR)	
Hazard Ratio (95% CI)		2.180 (0.952, 4.995)	
p-value		0.0582	
Post-menopausal			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	95	87	
Patients (%) With Events	23 (24.2%)	13 (14.9%)	
Patients (%) Without Events (Censored)	72 (75.8%)	74 (85.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.558 (0.788, 3.079)	
p-value		0.1985	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.22. Table 1.1.12.11: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alanine aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.6843
De novo			
Total Patients	29	26	
Patients (%) With Events	6 (20.7%)	14 (53.8%)	
Patients (%) Without Events (Censored)	23 (79.3%)	12 (46.2%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	4.14 (0.62, NR)	
Hazard Ratio (95% CI)		0.188 (0.062, 0.573)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0010	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	7 (22.6%)	15 (50.0%)	
Patients (%) Without Events (Censored)	24 (77.4%)	15 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	7.16 (1.61, NR)	
Hazard Ratio (95% CI)		0.273 (0.106, 0.705)	
p-value		0.0047	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	11 (17.2%)	25 (37.9%)	
Patients (%) Without Events (Censored)	53 (82.8%)	41 (62.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.397 (0.195, 0.808)	
p-value		0.0083	
Geographic region			0.0735
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	2 (6.7%)	14 (41.2%)	
Patients (%) Without Events (Censored)	28 (93.3%)	20 (58.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (1.45, NR)	
Hazard Ratio (95% CI)		0.124 (0.028, 0.556)	
p-value		0.0013	
Rest of the world			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	94	88	
Patients (%) With Events	22 (23.4%)	40 (45.5%)	
Patients (%) Without Events (Censored)	72 (76.6%)	48 (54.5%)	
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	NR (2.40, NR)	
Hazard Ratio (95% CI)		0.407 (0.241, 0.686)	
p-value		0.0005	
Age group			0.3276
< 65			
Total Patients	98	94	
Patients (%) With Events	23 (23.5%)	46 (48.9%)	
Patients (%) Without Events (Censored)	75 (76.5%)	48 (51.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	7.16 (1.64, NR)	
Hazard Ratio (95% CI)		0.339 (0.204, 0.562)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	1 (3.8%)	8 (28.6%)	
Patients (%) Without Events (Censored)	25 (96.2%)	20 (71.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (2.69, NR)	
Hazard Ratio (95% CI)		0.129 (0.016, 1.032)	
p-value		0.0224	
Race			0.3801
White			
Total Patients	80	75	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) With Events	15 (18.8%)	32 (42.7%)	
Patients (%) Without Events (Censored)	65 (81.2%)	43 (57.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.349 (0.189, 0.646)	
p-value		0.0005	
Asian			
Total Patients	26	26	
Patients (%) With Events	6 (23.1%)	10 (38.5%)	
Patients (%) Without Events (Censored)	20 (76.9%)	16 (61.5%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.450 (0.161, 1.256)	
p-value		0.1189	
Other			
Total Patients	16	21	
Patients (%) With Events	2 (12.5%)	12 (57.1%)	
Patients (%) Without Events (Censored)	14 (87.5%)	9 (42.9%)	
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	4.14 (0.92, NR)	
Hazard Ratio (95% CI)		0.134 (0.029, 0.613)	
p-value		0.0027	
Baseline ECOG status			0.1582
0			
Total Patients	81	79	
Patients (%) With Events	15 (18.5%)	40 (50.6%)	
Patients (%) Without Events (Censored)	66 (81.5%)	39 (49.4%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	7.16 (1.64, NR)	
Hazard Ratio (95% CI)		0.265 (0.146, 0.482)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	9 (20.9%)	14 (32.6%)	
Patients (%) Without Events (Censored)	34 (79.1%)	29 (67.4%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (4.14, NR)	
Hazard Ratio (95% CI)		0.566 (0.244, 1.309)	
p-value		0.1797	
History of liver metastasis			0.8830
Yes			
Total Patients	36	25	
Patients (%) With Events	10 (27.8%)	14 (56.0%)	
Patients (%) Without Events (Censored)	26 (72.2%)	11 (44.0%)	
Median Time to First TEAE, months (95% CI)	NR (5.49, NR)	1.61 (0.33, NR)	
Hazard Ratio (95% CI)		0.314 (0.137, 0.724)	
p-value		0.0042	
No			
Total Patients	88	97	
Patients (%) With Events	14 (15.9%)	40 (41.2%)	
Patients (%) Without Events (Censored)	74 (84.1%)	57 (58.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.301 (0.163, 0.554)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		<0.0001	
History of brain metastasis			0.0608
Yes			
Total Patients	6	7	
Patients (%) With Events	3 (50.0%)	2 (28.6%)	
Patients (%) Without Events (Censored)	3 (50.0%)	5 (71.4%)	
Median Time to First TEAE, months (95% CI)	4.58 (3.48, NR)	NR (0.95, NR)	
Hazard Ratio (95% CI)		1.653 (0.273, 10.030)	
p-value		0.5808	
No			
Total Patients	118	115	
Patients (%) With Events	21 (17.8%)	52 (45.2%)	
Patients (%) Without Events (Censored)	97 (82.2%)	63 (54.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (3.22, NR)	
Hazard Ratio (95% CI)		0.300 (0.180, 0.499)	
p-value		<0.0001	
PD-L1 Status			0.2719
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	11 (25.6%)	22 (43.1%)	
Patients (%) Without Events (Censored)	32 (74.4%)	29 (56.9%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	11.76 (1.64, NR)	
Hazard Ratio (95% CI)		0.461 (0.223, 0.955)	
p-value		0.0337	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	13 (16.0%)	32 (45.1%)	
Patients (%) Without Events (Censored)	68 (84.0%)	39 (54.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (2.33, NR)	
Hazard Ratio (95% CI)		0.271 (0.142, 0.519)	
p-value		<0.0001	
Menopausal status			0.9572
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	7 (24.1%)	18 (52.9%)	
Patients (%) Without Events (Censored)	22 (75.9%)	16 (47.1%)	
Median Time to First TEAE, months (95% CI)	15.41 (11.14, NR)	6.01 (1.02, NR)	
Hazard Ratio (95% CI)		0.286 (0.115, 0.710)	
p-value		0.0046	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	17 (17.9%)	35 (40.2%)	
Patients (%) Without Events (Censored)	78 (82.1%)	52 (59.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.354 (0.198, 0.633)	
p-value		0.0003	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.23. Table 1.1.12.12: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Aspartate aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Geographic region			0.4060
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	2 (6.7%)	8 (23.5%)	
Patients (%) Without Events (Censored)	28 (93.3%)	26 (76.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.265 (0.056, 1.251)	
p-value		0.0716	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	21 (22.3%)	35 (39.8%)	
Patients (%) Without Events (Censored)	73 (77.7%)	53 (60.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.458 (0.267, 0.788)	
p-value		0.0040	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Age group			0.3857
< 65			
Total Patients	98	94	
Patients (%) With Events	22 (22.4%)	37 (39.4%)	
Patients (%) Without Events (Censored)	76 (77.6%)	57 (60.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (4.37, NR)	
Hazard Ratio (95% CI)		0.444 (0.261, 0.754)	
p-value		0.0021	
>= 65			
Total Patients	26	28	
Patients (%) With Events	1 (3.8%)	6 (21.4%)	
Patients (%) Without Events (Censored)	25 (96.2%)	22 (78.6%)	
Median Time to First TEAE, months (95% CI)	NR (7.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.175 (0.021, 1.453)	
p-value		0.0678	
Race			0.6507
White			
Total Patients	80	75	
Patients (%) With Events	15 (18.8%)	23 (30.7%)	
Patients (%) Without Events (Censored)	65 (81.2%)	52 (69.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.516 (0.269, 0.990)	
p-value		0.0432	
Asian			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	26	26	
Patients (%) With Events	4 (15.4%)	10 (38.5%)	
Patients (%) Without Events (Censored)	22 (84.6%)	16 (61.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.58, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		0.299 (0.093, 0.963)	
p-value		0.0324	
Other			
Total Patients	16	21	
Patients (%) With Events	3 (18.8%)	10 (47.6%)	
Patients (%) Without Events (Censored)	13 (81.2%)	11 (52.4%)	
Median Time to First TEAE, months (95% CI)	NR (3.71, NR)	NR (0.99, NR)	
Hazard Ratio (95% CI)		0.320 (0.088, 1.167)	
p-value		0.0686	
Baseline ECOG status			0.1670
0			
Total Patients	81	79	
Patients (%) With Events	14 (17.3%)	32 (40.5%)	
Patients (%) Without Events (Censored)	67 (82.7%)	47 (59.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (3.48, NR)	
Hazard Ratio (95% CI)		0.345 (0.184, 0.648)	
p-value		0.0005	
1			
Total Patients	43	43	
Patients (%) With Events	9 (20.9%)	11 (25.6%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	34 (79.1%)	32 (74.4%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.672 (0.276, 1.637)	
p-value		0.3840	
History of liver metastasis			0.7356
Yes			
Total Patients	36	25	
Patients (%) With Events	9 (25.0%)	12 (48.0%)	
Patients (%) Without Events (Censored)	27 (75.0%)	13 (52.0%)	
Median Time to First TEAE, months (95% CI)	NR (7.72, NR)	NR (0.33, NR)	
Hazard Ratio (95% CI)		0.310 (0.125, 0.765)	
p-value		0.0079	
No			
Total Patients	88	97	
Patients (%) With Events	14 (15.9%)	31 (32.0%)	
Patients (%) Without Events (Censored)	74 (84.1%)	66 (68.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.429 (0.228, 0.808)	
p-value		0.0070	
History of brain metastasis			0.1381
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	1 (14.3%)	
Patients (%) Without Events (Censored)	4 (66.7%)	6 (85.7%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	7.97 (3.68, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		2.345 (0.212, 25.955)	
p-value		0.4741	
No			
Total Patients	118	115	
Patients (%) With Events	21 (17.8%)	42 (36.5%)	
Patients (%) Without Events (Censored)	97 (82.2%)	73 (63.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.401 (0.237, 0.677)	
p-value		0.0004	
PD-L1 Status			0.5105
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	10 (23.3%)	18 (35.3%)	
Patients (%) Without Events (Censored)	33 (76.7%)	33 (64.7%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (3.09, NR)	
Hazard Ratio (95% CI)		0.546 (0.251, 1.184)	
p-value		0.1222	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	13 (16.0%)	25 (35.2%)	
Patients (%) Without Events (Censored)	68 (84.0%)	46 (64.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (7.16, NR)	
Hazard Ratio (95% CI)		0.385 (0.197, 0.754)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0039	
Menopausal status			0.1786
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	5 (17.2%)	17 (50.0%)	
Patients (%) Without Events (Censored)	24 (82.8%)	17 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (12.58, NR)	7.16 (1.02, NR)	
Hazard Ratio (95% CI)		0.250 (0.091, 0.689)	
p-value		0.0040	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	18 (18.9%)	25 (28.7%)	
Patients (%) Without Events (Censored)	77 (81.1%)	62 (71.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.567 (0.309, 1.041)	
p-value		0.0641	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.24. Table 1.1.12.13: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Decreased appetite (SOC: Metabolism and nutrition disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of brain metastasis			0.9999
Yes			
Total Patients	6	7	
Patients (%) With Events	0 (0.0%)	0 (0.0%)	
Patients (%) Without Events (Censored)	6 (100.0%)	7 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		1.0000	
No			
Total Patients	118	115	
Patients (%) With Events	25 (21.2%)	11 (9.6%)	
Patients (%) Without Events (Censored)	93 (78.8%)	104 (90.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.193 (1.078, 4.460)	
p-value		0.0262	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.25. Table 1.1.12.14: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Cough (SOC: Respiratory, thoracic and mediastinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Baseline ECOG status			0.9556
0			
Total Patients	81	79	
Patients (%) With Events	21 (25.9%)	10 (12.7%)	
Patients (%) Without Events (Censored)	60 (74.1%)	69 (87.3%)	
Median Time to First TEAE, months (95% CI)	NR (14.23, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.161 (1.016, 4.595)	
p-value		0.0403	
1			
Total Patients	43	43	
Patients (%) With Events	3 (7.0%)	1 (2.3%)	
Patients (%) Without Events (Censored)	40 (93.0%)	42 (97.7%)	
Median Time to First TEAE, months (95% CI)	23.92 (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.959 (0.199, 19.316)	
p-value		0.5578	
History of brain metastasis			0.8577
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	5 (83.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	NR (2.99, NR)	NR (7.59, NR)	
Hazard Ratio (95% CI)		1.732 (0.108, 27.890)	
p-value		0.6949	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
No			
Total Patients	118	115	
Patients (%) With Events	23 (19.5%)	10 (8.7%)	
Patients (%) Without Events (Censored)	95 (80.5%)	105 (91.3%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.155 (1.024, 4.534)	
p-value		0.0382	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.26. Table 1.1.12.15: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alopecia (SOC: Skin and subcutaneous tissue disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.8140
De novo			
Total Patients	29	26	
Patients (%) With Events	17 (58.6%)	3 (11.5%)	
Patients (%) Without Events (Censored)	12 (41.4%)	23 (88.5%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.49, NR)	NR (NR, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		7.854 (2.286, 26.988)	
p-value		0.0001	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	15 (48.4%)	4 (13.3%)	
Patients (%) Without Events (Censored)	16 (51.6%)	26 (86.7%)	
Median Time to First TEAE, months (95% CI)	NR (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.910 (1.626, 14.831)	
p-value		0.0018	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	36 (56.2%)	11 (16.7%)	
Patients (%) Without Events (Censored)	28 (43.8%)	55 (83.3%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.345 (2.710, 10.543)	
p-value		<0.0001	
Geographic region			0.1481
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	15 (50.0%)	7 (20.6%)	
Patients (%) Without Events (Censored)	15 (50.0%)	27 (79.4%)	
Median Time to First TEAE, months (95% CI)	5.06 (0.85, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.342 (1.358, 8.227)	
p-value		0.0055	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	53 (56.4%)	11 (12.5%)	
Patients (%) Without Events (Censored)	41 (43.6%)	77 (87.5%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.992 (3.641, 13.428)	
p-value		<0.0001	
Age group			0.0236
< 65			
Total Patients	98	94	
Patients (%) With Events	57 (58.2%)	10 (10.6%)	
Patients (%) Without Events (Censored)	41 (41.8%)	84 (89.4%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.72, 11.93)	NR (NR, NR)	
Hazard Ratio (95% CI)		8.240 (4.198, 16.172)	
p-value		<0.0001	
>= 65			
Total Patients	26	28	
Patients (%) With Events	11 (42.3%)	8 (28.6%)	
Patients (%) Without Events (Censored)	15 (57.7%)	20 (71.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.76, NR)	NR (5.45, NR)	
Hazard Ratio (95% CI)		2.452 (0.972, 6.187)	
p-value		0.0513	
Race			0.6497
White			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	80	75	
Patients (%) With Events	42 (52.5%)	10 (13.3%)	
Patients (%) Without Events (Censored)	38 (47.5%)	65 (86.7%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.952 (2.978, 11.897)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	18 (69.2%)	4 (15.4%)	
Patients (%) Without Events (Censored)	8 (30.8%)	22 (84.6%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.49, 11.93)	NR (NR, NR)	
Hazard Ratio (95% CI)		7.660 (2.568, 22.849)	
p-value		<0.0001	
Other			
Total Patients	16	21	
Patients (%) With Events	8 (50.0%)	4 (19.0%)	
Patients (%) Without Events (Censored)	8 (50.0%)	17 (81.0%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.53, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.602 (1.080, 12.015)	
p-value		0.0262	
Baseline ECOG status			0.9908
0			
Total Patients	81	79	
Patients (%) With Events	45 (55.6%)	12 (15.2%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	36 (44.4%)	67 (84.8%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.72, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.541 (2.923, 10.504)	
p-value		<0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	23 (53.5%)	6 (14.0%)	
Patients (%) Without Events (Censored)	20 (46.5%)	37 (86.0%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.79, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.761 (2.335, 14.215)	
p-value		<0.0001	
History of liver metastasis			0.1554
Yes			
Total Patients	36	25	
Patients (%) With Events	18 (50.0%)	1 (4.0%)	
Patients (%) Without Events (Censored)	18 (50.0%)	24 (96.0%)	
Median Time to First TEAE, months (95% CI)	11.93 (0.56, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		16.067 (2.138, 120.749)	
p-value		0.0003	
No			
Total Patients	88	97	
Patients (%) With Events	50 (56.8%)	17 (17.5%)	
Patients (%) Without Events (Censored)	38 (43.2%)	80 (82.5%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.79, NR)	NR (NR, NR)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Hazard Ratio (95% CI)		5.103 (2.932, 8.880)	
p-value		<0.0001	
History of brain metastasis			0.2792
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	1 (14.3%)	
Patients (%) Without Events (Censored)	5 (83.3%)	6 (85.7%)	
Median Time to First TEAE, months (95% CI)	NR (5.06, NR)	NR (2.30, NR)	
Hazard Ratio (95% CI)		1.095 (0.068, 17.564)	
p-value		0.9486	
No			
Total Patients	118	115	
Patients (%) With Events	67 (56.8%)	17 (14.8%)	
Patients (%) Without Events (Censored)	51 (43.2%)	98 (85.2%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.962 (3.492, 10.180)	
p-value		<0.0001	
PD-L1 Status			0.7700
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	28 (65.1%)	10 (19.6%)	
Patients (%) Without Events (Censored)	15 (34.9%)	41 (80.4%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.49, 11.93)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.443 (2.628, 11.273)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		<0.0001	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	40 (49.4%)	8 (11.3%)	
Patients (%) Without Events (Censored)	41 (50.6%)	63 (88.7%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.268 (2.927, 13.424)	
p-value		<0.0001	
Menopausal status			0.1035
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	19 (65.5%)	3 (8.8%)	
Patients (%) Without Events (Censored)	10 (34.5%)	31 (91.2%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.49, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		11.998 (3.526, 40.828)	
p-value		<0.0001	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	49 (51.6%)	15 (17.2%)	
Patients (%) Without Events (Censored)	46 (48.4%)	72 (82.8%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.437 (2.482, 7.931)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.27. Table 1.1.13: Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Blood and lymphatic system disorders		
Total Patients	124	122
Patients (%) With Events	61 (49.2%)	103 (84.4%)
Patients (%) Without Events (Censored)	63 (50.8%)	19 (15.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	11.17 (2.56, NR)	1.64 (1.05, 2.30)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.451 (0.325, 0.624)
p-value		<0.0001
Anaemia		
Total Patients	124	122
Patients (%) With Events	4 (3.2%)	35 (28.7%)
Patients (%) Without Events (Censored)	120 (96.8%)	87 (71.3%)
Kaplan-Meier Quartiles of Time to Event (months)		

	SG (N=124)	TPC (N=122)
Median (95% CI)	NR (NR, NR)	NR (11.37, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.094 (0.033, 0.265)
p-value		<0.0001
Leukopenia		
Total Patients	124	122
Patients (%) With Events	11 (8.9%)	30 (24.6%)
Patients (%) Without Events (Censored)	113 (91.1%)	92 (75.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (23.66, NR)	NR (13.63, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.316 (0.158, 0.634)
p-value		0.0006
Neutropenia		
Total Patients	124	122
Patients (%) With Events	54 (43.5%)	89 (73.0%)
Patients (%) Without Events (Censored)	70 (56.5%)	33 (27.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	21.39 (5.09, NR)	2.10 (1.41, 3.02)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.482 (0.342, 0.681)
p-value		<0.0001
Thrombocytopenia		
Total Patients	124	122

	SG (N=124)	TPC (N=122)
Patients (%) With Events	2 (1.6%)	35 (28.7%)
Patients (%) Without Events (Censored)	122 (98.4%)	87 (71.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	17.31 (10.64, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.043 (0.010, 0.179)
p-value		<0.0001
Gastrointestinal disorders		
Total Patients	124	122
Patients (%) With Events	23 (18.5%)	5 (4.1%)
Patients (%) Without Events (Censored)	101 (81.5%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.728 (1.796, 12.446)
p-value		0.0005
Diarrhoea		
Total Patients	124	122
Patients (%) With Events	14 (11.3%)	2 (1.6%)
Patients (%) Without Events (Censored)	110 (88.7%)	120 (98.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		7.036 (1.598, 30.983)

	SG (N=124)	TPC (N=122)
p-value		0.0026
General disorders and administration site conditions		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	8 (6.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.43, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.074 (0.420, 2.745)
p-value		0.8811
Fatigue		
Total Patients	124	122
Patients (%) With Events	6 (4.8%)	6 (4.9%)
Patients (%) Without Events (Censored)	118 (95.2%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.843 (0.269, 2.639)
p-value		0.7701
Infections and infestations		
Total Patients	124	122
Patients (%) With Events	15 (12.1%)	11 (9.0%)
Patients (%) Without Events (Censored)	109 (87.9%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		

	SG (N=124)	TPC (N=122)
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.266 (0.580, 2.762)
p-value		0.5534
Investigations		
Total Patients	124	122
Patients (%) With Events	4 (3.2%)	17 (13.9%)
Patients (%) Without Events (Censored)	120 (96.8%)	105 (86.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.218 (0.073, 0.647)
p-value		0.0026
Alanine aminotransferase increased		
Total Patients	124	122
Patients (%) With Events	3 (2.4%)	13 (10.7%)
Patients (%) Without Events (Censored)	121 (97.6%)	109 (89.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.213 (0.061, 0.748)
p-value		0.0079
Metabolism and nutrition disorders		
Total Patients	124	122

	SG (N=124)	TPC (N=122)
Patients (%) With Events	7 (5.6%)	6 (4.9%)
Patients (%) Without Events (Censored)	117 (94.4%)	116 (95.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.996 (0.333, 2.980)
p-value		0.9945
Respiratory, thoracic and mediastinal disorders		
Total Patients	124	122
Patients (%) With Events	9 (7.3%)	7 (5.7%)
Patients (%) Without Events (Censored)	115 (92.7%)	115 (94.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.216 (0.452, 3.270)
p-value		0.6979

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.28. Table 1.1.14.1: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.4324
De novo			
Total Patients	29	26	
Patients (%) With Events	15 (51.7%)	22 (84.6%)	
Patients (%) Without Events (Censored)	14 (48.3%)	4 (15.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (0.49, NR)	1.84 (0.85, 3.09)	
Hazard Ratio (95% CI)		0.529 (0.269, 1.038)	
p-value		0.0576	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	20 (64.5%)	27 (90.0%)	
Patients (%) Without Events (Censored)	11 (35.5%)	3 (10.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.49, 23.66)	1.07 (0.92, 1.87)	
Hazard Ratio (95% CI)		0.663 (0.364, 1.207)	
p-value		0.1597	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	26 (40.6%)	54 (81.8%)	
Patients (%) Without Events (Censored)	38 (59.4%)	12 (18.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (5.09, NR)	2.10 (1.25, 3.02)	
Hazard Ratio (95% CI)		0.338 (0.209, 0.547)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Geographic region			0.9968
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	13 (43.3%)	26 (76.5%)	
Patients (%) Without Events (Censored)	17 (56.7%)	8 (23.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (0.95, NR)	1.76 (0.92, 3.12)	
Hazard Ratio (95% CI)		0.474 (0.242, 0.928)	
p-value		0.0235	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	48 (51.1%)	77 (87.5%)	
Patients (%) Without Events (Censored)	46 (48.9%)	11 (12.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (1.71, NR)	1.64 (0.95, 2.30)	
Hazard Ratio (95% CI)		0.445 (0.306, 0.647)	
p-value		<0.0001	
Age group			0.0834
< 65			
Total Patients	98	94	
Patients (%) With Events	46 (46.9%)	80 (85.1%)	
Patients (%) Without Events (Censored)	52 (53.1%)	14 (14.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (2.92, NR)	1.64 (0.95, 2.27)	
Hazard Ratio (95% CI)		0.394 (0.270, 0.574)	
p-value		<0.0001	
>= 65			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	26	28	
Patients (%) With Events	15 (57.7%)	23 (82.1%)	
Patients (%) Without Events (Censored)	11 (42.3%)	5 (17.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.49, NR)	2.40 (0.92, 4.27)	
Hazard Ratio (95% CI)		0.759 (0.395, 1.460)	
p-value		0.3964	
Race			0.0607
White			
Total Patients	80	75	
Patients (%) With Events	31 (38.8%)	62 (82.7%)	
Patients (%) Without Events (Censored)	49 (61.2%)	13 (17.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.17, NR)	1.61 (0.95, 2.33)	
Hazard Ratio (95% CI)		0.352 (0.227, 0.546)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	18 (69.2%)	21 (80.8%)	
Patients (%) Without Events (Censored)	8 (30.8%)	5 (19.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.92 (0.49, 11.24)	1.87 (0.92, 3.45)	
Hazard Ratio (95% CI)		0.779 (0.408, 1.488)	
p-value		0.4255	
Other			
Total Patients	16	21	
Patients (%) With Events	11 (68.8%)	20 (95.2%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	5 (31.2%)	1 (4.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.03 (0.30, NR)	0.99 (0.85, 4.27)	
Hazard Ratio (95% CI)		0.582 (0.266, 1.276)	
p-value		0.1673	
Baseline ECOG status			0.7927
0			
Total Patients	81	79	
Patients (%) With Events	41 (50.6%)	70 (88.6%)	
Patients (%) Without Events (Censored)	40 (49.4%)	9 (11.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (0.99, NR)	1.84 (1.05, 2.37)	
Hazard Ratio (95% CI)		0.468 (0.316, 0.695)	
p-value		0.0001	
1			
Total Patients	43	43	
Patients (%) With Events	20 (46.5%)	33 (76.7%)	
Patients (%) Without Events (Censored)	23 (53.5%)	10 (23.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (2.56, 23.66)	1.64 (0.92, 3.02)	
Hazard Ratio (95% CI)		0.406 (0.223, 0.738)	
p-value		0.0021	
History of liver metastasis			0.7779
Yes			
Total Patients	36	25	
Patients (%) With Events	18 (50.0%)	21 (84.0%)	
Patients (%) Without Events (Censored)	18 (50.0%)	4 (16.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (0.89, NR)	1.41 (0.92, 2.33)	
Hazard Ratio (95% CI)		0.455 (0.236, 0.876)	
p-value		0.0155	
No			
Total Patients	88	97	
Patients (%) With Events	43 (48.9%)	82 (84.5%)	
Patients (%) Without Events (Censored)	45 (51.1%)	15 (15.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (2.56, NR)	1.87 (1.15, 2.50)	
Hazard Ratio (95% CI)		0.441 (0.302, 0.645)	
p-value		<0.0001	
History of brain metastasis			0.9384
Yes			
Total Patients	6	7	
Patients (%) With Events	2 (33.3%)	5 (71.4%)	
Patients (%) Without Events (Censored)	4 (66.7%)	2 (28.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.43, NR)	2.10 (0.66, NR)	
Hazard Ratio (95% CI)		0.462 (0.088, 2.412)	
p-value		0.3481	
No			
Total Patients	118	115	
Patients (%) With Events	59 (50.0%)	98 (85.2%)	
Patients (%) Without Events (Censored)	59 (50.0%)	17 (14.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (1.77, 23.66)	1.64 (0.95, 2.30)	
Hazard Ratio (95% CI)		0.451 (0.324, 0.629)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		<0.0001	
PD-L1 Status			0.5331
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	19 (44.2%)	37 (72.5%)	
Patients (%) Without Events (Censored)	24 (55.8%)	14 (27.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.95, NR)	2.17 (1.18, 3.48)	
Hazard Ratio (95% CI)		0.553 (0.316, 0.970)	
p-value		0.0349	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	42 (51.9%)	66 (93.0%)	
Patients (%) Without Events (Censored)	39 (48.1%)	5 (7.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (1.71, 23.66)	1.64 (0.92, 2.10)	
Hazard Ratio (95% CI)		0.381 (0.254, 0.571)	
p-value		<0.0001	
BRCA 1/2 status			0.6461
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	21 (50.0%)	35 (77.8%)	
Patients (%) Without Events (Censored)	21 (50.0%)	10 (22.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (0.89, NR)	1.18 (0.72, 2.10)	
Hazard Ratio (95% CI)		0.490 (0.282, 0.854)	
p-value		0.0094	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	7 (100.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	0 (0.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (0.23, NR)	2.33 (0.95, 4.63)	
Hazard Ratio (95% CI)		0.487 (0.141, 1.690)	
p-value		0.2549	
Menopausal status			0.5975
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	12 (41.4%)	30 (88.2%)	
Patients (%) Without Events (Censored)	17 (58.6%)	4 (11.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.69, NR)	1.84 (0.92, 3.02)	
Hazard Ratio (95% CI)		0.401 (0.202, 0.793)	
p-value		0.0058	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	49 (51.6%)	73 (83.9%)	
Patients (%) Without Events (Censored)	46 (48.4%)	14 (16.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (1.77, 23.66)	1.64 (0.95, 2.50)	
Hazard Ratio (95% CI)		0.459 (0.316, 0.666)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.29. Table 1.1.14.2: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Leukopenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
History of brain metastasis			0.3060
Yes			
Total Patients	6	7	
Patients (%) With Events	0 (0.0%)	2 (28.6%)	
Patients (%) Without Events (Censored)	6 (100.0%)	5 (71.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.1761	
No			
Total Patients	118	115	
Patients (%) With Events	11 (9.3%)	28 (24.3%)	
Patients (%) Without Events (Censored)	107 (90.7%)	87 (75.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (23.66, NR)	NR (13.63, NR)	
Hazard Ratio (95% CI)		0.335 (0.166, 0.676)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0014	
Menopausal status			0.1540
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	1 (3.4%)	10 (29.4%)	
Patients (%) Without Events (Censored)	28 (96.6%)	24 (70.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (15.08, NR)	NR (7.66, NR)	
Hazard Ratio (95% CI)		0.087 (0.011, 0.688)	
p-value		0.0037	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	10 (10.5%)	20 (23.0%)	
Patients (%) Without Events (Censored)	85 (89.5%)	67 (77.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (23.66, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.421 (0.197, 0.903)	
p-value		0.0218	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.30. Table 1.1.14.3: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Disease stratification			0.3861
De novo			
Total Patients	29	26	
Patients (%) With Events	13 (44.8%)	17 (65.4%)	
Patients (%) Without Events (Censored)	16 (55.2%)	9 (34.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (0.69, NR)	2.33 (0.95, 4.63)	
Hazard Ratio (95% CI)		0.671 (0.324, 1.391)	
p-value		0.2713	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	31	30	
Patients (%) With Events	18 (58.1%)	23 (76.7%)	
Patients (%) Without Events (Censored)	13 (41.9%)	7 (23.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.69, NR)	1.07 (0.92, 2.37)	
Hazard Ratio (95% CI)		0.683 (0.362, 1.289)	
p-value		0.2211	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	64	66	
Patients (%) With Events	23 (35.9%)	49 (74.2%)	
Patients (%) Without Events (Censored)	41 (64.1%)	17 (25.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (6.28, NR)	2.50 (1.61, 3.22)	
Hazard Ratio (95% CI)		0.353 (0.213, 0.584)	
p-value		<0.0001	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Geographic region			0.7607
US/Canada/Western Europe			
Total Patients	30	34	
Patients (%) With Events	11 (36.7%)	22 (64.7%)	
Patients (%) Without Events (Censored)	19 (63.3%)	12 (35.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (1.38, NR)	2.10 (0.92, 5.82)	
Hazard Ratio (95% CI)		0.466 (0.225, 0.965)	
p-value		0.0315	
Rest of the world			
Total Patients	94	88	
Patients (%) With Events	43 (45.7%)	67 (76.1%)	
Patients (%) Without Events (Censored)	51 (54.3%)	21 (23.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.34, NR)	2.10 (1.25, 3.02)	
Hazard Ratio (95% CI)		0.490 (0.331, 0.726)	
p-value		0.0003	
Age group			0.1237
< 65			
Total Patients	98	94	
Patients (%) With Events	41 (41.8%)	69 (73.4%)	
Patients (%) Without Events (Censored)	57 (58.2%)	25 (26.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	23.66 (6.28, NR)	2.10 (1.15, 3.02)	
Hazard Ratio (95% CI)		0.422 (0.283, 0.628)	
p-value		<0.0001	
>= 65			

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Total Patients	26	28	
Patients (%) With Events	13 (50.0%)	20 (71.4%)	
Patients (%) Without Events (Censored)	13 (50.0%)	8 (28.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	5.09 (0.66, NR)	2.66 (1.05, 8.48)	
Hazard Ratio (95% CI)		0.795 (0.394, 1.603)	
p-value		0.5109	
Race			0.0655
White			
Total Patients	80	75	
Patients (%) With Events	27 (33.8%)	54 (72.0%)	
Patients (%) Without Events (Censored)	53 (66.2%)	21 (28.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.17, NR)	1.87 (1.15, 2.99)	
Hazard Ratio (95% CI)		0.365 (0.229, 0.583)	
p-value		<0.0001	
Asian			
Total Patients	26	26	
Patients (%) With Events	16 (61.5%)	18 (69.2%)	
Patients (%) Without Events (Censored)	10 (38.5%)	8 (30.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	4.34 (0.56, 11.24)	3.02 (1.64, 5.78)	
Hazard Ratio (95% CI)		0.846 (0.425, 1.685)	
p-value		0.6196	
Other			
Total Patients	16	21	
Patients (%) With Events	10 (62.5%)	17 (81.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Patients (%) Without Events (Censored)	6 (37.5%)	4 (19.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.24 (0.43, NR)	2.30 (0.89, 4.93)	
Hazard Ratio (95% CI)		0.692 (0.306, 1.568)	
p-value		0.3698	
Baseline ECOG status			0.9804
0			
Total Patients	81	79	
Patients (%) With Events	36 (44.4%)	61 (77.2%)	
Patients (%) Without Events (Censored)	45 (55.6%)	18 (22.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (4.14, NR)	2.30 (1.18, 3.02)	
Hazard Ratio (95% CI)		0.485 (0.320, 0.737)	
p-value		0.0005	
1			
Total Patients	43	43	
Patients (%) With Events	18 (41.9%)	28 (65.1%)	
Patients (%) Without Events (Censored)	25 (58.1%)	15 (34.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.86, NR)	2.10 (0.95, 4.27)	
Hazard Ratio (95% CI)		0.467 (0.250, 0.874)	
p-value		0.0141	
History of liver metastasis			0.9660
Yes			
Total Patients	36	25	
Patients (%) With Events	15 (41.7%)	16 (64.0%)	
Patients (%) Without Events (Censored)	21 (58.3%)	9 (36.0%)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.61, NR)	1.86 (0.92, 3.12)	
Hazard Ratio (95% CI)		0.537 (0.262, 1.102)	
p-value		0.0856	
No			
Total Patients	88	97	
Patients (%) With Events	39 (44.3%)	73 (75.3%)	
Patients (%) Without Events (Censored)	49 (55.7%)	24 (24.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.86, NR)	2.27 (1.25, 3.22)	
Hazard Ratio (95% CI)		0.473 (0.318, 0.702)	
p-value		0.0001	
History of brain metastasis			0.3198
Yes			
Total Patients	6	7	
Patients (%) With Events	1 (16.7%)	5 (71.4%)	
Patients (%) Without Events (Censored)	5 (83.3%)	2 (28.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.58, NR)	2.50 (0.66, NR)	
Hazard Ratio (95% CI)		0.187 (0.022, 1.609)	
p-value		0.0877	
No			
Total Patients	118	115	
Patients (%) With Events	53 (44.9%)	84 (73.0%)	
Patients (%) Without Events (Censored)	65 (55.1%)	31 (27.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.86, NR)	2.10 (1.18, 3.02)	
Hazard Ratio (95% CI)		0.501 (0.353, 0.712)	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
p-value		0.0001	
PD-L1 Status			0.4959
CPS < 1			
Total Patients	43	51	
Patients (%) With Events	17 (39.5%)	32 (62.7%)	
Patients (%) Without Events (Censored)	26 (60.5%)	19 (37.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.61, NR)	2.99 (1.61, 5.78)	
Hazard Ratio (95% CI)		0.589 (0.324, 1.071)	
p-value		0.0777	
CPS ≥ 1			
Total Patients	81	71	
Patients (%) With Events	37 (45.7%)	57 (80.3%)	
Patients (%) Without Events (Censored)	44 (54.3%)	14 (19.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.86, 23.66)	1.87 (0.95, 2.53)	
Hazard Ratio (95% CI)		0.414 (0.270, 0.635)	
p-value		<0.0001	
BRCA 1/2 status			0.7854
Wild-Type			
Total Patients	42	45	
Patients (%) With Events	19 (45.2%)	31 (68.9%)	
Patients (%) Without Events (Censored)	23 (54.8%)	14 (31.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.95, NR)	1.87 (0.92, 3.48)	
Hazard Ratio (95% CI)		0.539 (0.302, 0.960)	
p-value		0.0313	

	SG (N=124)	TPC (N=122)	Interaction p-value[1]
Mutant			
Total Patients	9	7	
Patients (%) With Events	5 (55.6%)	7 (100.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	0 (0.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (0.23, NR)	2.33 (0.95, 4.63)	
Hazard Ratio (95% CI)		0.487 (0.141, 1.690)	
p-value		0.2549	
Menopausal status			0.6724
Pre-menopausal			
Total Patients	29	34	
Patients (%) With Events	12 (41.4%)	24 (70.6%)	
Patients (%) Without Events (Censored)	17 (58.6%)	10 (29.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.69, NR)	2.30 (0.95, 4.40)	
Hazard Ratio (95% CI)		0.602 (0.299, 1.209)	
p-value		0.1397	
Post-menopausal			
Total Patients	95	87	
Patients (%) With Events	42 (44.2%)	65 (74.7%)	
Patients (%) Without Events (Censored)	53 (55.8%)	22 (25.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (5.09, NR)	1.87 (1.15, 3.02)	
Hazard Ratio (95% CI)		0.448 (0.301, 0.665)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=124)	TPC (N=122)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.31. Table 1.1.15: Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=124)	TPC (N=122)
Blood and lymphatic system disorders		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	19 (15.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	103 (84.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.513 (0.239, 1.104)
p-value		0.0815
Neutropenia		
Total Patients	124	122
Patients (%) With Events	5 (4.0%)	8 (6.6%)
Patients (%) Without Events (Censored)	119 (96.0%)	114 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)

	SG (N=124)	TPC (N=122)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.616 (0.201, 1.882)
p-value		0.3893
Thrombocytopenia		
Total Patients	124	122
Patients (%) With Events	0 (0.0%)	10 (8.2%)
Patients (%) Without Events (Censored)	124 (100.0%)	112 (91.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0012
Gastrointestinal disorders		
Total Patients	124	122
Patients (%) With Events	10 (8.1%)	2 (1.6%)
Patients (%) Without Events (Censored)	114 (91.9%)	120 (98.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.799 (1.050, 21.933)
p-value		0.0254
Infections and infestations		
Total Patients	124	122
Patients (%) With Events	16 (12.9%)	11 (9.0%)

	SG (N=124)	TPC (N=122)
Patients (%) Without Events (Censored)	108 (87.1%)	111 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.366 (0.633, 2.949)
p-value		0.4263
Respiratory, thoracic and mediastinal disorders		
Total Patients	124	122
Patients (%) With Events	7 (5.6%)	5 (4.1%)
Patients (%) Without Events (Censored)	117 (94.4%)	117 (95.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.316 (0.417, 4.155)
p-value		0.6391

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.32. Table 1.1.16: Subgroup Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

[NO TABLE OUTPUT CAPTURED]

6.33. Table 1.1.17: Incidence of TEAE leading to Study Drug Discontinuation by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

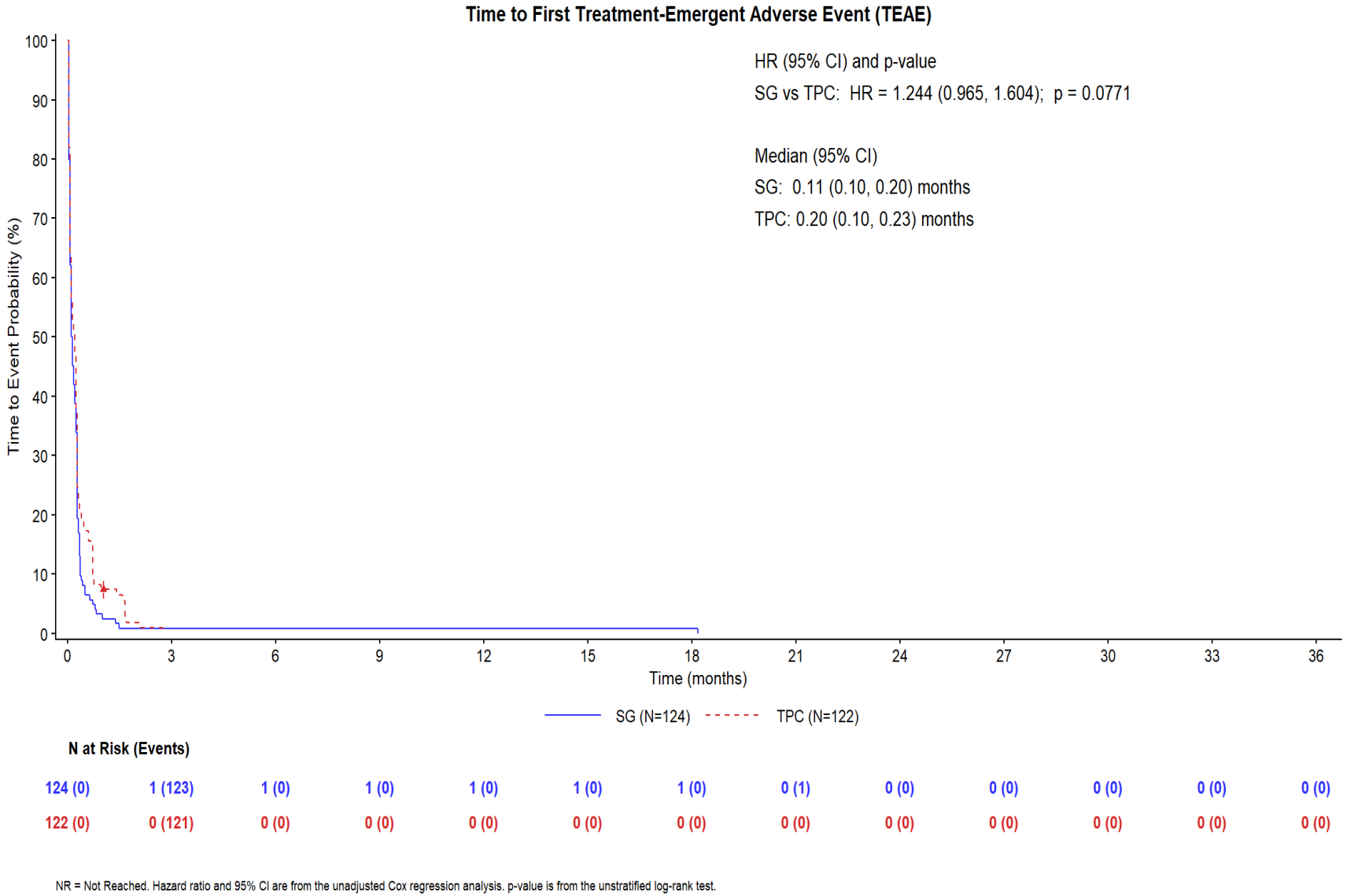
	SG (N=124)	TPC (N=122)
Number (%) of Participants with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	5 (4.0%)	22 (18.0%)
Blood and lymphatic system disorders	1 (0.8%)	14 (11.5%)
Thrombocytopenia	0	9 (7.4%)
Neutropenia	0	3 (2.5%)
Anaemia	0	2 (1.6%)
Febrile neutropenia	1 (0.8%)	0
Cardiac disorders	0	1 (0.8%)
Cardiac failure congestive	0	1 (0.8%)
Gastrointestinal disorders	1 (0.8%)	0
Neutropenic colitis	1 (0.8%)	0
General disorders and administration site conditions	0	1 (0.8%)
Fatigue	0	1 (0.8%)
Hepatobiliary disorders	0	1 (0.8%)
Hypertransaminasaemia	0	1 (0.8%)
Immune system disorders	0	2 (1.6%)
Hypersensitivity	0	2 (1.6%)
Injury, poisoning and procedural complications	1 (0.8%)	2 (1.6%)
Infusion related reaction	1 (0.8%)	2 (1.6%)
Respiratory, thoracic and mediastinal disorders	2 (1.6%)	1 (0.8%)

	SG (N=124)	TPC (N=122)
Interstitial lung disease	1 (0.8%)	0
Pneumonitis	1 (0.8%)	0
Pulmonary embolism	0	1 (0.8%)
Skin and subcutaneous tissue disorders	0	1 (0.8%)
Eczema	0	1 (0.8%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Adverse events were coded according to MedDRA Version 27.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

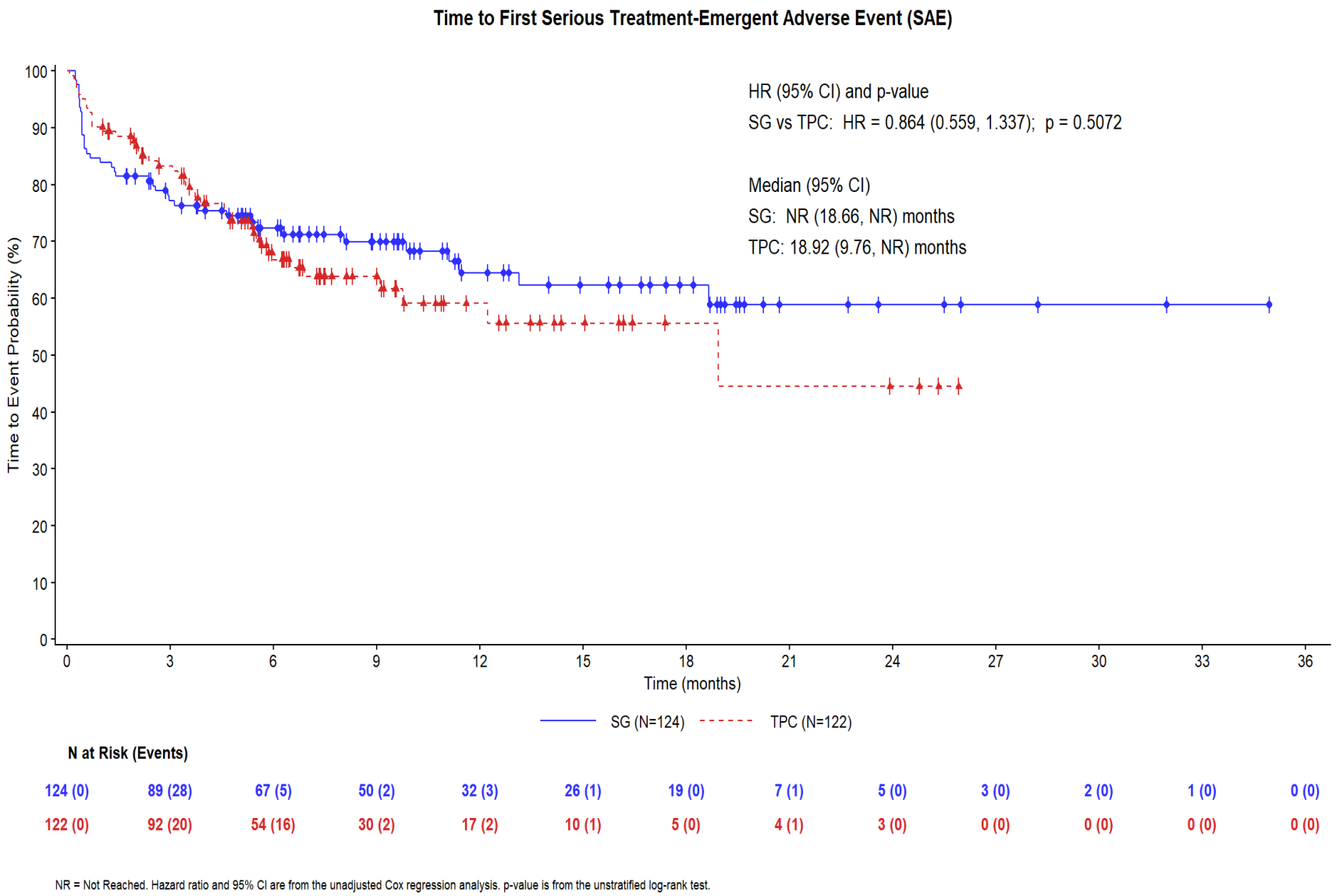
7. Safety - KM FIGURES — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

7.1. Figure 1.1.1: Kaplan Meier Plot of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



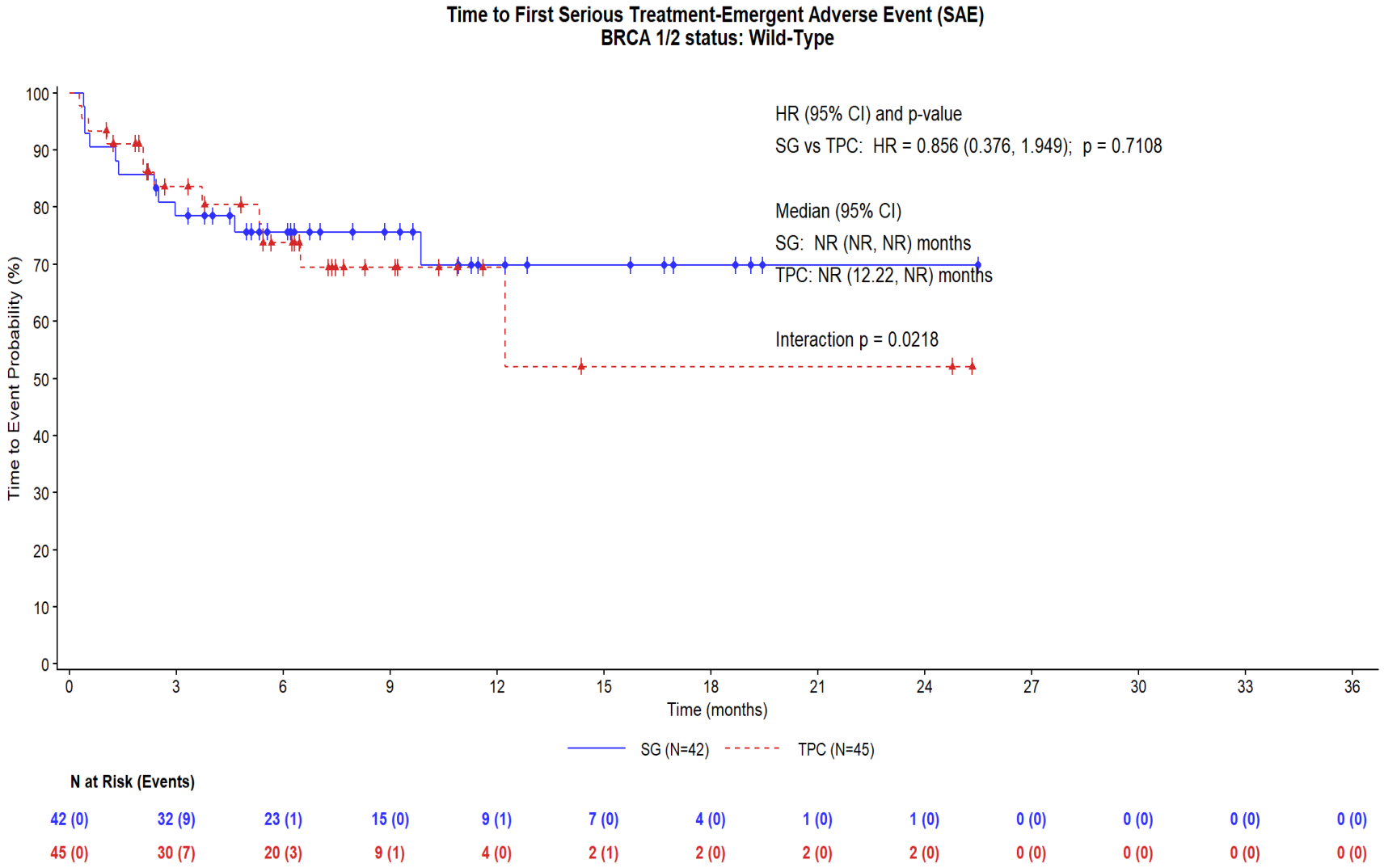
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.2. Figure 1.1.2: Kaplan Meier Plot of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



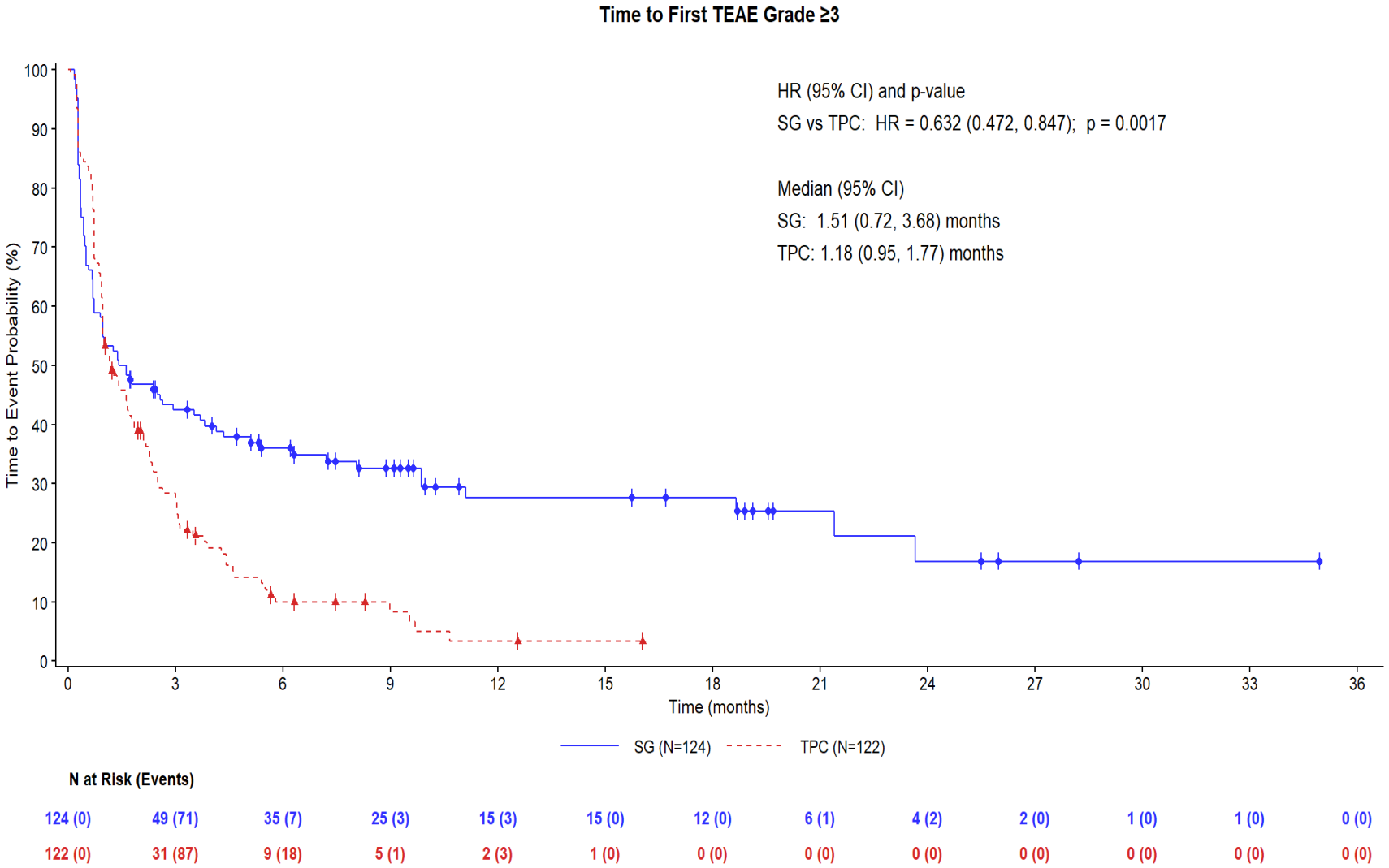
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.3. Figure 1.1.3: Kaplan Meier Plot of Time to First Serious TEAE (SAE) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



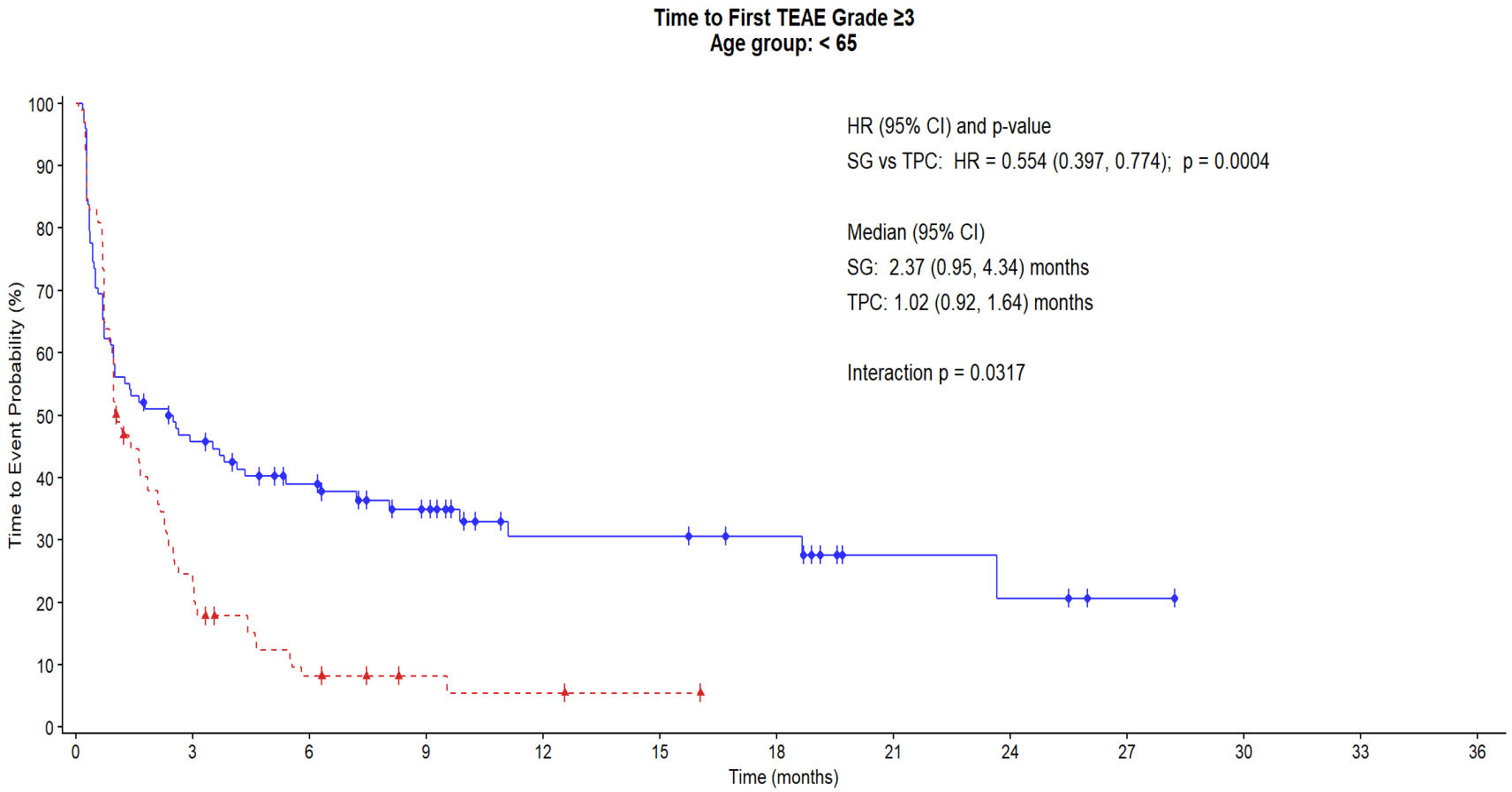
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.4. Figure 1.1.4: Kaplan Meier Plot of Time to First TEAE Grade 3 or higher — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



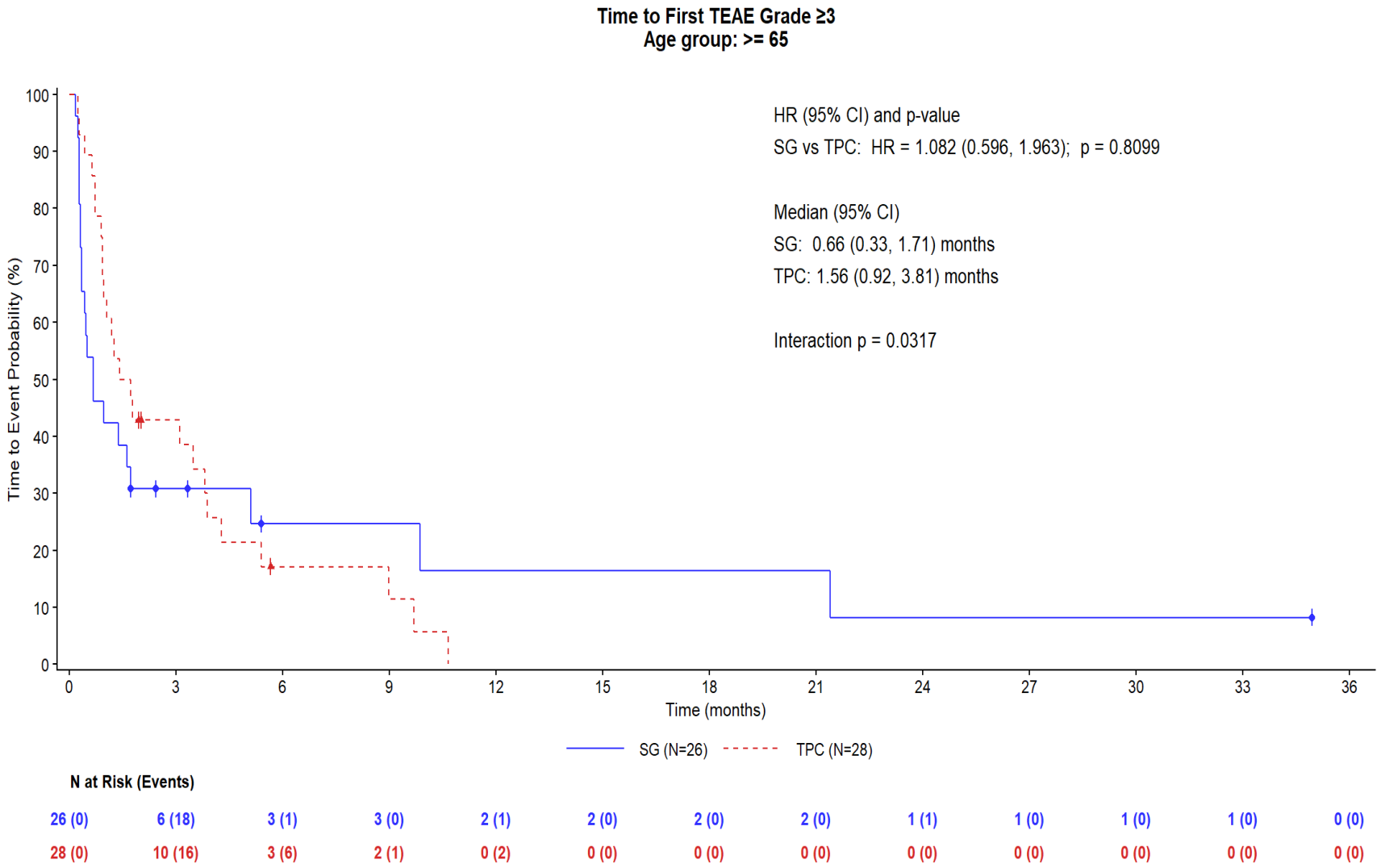
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.5. Figure 1.1.5: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



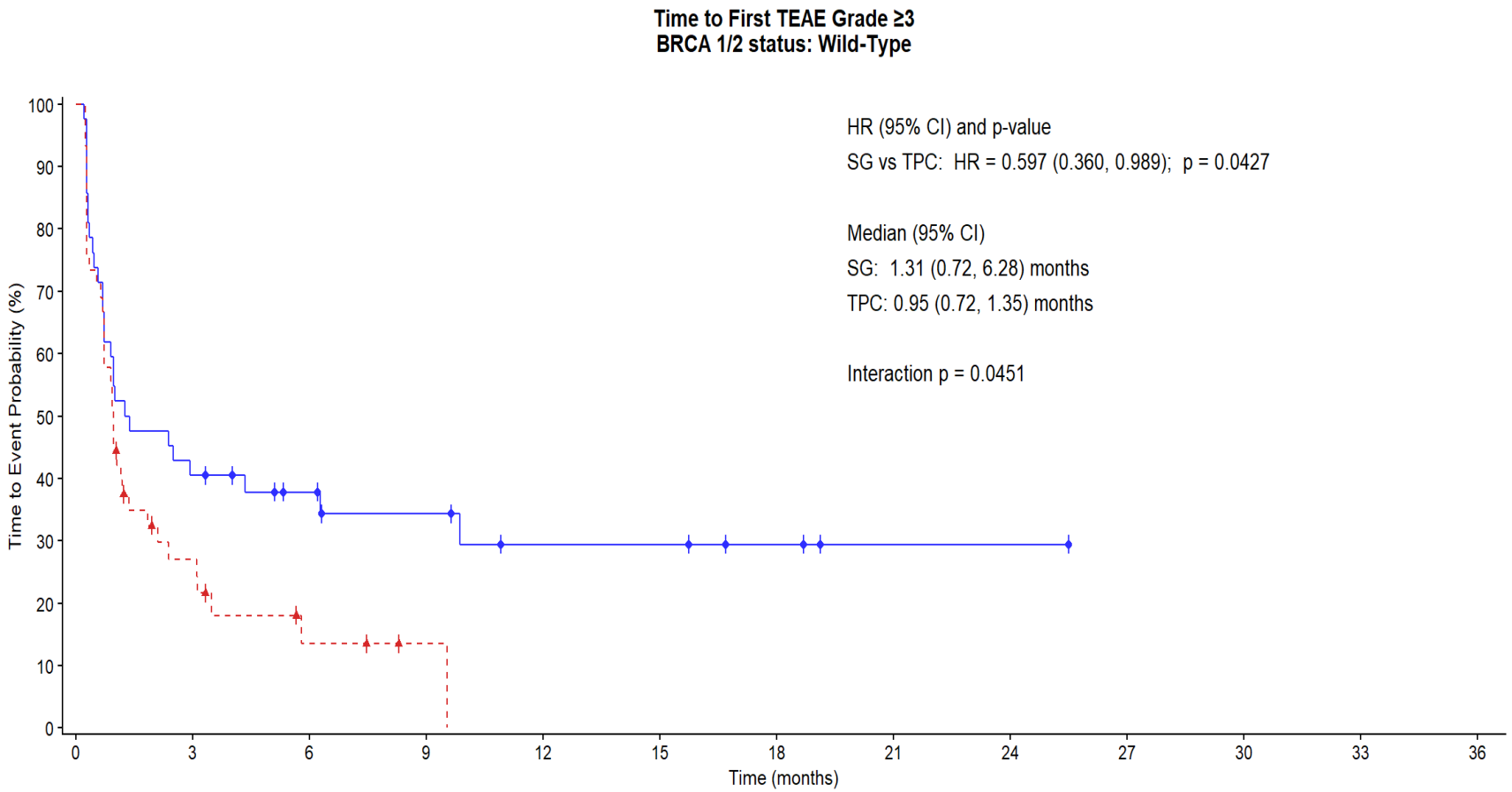
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.6. Figure 1.1.6: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



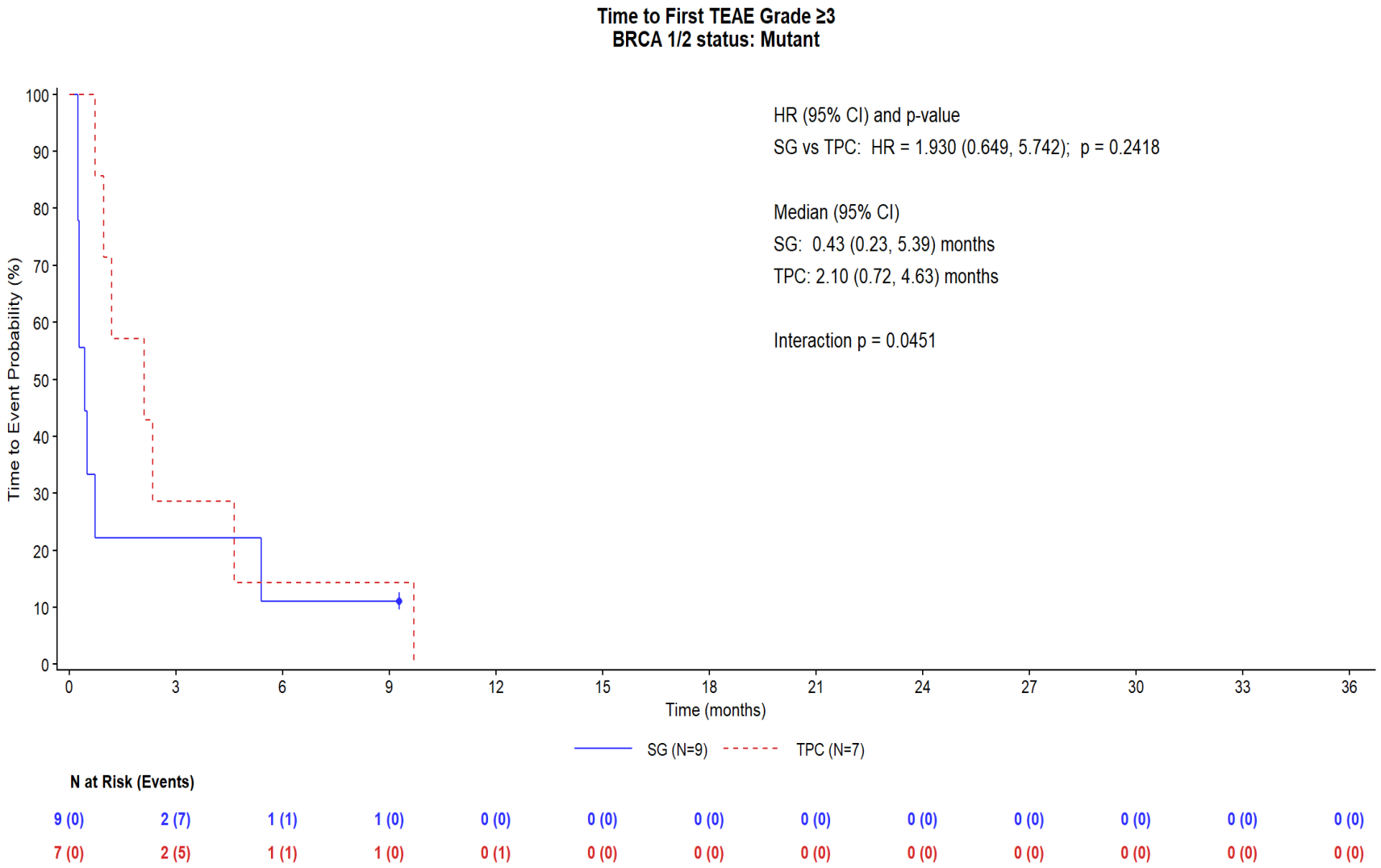
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.7. Figure 1.1.7: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



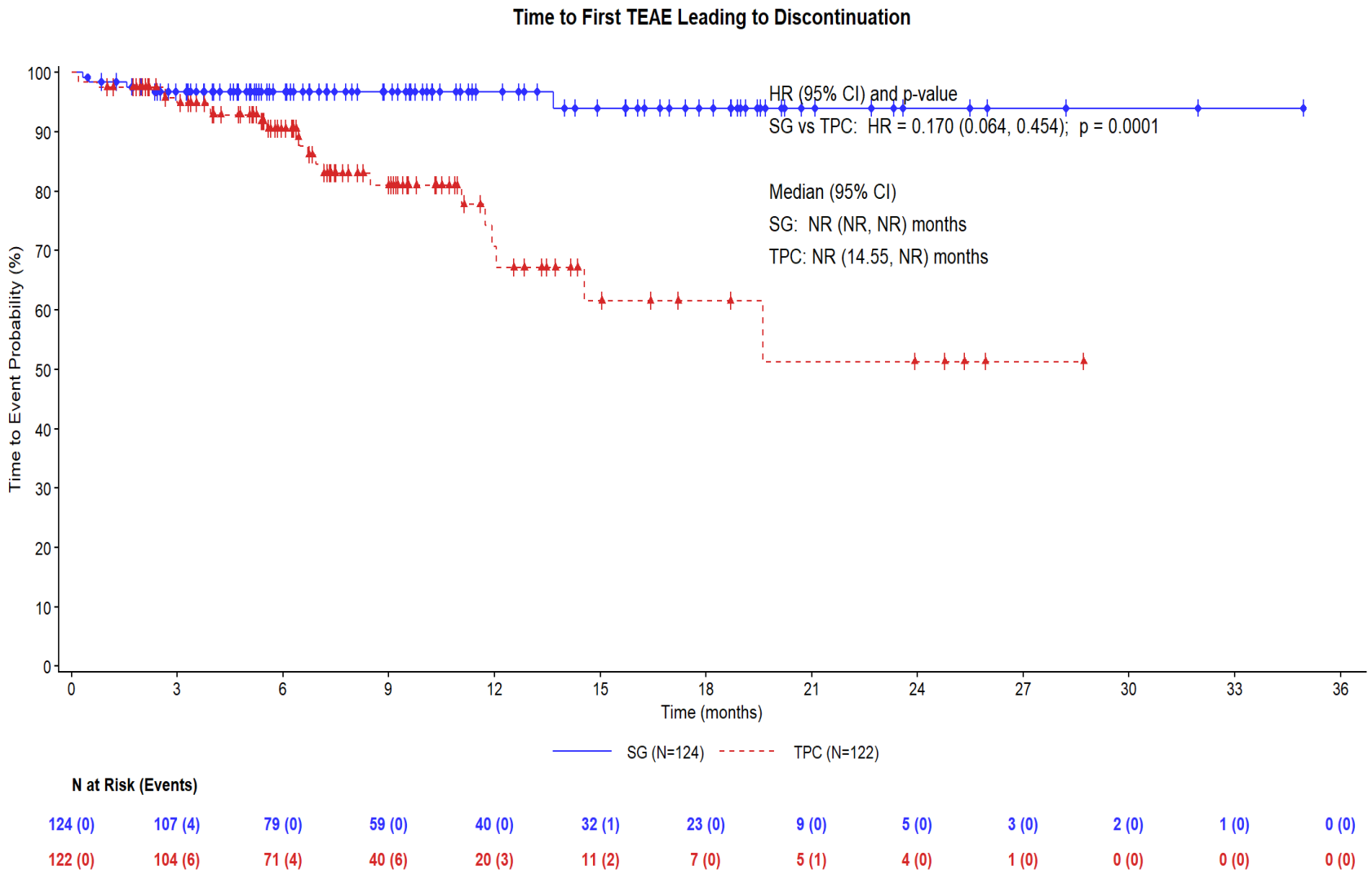
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.8. Figure 1.1.8: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



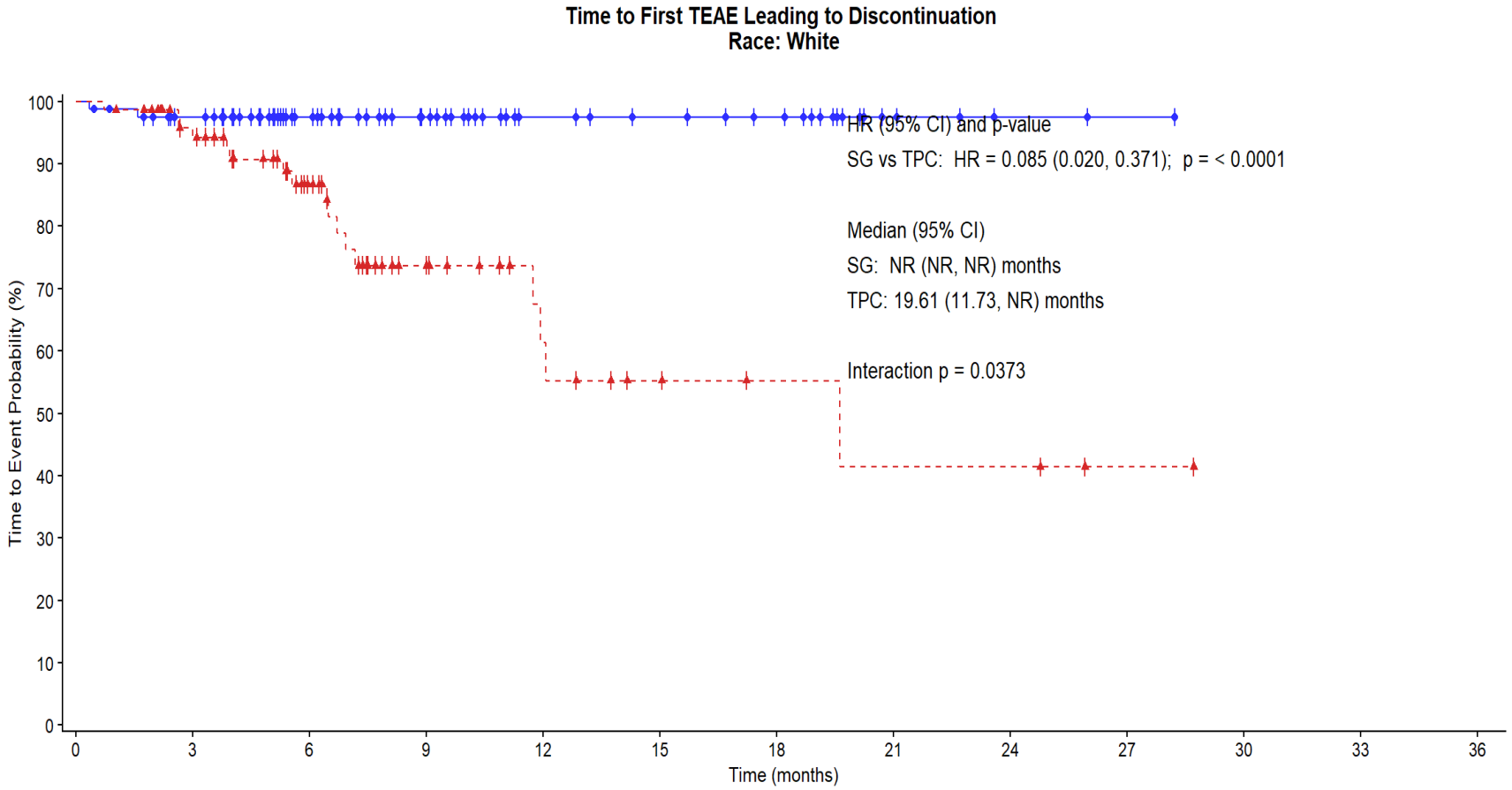
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.9. Figure 1.1.9: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



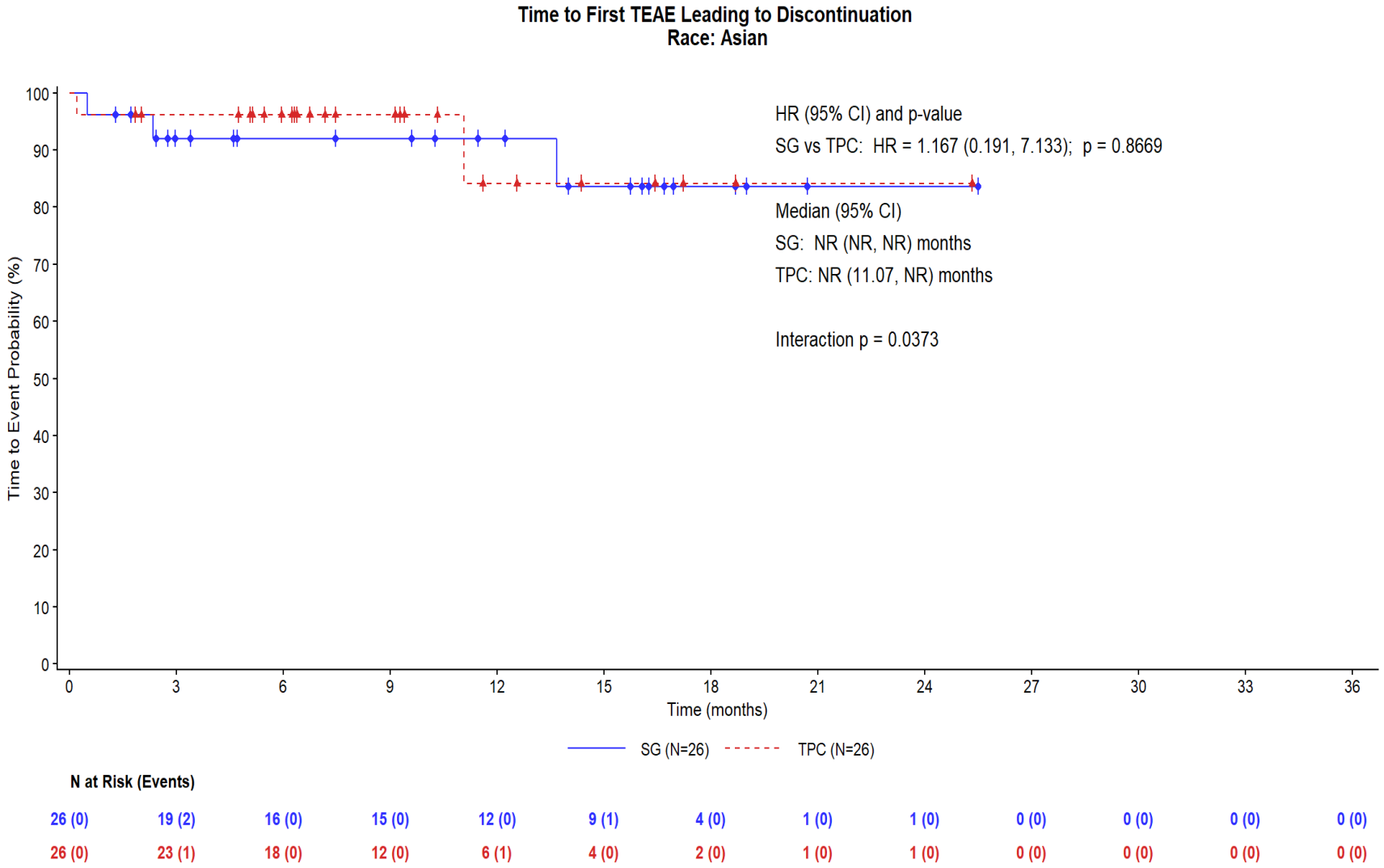
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.10. Figure 1.1.10: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



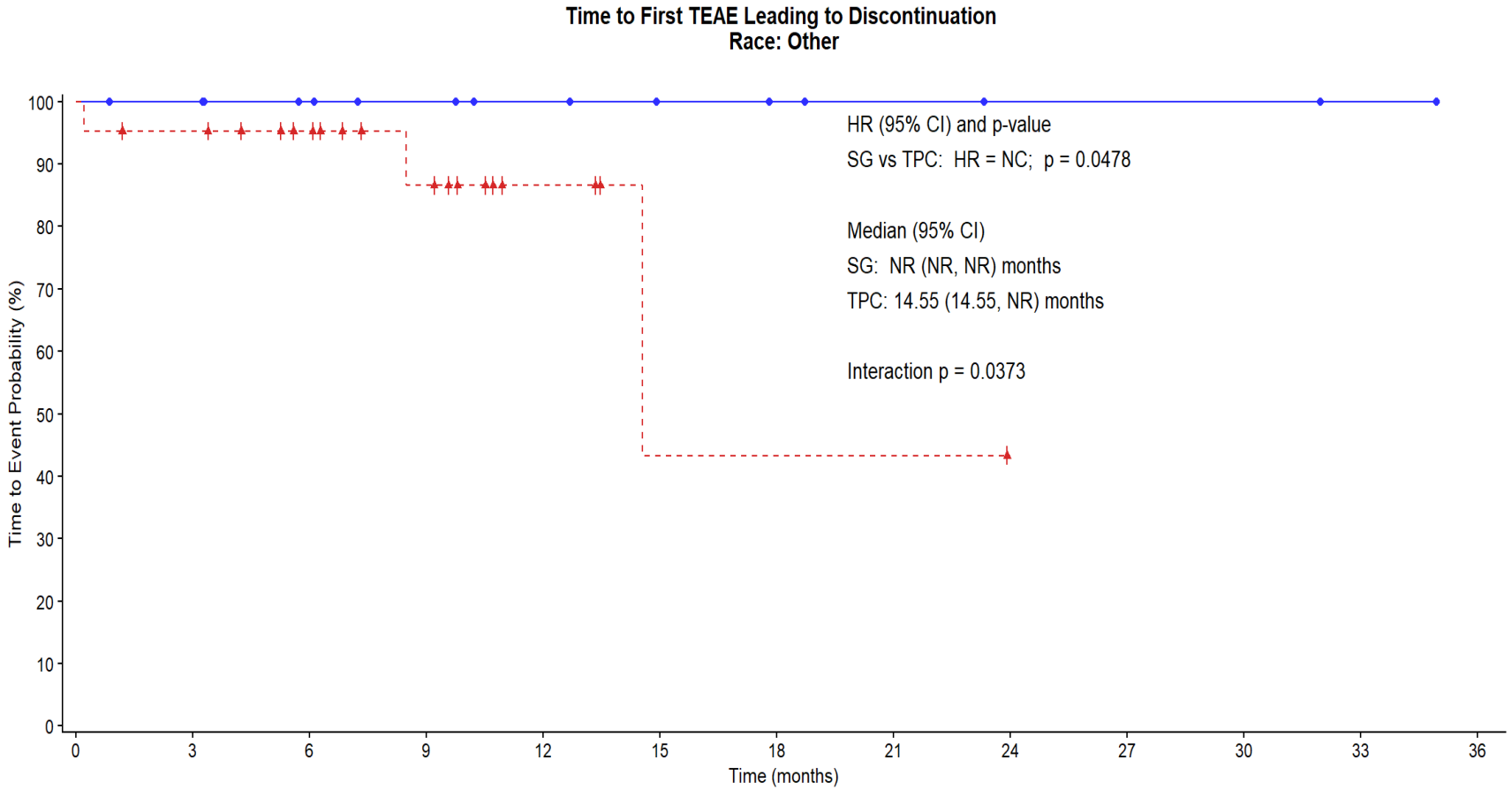
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.11. Figure 1.1.11: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Race Asian — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



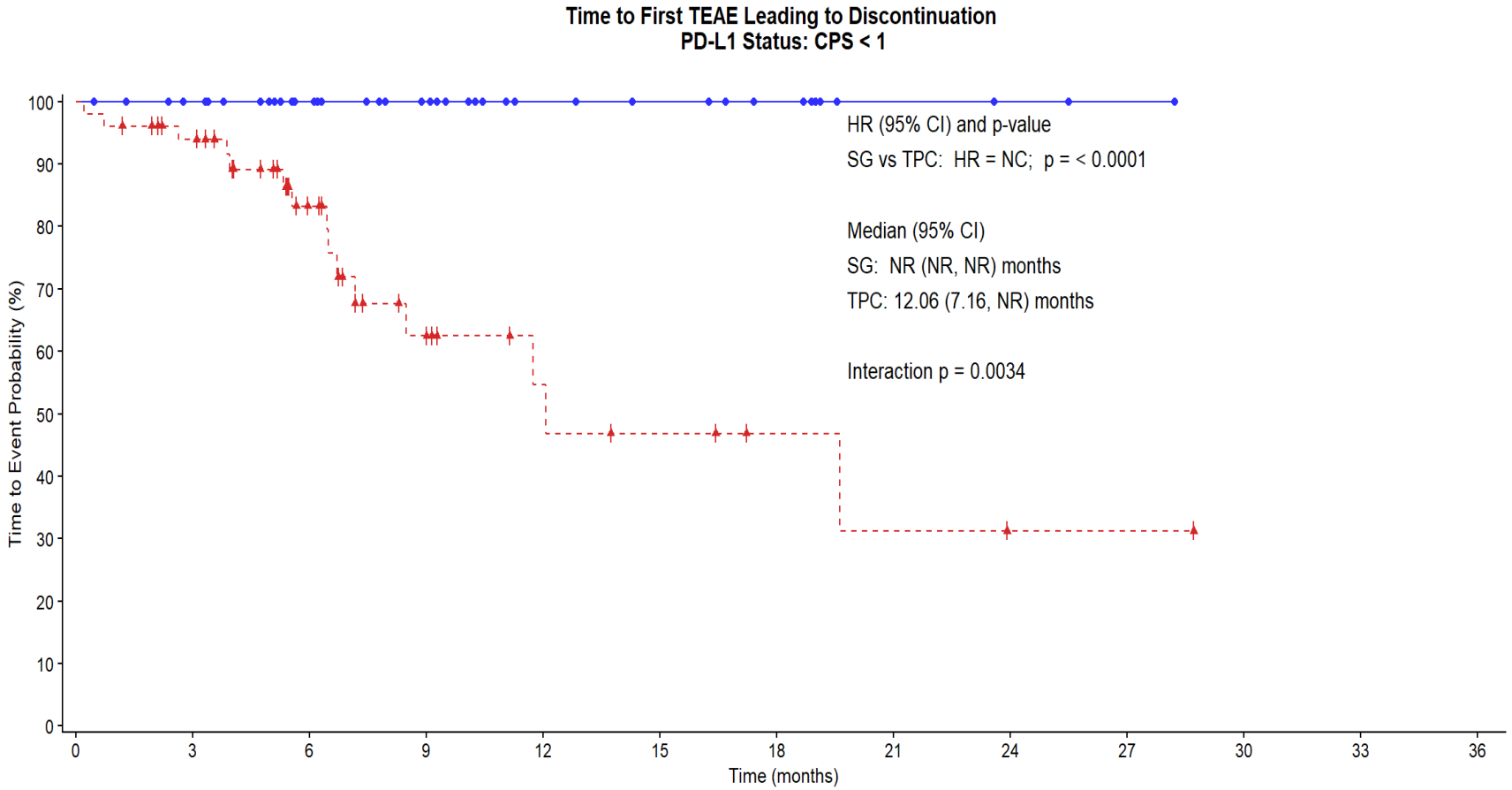
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.12. Figure 1.1.12: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



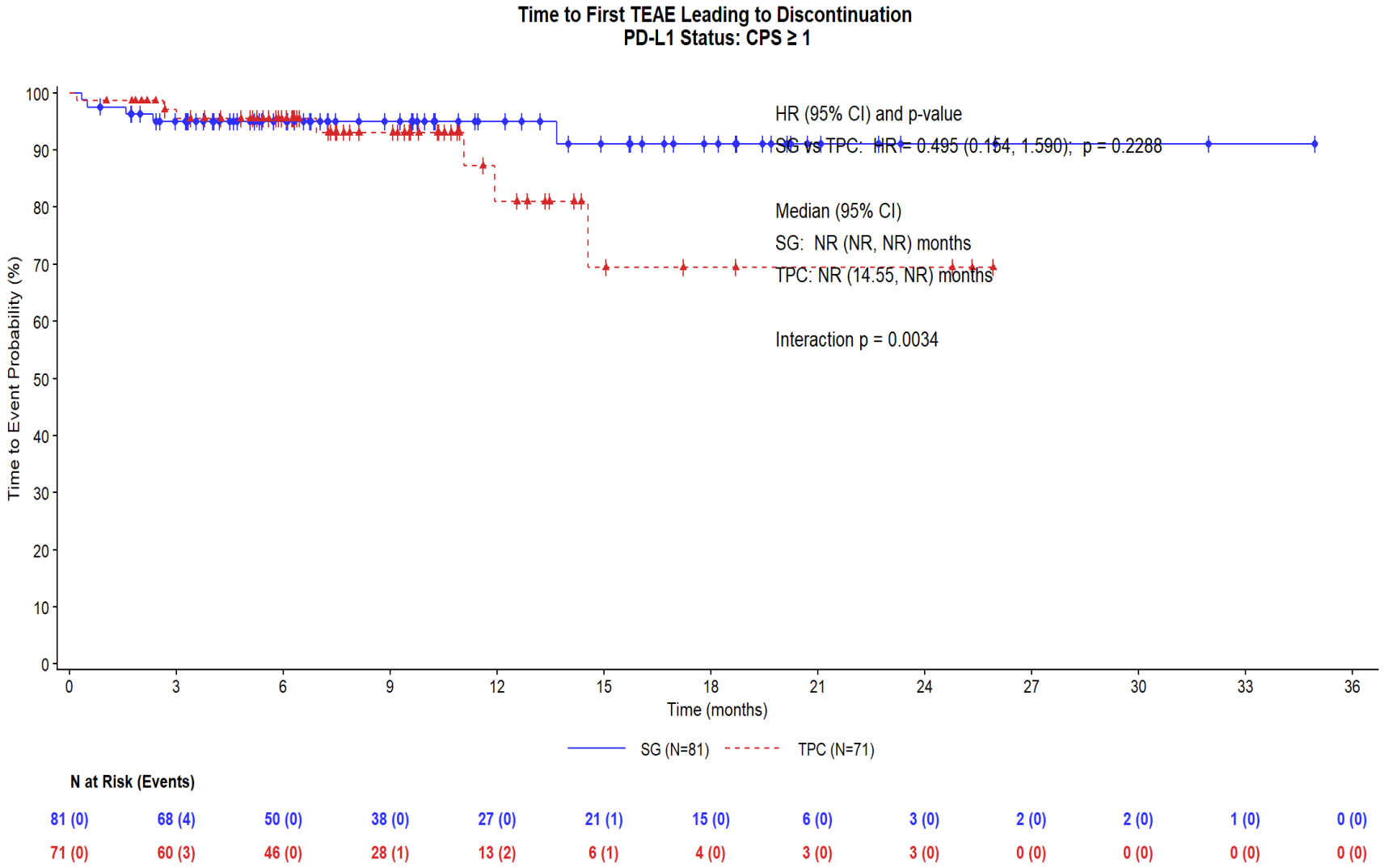
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.13. Figure 1.1.13: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



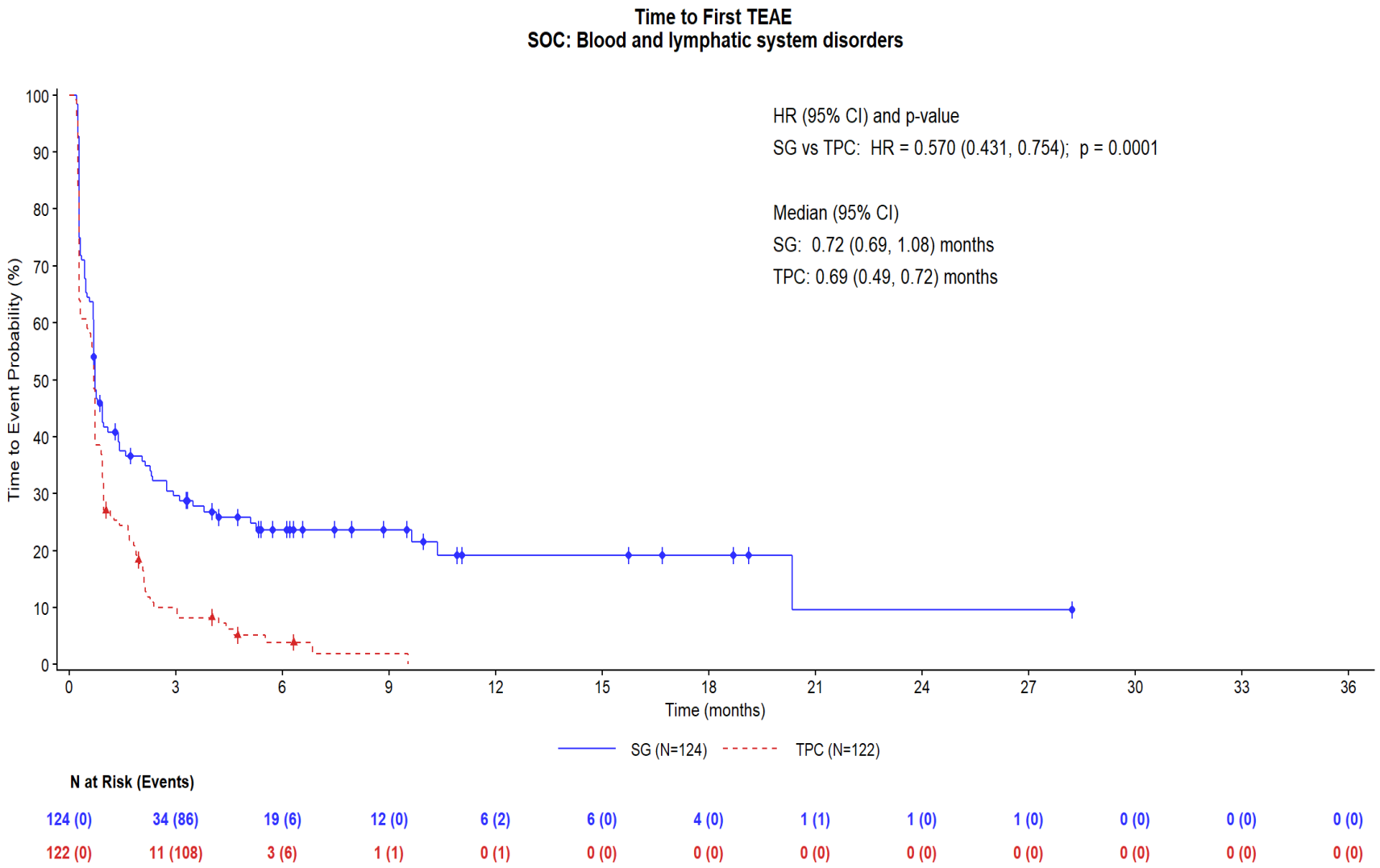
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.14. Figure 1.1.14: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS >= 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



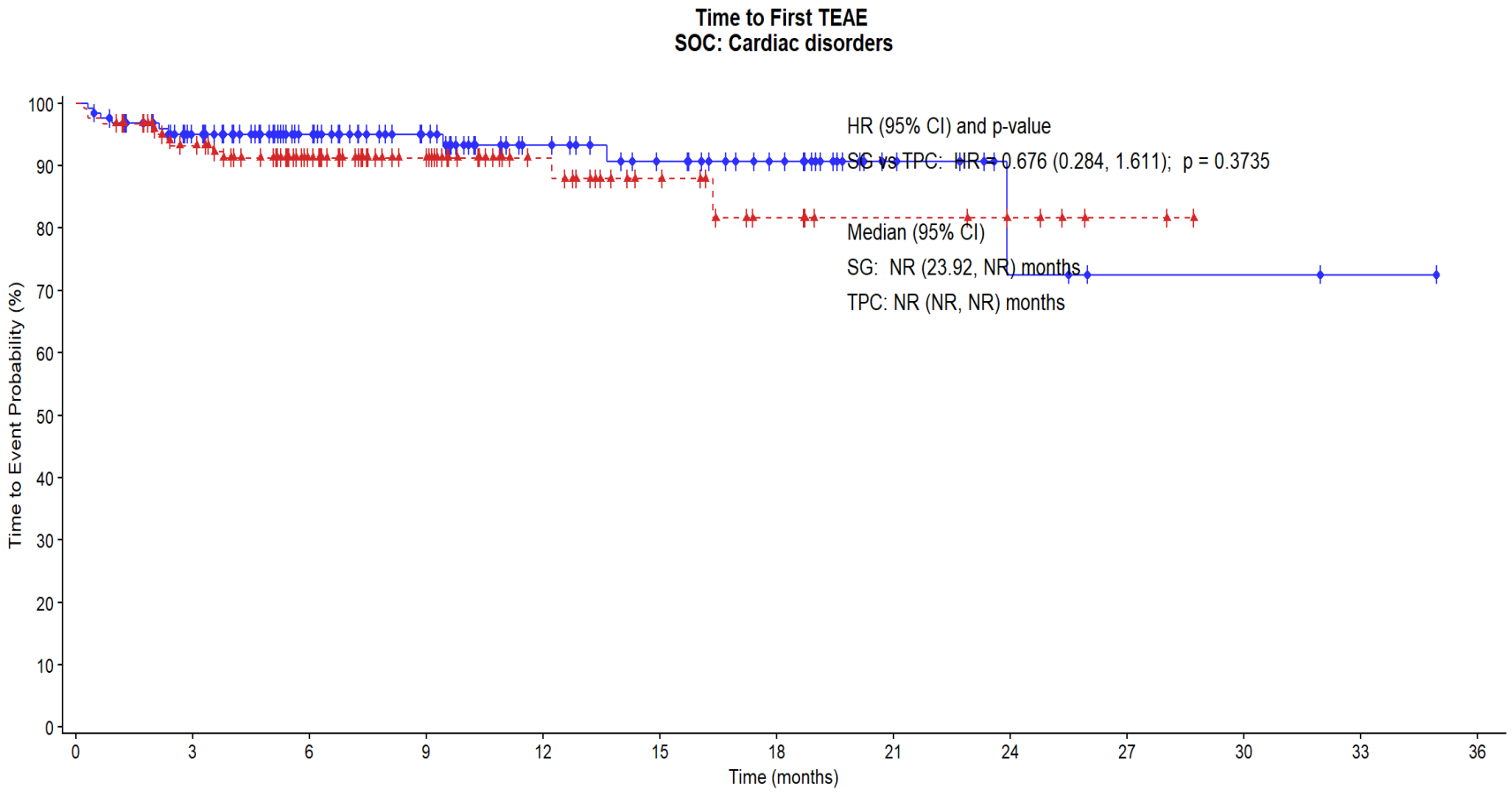
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.15. Figure 1.1.15: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



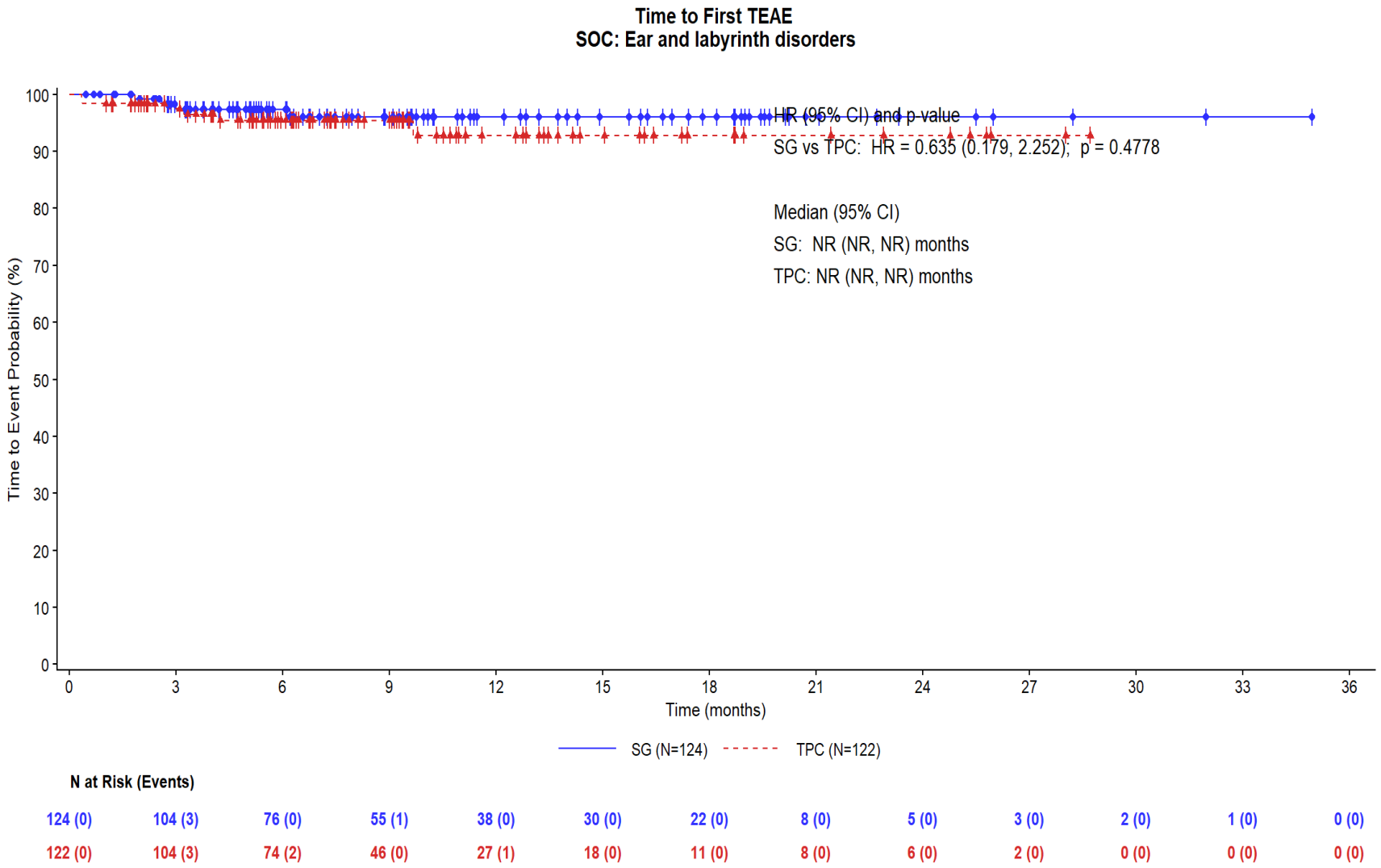
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.16. Figure 1.1.16: Kaplan Meier Plot of Time to First TEAE by SOC Cardiac disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



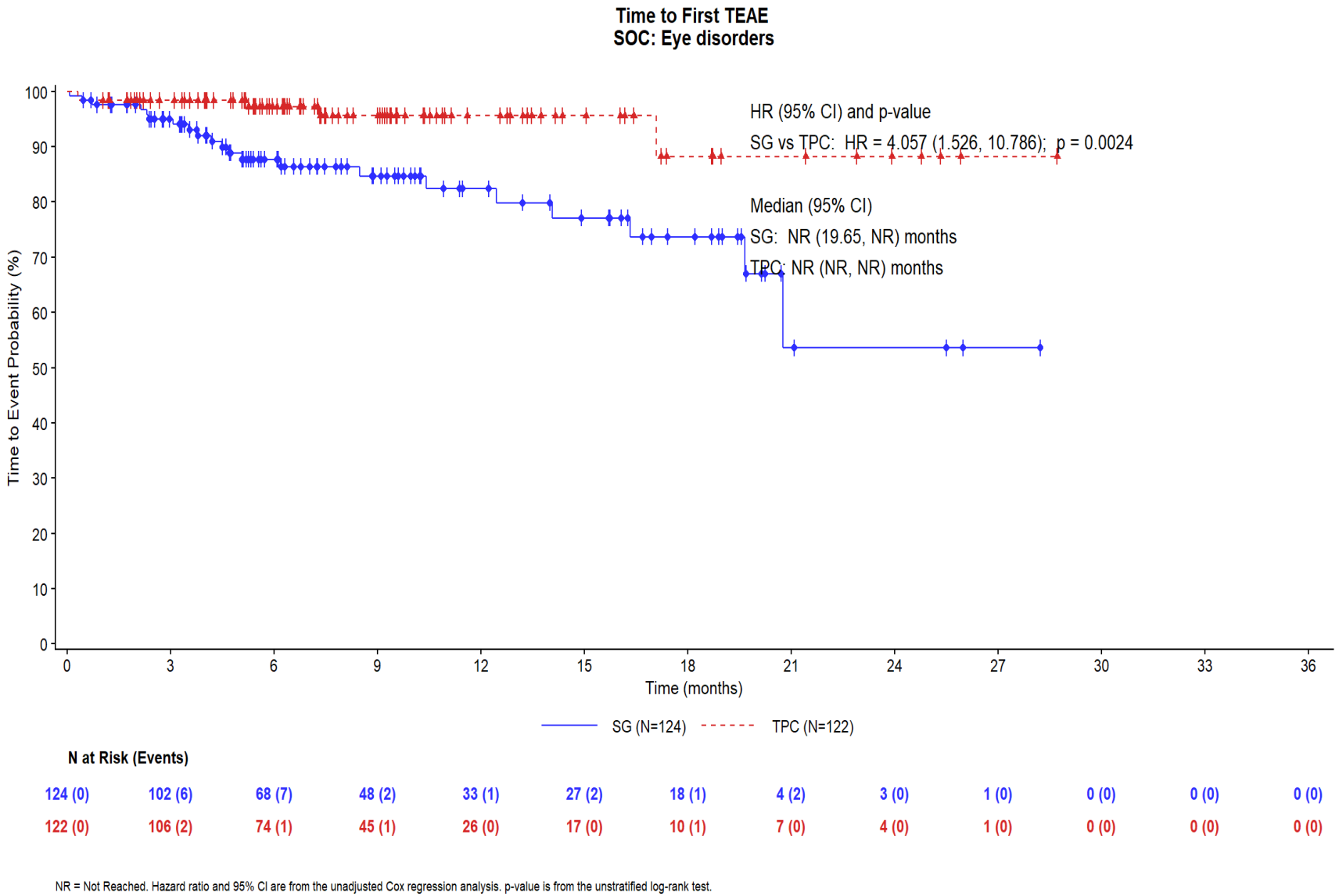
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.17. Figure 1.1.17: Kaplan Meier Plot of Time to First TEAE by SOC Ear and labyrinth disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



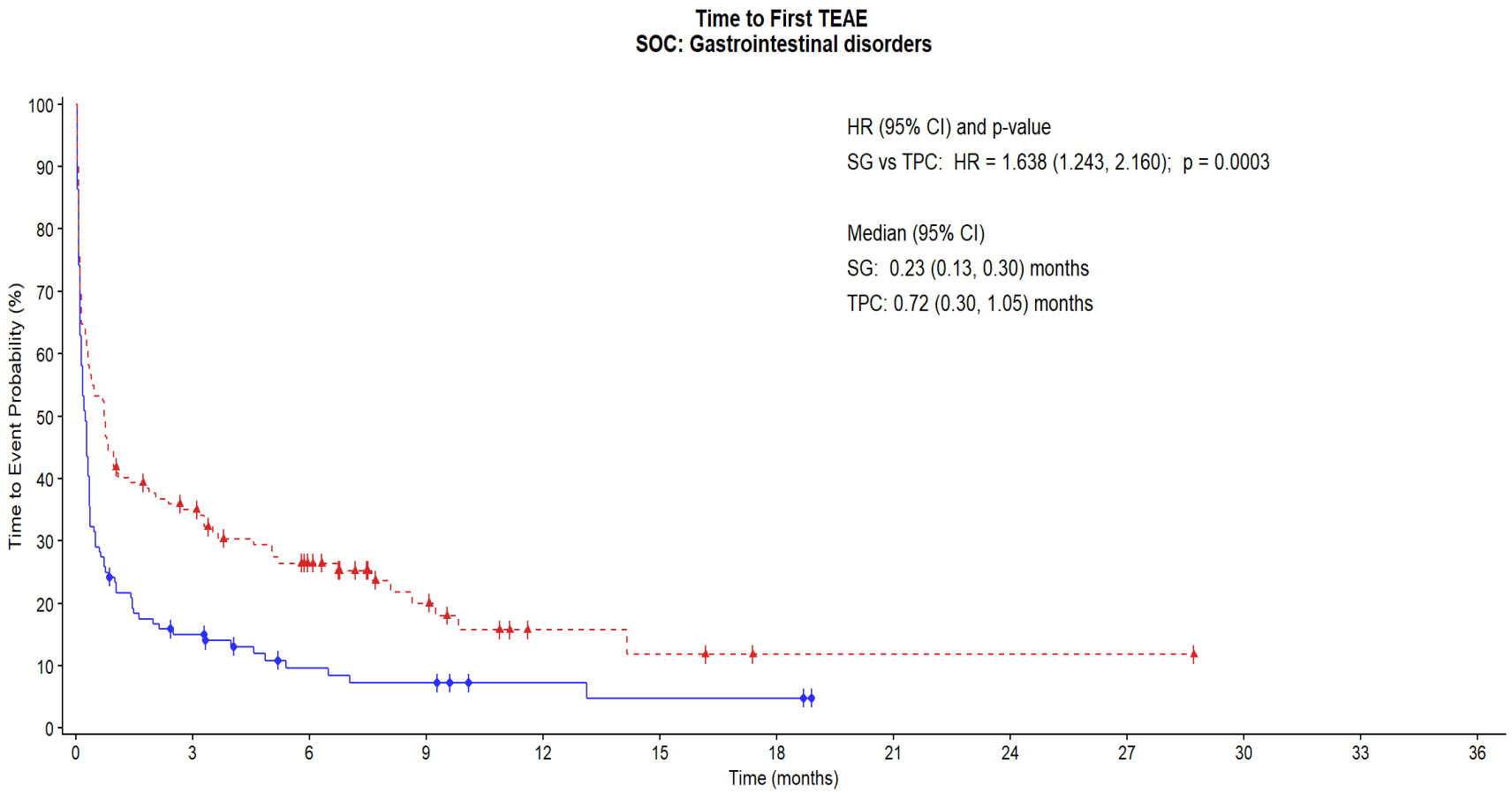
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.18. Figure 1.1.18: Kaplan Meier Plot of Time to First TEAE by SOC Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



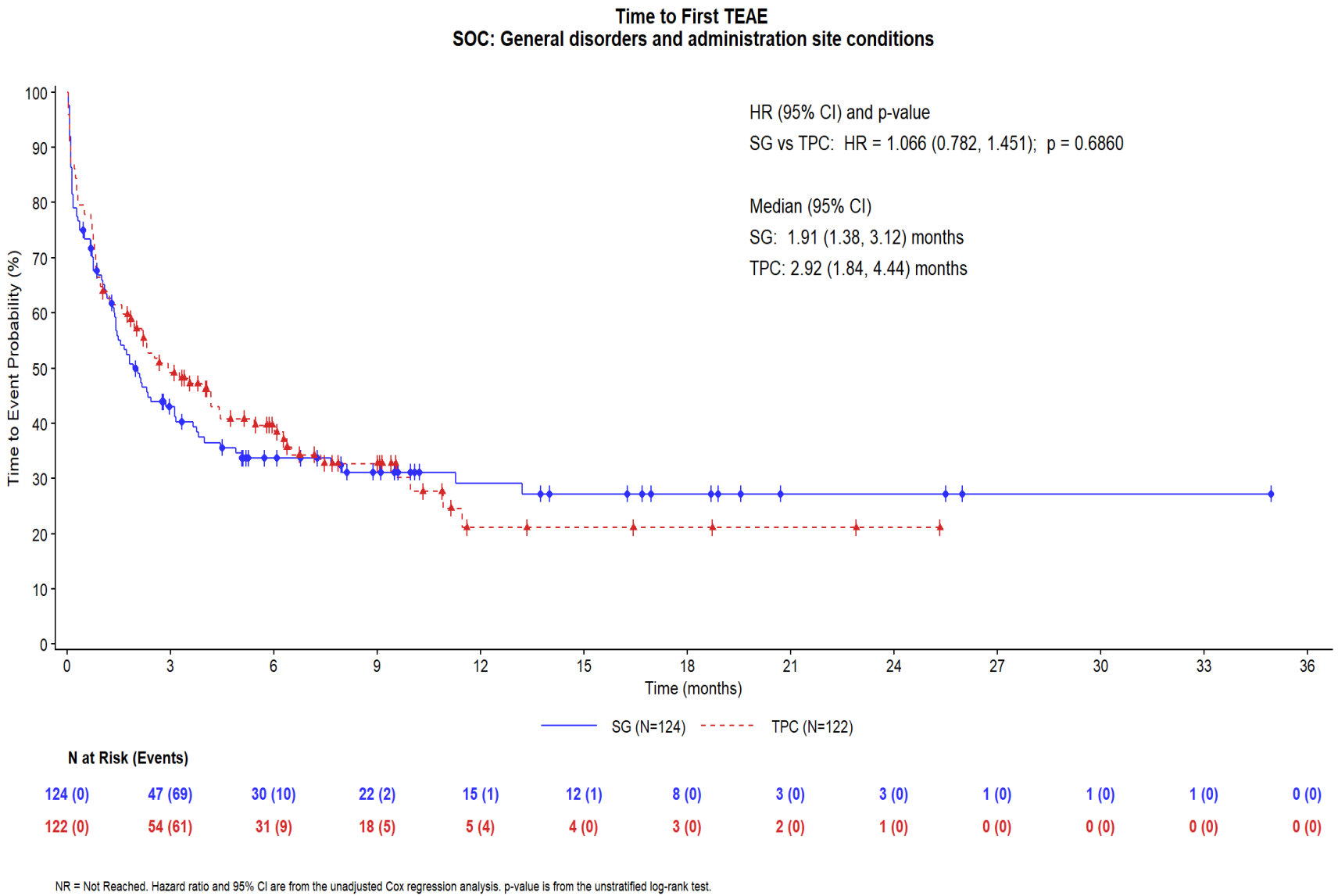
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.19. Figure 1.1.20: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



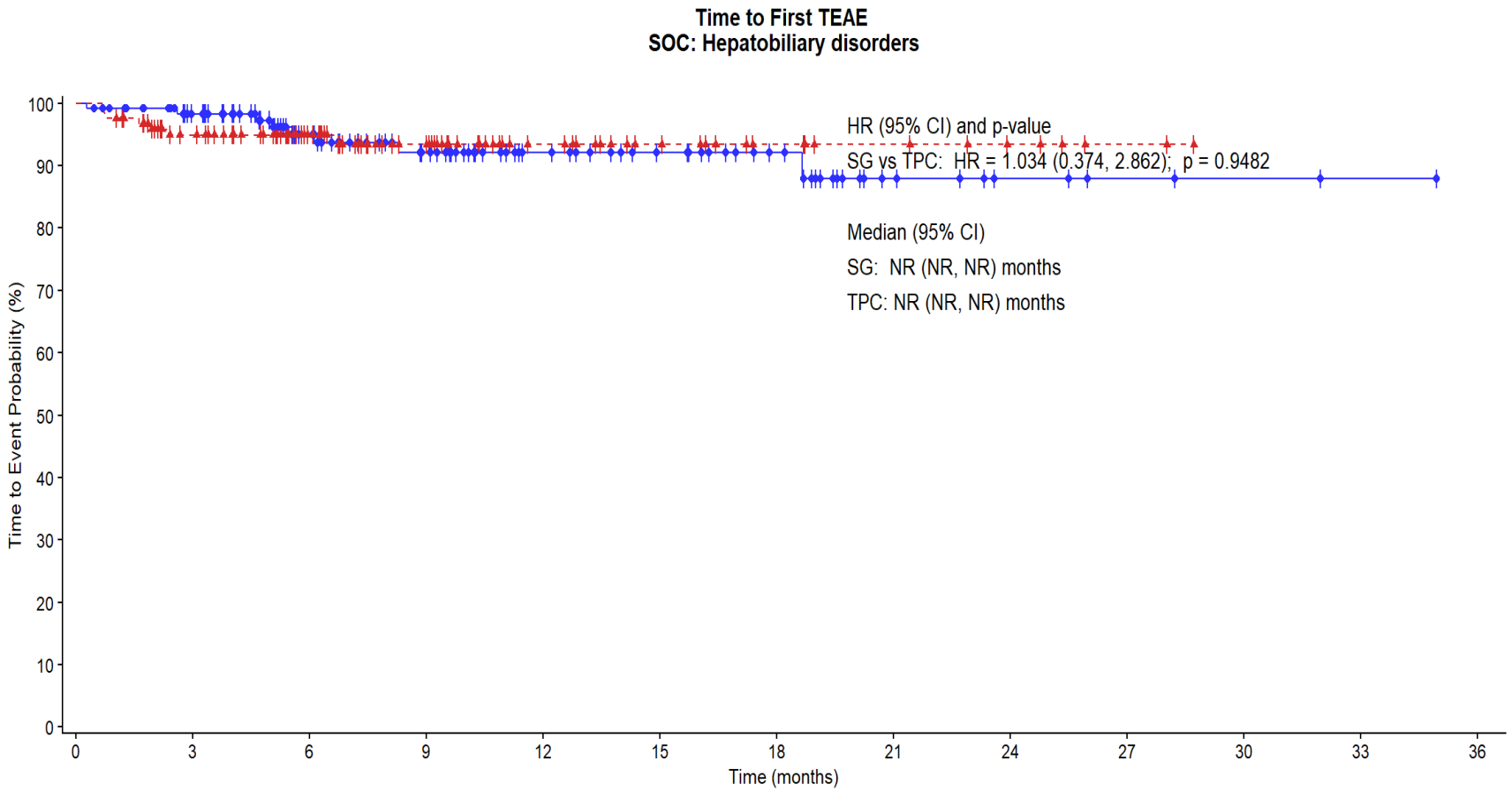
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.20. Figure 1.1.21: Kaplan Meier Plot of Time to First TEAE by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



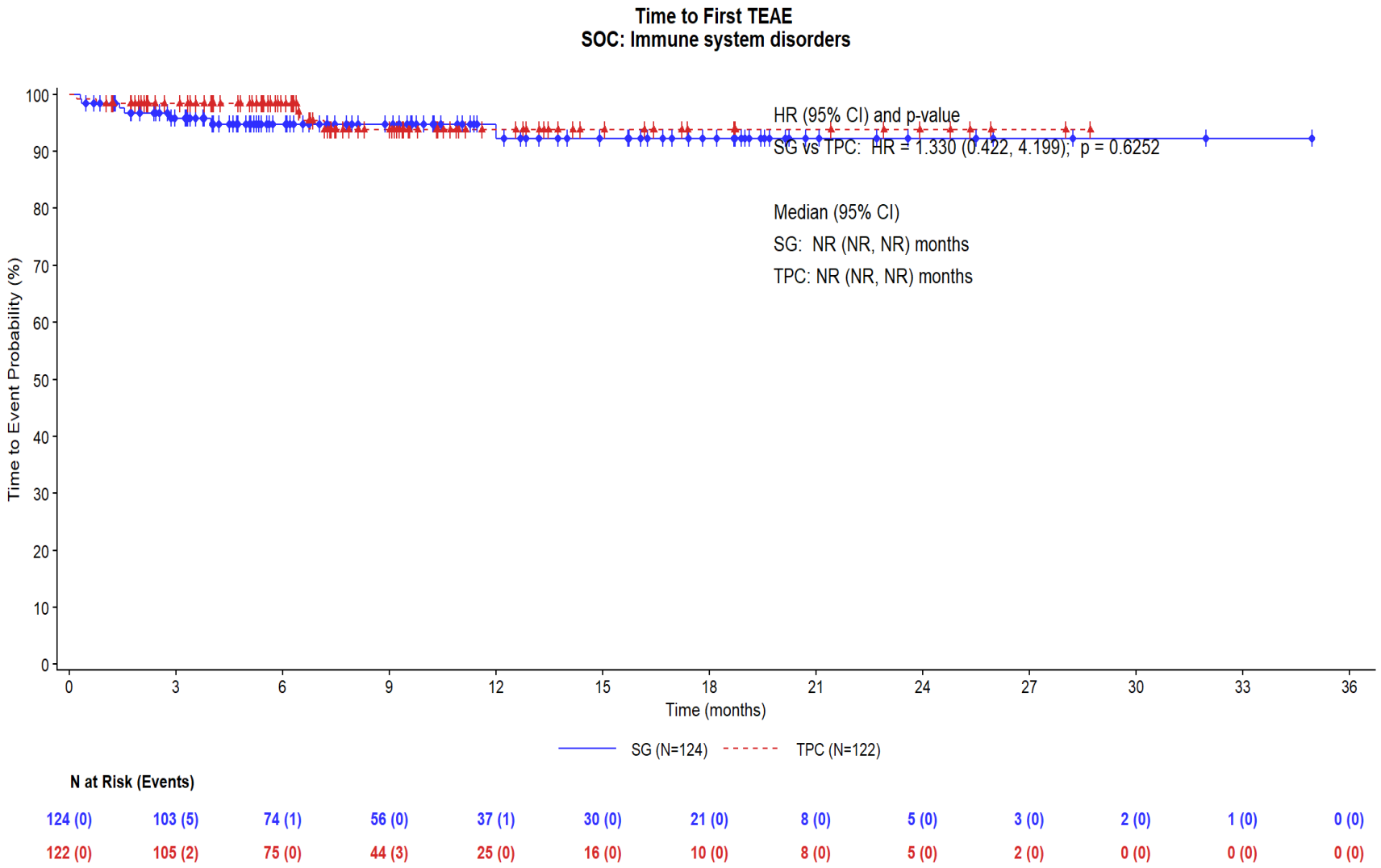
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.21. Figure 1.1.22: Kaplan Meier Plot of Time to First TEAE by SOC Hepatobiliary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



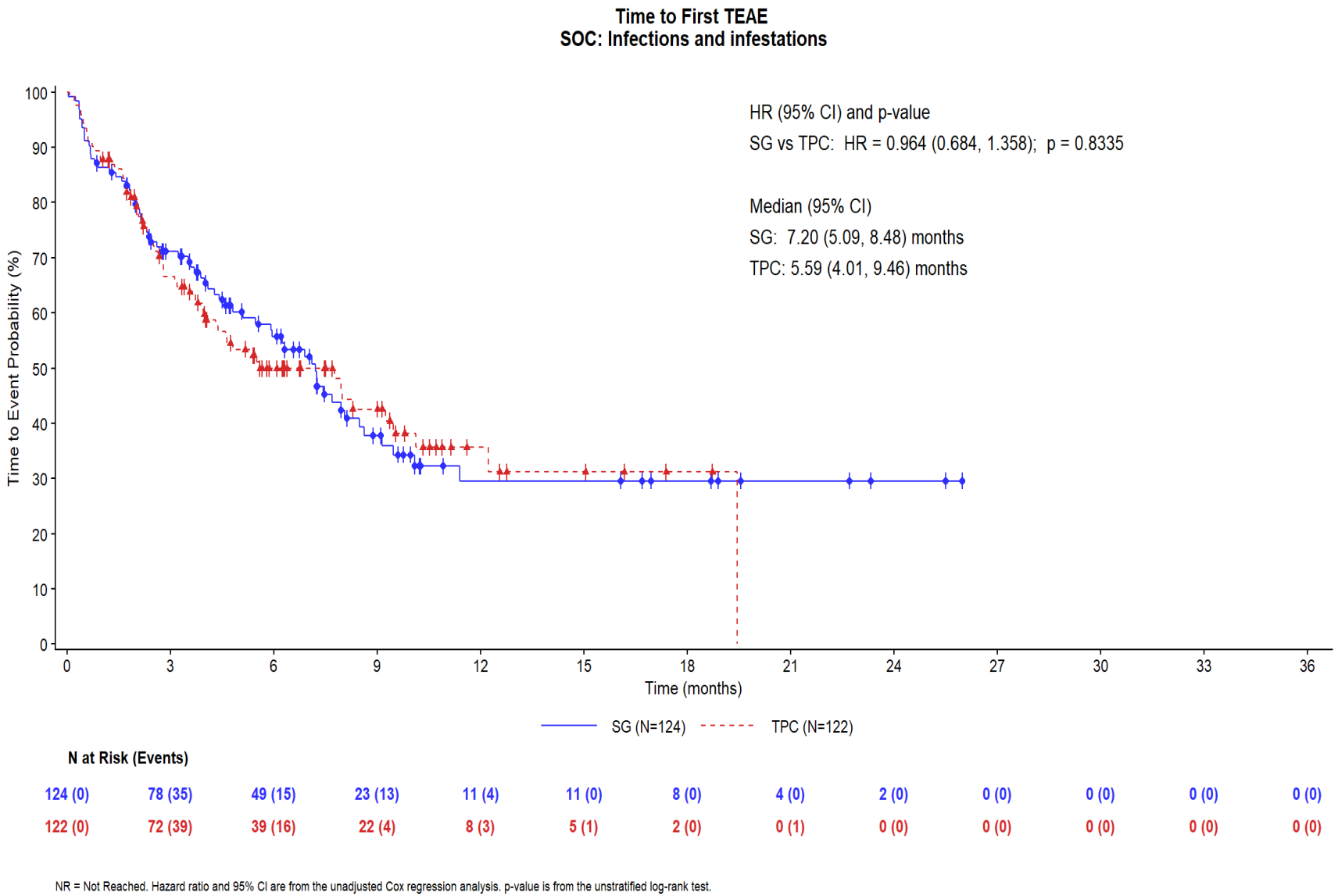
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.22. Figure 1.1.23: Kaplan Meier Plot of Time to First TEAE by SOC Immune system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



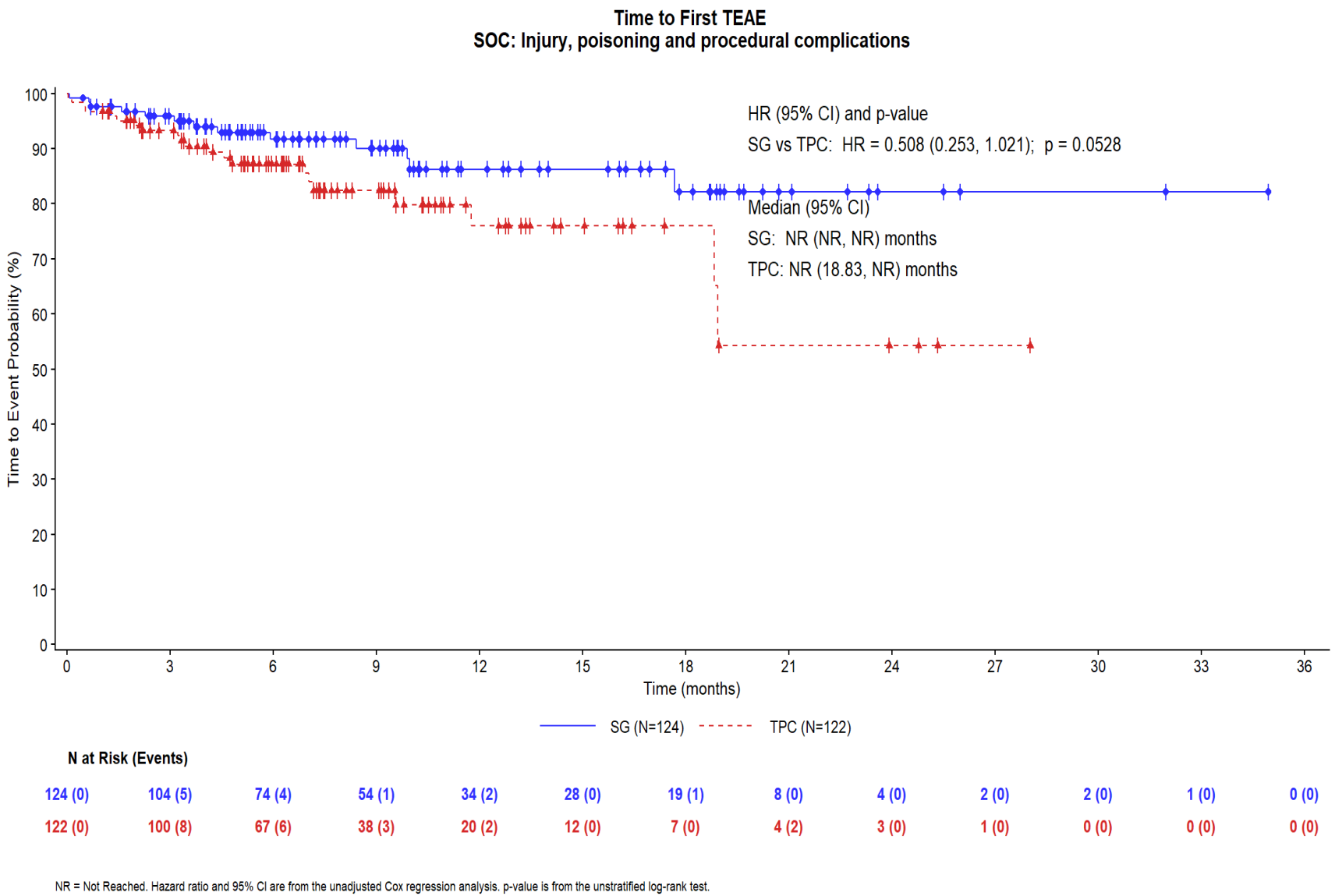
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7.23. Figure 1.1.24: Kaplan Meier Plot of Time to First TEAE by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



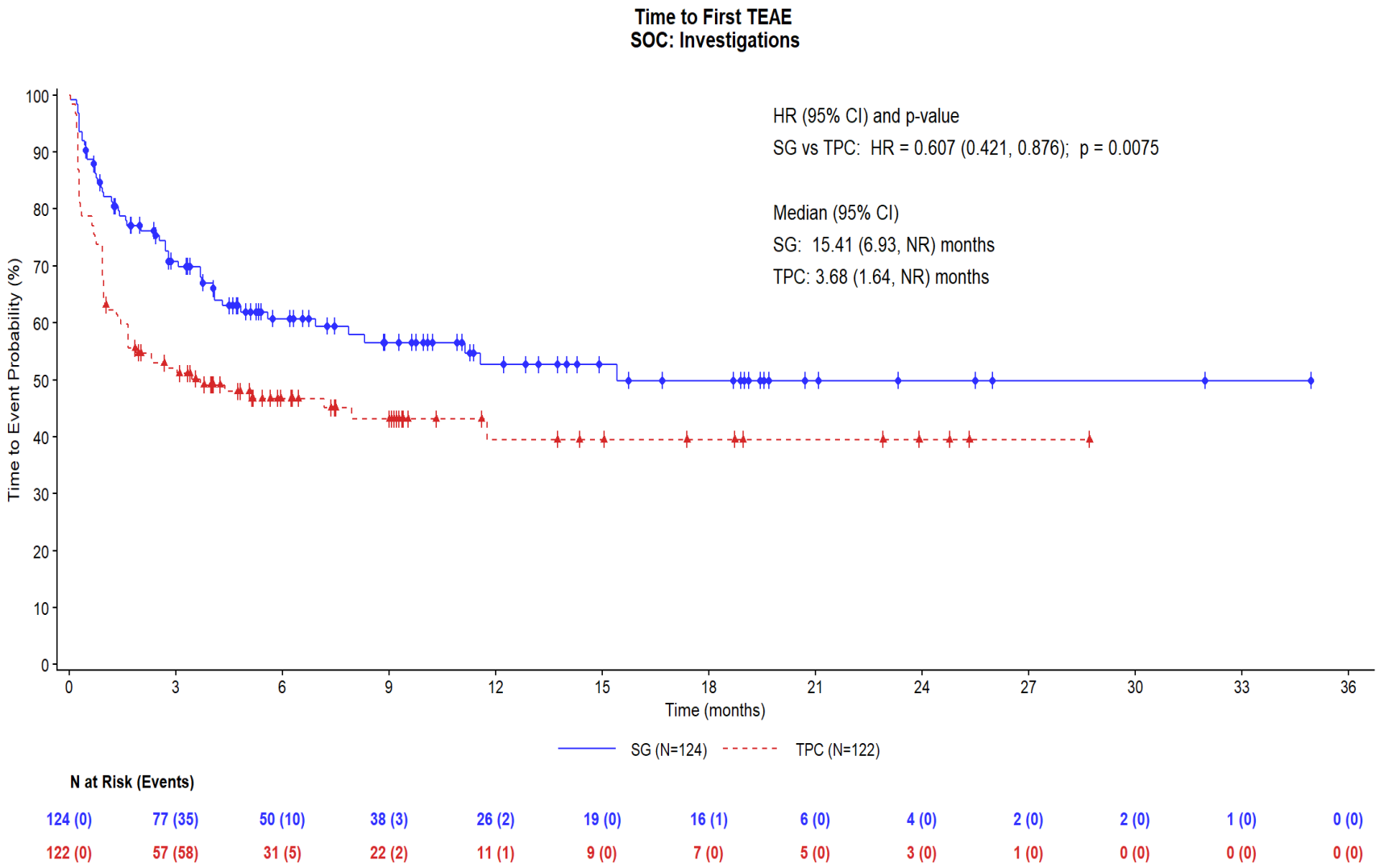
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.24. Figure 1.1.25: Kaplan Meier Plot of Time to First TEAE by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



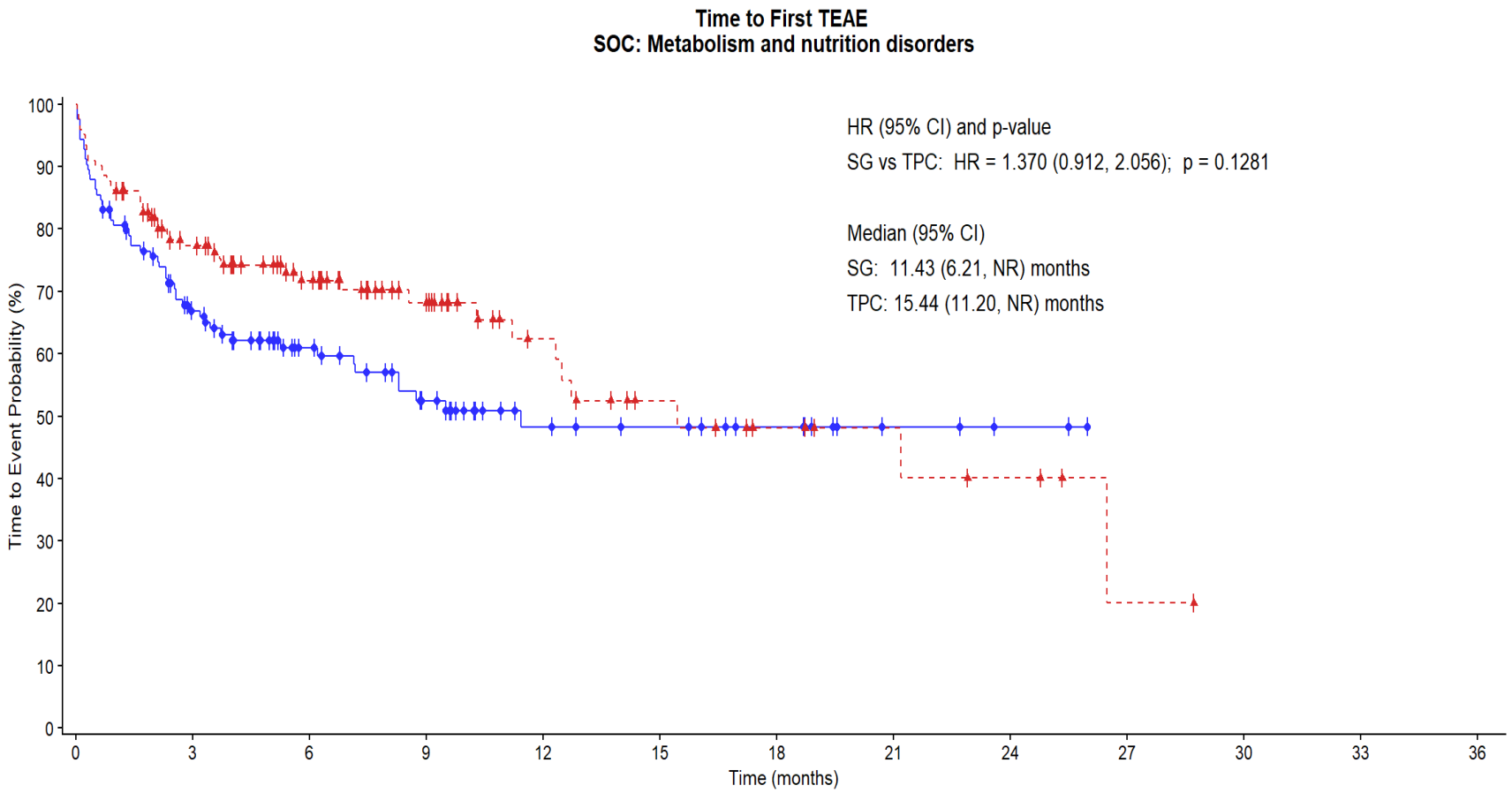
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.25. Figure 1.1.26: Kaplan Meier Plot of Time to First TEAE by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



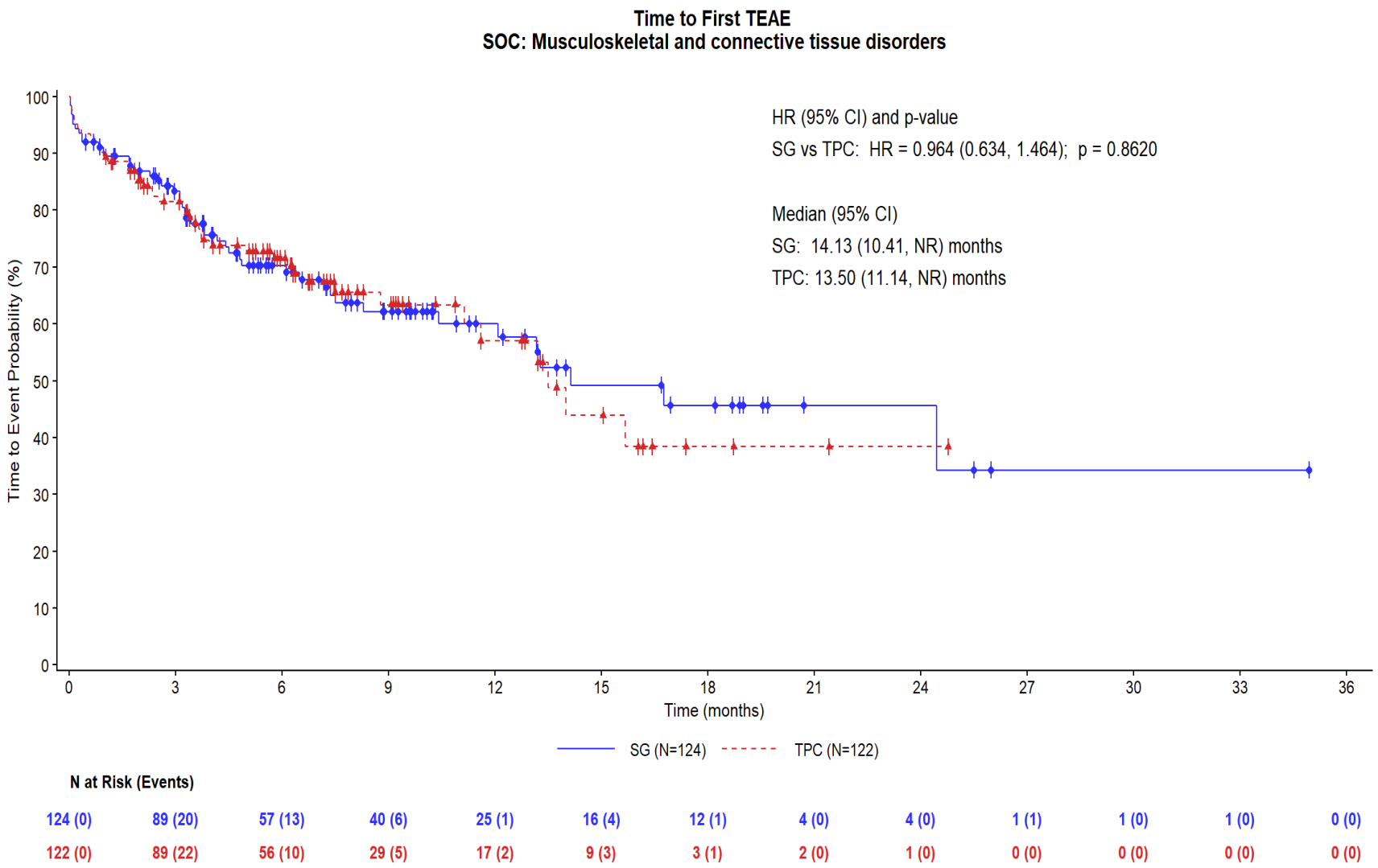
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.26. Figure 1.1.27: Kaplan Meier Plot of Time to First TEAE by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



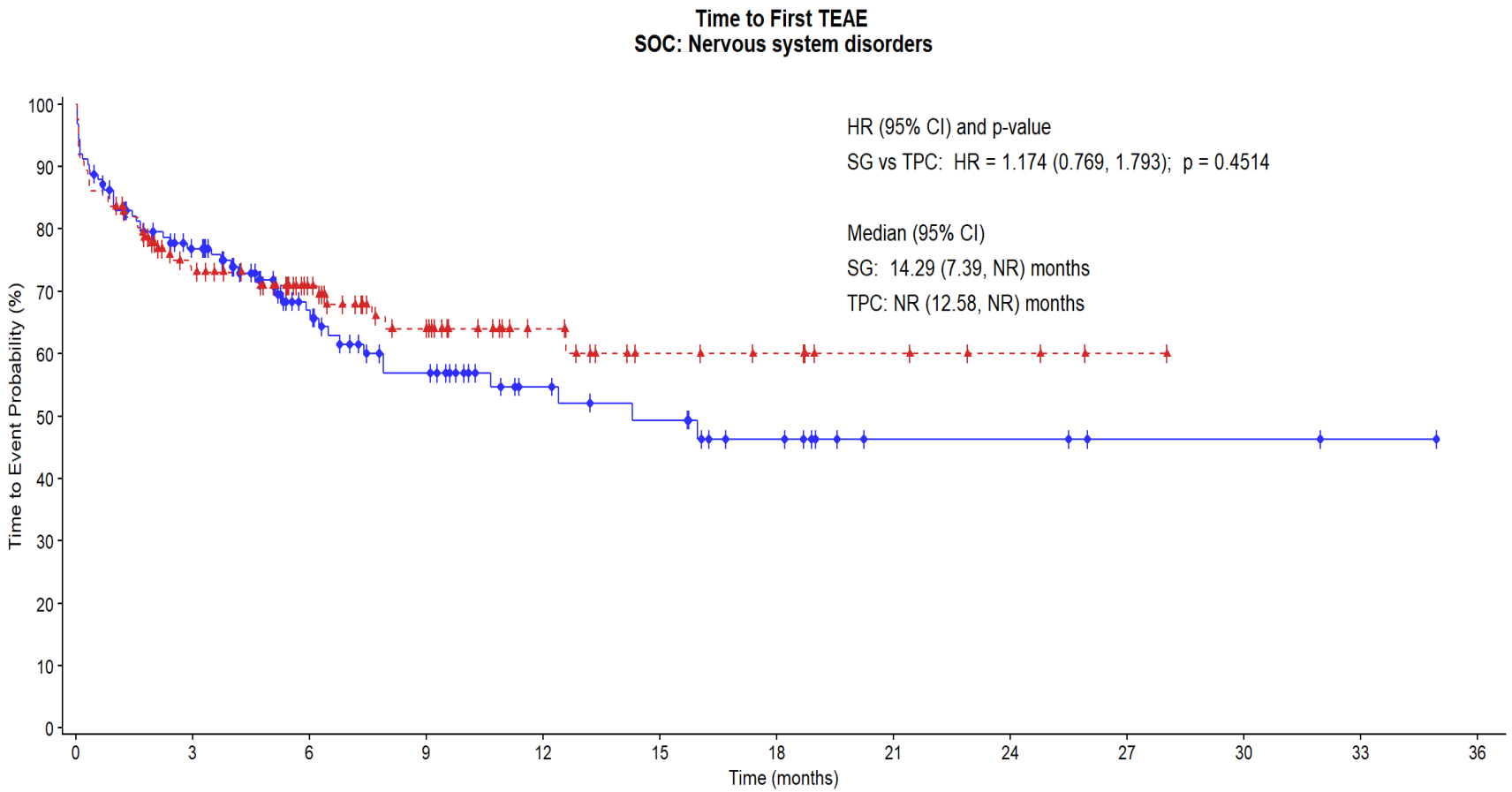
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.27. Figure 1.1.28: Kaplan Meier Plot of Time to First TEAE by SOC Musculoskeletal and connective tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



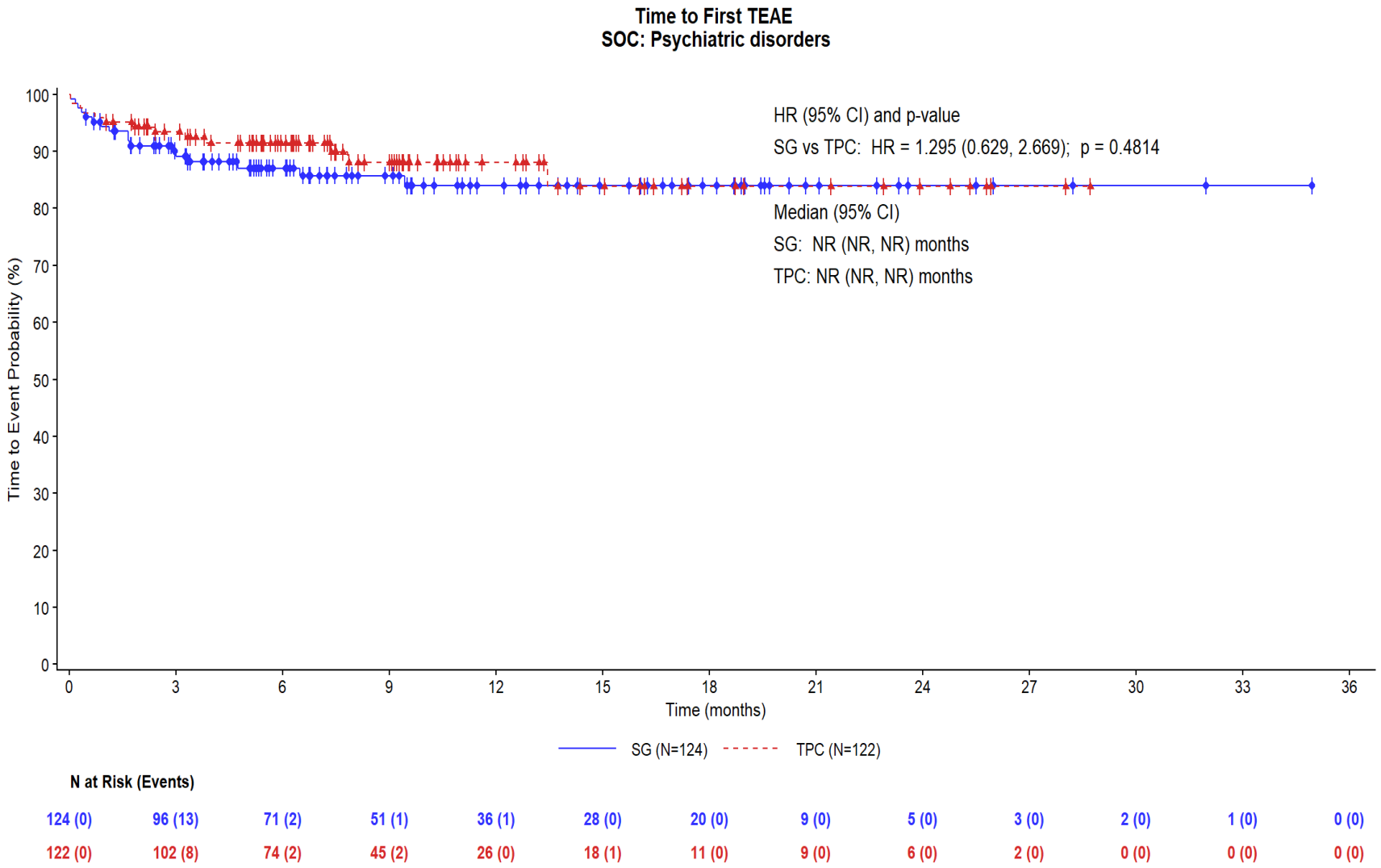
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7.28. Figure 1.1.29: Kaplan Meier Plot of Time to First TEAE by SOC Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



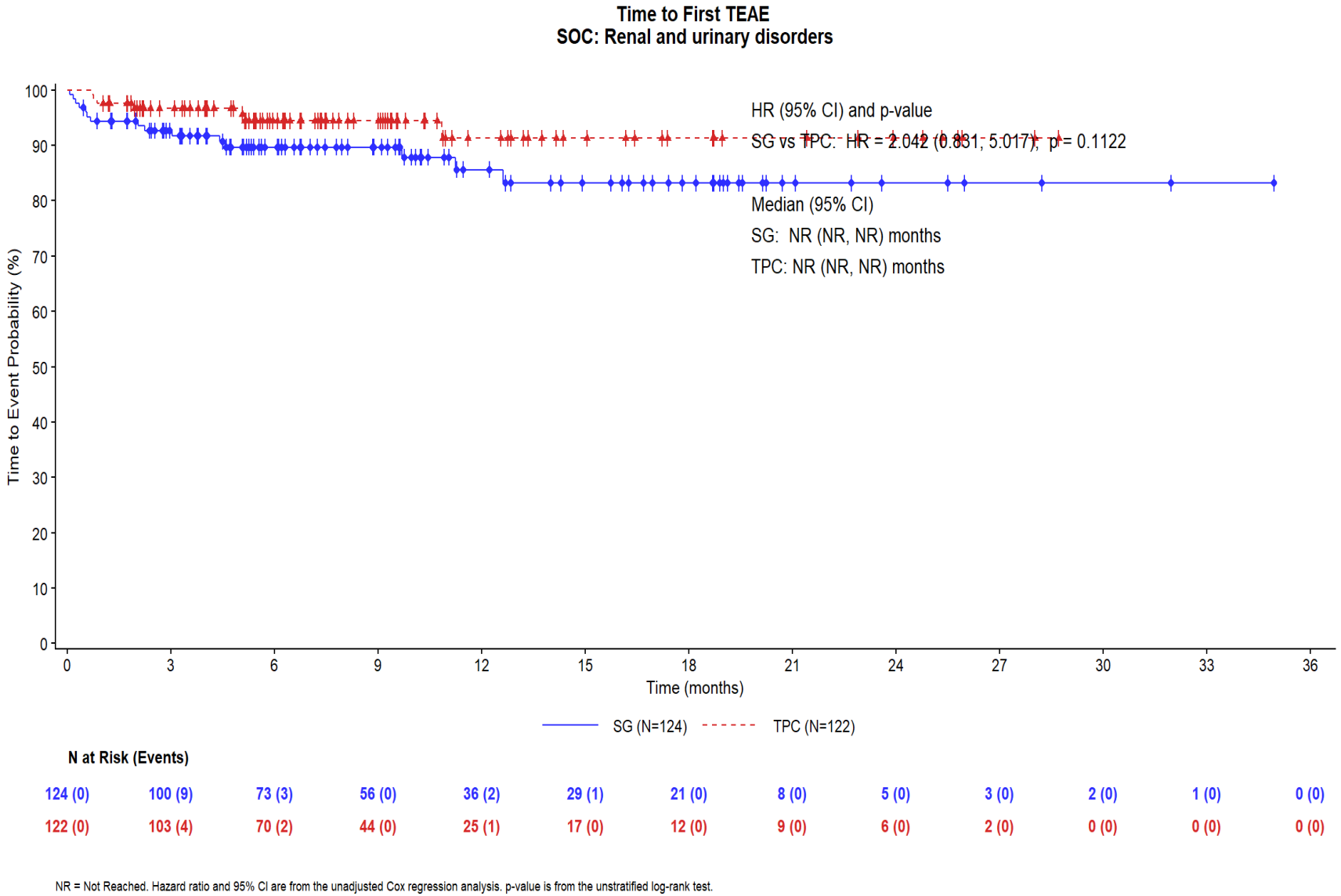
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.29. Figure 1.1.30: Kaplan Meier Plot of Time to First TEAE by SOC Psychiatric disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



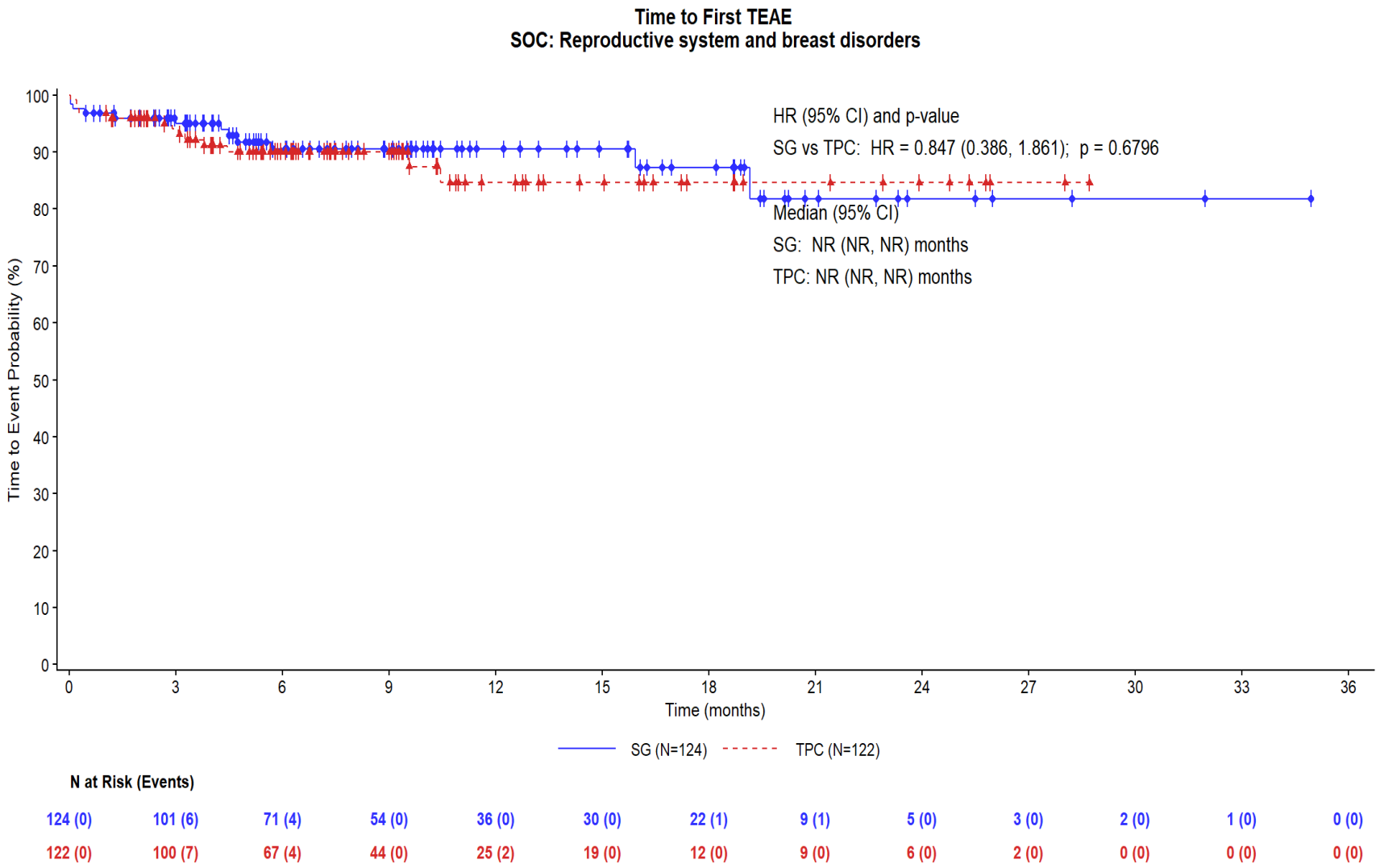
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.30. Figure 1.1.31: Kaplan Meier Plot of Time to First TEAE by SOC Renal and urinary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



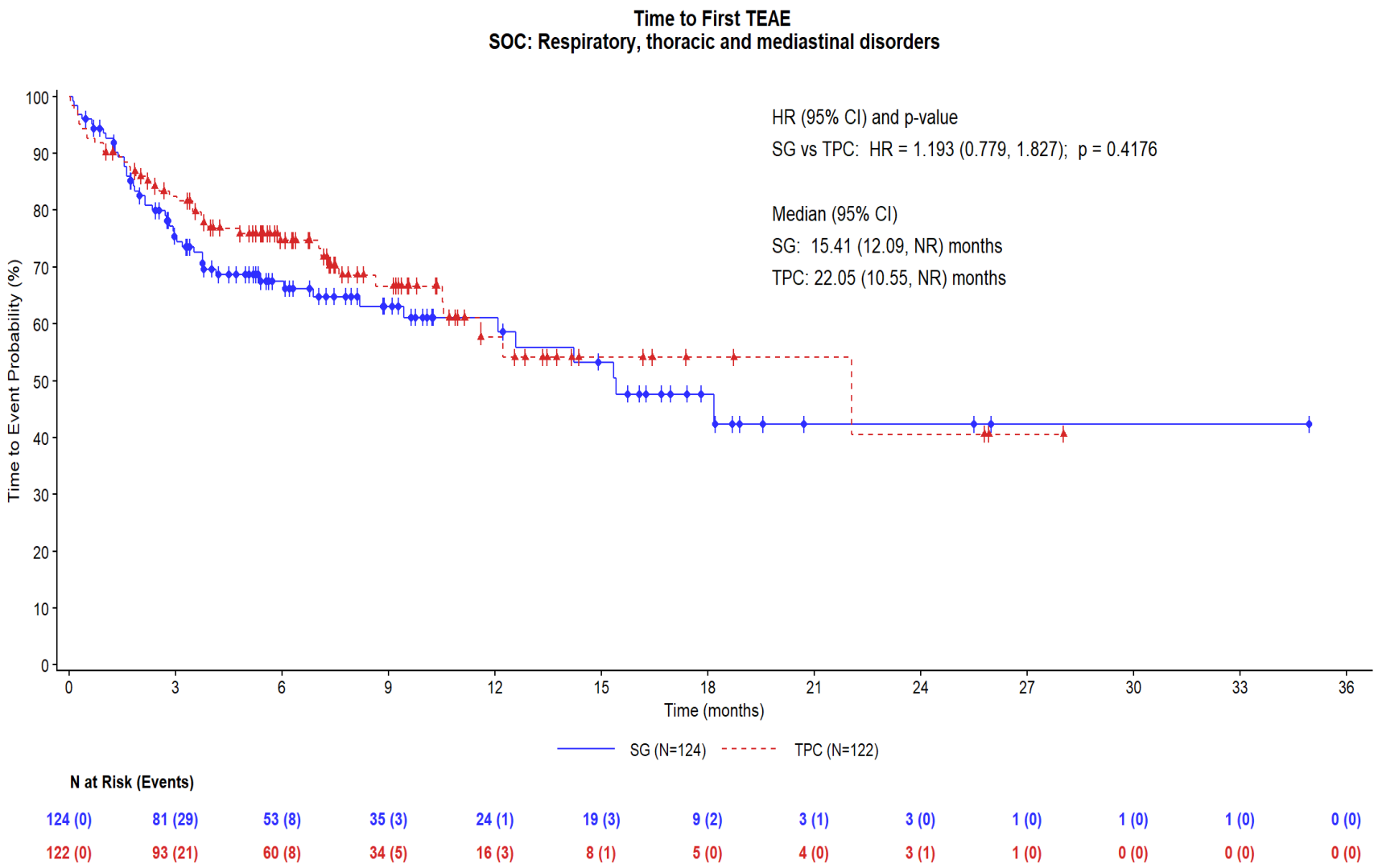
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.31. Figure 1.1.32: Kaplan Meier Plot of Time to First TEAE by SOC Reproductive system and breast disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



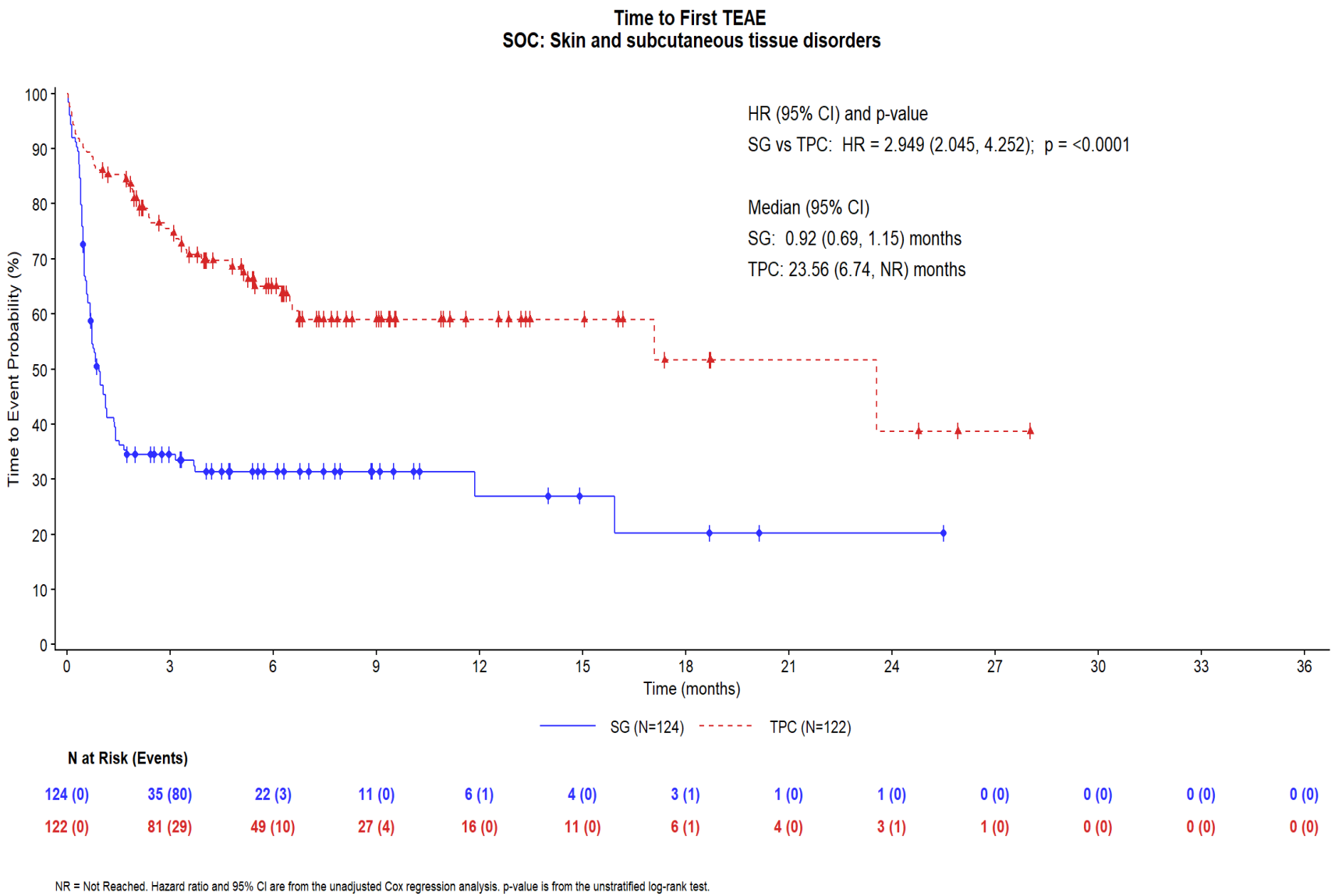
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.32. Figure 1.1.33: Kaplan Meier Plot of Time to First TEAE by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



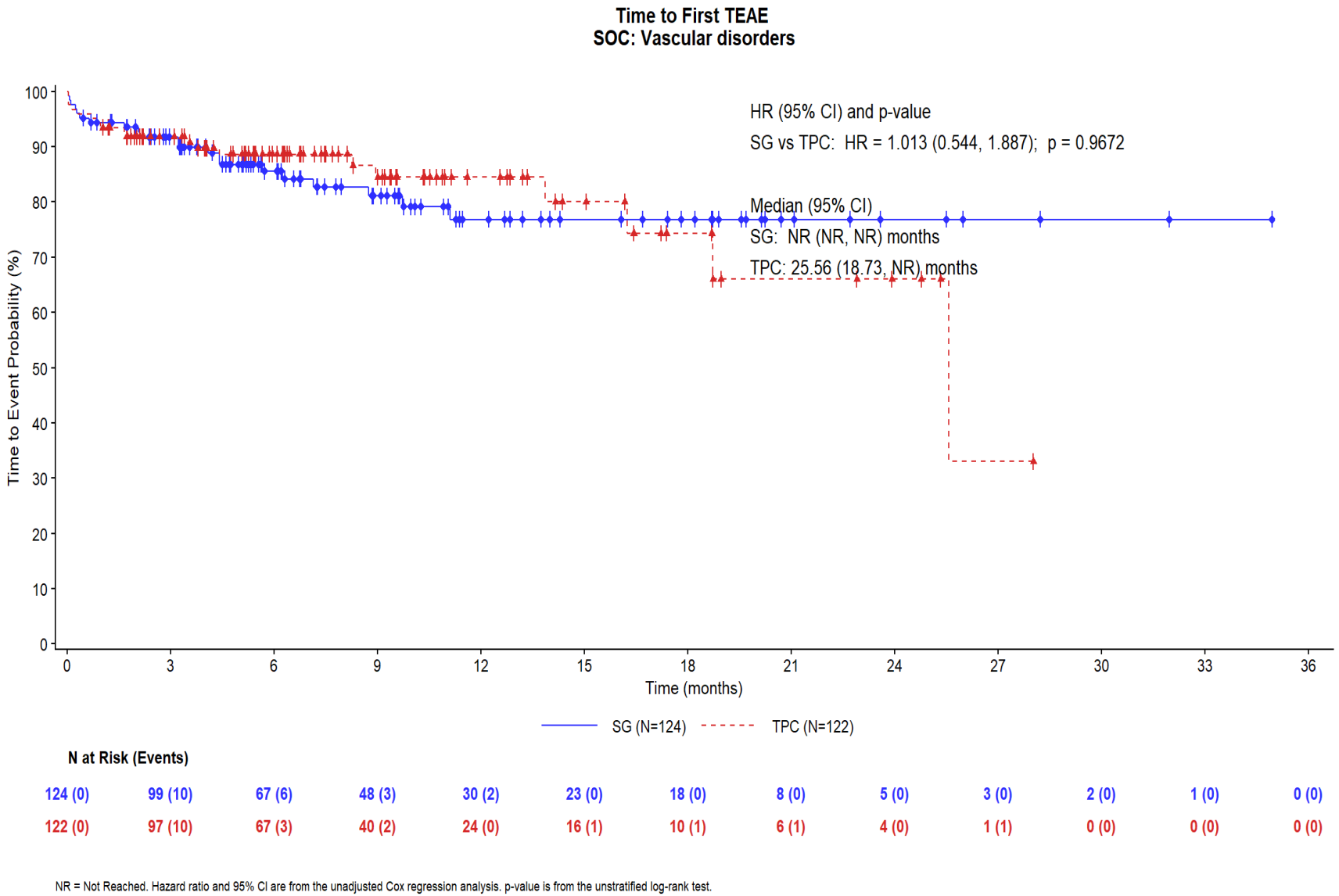
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.33. Figure 1.1.34: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



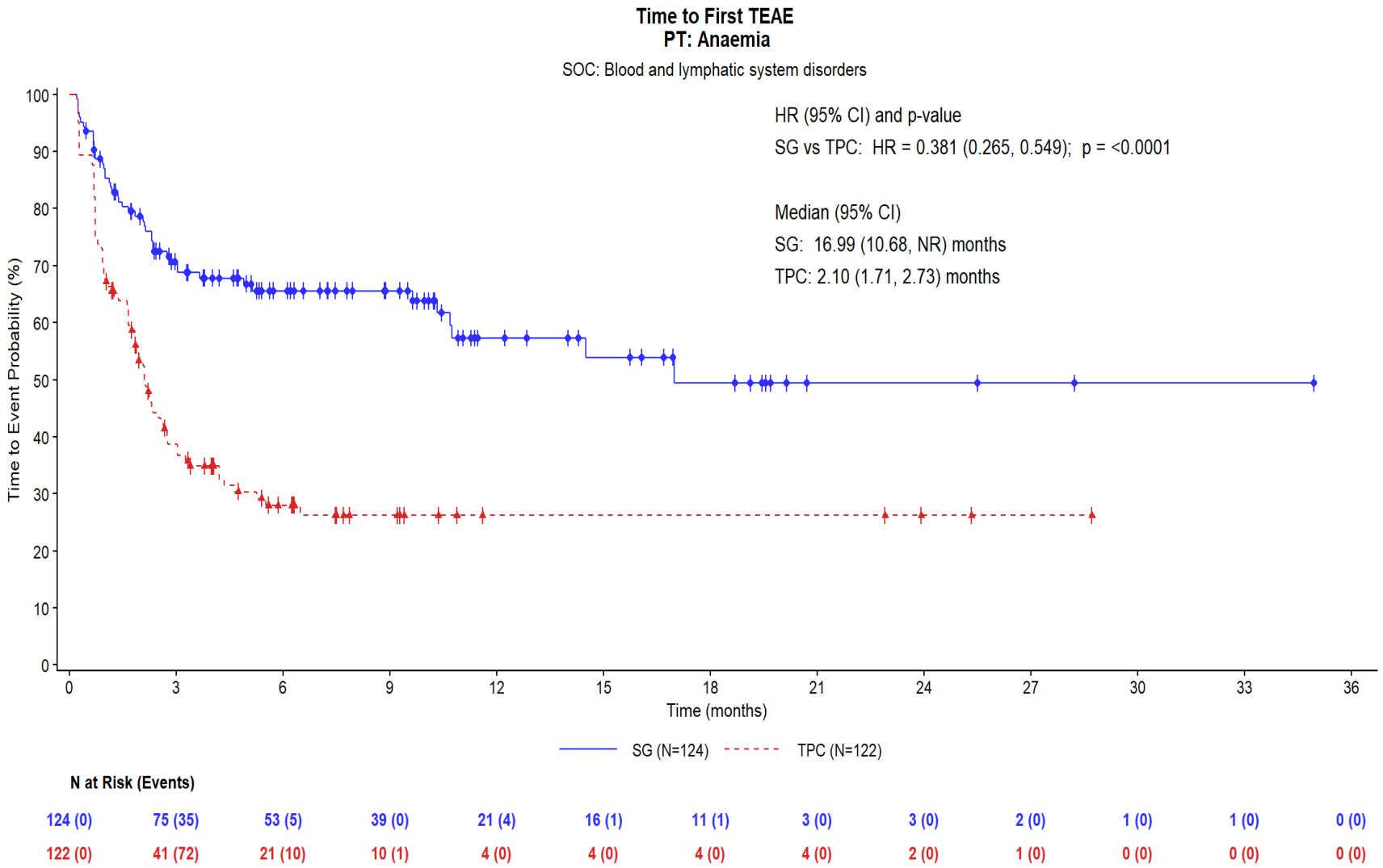
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.34. Figure 1.1.35: Kaplan Meier Plot of Time to First TEAE by SOC Vascular disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



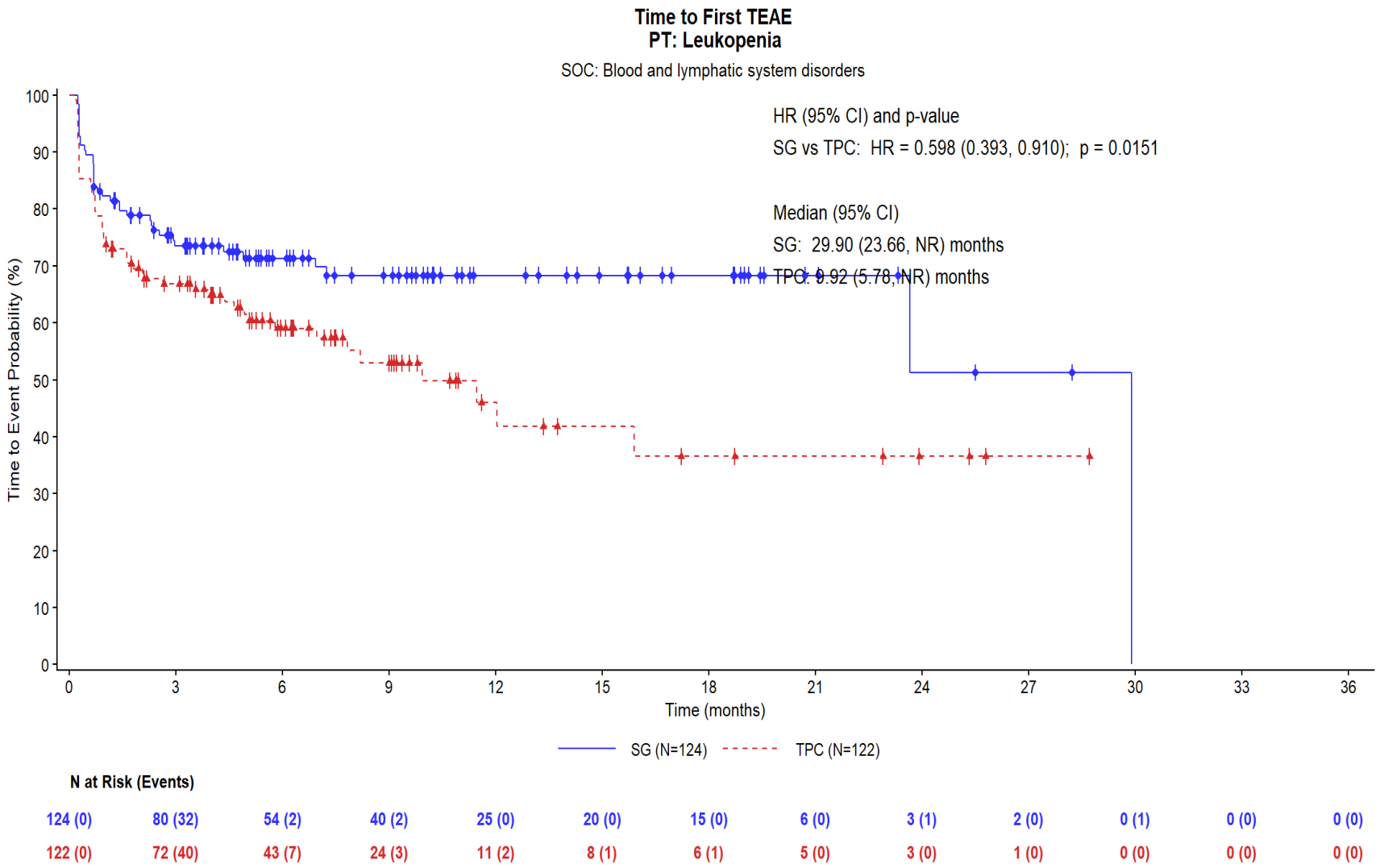
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.35. Figure 1.1.36: Kaplan Meier Plot of Time to First TEAE by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



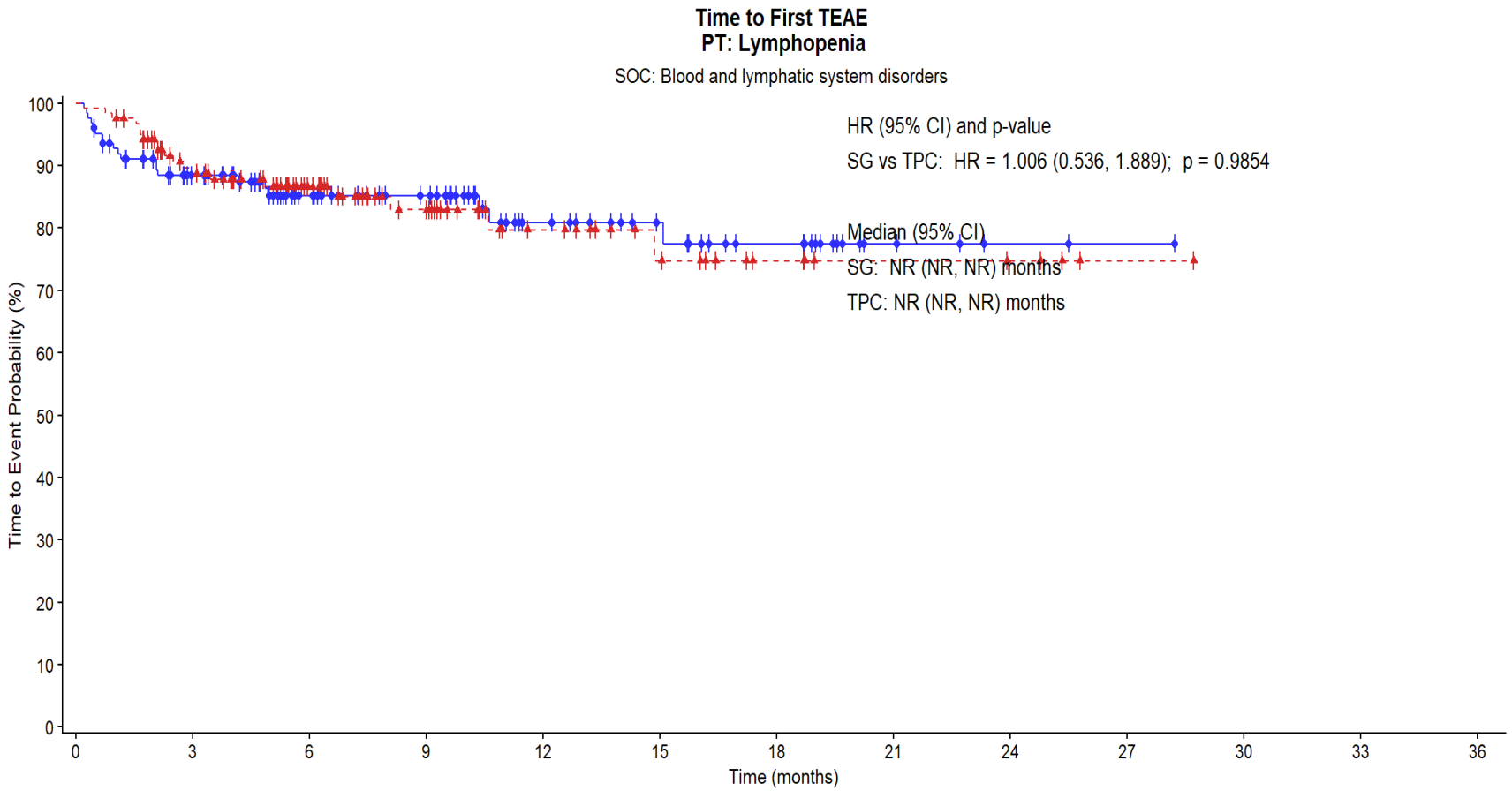
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.36. Figure 1.1.37: Kaplan Meier Plot of Time to First TEAE by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



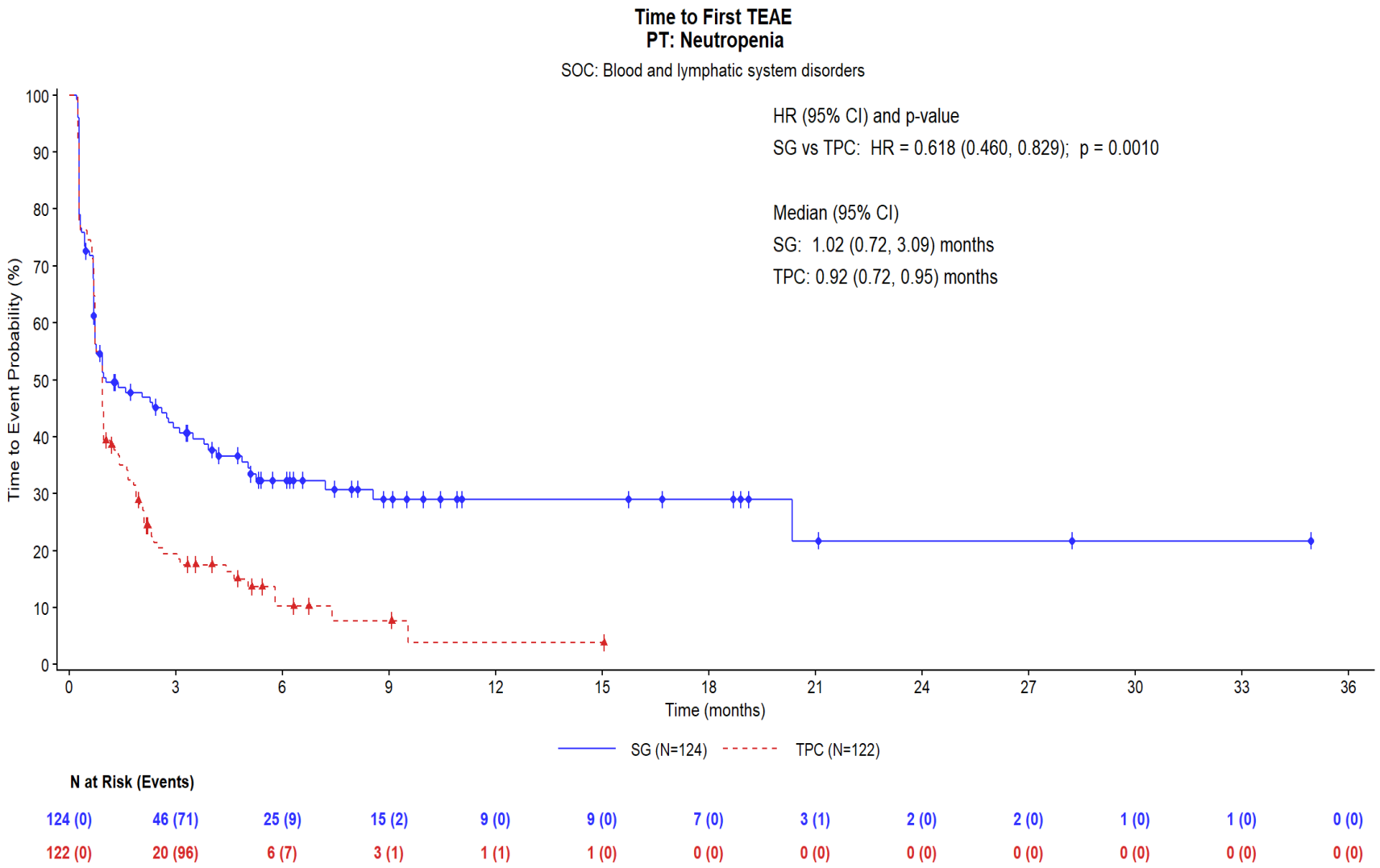
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.37. Figure 1.1.38: Kaplan Meier Plot of Time to First TEAE by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



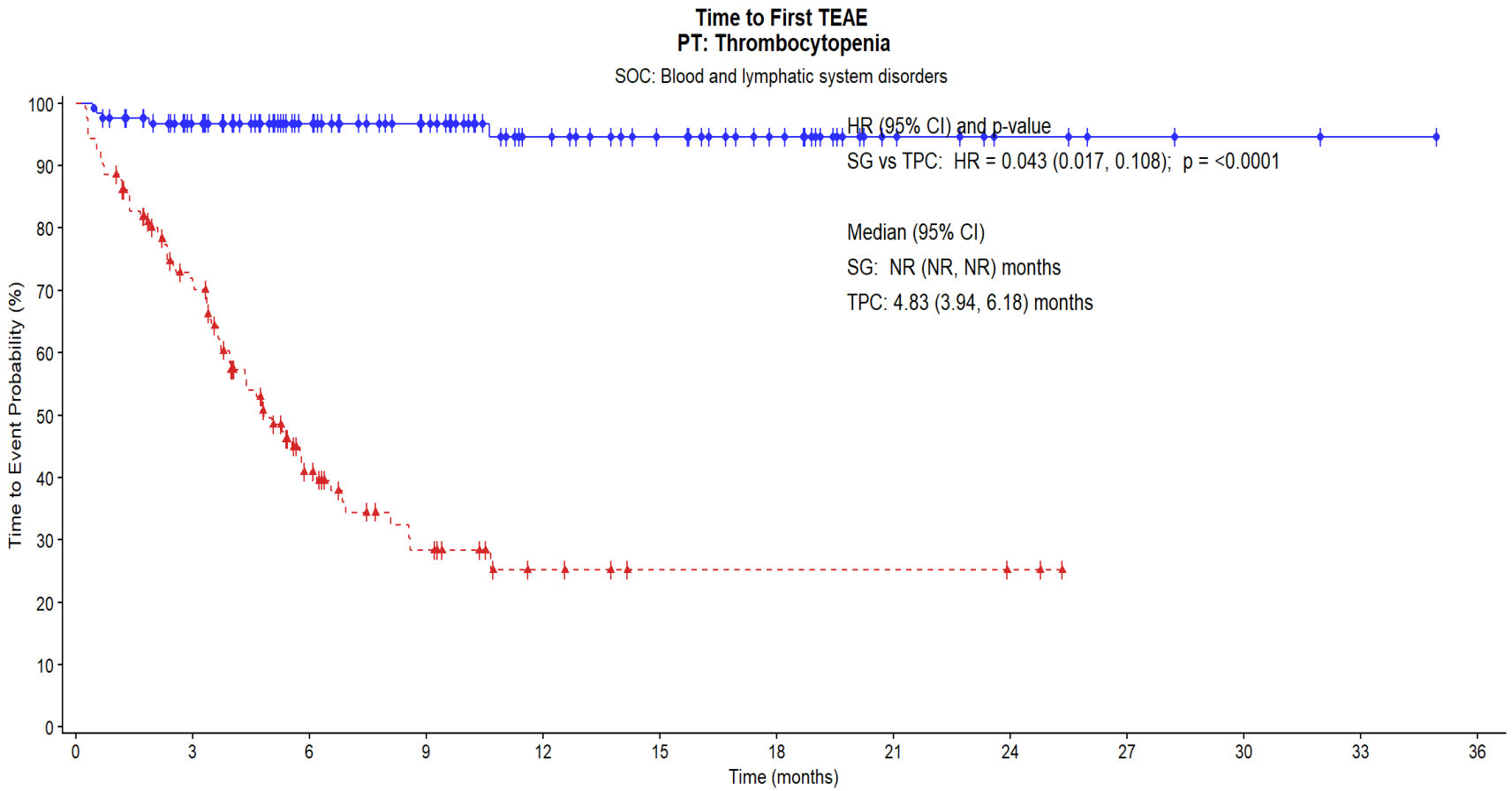
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.38. Figure 1.1.39: Kaplan Meier Plot of Time to First TEAE by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



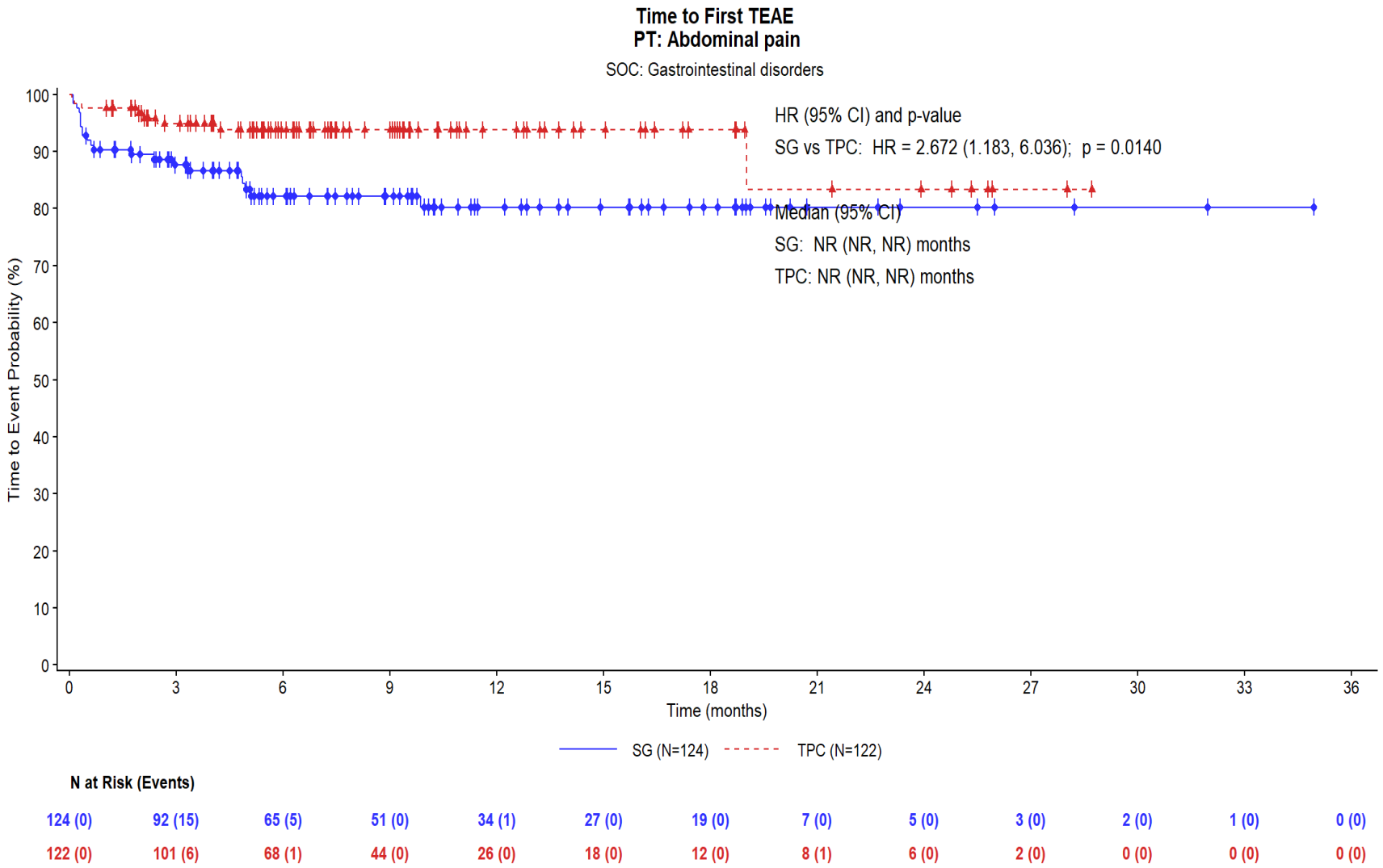
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.39. Figure 1.1.40: Kaplan Meier Plot of Time to First TEAE by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



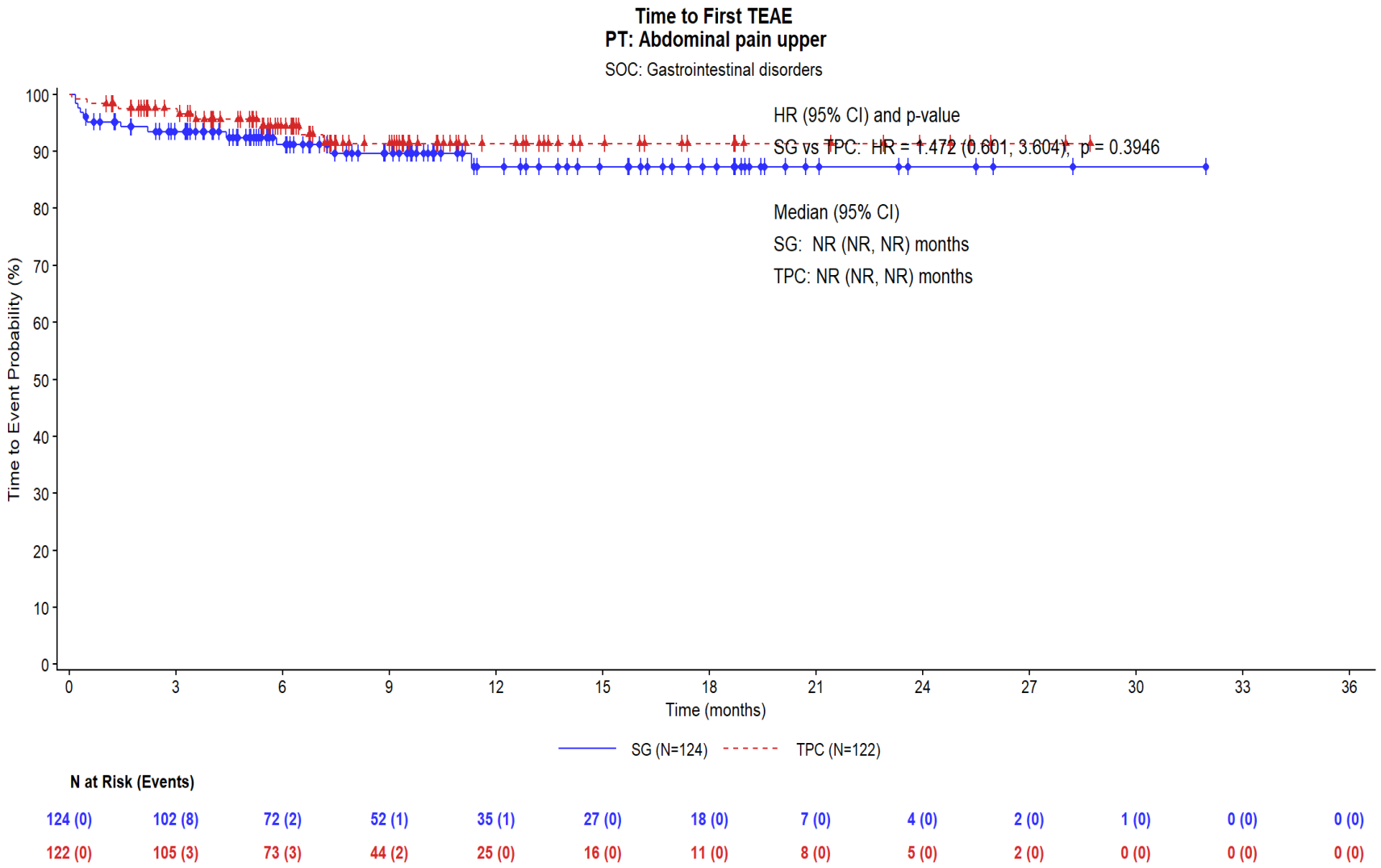
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.40. Figure 1.1.41: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



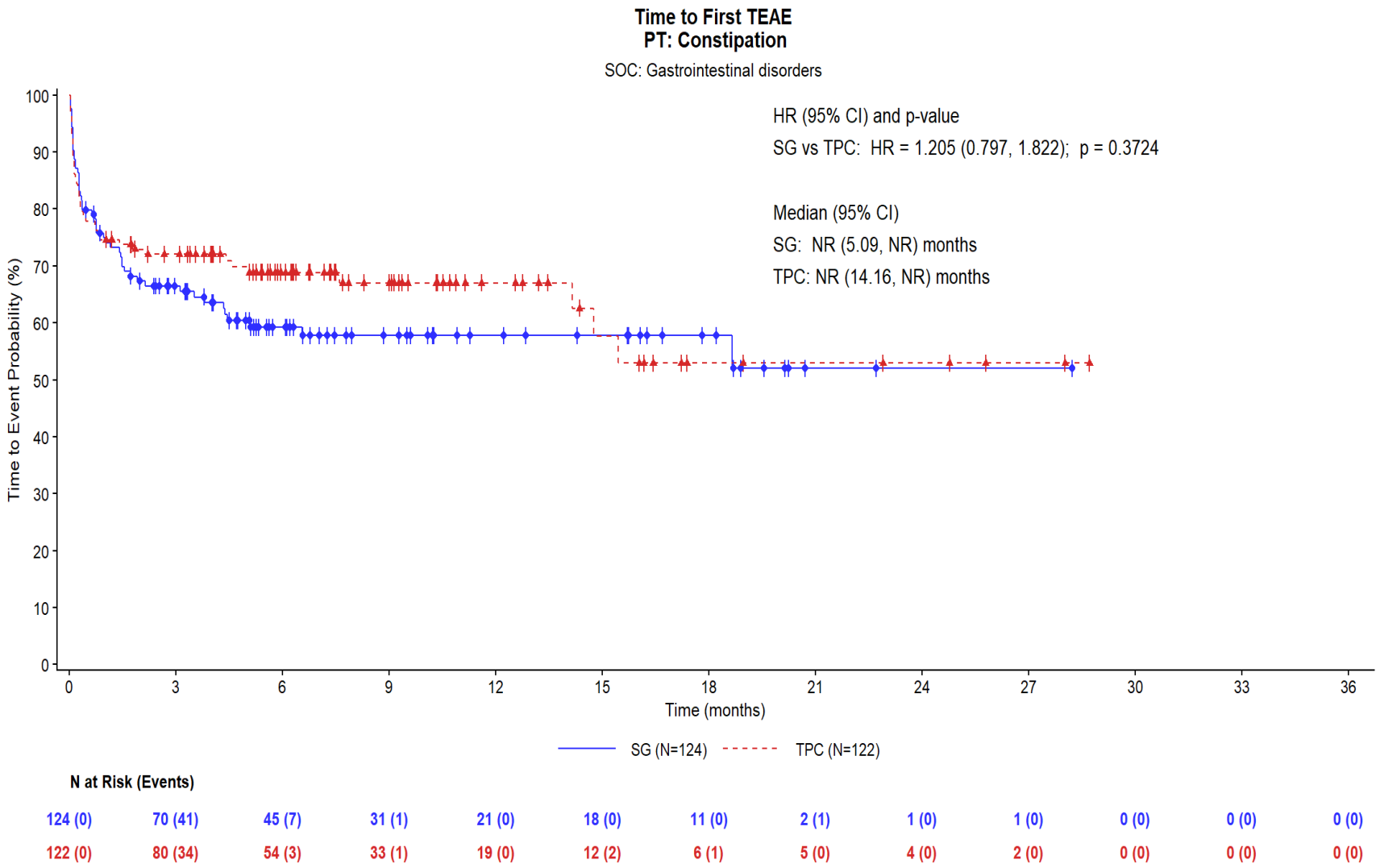
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.41. Figure 1.1.42: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain upper — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



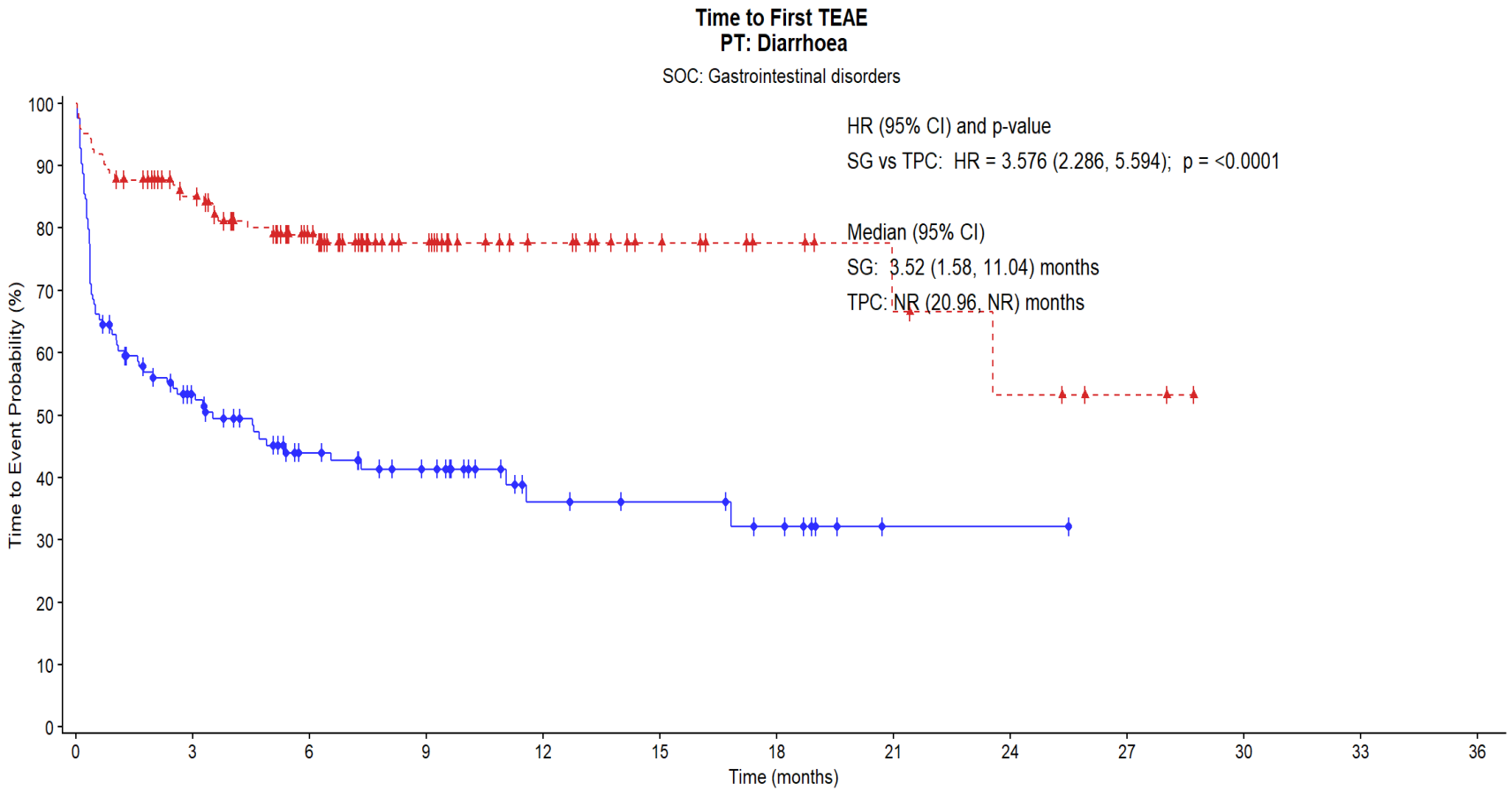
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.42. Figure 1.1.43: Kaplan Meier Plot of Time to First TEAE by PT Constipation — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



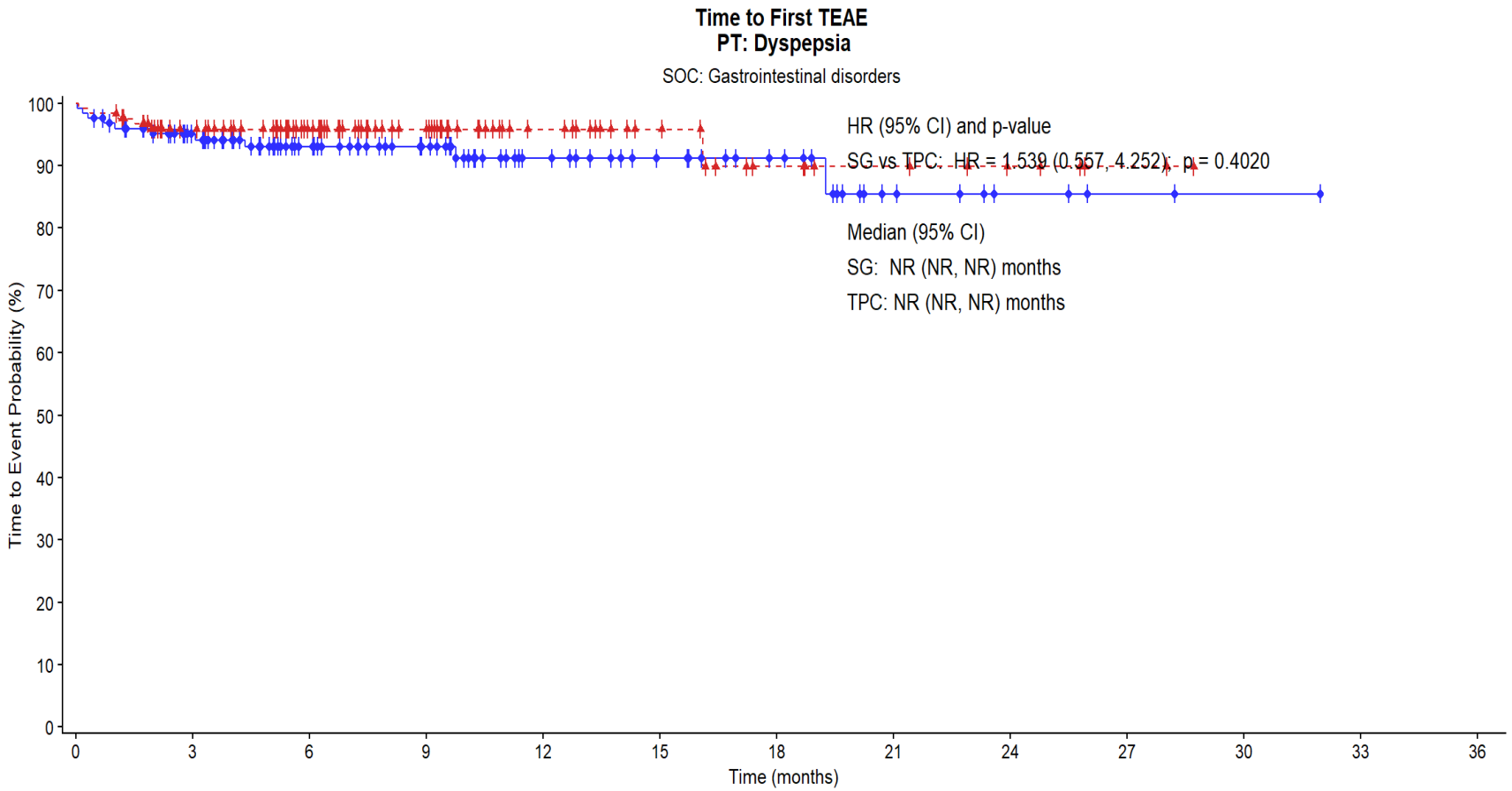
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.43. Figure 1.1.44: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



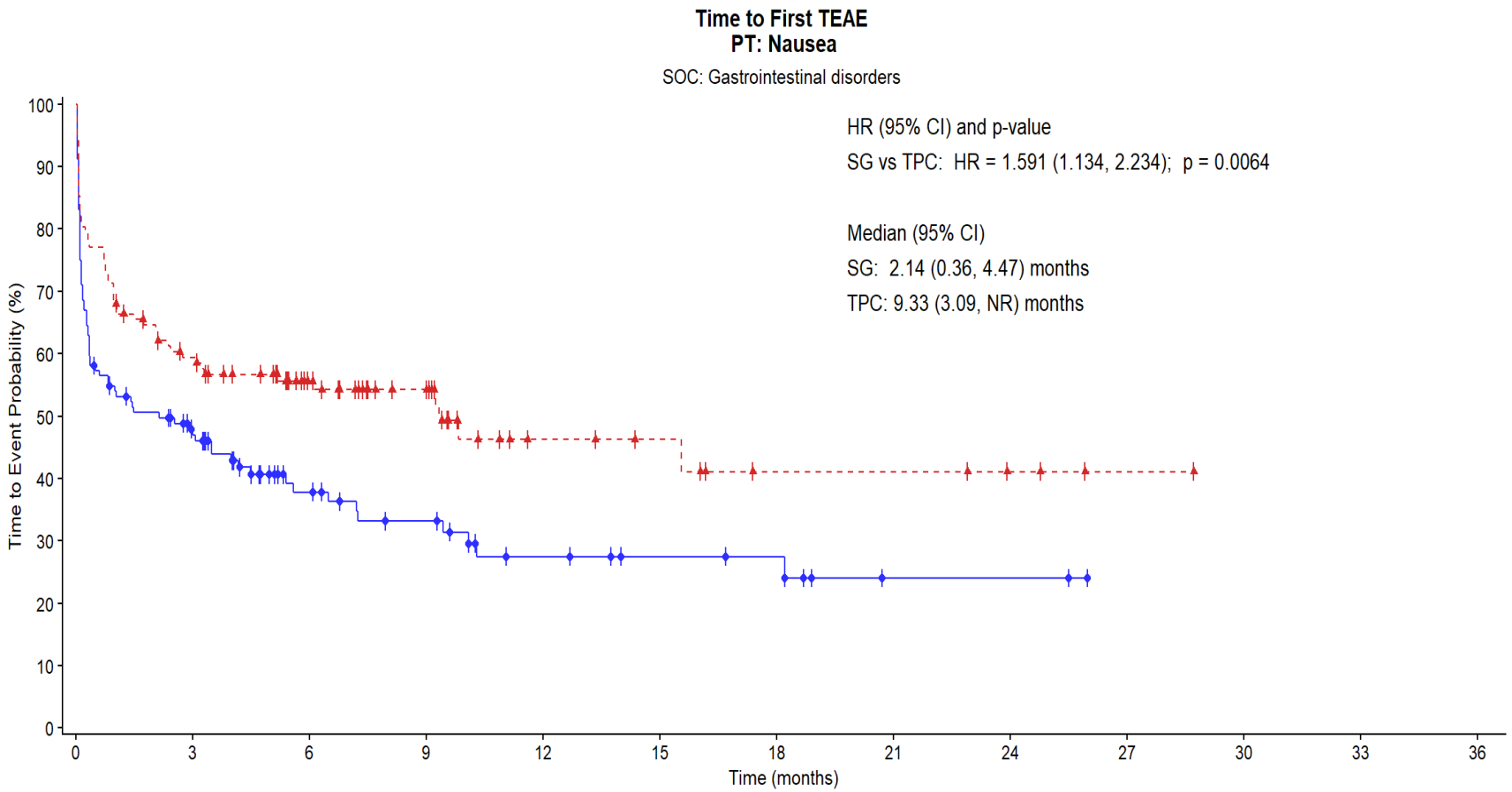
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.44. Figure 1.1.45: Kaplan Meier Plot of Time to First TEAE by PT Dyspepsia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



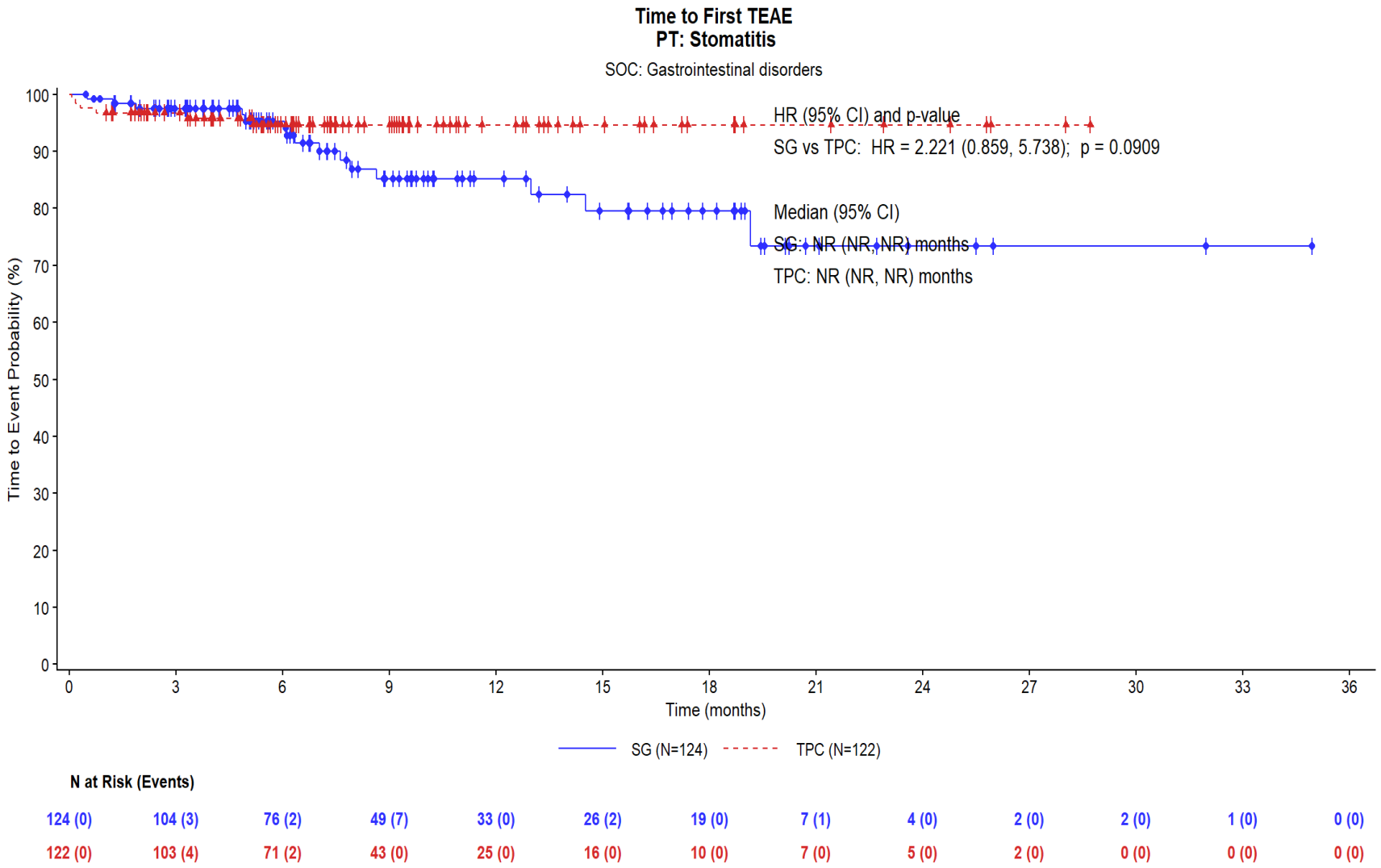
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.45. Figure 1.1.46: Kaplan Meier Plot of Time to First TEAE by PT Nausea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



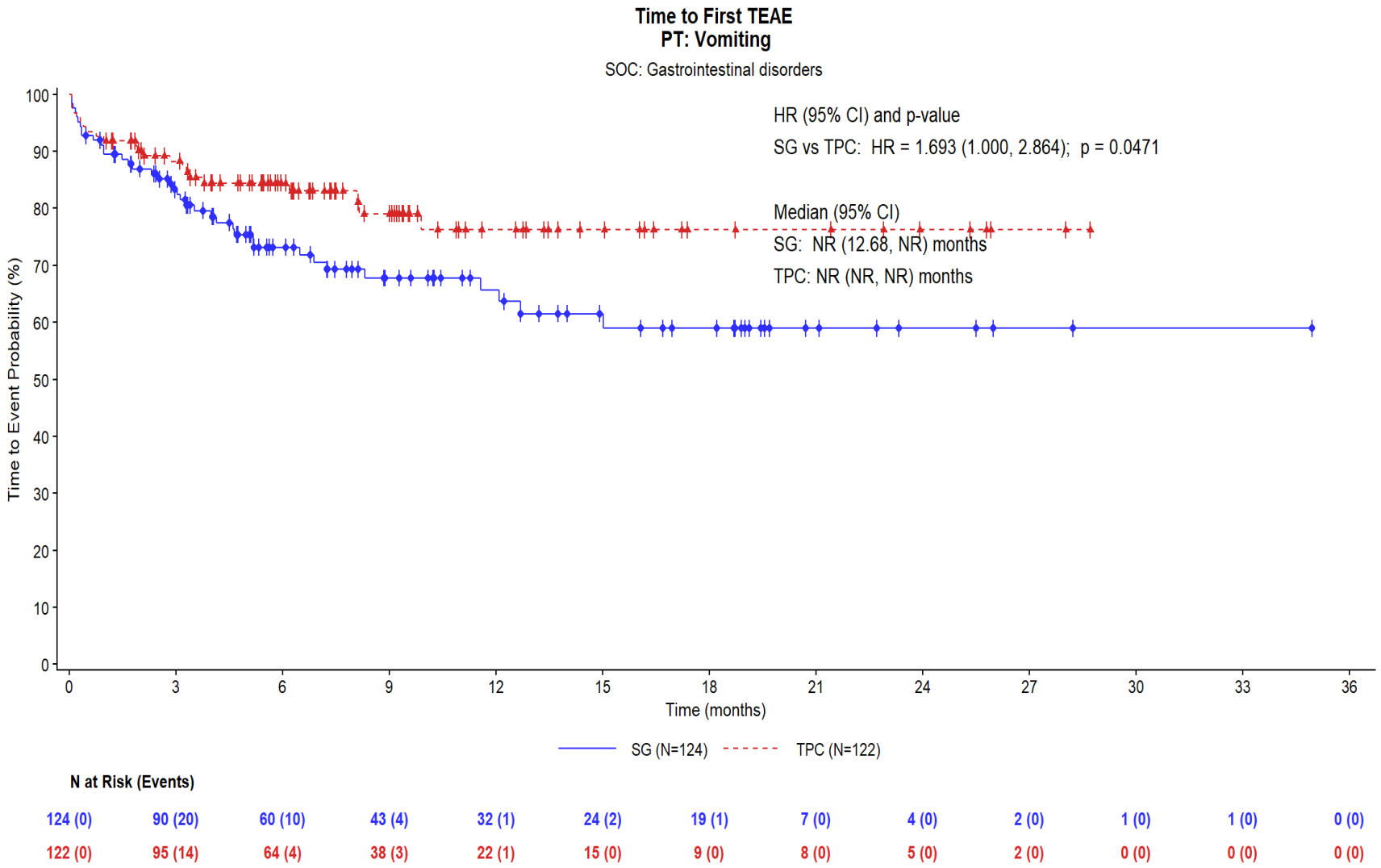
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.46. Figure 1.1.47: Kaplan Meier Plot of Time to First TEAE by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



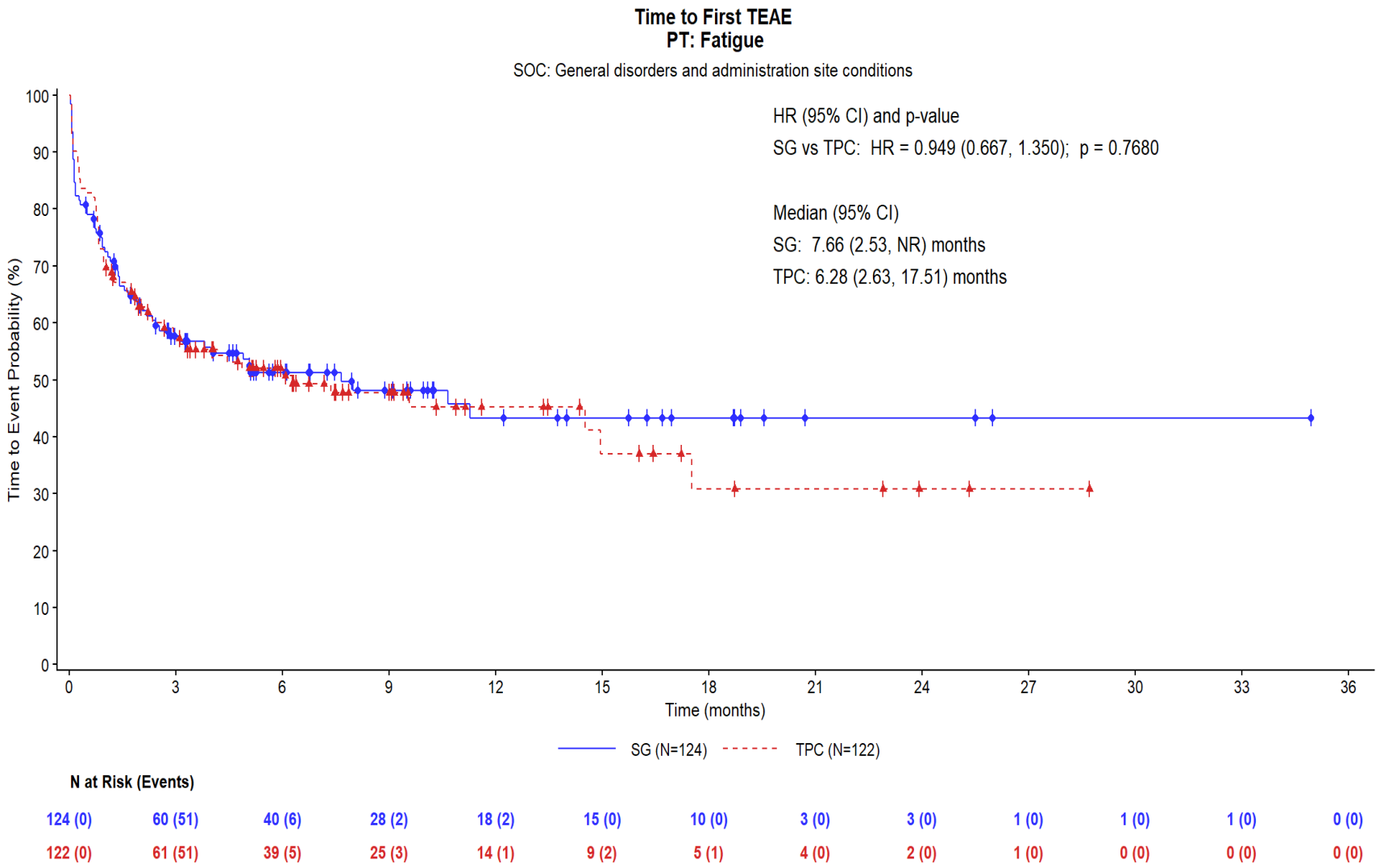
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.47. Figure 1.1.48: Kaplan Meier Plot of Time to First TEAE by PT Vomiting — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



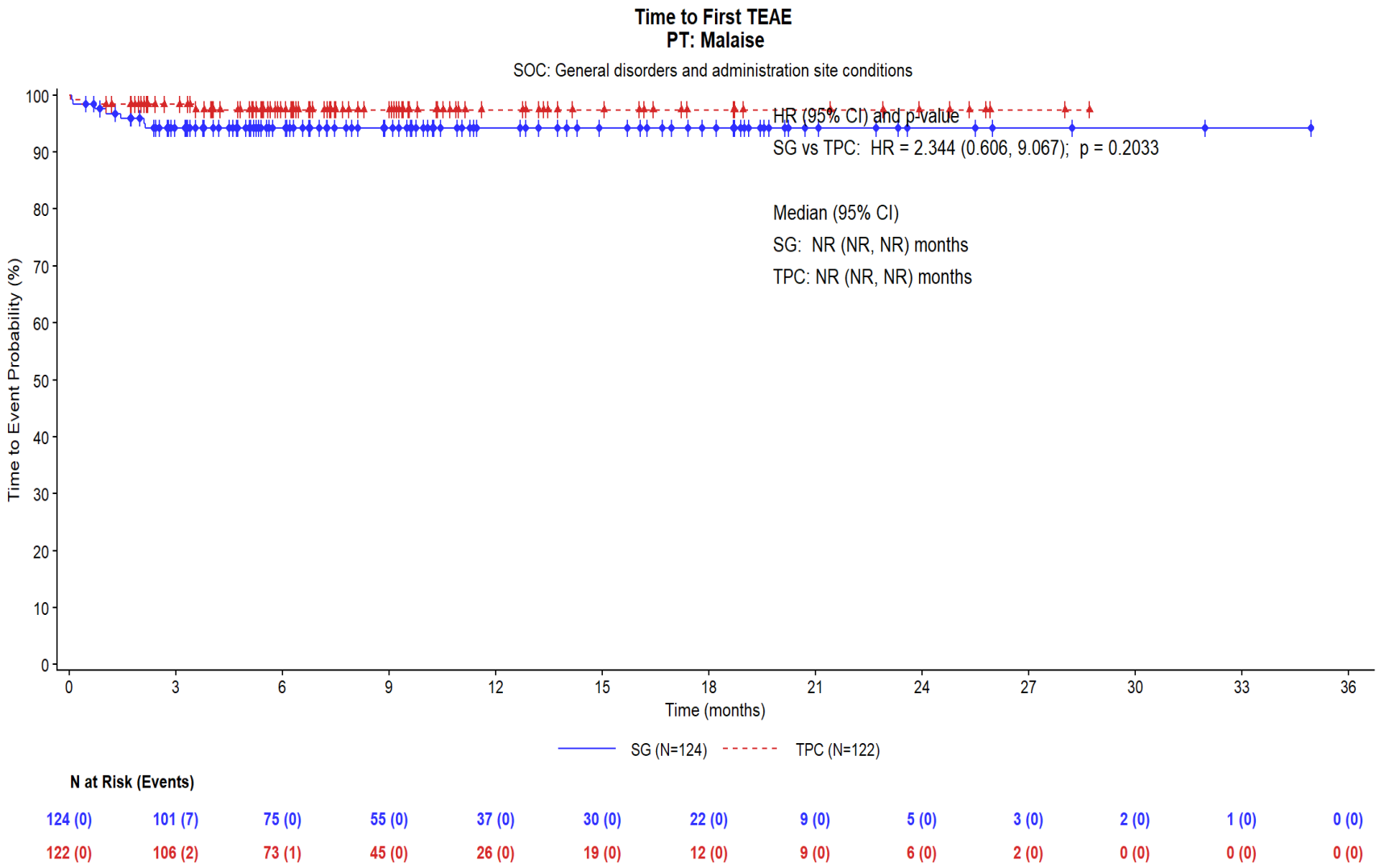
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.48. Figure 1.1.49: Kaplan Meier Plot of Time to First TEAE by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



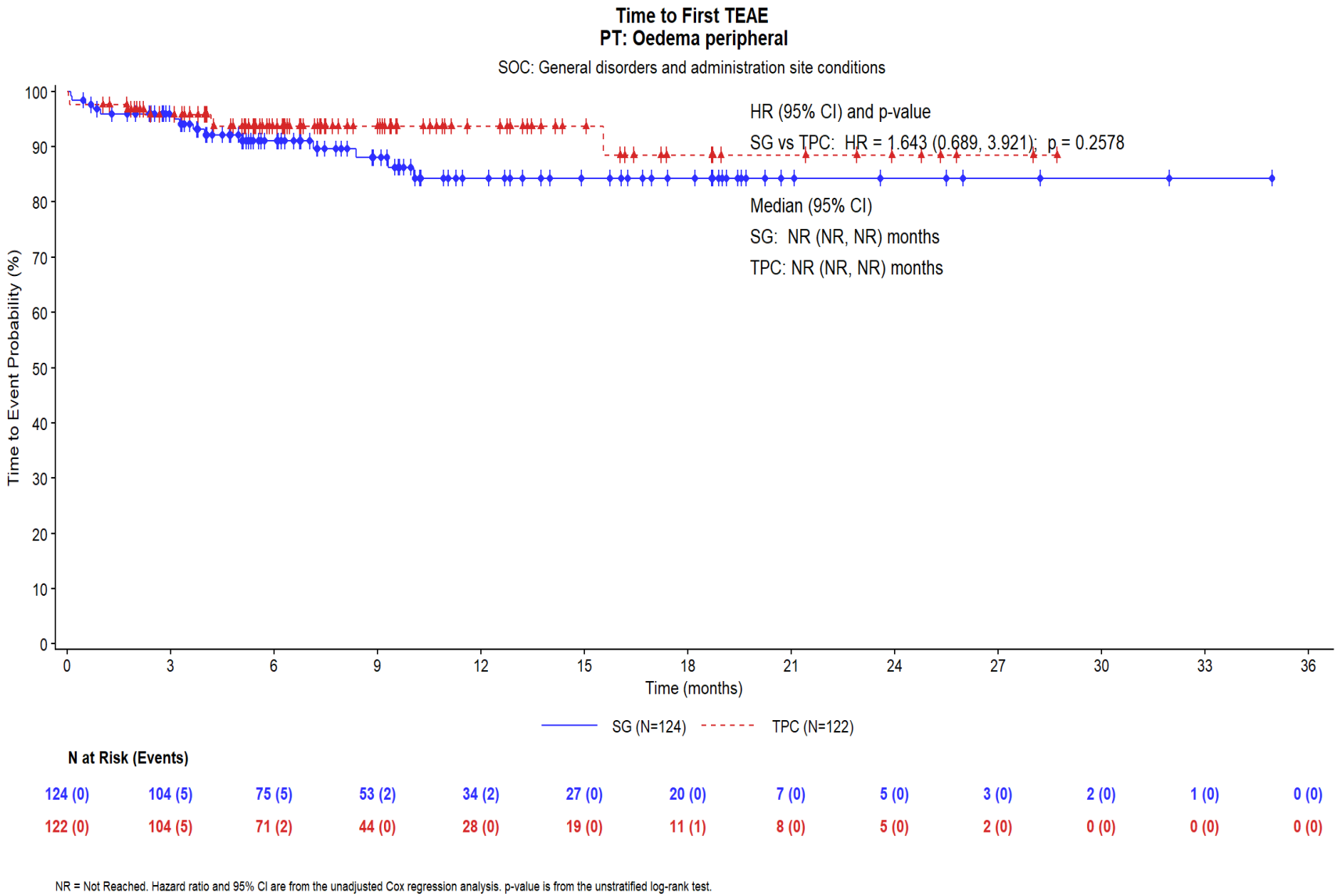
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.49. Figure 1.1.50: Kaplan Meier Plot of Time to First TEAE by PT Malaise — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



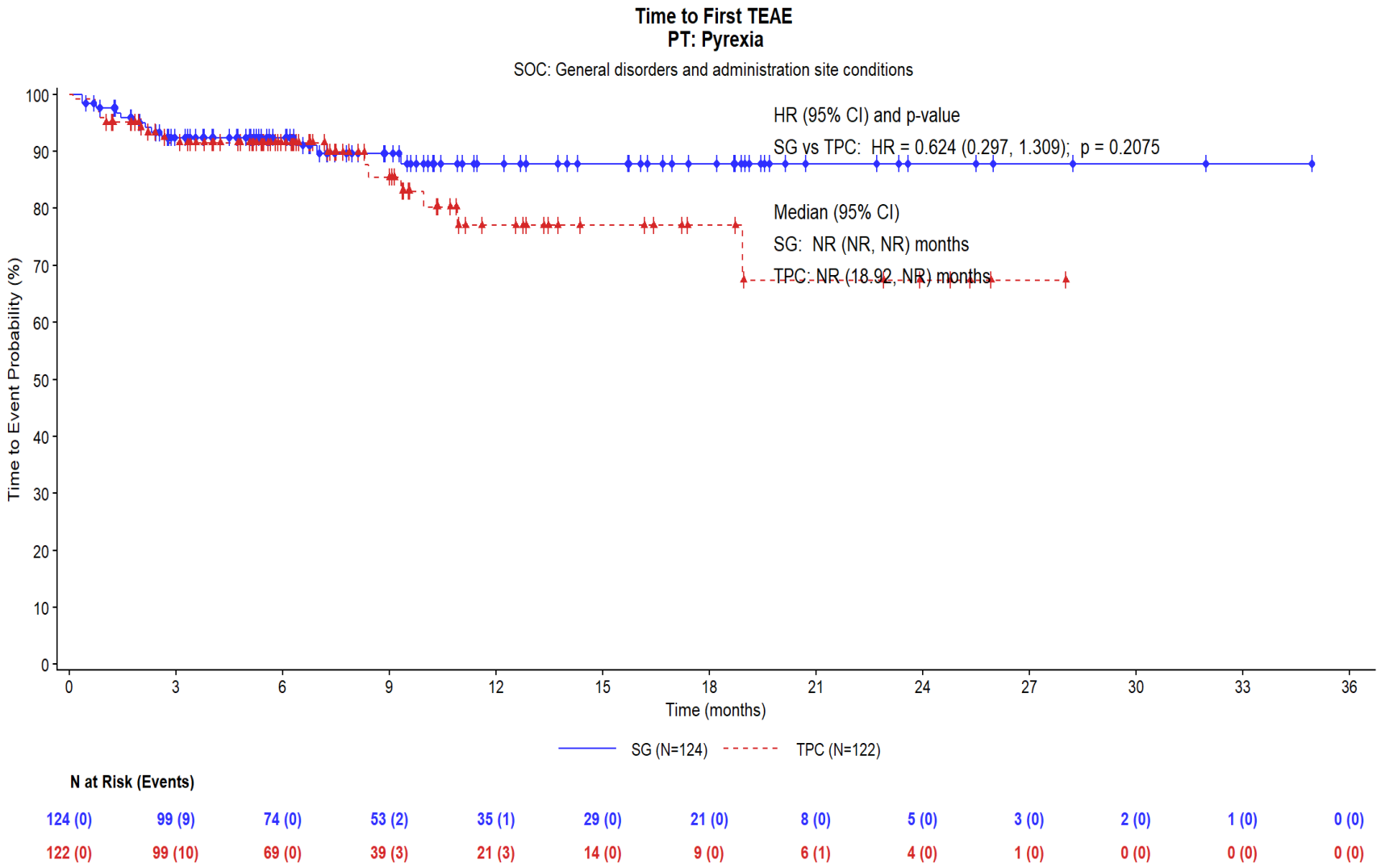
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.50. Figure 1.1.51: Kaplan Meier Plot of Time to First TEAE by PT Oedema peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



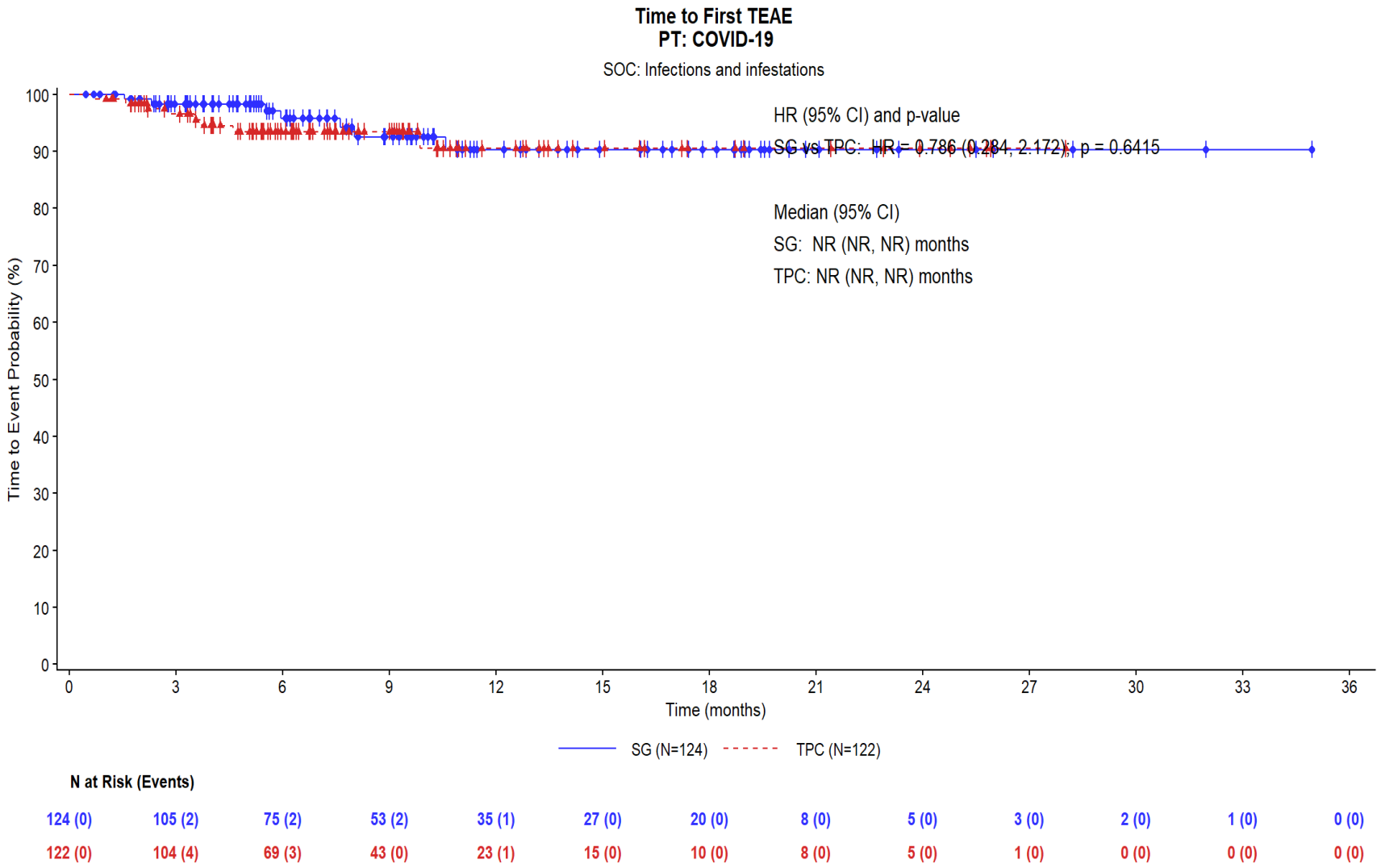
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.51. Figure 1.1.52: Kaplan Meier Plot of Time to First TEAE by PT Pyrexia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



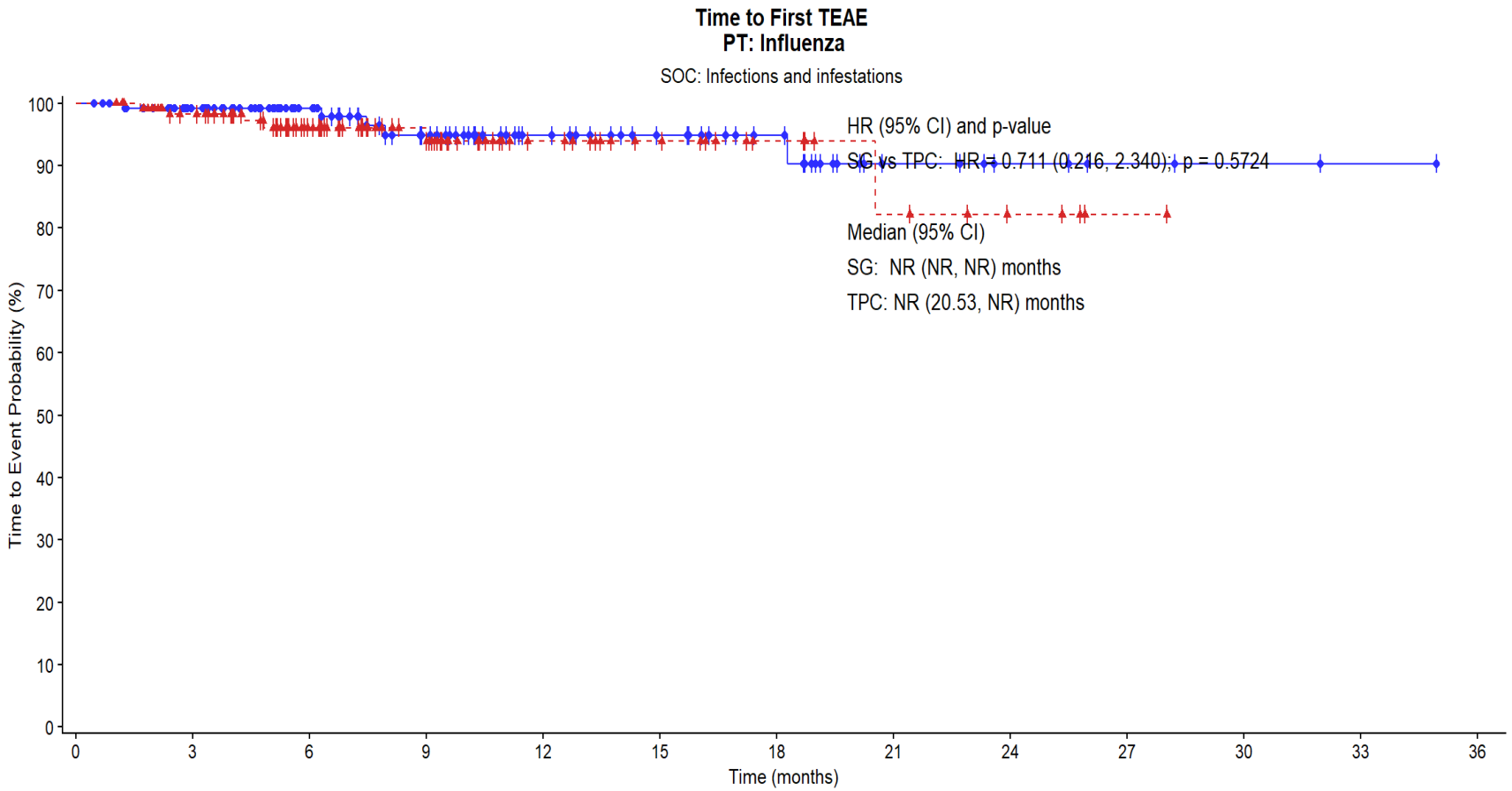
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.52. Figure 1.1.53: Kaplan Meier Plot of Time to First TEAE by PT COVID 19 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



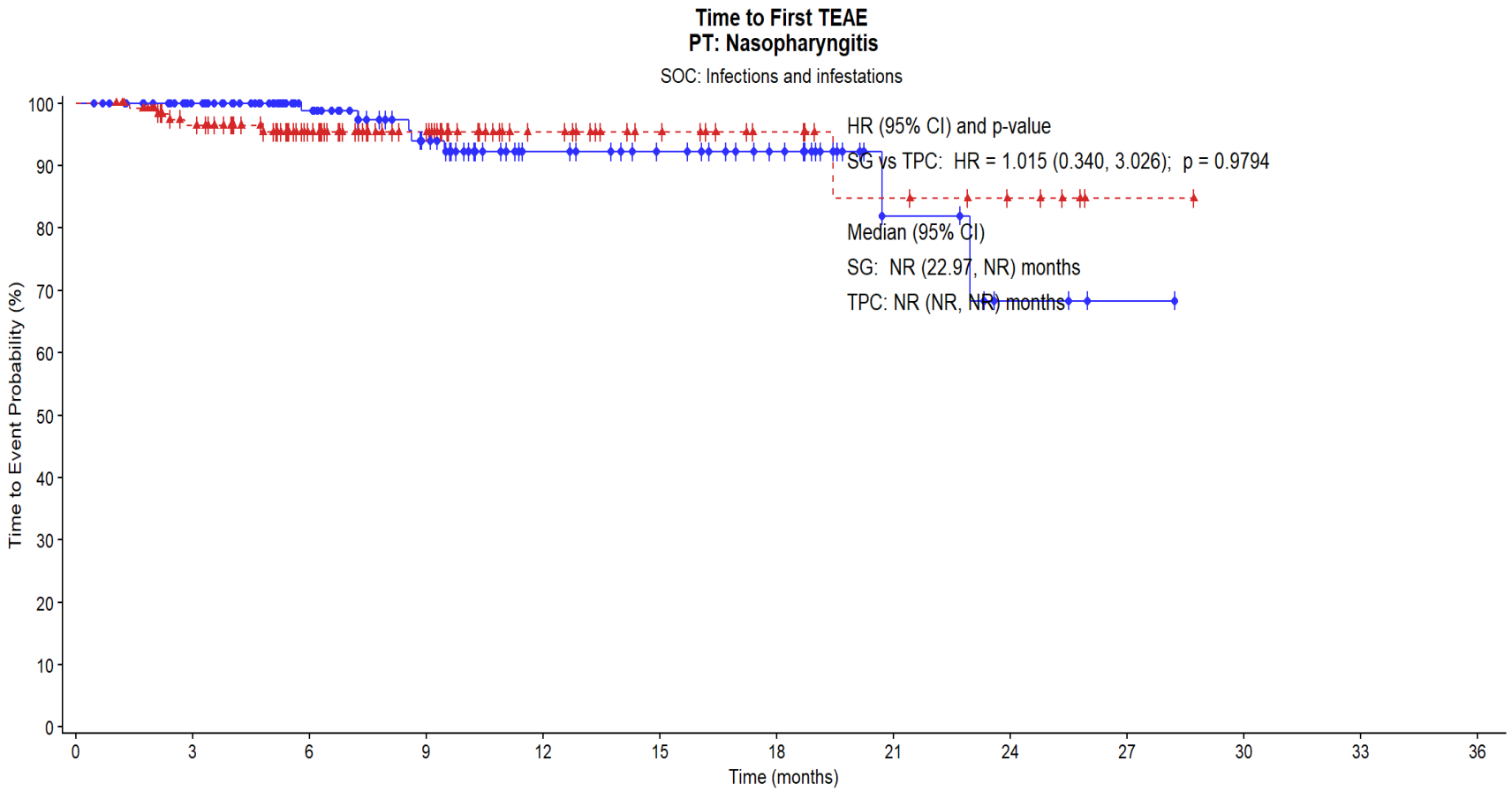
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.53. Figure 1.1.54: Kaplan Meier Plot of Time to First TEAE by PT Influenza — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



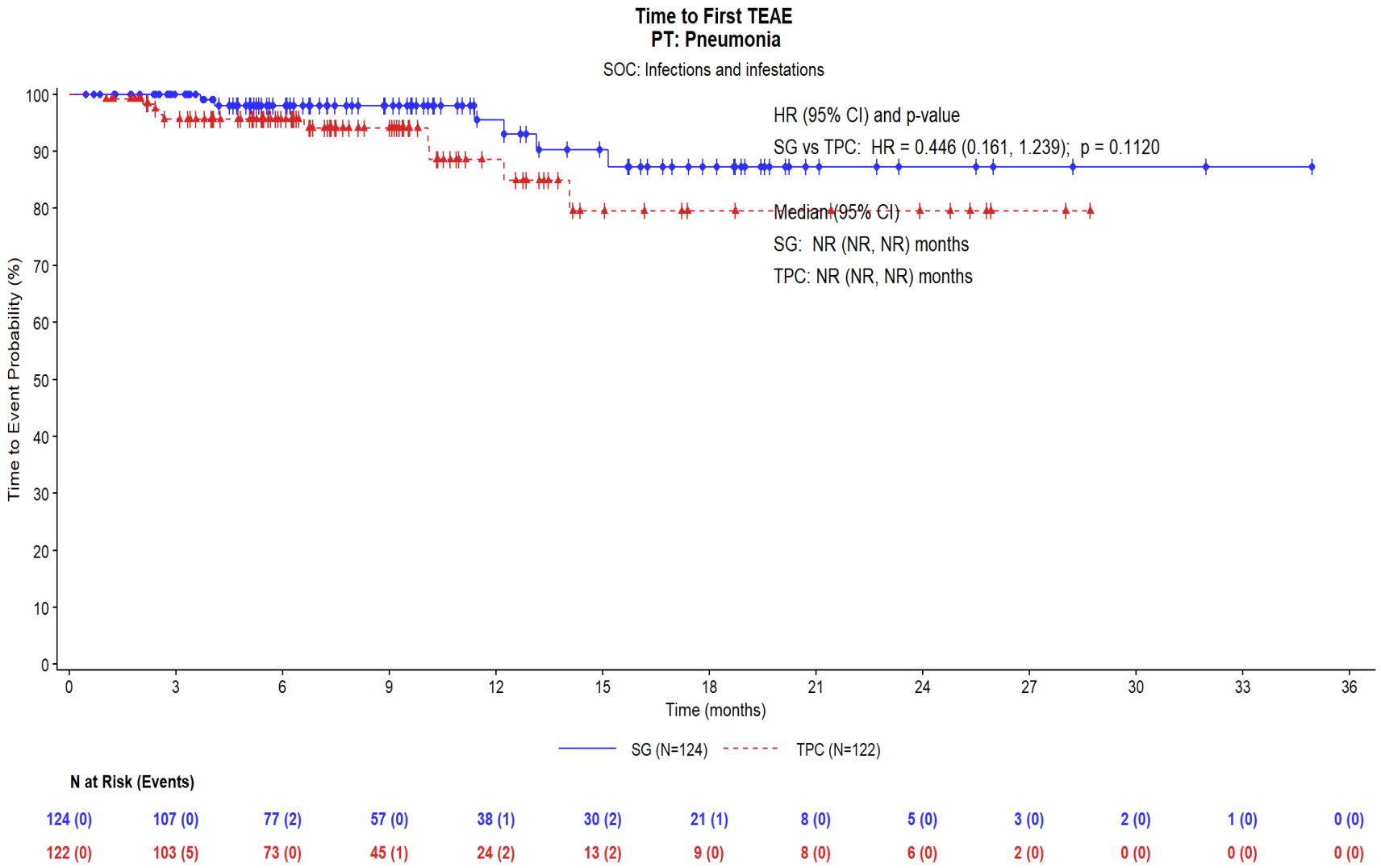
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.54. Figure 1.1.55: Kaplan Meier Plot of Time to First TEAE by PT Nasopharyngitis — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



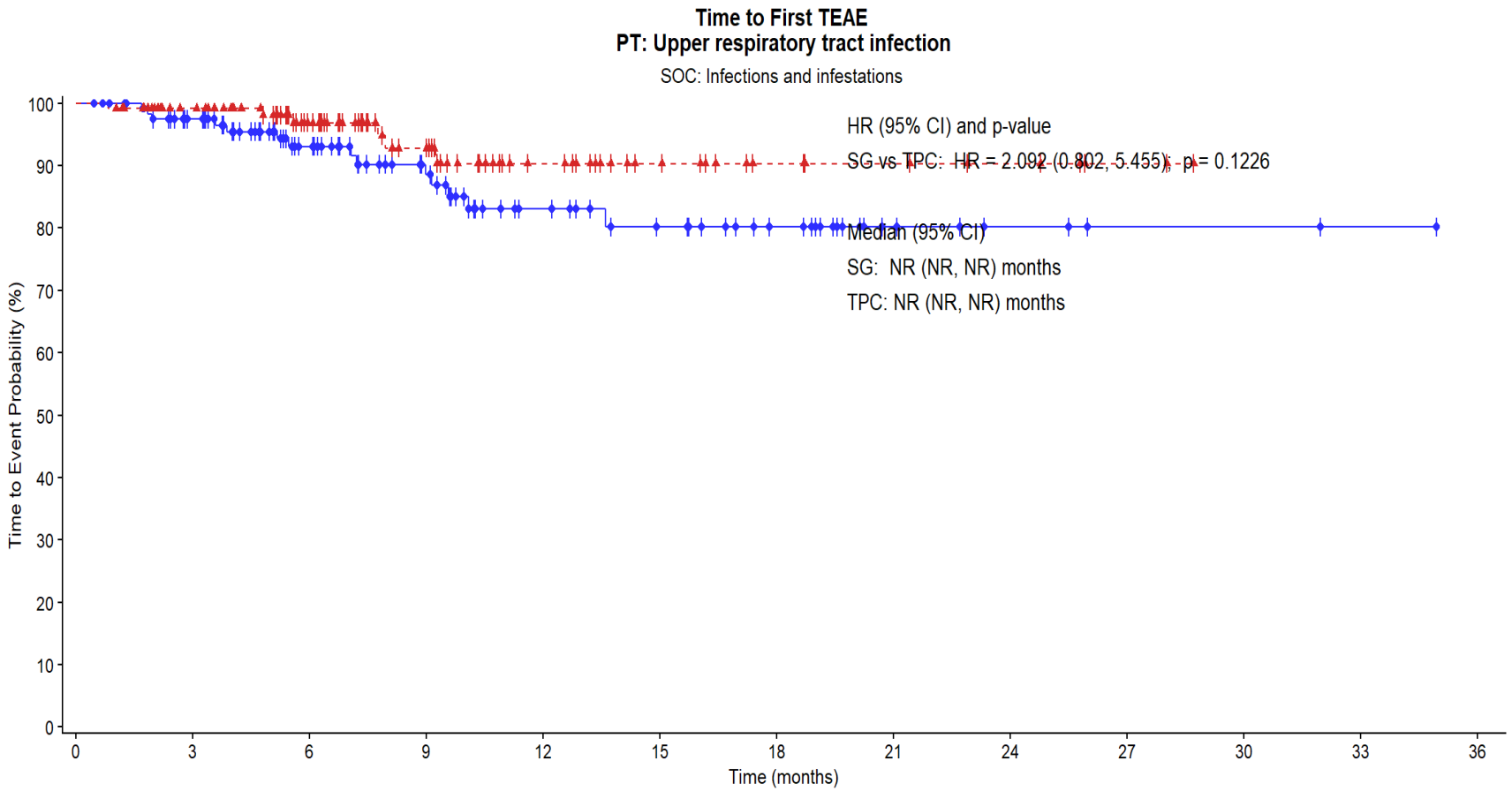
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.55. Figure 1.1.56: Kaplan Meier Plot of Time to First TEAE by PT Pneumonia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



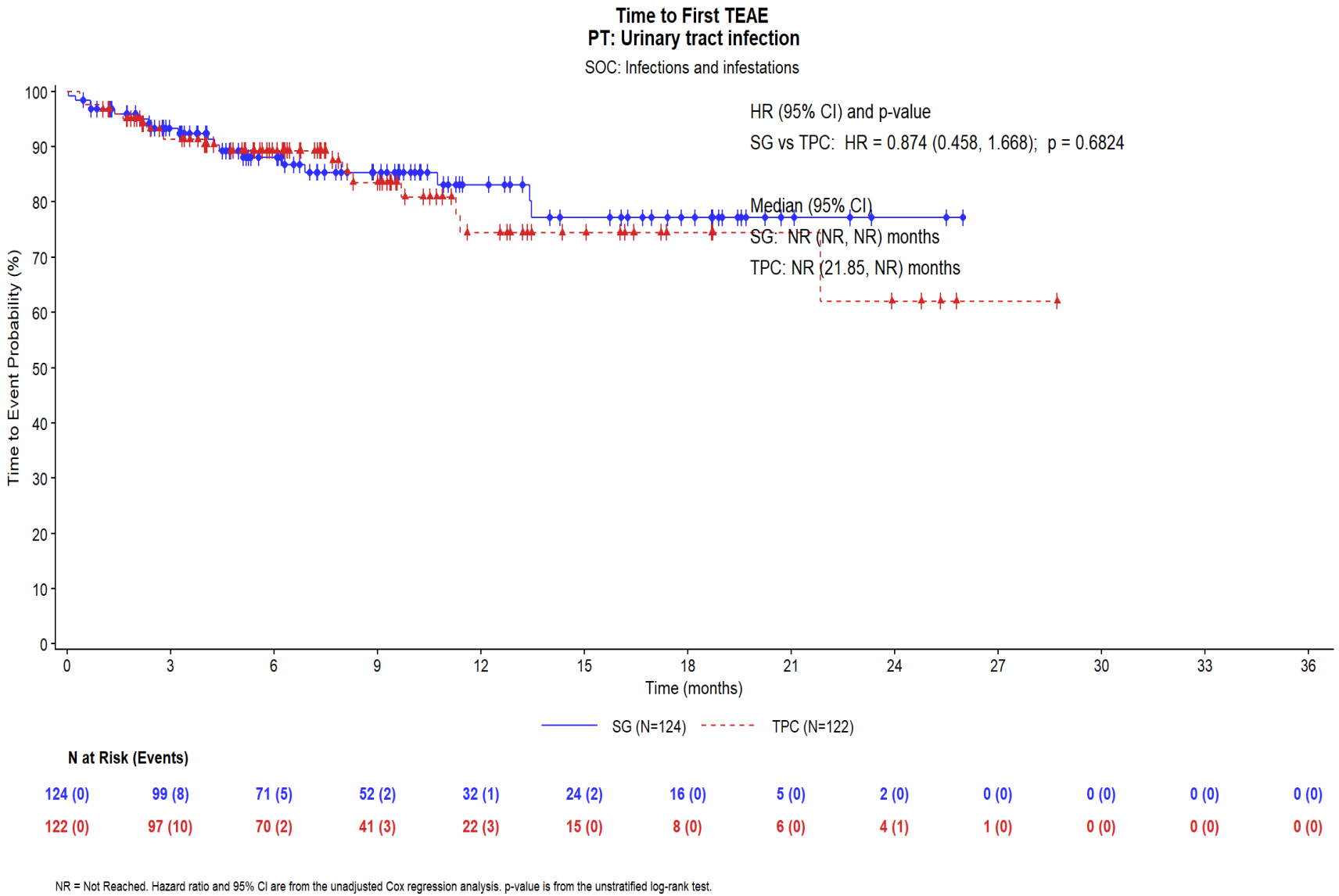
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.56. Figure 1.1.57: Kaplan Meier Plot of Time to First TEAE by PT Upper respiratory tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



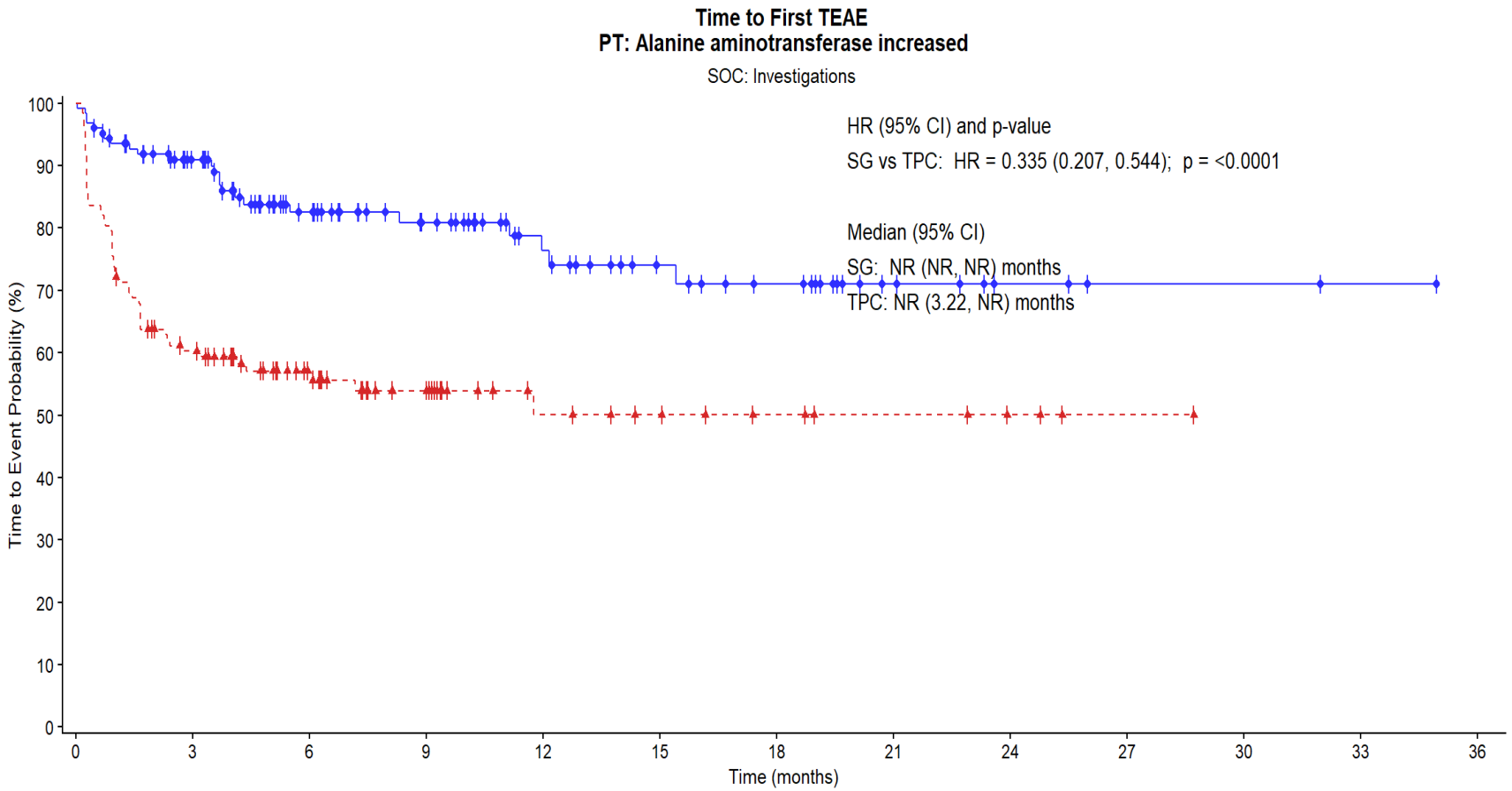
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.57. Figure 1.1.58: Kaplan Meier Plot of Time to First TEAE by PT Urinary tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



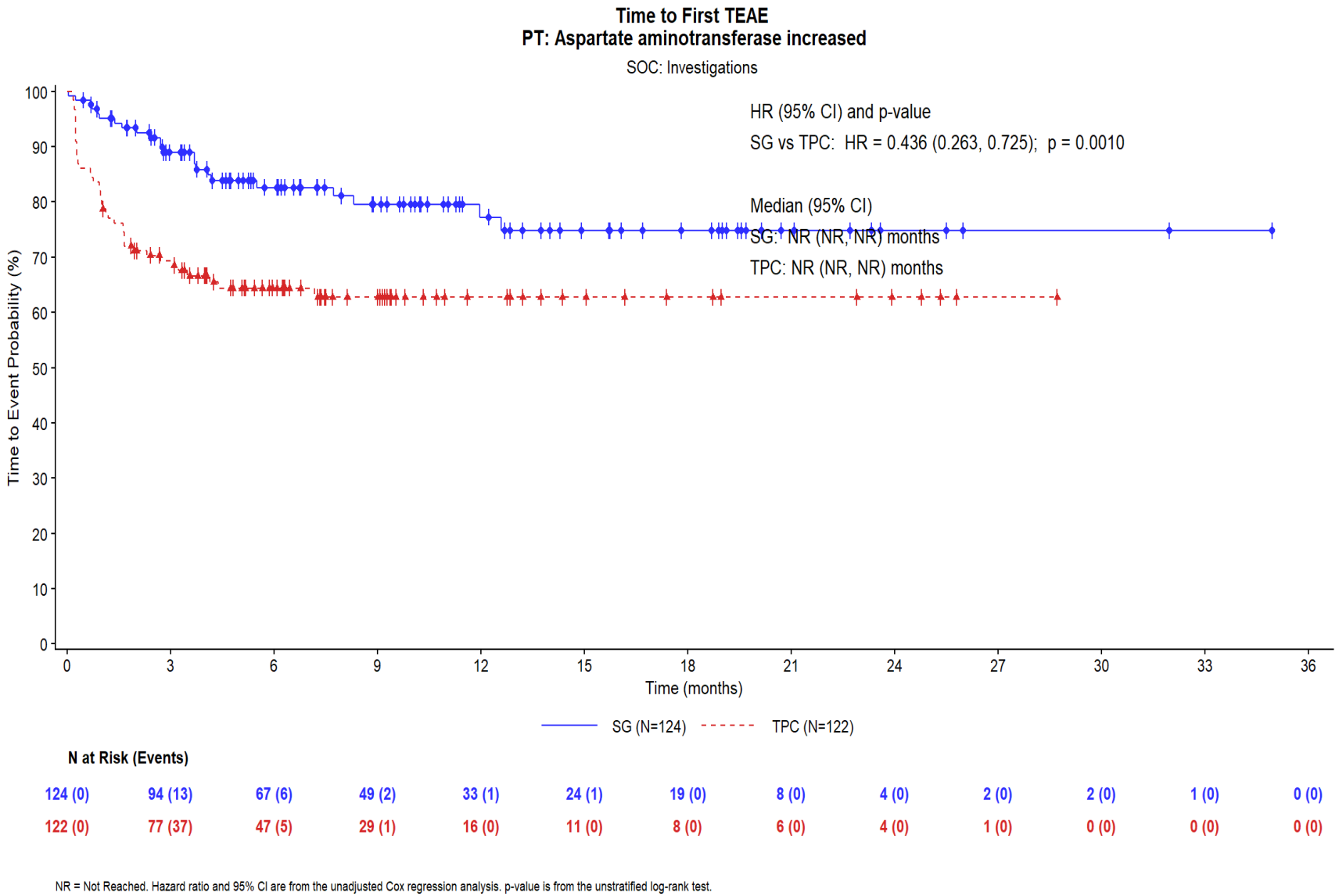
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.58. Figure 1.1.59: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



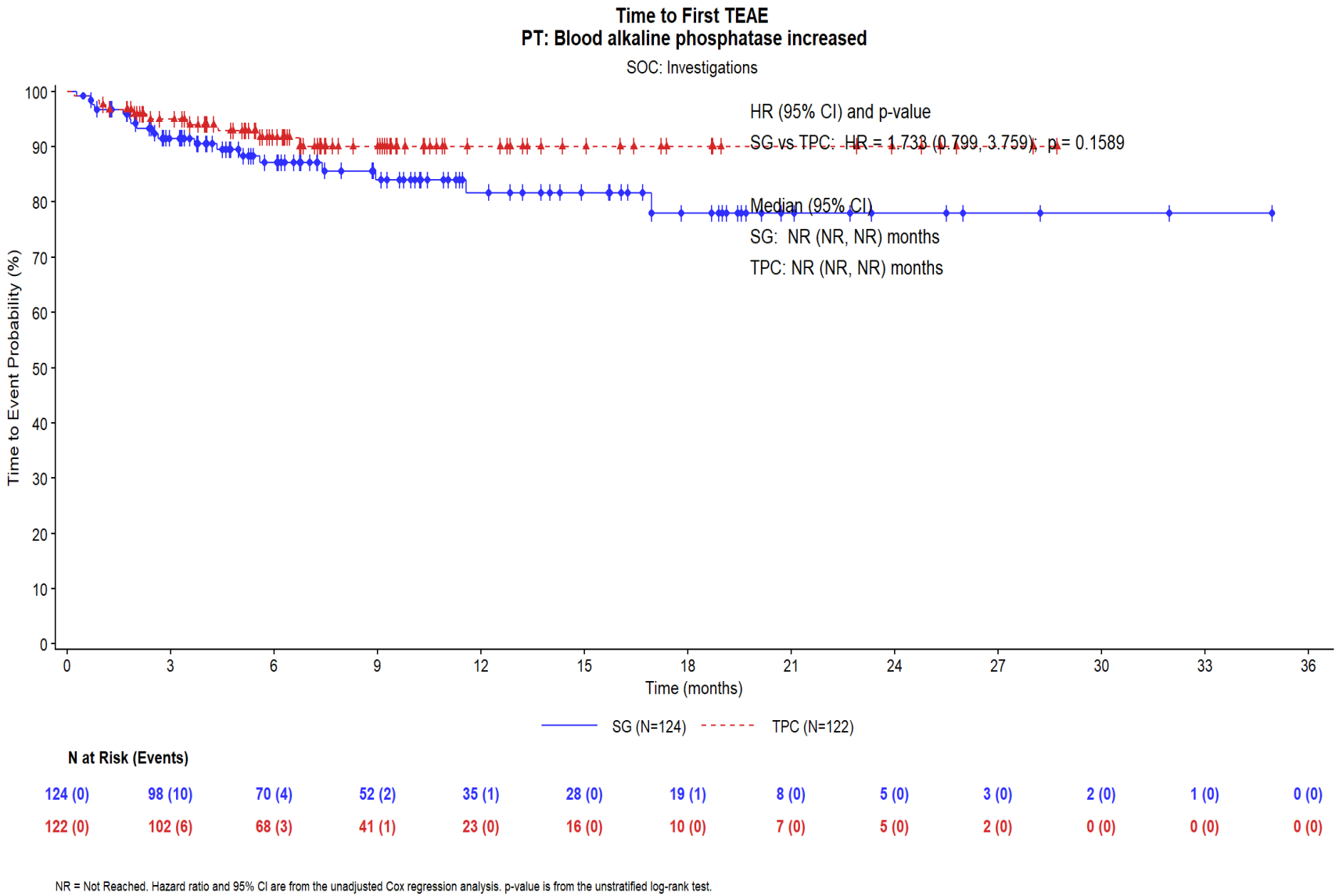
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.59. Figure 1.1.60: Kaplan Meier Plot of Time to First TEAE by PT Aspartate aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



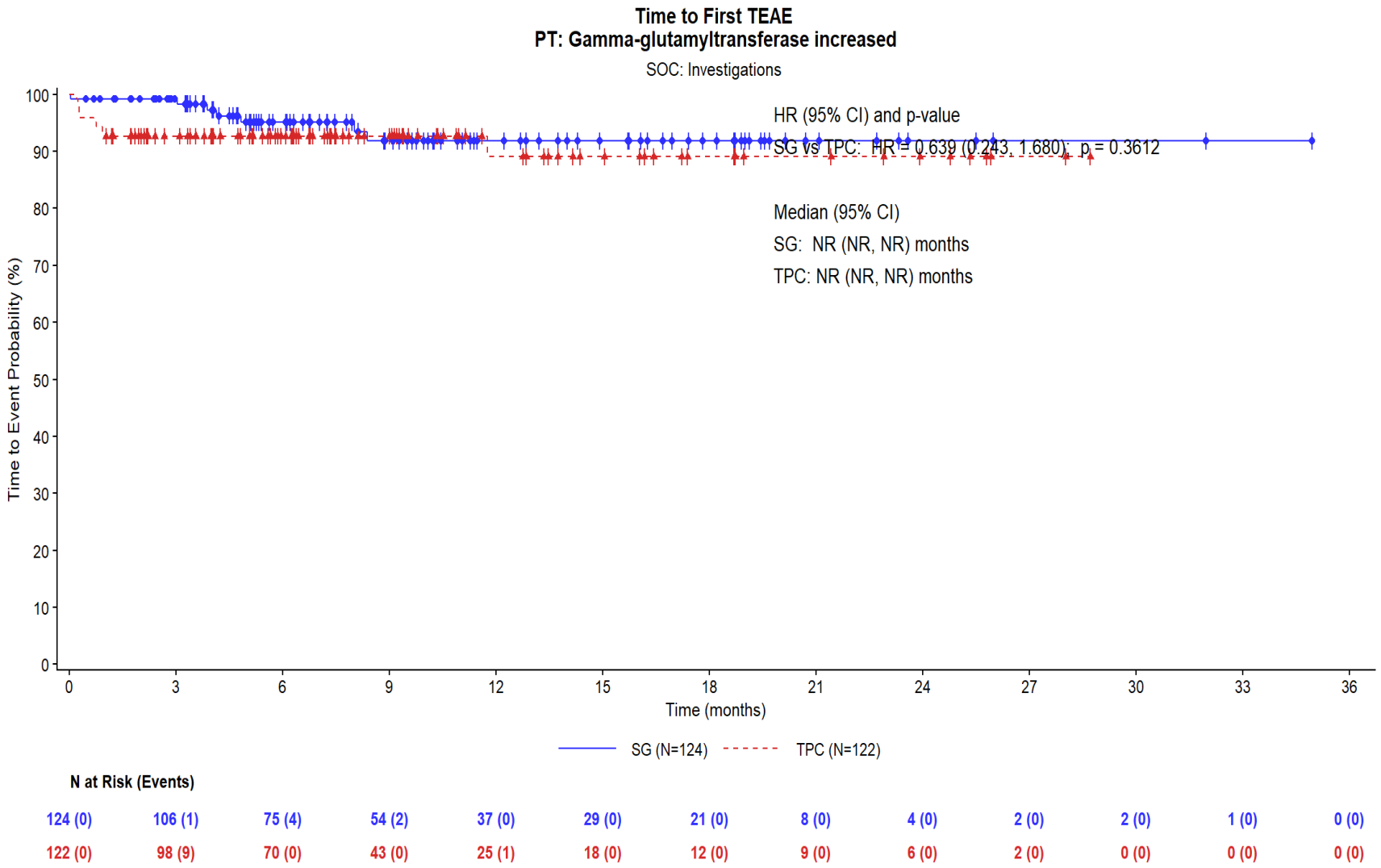
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.60. Figure 1.1.61: Kaplan Meier Plot of Time to First TEAE by PT Blood alkaline phosphatase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



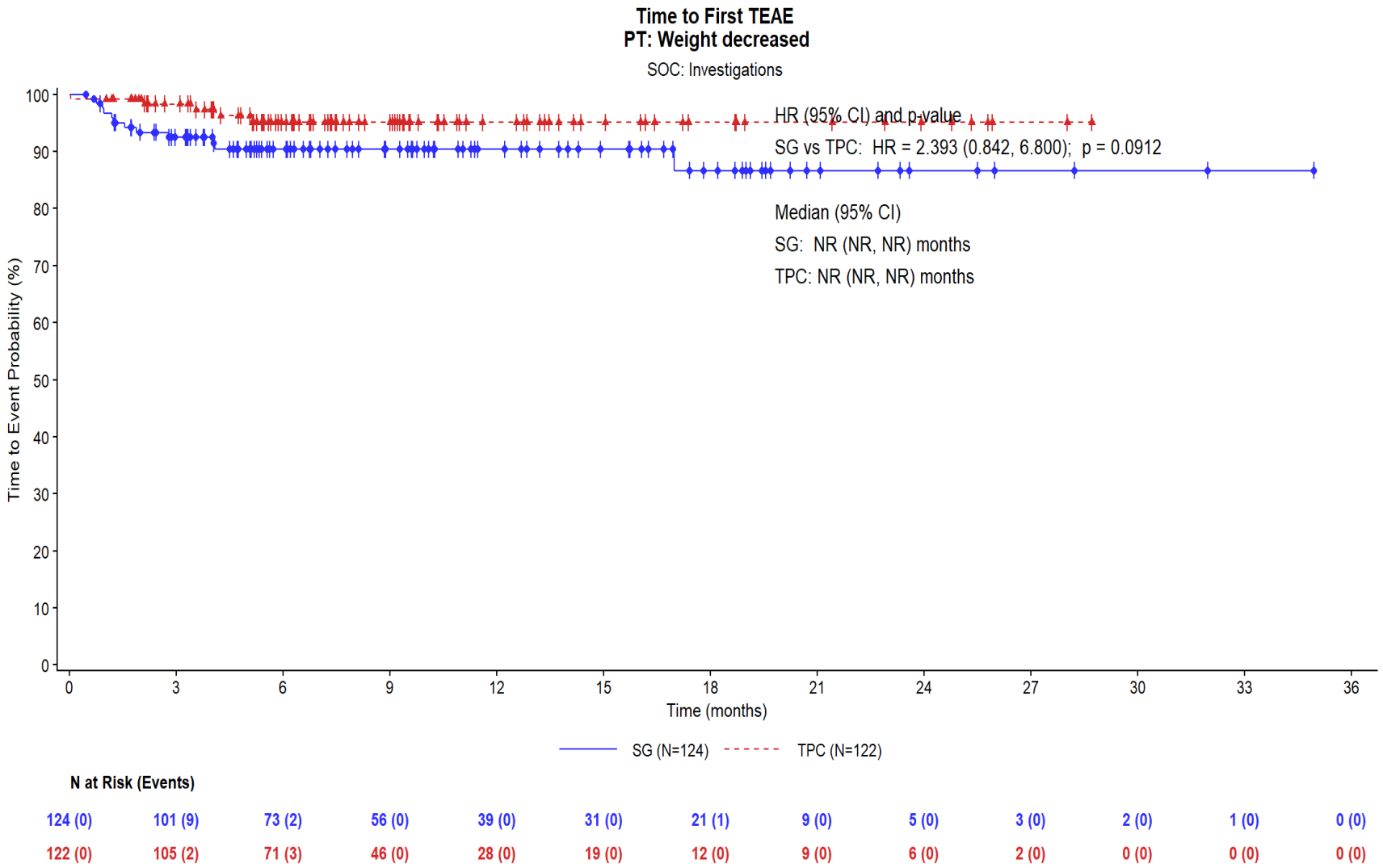
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.61. Figure 1.1.62: Kaplan Meier Plot of Time to First TEAE by PT Gamma glutamyltransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



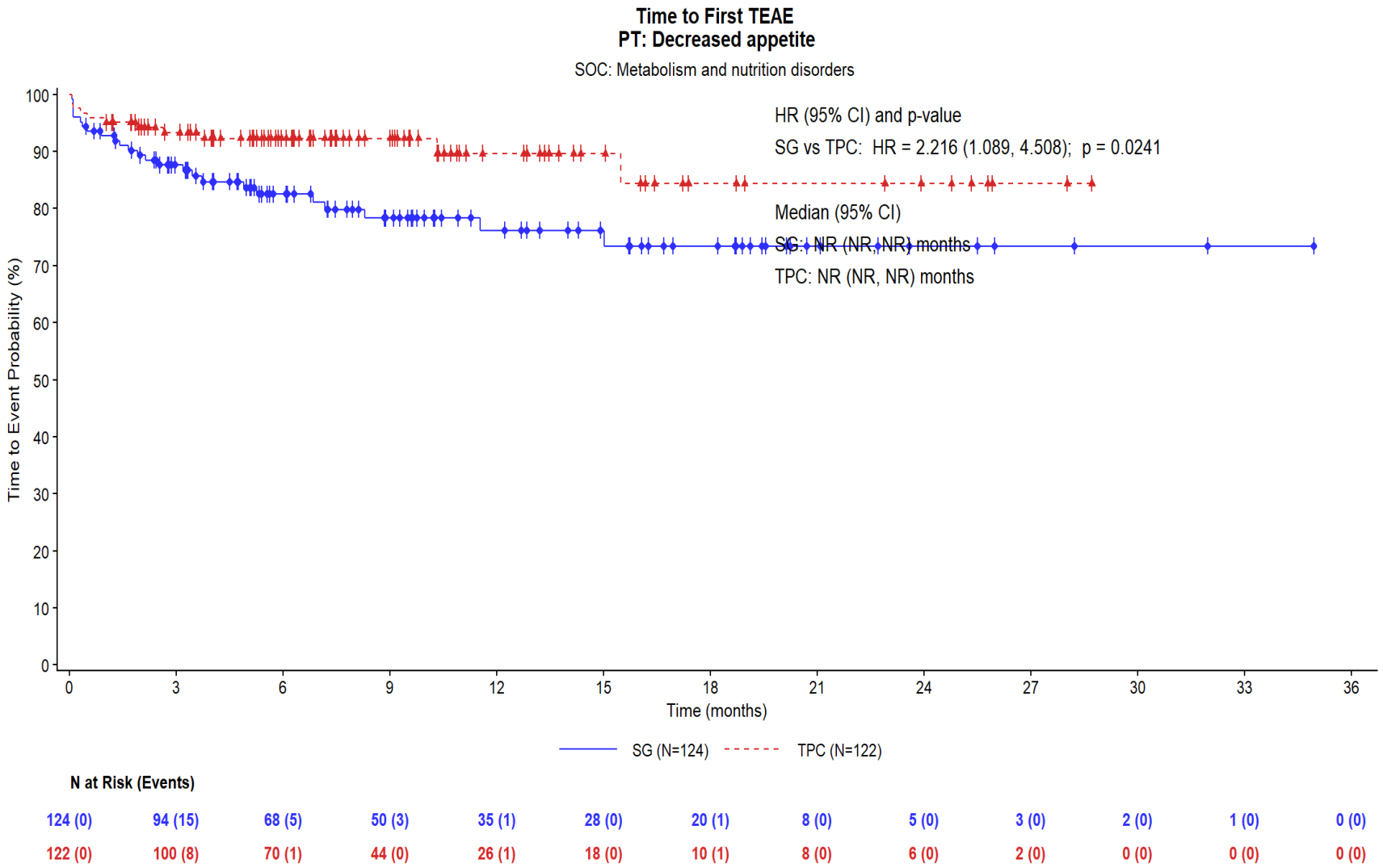
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7.62. Figure 1.1.63: Kaplan Meier Plot of Time to First TEAE by PT Weight decreased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



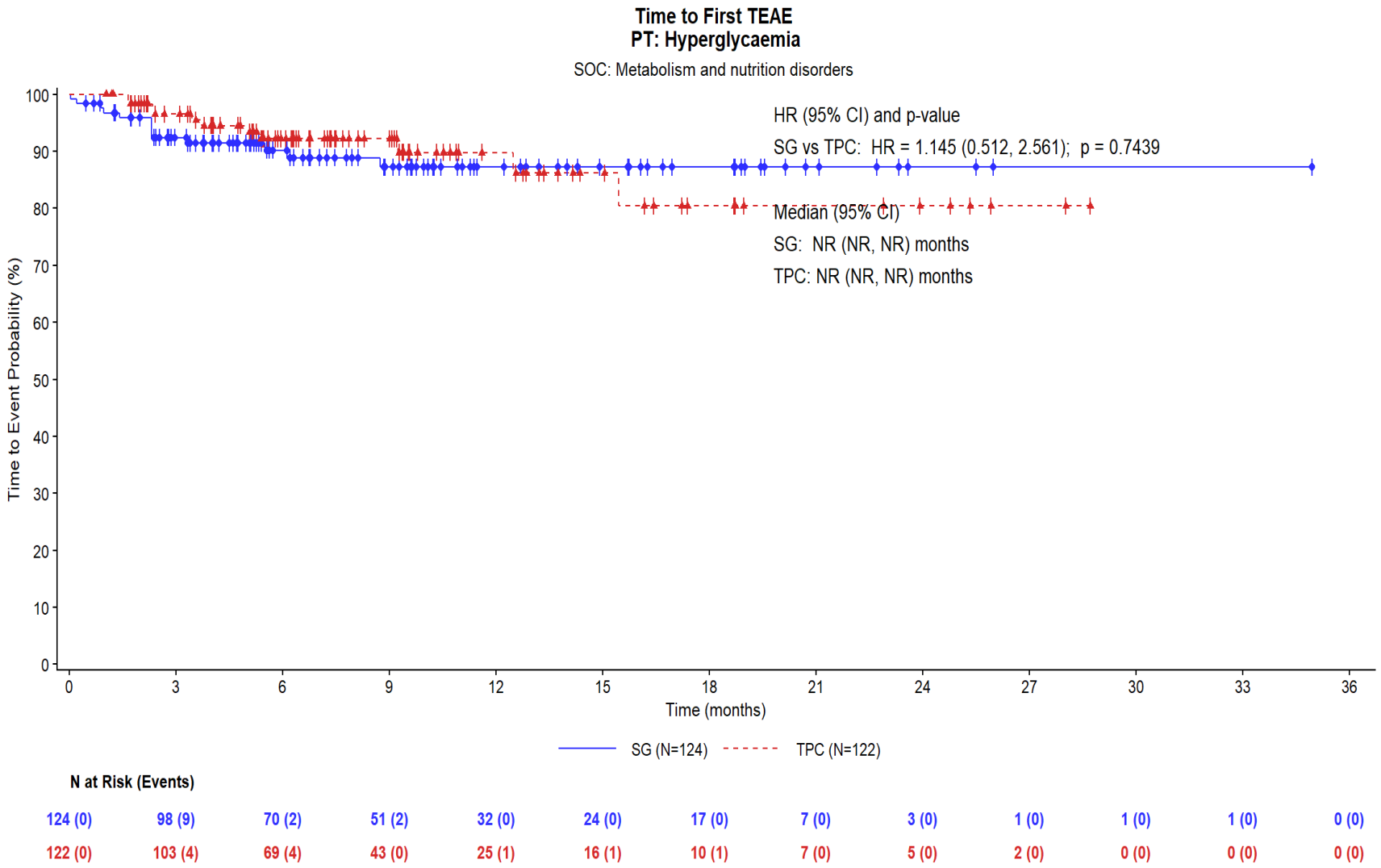
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.63. Figure 1.1.64: Kaplan Meier Plot of Time to First TEAE by PT Decreased appetite — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



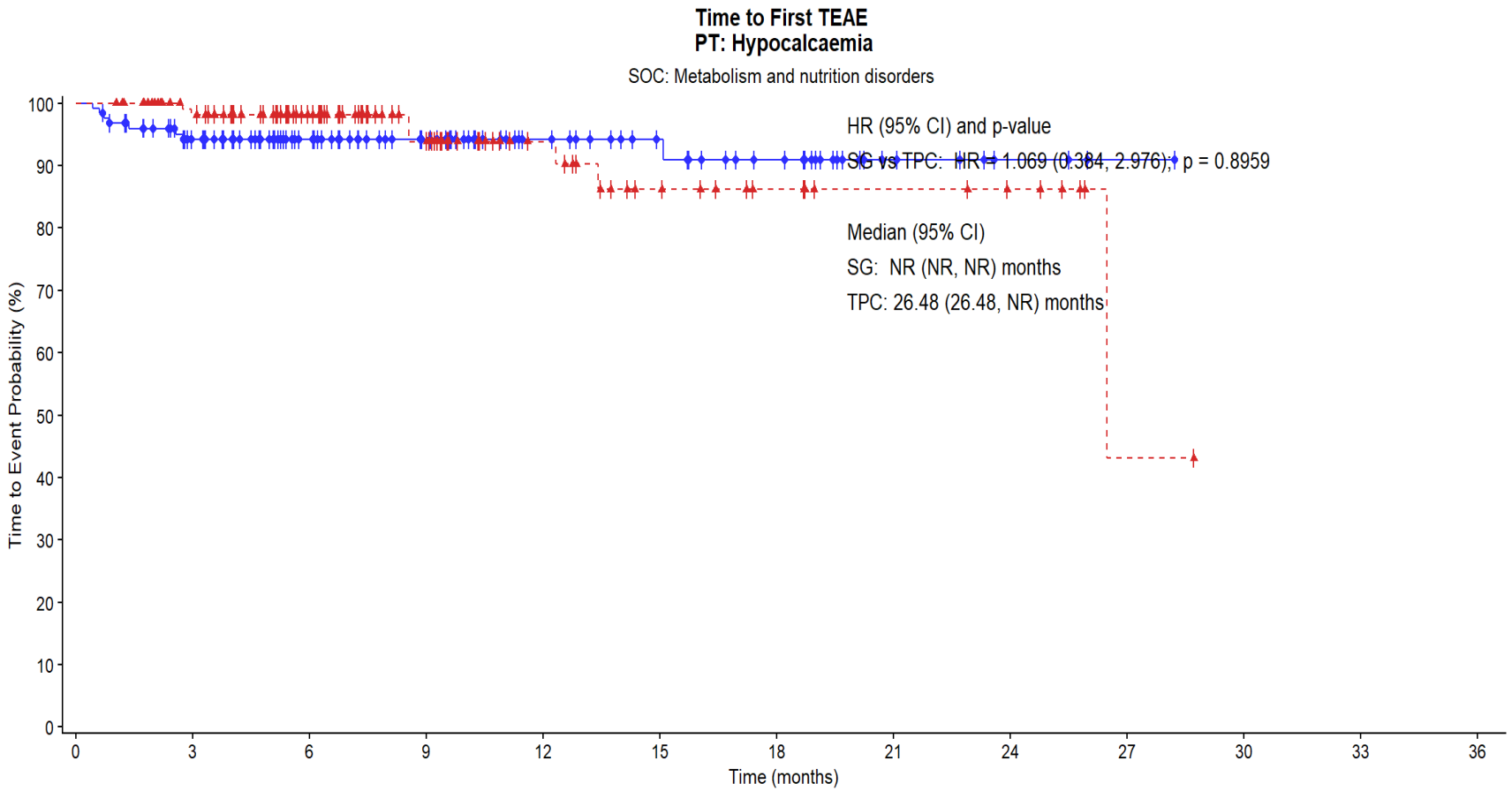
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.64. Figure 1.1.65: Kaplan Meier Plot of Time to First TEAE by PT Hyperglycaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



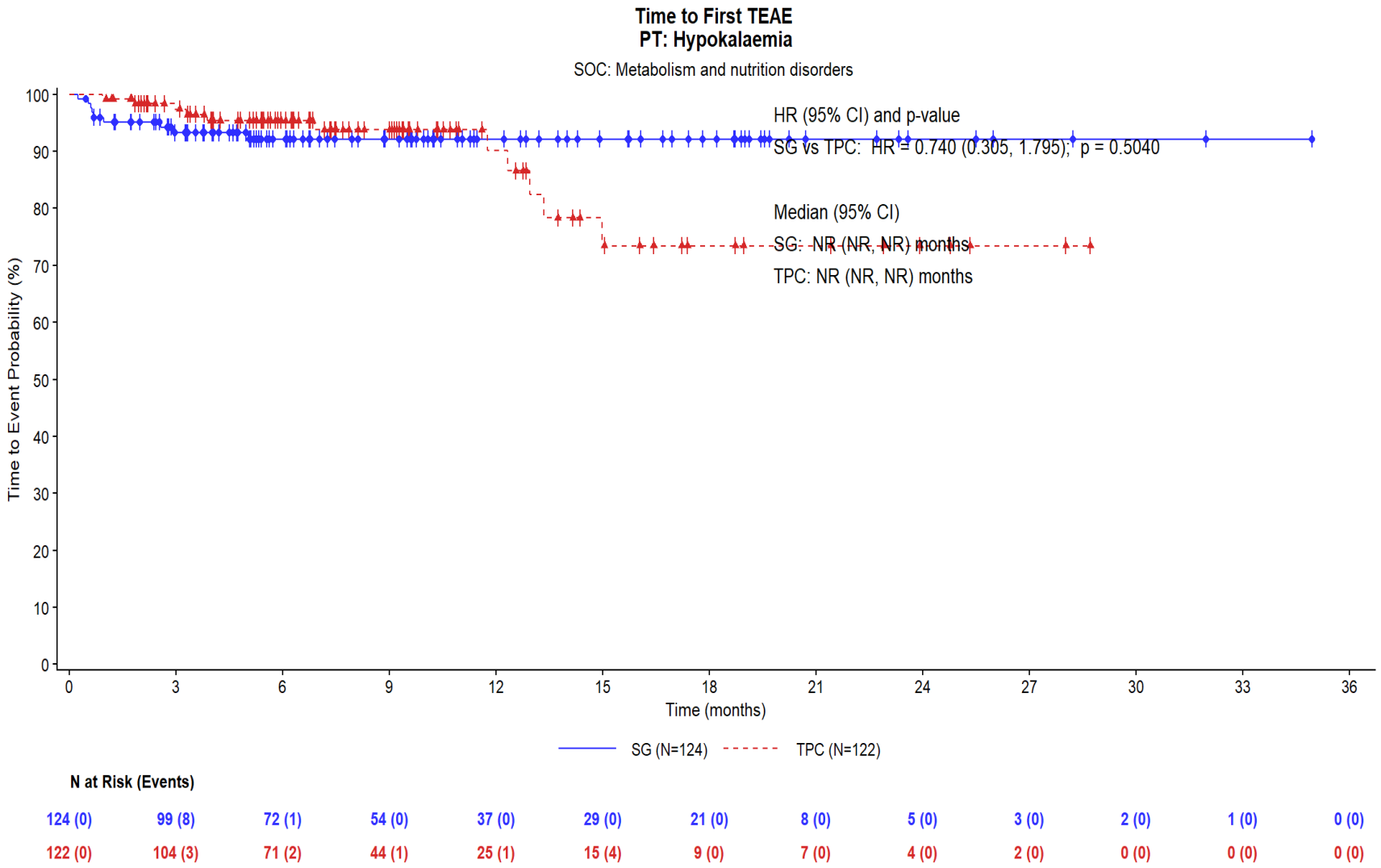
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.65. Figure 1.1.66: Kaplan Meier Plot of Time to First TEAE by PT Hypocalcaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



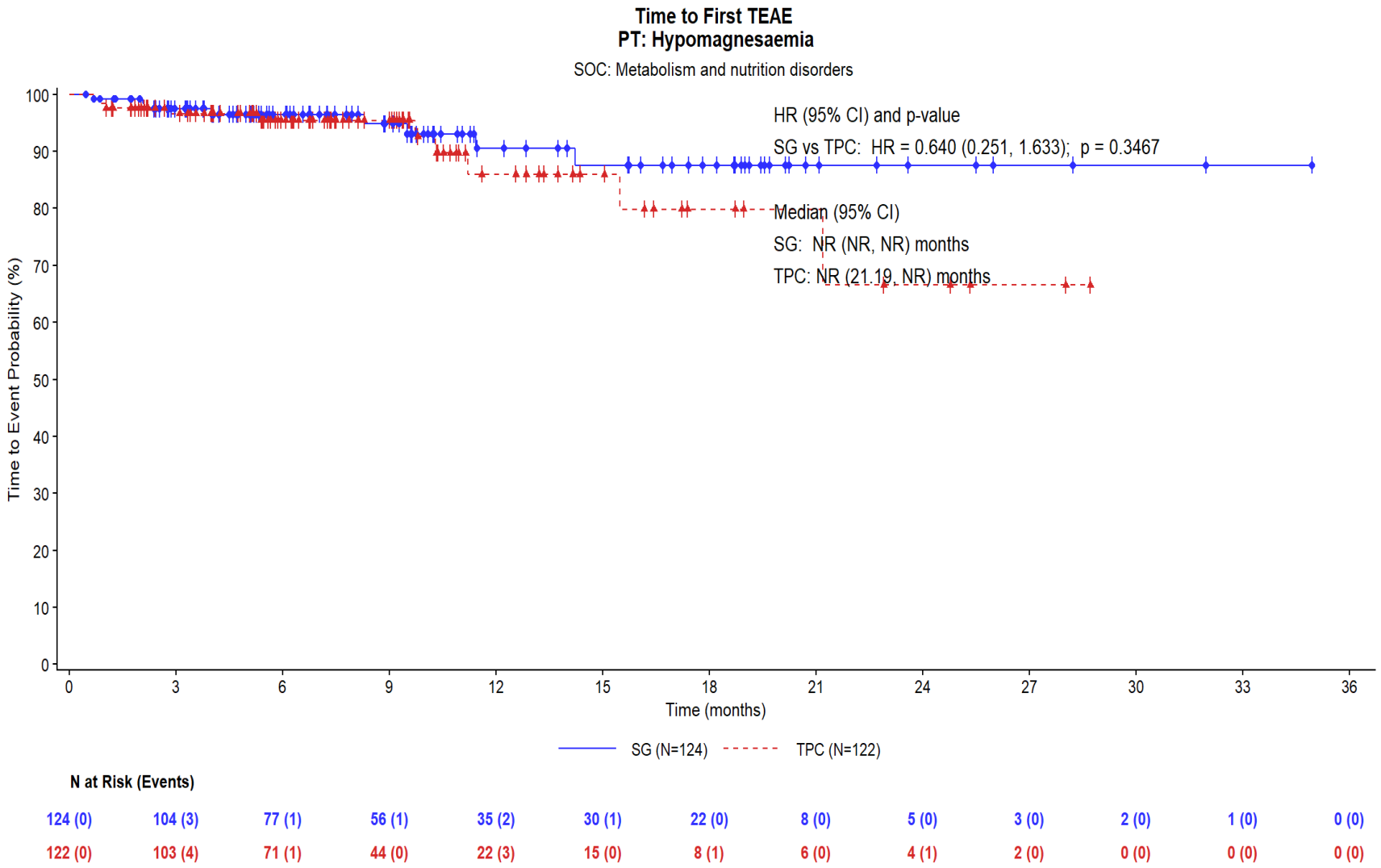
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7.66. Figure 1.1.67: Kaplan Meier Plot of Time to First TEAE by PT Hypokalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



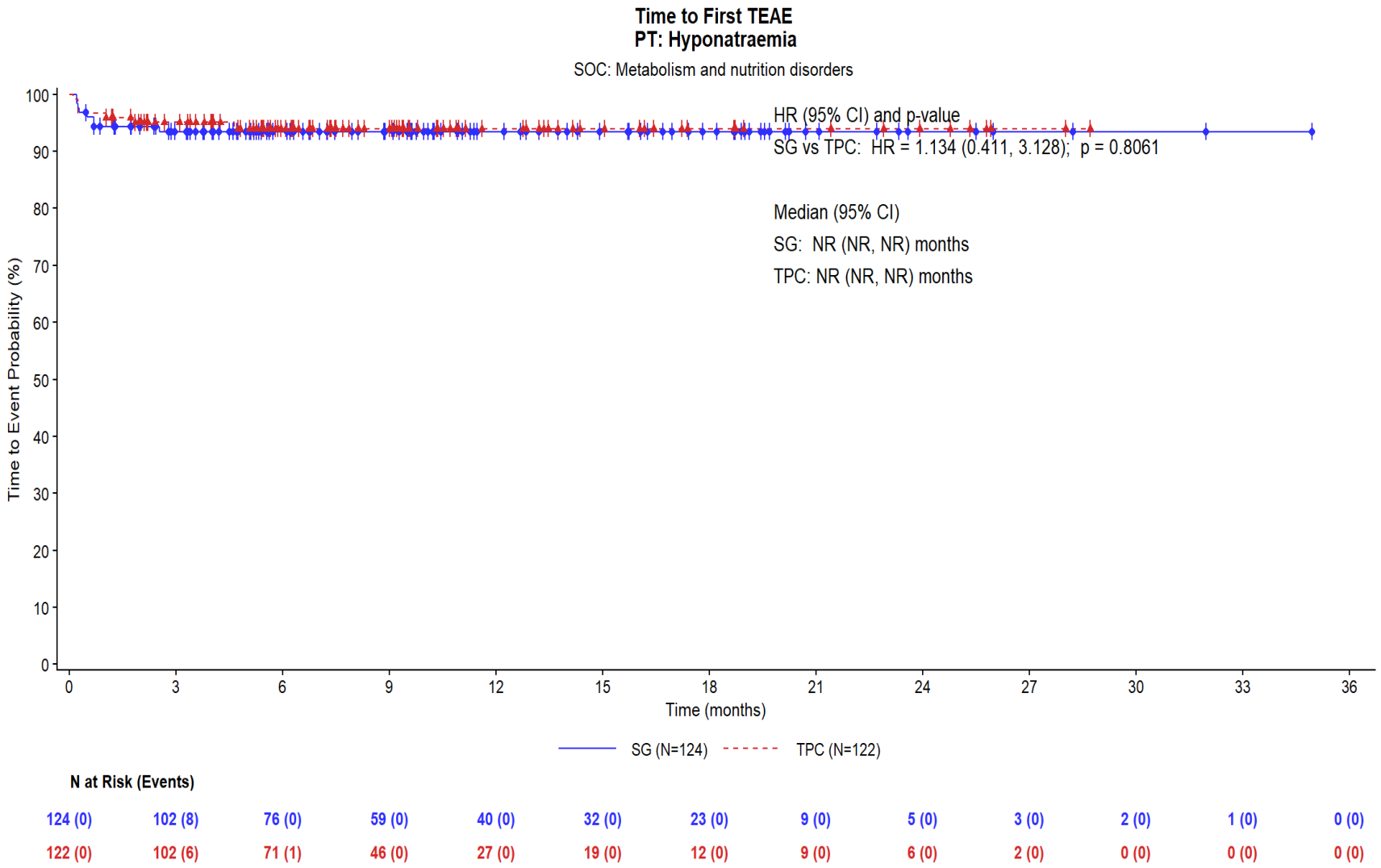
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.67. Figure 1.1.68: Kaplan Meier Plot of Time to First TEAE by PT Hypomagnesaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



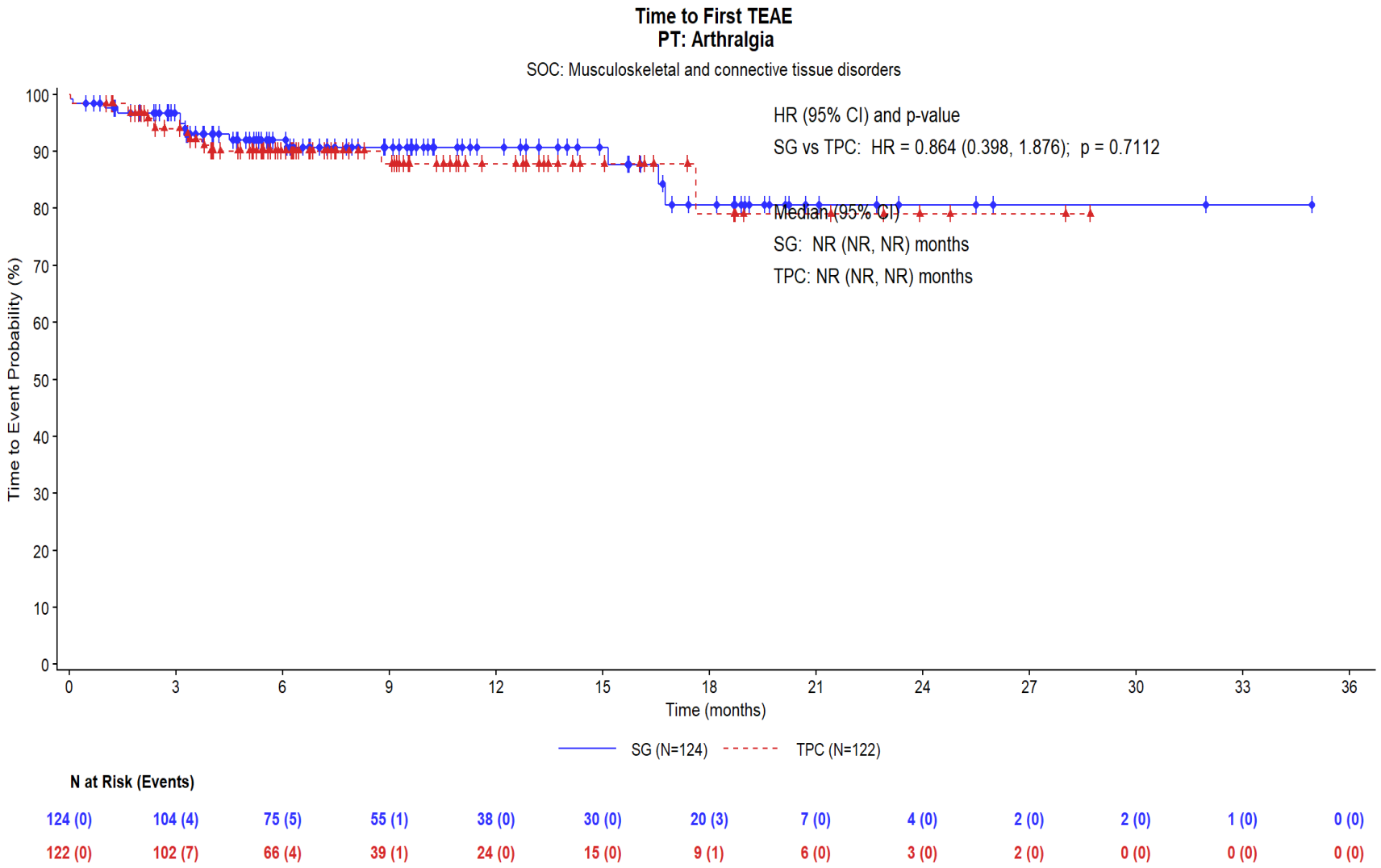
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.68. Figure 1.1.69: Kaplan Meier Plot of Time to First TEAE by PT Hyponatraemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



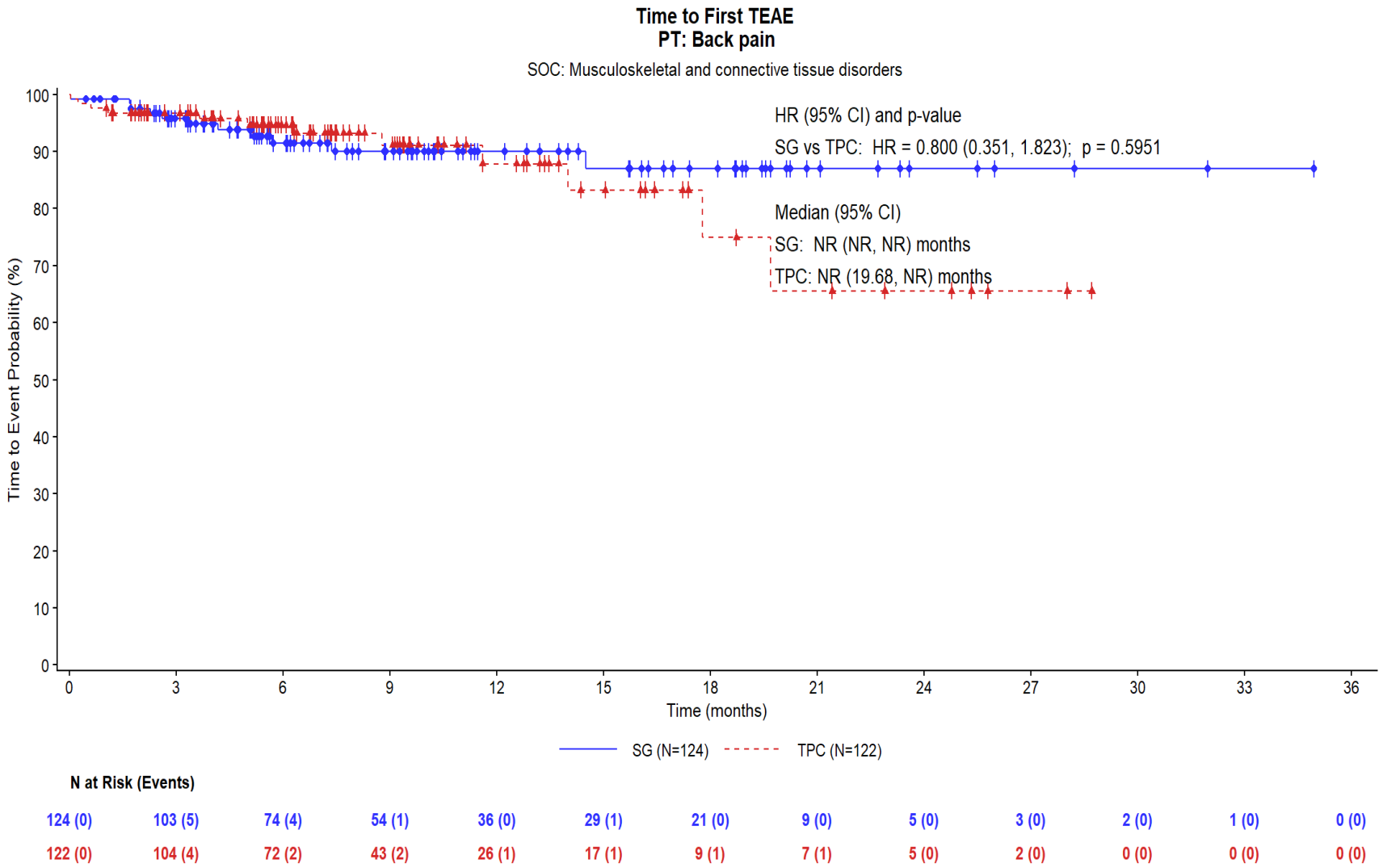
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.69. Figure 1.1.70: Kaplan Meier Plot of Time to First TEAE by PT Arthralgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



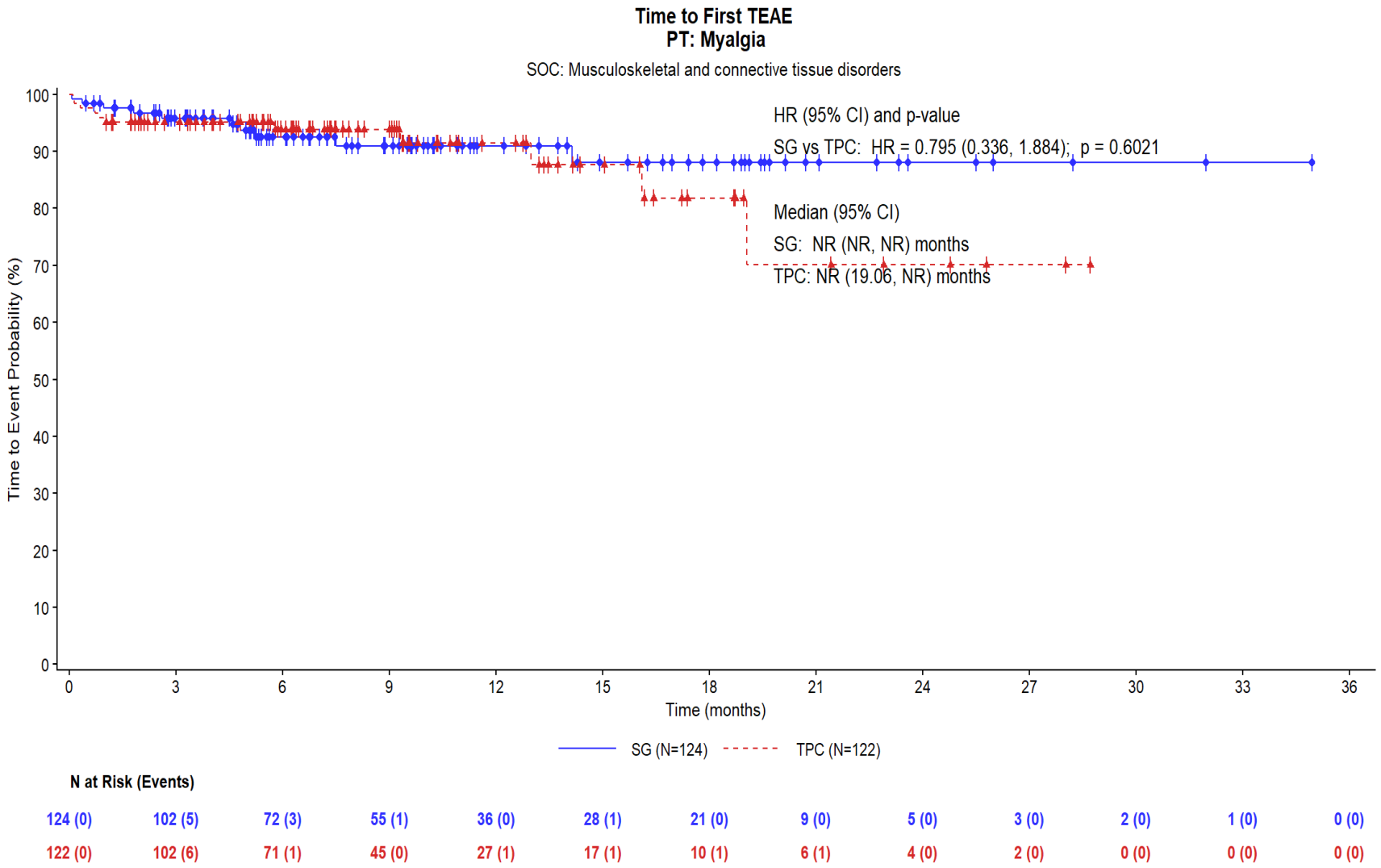
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.70. Figure 1.1.71: Kaplan Meier Plot of Time to First TEAE by PT Back pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



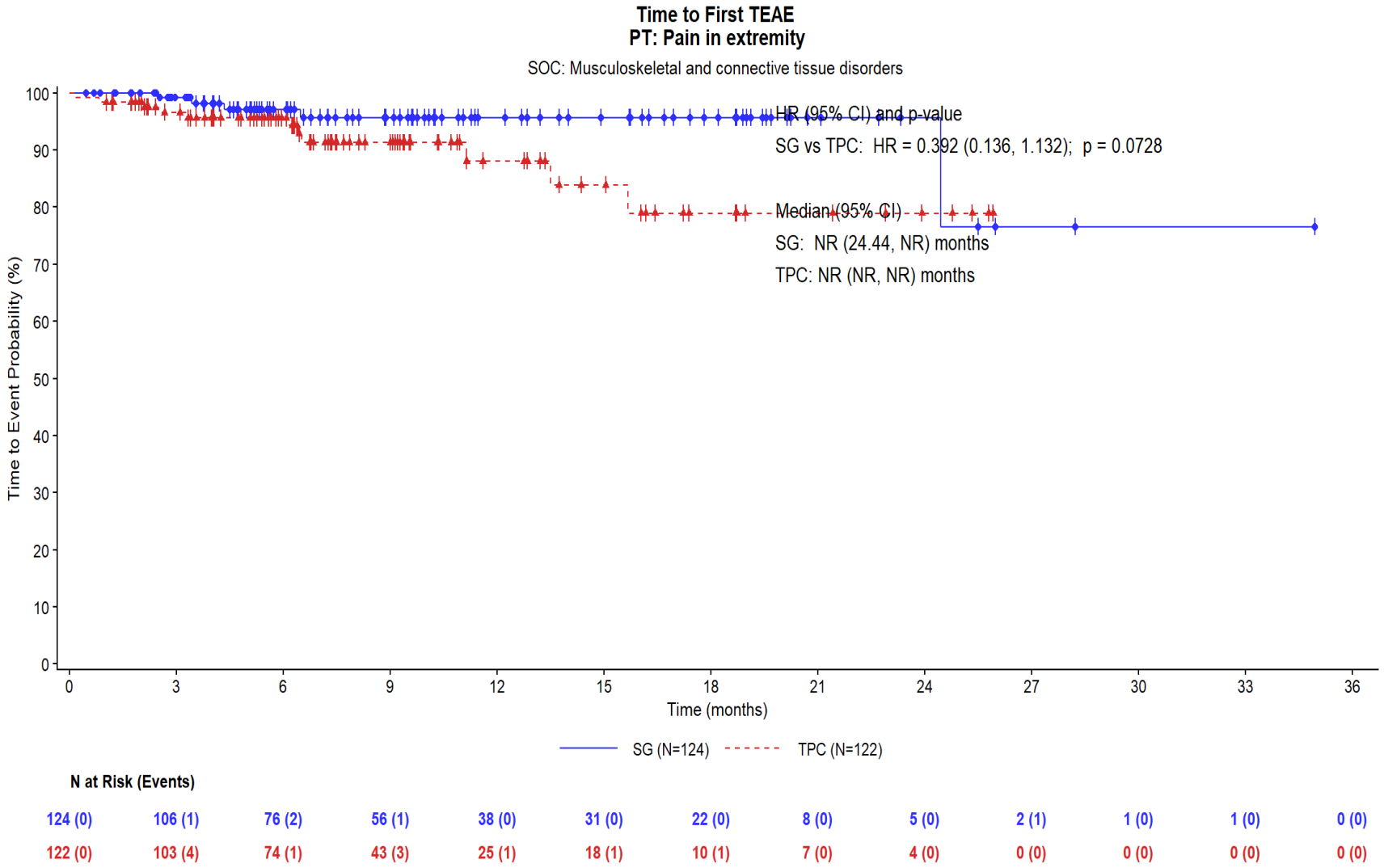
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.71. Figure 1.1.72: Kaplan Meier Plot of Time to First TEAE by PT Myalgia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



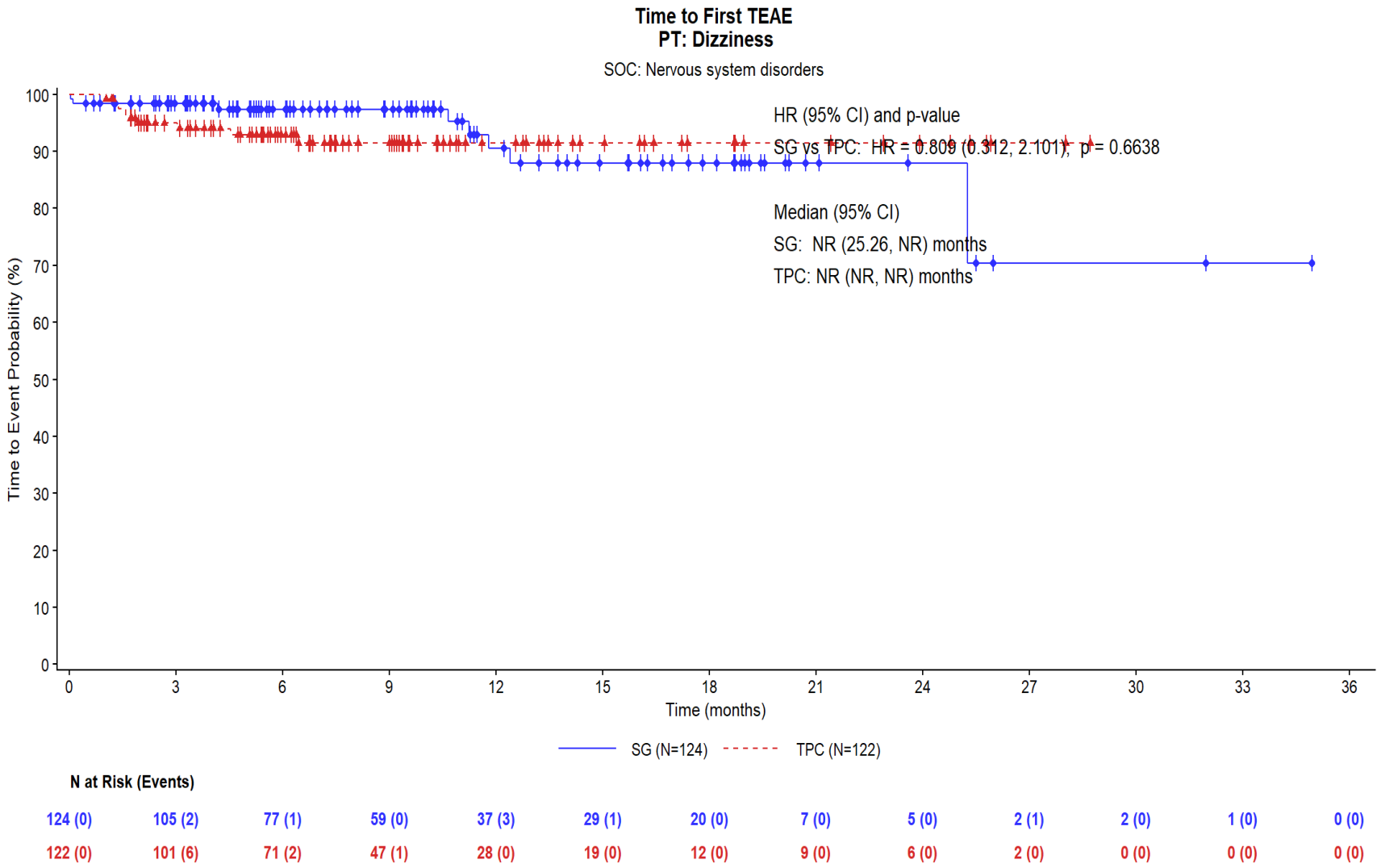
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.72. Figure 1.1.73: Kaplan Meier Plot of Time to First TEAE by PT Pain in extremity — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



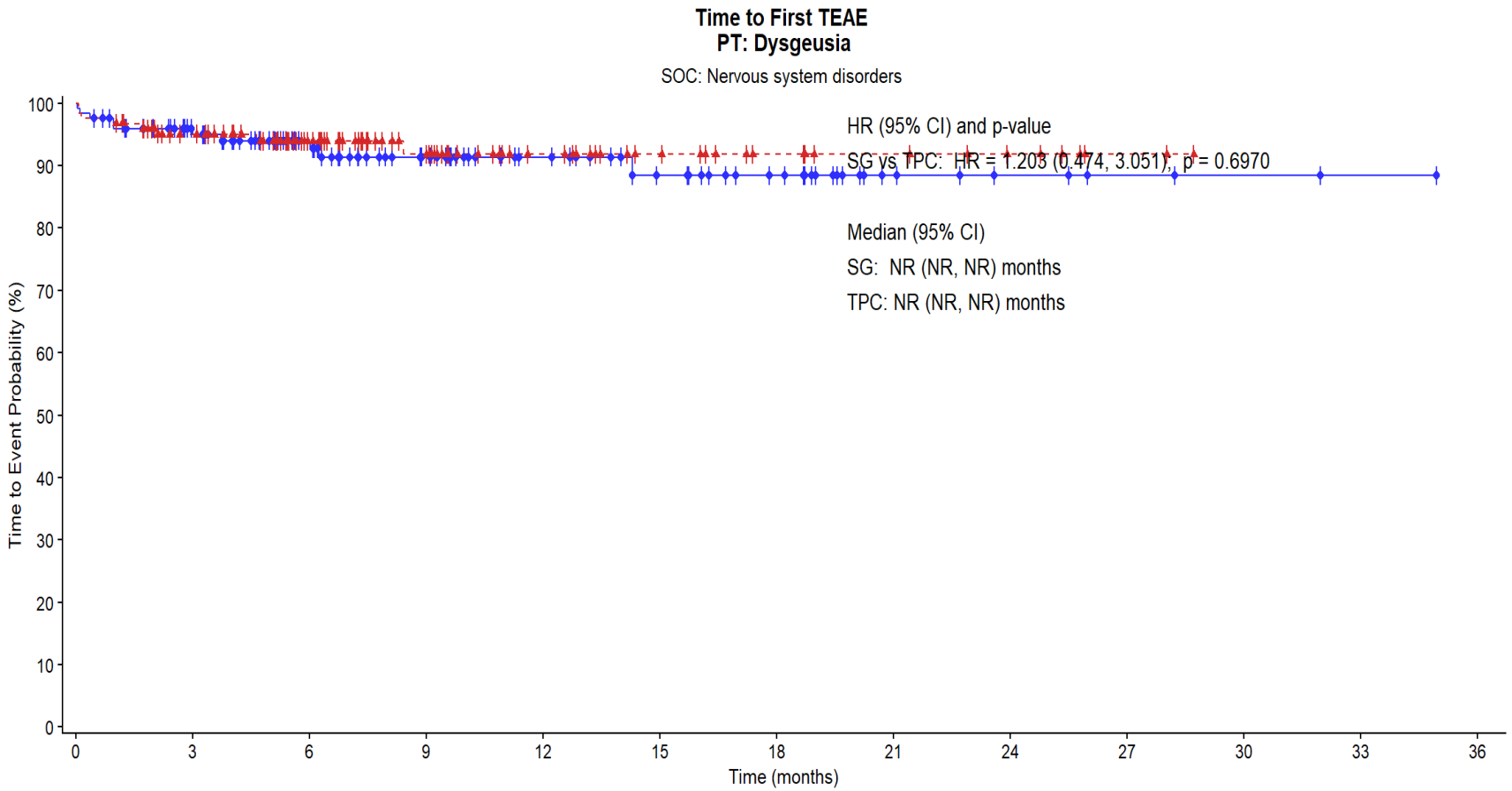
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.73. Figure 1.1.74: Kaplan Meier Plot of Time to First TEAE by PT Dizziness — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



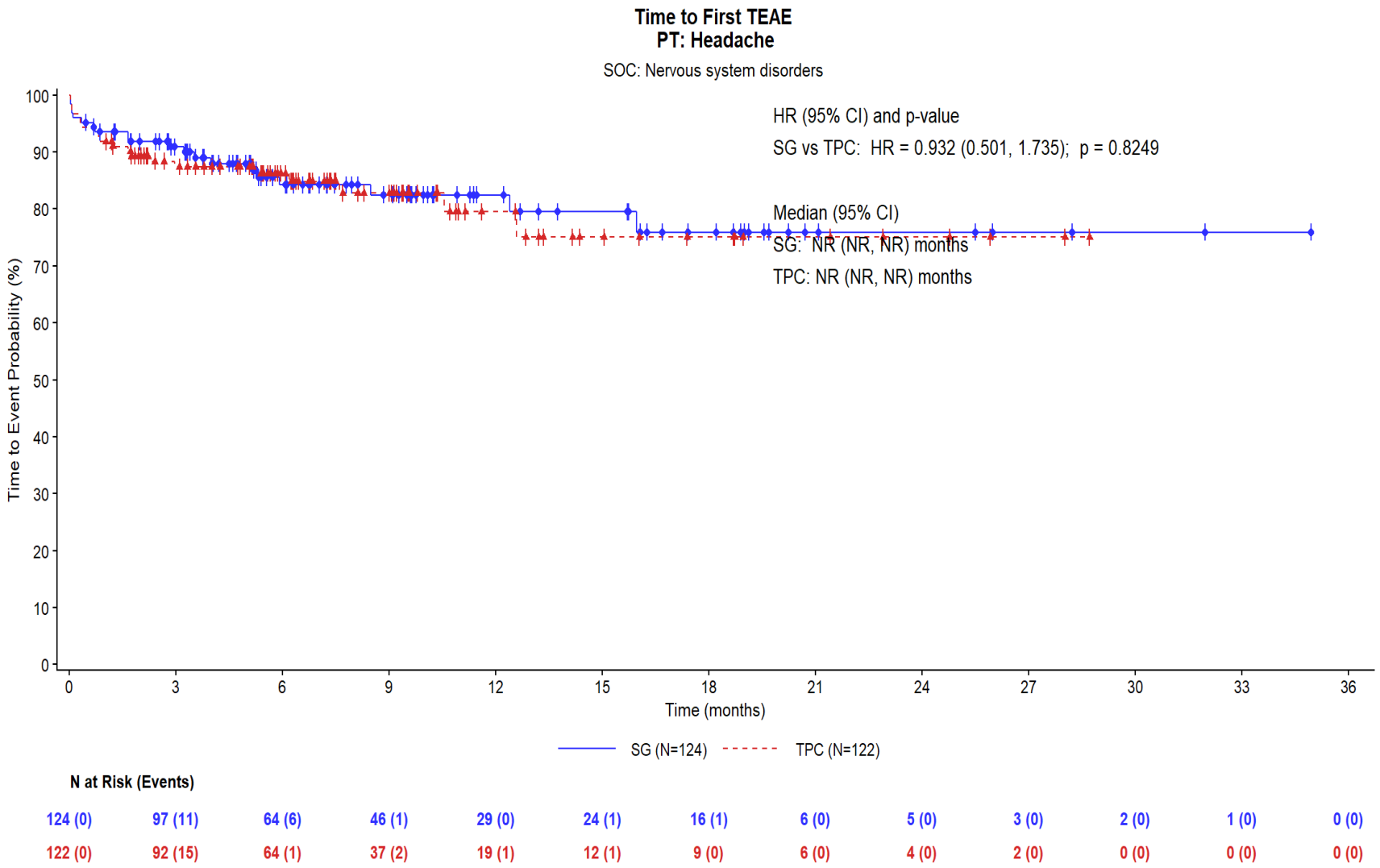
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.74. Figure 1.1.75: Kaplan Meier Plot of Time to First TEAE by PT Dysgeusia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



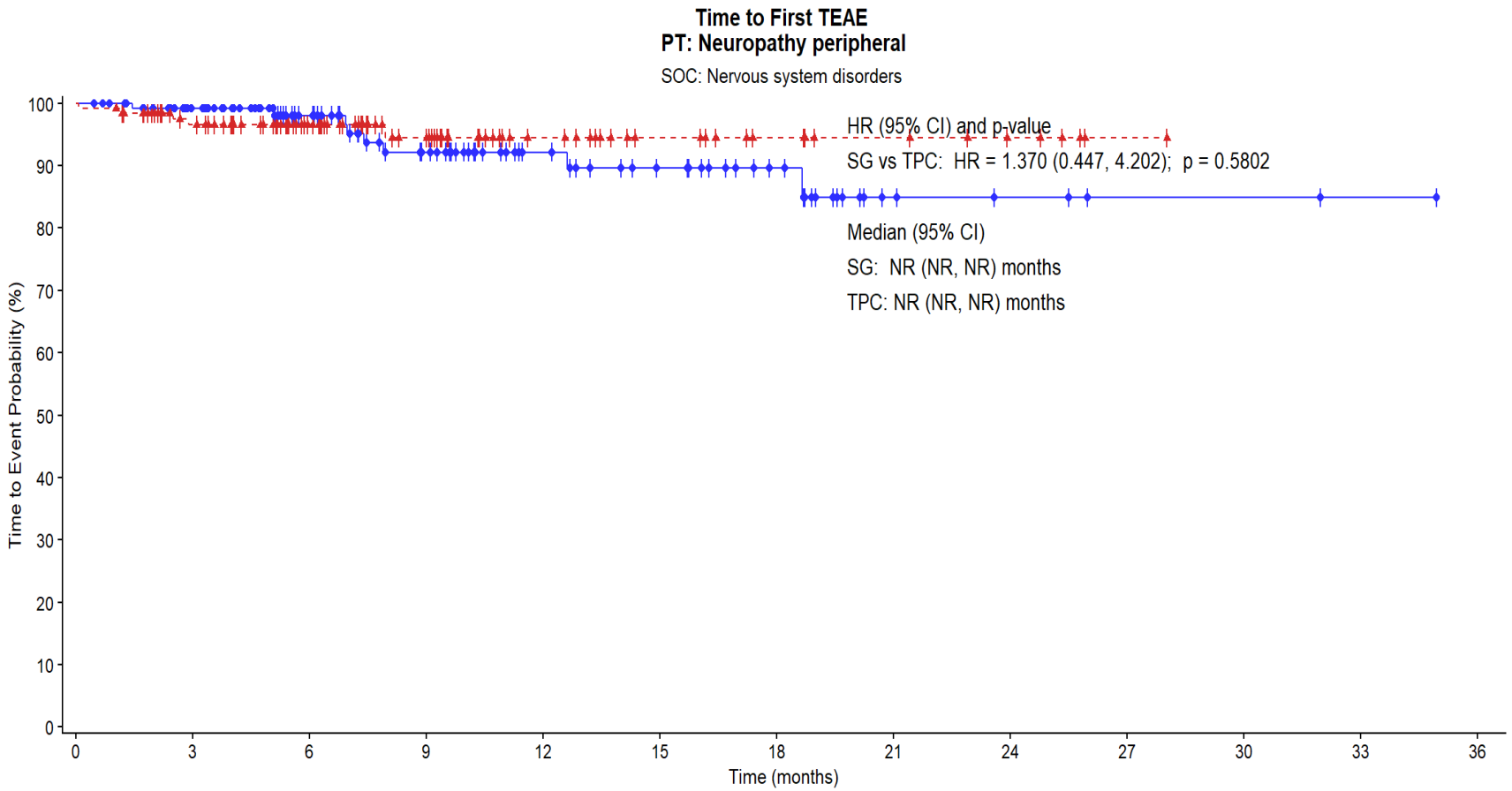
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.75. Figure 1.1.76: Kaplan Meier Plot of Time to First TEAE by PT Headache — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



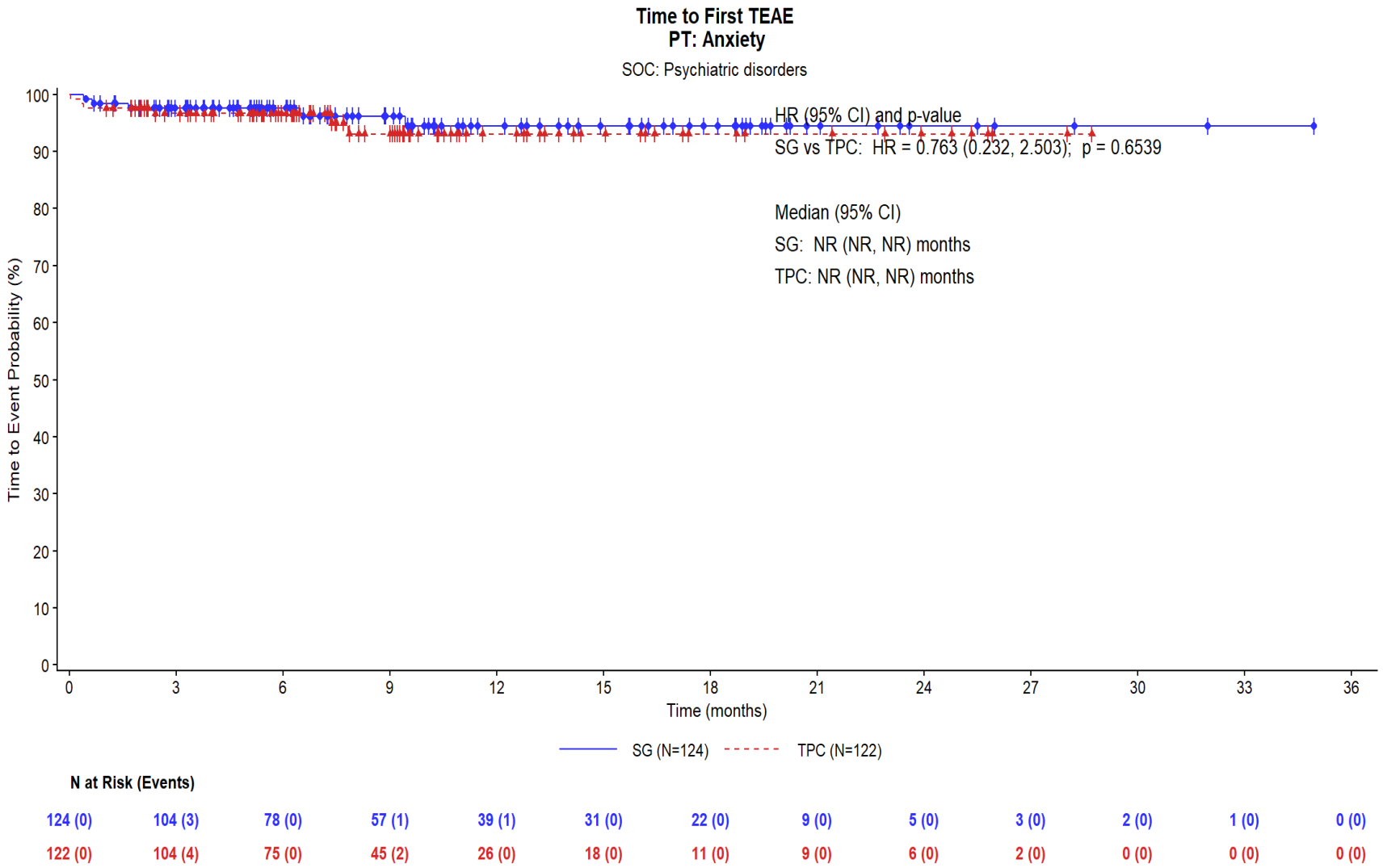
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.76. Figure 1.1.77: Kaplan Meier Plot of Time to First TEAE by PT Neuropathy peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



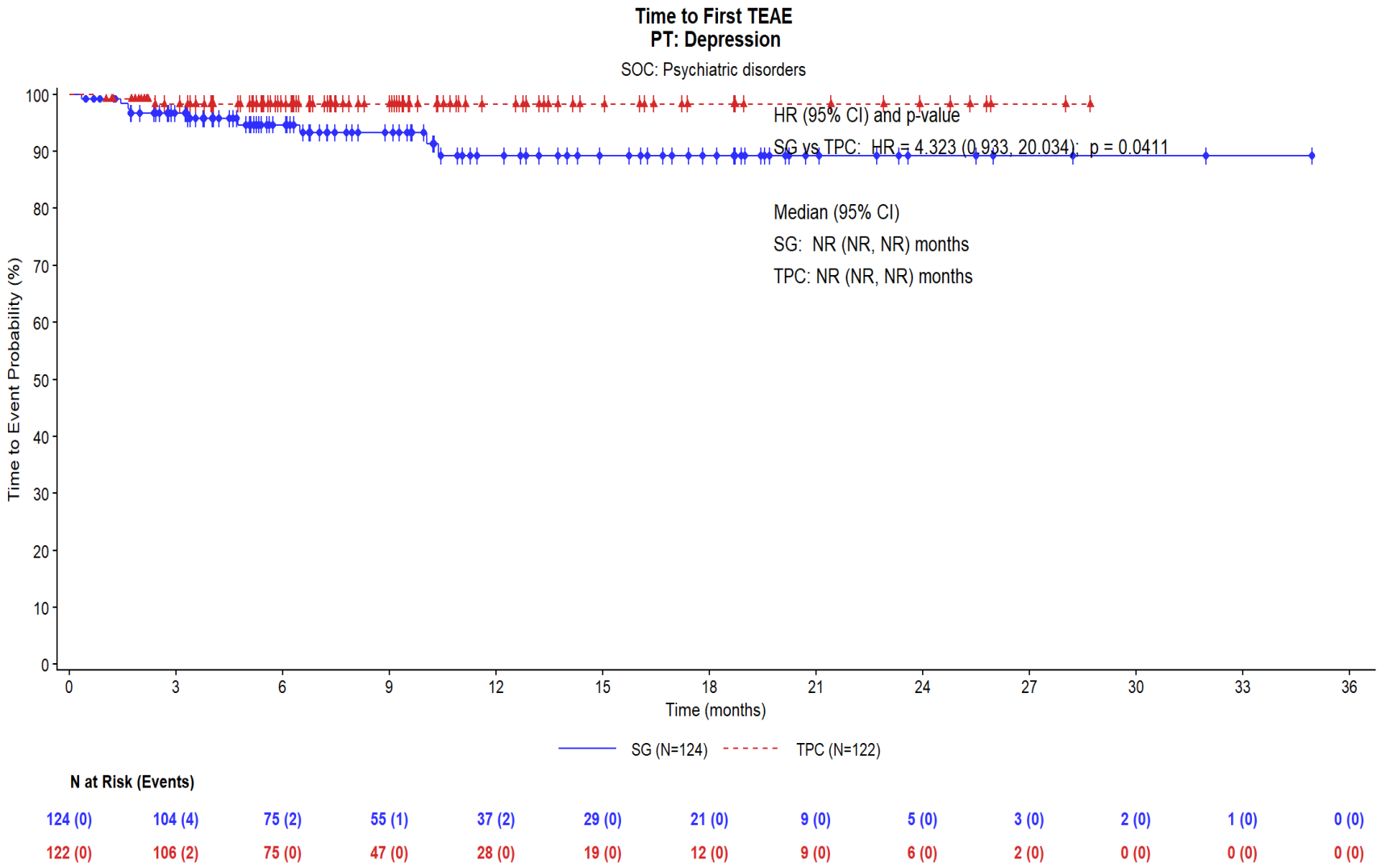
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.77. Figure 1.1.78: Kaplan Meier Plot of Time to First TEAE by PT Anxiety — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



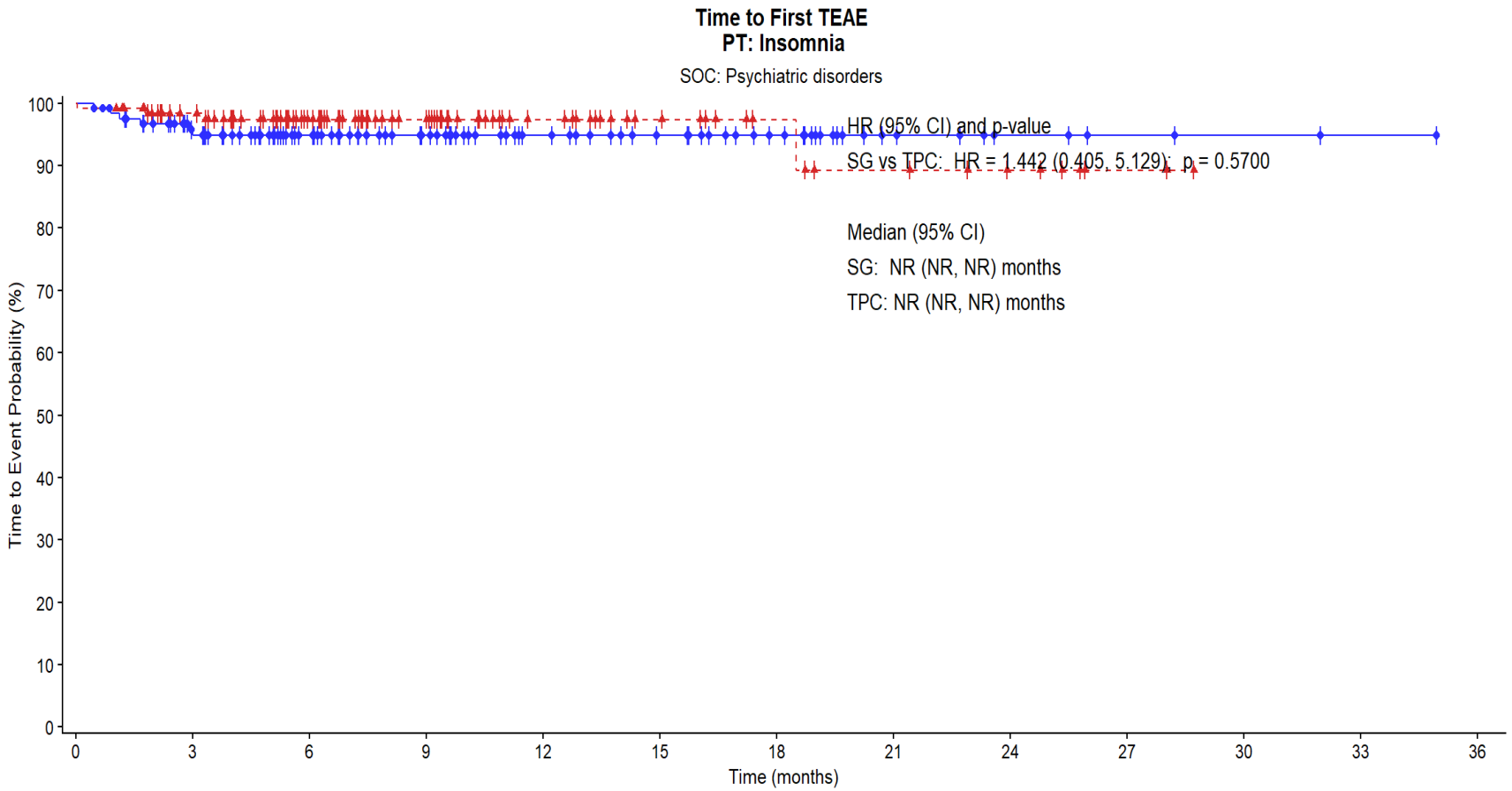
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7.78. Figure 1.1.79: Kaplan Meier Plot of Time to First TEAE by PT Depression — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



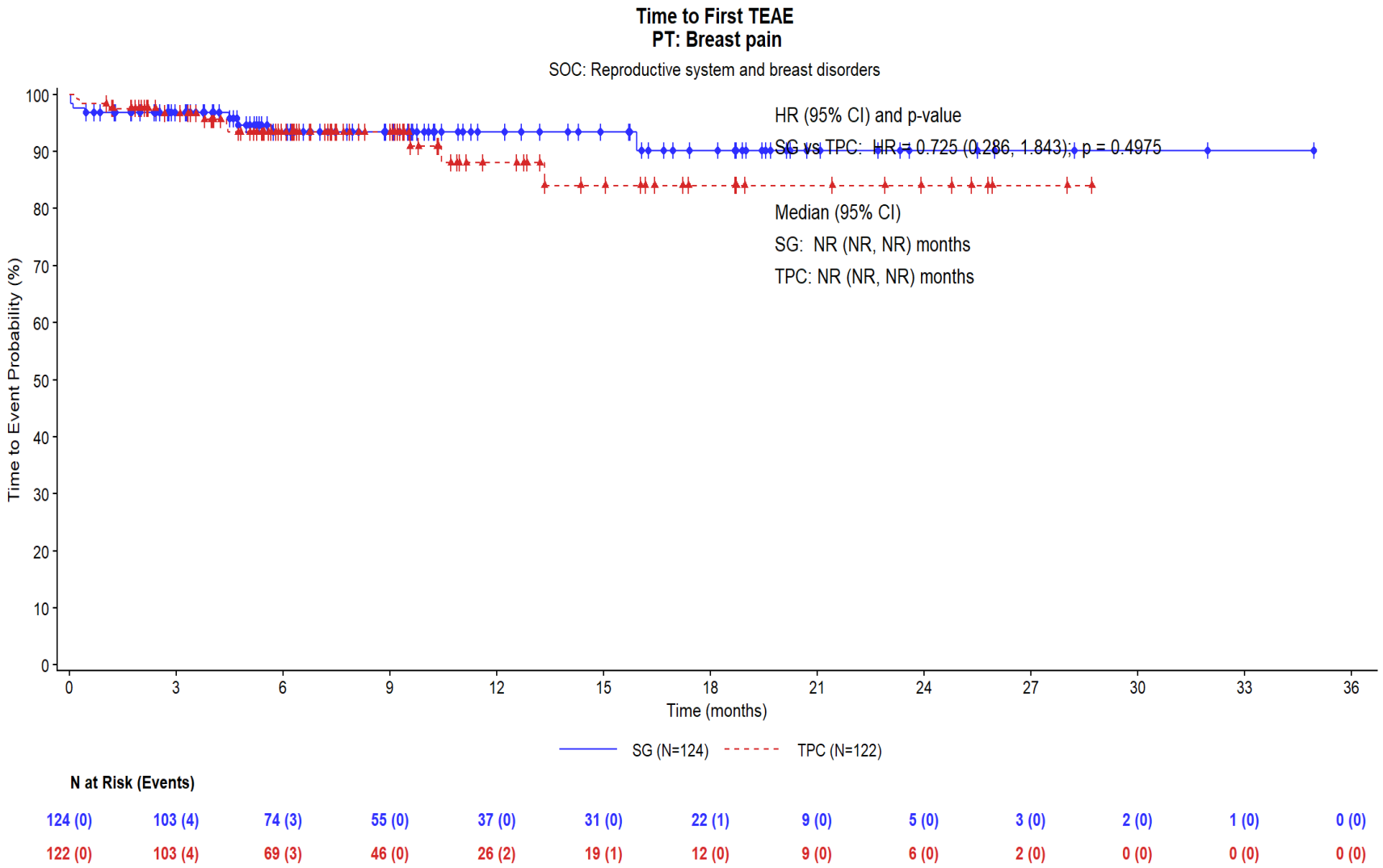
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.79. Figure 1.1.80: Kaplan Meier Plot of Time to First TEAE by PT Insomnia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



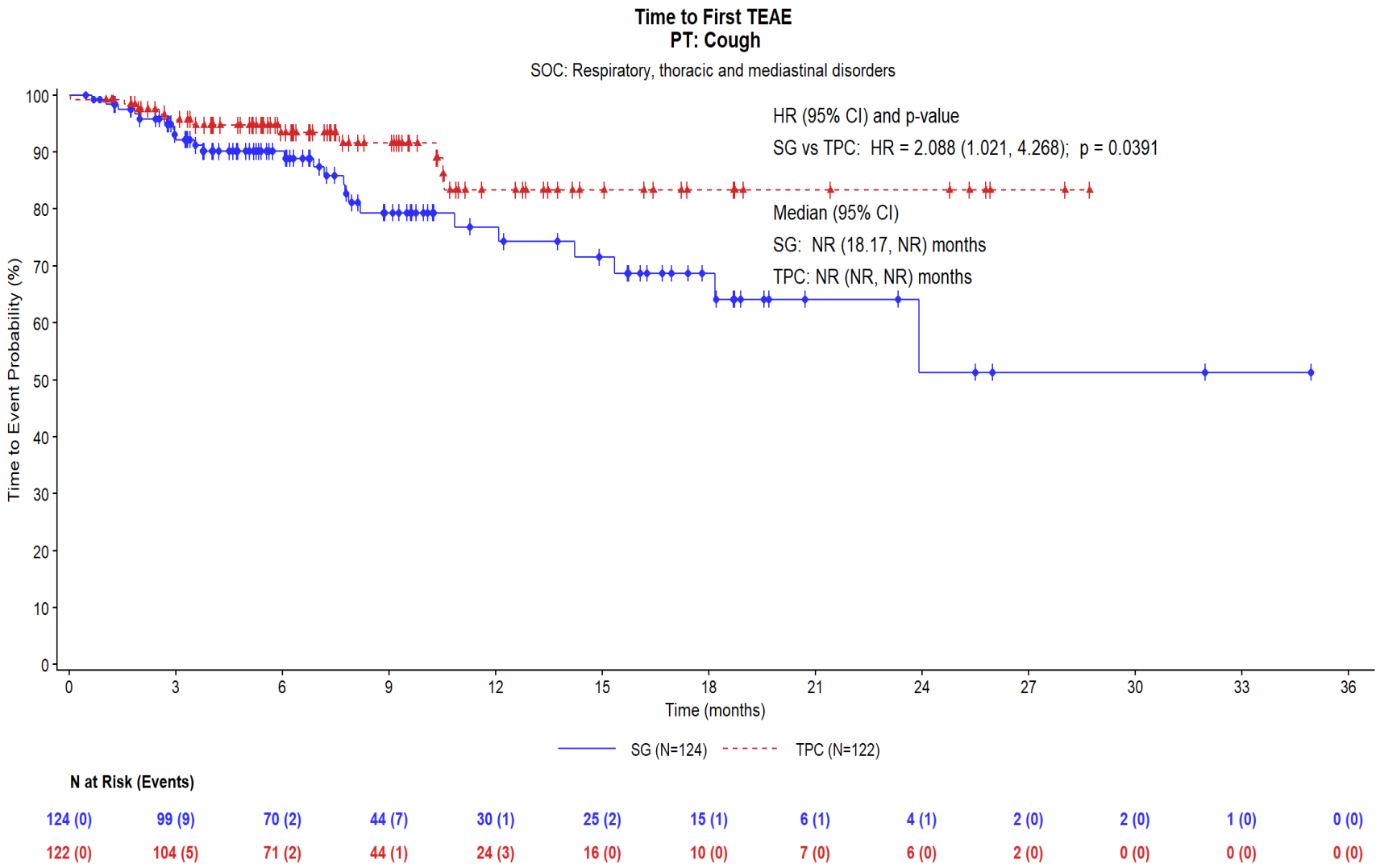
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.80. Figure 1.1.81: Kaplan Meier Plot of Time to First TEAE by PT Breast pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



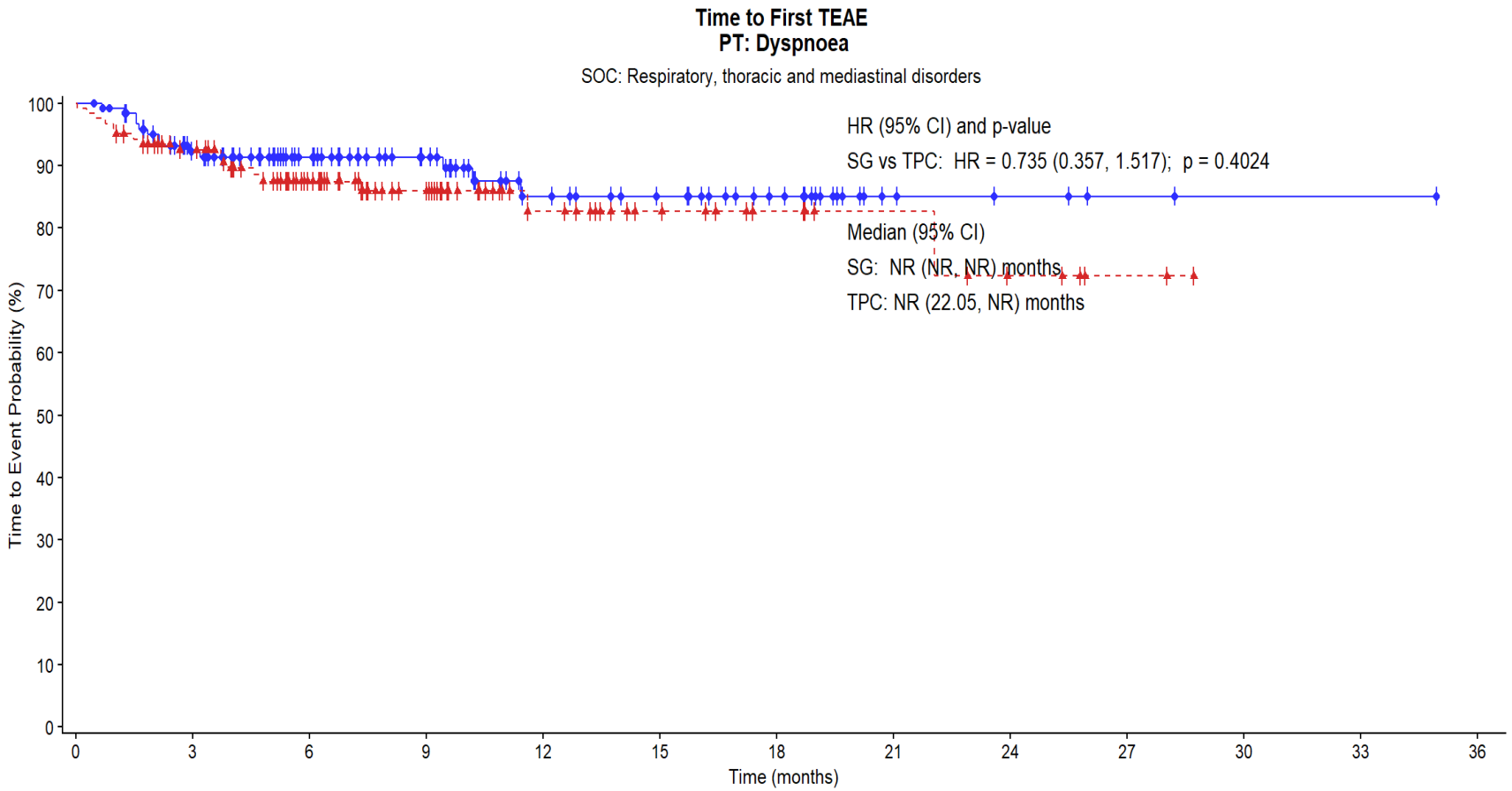
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.81. Figure 1.1.82: Kaplan Meier Plot of Time to First TEAE by PT Cough — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



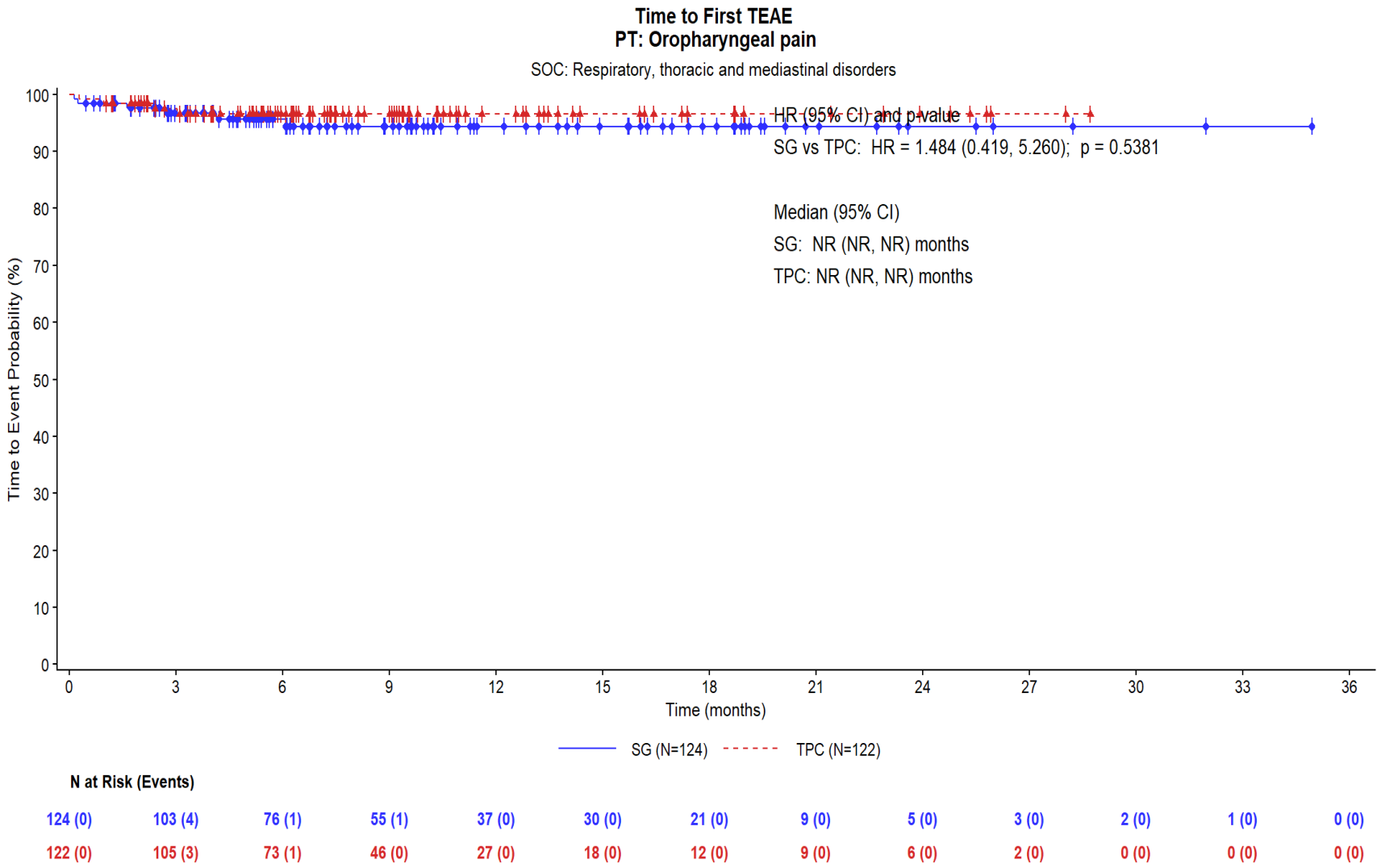
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.82. Figure 1.1.83: Kaplan Meier Plot of Time to First TEAE by PT Dyspnoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



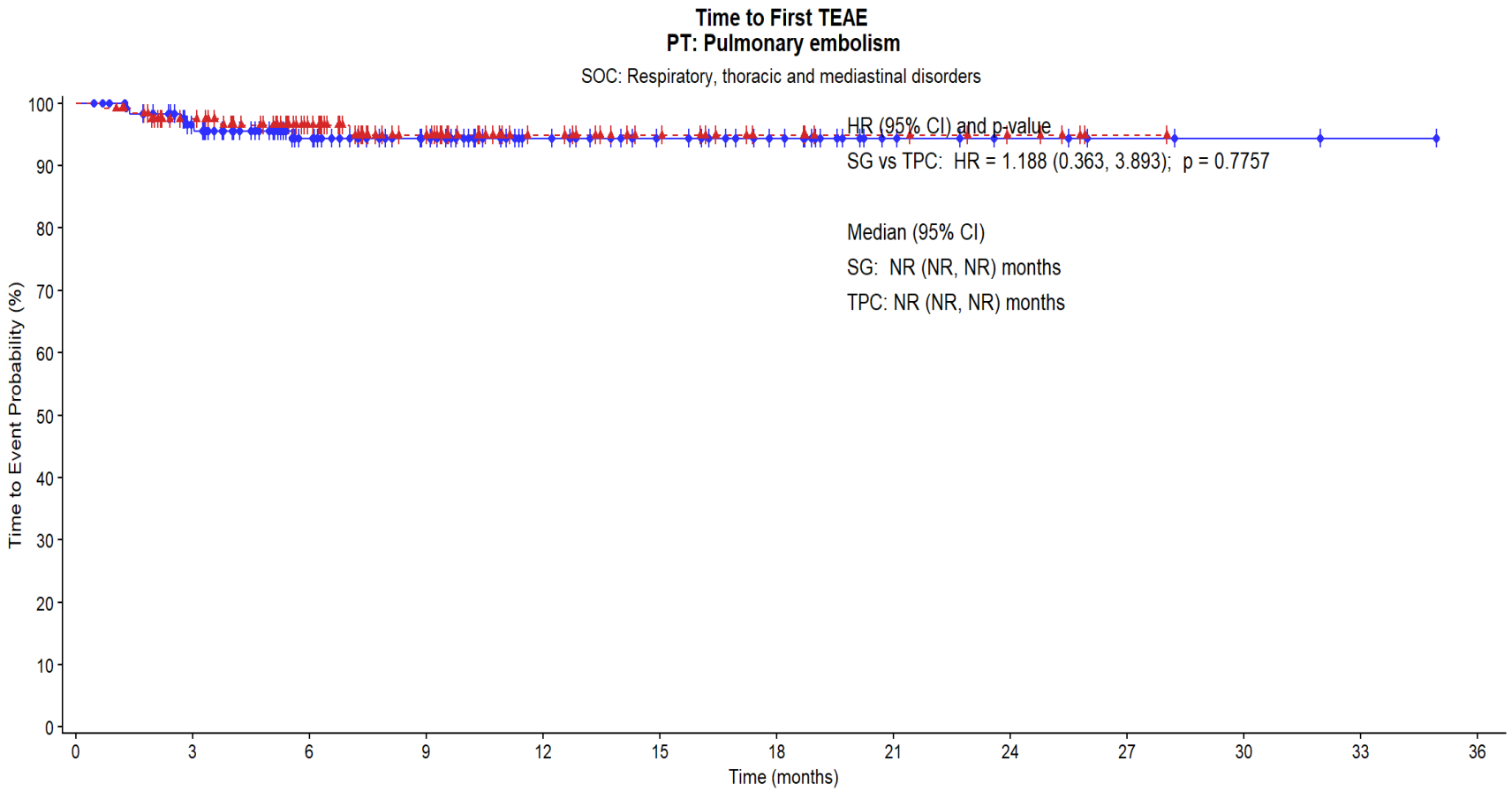
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.83. Figure 1.1.84: Kaplan Meier Plot of Time to First TEAE by PT Oropharyngeal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



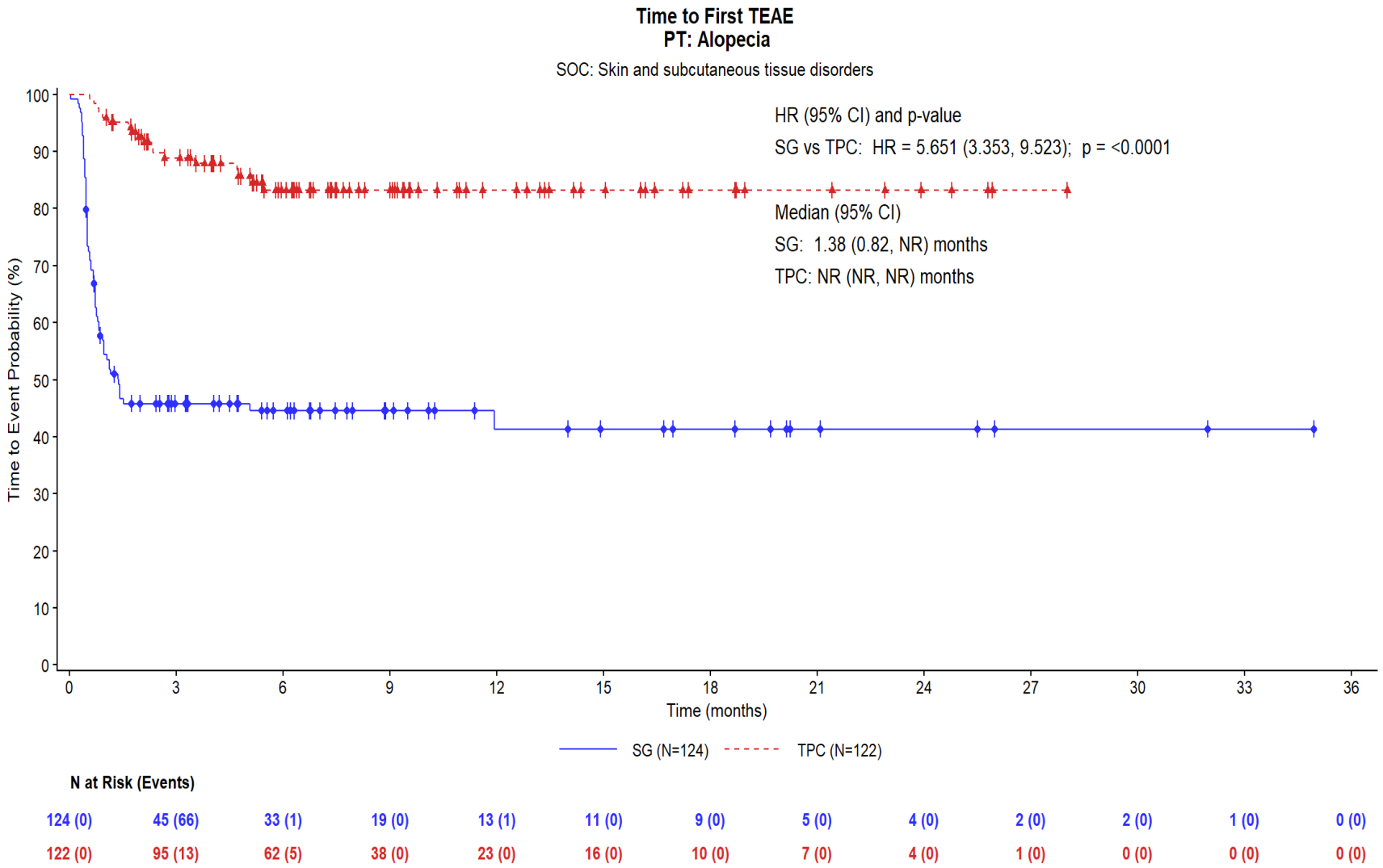
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.84. Figure 1.1.85: Kaplan Meier Plot of Time to First TEAE by PT Pulmonary embolism — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



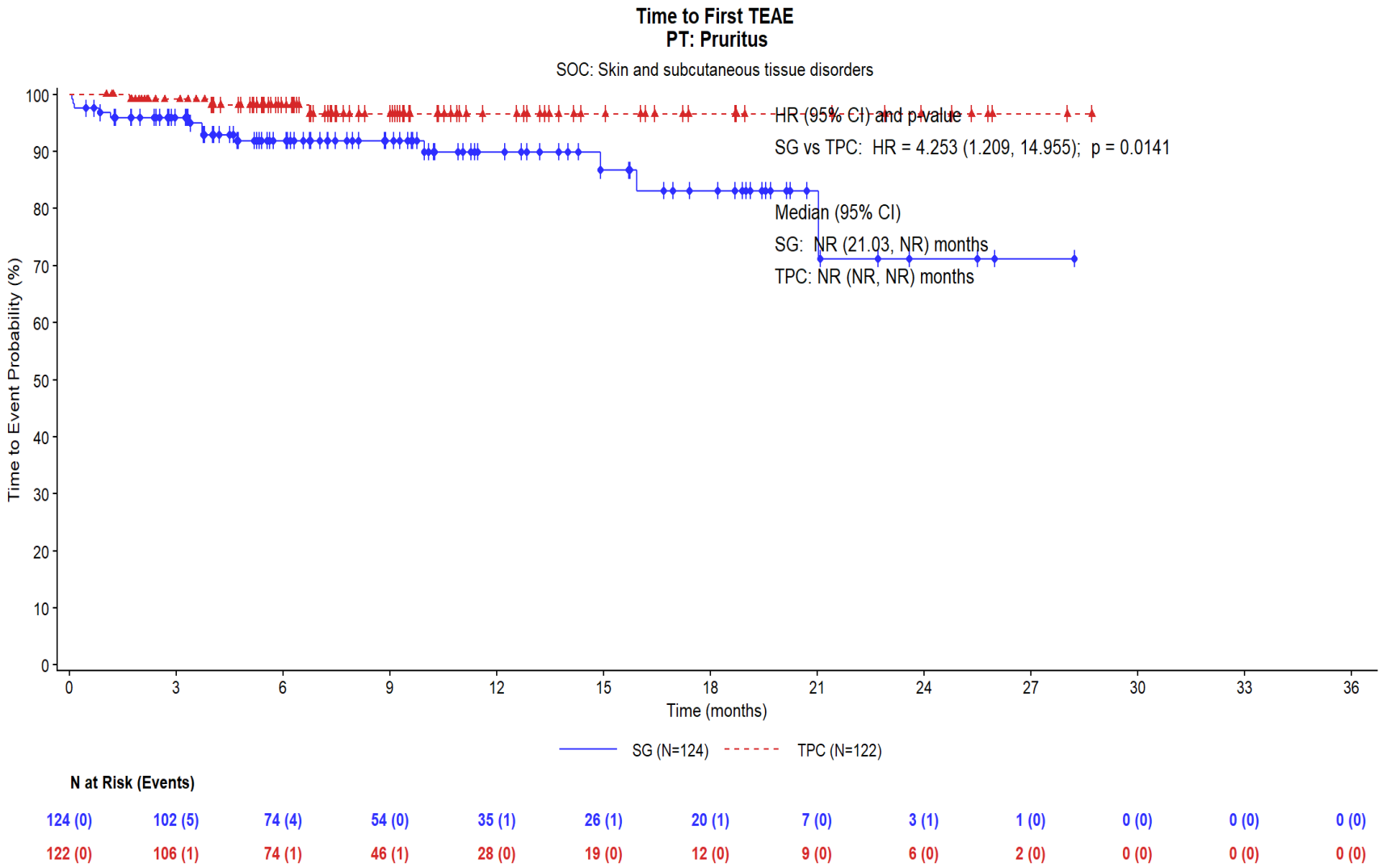
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.85. Figure 1.1.86: Kaplan Meier Plot of Time to First TEAE by PT Alopecia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



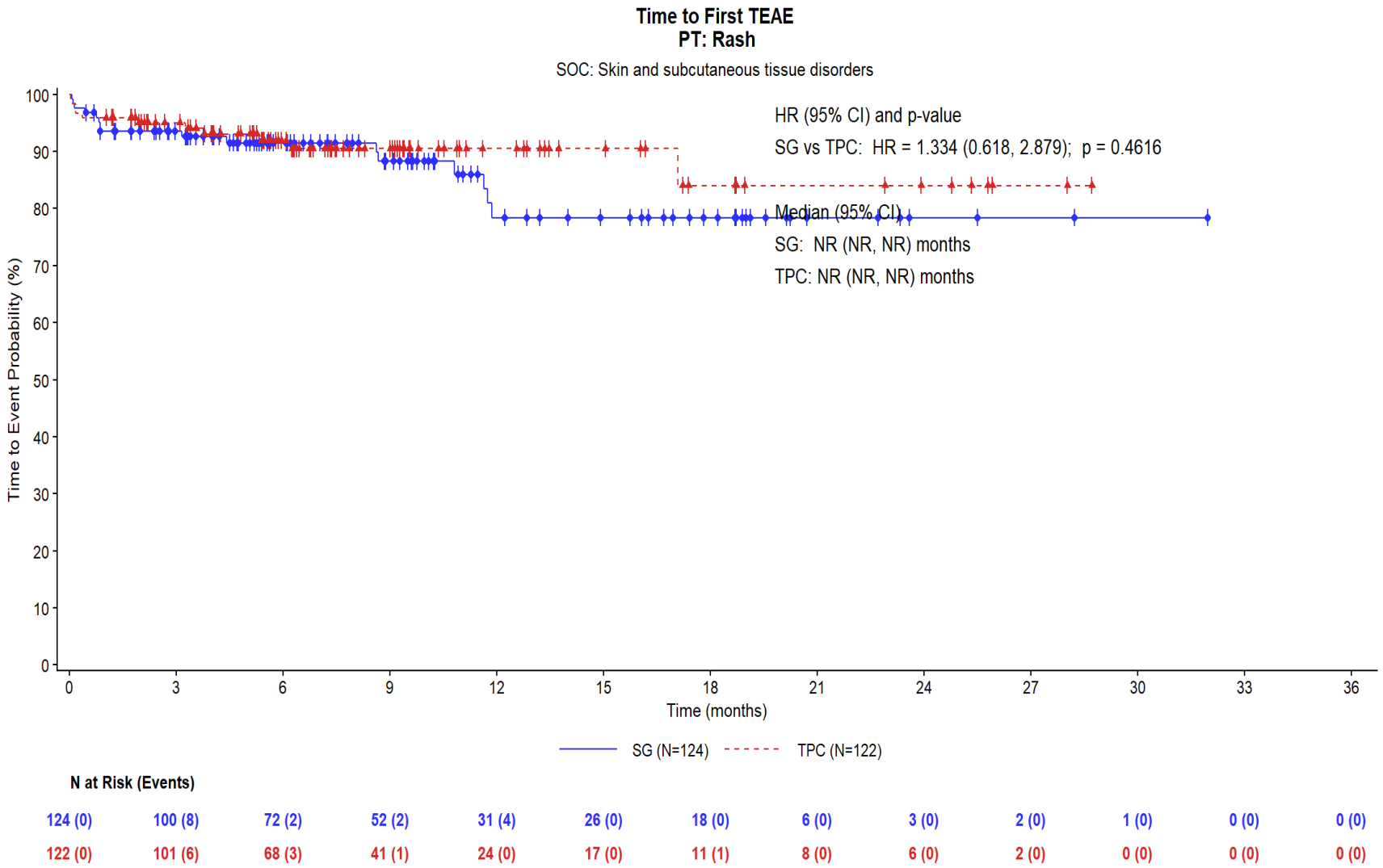
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.86. Figure 1.1.87: Kaplan Meier Plot of Time to First TEAE by PT Pruritus — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



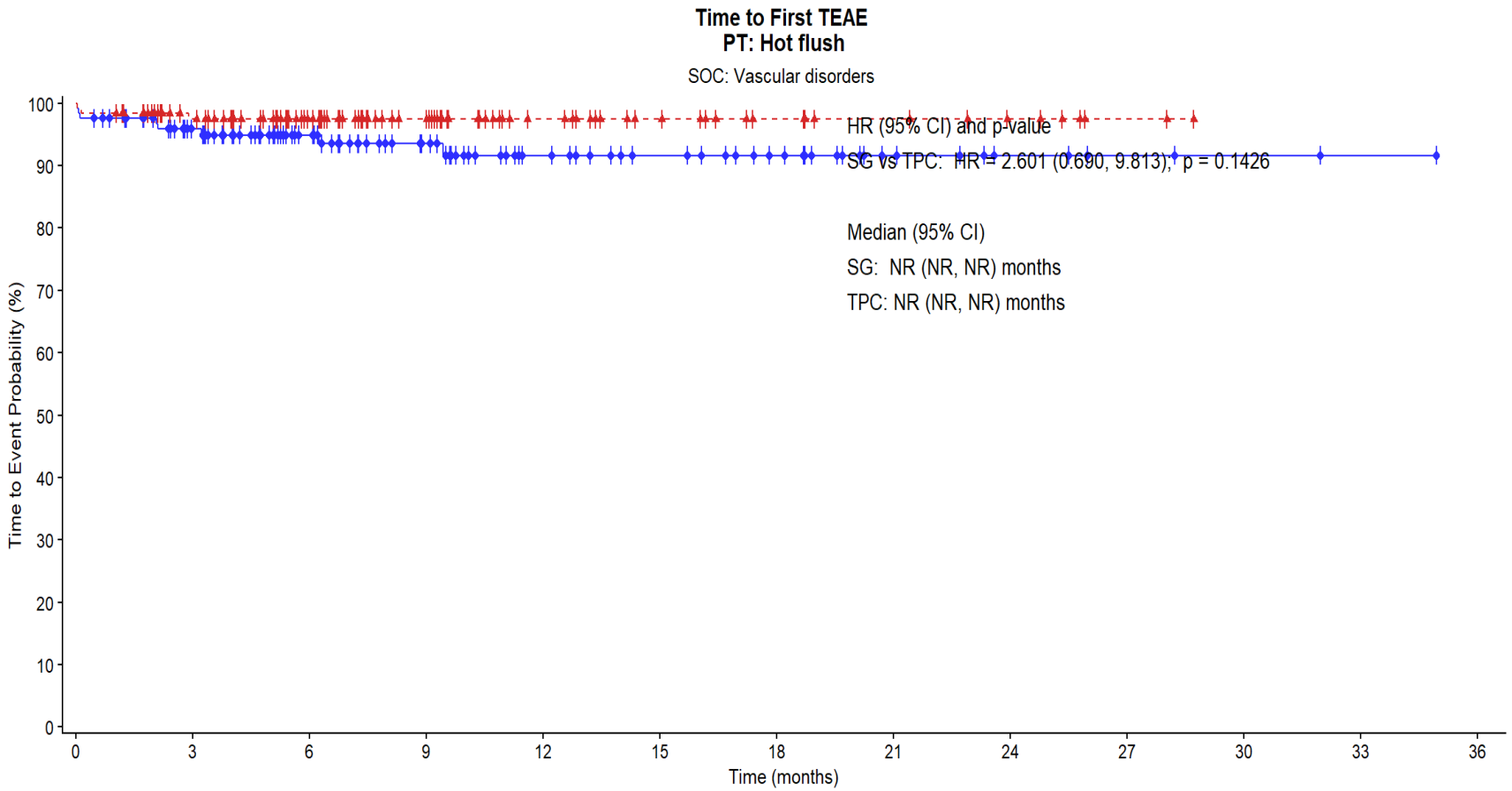
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.87. Figure 1.1.88: Kaplan Meier Plot of Time to First TEAE by PT Rash — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



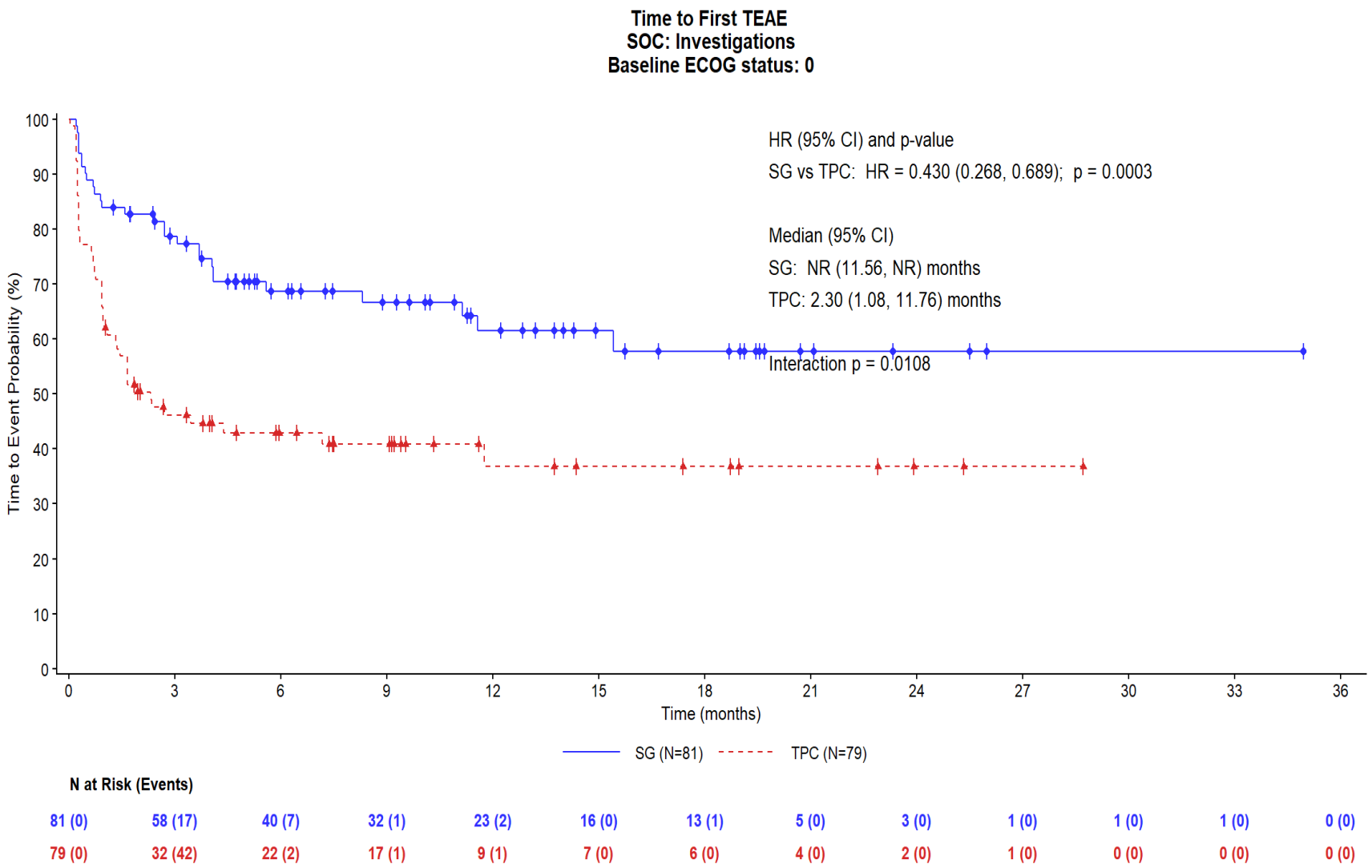
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.88. Figure 1.1.89: Kaplan Meier Plot of Time to First TEAE by PT Hot flush — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



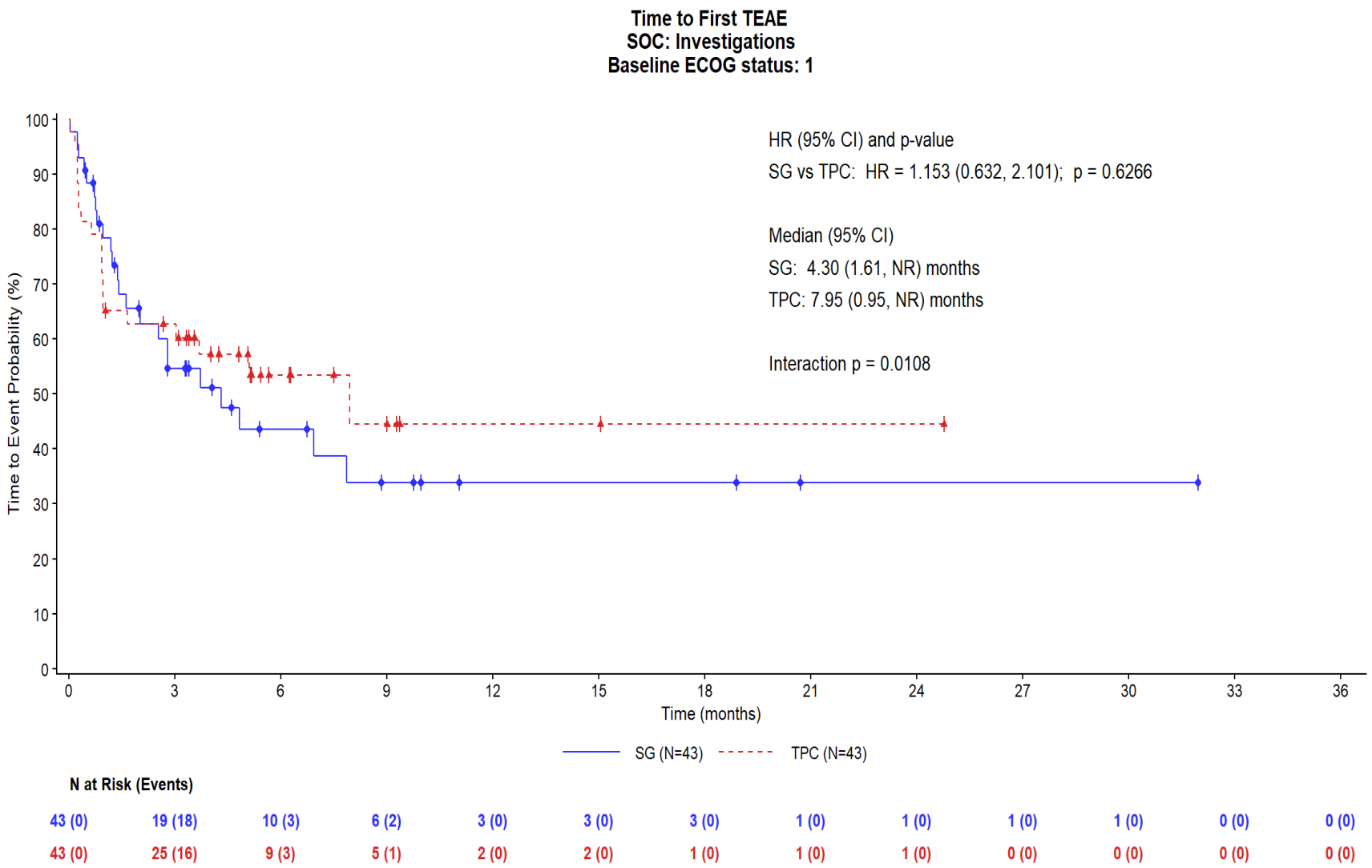
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.89. Figure 1.1.90: Kaplan Meier Plot of Time to First TEAE by SOC Investigations Baseline ECOG status 0 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



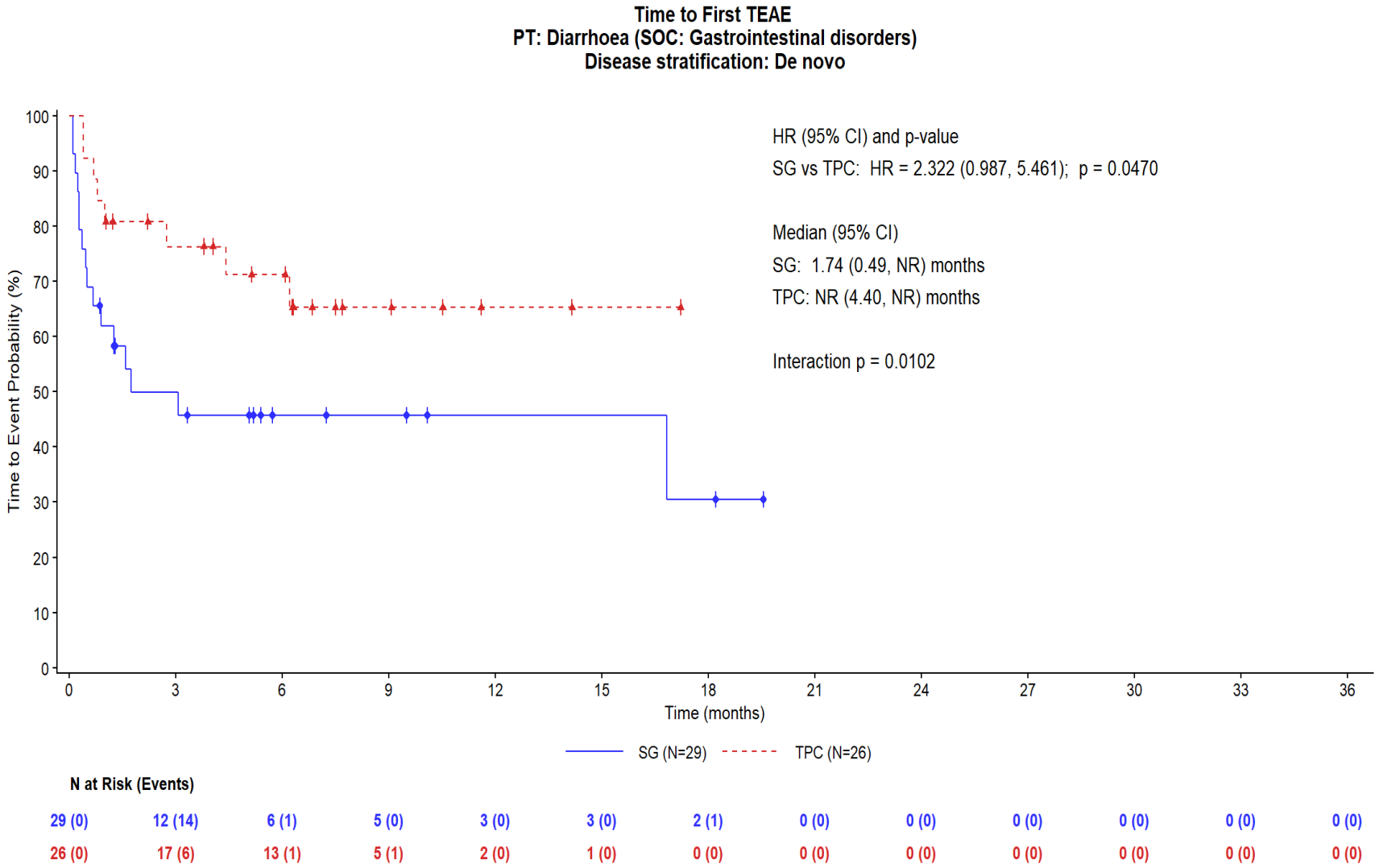
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.90. Figure 1.1.91: Kaplan Meier Plot of Time to First TEAE by SOC Investigations Baseline ECOG status 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



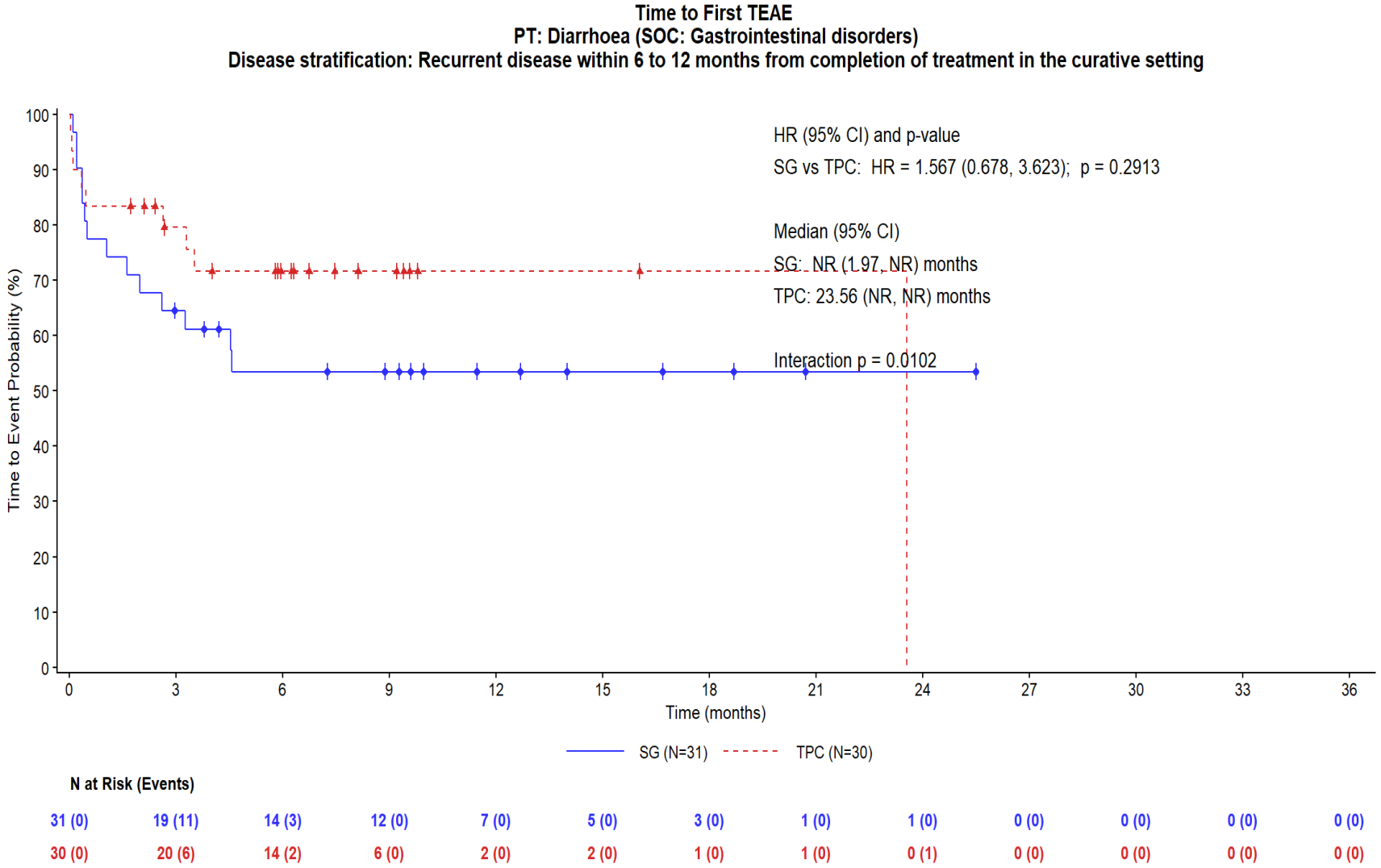
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.91. Figure 1.1.92: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification De novo — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



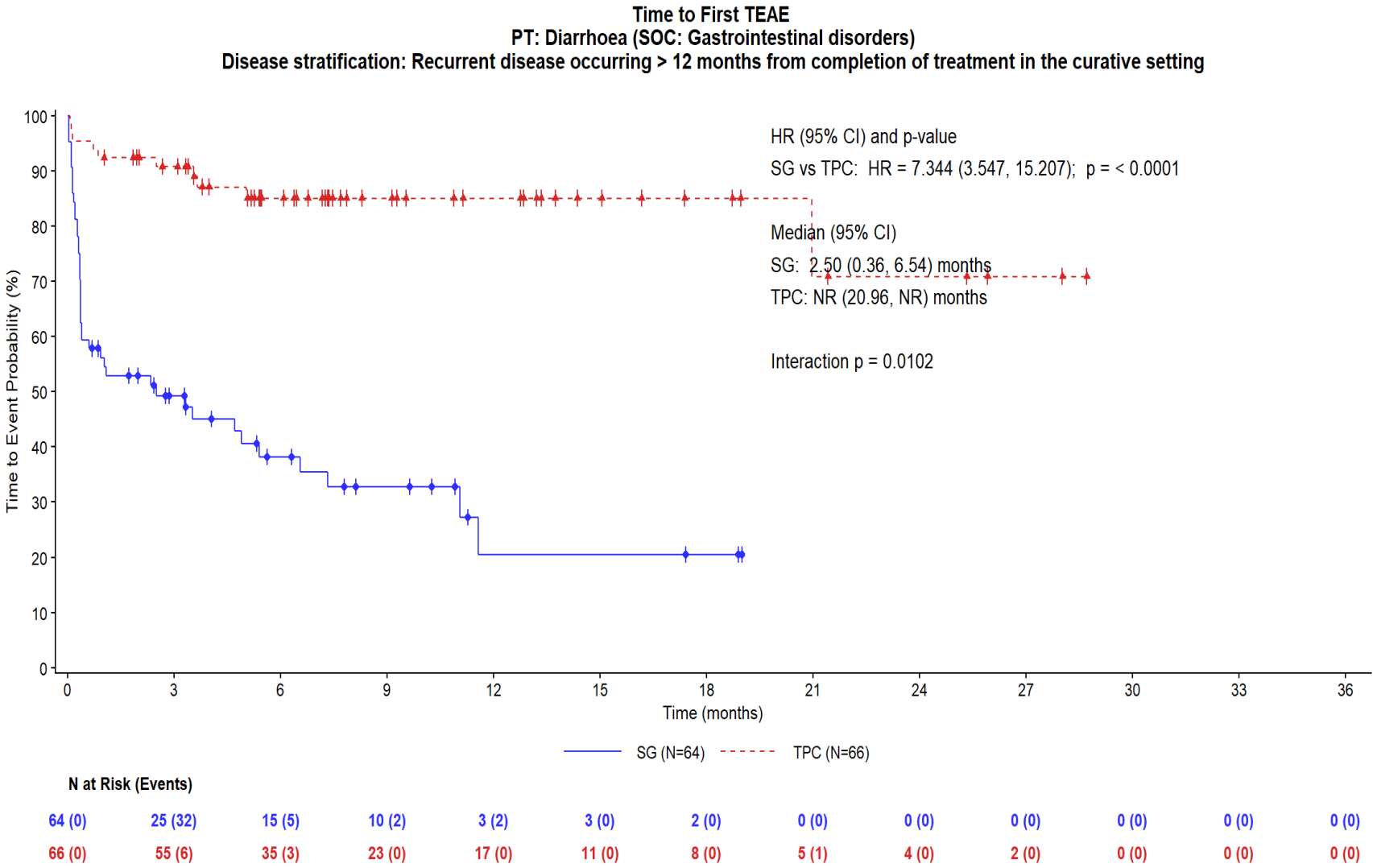
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.92. Figure 1.1.93: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease within 6 to 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



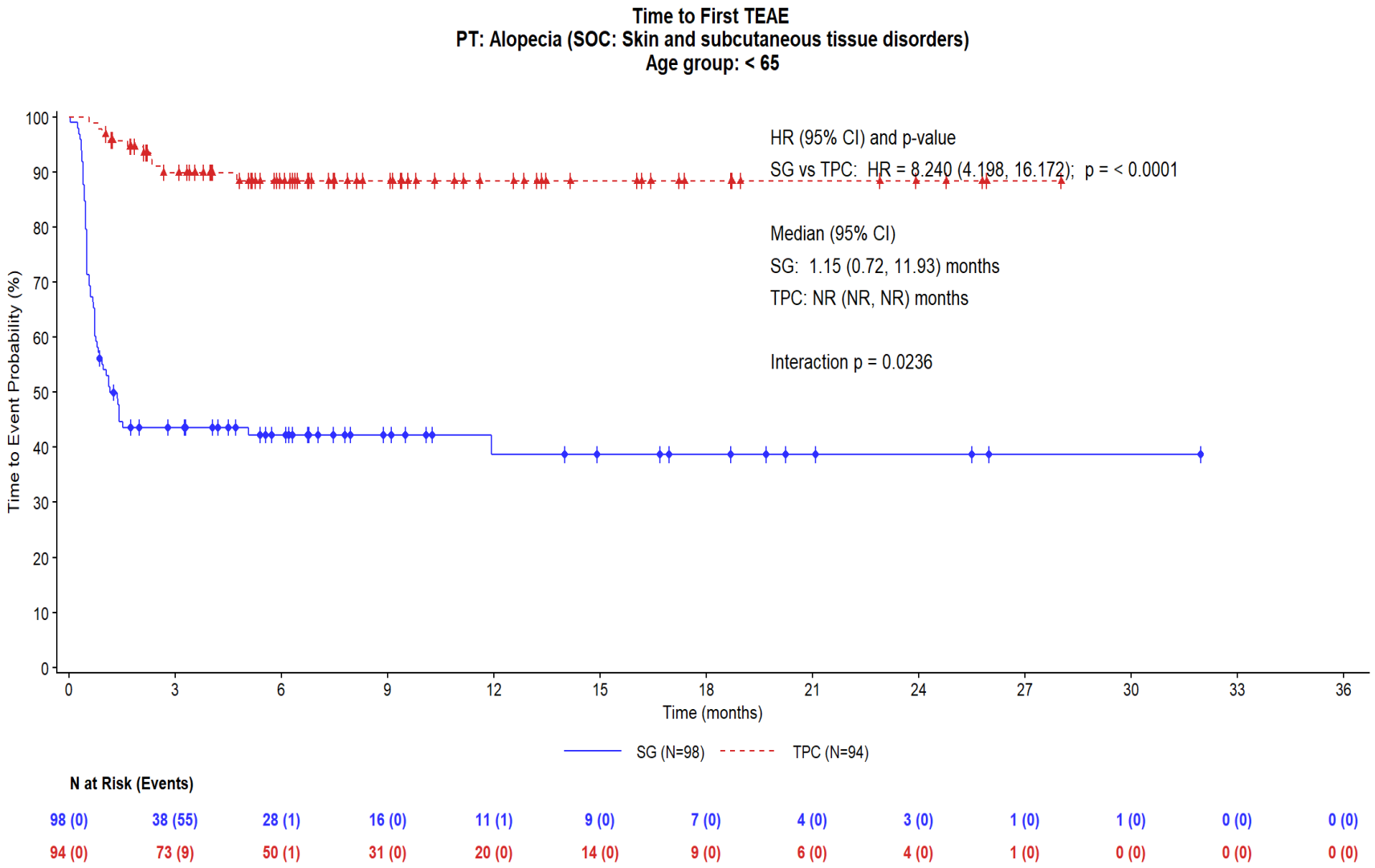
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.93. Figure 1.1.94: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease occurring greater than 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



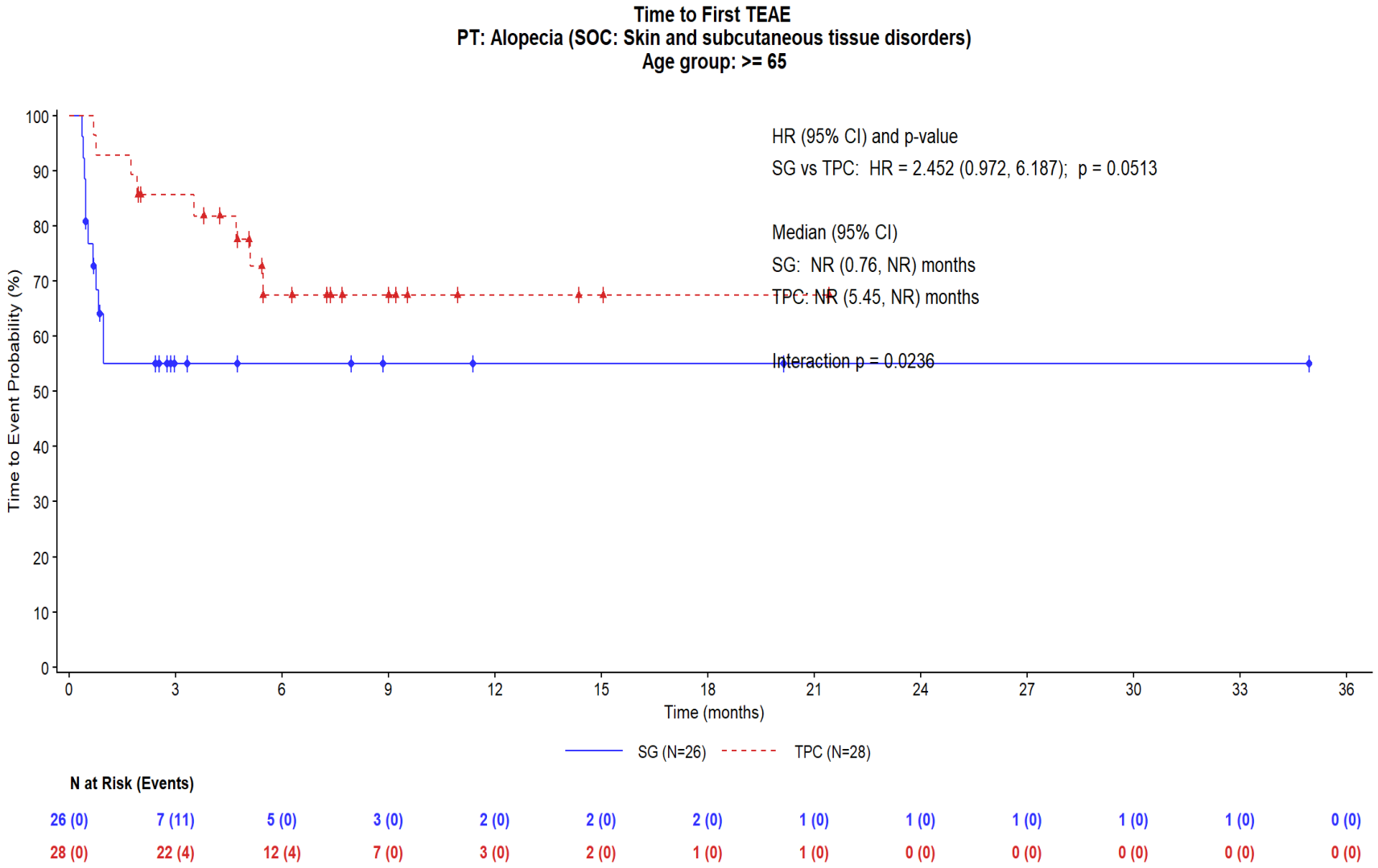
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.94. Figure 1.1.95: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



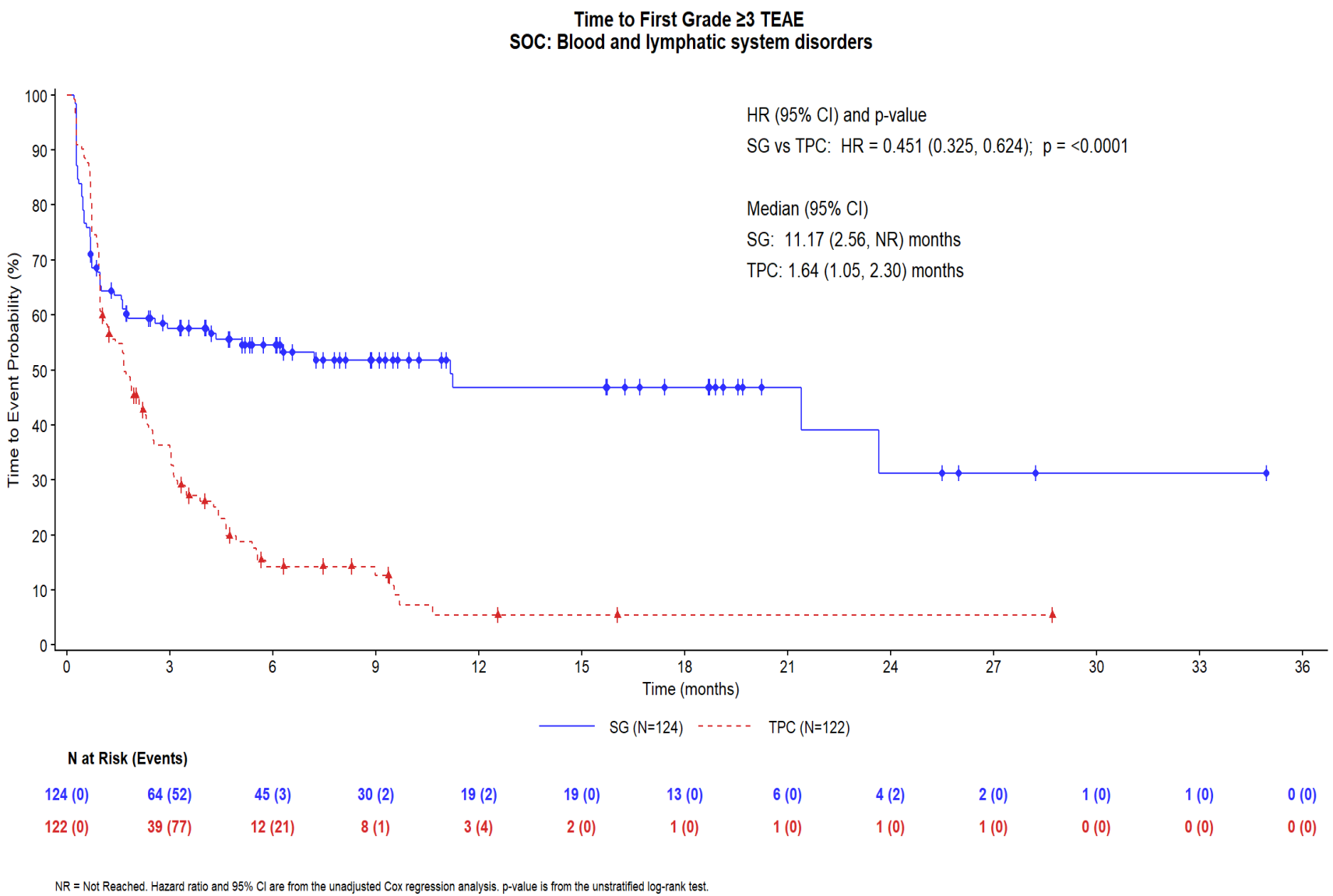
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.95. Figure 1.1.96: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



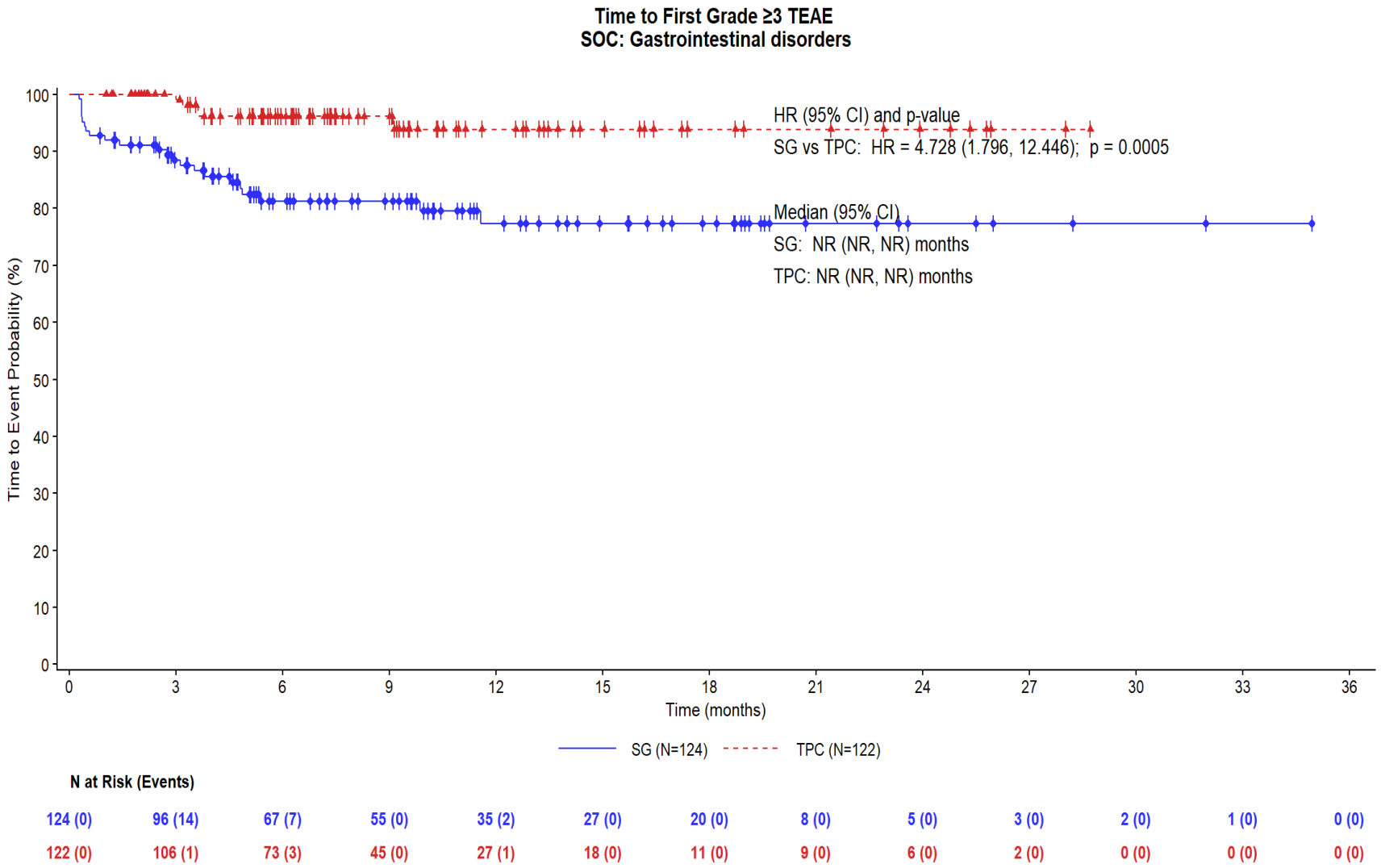
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

7.96. Figure 1.1.97: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



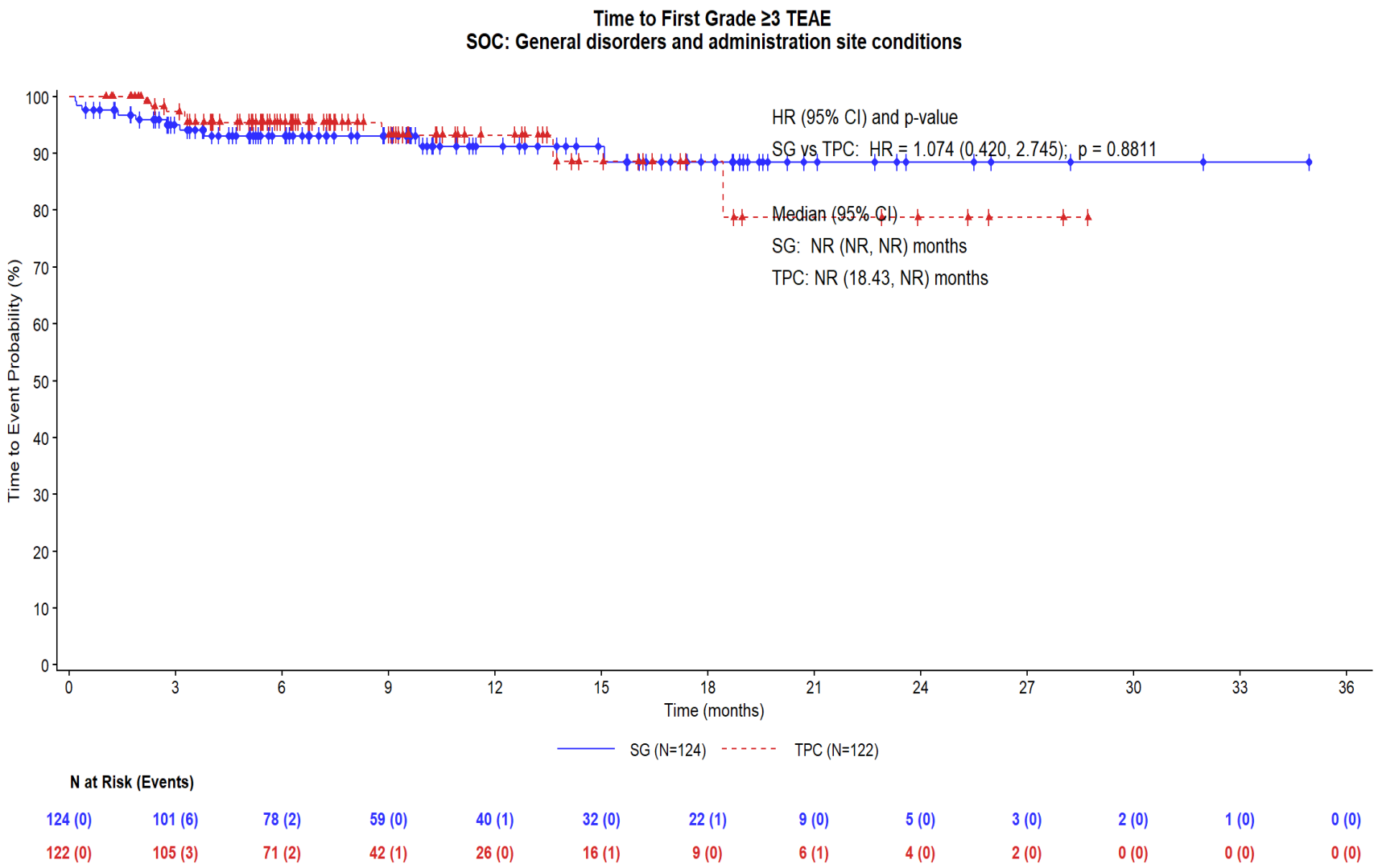
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.97. Figure 1.1.98: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



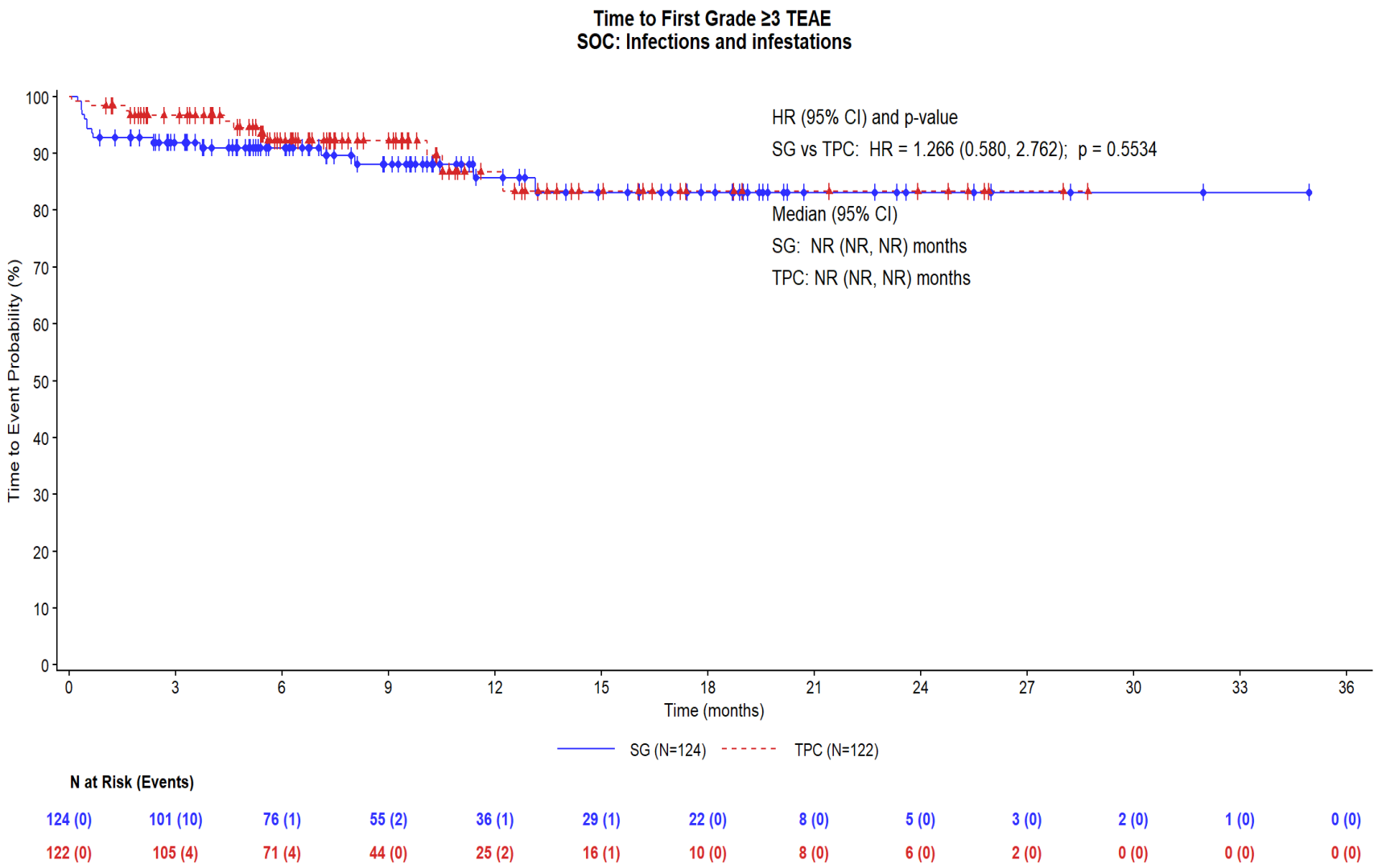
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.98. Figure 1.1.99: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



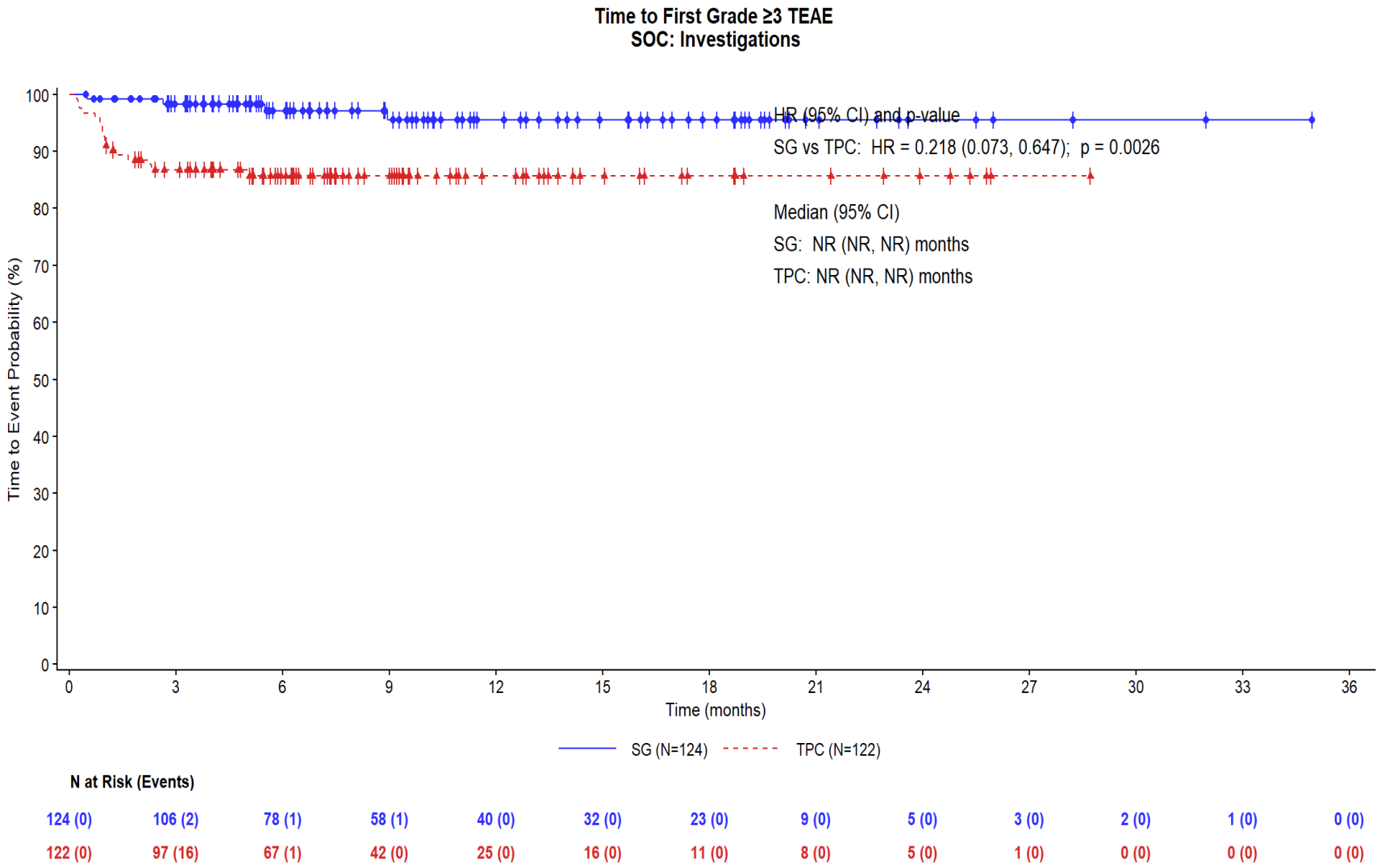
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.99. Figure 1.1.100: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



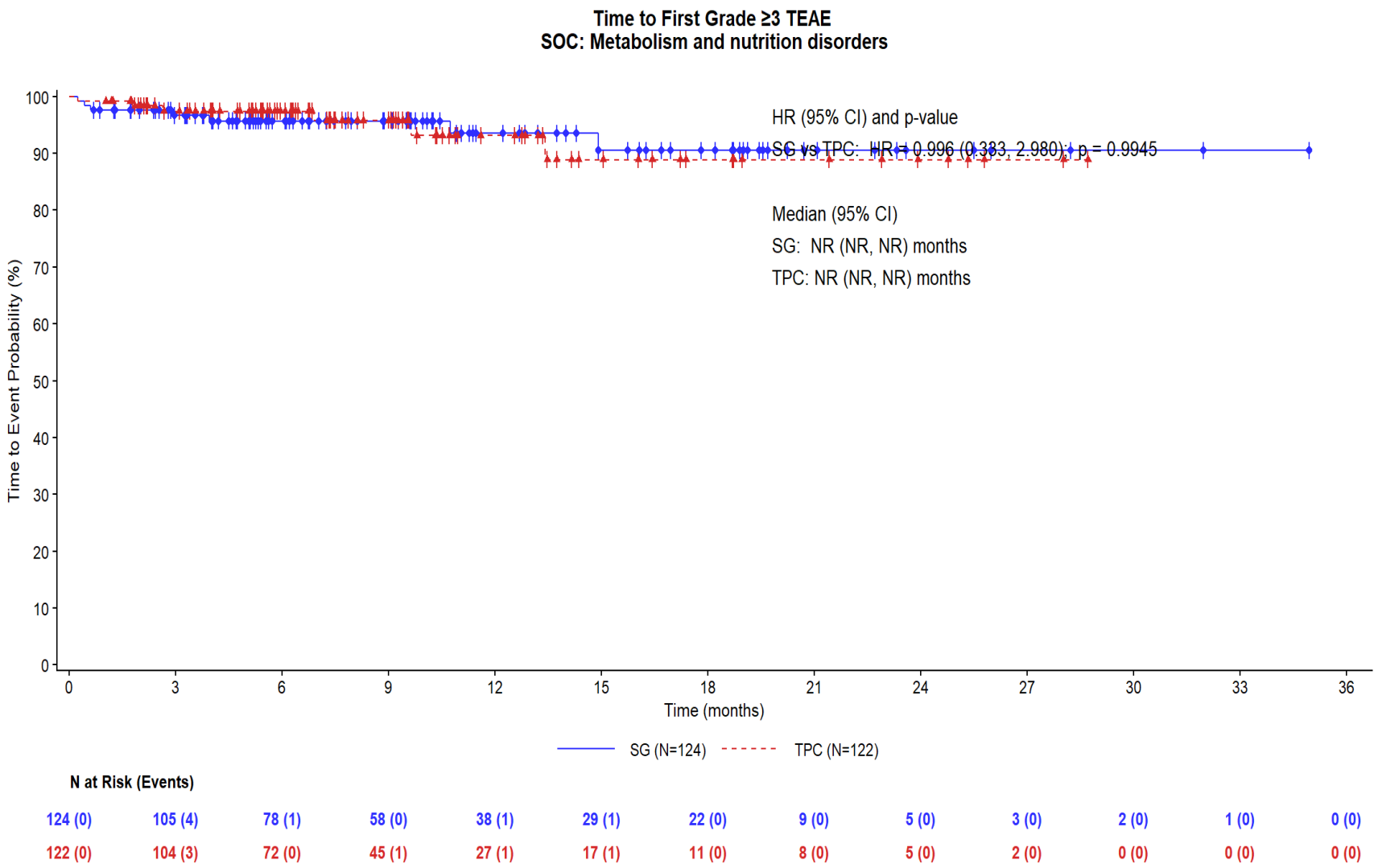
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.100. Figure 1.1.101: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



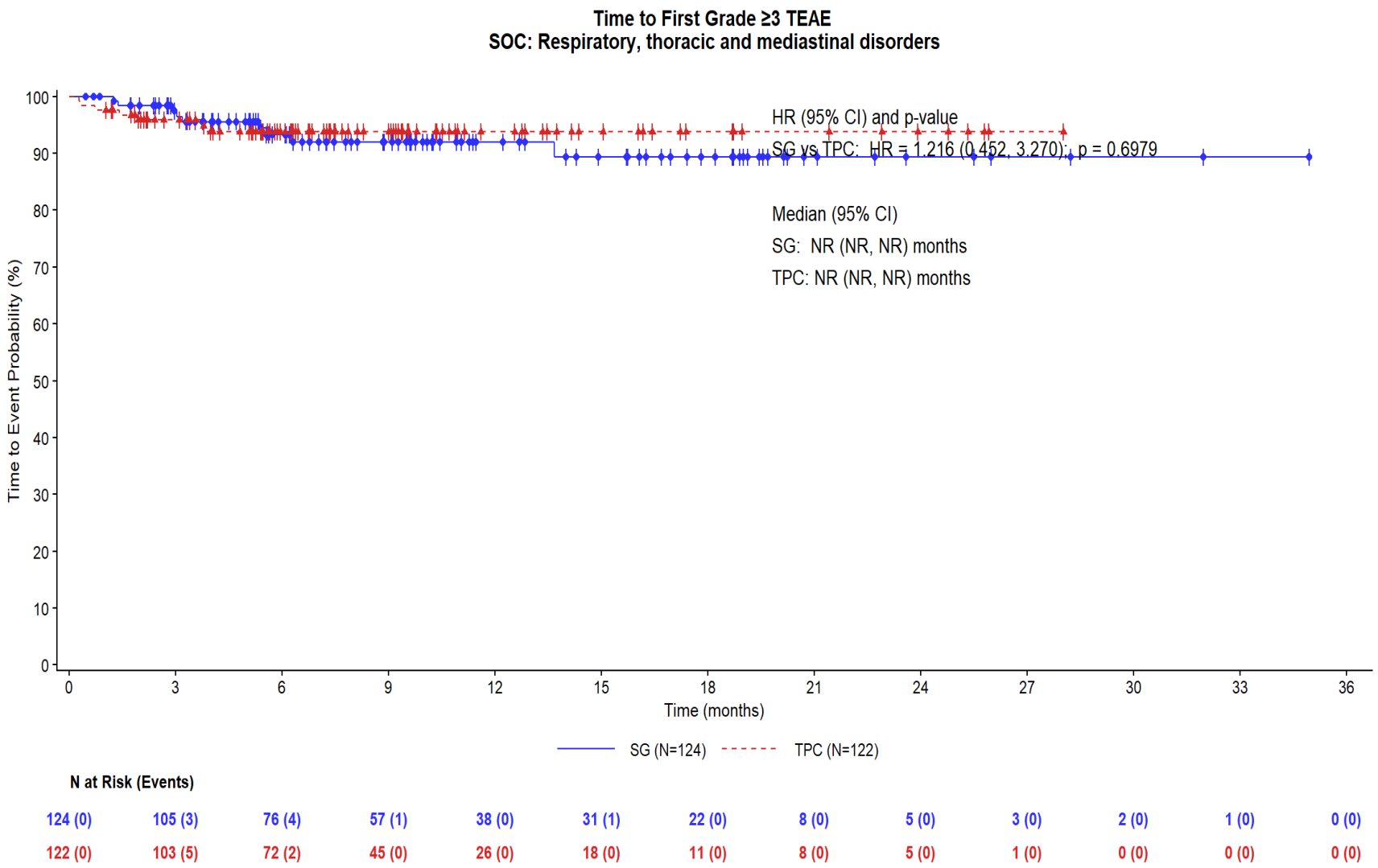
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.101. Figure 1.1.102: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



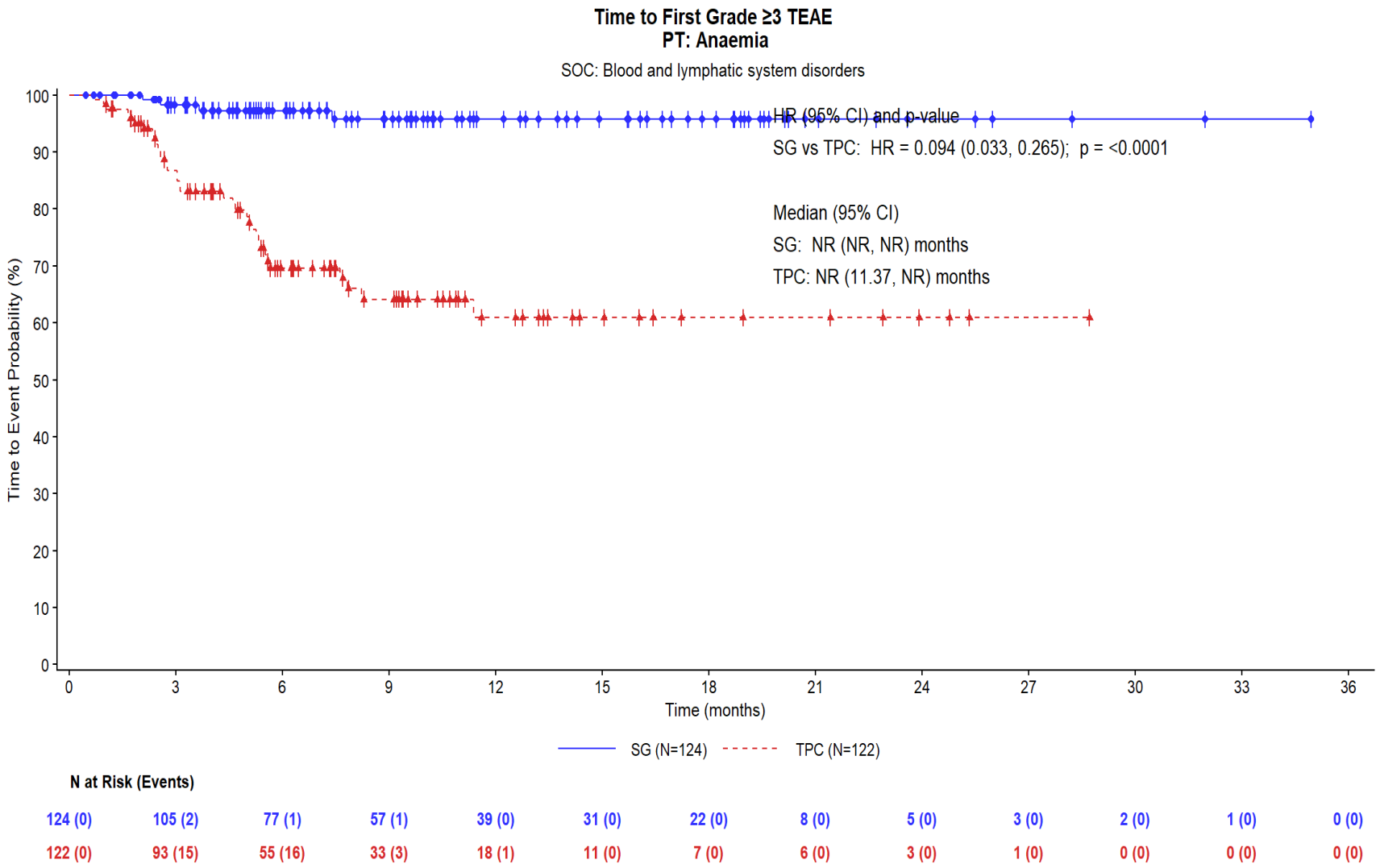
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.102. Figure 1.1.103: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



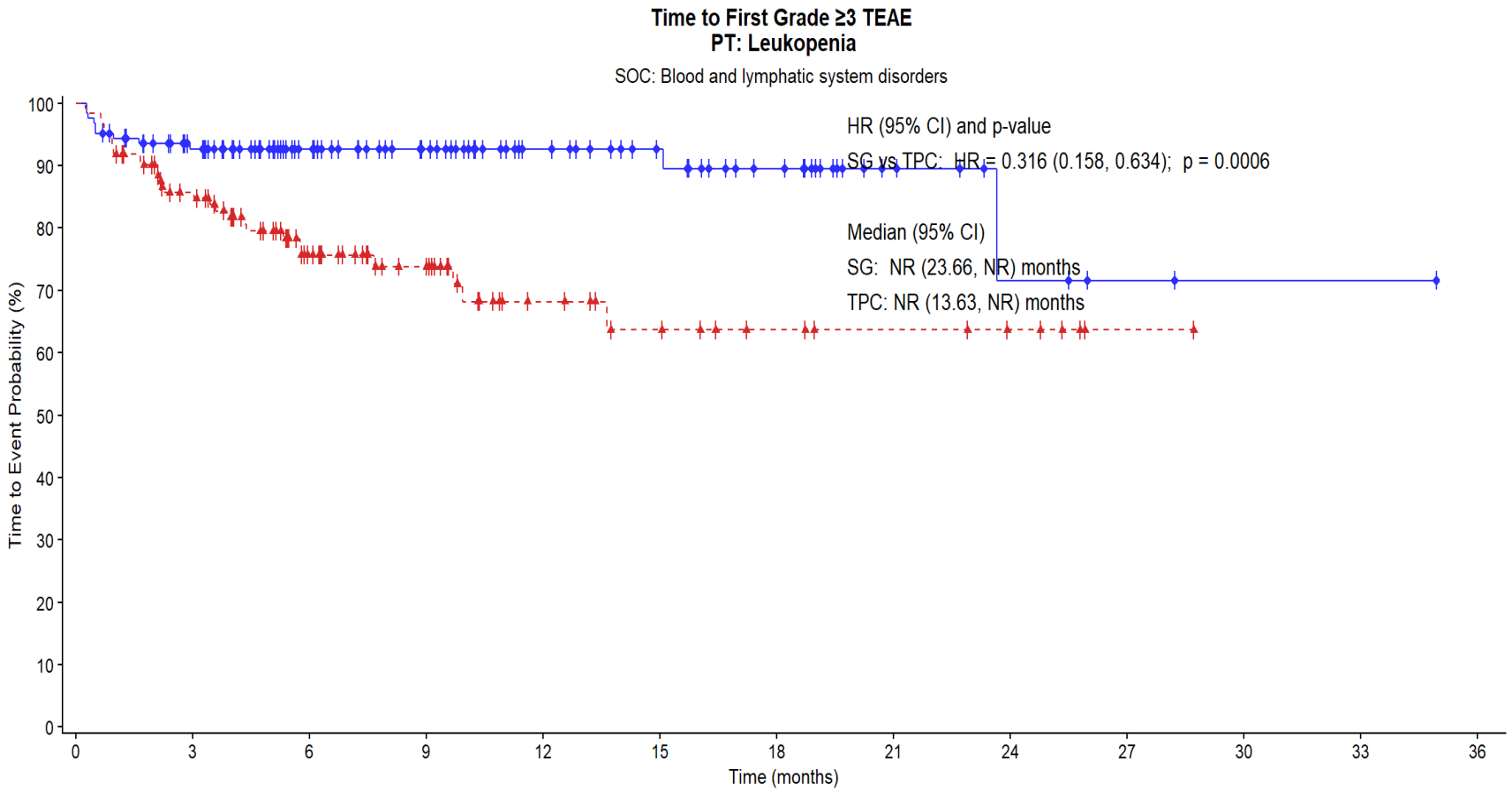
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.103. Figure 1.1.104: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



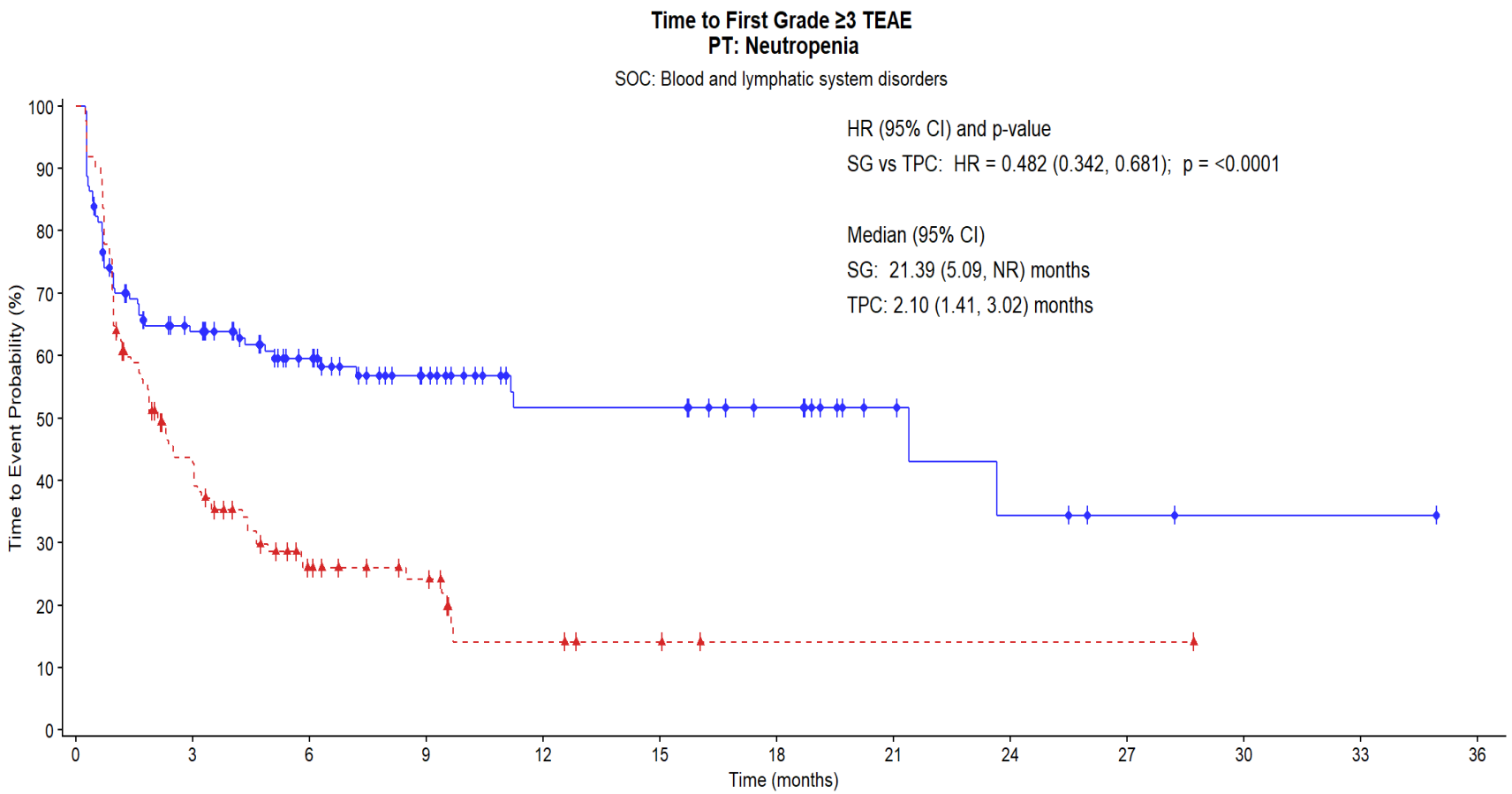
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.104. Figure 1.1.105: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



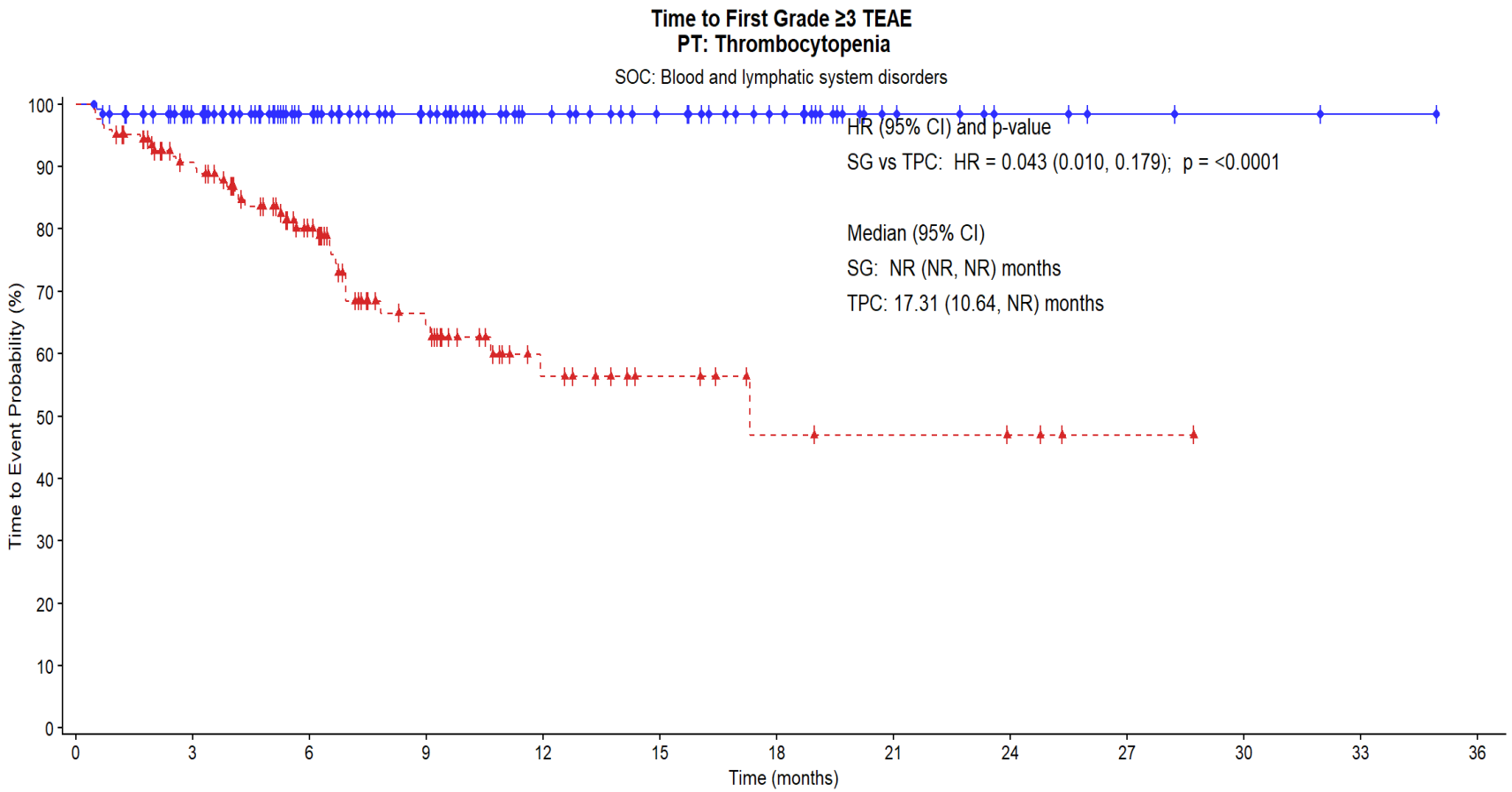
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.105. Figure 1.1.106: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



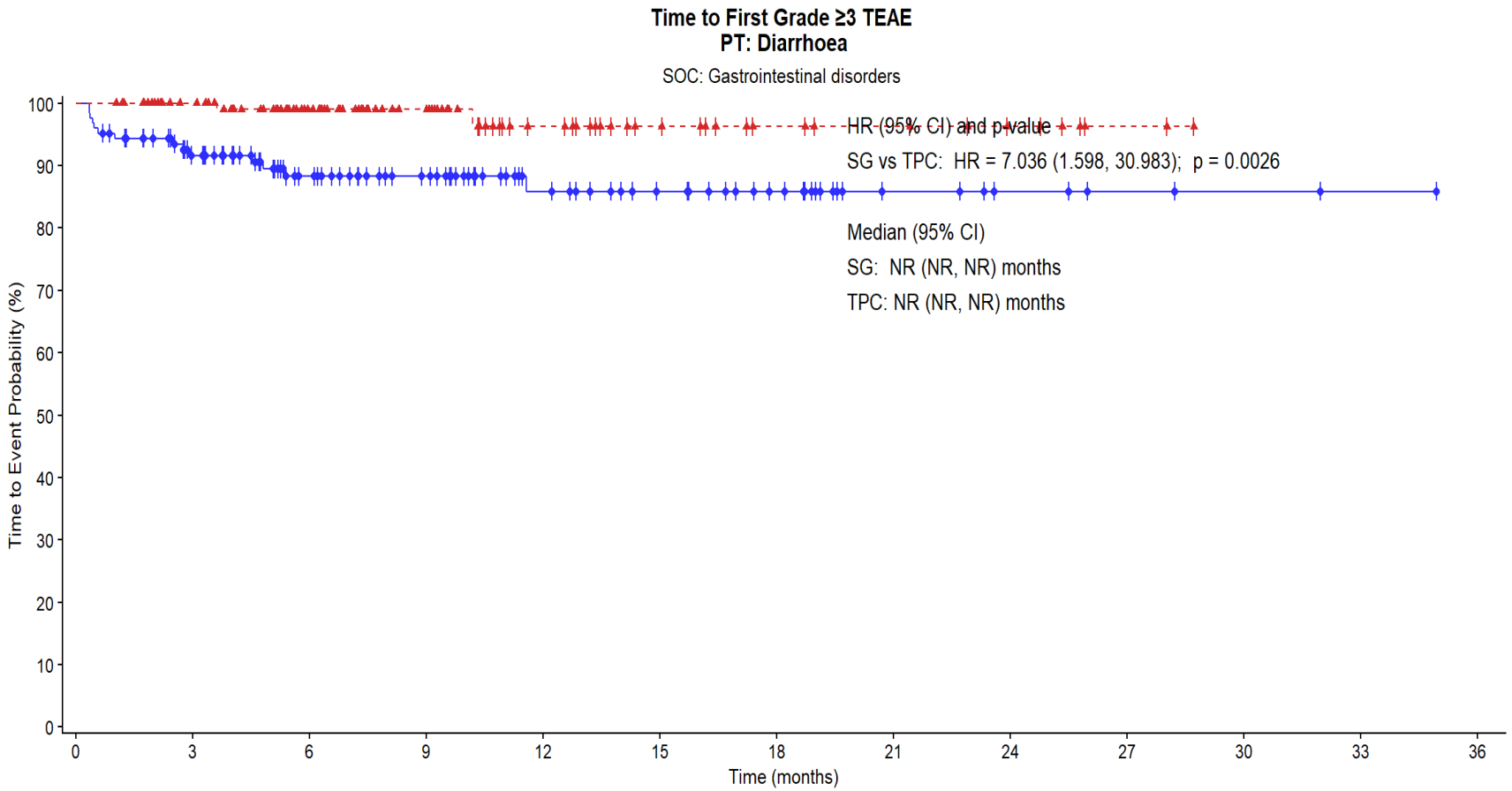
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.106. Figure 1.1.107: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



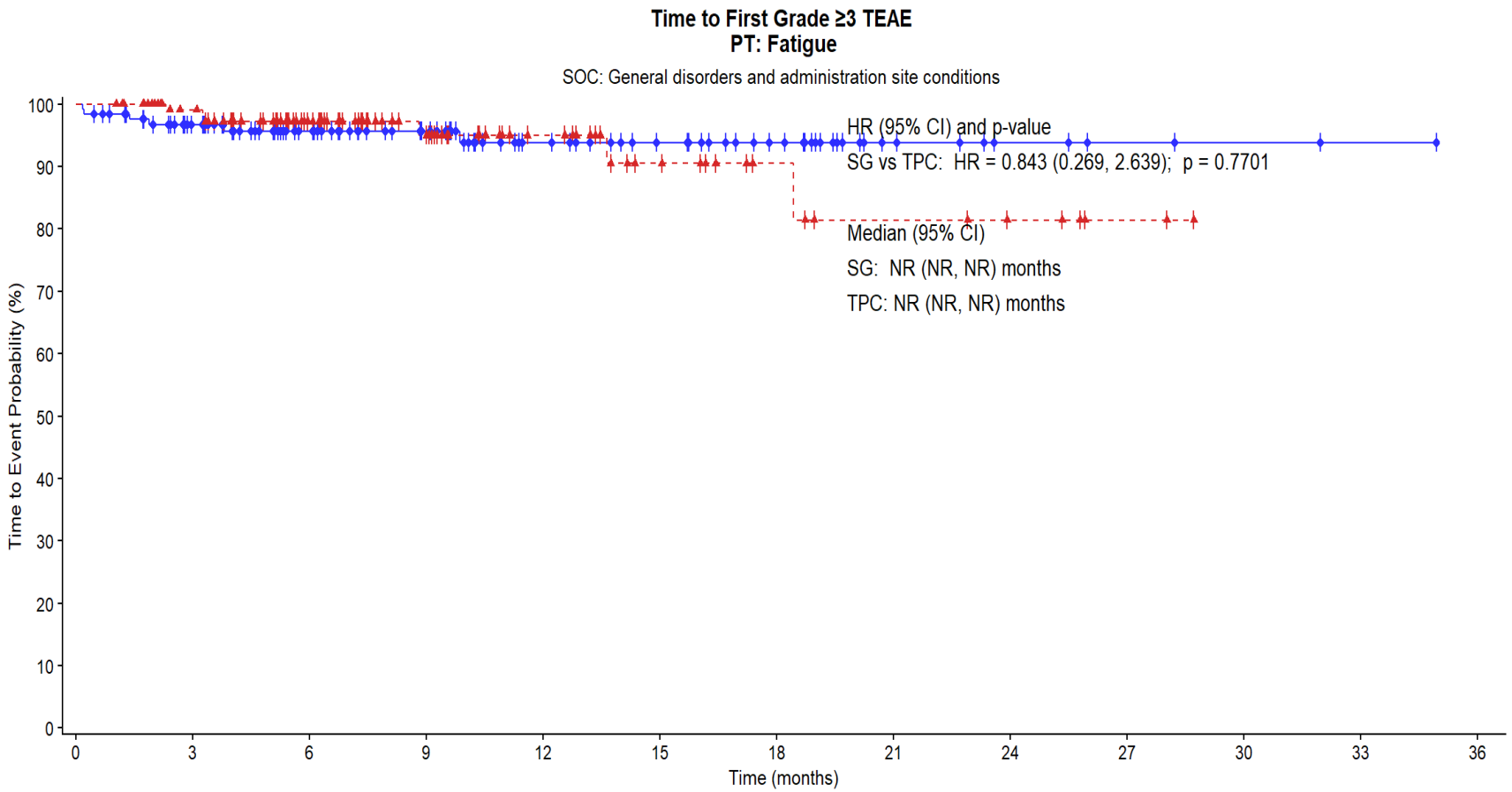
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.107. Figure 1.1.108: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



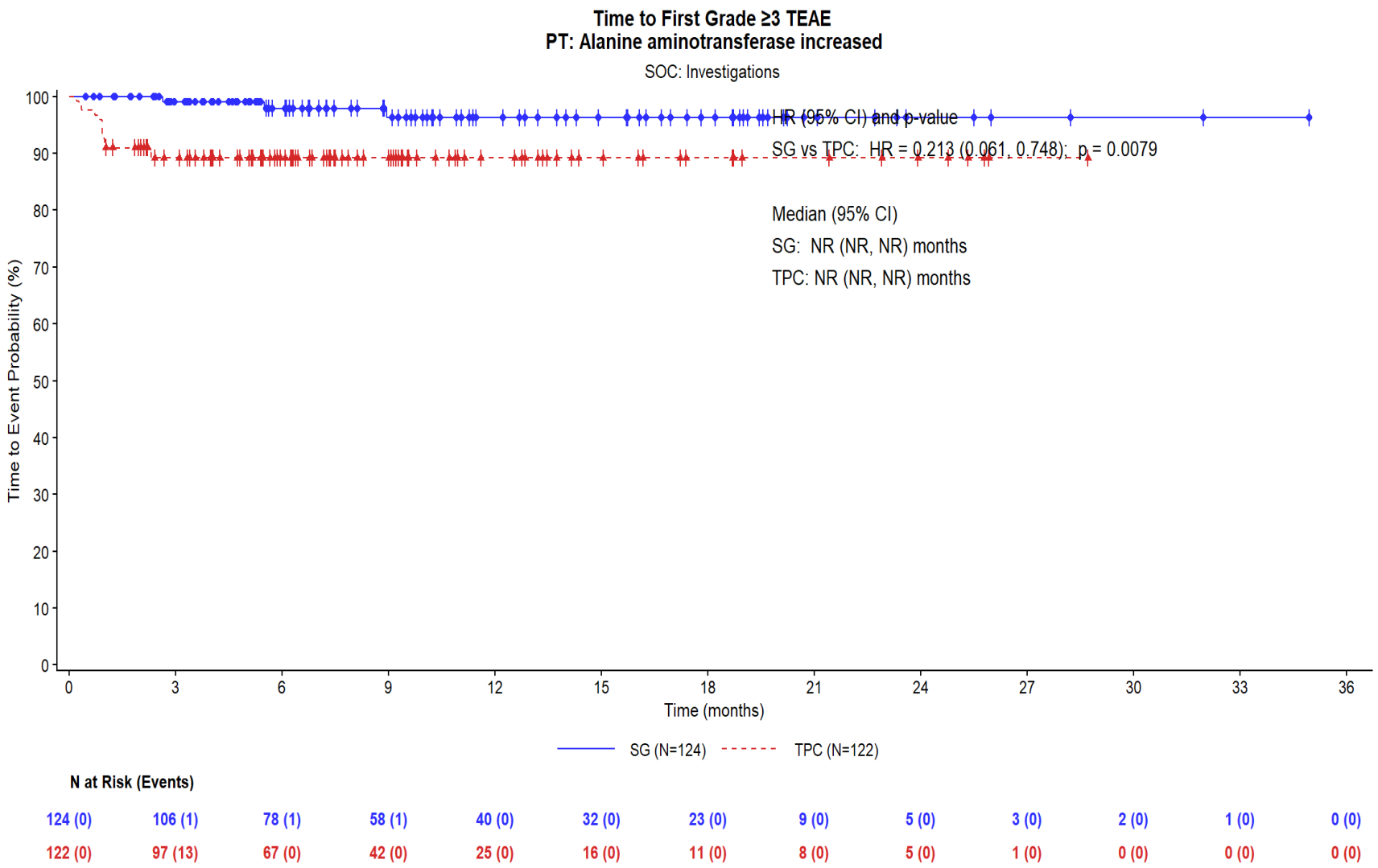
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.108. Figure 1.1.109: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



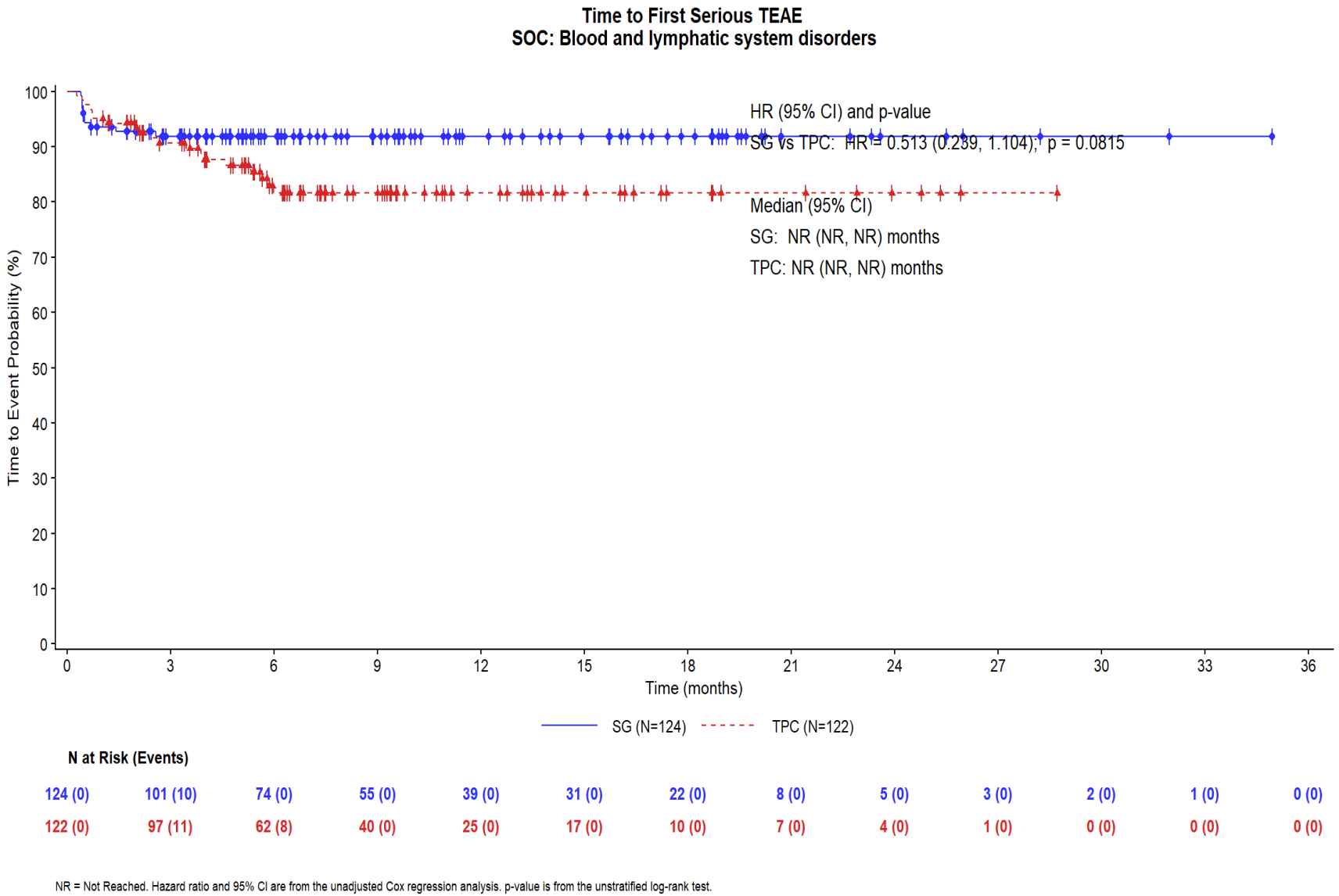
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.109. Figure 1.1.110: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



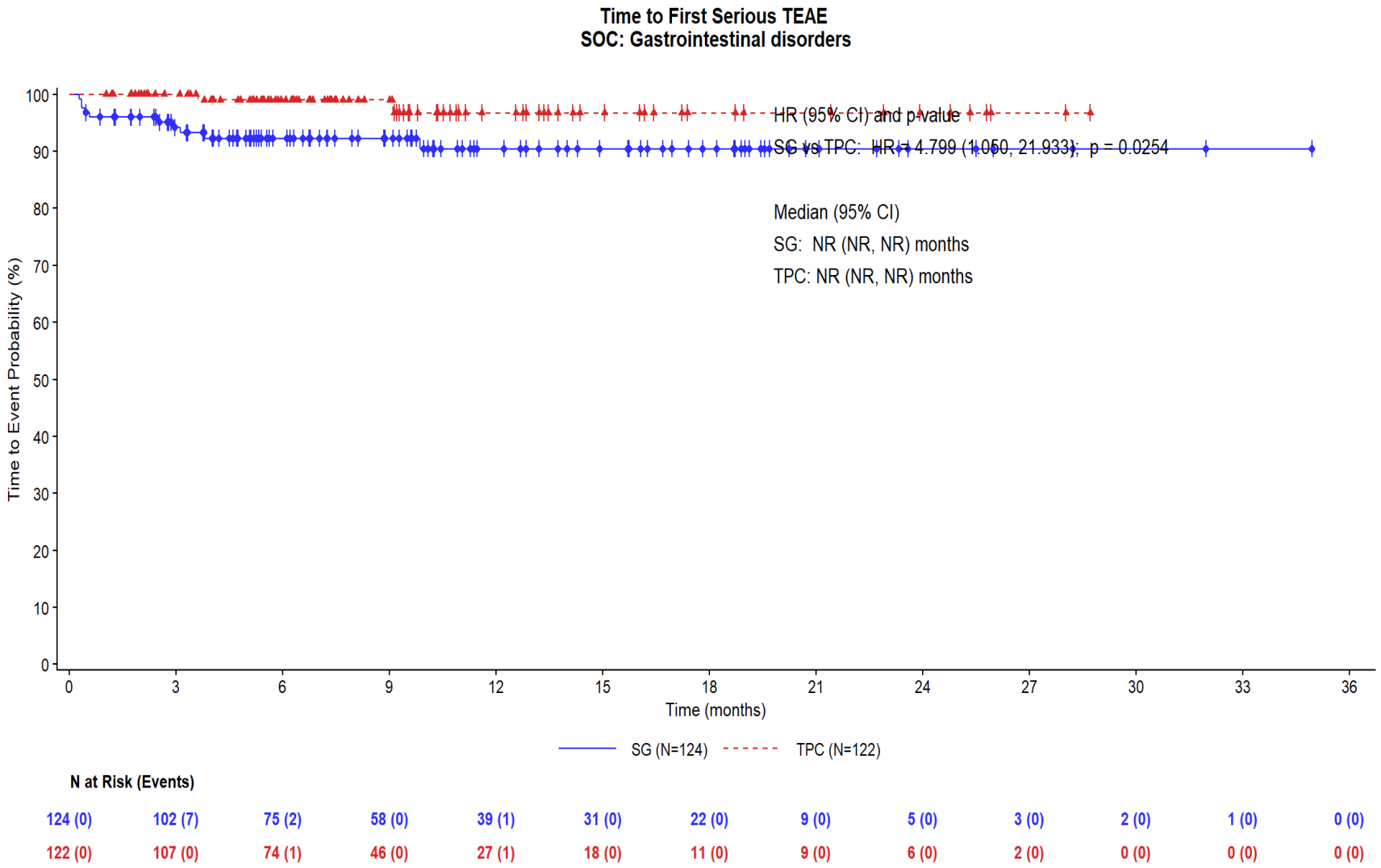
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.110. Figure 1.1.111: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



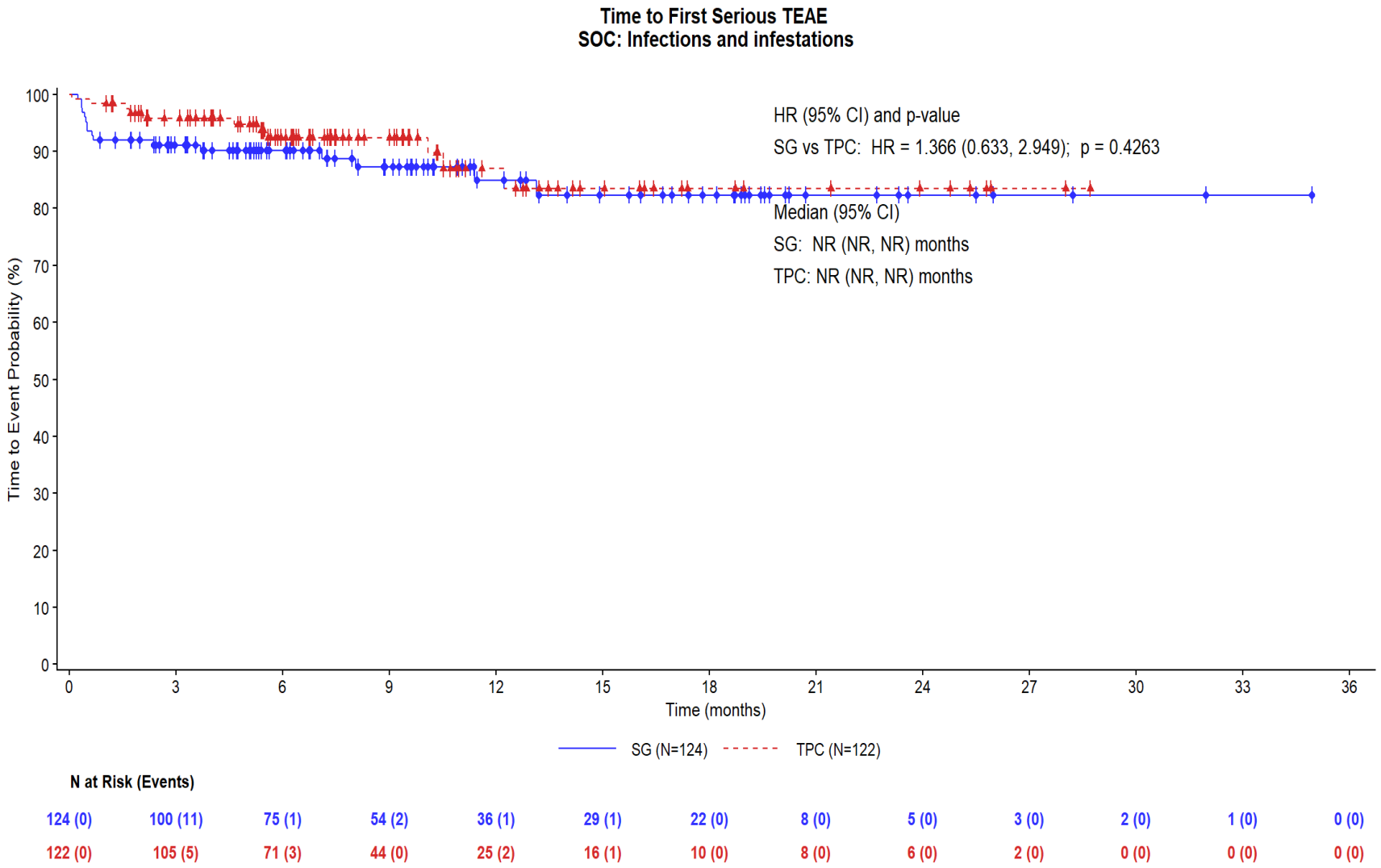
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.111. Figure 1.1.112: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



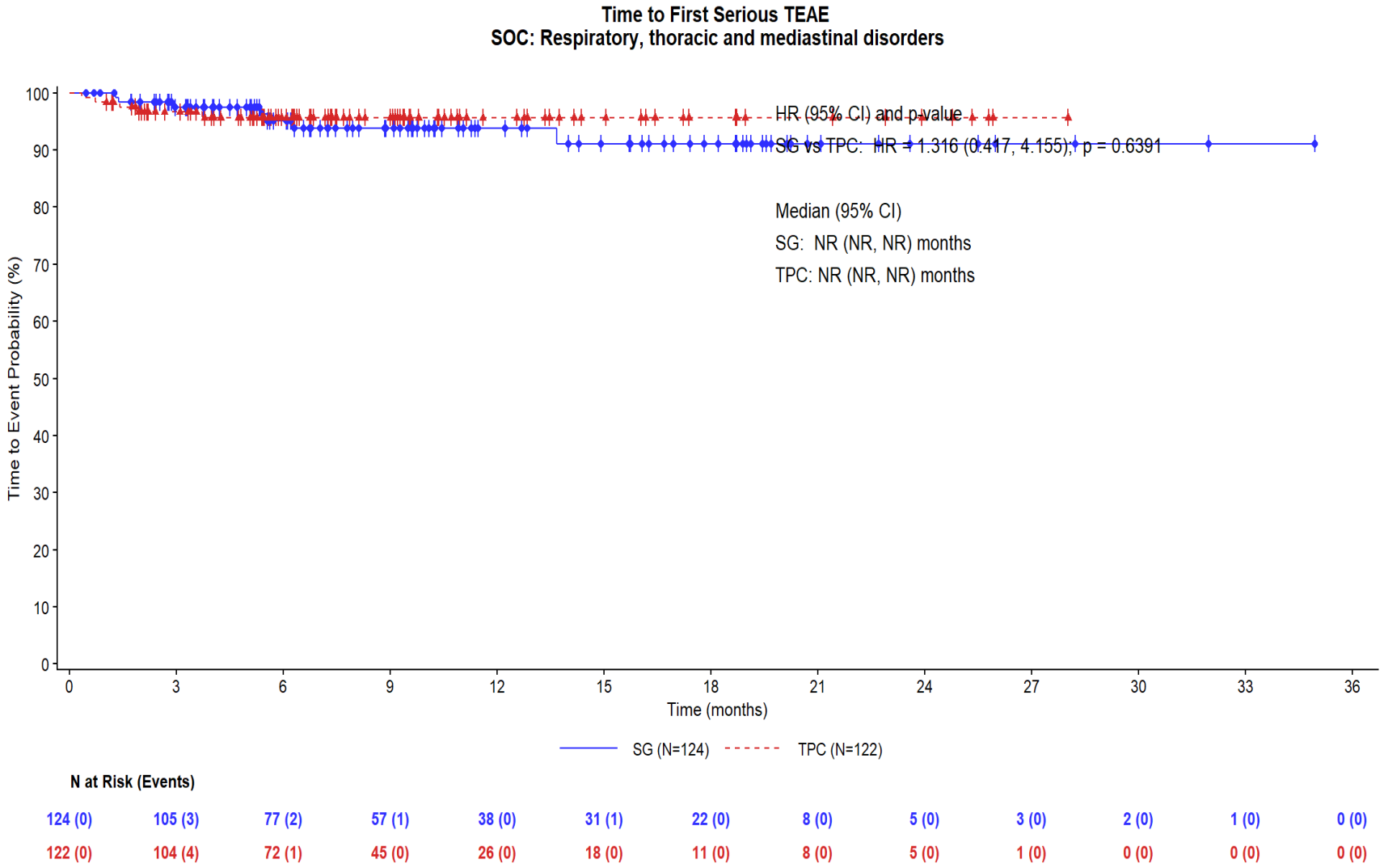
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.112. Figure 1.1.113: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



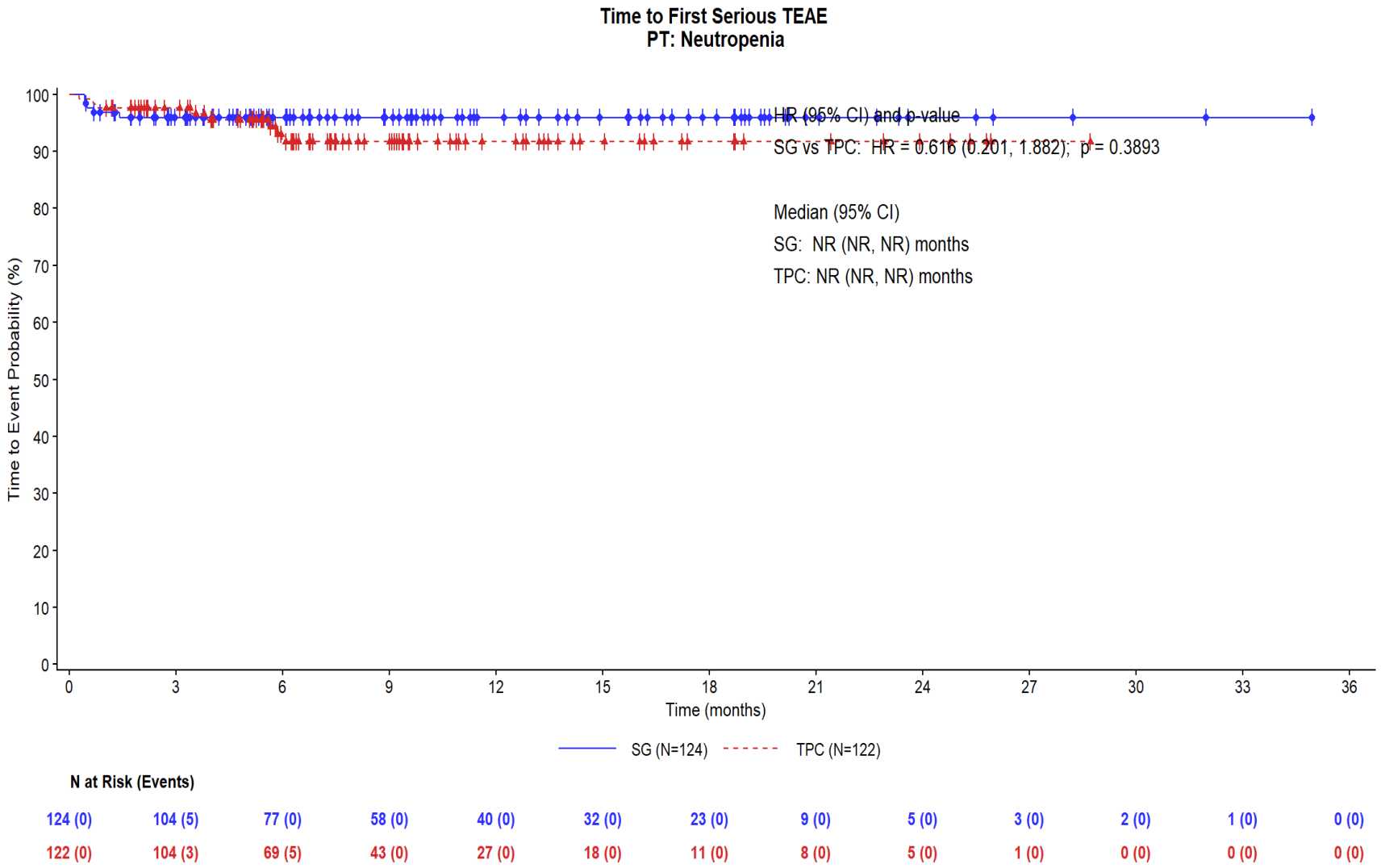
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.113. Figure 1.1.114: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



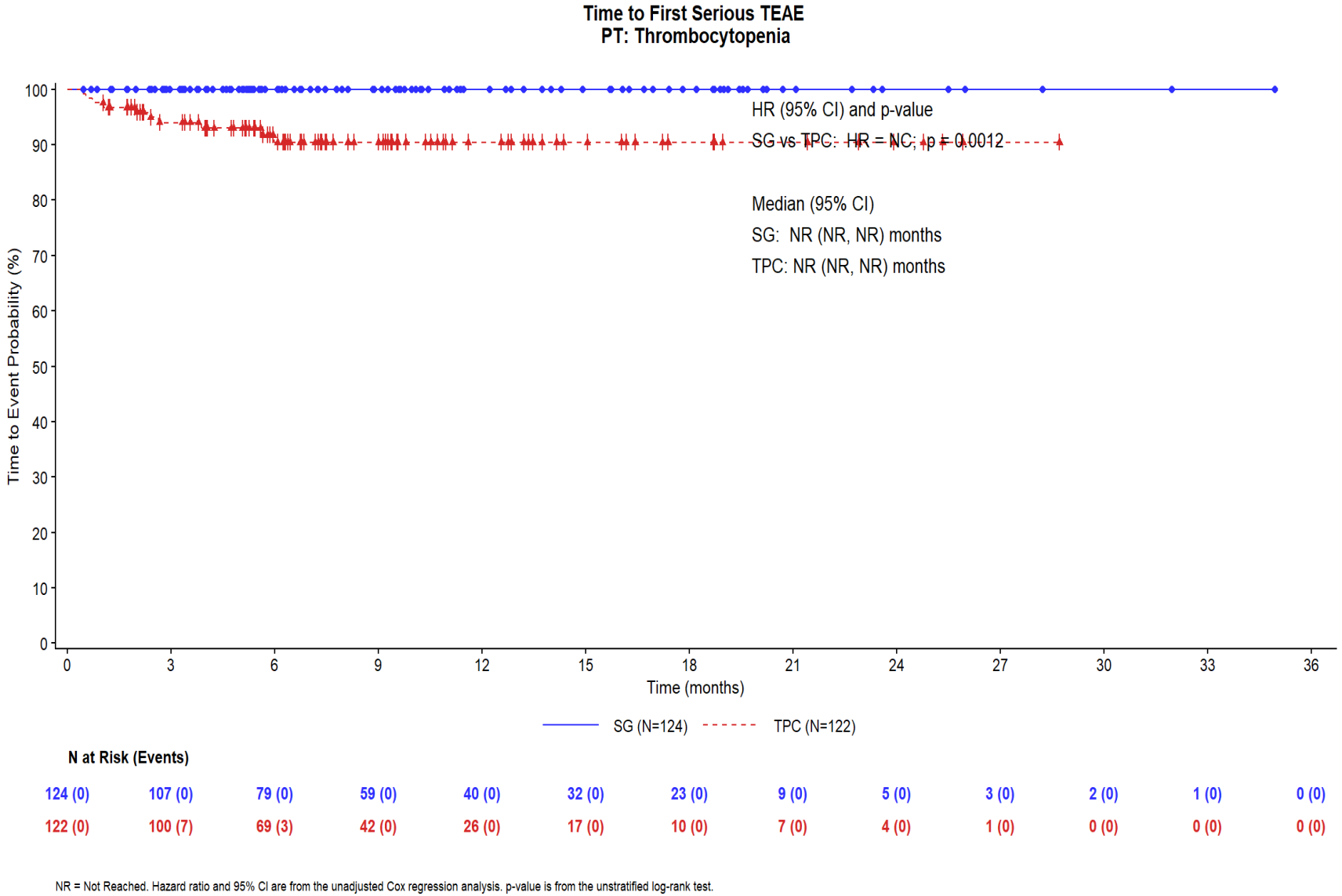
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

7.114. Figure 1.1.115: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

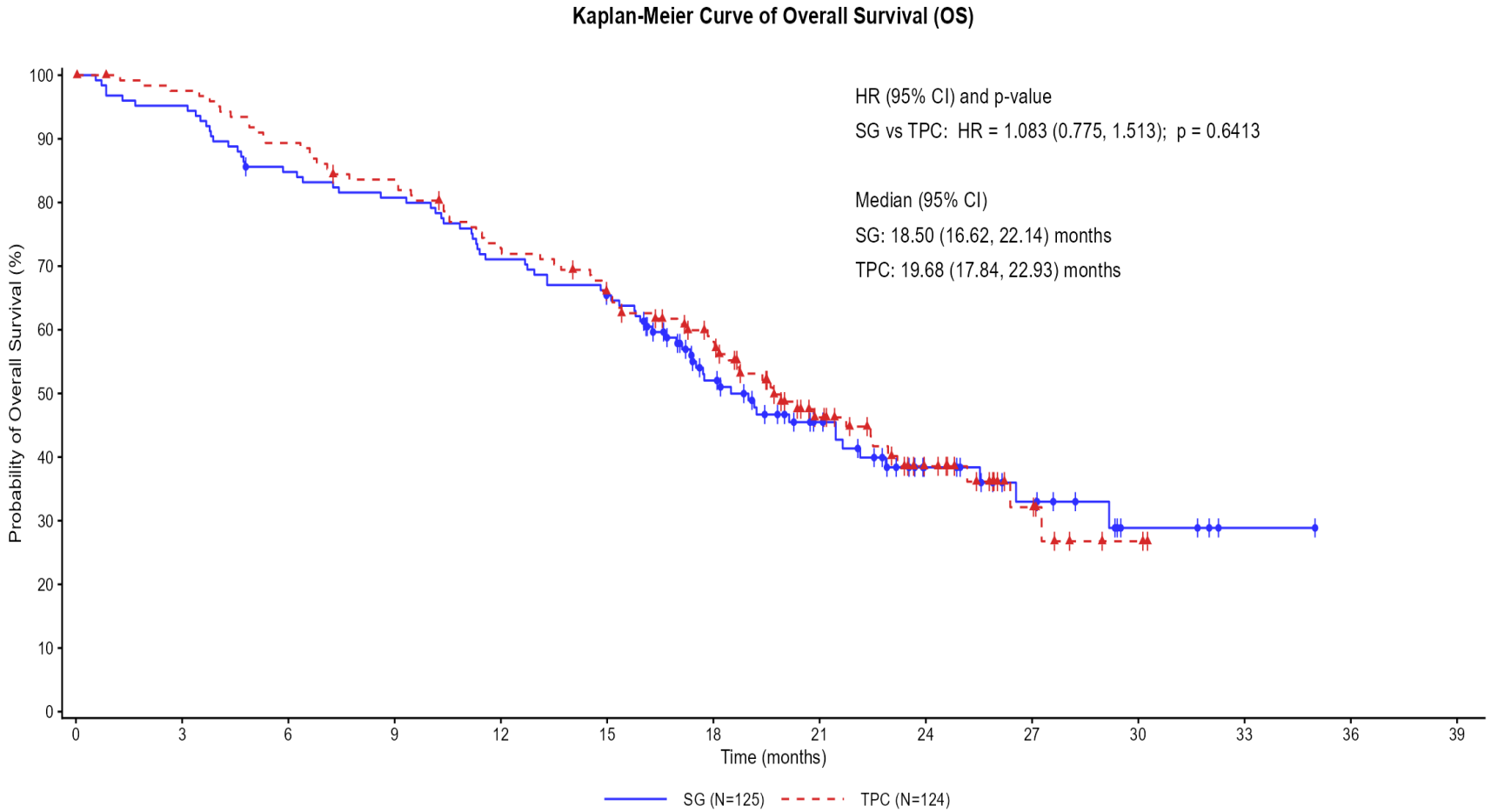
7.115. Figure 1.1.116: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

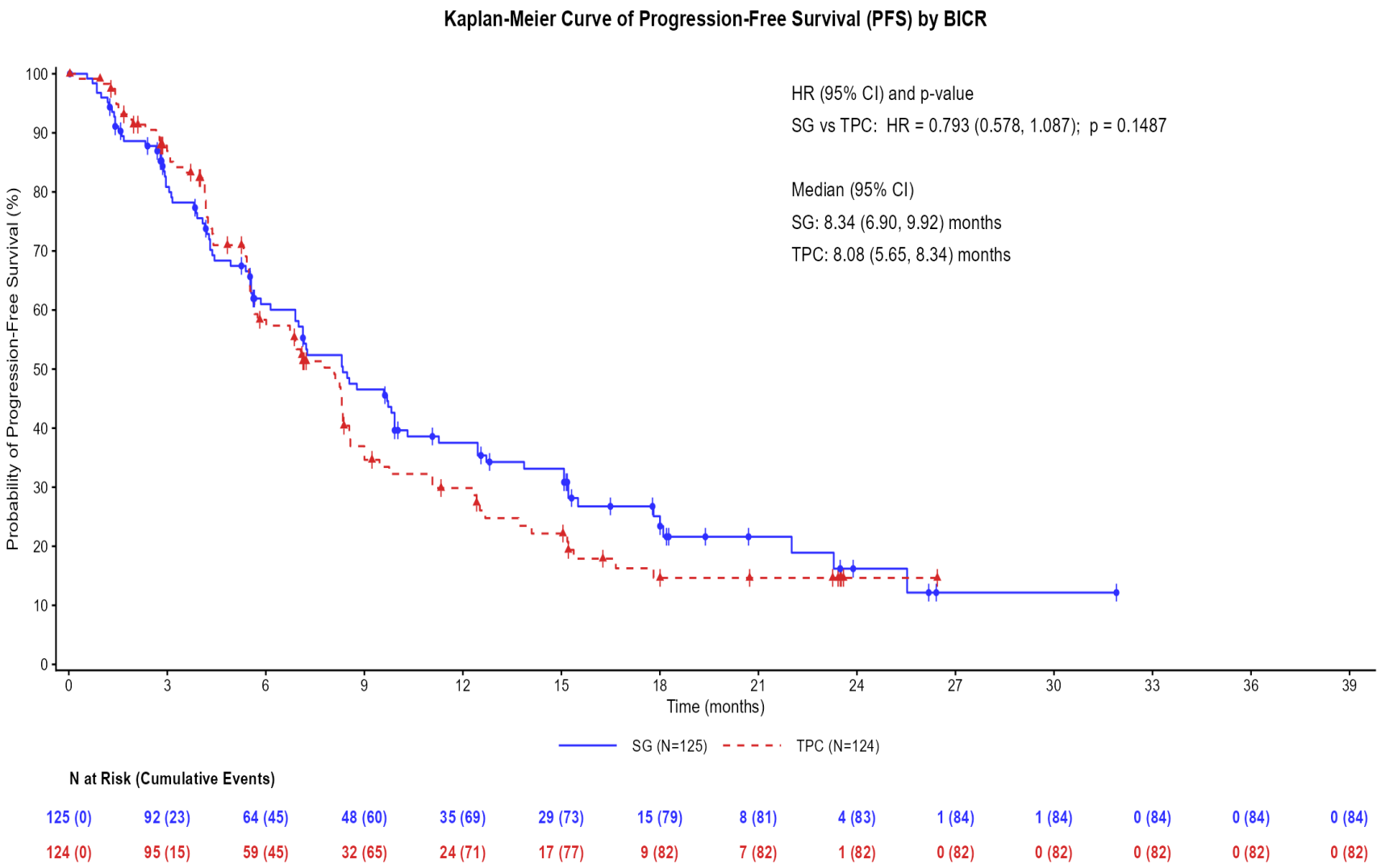
8. Efficacy - KM FIGURES — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

8.1. Figure 1.1.1: Kaplan-Meier Curve of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



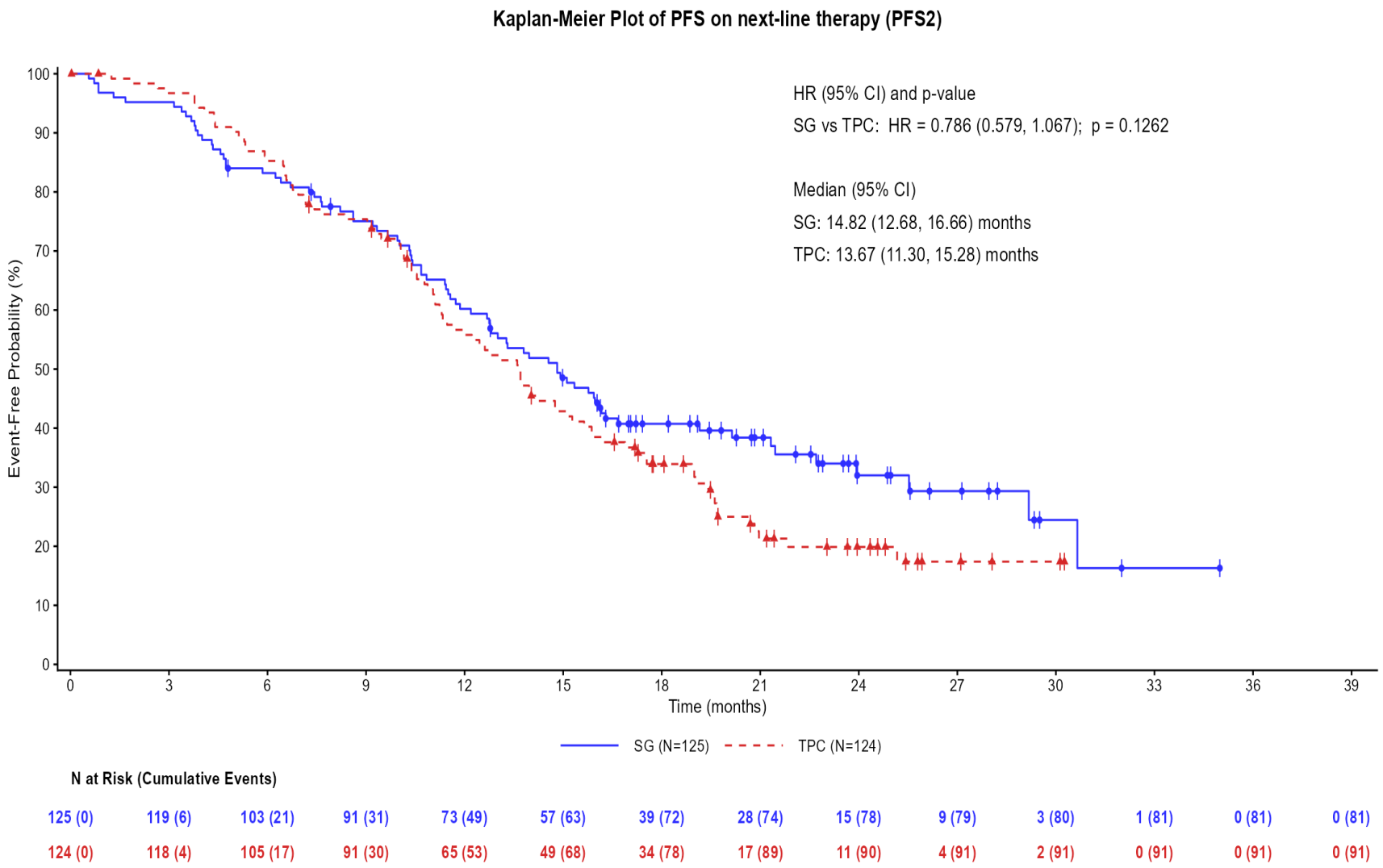
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

8.2. Figure 1.1.2: Kaplan-Meier Curve of Progression-Free Survival (PFS) by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



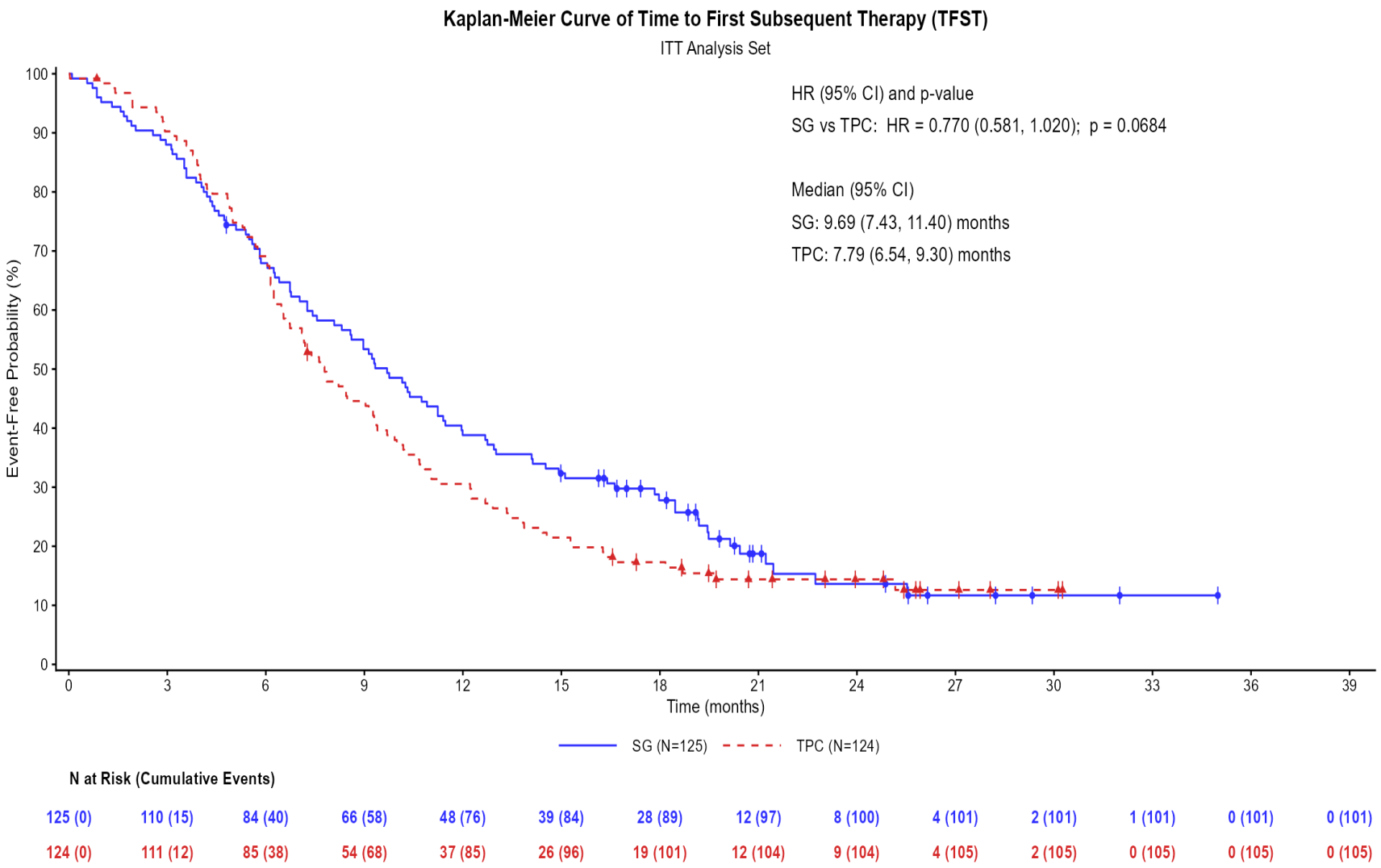
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

8.3. Figure 1.1.3: Kaplan-Meier Plot of PFS on next-line therapy (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



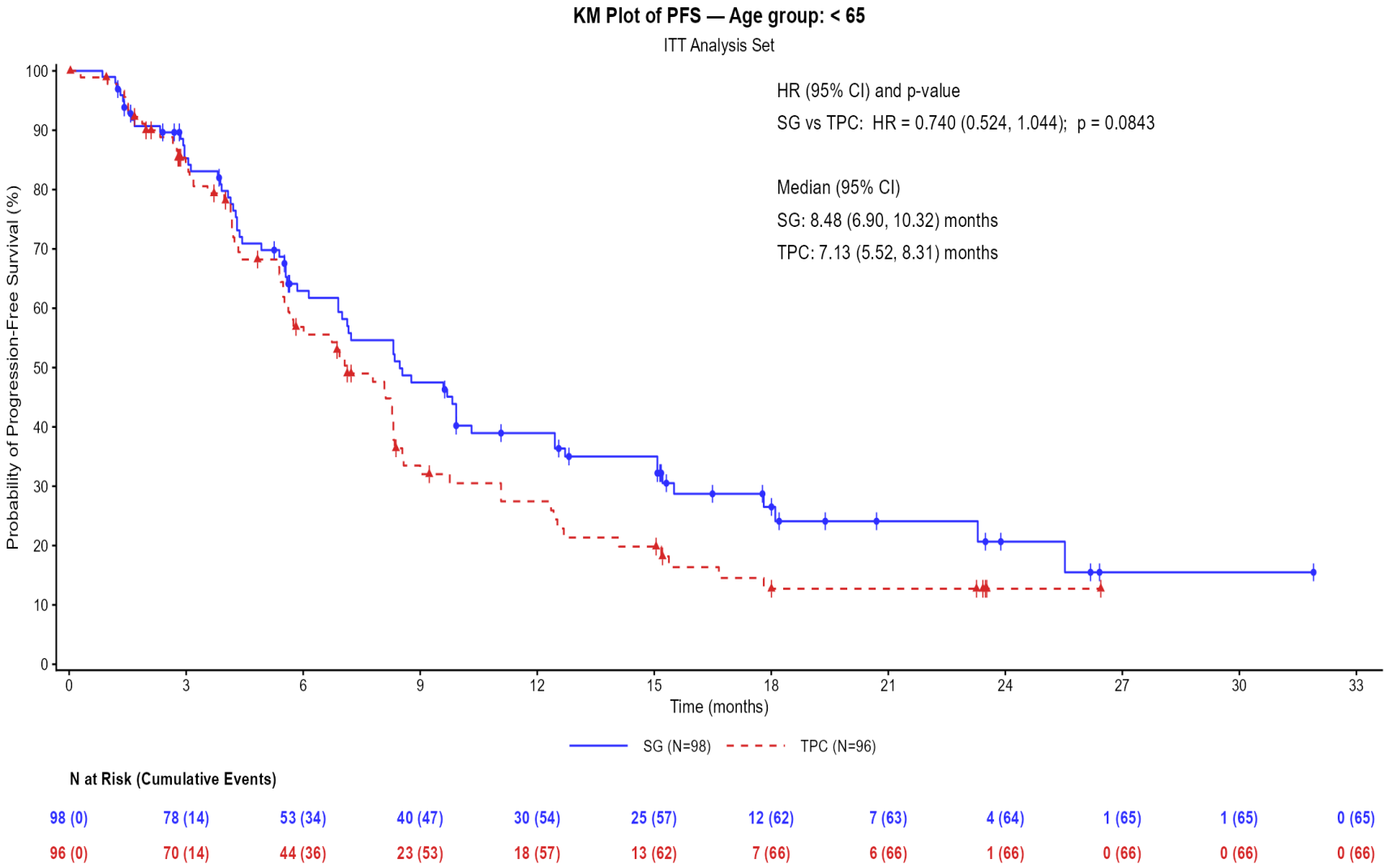
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

8.4. Figure 1.1.4: Kaplan-Meier Curve of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



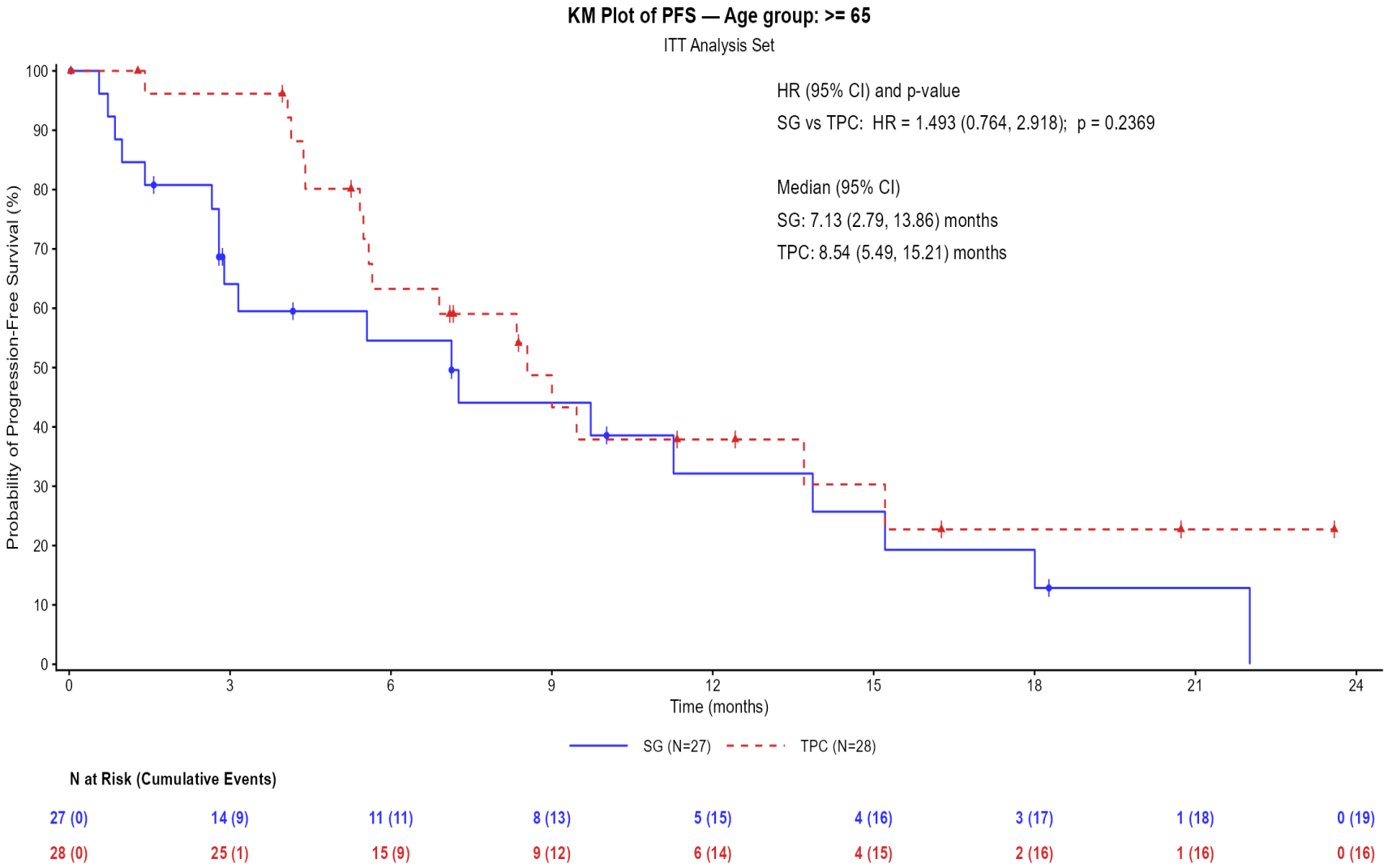
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

8.5. Figure 1.1.5: KM Plot of PFS — Age group: < 65 — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



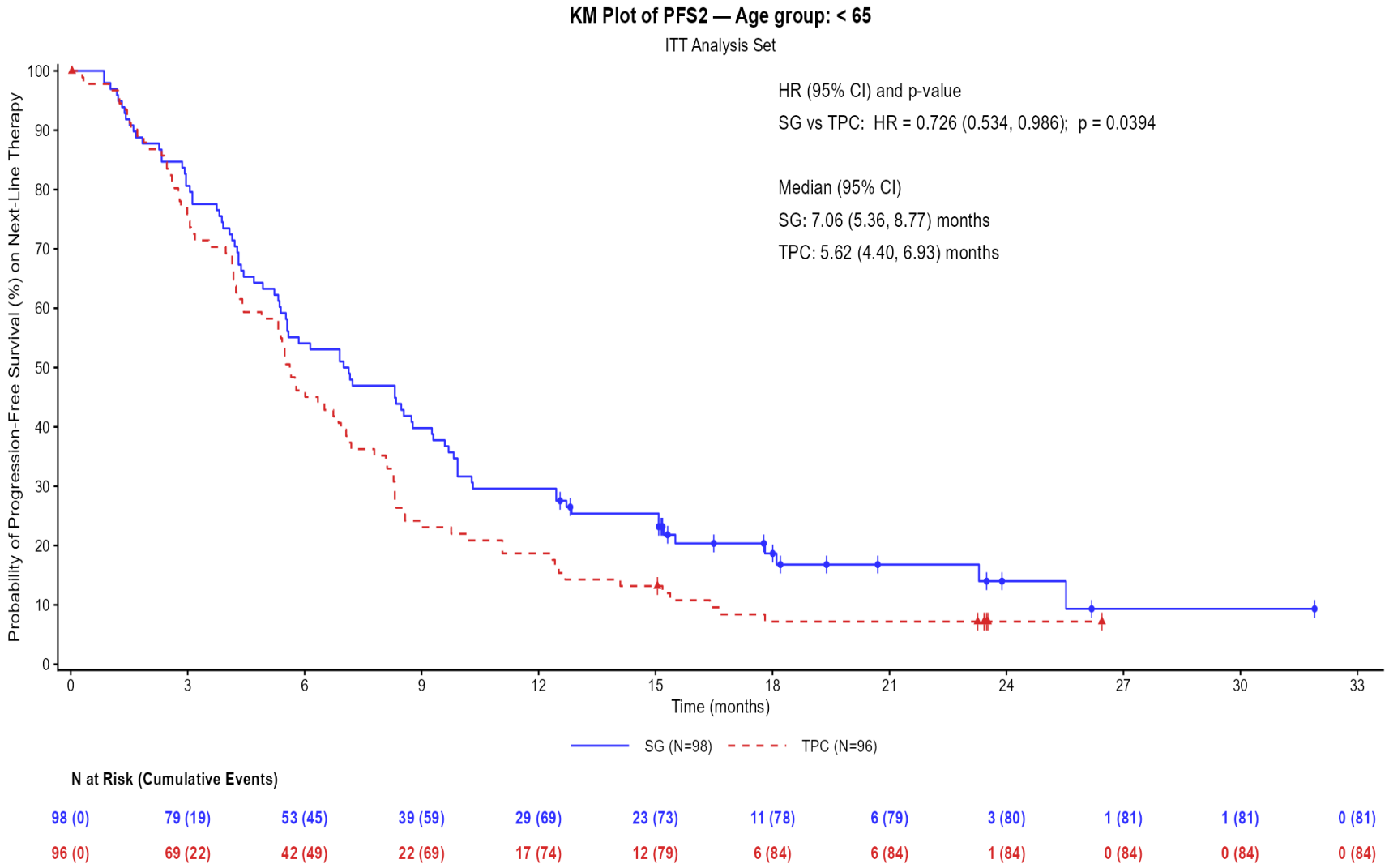
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

8.6. Figure 1.1.6: KM Plot of PFS — Age group: >= 65 — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



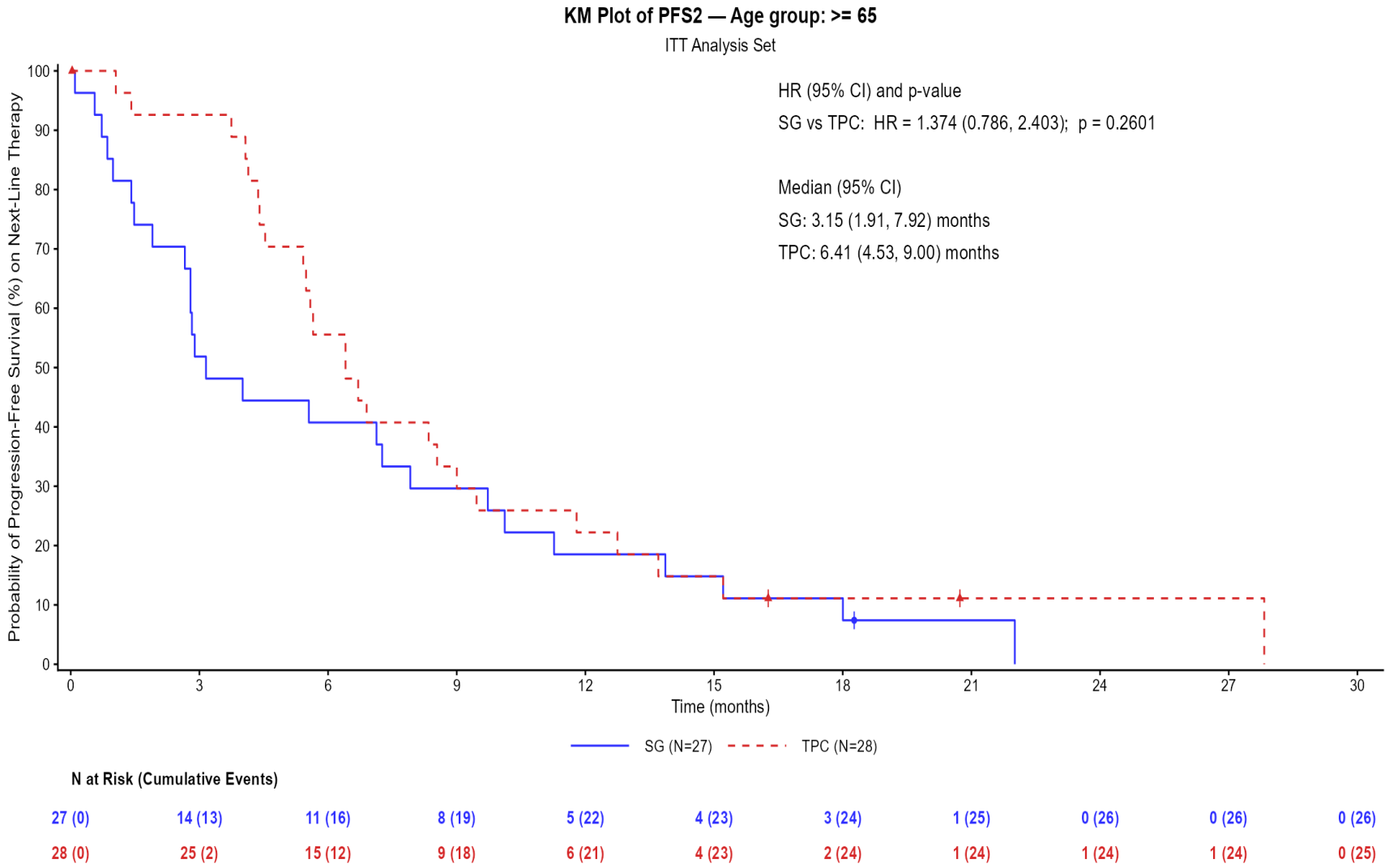
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

8.7. Figure 1.1.7: KM Plot of PFS2 — Age group: < 65 — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



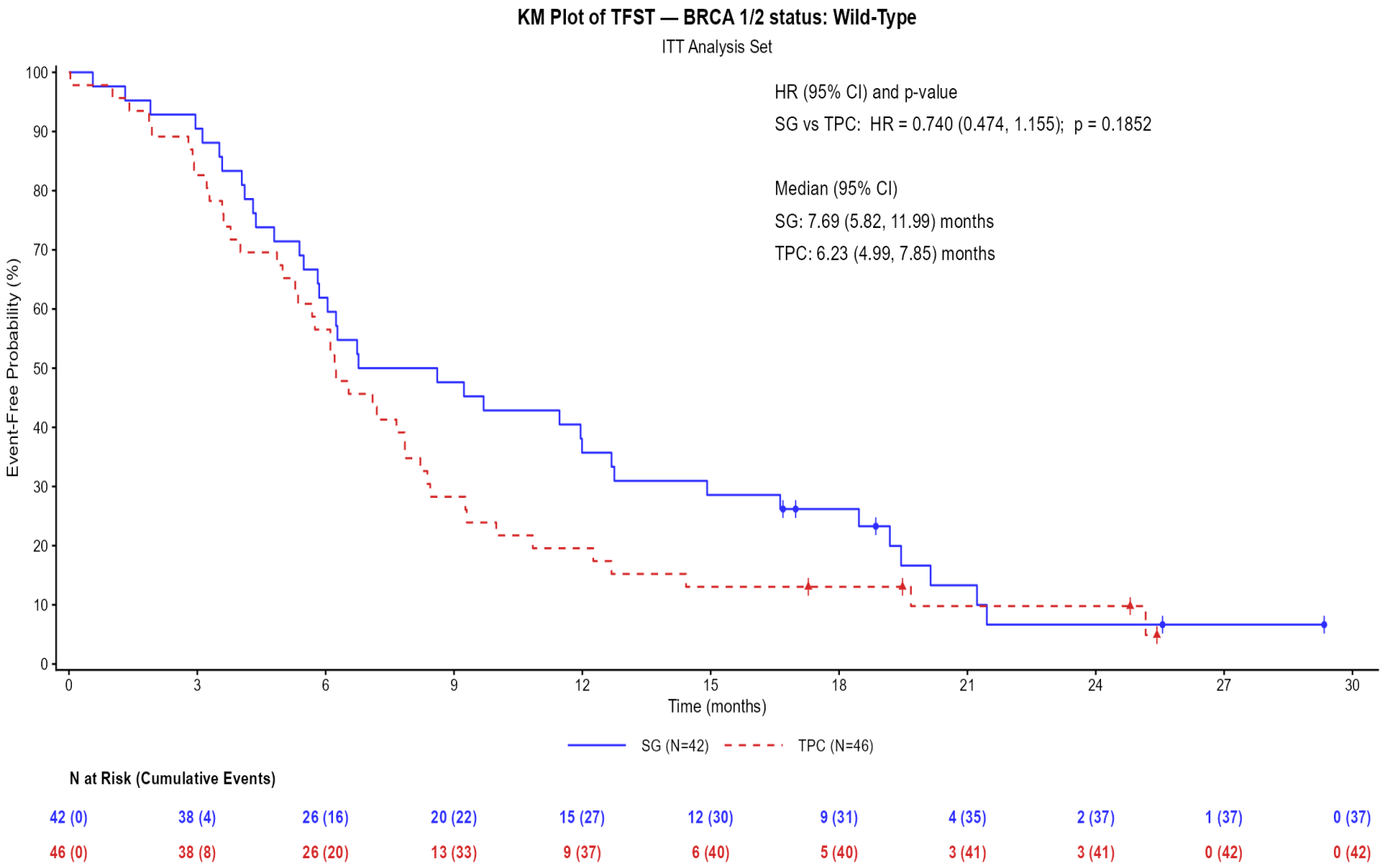
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

8.8. Figure 1.1.8: KM Plot of PFS2 — Age group: >= 65 — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



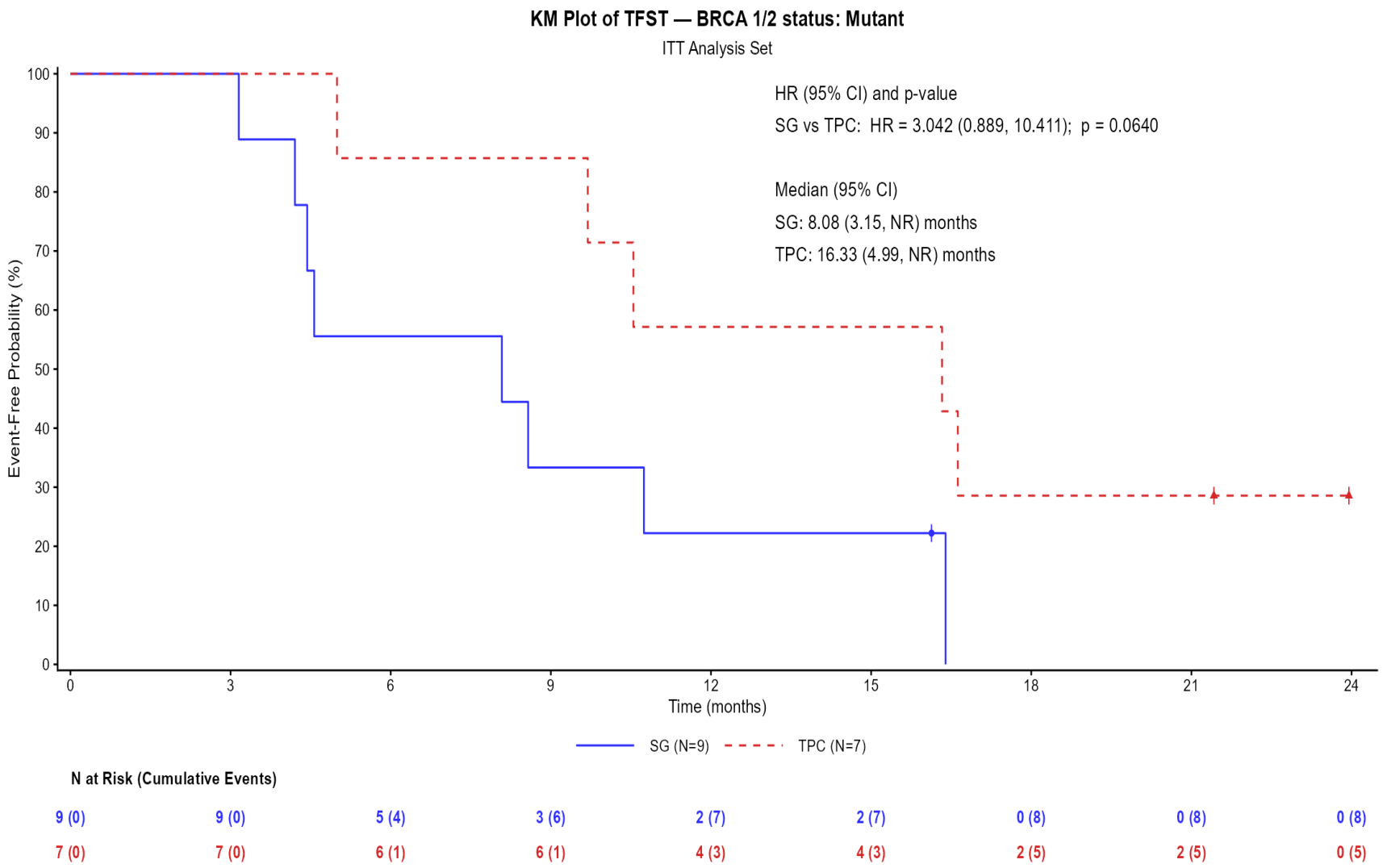
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

8.9. Figure 1.1.9: KM Plot of TFST — BRCA 1/2 status: Wild-Type — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

8.10. Figure 1.1.10: KM Plot of TFST — BRCA 1/2 status: Mutant — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

Table. Recurrence of diarrhoea TEAE — mSAF: Excluding patients preselected to nab-paclitaxel or paclitaxel

	SG (N=124)			TPC (N=122)		
Incidence of diarrhoea TEAE	**1 event**	**2 events**	**>2 events**	**1 event**	**2 events**	**>2 events**
Grade 1	29 (23.4%)	11 (8.9%)	14 (11.3%)	20 (16.4%)	2 (1.6%)	2 (1.6%)
Grade 2	28 (22.6%)	7 (5.6%)	5 (4.0%)	8 (6.6%)	1 (0.8%)	0
Grade ≥3	14 (11.3%)	0	0	2 (1.6%)	0	0
Grade 3	14 (11.3%)	0	0	2 (1.6%)	0	0
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

n = number of events per patient;

Inhaltsverzeichnis – Patientenberichtete Endpunkte

Studie ASCENT-03 – Datenschnitt: 27. Oktober 2025

(Teil-)Population: Patient/-innen mit hohem Remissionsdruck (Carboplatin+Gemcitabin-Teilpopulation)

- Beobachtungsdauer
- Rücklaufquoten
- Ergebnisse:
    - EORTC QLQ-C30
    - EORTC QLQ-BR23
    - EQ-5D-5L VAS
    - PGI-C
    - PGI-S
- Subgruppenanalysen
- Abbildungen
    - Veränderung zu Baseline
    - Kaplan-Meier-Kurven
    - Kaplan-Meier-Kurven: Subgruppen

Table 1.3.1
Summary of Observation Period (Months) for EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Statistic	SG (N=125)	TPC (N=124)	Overall (N=249)
N	125	123	248
Mean (SD)	9.5 (7.39)	8.4 (6.34)	9.0 (6.90)
95% CI	8.2, 10.8	7.3, 9.6	8.1, 9.8
Median	7.4	6.8	6.9
Q1, Q3	4.2, 14.8	4.2, 10.6	4.2, 12.8
Min, Max	0.0, 34.5	0.0, 27.3	0.0, 34.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 1.3.2
Summary of Observation Period (Months) for EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Statistic	SG (N=125)	TPC (N=124)	Overall (N=249)
N	124	123	247
Mean (SD)	9.4 (7.33)	8.4 (6.36)	8.9 (6.87)
95% CI	8.1, 10.7	7.3, 9.6	8.1, 9.8
Median	7.3	6.8	6.9
Q1, Q3	4.1, 14.7	4.2, 10.6	4.2, 12.6
Min, Max	0.0, 34.5	0.0, 27.3	0.0, 34.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.

CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 1.3.3
Summary of Observation Period (Months) for EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Statistic	SG (N=125)	TPC (N=124)	Overall (N=249)
N	125	123	248
Mean (SD)	9.5 (7.39)	8.4 (6.36)	9.0 (6.91)
95% CI	8.2, 10.8	7.3, 9.6	8.1, 9.8
Median	7.4	6.8	6.9
Q1, Q3	4.1, 14.8	4.2, 10.6	4.2, 12.8
Min, Max	0.0, 34.5	0.0, 27.3	0.0, 34.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 1.3.4
Summary of Observation Period (Months) for PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Statistic	SG (N=125)	TPC (N=124)	Overall (N=249)
N	95	99	194
Mean (SD)	5.5 (0.78)	5.4 (1.00)	5.4 (0.90)
95% CI	5.3, 5.6	5.2, 5.6	5.3, 5.5
Median	5.7	5.8	5.7
Q1, Q3	5.1, 6.0	4.9, 6.2	5.1, 6.0
Min, Max	2.8, 6.5	2.8, 6.5	2.8, 6.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 1.3.5
Summary of Observation Period (Months) for PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Statistic	SG (N=125)	TPC (N=124)	Overall (N=249)
N	122	123	245
Mean (SD)	4.3 (2.37)	4.3 (2.31)	4.3 (2.33)
95% CI	3.8, 4.7	3.9, 4.7	4.0, 4.6
Median	5.6	5.4	5.6
Q1, Q3	3.6, 5.8	3.5, 6.0	3.5, 5.9
Min, Max	0.0, 6.5	0.0, 6.5	0.0, 6.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.2.1
Available Data Rate for the EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	123/125 (98.4%)	121/124 (97.6%)	244/249 (98.0%)
Week 4	106/125 (84.8%)	110/124 (88.7%)	216/249 (86.7%)
Week 7	99/125 (79.2%)	94/124 (75.8%)	193/249 (77.5%)
Week 10	94/125 (75.2%)	91/124 (73.4%)	185/249 (74.3%)
Week 13	85/125 (68.0%)	87/124 (70.2%)	172/249 (69.1%)
Week 16	82/125 (65.6%)	72/124 (58.1%)	154/249 (61.8%)
Week 19	84/125 (67.2%)	79/124 (63.7%)	163/249 (65.5%)
Week 22	72/125 (57.6%)	66/124 (53.2%)	138/249 (55.4%)
Week 25	61/125 (48.8%)	57/124 (46.0%)	118/249 (47.4%)
Week 28	63/125 (50.4%)	49/124 (39.5%)	112/249 (45.0%)
Week 31	61/125 (48.8%)	38/124 (30.6%)	99/249 (39.8%)
Week 34	55/125 (44.0%)	45/124 (36.3%)	100/249 (40.2%)
Week 37	49/125 (39.2%)	32/124 (25.8%)	81/249 (32.5%)
Week 40	47/125 (37.6%)	31/124 (25.0%)	78/249 (31.3%)
Week 43	35/125 (28.0%)	28/124 (22.6%)	63/249 (25.3%)
Week 46	40/125 (32.0%)	21/124 (16.9%)	61/249 (24.5%)
Week 49	35/125 (28.0%)	20/124 (16.1%)	55/249 (22.1%)
Week 52	34/125 (27.2%)	24/124 (19.4%)	58/249 (23.3%)
Week 55	33/125 (26.4%)	20/124 (16.1%)	53/249 (21.3%)
Week 58	31/125 (24.8%)	18/124 (14.5%)	49/249 (19.7%)
Week 61	27/125 (21.6%)	17/124 (13.7%)	44/249 (17.7%)
Week 64	28/125 (22.4%)	18/124 (14.5%)	46/249 (18.5%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 67	28/125 (22.4%)	14/124 (11.3%)	42/249 (16.9%)
Week 70	26/125 (20.8%)	13/124 (10.5%)	39/249 (15.7%)
Week 73	24/125 (19.2%)	13/124 (10.5%)	37/249 (14.9%)
Week 76	19/125 (15.2%)	10/124 (8.1%)	29/249 (11.6%)
Week 79	16/125 (12.8%)	10/124 (8.1%)	26/249 (10.4%)
Week 82	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 85	11/125 (8.8%)	7/124 (5.6%)	18/249 (7.2%)
Week 88	9/125 (7.2%)	8/124 (6.5%)	17/249 (6.8%)
Week 91	8/125 (6.4%)	6/124 (4.8%)	14/249 (5.6%)
Week 94	7/125 (5.6%)	6/124 (4.8%)	13/249 (5.2%)
Week 97	7/125 (5.6%)	7/124 (5.6%)	14/249 (5.6%)
Week 100	5/125 (4.0%)	5/124 (4.0%)	10/249 (4.0%)
Week 103	4/125 (3.2%)	5/124 (4.0%)	9/249 (3.6%)
Week 106	5/125 (4.0%)	5/124 (4.0%)	10/249 (4.0%)
Week 109	4/125 (3.2%)	5/124 (4.0%)	9/249 (3.6%)
Week 112	4/125 (3.2%)	2/124 (1.6%)	6/249 (2.4%)
Week 115	4/125 (3.2%)	0/124 (0.0%)	4/249 (1.6%)
Week 118	3/125 (2.4%)	2/124 (1.6%)	5/249 (2.0%)
Week 121	3/125 (2.4%)	1/124 (0.8%)	4/249 (1.6%)
Week 124	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 136	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 139	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 142	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 145	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 148	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 151	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
End of Treatment	60/125 (48.0%)	77/124 (62.1%)	137/249 (55.0%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ITT = intent-to-treat.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.2.2
Available Data Rate for the EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/125 (84.0%)	108/124 (87.1%)	213/249 (85.5%)
Week 7	97/125 (77.6%)	93/124 (75.0%)	190/249 (76.3%)
Week 10	91/125 (72.8%)	90/124 (72.6%)	181/249 (72.7%)
Week 13	84/125 (67.2%)	87/124 (70.2%)	171/249 (68.7%)
Week 16	82/125 (65.6%)	72/124 (58.1%)	154/249 (61.8%)
Week 19	85/125 (68.0%)	79/124 (63.7%)	164/249 (65.9%)
Week 22	71/125 (56.8%)	66/124 (53.2%)	137/249 (55.0%)
Week 25	62/125 (49.6%)	57/124 (46.0%)	119/249 (47.8%)
Week 28	63/125 (50.4%)	49/124 (39.5%)	112/249 (45.0%)
Week 31	60/125 (48.0%)	38/124 (30.6%)	98/249 (39.4%)
Week 34	53/125 (42.4%)	44/124 (35.5%)	97/249 (39.0%)
Week 37	48/125 (38.4%)	32/124 (25.8%)	80/249 (32.1%)
Week 40	46/125 (36.8%)	31/124 (25.0%)	77/249 (30.9%)
Week 43	34/125 (27.2%)	28/124 (22.6%)	62/249 (24.9%)
Week 46	39/125 (31.2%)	22/124 (17.7%)	61/249 (24.5%)
Week 49	34/125 (27.2%)	20/124 (16.1%)	54/249 (21.7%)
Week 52	34/125 (27.2%)	24/124 (19.4%)	58/249 (23.3%)
Week 55	32/125 (25.6%)	20/124 (16.1%)	52/249 (20.9%)
Week 58	30/125 (24.0%)	18/124 (14.5%)	48/249 (19.3%)
Week 61	26/125 (20.8%)	17/124 (13.7%)	43/249 (17.3%)
Week 64	27/125 (21.6%)	18/124 (14.5%)	45/249 (18.1%)
Week 67	27/125 (21.6%)	14/124 (11.3%)	41/249 (16.5%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 70	26/125 (20.8%)	13/124 (10.5%)	39/249 (15.7%)
Week 73	23/125 (18.4%)	13/124 (10.5%)	36/249 (14.5%)
Week 76	18/125 (14.4%)	10/124 (8.1%)	28/249 (11.2%)
Week 79	15/125 (12.0%)	10/124 (8.1%)	25/249 (10.0%)
Week 82	15/125 (12.0%)	7/124 (5.6%)	22/249 (8.8%)
Week 85	10/125 (8.0%)	7/124 (5.6%)	17/249 (6.8%)
Week 88	8/125 (6.4%)	8/124 (6.5%)	16/249 (6.4%)
Week 91	7/125 (5.6%)	6/124 (4.8%)	13/249 (5.2%)
Week 94	7/125 (5.6%)	6/124 (4.8%)	13/249 (5.2%)
Week 97	6/125 (4.8%)	7/124 (5.6%)	13/249 (5.2%)
Week 100	5/125 (4.0%)	5/124 (4.0%)	10/249 (4.0%)
Week 103	4/125 (3.2%)	5/124 (4.0%)	9/249 (3.6%)
Week 106	5/125 (4.0%)	5/124 (4.0%)	10/249 (4.0%)
Week 109	4/125 (3.2%)	5/124 (4.0%)	9/249 (3.6%)
Week 112	4/125 (3.2%)	2/124 (1.6%)	6/249 (2.4%)
Week 115	4/125 (3.2%)	0/124 (0.0%)	4/249 (1.6%)
Week 118	3/125 (2.4%)	2/124 (1.6%)	5/249 (2.0%)
Week 121	3/125 (2.4%)	1/124 (0.8%)	4/249 (1.6%)
Week 124	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 136	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 139	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 142	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 145	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 148	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 151	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
End of Treatment	61/125 (48.8%)	76/124 (61.3%)	137/249 (55.0%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer Module Questionnaire; ITT = intent-to-treat.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.2.3
Available Data Rate for the EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/125 (84.0%)	106/124 (85.5%)	211/249 (84.7%)
Week 7	97/125 (77.6%)	93/124 (75.0%)	190/249 (76.3%)
Week 10	91/125 (72.8%)	90/124 (72.6%)	181/249 (72.7%)
Week 13	84/125 (67.2%)	87/124 (70.2%)	171/249 (68.7%)
Week 16	82/125 (65.6%)	72/124 (58.1%)	154/249 (61.8%)
Week 19	85/125 (68.0%)	79/124 (63.7%)	164/249 (65.9%)
Week 22	71/125 (56.8%)	66/124 (53.2%)	137/249 (55.0%)
Week 25	61/125 (48.8%)	57/124 (46.0%)	118/249 (47.4%)
Week 28	64/125 (51.2%)	49/124 (39.5%)	113/249 (45.4%)
Week 31	61/125 (48.8%)	38/124 (30.6%)	99/249 (39.8%)
Week 34	54/125 (43.2%)	44/124 (35.5%)	98/249 (39.4%)
Week 37	49/125 (39.2%)	32/124 (25.8%)	81/249 (32.5%)
Week 40	47/125 (37.6%)	31/124 (25.0%)	78/249 (31.3%)
Week 43	35/125 (28.0%)	28/124 (22.6%)	63/249 (25.3%)
Week 46	40/125 (32.0%)	21/124 (16.9%)	61/249 (24.5%)
Week 49	35/125 (28.0%)	20/124 (16.1%)	55/249 (22.1%)
Week 52	34/125 (27.2%)	24/124 (19.4%)	58/249 (23.3%)
Week 55	33/125 (26.4%)	20/124 (16.1%)	53/249 (21.3%)
Week 58	31/125 (24.8%)	18/124 (14.5%)	49/249 (19.7%)
Week 61	27/125 (21.6%)	17/124 (13.7%)	44/249 (17.7%)
Week 64	28/125 (22.4%)	18/124 (14.5%)	46/249 (18.5%)
Week 67	28/125 (22.4%)	14/124 (11.3%)	42/249 (16.9%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 70	26/125 (20.8%)	13/124 (10.5%)	39/249 (15.7%)
Week 73	24/125 (19.2%)	13/124 (10.5%)	37/249 (14.9%)
Week 76	19/125 (15.2%)	10/124 (8.1%)	29/249 (11.6%)
Week 79	16/125 (12.8%)	10/124 (8.1%)	26/249 (10.4%)
Week 82	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 85	11/125 (8.8%)	7/124 (5.6%)	18/249 (7.2%)
Week 88	9/125 (7.2%)	8/124 (6.5%)	17/249 (6.8%)
Week 91	8/125 (6.4%)	6/124 (4.8%)	14/249 (5.6%)
Week 94	7/125 (5.6%)	6/124 (4.8%)	13/249 (5.2%)
Week 97	7/125 (5.6%)	7/124 (5.6%)	14/249 (5.6%)
Week 100	5/125 (4.0%)	5/124 (4.0%)	10/249 (4.0%)
Week 103	4/125 (3.2%)	5/124 (4.0%)	9/249 (3.6%)
Week 106	5/125 (4.0%)	5/124 (4.0%)	10/249 (4.0%)
Week 109	4/125 (3.2%)	5/124 (4.0%)	9/249 (3.6%)
Week 112	4/125 (3.2%)	2/124 (1.6%)	6/249 (2.4%)
Week 115	4/125 (3.2%)	0/124 (0.0%)	4/249 (1.6%)
Week 118	3/125 (2.4%)	2/124 (1.6%)	5/249 (2.0%)
Week 121	3/125 (2.4%)	1/124 (0.8%)	4/249 (1.6%)
Week 124	3/125 (2.4%)	0/124 (0.0%)	3/249 (1.2%)
Week 127	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 130	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 133	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 136	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 139	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 142	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 145	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 148	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 151	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
End of Treatment	59/125 (47.2%)	76/124 (61.3%)	135/249 (54.2%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; VAS = Visual analogue scale.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.2.4
Available Data Rate for the PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 13	62/125 (49.6%)	56/124 (45.2%)	118/249 (47.4%)
Week 16	79/125 (63.2%)	68/124 (54.8%)	147/249 (59.0%)
Week 19	84/125 (67.2%)	75/124 (60.5%)	159/249 (63.9%)
Week 22	71/125 (56.8%)	65/124 (52.4%)	136/249 (54.6%)
Week 25	63/125 (50.4%)	57/124 (46.0%)	120/249 (48.2%)
Week 28	32/125 (25.6%)	40/124 (32.3%)	72/249 (28.9%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; PGIC = Patient Global Impression of Change.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.2.5
Available Data Rate for the PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	119/125 (95.2%)	121/124 (97.6%)	240/249 (96.4%)
Week 13	62/125 (49.6%)	56/124 (45.2%)	118/249 (47.4%)
Week 16	79/125 (63.2%)	68/124 (54.8%)	147/249 (59.0%)
Week 19	84/125 (67.2%)	75/124 (60.5%)	159/249 (63.9%)
Week 22	71/125 (56.8%)	65/124 (52.4%)	136/249 (54.6%)
Week 25	63/125 (50.4%)	57/124 (46.0%)	120/249 (48.2%)
Week 28	32/125 (25.6%)	40/124 (32.3%)	72/249 (28.9%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; PGIS = Patient Global Impression of Severity.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.3.1
Modified Available Data Rate for the EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	123/125 (98.4%)	121/124 (97.6%)	244/249 (98.0%)
Week 4	106/123 (86.2%)	110/124 (88.7%)	216/247 (87.4%)
Week 7	99/120 (82.5%)	94/123 (76.4%)	193/243 (79.4%)
Week 10	94/119 (79.0%)	91/122 (74.6%)	185/241 (76.8%)
Week 13	85/119 (71.4%)	87/121 (71.9%)	172/240 (71.7%)
Week 16	82/116 (70.7%)	72/120 (60.0%)	154/236 (65.3%)
Week 19	84/112 (75.0%)	79/117 (67.5%)	163/229 (71.2%)
Week 22	72/107 (67.3%)	66/115 (57.4%)	138/222 (62.2%)
Week 25	61/107 (57.0%)	57/111 (51.4%)	118/218 (54.1%)
Week 28	63/105 (60.0%)	49/111 (44.1%)	112/216 (51.9%)
Week 31	61/104 (58.7%)	38/107 (35.5%)	99/211 (46.9%)
Week 34	55/102 (53.9%)	45/105 (42.9%)	100/207 (48.3%)
Week 37	49/102 (48.0%)	32/104 (30.8%)	81/206 (39.3%)
Week 40	47/101 (46.5%)	31/103 (30.1%)	78/204 (38.2%)
Week 43	35/100 (35.0%)	28/100 (28.0%)	63/200 (31.5%)
Week 46	40/97 (41.2%)	21/99 (21.2%)	61/196 (31.1%)
Week 49	35/95 (36.8%)	20/96 (20.8%)	55/191 (28.8%)
Week 52	34/89 (38.2%)	24/92 (26.1%)	58/181 (32.0%)
Week 55	33/89 (37.1%)	20/90 (22.2%)	53/179 (29.6%)
Week 58	31/86 (36.0%)	18/89 (20.2%)	49/175 (28.0%)
Week 61	27/84 (32.1%)	17/87 (19.5%)	44/171 (25.7%)
Week 64	28/84 (33.3%)	18/86 (20.9%)	46/170 (27.1%)
Week 67	28/81 (34.6%)	14/81 (17.3%)	42/162 (25.9%)
Week 70	26/78 (33.3%)	13/79 (16.5%)	39/157 (24.8%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 73	24/74 (32.4%)	13/78 (16.7%)	37/152 (24.3%)
Week 76	19/72 (26.4%)	10/76 (13.2%)	29/148 (19.6%)
Week 79	16/67 (23.9%)	10/74 (13.5%)	26/141 (18.4%)
Week 82	16/65 (24.6%)	7/71 (9.9%)	23/136 (16.9%)
Week 85	11/62 (17.7%)	7/69 (10.1%)	18/131 (13.7%)
Week 88	9/62 (14.5%)	8/65 (12.3%)	17/127 (13.4%)
Week 91	8/61 (13.1%)	6/64 (9.4%)	14/125 (11.2%)
Week 94	7/60 (11.7%)	6/63 (9.5%)	13/123 (10.6%)
Week 97	7/58 (12.1%)	7/62 (11.3%)	14/120 (11.7%)
Week 100	5/57 (8.8%)	5/60 (8.3%)	10/117 (8.5%)
Week 103	4/56 (7.1%)	5/58 (8.6%)	9/114 (7.9%)
Week 106	5/56 (8.9%)	5/58 (8.6%)	10/114 (8.8%)
Week 109	4/56 (7.1%)	5/58 (8.6%)	9/114 (7.9%)
Week 112	4/55 (7.3%)	2/57 (3.5%)	6/112 (5.4%)
Week 115	4/55 (7.3%)	0/57 (0.0%)	4/112 (3.6%)
Week 118	3/54 (5.6%)	2/56 (3.6%)	5/110 (4.5%)
Week 121	3/54 (5.6%)	1/55 (1.8%)	4/109 (3.7%)
Week 124	1/54 (1.9%)	0/55 (0.0%)	1/109 (0.9%)
Week 136	2/53 (3.8%)	0/55 (0.0%)	2/108 (1.9%)
Week 139	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 142	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 145	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 148	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 151	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
End of Treatment	60/97 (61.9%)	77/112 (68.8%)	137/209 (65.6%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ITT = intent-to-treat.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.3.2
Modified Available Data Rate for the EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/123 (85.4%)	108/124 (87.1%)	213/247 (86.2%)
Week 7	97/120 (80.8%)	93/123 (75.6%)	190/243 (78.2%)
Week 10	91/119 (76.5%)	90/122 (73.8%)	181/241 (75.1%)
Week 13	84/119 (70.6%)	87/121 (71.9%)	171/240 (71.3%)
Week 16	82/116 (70.7%)	72/120 (60.0%)	154/236 (65.3%)
Week 19	85/112 (75.9%)	79/117 (67.5%)	164/229 (71.6%)
Week 22	71/107 (66.4%)	66/115 (57.4%)	137/222 (61.7%)
Week 25	62/107 (57.9%)	57/111 (51.4%)	119/218 (54.6%)
Week 28	63/105 (60.0%)	49/111 (44.1%)	112/216 (51.9%)
Week 31	60/104 (57.7%)	38/107 (35.5%)	98/211 (46.4%)
Week 34	53/102 (52.0%)	44/105 (41.9%)	97/207 (46.9%)
Week 37	48/102 (47.1%)	32/104 (30.8%)	80/206 (38.8%)
Week 40	46/101 (45.5%)	31/103 (30.1%)	77/204 (37.7%)
Week 43	34/100 (34.0%)	28/100 (28.0%)	62/200 (31.0%)
Week 46	39/97 (40.2%)	22/99 (22.2%)	61/196 (31.1%)
Week 49	34/95 (35.8%)	20/96 (20.8%)	54/191 (28.3%)
Week 52	34/89 (38.2%)	24/92 (26.1%)	58/181 (32.0%)
Week 55	32/89 (36.0%)	20/90 (22.2%)	52/179 (29.1%)
Week 58	30/86 (34.9%)	18/89 (20.2%)	48/175 (27.4%)
Week 61	26/84 (31.0%)	17/87 (19.5%)	43/171 (25.1%)
Week 64	27/84 (32.1%)	18/86 (20.9%)	45/170 (26.5%)
Week 67	27/81 (33.3%)	14/81 (17.3%)	41/162 (25.3%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 70	26/78 (33.3%)	13/79 (16.5%)	39/157 (24.8%)
Week 73	23/74 (31.1%)	13/78 (16.7%)	36/152 (23.7%)
Week 76	18/72 (25.0%)	10/76 (13.2%)	28/148 (18.9%)
Week 79	15/67 (22.4%)	10/74 (13.5%)	25/141 (17.7%)
Week 82	15/65 (23.1%)	7/71 (9.9%)	22/136 (16.2%)
Week 85	10/62 (16.1%)	7/69 (10.1%)	17/131 (13.0%)
Week 88	8/62 (12.9%)	8/65 (12.3%)	16/127 (12.6%)
Week 91	7/61 (11.5%)	6/64 (9.4%)	13/125 (10.4%)
Week 94	7/60 (11.7%)	6/63 (9.5%)	13/123 (10.6%)
Week 97	6/58 (10.3%)	7/62 (11.3%)	13/120 (10.8%)
Week 100	5/57 (8.8%)	5/60 (8.3%)	10/117 (8.5%)
Week 103	4/56 (7.1%)	5/58 (8.6%)	9/114 (7.9%)
Week 106	5/56 (8.9%)	5/58 (8.6%)	10/114 (8.8%)
Week 109	4/56 (7.1%)	5/58 (8.6%)	9/114 (7.9%)
Week 112	4/55 (7.3%)	2/57 (3.5%)	6/112 (5.4%)
Week 115	4/55 (7.3%)	0/57 (0.0%)	4/112 (3.6%)
Week 118	3/54 (5.6%)	2/56 (3.6%)	5/110 (4.5%)
Week 121	3/54 (5.6%)	1/55 (1.8%)	4/109 (3.7%)
Week 124	1/54 (1.9%)	0/55 (0.0%)	1/109 (0.9%)
Week 136	2/53 (3.8%)	0/55 (0.0%)	2/108 (1.9%)
Week 139	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 142	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 145	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 148	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 151	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
End of Treatment	61/97 (62.9%)	76/112 (67.9%)	137/209 (65.6%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer Module Questionnaire; ITT = intent-to-treat.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.3.3
Modified Available Data Rate for the EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/123 (85.4%)	106/124 (85.5%)	211/247 (85.4%)
Week 7	97/120 (80.8%)	93/123 (75.6%)	190/243 (78.2%)
Week 10	91/119 (76.5%)	90/122 (73.8%)	181/241 (75.1%)
Week 13	84/119 (70.6%)	87/121 (71.9%)	171/240 (71.3%)
Week 16	82/116 (70.7%)	72/120 (60.0%)	154/236 (65.3%)
Week 19	85/112 (75.9%)	79/117 (67.5%)	164/229 (71.6%)
Week 22	71/107 (66.4%)	66/115 (57.4%)	137/222 (61.7%)
Week 25	61/107 (57.0%)	57/111 (51.4%)	118/218 (54.1%)
Week 28	64/105 (61.0%)	49/111 (44.1%)	113/216 (52.3%)
Week 31	61/104 (58.7%)	38/107 (35.5%)	99/211 (46.9%)
Week 34	54/102 (52.9%)	44/105 (41.9%)	98/207 (47.3%)
Week 37	49/102 (48.0%)	32/104 (30.8%)	81/206 (39.3%)
Week 40	47/101 (46.5%)	31/103 (30.1%)	78/204 (38.2%)
Week 43	35/100 (35.0%)	28/100 (28.0%)	63/200 (31.5%)
Week 46	40/97 (41.2%)	21/99 (21.2%)	61/196 (31.1%)
Week 49	35/95 (36.8%)	20/96 (20.8%)	55/191 (28.8%)
Week 52	34/89 (38.2%)	24/92 (26.1%)	58/181 (32.0%)
Week 55	33/89 (37.1%)	20/90 (22.2%)	53/179 (29.6%)
Week 58	31/86 (36.0%)	18/89 (20.2%)	49/175 (28.0%)
Week 61	27/84 (32.1%)	17/87 (19.5%)	44/171 (25.7%)
Week 64	28/84 (33.3%)	18/86 (20.9%)	46/170 (27.1%)
Week 67	28/81 (34.6%)	14/81 (17.3%)	42/162 (25.9%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 70	26/78 (33.3%)	13/79 (16.5%)	39/157 (24.8%)
Week 73	24/74 (32.4%)	13/78 (16.7%)	37/152 (24.3%)
Week 76	19/72 (26.4%)	10/76 (13.2%)	29/148 (19.6%)
Week 79	16/67 (23.9%)	10/74 (13.5%)	26/141 (18.4%)
Week 82	16/65 (24.6%)	7/71 (9.9%)	23/136 (16.9%)
Week 85	11/62 (17.7%)	7/69 (10.1%)	18/131 (13.7%)
Week 88	9/62 (14.5%)	8/65 (12.3%)	17/127 (13.4%)
Week 91	8/61 (13.1%)	6/64 (9.4%)	14/125 (11.2%)
Week 94	7/60 (11.7%)	6/63 (9.5%)	13/123 (10.6%)
Week 97	7/58 (12.1%)	7/62 (11.3%)	14/120 (11.7%)
Week 100	5/57 (8.8%)	5/60 (8.3%)	10/117 (8.5%)
Week 103	4/56 (7.1%)	5/58 (8.6%)	9/114 (7.9%)
Week 106	5/56 (8.9%)	5/58 (8.6%)	10/114 (8.8%)
Week 109	4/56 (7.1%)	5/58 (8.6%)	9/114 (7.9%)
Week 112	4/55 (7.3%)	2/57 (3.5%)	6/112 (5.4%)
Week 115	4/55 (7.3%)	0/57 (0.0%)	4/112 (3.6%)
Week 118	3/54 (5.6%)	2/56 (3.6%)	5/110 (4.5%)
Week 121	3/54 (5.6%)	1/55 (1.8%)	4/109 (3.7%)
Week 124	3/54 (5.6%)	0/55 (0.0%)	3/109 (2.8%)
Week 127	1/54 (1.9%)	0/55 (0.0%)	1/109 (0.9%)
Week 130	2/53 (3.8%)	0/55 (0.0%)	2/108 (1.9%)
Week 133	2/53 (3.8%)	0/55 (0.0%)	2/108 (1.9%)
Week 136	2/53 (3.8%)	0/55 (0.0%)	2/108 (1.9%)
Week 139	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 142	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 145	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
Week 148	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 151	1/53 (1.9%)	0/55 (0.0%)	1/108 (0.9%)
End of Treatment	59/97 (60.8%)	76/112 (67.9%)	135/209 (64.6%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; VAS = Visual analogue scale.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.3.4
Modified Available Data Rate for the PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 13	62/119 (52.1%)	56/121 (46.3%)	118/240 (49.2%)
Week 16	79/116 (68.1%)	68/120 (56.7%)	147/236 (62.3%)
Week 19	84/112 (75.0%)	75/117 (64.1%)	159/229 (69.4%)
Week 22	71/107 (66.4%)	65/115 (56.5%)	136/222 (61.3%)
Week 25	63/107 (58.9%)	57/111 (51.4%)	120/218 (55.0%)
Week 28	32/105 (30.5%)	40/111 (36.0%)	72/216 (33.3%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; PGIC = Patient Global Impression of Change.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.3.3.5
Modified Available Data Rate for the PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	119/125 (95.2%)	121/124 (97.6%)	240/249 (96.4%)
Week 13	62/119 (52.1%)	56/121 (46.3%)	118/240 (49.2%)
Week 16	79/116 (68.1%)	68/120 (56.7%)	147/236 (62.3%)
Week 19	84/112 (75.0%)	75/117 (64.1%)	159/229 (69.4%)
Week 22	71/107 (66.4%)	65/115 (56.5%)	136/222 (61.3%)
Week 25	63/107 (58.9%)	57/111 (51.4%)	120/218 (55.0%)
Week 28	32/105 (30.5%)	40/111 (36.0%)	72/216 (33.3%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; PGIS = Patient Global Impression of Severity.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 3.3.2.1
Distribution of Responses to PGIC by Visit
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Item	Visit	Response Level	SG (N=125)	TPC (N=124)	Overall (N=249)
PGIC	Week 13		N=62	N=56	N=118
		Very Much Improved	7 (11.3%)	8 (14.3%)	15 (12.7%)
		Much Improved	24 (38.7%)	20 (35.7%)	44 (37.3%)
		Minimally Improved	12 (19.4%)	14 (25.0%)	26 (22.0%)
		No Change	12 (19.4%)	7 (12.5%)	19 (16.1%)
		Minimally Worsened	6 (9.7%)	5 (8.9%)	11 (9.3%)
		Much Worsened	1 (1.6%)	2 (3.6%)	3 (2.5%)
		Very Much Worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 16		N=79	N=68	N=147
		Very Much Improved	13 (16.5%)	8 (11.8%)	21 (14.3%)
		Much Improved	24 (30.4%)	17 (25.0%)	41 (27.9%)
		Minimally Improved	20 (25.3%)	16 (23.5%)	36 (24.5%)
		No Change	10 (12.7%)	13 (19.1%)	23 (15.6%)
		Minimally Worsened	10 (12.7%)	11 (16.2%)	21 (14.3%)
		Much Worsened	2 (2.5%)	3 (4.4%)	5 (3.4%)
		Very Much Worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 19		N=84	N=75	N=159
		Very Much Improved	9 (10.7%)	8 (10.7%)	17 (10.7%)
		Much Improved	24 (28.6%)	24 (32.0%)	48 (30.2%)
		Minimally Improved	27 (32.1%)	21 (28.0%)	48 (30.2%)
		No Change	16 (19.0%)	14 (18.7%)	30 (18.9%)
		Minimally Worsened	5 (6.0%)	5 (6.7%)	10 (6.3%)
		Much Worsened	3 (3.6%)	2 (2.7%)	5 (3.1%)
		Very Much Worsened	0 (0.0%)	1 (1.3%)	1 (0.6%)
	Week 22		N=71	N=65	N=136
		Very Much Improved	15 (21.1%)	8 (12.3%)	23 (16.9%)
		Much Improved	18 (25.4%)	18 (27.7%)	36 (26.5%)
		Minimally Improved	17 (23.9%)	16 (24.6%)	33 (24.3%)
		No Change	13 (18.3%)	16 (24.6%)	29 (21.3%)
		Minimally Worsened	4 (5.6%)	5 (7.7%)	9 (6.6%)
		Much Worsened	4 (5.6%)	2 (3.1%)	6 (4.4%)
		Very Much Worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 25		N=63	N=57	N=120
		Very Much Improved	7 (11.1%)	4 (7.0%)	11 (9.2%)
		Much Improved	23 (36.5%)	20 (35.1%)	43 (35.8%)
		Minimally Improved	17 (27.0%)	12 (21.1%)	29 (24.2%)
		No Change	10 (15.9%)	11 (19.3%)	21 (17.5%)
		Minimally Worsened	4 (6.3%)	5 (8.8%)	9 (7.5%)
		Much Worsened	2 (3.2%)	4 (7.0%)	6 (5.0%)
		Very Much Worsened	0 (0.0%)	1 (1.8%)	1 (0.8%)
	Week 28		N=32	N=40	N=72
		Very Much Improved	5 (15.6%)	6 (15.0%)	11 (15.3%)

Item	Visit	Response Level	SG (N=125)	TPC (N=124)	Overall (N=249)
		Much Improved	14 (43.8%)	14 (35.0%)	28 (38.9%)
		Minimally Improved	4 (12.5%)	7 (17.5%)	11 (15.3%)
		No Change	5 (15.6%)	4 (10.0%)	9 (12.5%)
		Minimally Worsened	3 (9.4%)	6 (15.0%)	9 (12.5%)
		Much Worsened	0 (0.0%)	3 (7.5%)	3 (4.2%)
		Very Much Worsened	1 (3.1%)	0 (0.0%)	1 (1.4%)

PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 3.3.2.2
Distribution of Responses to PGIS by Visit
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Item	Visit	Response Level	SG (N=125)	TPC (N=124)	Overall (N=249)
PGIS	Baseline (Week 1)		N=119	N=121	N=240
		Very Poor	5 (4.2%)	5 (4.1%)	10 (4.2%)
		Poor	10 (8.4%)	21 (17.4%)	31 (12.9%)
		Fair	48 (40.3%)	41 (33.9%)	89 (37.1%)
		Good	43 (36.1%)	45 (37.2%)	88 (36.7%)
		Excellent	13 (10.9%)	9 (7.4%)	22 (9.2%)
	Week 13		N=62	N=56	N=118
		Very Poor	0 (0.0%)	2 (3.6%)	2 (1.7%)
		Poor	1 (1.6%)	7 (12.5%)	8 (6.8%)
		Fair	30 (48.4%)	16 (28.6%)	46 (39.0%)
		Good	27 (43.5%)	24 (42.9%)	51 (43.2%)
		Excellent	4 (6.5%)	7 (12.5%)	11 (9.3%)
	Week 16		N=79	N=68	N=147
		Very Poor	1 (1.3%)	0 (0.0%)	1 (0.7%)
		Poor	5 (6.3%)	5 (7.4%)	10 (6.8%)
		Fair	42 (53.2%)	41 (60.3%)	83 (56.5%)
		Good	24 (30.4%)	18 (26.5%)	42 (28.6%)
		Excellent	7 (8.9%)	4 (5.9%)	11 (7.5%)
	Week 19		N=84	N=75	N=159
		Very Poor	1 (1.2%)	0 (0.0%)	1 (0.6%)
		Poor	3 (3.6%)	6 (8.0%)	9 (5.7%)
		Fair	45 (53.6%)	38 (50.7%)	83 (52.2%)
		Good	29 (34.5%)	24 (32.0%)	53 (33.3%)
		Excellent	6 (7.1%)	7 (9.3%)	13 (8.2%)
	Week 22		N=71	N=65	N=136
		Very Poor	1 (1.4%)	1 (1.5%)	2 (1.5%)
		Poor	4 (5.6%)	8 (12.3%)	12 (8.8%)
		Fair	27 (38.0%)	26 (40.0%)	53 (39.0%)
		Good	35 (49.3%)	27 (41.5%)	62 (45.6%)
		Excellent	4 (5.6%)	3 (4.6%)	7 (5.1%)
	Week 25		N=63	N=57	N=120
		Very Poor	0 (0.0%)	3 (5.3%)	3 (2.5%)
		Poor	1 (1.6%)	7 (12.3%)	8 (6.7%)
		Fair	32 (50.8%)	24 (42.1%)	56 (46.7%)
		Good	27 (42.9%)	19 (33.3%)	46 (38.3%)
		Excellent	3 (4.8%)	4 (7.0%)	7 (5.8%)
	Week 28		N=32	N=40	N=72
		Very Poor	1 (3.1%)	0 (0.0%)	1 (1.4%)
		Poor	2 (6.3%)	5 (12.5%)	7 (9.7%)
		Fair	12 (37.5%)	20 (50.0%)	32 (44.4%)
		Good	12 (37.5%)	13 (32.5%)	25 (34.7%)

Item	Visit	Response Level	SG (N=125)	TPC (N=124)	Overall (N=249)
		Excellent	5 (15.6%)	2 (5.0%)	7 (9.7%)

PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_chg_item.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 5.3.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	70 (56.0%)	73 (58.9%)
The number (%) of patients censored [a]	55 (44.0%)	51 (41.1%)
Not at risk at baseline n (%) [a]	2 (1.6%)	4 (3.2%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	9 (7.2%)	3 (2.4%)
Premature treatment discontinuation n (%) [a]	27 (21.6%)	36 (29.0%)
Others n (%) [a]	9 (7.2%)	2 (1.6%)
Median time to event (95% CI) [b]	4.1 (2.1, 6.3)	3.3 (2.1, 4.9)
Q1	0.8 (0.8, 1.5)	0.9 (0.8, 1.4)
Q3	NE (9.8, NE)	13.2 (6.9, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	53.0% (43.2%, 61.8%)	53.3% (43.6%, 62.1%)
by 6 Months, % (95% CI)	45.3% (35.5%, 54.5%)	35.3% (25.8%, 44.8%)
by 12 Months, % (95% CI)	32.8% (23.2%, 42.8%)	30.9% (21.0%, 41.3%)
by 18 Months, % (95% CI)	27.8% (17.8%, 38.6%)	17.7% (7.2%, 31.9%)
by 24 Months, % (95% CI)	27.8% (17.8%, 38.6%)	17.7% (7.2%, 31.9%)
Nominal p-value for stratified log-rank test [c]	0.649	
HR (95% CI) [d]	0.89 (0.64, 1.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 5.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	58 (46.4%)	69 (55.6%)
The number (%) of patients censored [a]	67 (53.6%)	55 (44.4%)
Not at risk at baseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	9 (7.2%)	7 (5.6%)
Premature treatment discontinuation n (%) [a]	40 (32.0%)	39 (31.5%)
Others n (%) [a]	8 (6.4%)	2 (1.6%)
Median time to event (95% CI) [b]	7.5 (3.6, 20.1)	4.9 (2.8, 8.3)
Q1	1.4 (0.9, 2.2)	1.4 (0.9, 1.6)
Q3	NE (20.1, NE)	19.4 (12.4, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	64.3% (54.7%, 72.4%)	58.6% (48.8%, 67.1%)
by 6 Months, % (95% CI)	57.1% (47.2%, 65.8%)	43.6% (33.8%, 53.0%)
by 12 Months, % (95% CI)	44.0% (33.0%, 54.4%)	36.4% (26.2%, 46.7%)
by 18 Months, % (95% CI)	41.1% (29.5%, 52.3%)	26.1% (14.7%, 39.0%)
by 24 Months, % (95% CI)	25.7% (9.8%, 45.1%)	20.9% (9.3%, 35.5%)
Nominal p-value for stratified log-rank test [c]	0.238	
HR (95% CI) [d]	0.78 (0.55, 1.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 5.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	72 (57.6%)	84 (67.7%)
The number (%) of patients censored [a]	53 (42.4%)	40 (32.3%)
Not at risk at baseline n (%) [a]	5 (4.0%)	3 (2.4%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	9 (7.2%)	3 (2.4%)
Premature treatment discontinuation n (%) [a]	25 (20.0%)	27 (21.8%)
Others n (%) [a]	5 (4.0%)	1 (0.8%)
Median time to event (95% CI) [b]	1.7 (1.4, 2.8)	3.5 (1.7, 5.0)
Q1	0.8 (0.8, 1.0)	0.9 (0.8, 1.0)
Q3	20.8 (8.4, NE)	7.8 (5.6, 10.6)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	40.2% (30.8%, 49.3%)	51.9% (42.2%, 60.7%)
by 6 Months, % (95% CI)	36.8% (27.6%, 46.0%)	32.3% (23.5%, 41.5%)
by 12 Months, % (95% CI)	31.3% (21.8%, 41.3%)	14.1% (6.9%, 23.8%)
by 18 Months, % (95% CI)	27.8% (17.6%, 39.0%)	14.1% (6.9%, 23.8%)
by 24 Months, % (95% CI)	20.9% (8.8%, 36.4%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.959	
HR (95% CI) [d]	0.98 (0.71, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	59 (47.2%)	56 (45.2%)
The number (%) of patients censored [a]	66 (52.8%)	68 (54.8%)
Not at risk at baseline n (%) [a]	0 (0.0%)	4 (3.2%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	8 (6.4%)	5 (4.0%)
Premature treatment discontinuation n (%) [a]	43 (34.4%)	52 (41.9%)
Others n (%) [a]	7 (5.6%)	1 (0.8%)
Median time to event (95% CI) [b]	7.8 (4.4, 11.4)	9.1 (4.7, 12.3)
Q1	2.8 (1.5, 3.4)	3.0 (1.6, 3.8)
Q3	NE (11.8, NE)	14.0 (10.8, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	73.1% (63.8%, 80.4%)	76.6% (67.3%, 83.6%)
by 6 Months, % (95% CI)	55.6% (45.2%, 64.7%)	54.9% (44.2%, 64.4%)
by 12 Months, % (95% CI)	35.9% (24.2%, 47.7%)	37.7% (24.0%, 51.4%)
by 18 Months, % (95% CI)	27.7% (16.2%, 40.4%)	7.5% (0.7%, 25.8%)
by 24 Months, % (95% CI)	27.7% (16.2%, 40.4%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.776	
HR (95% CI) [d]	1.01 (0.70, 1.47)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	69 (55.2%)	79 (63.7%)
The number (%) of patients censored [a]	56 (44.8%)	45 (36.3%)
Not at risk at baseline n (%) [a]	1 (0.8%)	0 (0.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	8 (6.4%)	5 (4.0%)
Premature treatment discontinuation n (%) [a]	32 (25.6%)	33 (26.6%)
Others n (%) [a]	6 (4.8%)	1 (0.8%)
Median time to event (95% CI) [b]	4.5 (2.8, 6.9)	2.9 (2.1, 4.1)
Q1	1.6 (1.0, 2.2)	1.0 (0.8, 1.7)
Q3	18.5 (9.8, NE)	11.8 (7.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	57.8% (47.9%, 66.5%)	49.2% (39.6%, 58.1%)
by 6 Months, % (95% CI)	42.7% (32.7%, 52.3%)	35.5% (26.5%, 44.5%)
by 12 Months, % (95% CI)	34.3% (24.2%, 44.7%)	23.9% (14.6%, 34.5%)
by 18 Months, % (95% CI)	25.4% (14.8%, 37.5%)	20.5% (11.1%, 32.0%)
by 24 Months, % (95% CI)	0.0% (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.164	
HR (95% CI) [d]	0.77 (0.55, 1.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	68 (54.4%)	77 (62.1%)
The number (%) of patients censored [a]	57 (45.6%)	47 (37.9%)
Not at risk at baseline n (%) [a]	5 (4.0%)	0 (0.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	8 (6.4%)	7 (5.6%)
Premature treatment discontinuation n (%) [a]	29 (23.2%)	33 (26.6%)
Others n (%) [a]	7 (5.6%)	1 (0.8%)
Median time to event (95% CI) [b]	2.8 (1.4, 7.5)	3.5 (2.2, 4.9)
Q1	0.8 (0.8, 1.0)	0.8 (0.8, 1.0)
Q3	21.5 (16.1, NE)	15.2 (5.8, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	49.1% (39.4%, 58.2%)	55.4% (45.8%, 64.0%)
by 6 Months, % (95% CI)	41.5% (31.9%, 50.8%)	33.5% (24.3%, 43.0%)
by 12 Months, % (95% CI)	38.3% (28.6%, 47.9%)	26.4% (17.2%, 36.5%)
by 18 Months, % (95% CI)	31.4% (20.1%, 43.4%)	22.0% (11.9%, 34.0%)
by 24 Months, % (95% CI)	23.6% (9.9%, 40.6%)	14.7% (4.3%, 31.1%)
Nominal p-value for stratified log-rank test [c]	0.452	
HR (95% CI) [d]	0.84 (0.60, 1.17)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	83 (66.4%)	92 (74.2%)
The number (%) of patients censored [a]	42 (33.6%)	32 (25.8%)
Not at risk at baseline n (%) [a]	2 (1.6%)	1 (0.8%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	8 (6.4%)	0 (0.0%)
Premature treatment discontinuation n (%) [a]	19 (15.2%)	23 (18.5%)
Others n (%) [a]	5 (4.0%)	2 (1.6%)
Median time to event (95% CI) [b]	1.4 (1.0, 1.8)	1.4 (1.0, 2.1)
Q1	0.8 (0.8, 0.8)	0.8 (0.8, 0.9)
Q3	9.8 (3.2, NE)	4.9 (3.5, 7.0)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	35.2% (26.4%, 44.0%)	37.8% (28.8%, 46.7%)
by 6 Months, % (95% CI)	28.0% (19.9%, 36.7%)	18.3% (11.1%, 26.8%)
by 12 Months, % (95% CI)	24.4% (16.2%, 33.5%)	9.2% (3.6%, 17.9%)
by 18 Months, % (95% CI)	24.4% (16.2%, 33.5%)	9.2% (3.6%, 17.9%)
by 24 Months, % (95% CI)	16.3% (5.3%, 32.6%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.565	
HR (95% CI) [d]	0.89 (0.66, 1.21)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	80 (64.0%)	79 (63.7%)
The number (%) of patients censored [a]	45 (36.0%)	45 (36.3%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	6 (4.8%)	7 (5.6%)
Premature treatment discontinuation n (%) [a]	27 (21.6%)	31 (25.0%)
Others n (%) [a]	3 (2.4%)	1 (0.8%)
Median time to event (95% CI) [b]	1.7 (1.4, 2.6)	1.7 (1.4, 3.1)
Q1	0.8 (0.8, 0.9)	0.8 (0.8, 1.0)
Q3	11.2 (3.5, NE)	19.6 (8.1, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	37.4% (28.4%, 46.3%)	41.4% (32.2%, 50.2%)
by 6 Months, % (95% CI)	30.6% (22.0%, 39.6%)	34.2% (25.4%, 43.1%)
by 12 Months, % (95% CI)	20.1% (11.0%, 31.1%)	26.2% (16.4%, 37.0%)
by 18 Months, % (95% CI)	20.1% (11.0%, 31.1%)	26.2% (16.4%, 37.0%)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.981	
HR (95% CI) [d]	1.01 (0.73, 1.39)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	58 (46.4%)	76 (61.3%)
The number (%) of patients censored [a]	67 (53.6%)	48 (38.7%)
Not at risk at baseline n (%) [a]	8 (6.4%)	5 (4.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	9 (7.2%)	2 (1.6%)
Premature treatment discontinuation n (%) [a]	35 (28.0%)	34 (27.4%)
Others n (%) [a]	7 (5.6%)	1 (0.8%)
Median time to event (95% CI) [b]	7.7 (2.5, 11.8)	2.8 (2.1, 5.1)
Q1	1.4 (0.8, 1.6)	1.1 (0.8, 1.6)
Q3	NE (15.5, NE)	10.9 (6.5, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	58.4% (48.2%, 67.3%)	48.0% (38.3%, 57.1%)
by 6 Months, % (95% CI)	53.6% (43.3%, 62.9%)	37.5% (28.2%, 46.8%)
by 12 Months, % (95% CI)	38.5% (27.1%, 49.8%)	22.7% (13.4%, 33.5%)
by 18 Months, % (95% CI)	28.3% (16.1%, 41.8%)	14.2% (5.2%, 27.5%)
by 24 Months, % (95% CI)	28.3% (16.1%, 41.8%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.166	
HR (95% CI) [d]	0.75 (0.53, 1.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	43 (34.4%)	65 (52.4%)
The number (%) of patients censored [a]	82 (65.6%)	59 (47.6%)
Not at risk at baseline n (%) [a]	1 (0.8%)	3 (2.4%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	10 (8.0%)	7 (5.6%)
Premature treatment discontinuation n (%) [a]	52 (41.6%)	42 (33.9%)
Others n (%) [a]	10 (8.0%)	1 (0.8%)
Median time to event (95% CI) [b]	15.5 (9.6, NE)	4.9 (3.3, 6.7)
Q1	2.8 (1.4, 6.7)	1.4 (0.9, 2.1)
Q3	NE (NE, NE)	NE (9.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	73.7% (64.4%, 81.0%)	61.7% (51.9%, 70.1%)
by 6 Months, % (95% CI)	66.8% (56.7%, 75.0%)	44.5% (34.4%, 54.1%)
by 12 Months, % (95% CI)	55.2% (43.1%, 65.7%)	33.6% (23.1%, 44.5%)
by 18 Months, % (95% CI)	49.6% (36.4%, 61.4%)	30.3% (19.2%, 42.0%)
by 24 Months, % (95% CI)	49.6% (36.4%, 61.4%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.003	
HR (95% CI) [d]	0.53 (0.36, 0.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	59 (47.2%)	67 (54.0%)
The number (%) of patients censored [a]	66 (52.8%)	57 (46.0%)
Not at risk at baseline n (%) [a]	6 (4.8%)	7 (5.6%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	9 (7.2%)	5 (4.0%)
Premature treatment discontinuation n (%) [a]	39 (31.2%)	37 (29.8%)
Others n (%) [a]	3 (2.4%)	2 (1.6%)
Median time to event (95% CI) [b]	5.3 (3.5, 10.8)	4.2 (3.3, 6.0)
Q1	1.4 (1.0, 2.3)	1.2 (0.9, 1.9)
Q3	18.0 (14.4, NE)	13.8 (7.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	63.7% (53.7%, 72.1%)	62.2% (52.2%, 70.7%)
by 6 Months, % (95% CI)	49.6% (39.1%, 59.2%)	41.2% (31.2%, 50.9%)
by 12 Months, % (95% CI)	37.3% (26.0%, 48.6%)	31.2% (21.2%, 41.7%)
by 18 Months, % (95% CI)	26.5% (12.7%, 42.5%)	22.3% (11.0%, 35.9%)
by 24 Months, % (95% CI)	19.9% (6.9%, 37.6%)	22.3% (11.0%, 35.9%)
Nominal p-value for stratified log-rank test [c]	0.278	
HR (95% CI) [d]	0.82 (0.57, 1.17)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	64 (51.2%)	68 (54.8%)
The number (%) of patients censored [a]	61 (48.8%)	56 (45.2%)
Not at risk at baseline n (%) [a]	1 (0.8%)	3 (2.4%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	11 (8.8%)	5 (4.0%)
Premature treatment discontinuation n (%) [a]	34 (27.2%)	40 (32.3%)
Others n (%) [a]	6 (4.8%)	2 (1.6%)
Median time to event (95% CI) [b]	3.4 (1.8, 11.8)	3.5 (2.1, 7.9)
Q1	0.9 (0.8, 1.4)	1.0 (0.8, 1.4)
Q3	NE (13.6, NE)	14.5 (11.1, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	53.1% (43.4%, 61.9%)	55.3% (45.5%, 64.1%)
by 6 Months, % (95% CI)	43.3% (33.6%, 52.6%)	43.2% (33.3%, 52.6%)
by 12 Months, % (95% CI)	39.1% (28.8%, 49.3%)	33.0% (21.4%, 45.1%)
by 18 Months, % (95% CI)	35.2% (23.7%, 46.9%)	16.5% (5.3%, 33.1%)
by 24 Months, % (95% CI)	35.2% (23.7%, 46.9%)	11.0% (2.3%, 27.6%)
Nominal p-value for stratified log-rank test [c]	0.759	
HR (95% CI) [d]	0.91 (0.65, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	67 (53.6%)	72 (58.1%)
The number (%) of patients censored [a]	58 (46.4%)	52 (41.9%)
Not at risk at baseline n (%) [a]	4 (3.2%)	4 (3.2%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	6 (4.8%)	7 (5.6%)
Premature treatment discontinuation n (%) [a]	34 (27.2%)	32 (25.8%)
Others n (%) [a]	6 (4.8%)	3 (2.4%)
Median time to event (95% CI) [b]	2.5 (1.8, 6.9)	2.3 (1.5, 6.2)
Q1	1.0 (0.8, 1.4)	0.8 (0.8, 0.9)
Q3	19.4 (15.9, NE)	13.3 (6.6, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	46.4% (36.7%, 55.5%)	44.3% (34.8%, 53.4%)
by 6 Months, % (95% CI)	40.8% (31.3%, 50.2%)	41.0% (31.5%, 50.2%)
by 12 Months, % (95% CI)	39.2% (29.6%, 48.7%)	30.4% (20.6%, 40.8%)
by 18 Months, % (95% CI)	32.5% (21.2%, 44.4%)	21.7% (10.8%, 35.1%)
by 24 Months, % (95% CI)	21.7% (6.6%, 42.3%)	21.7% (10.8%, 35.1%)
Nominal p-value for stratified log-rank test [c]	0.395	
HR (95% CI) [d]	0.83 (0.60, 1.17)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	84 (67.2%)	47 (37.9%)
The number (%) of patients censored [a]	41 (32.8%)	77 (62.1%)
Not at risk at baseline n (%) [a]	1 (0.8%)	0 (0.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	5 (4.0%)	12 (9.7%)
Premature treatment discontinuation n (%) [a]	21 (16.8%)	58 (46.8%)
Others n (%) [a]	5 (4.0%)	1 (0.8%)
Median time to event (95% CI) [b]	1.6 (1.0, 2.8)	10.1 (5.8, NE)
Q1	0.8 (0.8, 0.9)	2.5 (1.6, 4.2)
Q3	7.2 (3.7, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	38.1% (29.1%, 47.1%)	72.1% (62.8%, 79.5%)
by 6 Months, % (95% CI)	26.9% (18.7%, 35.8%)	59.2% (48.7%, 68.2%)
by 12 Months, % (95% CI)	22.1% (14.1%, 31.3%)	49.6% (36.3%, 61.6%)
by 18 Months, % (95% CI)	16.4% (8.3%, 26.9%)	44.1% (28.6%, 58.5%)
by 24 Months, % (95% CI)	16.4% (8.3%, 26.9%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	<.001	
HR (95% CI) [d]	2.71 (1.88, 3.91)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	42 (33.6%)	45 (36.3%)
The number (%) of patients censored [a]	83 (66.4%)	79 (63.7%)
Not at risk at baseline n (%) [a]	10 (8.0%)	9 (7.3%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	6 (4.8%)	10 (8.1%)
Premature treatment discontinuation n (%) [a]	49 (39.2%)	53 (42.7%)
Others n (%) [a]	9 (7.2%)	1 (0.8%)
Median time to event (95% CI) [b]	19.0 (7.9, 27.9)	19.4 (5.1, NE)
Q1	2.8 (1.7, 5.1)	2.4 (1.4, 3.7)
Q3	27.9 (21.5, NE)	NE (19.4, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	75.0% (65.2%, 82.4%)	72.4% (62.6%, 80.1%)
by 6 Months, % (95% CI)	65.2% (54.5%, 74.0%)	56.8% (45.9%, 66.3%)
by 12 Months, % (95% CI)	56.2% (44.4%, 66.5%)	51.0% (39.4%, 61.5%)
by 18 Months, % (95% CI)	52.7% (39.7%, 64.2%)	51.0% (39.4%, 61.5%)
by 24 Months, % (95% CI)	36.9% (17.3%, 56.7%)	25.5% (2.2%, 61.3%)
Nominal p-value for stratified log-rank test [c]	0.274	
HR (95% CI) [d]	0.77 (0.50, 1.19)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	70 (56.0%)	58 (46.8%)
The number (%) of patients censored [a]	55 (44.0%)	66 (53.2%)
Not at risk at baseline n (%) [a]	6 (4.8%)	4 (3.2%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	7 (5.6%)	5 (4.0%)
Premature treatment discontinuation n (%) [a]	28 (22.4%)	49 (39.5%)
Others n (%) [a]	4 (3.2%)	2 (1.6%)
Median time to event (95% CI) [b]	3.0 (1.8, 4.6)	5.2 (3.3, 15.2)
Q1	1.0 (0.8, 1.5)	1.4 (0.9, 2.0)
Q3	13.2 (6.9, NE)	NE (12.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	50.5% (40.5%, 59.8%)	61.4% (51.4%, 69.9%)
by 6 Months, % (95% CI)	36.3% (26.7%, 46.0%)	48.4% (38.0%, 58.0%)
by 12 Months, % (95% CI)	30.3% (20.9%, 40.2%)	43.1% (32.4%, 53.4%)
by 18 Months, % (95% CI)	22.2% (12.6%, 33.5%)	25.1% (10.6%, 42.8%)
by 24 Months, % (95% CI)	22.2% (12.6%, 33.5%)	25.1% (10.6%, 42.8%)
Nominal p-value for stratified log-rank test [c]	0.039	
HR (95% CI) [d]	1.45 (1.01, 2.07)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	35 (28.0%)	37 (29.8%)
The number (%) of patients censored [a]	90 (72.0%)	87 (70.2%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	13 (10.4%)	11 (8.9%)
Premature treatment discontinuation n (%) [a]	59 (47.2%)	69 (55.6%)
Others n (%) [a]	8 (6.4%)	1 (0.8%)
Median time to event (95% CI) [b]	NE (13.3, NE)	NE (8.7, NE)
Q1	4.5 (1.8, 11.7)	3.5 (1.5, 6.2)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	80.8% (72.1%, 87.1%)	79.0% (70.1%, 85.5%)
by 6 Months, % (95% CI)	72.8% (62.9%, 80.5%)	67.4% (57.1%, 75.8%)
by 12 Months, % (95% CI)	63.4% (51.3%, 73.2%)	60.1% (48.5%, 69.9%)
by 18 Months, % (95% CI)	60.1% (46.8%, 71.0%)	60.1% (48.5%, 69.9%)
by 24 Months, % (95% CI)	54.6% (38.5%, 68.1%)	60.1% (48.5%, 69.9%)
Nominal p-value for stratified log-rank test [c]	0.557	
HR (95% CI) [d]	0.86 (0.54, 1.38)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	6 (4.8%)	5 (4.0%)
The number (%) of patients censored [a]	119 (95.2%)	119 (96.0%)
Not at risk at baseline n (%) [a]	3 (2.4%)	6 (4.8%)
Missing baseline only n (%) [a]	16 (12.8%)	15 (12.1%)
Having baseline but no postbaseline visit n (%) [a]	9 (7.2%)	13 (10.5%)
No baseline or any postbaseline n (%) [a]	62 (49.6%)	53 (42.7%)
Missing PRO for two consecutive visits n (%) [a]	18 (14.4%)	17 (13.7%)
Premature treatment discontinuation n (%) [a]	8 (6.4%)	14 (11.3%)
Others n (%) [a]	3 (2.4%)	1 (0.8%)
Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
Q1	2.7 (0.7, NE)	NE (1.2, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	73.1% (49.4%, 87.0%)	88.6% (68.6%, 96.2%)
by 6 Months, % (95% CI)	73.1% (49.4%, 87.0%)	77.8% (53.8%, 90.3%)
by 12 Months, % (95% CI)	73.1% (49.4%, 87.0%)	77.8% (53.8%, 90.3%)
by 18 Months, % (95% CI)	73.1% (49.4%, 87.0%)	77.8% (53.8%, 90.3%)
by 24 Months, % (95% CI)	NE (NE, NE)	77.8% (53.8%, 90.3%)
Nominal p-value for stratified log-rank test [c]	0.329	
HR (95% CI) [d]	2.33 (0.66, 8.21)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	50 (40.0%)	55 (44.4%)
The number (%) of patients censored [a]	75 (60.0%)	69 (55.6%)
Not at risk at baseline n (%) [a]	26 (20.8%)	21 (16.9%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	7 (5.6%)	6 (4.8%)
Premature treatment discontinuation n (%) [a]	26 (20.8%)	34 (27.4%)
Others n (%) [a]	6 (4.8%)	2 (1.6%)
Median time to event (95% CI) [b]	6.3 (2.4, 12.2)	4.9 (2.5, 8.8)
Q1	1.5 (1.1, 2.1)	1.4 (0.9, 1.6)
Q3	27.9 (12.6, NE)	15.2 (10.2, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	61.3% (49.9%, 70.9%)	59.6% (48.8%, 68.9%)
by 6 Months, % (95% CI)	50.8% (39.1%, 61.4%)	48.4% (37.5%, 58.4%)
by 12 Months, % (95% CI)	39.4% (27.6%, 51.0%)	33.4% (21.4%, 45.7%)
by 18 Months, % (95% CI)	31.8% (20.1%, 44.2%)	17.8% (4.7%, 37.7%)
by 24 Months, % (95% CI)	27.3% (15.0%, 41.1%)	17.8% (4.7%, 37.7%)
Nominal p-value for stratified log-rank test [c]	0.407	
HR (95% CI) [d]	0.86 (0.58, 1.28)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	91 (72.8%)	74 (59.7%)
The number (%) of patients censored [a]	34 (27.2%)	50 (40.3%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	4 (3.2%)	3 (2.4%)
Premature treatment discontinuation n (%) [a]	17 (13.6%)	38 (30.6%)
Others n (%) [a]	3 (2.4%)	3 (2.4%)
Median time to event (95% CI) [b]	0.9 (0.8, 1.1)	3.1 (1.7, 5.1)
Q1	0.8 (0.8, 0.8)	0.9 (0.8, 1.4)
Q3	2.8 (1.5, 8.5)	15.0 (6.5, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	24.8% (17.2%, 33.2%)	51.8% (42.1%, 60.6%)
by 6 Months, % (95% CI)	19.1% (12.1%, 27.2%)	35.5% (26.0%, 45.1%)
by 12 Months, % (95% CI)	15.0% (8.1%, 23.8%)	26.1% (15.7%, 37.6%)
by 18 Months, % (95% CI)	15.0% (8.1%, 23.8%)	13.9% (3.7%, 30.6%)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	<.001	
HR (95% CI) [d]	1.89 (1.38, 2.59)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	36 (28.8%)	35 (28.2%)
The number (%) of patients censored [a]	89 (71.2%)	89 (71.8%)
Not at risk at baseline n (%) [a]	5 (4.0%)	3 (2.4%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	12 (9.6%)	12 (9.7%)
Premature treatment discontinuation n (%) [a]	51 (40.8%)	65 (52.4%)
Others n (%) [a]	12 (9.6%)	3 (2.4%)
Median time to event (95% CI) [b]	24.7 (17.1, NE)	NE (8.7, NE)
Q1	5.1 (2.2, 9.3)	3.9 (2.1, 7.4)
Q3	NE (24.7, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	79.6% (70.5%, 86.2%)	77.9% (68.6%, 84.7%)
by 6 Months, % (95% CI)	69.7% (59.1%, 78.0%)	69.2% (58.7%, 77.5%)
by 12 Months, % (95% CI)	62.4% (50.5%, 72.1%)	60.6% (48.2%, 70.9%)
by 18 Months, % (95% CI)	54.0% (38.9%, 67.0%)	55.1% (39.4%, 68.2%)
by 24 Months, % (95% CI)	54.0% (38.9%, 67.0%)	55.1% (39.4%, 68.2%)
Nominal p-value for stratified log-rank test [c]	0.704	
HR (95% CI) [d]	0.91 (0.56, 1.46)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	62 (49.6%)	69 (55.6%)
The number (%) of patients censored [a]	63 (50.4%)	55 (44.4%)
Not at risk at baseline n (%) [a]	2 (1.6%)	3 (2.4%)
Missing baseline only n (%) [a]	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	8 (6.4%)	9 (7.3%)
Premature treatment discontinuation n (%) [a]	38 (30.4%)	36 (29.0%)
Others n (%) [a]	6 (4.8%)	1 (0.8%)
Median time to event (95% CI) [b]	6.8 (3.6, 10.8)	3.7 (2.8, 5.6)
Q1	1.6 (1.1, 2.9)	1.2 (0.9, 1.7)
Q3	16.5 (13.3, NE)	12.7 (6.5, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	66.8% (57.0%, 74.8%)	56.9% (46.8%, 65.7%)
by 6 Months, % (95% CI)	53.3% (42.9%, 62.6%)	38.1% (28.2%, 47.9%)
by 12 Months, % (95% CI)	38.1% (27.2%, 49.0%)	27.2% (17.2%, 38.1%)
by 18 Months, % (95% CI)	24.4% (13.6%, 37.0%)	23.3% (12.9%, 35.4%)
by 24 Months, % (95% CI)	24.4% (13.6%, 37.0%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.077	
HR (95% CI) [d]	0.73 (0.51, 1.03)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	13 (10.4%)	13 (10.5%)
The number (%) of patients censored [a]	112 (89.6%)	111 (89.5%)
Not at risk at baseline n (%) [a]	2 (1.6%)	2 (1.6%)
Missing baseline only n (%) [a]	96 (76.8%)	66 (53.2%)
Having baseline but no postbaseline visit n (%) [a]	1 (0.8%)	3 (2.4%)
No baseline or any postbaseline n (%) [a]	6 (4.8%)	29 (23.4%)
Missing PRO for two consecutive visits n (%) [a]	3 (2.4%)	5 (4.0%)
Premature treatment discontinuation n (%) [a]	3 (2.4%)	6 (4.8%)
Others n (%) [a]	1 (0.8%)	0 (0.0%)
Median time to event (95% CI) [b]	1.2 (0.8, NE)	1.4 (0.8, NE)
Q1	0.8 (0.1, 1.0)	0.8 (0.7, 1.4)
Q3	NE (1.2, NE)	NE (1.4, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	42.5% (20.6%, 62.9%)	42.1% (20.4%, 62.5%)
by 6 Months, % (95% CI)	36.4% (15.9%, 57.4%)	31.6% (12.9%, 52.2%)
by 12 Months, % (95% CI)	29.1% (10.4%, 51.0%)	31.6% (12.9%, 52.2%)
by 18 Months, % (95% CI)	29.1% (10.4%, 51.0%)	NE (NE, NE)
by 24 Months, % (95% CI)	29.1% (10.4%, 51.0%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.639	
HR (95% CI) [d]	0.98 (0.45, 2.13)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.1
Time to First Meaningful Deterioration for EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	43 (34.4%)	44 (35.5%)
The number (%) of patients censored [a]	82 (65.6%)	80 (64.5%)
Not at risk at baseline n (%) [a]	1 (0.8%)	1 (0.8%)
Missing baseline only n (%) [a]	3 (2.4%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	7 (5.6%)	4 (3.2%)
No baseline or any postbaseline n (%) [a]	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	11 (8.8%)	9 (7.3%)
Premature treatment discontinuation n (%) [a]	47 (37.6%)	60 (48.4%)
Others n (%) [a]	13 (10.4%)	3 (2.4%)
Median time to event (95% CI) [b]	18.7 (9.0, NE)	13.0 (10.3, NE)
Q1	2.3 (1.3, 4.9)	2.5 (1.1, 4.4)
Q3	NE (NE, NE)	NE (15.4, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	72.1% (62.5%, 79.6%)	73.8% (64.5%, 81.0%)
by 6 Months, % (95% CI)	65.0% (54.7%, 73.5%)	64.0% (53.9%, 72.5%)
by 12 Months, % (95% CI)	55.6% (43.8%, 65.8%)	55.5% (42.3%, 66.8%)
by 18 Months, % (95% CI)	52.5% (39.9%, 63.7%)	39.0% (21.3%, 56.4%)
by 24 Months, % (95% CI)	47.2% (32.3%, 60.8%)	39.0% (21.3%, 56.4%)
Nominal p-value for stratified log-rank test [c]	0.893	
HR (95% CI) [d]	0.96 (0.63, 1.46)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.

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Table 5.3.2
Time to First Meaningful Deterioration for PGIC
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	25 (20.0%)	29 (23.4%)
The number (%) of patients censored [a]	100 (80.0%)	95 (76.6%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	0 (0.0%)	0 (0.0%)
No baseline or any postbaseline n (%) [a]	30 (24.0%)	25 (20.2%)
Missing PRO for two consecutive visits n (%) [a]	3 (2.4%)	1 (0.8%)
Premature treatment discontinuation n (%) [a]	55 (44.0%)	65 (52.4%)
Others n (%) [a]	12 (9.6%)	4 (3.2%)
Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
Q1	5.6 (3.7, NE)	5.6 (3.7, 6.4)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	92.6% (85.1%, 96.4%)	95.9% (89.6%, 98.5%)
by 6 Months, % (95% CI)	71.0% (59.1%, 80.0%)	68.3% (56.2%, 77.6%)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.852	
HR (95% CI) [d]	0.93 (0.54, 1.60)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.3.3
Time to First Meaningful Deterioration for PGIS
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Parameter	SG (N=125)	TPC (N=124)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	125	124
The number (%) of patients with an event [a]	11 (8.8%)	8 (6.5%)
The number (%) of patients censored [a]	114 (91.2%)	116 (93.5%)
Not at risk at baseline n (%) [a]	11 (8.8%)	19 (15.3%)
Missing baseline only n (%) [a]	3 (2.4%)	2 (1.6%)
Having baseline but no postbaseline visit n (%) [a]	27 (21.6%)	24 (19.4%)
No baseline or any postbaseline n (%) [a]	3 (2.4%)	1 (0.8%)
Missing PRO for two consecutive visits n (%) [a]	8 (6.4%)	11 (8.9%)
Premature treatment discontinuation n (%) [a]	46 (36.8%)	53 (42.7%)
Others n (%) [a]	16 (12.8%)	6 (4.8%)
Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
Q1	6.3 (5.1, NE)	NE (5.8, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	98.7% (90.9%, 99.8%)	97.0% (88.5%, 99.2%)
by 6 Months, % (95% CI)	85.3% (74.4%, 91.9%)	84.5% (70.0%, 92.3%)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.872	
HR (95% CI) [d]	1.28 (0.51, 3.20)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 7.3.1.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	13 (44.8%)	11 (42.3%)
	The number (%) of patients censored [a]	16 (55.2%)	15 (57.7%)
	Median time to event (95% CI) [b]	9.8 (1.7, NE)	10.9 (2.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.991	
	HR (95% CI) [d]	1.01 (0.45, 2.28)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	21 (67.7%)	23 (74.2%)
	The number (%) of patients censored [a]	10 (32.3%)	8 (25.8%)
	Median time to event (95% CI) [b]	5.4 (1.0, 7.7)	1.7 (0.9, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.175	
	HR (95% CI) [d]	0.67 (0.37, 1.22)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	36 (55.4%)	39 (58.2%)
	The number (%) of patients censored [a]	29 (44.6%)	28 (41.8%)
	Median time to event (95% CI) [b]	2.3 (1.6, 6.3)	3.9 (1.7, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.930	
	HR (95% CI) [d]	1.02 (0.65, 1.61)	
	P-value of subgroup*treatment interaction [e]	0.477	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	12 (41.4%)	14 (53.8%)
	The number (%) of patients censored [a]	17 (58.6%)	12 (46.2%)
	Median time to event (95% CI) [b]	20.1 (2.1, NE)	2.6 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	0.55 (0.25, 1.19)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	19 (61.3%)	17 (54.8%)
	The number (%) of patients censored [a]	12 (38.7%)	14 (45.2%)
	Median time to event (95% CI) [b]	3.6 (1.4, NE)	5.1 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.797	
	HR (95% CI) [d]	0.92 (0.48, 1.77)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	27 (41.5%)	38 (56.7%)
	The number (%) of patients censored [a]	38 (58.5%)	29 (43.3%)
	Median time to event (95% CI) [b]	7.5 (3.6, NE)	5.4 (3.5, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.550	
	HR (95% CI) [d]	0.86 (0.52, 1.41)	
	P-value of subgroup*treatment interaction [e]	0.514	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	11 (37.9%)	16 (61.5%)
	The number (%) of patients censored [a]	18 (62.1%)	10 (38.5%)
	Median time to event (95% CI) [b]	17.8 (1.5, NE)	3.7 (0.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.052	
	HR (95% CI) [d]	0.46 (0.21, 1.02)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	23 (74.2%)	20 (64.5%)
	The number (%) of patients censored [a]	8 (25.8%)	11 (35.5%)
	Median time to event (95% CI) [b]	1.3 (0.9, 5.1)	1.7 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.706	
	HR (95% CI) [d]	1.13 (0.62, 2.06)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	38 (58.5%)	48 (71.6%)
	The number (%) of patients censored [a]	27 (41.5%)	19 (28.4%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.7)	3.3 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.625	
	HR (95% CI) [d]	1.12 (0.73, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.144	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	8 (27.6%)	9 (34.6%)
	The number (%) of patients censored [a]	21 (72.4%)	17 (65.4%)
	Median time to event (95% CI) [b]	NE (7.3, NE)	10.0 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	0.60 (0.23, 1.57)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	20 (64.5%)	13 (41.9%)
	The number (%) of patients censored [a]	11 (35.5%)	18 (58.1%)
	Median time to event (95% CI) [b]	4.1 (3.0, 12.2)	5.6 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.628	
	HR (95% CI) [d]	1.19 (0.59, 2.40)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	31 (47.7%)	34 (50.7%)
	The number (%) of patients censored [a]	34 (52.3%)	33 (49.3%)
	Median time to event (95% CI) [b]	6.0 (4.2, 11.4)	9.1 (4.4, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.617	
	HR (95% CI) [d]	1.13 (0.70, 1.85)	
	P-value of subgroup*treatment interaction [e]	0.242	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	16 (55.2%)	19 (73.1%)
	The number (%) of patients censored [a]	13 (44.8%)	7 (26.9%)
	Median time to event (95% CI) [b]	1.8 (0.9, NE)	2.1 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.147	
	HR (95% CI) [d]	0.60 (0.30, 1.22)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	21 (67.7%)	16 (51.6%)
	The number (%) of patients censored [a]	10 (32.3%)	15 (48.4%)
	Median time to event (95% CI) [b]	4.2 (2.8, 8.4)	7.0 (2.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.827	
	HR (95% CI) [d]	1.07 (0.56, 2.08)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	32 (49.2%)	44 (65.7%)
	The number (%) of patients censored [a]	33 (50.8%)	23 (34.3%)
	Median time to event (95% CI) [b]	5.1 (2.8, 12.6)	2.7 (1.8, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.259	
	HR (95% CI) [d]	0.77 (0.49, 1.21)	
	P-value of subgroup*treatment interaction [e]	0.298	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	14 (48.3%)	19 (73.1%)
	The number (%) of patients censored [a]	15 (51.7%)	7 (26.9%)
	Median time to event (95% CI) [b]	3.8 (0.8, NE)	2.4 (0.8, 4.5)
	Nominal p-value for unstratified log-rank test [c]	0.156	
	HR (95% CI) [d]	0.62 (0.31, 1.23)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	19 (61.3%)	22 (71.0%)
	The number (%) of patients censored [a]	12 (38.7%)	9 (29.0%)
	Median time to event (95% CI) [b]	3.2 (1.0, 12.2)	1.4 (0.9, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.078	
	HR (95% CI) [d]	0.57 (0.30, 1.08)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	35 (53.8%)	36 (53.7%)
	The number (%) of patients censored [a]	30 (46.2%)	31 (46.3%)
	Median time to event (95% CI) [b]	2.2 (1.4, 16.1)	4.9 (3.1, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.343	
	HR (95% CI) [d]	1.25 (0.78, 1.99)	
	P-value of subgroup*treatment interaction [e]	0.065	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	16 (55.2%)	18 (69.2%)
	The number (%) of patients censored [a]	13 (44.8%)	8 (30.8%)
	Median time to event (95% CI) [b]	3.9 (1.7, NE)	1.4 (0.8, 1.6)
	Nominal p-value for unstratified log-rank test [c]	0.023	
	HR (95% CI) [d]	0.46 (0.23, 0.92)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	22 (71.0%)	24 (77.4%)
	The number (%) of patients censored [a]	9 (29.0%)	7 (22.6%)
	Median time to event (95% CI) [b]	1.3 (0.8, 1.8)	1.2 (0.9, 3.2)
	Nominal p-value for unstratified log-rank test [c]	0.506	
	HR (95% CI) [d]	0.82 (0.46, 1.46)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	45 (69.2%)	50 (74.6%)
	The number (%) of patients censored [a]	20 (30.8%)	17 (25.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.6)	1.6 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.554	
	HR (95% CI) [d]	1.14 (0.76, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.095	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	19 (65.5%)	20 (76.9%)
	The number (%) of patients censored [a]	10 (34.5%)	6 (23.1%)
	Median time to event (95% CI) [b]	2.9 (1.1, 4.2)	1.4 (0.8, 1.7)
	Nominal p-value for unstratified log-rank test [c]	0.007	
	HR (95% CI) [d]	0.41 (0.21, 0.80)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	25 (80.6%)	17 (54.8%)
	The number (%) of patients censored [a]	6 (19.4%)	14 (45.2%)
	Median time to event (95% CI) [b]	1.4 (0.9, 2.0)	2.1 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.176	
	HR (95% CI) [d]	1.52 (0.82, 2.83)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	36 (55.4%)	42 (62.7%)
	The number (%) of patients censored [a]	29 (44.6%)	25 (37.3%)
	Median time to event (95% CI) [b]	1.8 (0.9, 4.5)	3.4 (1.3, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.456	
	HR (95% CI) [d]	1.19 (0.76, 1.88)	
	P-value of subgroup*treatment interaction [e]	0.014	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	9 (31.0%)	11 (42.3%)
	The number (%) of patients censored [a]	20 (69.0%)	15 (57.7%)
	Median time to event (95% CI) [b]	17.8 (7.8, NE)	6.3 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.047	
	HR (95% CI) [d]	0.39 (0.15, 1.02)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	16 (51.6%)	20 (64.5%)
	The number (%) of patients censored [a]	15 (48.4%)	11 (35.5%)
	Median time to event (95% CI) [b]	4.3 (1.4, NE)	1.4 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	0.67 (0.34, 1.29)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	33 (50.8%)	45 (67.2%)
	The number (%) of patients censored [a]	32 (49.2%)	22 (32.8%)
	Median time to event (95% CI) [b]	4.4 (1.4, 9.1)	2.8 (2.1, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	0.95 (0.60, 1.49)	
	P-value of subgroup*treatment interaction [e]	0.227	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	9 (31.0%)	14 (53.8%)
	The number (%) of patients censored [a]	20 (69.0%)	12 (46.2%)
	Median time to event (95% CI) [b]	NE (5.3, NE)	2.8 (1.4, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.031	
	HR (95% CI) [d]	0.40 (0.17, 0.95)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	18 (58.1%)
	The number (%) of patients censored [a]	18 (58.1%)	13 (41.9%)
	Median time to event (95% CI) [b]	12.2 (3.5, NE)	4.4 (1.4, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.020	
	HR (95% CI) [d]	0.44 (0.21, 0.90)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	21 (32.3%)	33 (49.3%)
	The number (%) of patients censored [a]	44 (67.7%)	34 (50.7%)
	Median time to event (95% CI) [b]	11.4 (6.7, NE)	6.7 (3.7, 18.5)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	0.70 (0.40, 1.21)	
	P-value of subgroup*treatment interaction [e]	0.403	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	12 (41.4%)	12 (46.2%)
	The number (%) of patients censored [a]	17 (58.6%)	14 (53.8%)
	Median time to event (95% CI) [b]	10.8 (3.1, NE)	4.4 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.198	
	HR (95% CI) [d]	0.59 (0.26, 1.33)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	16 (51.6%)	20 (64.5%)
	The number (%) of patients censored [a]	15 (48.4%)	11 (35.5%)
	Median time to event (95% CI) [b]	4.2 (1.5, NE)	1.2 (0.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.089	
	HR (95% CI) [d]	0.56 (0.29, 1.08)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	31 (47.7%)	35 (52.2%)
	The number (%) of patients censored [a]	34 (52.3%)	32 (47.8%)
	Median time to event (95% CI) [b]	4.0 (1.7, 14.4)	4.6 (3.3, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.648	
	HR (95% CI) [d]	1.12 (0.69, 1.82)	
	P-value of subgroup*treatment interaction [e]	0.207	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	13 (44.8%)	15 (57.7%)
	The number (%) of patients censored [a]	16 (55.2%)	11 (42.3%)
	Median time to event (95% CI) [b]	8.8 (1.4, NE)	2.6 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.231	
	HR (95% CI) [d]	0.64 (0.30, 1.35)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	19 (61.3%)	13 (41.9%)
	The number (%) of patients censored [a]	12 (38.7%)	18 (58.1%)
	Median time to event (95% CI) [b]	3.4 (0.9, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.360	
	HR (95% CI) [d]	1.39 (0.69, 2.82)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	32 (49.2%)	40 (59.7%)
	The number (%) of patients censored [a]	33 (50.8%)	27 (40.3%)
	Median time to event (95% CI) [b]	3.6 (1.6, 13.6)	4.1 (1.7, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.675	
	HR (95% CI) [d]	0.91 (0.57, 1.45)	
	P-value of subgroup*treatment interaction [e]	0.306	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	13 (44.8%)	17 (65.4%)
	The number (%) of patients censored [a]	16 (55.2%)	9 (34.6%)
	Median time to event (95% CI) [b]	12.4 (1.7, NE)	1.1 (0.8, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.011	
	HR (95% CI) [d]	0.39 (0.18, 0.83)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	21 (67.7%)	14 (45.2%)
	The number (%) of patients censored [a]	10 (32.3%)	17 (54.8%)
	Median time to event (95% CI) [b]	2.2 (1.3, 3.7)	2.2 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.599	
	HR (95% CI) [d]	1.19 (0.60, 2.35)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	33 (50.8%)	41 (61.2%)
	The number (%) of patients censored [a]	32 (49.2%)	26 (38.8%)
	Median time to event (95% CI) [b]	2.3 (1.4, NE)	2.8 (1.5, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.654	
	HR (95% CI) [d]	0.89 (0.57, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.098	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	15 (51.7%)	13 (50.0%)
	The number (%) of patients censored [a]	14 (48.3%)	13 (50.0%)
	Median time to event (95% CI) [b]	1.7 (1.0, NE)	6.0 (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.863	
	HR (95% CI) [d]	1.07 (0.50, 2.30)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	23 (74.2%)	11 (35.5%)
	The number (%) of patients censored [a]	8 (25.8%)	20 (64.5%)
	Median time to event (95% CI) [b]	2.1 (1.0, 4.4)	NE (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	2.15 (1.04, 4.42)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	46 (70.8%)	23 (34.3%)
	The number (%) of patients censored [a]	19 (29.2%)	44 (65.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.4)	NE (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	4.17 (2.51, 6.93)	
	P-value of subgroup*treatment interaction [e]	0.012	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	8 (27.6%)	9 (34.6%)
	The number (%) of patients censored [a]	21 (72.4%)	17 (65.4%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	5.2 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.117	
	HR (95% CI) [d]	0.46 (0.17, 1.24)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	13 (41.9%)
	The number (%) of patients censored [a]	18 (58.1%)	18 (58.1%)
	Median time to event (95% CI) [b]	21.5 (3.6, NE)	3.1 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.231	
	HR (95% CI) [d]	0.62 (0.28, 1.37)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	21 (32.3%)	23 (34.3%)
	The number (%) of patients censored [a]	44 (67.7%)	44 (65.7%)
	Median time to event (95% CI) [b]	16.1 (5.1, NE)	19.4 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.714	
	HR (95% CI) [d]	1.12 (0.61, 2.04)	
	P-value of subgroup*treatment interaction [e]	0.167	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	15 (51.7%)	9 (34.6%)
	The number (%) of patients censored [a]	14 (48.3%)	17 (65.4%)
	Median time to event (95% CI) [b]	4.6 (1.7, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.465	
	HR (95% CI) [d]	1.36 (0.59, 3.13)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	17 (54.8%)	13 (41.9%)
	The number (%) of patients censored [a]	14 (45.2%)	18 (58.1%)
	Median time to event (95% CI) [b]	6.9 (1.4, NE)	7.0 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.89 (0.42, 1.86)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	38 (58.5%)	36 (53.7%)
	The number (%) of patients censored [a]	27 (41.5%)	31 (46.3%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	5.0 (2.4, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.011	
	HR (95% CI) [d]	1.81 (1.14, 2.87)	
	P-value of subgroup*treatment interaction [e]	0.330	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	9 (31.0%)	8 (30.8%)
	The number (%) of patients censored [a]	20 (69.0%)	18 (69.2%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.768	
	HR (95% CI) [d]	0.86 (0.33, 2.24)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	6 (19.4%)
	The number (%) of patients censored [a]	18 (58.1%)	25 (80.6%)
	Median time to event (95% CI) [b]	18.5 (3.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	1.71 (0.64, 4.56)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	13 (20.0%)	23 (34.3%)
	The number (%) of patients censored [a]	52 (80.0%)	44 (65.7%)
	Median time to event (95% CI) [b]	NE (13.3, NE)	NE (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.141	
	HR (95% CI) [d]	0.60 (0.31, 1.19)	
	P-value of subgroup*treatment interaction [e]	0.203	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	1 (3.4%)	0 (0.0%)
	The number (%) of patients censored [a]	28 (96.6%)	26 (100.0%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	NE (NE, NE)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	0 (0.0%)	1 (3.2%)
	The number (%) of patients censored [a]	31 (100.0%)	30 (96.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.456	
	HR (95% CI) [d]	NE (NE, NE)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	5 (7.7%)	4 (6.0%)
	The number (%) of patients censored [a]	60 (92.3%)	63 (94.0%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.283	
	HR (95% CI) [d]	2.04 (0.55, 7.64)	
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	12 (41.4%)	12 (46.2%)
	The number (%) of patients censored [a]	17 (58.6%)	14 (53.8%)
	Median time to event (95% CI) [b]	7.0 (2.2, NE)	6.3 (0.9, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.311	
	HR (95% CI) [d]	0.66 (0.29, 1.47)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	14 (45.2%)	15 (48.4%)
	The number (%) of patients censored [a]	17 (54.8%)	16 (51.6%)
	Median time to event (95% CI) [b]	8.4 (1.4, 18.5)	3.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.133	
	HR (95% CI) [d]	0.55 (0.25, 1.22)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	24 (36.9%)	28 (41.8%)
	The number (%) of patients censored [a]	41 (63.1%)	39 (58.2%)
	Median time to event (95% CI) [b]	3.8 (1.7, 9.8)	5.4 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.540	
	HR (95% CI) [d]	1.19 (0.68, 2.08)	
	P-value of subgroup*treatment interaction [e]	0.314	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	21 (72.4%)	18 (69.2%)
	The number (%) of patients censored [a]	8 (27.6%)	8 (30.8%)
	Median time to event (95% CI) [b]	1.5 (0.8, 3.2)	1.7 (0.8, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.863	
	HR (95% CI) [d]	1.06 (0.56, 1.99)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	26 (83.9%)	18 (58.1%)
	The number (%) of patients censored [a]	5 (16.1%)	13 (41.9%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.3)	2.9 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.019	
	HR (95% CI) [d]	2.05 (1.12, 3.75)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	44 (67.7%)	38 (56.7%)
	The number (%) of patients censored [a]	21 (32.3%)	29 (43.3%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	4.9 (2.0, 8.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.38 (1.52, 3.73)	
	P-value of subgroup*treatment interaction [e]	0.087	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	4 (13.8%)	8 (30.8%)
	The number (%) of patients censored [a]	25 (86.2%)	18 (69.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	7.4 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.081	
	HR (95% CI) [d]	0.35 (0.11, 1.20)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	11 (35.5%)
	The number (%) of patients censored [a]	18 (58.1%)	20 (64.5%)
	Median time to event (95% CI) [b]	17.5 (3.9, NE)	12.7 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.394	
	HR (95% CI) [d]	0.70 (0.31, 1.60)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	19 (29.2%)	16 (23.9%)
	The number (%) of patients censored [a]	46 (70.8%)	51 (76.1%)
	Median time to event (95% CI) [b]	17.1 (5.6, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.240	
	HR (95% CI) [d]	1.49 (0.76, 2.90)	
	P-value of subgroup*treatment interaction [e]	0.063	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	14 (48.3%)	16 (61.5%)
	The number (%) of patients censored [a]	15 (51.7%)	10 (38.5%)
	Median time to event (95% CI) [b]	6.8 (3.2, NE)	2.8 (0.8, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.023	
	HR (95% CI) [d]	0.43 (0.21, 0.91)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	23 (74.2%)	17 (54.8%)
	The number (%) of patients censored [a]	8 (25.8%)	14 (45.2%)
	Median time to event (95% CI) [b]	3.0 (1.5, 5.6)	3.7 (1.7, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.565	
	HR (95% CI) [d]	1.20 (0.64, 2.26)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	25 (38.5%)	36 (53.7%)
	The number (%) of patients censored [a]	40 (61.5%)	31 (46.3%)
	Median time to event (95% CI) [b]	9.6 (6.9, 15.5)	4.9 (2.5, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.144	
	HR (95% CI) [d]	0.68 (0.41, 1.14)	
	P-value of subgroup*treatment interaction [e]	0.054	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	3 (10.3%)	3 (11.5%)
	The number (%) of patients censored [a]	26 (89.7%)	23 (88.5%)
	Median time to event (95% CI) [b]	7.2 (0.8, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.917	
	HR (95% CI) [d]	0.89 (0.17, 4.60)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	3 (9.7%)	3 (9.7%)
	The number (%) of patients censored [a]	28 (90.3%)	28 (90.3%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	2.2 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.874	
	HR (95% CI) [d]	1.14 (0.23, 5.73)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	7 (10.8%)	7 (10.4%)
	The number (%) of patients censored [a]	58 (89.2%)	60 (89.6%)
	Median time to event (95% CI) [b]	1.0 (0.1, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.904	
	HR (95% CI) [d]	0.91 (0.32, 2.62)	
	P-value of subgroup*treatment interaction [e]	0.986	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	6 (20.7%)	10 (38.5%)
	The number (%) of patients censored [a]	23 (79.3%)	16 (61.5%)
	Median time to event (95% CI) [b]	NE (18.7, NE)	10.5 (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.110	
	HR (95% CI) [d]	0.43 (0.15, 1.25)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	15 (48.4%)	12 (38.7%)
	The number (%) of patients censored [a]	16 (51.6%)	19 (61.3%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.738	
	HR (95% CI) [d]	1.14 (0.53, 2.44)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	22 (33.8%)	22 (32.8%)
	The number (%) of patients censored [a]	43 (66.2%)	45 (67.2%)
	Median time to event (95% CI) [b]	9.8 (7.2, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.623	
	HR (95% CI) [d]	1.16 (0.64, 2.10)	
	P-value of subgroup*treatment interaction [e]	0.256	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.1.2
Time to First Meaningful Deterioration for PGIC by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	2 (6.9%)	7 (26.9%)
	The number (%) of patients censored [a]	27 (93.1%)	19 (73.1%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (4.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.042	
	HR (95% CI) [d]	0.23 (0.05, 1.09)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	6 (19.4%)	7 (22.6%)
	The number (%) of patients censored [a]	25 (80.6%)	24 (77.4%)
	Median time to event (95% CI) [b]	NE (5.8, NE)	6.5 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.890	
	HR (95% CI) [d]	0.93 (0.30, 2.88)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	17 (26.2%)	15 (22.4%)
	The number (%) of patients censored [a]	48 (73.8%)	52 (77.6%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	6.4 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.309	
	HR (95% CI) [d]	1.44 (0.71, 2.92)	
	P-value of subgroup*treatment interaction [e]	0.111	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.3
Time to First Meaningful Deterioration for PGIS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	1 (3.4%)	1 (3.8%)
	The number (%) of patients censored [a]	28 (96.6%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.784	
	HR (95% CI) [d]	0.68 (0.04, 10.88)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	2 (6.5%)	4 (12.9%)
	The number (%) of patients censored [a]	29 (93.5%)	27 (87.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.282	
	HR (95% CI) [d]	0.41 (0.07, 2.22)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	8 (12.3%)	3 (4.5%)
	The number (%) of patients censored [a]	57 (87.7%)	64 (95.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.131	
	HR (95% CI) [d]	2.67 (0.71, 10.10)	
	P-value of subgroup*treatment interaction [e]	0.249	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	14 (46.7%)	24 (68.6%)
	The number (%) of patients censored [a]	16 (53.3%)	11 (31.4%)
	Median time to event (95% CI) [b]	4.9 (1.7, NE)	1.4 (0.9, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.065	
	HR (95% CI) [d]	0.54 (0.28, 1.06)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	56 (58.9%)	49 (55.1%)
	The number (%) of patients censored [a]	39 (41.1%)	40 (44.9%)
	Median time to event (95% CI) [b]	4.1 (1.8, 7.2)	4.2 (2.5, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.768	
	HR (95% CI) [d]	1.06 (0.72, 1.56)	
	P-value of subgroup*treatment interaction [e]	0.095	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	13 (43.3%)	23 (65.7%)
	The number (%) of patients censored [a]	17 (56.7%)	12 (34.3%)
	Median time to event (95% CI) [b]	7.4 (1.7, NE)	2.4 (1.4, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.127	
	HR (95% CI) [d]	0.59 (0.30, 1.18)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	45 (47.4%)	46 (51.7%)
	The number (%) of patients censored [a]	50 (52.6%)	43 (48.3%)
	Median time to event (95% CI) [b]	7.9 (3.6, 21.5)	5.8 (3.1, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.547	
	HR (95% CI) [d]	0.88 (0.58, 1.33)	
	P-value of subgroup*treatment interaction [e]	0.300	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	17 (56.7%)	28 (80.0%)
	The number (%) of patients censored [a]	13 (43.3%)	7 (20.0%)
	Median time to event (95% CI) [b]	1.4 (0.8, NE)	2.5 (0.9, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.406	
	HR (95% CI) [d]	0.77 (0.42, 1.42)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	55 (57.9%)	56 (62.9%)
	The number (%) of patients censored [a]	40 (42.1%)	33 (37.1%)
	Median time to event (95% CI) [b]	1.8 (1.4, 3.2)	3.7 (2.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.919	
	HR (95% CI) [d]	1.02 (0.70, 1.48)	
	P-value of subgroup*treatment interaction [e]	0.500	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	12 (40.0%)	14 (40.0%)
	The number (%) of patients censored [a]	18 (60.0%)	21 (60.0%)
	Median time to event (95% CI) [b]	10.4 (3.2, NE)	10.8 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.983	
	HR (95% CI) [d]	0.99 (0.46, 2.15)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	47 (49.5%)	42 (47.2%)
	The number (%) of patients censored [a]	48 (50.5%)	47 (52.8%)
	Median time to event (95% CI) [b]	7.8 (4.3, 11.8)	9.1 (4.4, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.769	
	HR (95% CI) [d]	0.94 (0.62, 1.43)	
	P-value of subgroup*treatment interaction [e]	0.907	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	14 (46.7%)	23 (65.7%)
	The number (%) of patients censored [a]	16 (53.3%)	12 (34.3%)
	Median time to event (95% CI) [b]	6.4 (2.8, NE)	2.2 (1.5, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.060	
	HR (95% CI) [d]	0.53 (0.27, 1.04)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	55 (57.9%)	56 (62.9%)
	The number (%) of patients censored [a]	40 (42.1%)	33 (37.1%)
	Median time to event (95% CI) [b]	3.6 (2.6, 6.9)	3.5 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.564	
	HR (95% CI) [d]	0.90 (0.62, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.169	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	12 (40.0%)	21 (60.0%)
	The number (%) of patients censored [a]	18 (60.0%)	14 (40.0%)
	Median time to event (95% CI) [b]	3.8 (0.8, NE)	3.3 (0.9, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.404	
	HR (95% CI) [d]	0.74 (0.36, 1.51)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	56 (58.9%)	56 (62.9%)
	The number (%) of patients censored [a]	39 (41.1%)	33 (37.1%)
	Median time to event (95% CI) [b]	2.4 (1.4, 7.5)	3.5 (1.6, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.734	
	HR (95% CI) [d]	0.94 (0.65, 1.36)	
	P-value of subgroup*treatment interaction [e]	0.482	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	18 (60.0%)	29 (82.9%)
	The number (%) of patients censored [a]	12 (40.0%)	6 (17.1%)
	Median time to event (95% CI) [b]	0.9 (0.8, 5.7)	1.1 (0.9, 1.4)
	Nominal p-value for unstratified log-rank test [c]	0.229	
	HR (95% CI) [d]	0.70 (0.38, 1.29)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	65 (68.4%)	63 (70.8%)
	The number (%) of patients censored [a]	30 (31.6%)	26 (29.2%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.2)	1.9 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.747	
	HR (95% CI) [d]	0.95 (0.67, 1.34)	
	P-value of subgroup*treatment interaction [e]	0.371	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	19 (54.3%)
	The number (%) of patients censored [a]	15 (50.0%)	16 (45.7%)
	Median time to event (95% CI) [b]	3.2 (0.9, NE)	2.1 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.556	
	HR (95% CI) [d]	0.81 (0.41, 1.64)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	65 (68.4%)	60 (67.4%)
	The number (%) of patients censored [a]	30 (31.6%)	29 (32.6%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.9)	1.7 (1.0, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.527	
	HR (95% CI) [d]	1.12 (0.78, 1.59)	
	P-value of subgroup*treatment interaction [e]	0.502	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	12 (40.0%)	22 (62.9%)
	The number (%) of patients censored [a]	18 (60.0%)	13 (37.1%)
	Median time to event (95% CI) [b]	16.0 (1.7, NE)	3.0 (1.8, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.190	
	HR (95% CI) [d]	0.62 (0.30, 1.29)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	46 (48.4%)	54 (60.7%)
	The number (%) of patients censored [a]	49 (51.6%)	35 (39.3%)
	Median time to event (95% CI) [b]	6.5 (2.4, 11.8)	2.8 (1.9, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.73 (0.49, 1.08)	
	P-value of subgroup*treatment interaction [e]	0.767	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	11 (36.7%)	22 (62.9%)
	The number (%) of patients censored [a]	19 (63.3%)	13 (37.1%)
	Median time to event (95% CI) [b]	15.5 (1.5, NE)	3.1 (1.2, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.44 (0.21, 0.94)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	32 (33.7%)	43 (48.3%)
	The number (%) of patients censored [a]	63 (66.3%)	46 (51.7%)
	Median time to event (95% CI) [b]	NE (7.7, NE)	6.7 (3.7, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.028	
	HR (95% CI) [d]	0.60 (0.38, 0.95)	
	P-value of subgroup*treatment interaction [e]	0.474	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	16 (45.7%)
	The number (%) of patients censored [a]	15 (50.0%)	19 (54.3%)
	Median time to event (95% CI) [b]	5.1 (2.5, NE)	6.0 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.693	
	HR (95% CI) [d]	1.15 (0.57, 2.33)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	44 (46.3%)	51 (57.3%)
	The number (%) of patients censored [a]	51 (53.7%)	38 (42.7%)
	Median time to event (95% CI) [b]	7.2 (3.2, 14.4)	4.1 (2.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.123	
	HR (95% CI) [d]	0.73 (0.49, 1.09)	
	P-value of subgroup*treatment interaction [e]	0.277	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	11 (36.7%)	20 (57.1%)
	The number (%) of patients censored [a]	19 (63.3%)	15 (42.9%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	3.5 (1.8, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.180	
	HR (95% CI) [d]	0.60 (0.29, 1.28)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	53 (55.8%)	48 (53.9%)
	The number (%) of patients censored [a]	42 (44.2%)	41 (46.1%)
	Median time to event (95% CI) [b]	3.1 (1.5, 4.2)	3.5 (1.4, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.839	
	HR (95% CI) [d]	1.04 (0.71, 1.54)	
	P-value of subgroup*treatment interaction [e]	0.166	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	23 (65.7%)
	The number (%) of patients censored [a]	15 (50.0%)	12 (34.3%)
	Median time to event (95% CI) [b]	3.1 (1.4, NE)	1.7 (1.2, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.438	
	HR (95% CI) [d]	0.77 (0.40, 1.48)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	52 (54.7%)	49 (55.1%)
	The number (%) of patients censored [a]	43 (45.3%)	40 (44.9%)
	Median time to event (95% CI) [b]	2.4 (1.8, 12.4)	2.6 (1.0, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	0.87 (0.59, 1.28)	
	P-value of subgroup*treatment interaction [e]	0.764	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	23 (76.7%)	11 (31.4%)
	The number (%) of patients censored [a]	7 (23.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	1.4 (0.8, 2.9)	10.1 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.49 (1.68, 7.25)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	61 (64.2%)	36 (40.4%)
	The number (%) of patients censored [a]	34 (35.8%)	53 (59.6%)
	Median time to event (95% CI) [b]	1.6 (1.0, 3.3)	13.2 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.28 (1.51, 3.46)	
	P-value of subgroup*treatment interaction [e]	0.252	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	8 (26.7%)	11 (31.4%)
	The number (%) of patients censored [a]	22 (73.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.716	
	HR (95% CI) [d]	0.85 (0.34, 2.10)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	34 (35.8%)	34 (38.2%)
	The number (%) of patients censored [a]	61 (64.2%)	55 (61.8%)
	Median time to event (95% CI) [b]	19.0 (7.0, 27.9)	8.7 (4.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.375	
	HR (95% CI) [d]	0.80 (0.50, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.933	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	14 (46.7%)	17 (48.6%)
	The number (%) of patients censored [a]	16 (53.3%)	18 (51.4%)
	Median time to event (95% CI) [b]	1.8 (1.5, NE)	4.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.786	
	HR (95% CI) [d]	1.10 (0.54, 2.23)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	56 (58.9%)	41 (46.1%)
	The number (%) of patients censored [a]	39 (41.1%)	48 (53.9%)
	Median time to event (95% CI) [b]	3.5 (2.1, 5.0)	6.5 (3.5, 17.1)
	Nominal p-value for unstratified log-rank test [c]	0.075	
	HR (95% CI) [d]	1.44 (0.96, 2.15)	
	P-value of subgroup*treatment interaction [e]	0.445	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	7 (23.3%)	13 (37.1%)
	The number (%) of patients censored [a]	23 (76.7%)	22 (62.9%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	5.3 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.141	
	HR (95% CI) [d]	0.51 (0.20, 1.28)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	28 (29.5%)	24 (27.0%)
	The number (%) of patients censored [a]	67 (70.5%)	65 (73.0%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.782	
	HR (95% CI) [d]	1.08 (0.63, 1.86)	
	P-value of subgroup*treatment interaction [e]	0.137	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	1 (3.3%)	3 (8.6%)
	The number (%) of patients censored [a]	29 (96.7%)	32 (91.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.890	
	HR (95% CI) [d]	1.18 (0.11, 13.16)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	5 (5.3%)	2 (2.2%)
	The number (%) of patients censored [a]	90 (94.7%)	87 (97.8%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.221	
	HR (95% CI) [d]	2.68 (0.52, 13.80)	
	P-value of subgroup*treatment interaction [e]	0.490	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	10 (33.3%)	14 (40.0%)
	The number (%) of patients censored [a]	20 (66.7%)	21 (60.0%)
	Median time to event (95% CI) [b]	3.5 (1.4, NE)	6.3 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.959	
	HR (95% CI) [d]	0.98 (0.43, 2.21)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	40 (42.1%)	41 (46.1%)
	The number (%) of patients censored [a]	55 (57.9%)	48 (53.9%)
	Median time to event (95% CI) [b]	7.0 (2.4, 12.6)	4.9 (2.0, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.399	
	HR (95% CI) [d]	0.82 (0.53, 1.28)	
	P-value of subgroup*treatment interaction [e]	0.686	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	23 (76.7%)	19 (54.3%)
	The number (%) of patients censored [a]	7 (23.3%)	16 (45.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.2)	3.1 (1.3, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.55 (1.36, 4.77)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	68 (71.6%)	55 (61.8%)
	The number (%) of patients censored [a]	27 (28.4%)	34 (38.2%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.0 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	1.71 (1.20, 2.45)	
	P-value of subgroup*treatment interaction [e]	0.344	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	7 (23.3%)	11 (31.4%)
	The number (%) of patients censored [a]	23 (76.7%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.204	
	HR (95% CI) [d]	0.54 (0.21, 1.42)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	29 (30.5%)	24 (27.0%)
	The number (%) of patients censored [a]	66 (69.5%)	65 (73.0%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.667	
	HR (95% CI) [d]	1.13 (0.65, 1.94)	
	P-value of subgroup*treatment interaction [e]	0.168	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	13 (43.3%)	19 (54.3%)
	The number (%) of patients censored [a]	17 (56.7%)	16 (45.7%)
	Median time to event (95% CI) [b]	7.9 (2.8, NE)	4.2 (2.1, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.189	
	HR (95% CI) [d]	0.61 (0.30, 1.27)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	49 (51.6%)	50 (56.2%)
	The number (%) of patients censored [a]	46 (48.4%)	39 (43.8%)
	Median time to event (95% CI) [b]	6.8 (3.5, 10.8)	3.5 (2.2, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.234	
	HR (95% CI) [d]	0.79 (0.53, 1.17)	
	P-value of subgroup*treatment interaction [e]	0.598	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	5 (16.7%)	2 (5.7%)
	The number (%) of patients censored [a]	25 (83.3%)	33 (94.3%)
	Median time to event (95% CI) [b]	0.9 (0.7, NE)	1.4 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.154	
	HR (95% CI) [d]	3.23 (0.60, 17.45)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	8 (8.4%)	11 (12.4%)
	The number (%) of patients censored [a]	87 (91.6%)	78 (87.6%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.579	
	HR (95% CI) [d]	0.76 (0.31, 1.89)	
	P-value of subgroup*treatment interaction [e]	0.216	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	10 (33.3%)	14 (40.0%)
	The number (%) of patients censored [a]	20 (66.7%)	21 (60.0%)
	Median time to event (95% CI) [b]	18.7 (3.9, NE)	5.1 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.453	
	HR (95% CI) [d]	0.73 (0.31, 1.70)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	33 (34.7%)	30 (33.7%)
	The number (%) of patients censored [a]	62 (65.3%)	59 (66.3%)
	Median time to event (95% CI) [b]	NE (8.8, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.865	
	HR (95% CI) [d]	1.04 (0.63, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.521	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.2.2
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	8 (26.7%)	11 (31.4%)
	The number (%) of patients censored [a]	22 (73.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	6.4 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.366	
	HR (95% CI) [d]	0.66 (0.26, 1.64)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	17 (17.9%)	18 (20.2%)
	The number (%) of patients censored [a]	78 (82.1%)	71 (79.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.927	
	HR (95% CI) [d]	1.03 (0.53, 2.01)	
	P-value of subgroup*treatment interaction [e]	0.462	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.3
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	2 (6.7%)	2 (5.7%)
	The number (%) of patients censored [a]	28 (93.3%)	33 (94.3%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	0.82 (0.11, 6.22)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	9 (9.5%)	6 (6.7%)
	The number (%) of patients censored [a]	86 (90.5%)	83 (93.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.678	
	HR (95% CI) [d]	1.25 (0.44, 3.50)	
	P-value of subgroup*treatment interaction [e]	0.840	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	58 (59.2%)	55 (57.3%)
	The number (%) of patients censored [a]	40 (40.8%)	41 (42.7%)
	Median time to event (95% CI) [b]	5.0 (2.1, 7.7)	3.7 (2.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.610	
	HR (95% CI) [d]	0.91 (0.63, 1.32)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	18 (64.3%)
	The number (%) of patients censored [a]	15 (55.6%)	10 (35.7%)
	Median time to event (95% CI) [b]	2.3 (1.0, NE)	2.6 (1.1, 10.9)
	Nominal p-value for unstratified log-rank test [c]	0.633	
	HR (95% CI) [d]	0.83 (0.40, 1.74)	
	P-value of subgroup*treatment interaction [e]	0.809	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	47 (48.0%)	54 (56.3%)
	The number (%) of patients censored [a]	51 (52.0%)	42 (43.8%)
	Median time to event (95% CI) [b]	8.8 (5.3, 21.5)	4.4 (2.6, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.111	
	HR (95% CI) [d]	0.73 (0.49, 1.08)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	11 (40.7%)	15 (53.6%)
	The number (%) of patients censored [a]	16 (59.3%)	13 (46.4%)
	Median time to event (95% CI) [b]	4.3 (1.0, NE)	5.1 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.718	
	HR (95% CI) [d]	1.15 (0.53, 2.52)	
	P-value of subgroup*treatment interaction [e]	0.383	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	59 (60.2%)	65 (67.7%)
	The number (%) of patients censored [a]	39 (39.8%)	31 (32.3%)
	Median time to event (95% CI) [b]	1.7 (1.3, 5.1)	3.5 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.576	
	HR (95% CI) [d]	0.91 (0.64, 1.30)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	19 (67.9%)
	The number (%) of patients censored [a]	14 (51.9%)	9 (32.1%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.4)	3.1 (0.9, 7.8)
	Nominal p-value for unstratified log-rank test [c]	0.664	
	HR (95% CI) [d]	1.16 (0.57, 2.39)	
	P-value of subgroup*treatment interaction [e]	0.592	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	53 (54.1%)	44 (45.8%)
	The number (%) of patients censored [a]	45 (45.9%)	52 (54.2%)
	Median time to event (95% CI) [b]	7.7 (4.2, 11.3)	10.0 (4.4, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.998	
	HR (95% CI) [d]	1.00 (0.67, 1.50)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	6 (22.2%)	12 (42.9%)
	The number (%) of patients censored [a]	21 (77.8%)	16 (57.1%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	9.1 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	0.70 (0.26, 1.90)	
	P-value of subgroup*treatment interaction [e]	0.391	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	62 (63.3%)	64 (66.7%)
	The number (%) of patients censored [a]	36 (36.7%)	32 (33.3%)
	Median time to event (95% CI) [b]	4.2 (2.8, 6.4)	2.4 (1.9, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.157	
	HR (95% CI) [d]	0.78 (0.55, 1.10)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	7 (25.9%)	15 (53.6%)
	The number (%) of patients censored [a]	20 (74.1%)	13 (46.4%)
	Median time to event (95% CI) [b]	22.4 (2.1, NE)	8.4 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	0.55 (0.21, 1.44)	
	P-value of subgroup*treatment interaction [e]	0.657	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	53 (54.1%)	59 (61.5%)
	The number (%) of patients censored [a]	45 (45.9%)	37 (38.5%)
	Median time to event (95% CI) [b]	3.6 (1.5, 12.2)	3.3 (1.6, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.269	
	HR (95% CI) [d]	0.81 (0.56, 1.18)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	15 (55.6%)	18 (64.3%)
	The number (%) of patients censored [a]	12 (44.4%)	10 (35.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	3.6 (0.9, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.604	
	HR (95% CI) [d]	1.21 (0.59, 2.44)	
	P-value of subgroup*treatment interaction [e]	0.273	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	67 (68.4%)	69 (71.9%)
	The number (%) of patients censored [a]	31 (31.6%)	27 (28.1%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.2)	1.4 (0.9, 2.7)
	Nominal p-value for unstratified log-rank test [c]	0.479	
	HR (95% CI) [d]	0.89 (0.64, 1.25)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	16 (59.3%)	23 (82.1%)
	The number (%) of patients censored [a]	11 (40.7%)	5 (17.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.6)	1.1 (0.9, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.85 (0.45, 1.61)	
	P-value of subgroup*treatment interaction [e]	0.822	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	71 (72.4%)	64 (66.7%)
	The number (%) of patients censored [a]	27 (27.6%)	32 (33.3%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.4)	1.5 (1.2, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.737	
	HR (95% CI) [d]	1.06 (0.76, 1.49)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	9 (33.3%)	15 (53.6%)
	The number (%) of patients censored [a]	18 (66.7%)	13 (46.4%)
	Median time to event (95% CI) [b]	3.2 (1.4, NE)	4.9 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.818	
	HR (95% CI) [d]	0.90 (0.39, 2.08)	
	P-value of subgroup*treatment interaction [e]	0.607	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	48 (49.0%)	57 (59.4%)
	The number (%) of patients censored [a]	50 (51.0%)	39 (40.6%)
	Median time to event (95% CI) [b]	7.7 (2.8, 15.5)	2.8 (1.9, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.076	
	HR (95% CI) [d]	0.71 (0.48, 1.04)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	10 (37.0%)	19 (67.9%)
	The number (%) of patients censored [a]	17 (63.0%)	9 (32.1%)
	Median time to event (95% CI) [b]	11.8 (1.0, NE)	2.6 (1.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.502	
	HR (95% CI) [d]	0.77 (0.35, 1.68)	
	P-value of subgroup*treatment interaction [e]	0.867	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	36 (36.7%)	50 (52.1%)
	The number (%) of patients censored [a]	62 (63.3%)	46 (47.9%)
	Median time to event (95% CI) [b]	NE (7.7, NE)	4.9 (2.8, 8.0)
	Nominal p-value for unstratified log-rank test [c]	0.004	
	HR (95% CI) [d]	0.53 (0.35, 0.82)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	7 (25.9%)	15 (53.6%)
	The number (%) of patients censored [a]	20 (74.1%)	13 (46.4%)
	Median time to event (95% CI) [b]	15.5 (3.1, NE)	5.0 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.326	
	HR (95% CI) [d]	0.62 (0.24, 1.62)	
	P-value of subgroup*treatment interaction [e]	0.667	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	51 (52.0%)	52 (54.2%)
	The number (%) of patients censored [a]	47 (48.0%)	44 (45.8%)
	Median time to event (95% CI) [b]	5.3 (3.2, 10.8)	4.4 (3.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.335	
	HR (95% CI) [d]	0.83 (0.56, 1.22)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	8 (29.6%)	15 (53.6%)
	The number (%) of patients censored [a]	19 (70.4%)	13 (46.4%)
	Median time to event (95% CI) [b]	4.0 (1.0, NE)	3.6 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.658	
	HR (95% CI) [d]	0.83 (0.35, 1.97)	
	P-value of subgroup*treatment interaction [e]	0.915	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	51 (52.0%)	57 (59.4%)
	The number (%) of patients censored [a]	47 (48.0%)	39 (40.6%)
	Median time to event (95% CI) [b]	4.1 (1.6, NE)	2.4 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.133	
	HR (95% CI) [d]	0.75 (0.52, 1.10)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	11 (39.3%)
	The number (%) of patients censored [a]	14 (51.9%)	17 (60.7%)
	Median time to event (95% CI) [b]	2.1 (1.4, 4.0)	14.5 (4.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.018	
	HR (95% CI) [d]	2.64 (1.15, 6.02)	
	P-value of subgroup*treatment interaction [e]	0.021	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	55 (56.1%)	57 (59.4%)
	The number (%) of patients censored [a]	43 (43.9%)	39 (40.6%)
	Median time to event (95% CI) [b]	2.5 (1.8, 12.4)	2.1 (1.4, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.199	
	HR (95% CI) [d]	0.78 (0.54, 1.13)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	15 (53.6%)
	The number (%) of patients censored [a]	15 (55.6%)	13 (46.4%)
	Median time to event (95% CI) [b]	1.9 (1.0, NE)	3.5 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.702	
	HR (95% CI) [d]	1.16 (0.54, 2.48)	
	P-value of subgroup*treatment interaction [e]	0.430	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	71 (72.4%)	39 (40.6%)
	The number (%) of patients censored [a]	27 (27.6%)	57 (59.4%)
	Median time to event (95% CI) [b]	1.7 (1.1, 2.8)	7.4 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.28 (1.54, 3.38)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	8 (28.6%)
	The number (%) of patients censored [a]	14 (51.9%)	20 (71.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 3.3)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	3.76 (1.51, 9.36)	
	P-value of subgroup*treatment interaction [e]	0.203	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	37 (37.8%)	36 (37.5%)
	The number (%) of patients censored [a]	61 (62.2%)	60 (62.5%)
	Median time to event (95% CI) [b]	16.1 (6.9, NE)	6.5 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.290	
	HR (95% CI) [d]	0.78 (0.49, 1.24)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	5 (18.5%)	9 (32.1%)
	The number (%) of patients censored [a]	22 (81.5%)	19 (67.9%)
	Median time to event (95% CI) [b]	27.9 (2.4, NE)	19.4 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.473	
	HR (95% CI) [d]	0.65 (0.20, 2.12)	
	P-value of subgroup*treatment interaction [e]	0.963	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	58 (59.2%)	46 (47.9%)
	The number (%) of patients censored [a]	40 (40.8%)	50 (52.1%)
	Median time to event (95% CI) [b]	3.6 (2.1, 5.2)	5.2 (2.4, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.431	
	HR (95% CI) [d]	1.17 (0.79, 1.72)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	12 (42.9%)
	The number (%) of patients censored [a]	15 (55.6%)	16 (57.1%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.3)	15.2 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.046	
	HR (95% CI) [d]	2.30 (1.00, 5.33)	
	P-value of subgroup*treatment interaction [e]	0.099	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	31 (31.6%)	28 (29.2%)
	The number (%) of patients censored [a]	67 (68.4%)	68 (70.8%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.705	
	HR (95% CI) [d]	0.91 (0.54, 1.51)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	4 (14.8%)	9 (32.1%)
	The number (%) of patients censored [a]	23 (85.2%)	19 (67.9%)
	Median time to event (95% CI) [b]	NE (4.9, NE)	NE (5.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.819	
	HR (95% CI) [d]	0.87 (0.26, 2.87)	
	P-value of subgroup*treatment interaction [e]	0.699	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	6 (6.1%)	5 (5.2%)
	The number (%) of patients censored [a]	92 (93.9%)	91 (94.8%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.411	
	HR (95% CI) [d]	1.64 (0.50, 5.39)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	27 (100.0%)	28 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	44 (44.9%)	43 (44.8%)
	The number (%) of patients censored [a]	54 (55.1%)	53 (55.2%)
	Median time to event (95% CI) [b]	6.3 (2.2, 12.2)	4.9 (2.0, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.502	
	HR (95% CI) [d]	0.86 (0.56, 1.32)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	6 (22.2%)	12 (42.9%)
	The number (%) of patients censored [a]	21 (77.8%)	16 (57.1%)
	Median time to event (95% CI) [b]	27.9 (1.2, NE)	13.8 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.482	
	HR (95% CI) [d]	0.68 (0.24, 1.96)	
	P-value of subgroup*treatment interaction [e]	0.942	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	78 (79.6%)	60 (62.5%)
	The number (%) of patients censored [a]	20 (20.4%)	36 (37.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	2.7 (1.4, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.82 (1.30, 2.56)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	14 (50.0%)
	The number (%) of patients censored [a]	14 (51.9%)	14 (50.0%)
	Median time to event (95% CI) [b]	1.1 (0.8, 3.8)	5.1 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.071	
	HR (95% CI) [d]	2.01 (0.93, 4.34)	
	P-value of subgroup*treatment interaction [e]	0.998	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	30 (30.6%)	25 (26.0%)
	The number (%) of patients censored [a]	68 (69.4%)	71 (74.0%)
	Median time to event (95% CI) [b]	24.7 (17.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	0.97 (0.57, 1.65)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	6 (22.2%)	10 (35.7%)
	The number (%) of patients censored [a]	21 (77.8%)	18 (64.3%)
	Median time to event (95% CI) [b]	NE (1.5, NE)	NE (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.964	
	HR (95% CI) [d]	1.02 (0.37, 2.83)	
	P-value of subgroup*treatment interaction [e]	0.874	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	52 (53.1%)	53 (55.2%)
	The number (%) of patients censored [a]	46 (46.9%)	43 (44.8%)
	Median time to event (95% CI) [b]	6.9 (3.5, 13.3)	3.5 (2.8, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.156	
	HR (95% CI) [d]	0.76 (0.52, 1.11)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	10 (37.0%)	16 (57.1%)
	The number (%) of patients censored [a]	17 (63.0%)	12 (42.9%)
	Median time to event (95% CI) [b]	6.8 (2.5, NE)	3.7 (1.0, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.530	
	HR (95% CI) [d]	0.77 (0.35, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.920	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	9 (9.2%)	10 (10.4%)
	The number (%) of patients censored [a]	89 (90.8%)	86 (89.6%)
	Median time to event (95% CI) [b]	2.2 (0.8, NE)	1.4 (0.8, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.503	
	HR (95% CI) [d]	0.72 (0.29, 1.80)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	4 (14.8%)	3 (10.7%)
	The number (%) of patients censored [a]	23 (85.2%)	25 (89.3%)
	Median time to event (95% CI) [b]	1.2 (0.1, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.234	
	HR (95% CI) [d]	2.44 (0.54, 11.06)	
	P-value of subgroup*treatment interaction [e]	0.175	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.3.1
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	38 (38.8%)	34 (35.4%)
	The number (%) of patients censored [a]	60 (61.2%)	62 (64.6%)
	Median time to event (95% CI) [b]	18.7 (8.8, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.911	
	HR (95% CI) [d]	0.97 (0.61, 1.55)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	5 (18.5%)	10 (35.7%)
	The number (%) of patients censored [a]	22 (81.5%)	18 (64.3%)
	Median time to event (95% CI) [b]	NE (2.3, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.783	
	HR (95% CI) [d]	0.86 (0.29, 2.53)	
	P-value of subgroup*treatment interaction [e]	0.657	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.3.2
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	22 (22.4%)	24 (25.0%)
	The number (%) of patients censored [a]	76 (77.6%)	72 (75.0%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.389	
	HR (95% CI) [d]	0.77 (0.43, 1.38)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	3 (11.1%)	5 (17.9%)
	The number (%) of patients censored [a]	24 (88.9%)	23 (82.1%)
	Median time to event (95% CI) [b]	NE (3.3, NE)	NE (6.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	1.62 (0.39, 6.82)	
	P-value of subgroup*treatment interaction [e]	0.398	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.3.3
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	9 (9.2%)	5 (5.2%)
	The number (%) of patients censored [a]	89 (90.8%)	91 (94.8%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.643	
	HR (95% CI) [d]	1.29 (0.43, 3.86)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	2 (7.4%)	3 (10.7%)
	The number (%) of patients censored [a]	25 (92.6%)	25 (89.3%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.485	
	HR (95% CI) [d]	1.88 (0.31, 11.32)	
	P-value of subgroup*treatment interaction [e]	0.778	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.4.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	46 (56.8%)	52 (67.5%)
	The number (%) of patients censored [a]	35 (43.2%)	25 (32.5%)
	Median time to event (95% CI) [b]	2.4 (1.4, 6.0)	2.7 (1.4, 3.9)
	Nominal p-value for unstratified log-rank test [c]	0.255	
	HR (95% CI) [d]	0.80 (0.53, 1.19)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	14 (53.8%)
	The number (%) of patients censored [a]	11 (42.3%)	12 (46.2%)
	Median time to event (95% CI) [b]	6.3 (1.8, 15.5)	5.6 (1.6, 14.0)
	Nominal p-value for unstratified log-rank test [c]	0.834	
	HR (95% CI) [d]	0.92 (0.44, 1.93)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	7 (43.8%)	7 (33.3%)
	The number (%) of patients censored [a]	9 (56.3%)	14 (66.7%)
	Median time to event (95% CI) [b]	15.2 (2.4, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.839	
	HR (95% CI) [d]	1.12 (0.39, 3.20)	
	P-value of subgroup*treatment interaction [e]	0.775	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	36 (44.4%)	43 (55.8%)
	The number (%) of patients censored [a]	45 (55.6%)	34 (44.2%)
	Median time to event (95% CI) [b]	7.4 (3.5, NE)	3.7 (2.2, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.239	
	HR (95% CI) [d]	0.77 (0.49, 1.20)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	16 (61.5%)	14 (53.8%)
	The number (%) of patients censored [a]	10 (38.5%)	12 (46.2%)
	Median time to event (95% CI) [b]	3.6 (0.9, 8.8)	5.6 (1.6, 14.0)
	Nominal p-value for unstratified log-rank test [c]	0.649	
	HR (95% CI) [d]	1.18 (0.57, 2.43)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	6 (37.5%)	12 (57.1%)
	The number (%) of patients censored [a]	10 (62.5%)	9 (42.9%)
	Median time to event (95% CI) [b]	21.5 (2.4, NE)	5.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	0.45 (0.17, 1.22)	
	P-value of subgroup*treatment interaction [e]	0.290	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	48 (59.3%)	49 (63.6%)
	The number (%) of patients censored [a]	33 (40.7%)	28 (36.4%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.4)	3.8 (1.6, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.538	
	HR (95% CI) [d]	1.14 (0.76, 1.70)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	18 (69.2%)
	The number (%) of patients censored [a]	11 (42.3%)	8 (30.8%)
	Median time to event (95% CI) [b]	3.2 (0.9, 8.4)	3.5 (0.9, 7.8)
	Nominal p-value for unstratified log-rank test [c]	0.880	
	HR (95% CI) [d]	0.94 (0.47, 1.86)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	7 (43.8%)	17 (81.0%)
	The number (%) of patients censored [a]	9 (56.3%)	4 (19.0%)
	Median time to event (95% CI) [b]	17.8 (1.0, NE)	3.1 (0.8, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.017	
	HR (95% CI) [d]	0.35 (0.14, 0.87)	
	P-value of subgroup*treatment interaction [e]	0.075	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	37 (45.7%)	34 (44.2%)
	The number (%) of patients censored [a]	44 (54.3%)	43 (55.8%)
	Median time to event (95% CI) [b]	7.8 (3.4, NE)	5.9 (3.5, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.931	
	HR (95% CI) [d]	0.98 (0.61, 1.56)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	14 (53.8%)
	The number (%) of patients censored [a]	14 (53.8%)	12 (46.2%)
	Median time to event (95% CI) [b]	11.3 (4.1, 15.5)	9.1 (4.9, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.363	
	HR (95% CI) [d]	0.69 (0.31, 1.53)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	8 (38.1%)
	The number (%) of patients censored [a]	8 (50.0%)	13 (61.9%)
	Median time to event (95% CI) [b]	7.3 (3.1, NE)	14.0 (1.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.924	
	HR (95% CI) [d]	1.05 (0.39, 2.82)	
	P-value of subgroup*treatment interaction [e]	0.947	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	41 (50.6%)	49 (63.6%)
	The number (%) of patients censored [a]	40 (49.4%)	28 (36.4%)
	Median time to event (95% CI) [b]	5.1 (2.8, 9.8)	2.2 (1.7, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	0.71 (0.47, 1.08)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	17 (65.4%)
	The number (%) of patients censored [a]	11 (42.3%)	9 (34.6%)
	Median time to event (95% CI) [b]	3.6 (2.3, 18.5)	4.2 (2.2, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.479	
	HR (95% CI) [d]	0.77 (0.37, 1.58)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	11 (68.8%)	13 (61.9%)
	The number (%) of patients censored [a]	5 (31.3%)	8 (38.1%)
	Median time to event (95% CI) [b]	4.3 (1.0, 13.1)	3.3 (1.4, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.751	
	HR (95% CI) [d]	0.87 (0.38, 1.99)	
	P-value of subgroup*treatment interaction [e]	0.820	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	40 (49.4%)	45 (58.4%)
	The number (%) of patients censored [a]	41 (50.6%)	32 (41.6%)
	Median time to event (95% CI) [b]	2.2 (1.4, NE)	3.6 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.774	
	HR (95% CI) [d]	0.94 (0.61, 1.44)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	16 (61.5%)
	The number (%) of patients censored [a]	11 (42.3%)	10 (38.5%)
	Median time to event (95% CI) [b]	3.6 (1.0, NE)	4.9 (2.2, 7.1)
	Nominal p-value for unstratified log-rank test [c]	0.750	
	HR (95% CI) [d]	0.89 (0.44, 1.80)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	11 (68.8%)	16 (76.2%)
	The number (%) of patients censored [a]	5 (31.3%)	5 (23.8%)
	Median time to event (95% CI) [b]	2.4 (1.0, 21.5)	1.4 (0.8, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.175	
	HR (95% CI) [d]	0.57 (0.25, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.563	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	53 (65.4%)	58 (75.3%)
	The number (%) of patients censored [a]	28 (34.6%)	19 (24.7%)
	Median time to event (95% CI) [b]	1.5 (0.8, 2.3)	1.2 (0.9, 1.6)
	Nominal p-value for unstratified log-rank test [c]	0.142	
	HR (95% CI) [d]	0.76 (0.52, 1.11)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	19 (73.1%)	18 (69.2%)
	The number (%) of patients censored [a]	7 (26.9%)	8 (30.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.8)	4.1 (0.9, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.182	
	HR (95% CI) [d]	1.56 (0.81, 3.00)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	9 (56.3%)	16 (76.2%)
	The number (%) of patients censored [a]	7 (43.8%)	5 (23.8%)
	Median time to event (95% CI) [b]	2.3 (0.8, NE)	2.1 (0.8, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.138	
	HR (95% CI) [d]	0.54 (0.24, 1.24)	
	P-value of subgroup*treatment interaction [e]	0.088	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	54 (66.7%)	48 (62.3%)
	The number (%) of patients censored [a]	27 (33.3%)	29 (37.7%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.8)	2.1 (1.4, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.416	
	HR (95% CI) [d]	1.18 (0.80, 1.74)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	14 (53.8%)	17 (65.4%)
	The number (%) of patients censored [a]	12 (46.2%)	9 (34.6%)
	Median time to event (95% CI) [b]	2.0 (1.0, NE)	1.6 (0.8, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.574	
	HR (95% CI) [d]	0.81 (0.40, 1.66)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	10 (62.5%)	14 (66.7%)
	The number (%) of patients censored [a]	6 (37.5%)	7 (33.3%)
	Median time to event (95% CI) [b]	2.2 (0.8, 3.1)	1.3 (0.8, 3.4)
	Nominal p-value for unstratified log-rank test [c]	0.780	
	HR (95% CI) [d]	0.89 (0.39, 2.02)	
	P-value of subgroup*treatment interaction [e]	0.616	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	39 (48.1%)	49 (63.6%)
	The number (%) of patients censored [a]	42 (51.9%)	28 (36.4%)
	Median time to event (95% CI) [b]	4.4 (1.8, 9.8)	2.4 (1.6, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.140	
	HR (95% CI) [d]	0.73 (0.48, 1.11)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	17 (65.4%)
	The number (%) of patients censored [a]	14 (53.8%)	9 (34.6%)
	Median time to event (95% CI) [b]	8.8 (1.4, NE)	2.5 (1.7, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.106	
	HR (95% CI) [d]	0.53 (0.24, 1.16)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	5 (31.3%)	10 (47.6%)
	The number (%) of patients censored [a]	11 (68.8%)	11 (52.4%)
	Median time to event (95% CI) [b]	17.8 (0.8, NE)	6.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.446	
	HR (95% CI) [d]	0.66 (0.22, 1.95)	
	P-value of subgroup*treatment interaction [e]	0.805	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	27 (33.3%)	42 (54.5%)
	The number (%) of patients censored [a]	54 (66.7%)	35 (45.5%)
	Median time to event (95% CI) [b]	NE (7.7, NE)	4.9 (2.1, 8.0)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	0.51 (0.32, 0.84)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	11 (42.3%)	12 (46.2%)
	The number (%) of patients censored [a]	15 (57.7%)	14 (53.8%)
	Median time to event (95% CI) [b]	11.4 (3.5, NE)	5.8 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.525	
	HR (95% CI) [d]	0.76 (0.33, 1.74)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	5 (31.3%)	11 (52.4%)
	The number (%) of patients censored [a]	11 (68.8%)	10 (47.6%)
	Median time to event (95% CI) [b]	NE (1.5, NE)	4.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.182	
	HR (95% CI) [d]	0.49 (0.17, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.568	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	38 (46.9%)	42 (54.5%)
	The number (%) of patients censored [a]	43 (53.1%)	35 (45.5%)
	Median time to event (95% CI) [b]	5.1 (3.1, 9.1)	3.5 (2.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.555	
	HR (95% CI) [d]	0.88 (0.57, 1.36)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	15 (57.7%)
	The number (%) of patients censored [a]	14 (53.8%)	11 (42.3%)
	Median time to event (95% CI) [b]	9.1 (1.8, NE)	6.0 (0.9, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.163	
	HR (95% CI) [d]	0.57 (0.26, 1.26)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	10 (47.6%)
	The number (%) of patients censored [a]	8 (50.0%)	11 (52.4%)
	Median time to event (95% CI) [b]	6.6 (1.1, NE)	4.4 (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.936	
	HR (95% CI) [d]	0.96 (0.37, 2.47)	
	P-value of subgroup*treatment interaction [e]	0.751	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	43 (53.1%)	46 (59.7%)
	The number (%) of patients censored [a]	38 (46.9%)	31 (40.3%)
	Median time to event (95% CI) [b]	2.8 (1.4, 13.6)	2.6 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.513	
	HR (95% CI) [d]	0.88 (0.58, 1.33)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	13 (50.0%)
	The number (%) of patients censored [a]	14 (53.8%)	13 (50.0%)
	Median time to event (95% CI) [b]	4.1 (1.8, NE)	5.6 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.936	
	HR (95% CI) [d]	1.02 (0.46, 2.23)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	9 (42.9%)
	The number (%) of patients censored [a]	8 (50.0%)	12 (57.1%)
	Median time to event (95% CI) [b]	4.1 (1.4, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.926	
	HR (95% CI) [d]	1.04 (0.40, 2.70)	
	P-value of subgroup*treatment interaction [e]	0.972	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	43 (53.1%)	46 (59.7%)
	The number (%) of patients censored [a]	38 (46.9%)	31 (40.3%)
	Median time to event (95% CI) [b]	2.4 (1.7, 6.9)	2.2 (1.4, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.401	
	HR (95% CI) [d]	0.83 (0.55, 1.26)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	14 (53.8%)	15 (57.7%)
	The number (%) of patients censored [a]	12 (46.2%)	11 (42.3%)
	Median time to event (95% CI) [b]	2.3 (1.0, NE)	6.5 (0.9, 13.3)
	Nominal p-value for unstratified log-rank test [c]	0.688	
	HR (95% CI) [d]	0.85 (0.41, 1.78)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	9 (56.3%)	11 (52.4%)
	The number (%) of patients censored [a]	7 (43.8%)	10 (47.6%)
	Median time to event (95% CI) [b]	3.1 (1.0, 19.4)	2.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.584	
	HR (95% CI) [d]	0.77 (0.32, 1.88)	
	P-value of subgroup*treatment interaction [e]	0.981	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	52 (64.2%)	23 (29.9%)
	The number (%) of patients censored [a]	29 (35.8%)	54 (70.1%)
	Median time to event (95% CI) [b]	2.1 (1.0, 3.6)	13.2 (10.1, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.10 (1.89, 5.08)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	17 (65.4%)	11 (42.3%)
	The number (%) of patients censored [a]	9 (34.6%)	15 (57.7%)
	Median time to event (95% CI) [b]	1.8 (0.8, 5.8)	6.2 (2.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.035	
	HR (95% CI) [d]	2.24 (1.04, 4.80)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	13 (81.3%)	13 (61.9%)
	The number (%) of patients censored [a]	3 (18.8%)	8 (38.1%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.045	
	HR (95% CI) [d]	2.23 (1.01, 4.91)	
	P-value of subgroup*treatment interaction [e]	0.591	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	27 (33.3%)	33 (42.9%)
	The number (%) of patients censored [a]	54 (66.7%)	44 (57.1%)
	Median time to event (95% CI) [b]	16.1 (5.1, NE)	5.2 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	0.67 (0.40, 1.12)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	10 (38.5%)	7 (26.9%)
	The number (%) of patients censored [a]	16 (61.5%)	19 (73.1%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.521	
	HR (95% CI) [d]	1.37 (0.52, 3.61)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	4 (25.0%)	5 (23.8%)
	The number (%) of patients censored [a]	12 (75.0%)	16 (76.2%)
	Median time to event (95% CI) [b]	27.9 (1.4, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.591	
	HR (95% CI) [d]	0.64 (0.12, 3.31)	
	P-value of subgroup*treatment interaction [e]	0.401	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	40 (49.4%)	39 (50.6%)
	The number (%) of patients censored [a]	41 (50.6%)	38 (49.4%)
	Median time to event (95% CI) [b]	3.5 (1.7, 5.2)	5.0 (2.6, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.353	
	HR (95% CI) [d]	1.24 (0.79, 1.92)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	21 (80.8%)	11 (42.3%)
	The number (%) of patients censored [a]	5 (19.2%)	15 (57.7%)
	Median time to event (95% CI) [b]	2.9 (1.3, 5.1)	17.1 (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.017	
	HR (95% CI) [d]	2.43 (1.14, 5.19)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	8 (38.1%)
	The number (%) of patients censored [a]	8 (50.0%)	13 (61.9%)
	Median time to event (95% CI) [b]	5.0 (1.0, NE)	5.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.950	
	HR (95% CI) [d]	0.97 (0.36, 2.58)	
	P-value of subgroup*treatment interaction [e]	0.221	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	25 (30.9%)	26 (33.8%)
	The number (%) of patients censored [a]	56 (69.1%)	51 (66.2%)
	Median time to event (95% CI) [b]	13.3 (6.9, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.524	
	HR (95% CI) [d]	0.84 (0.48, 1.45)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	5 (19.2%)	6 (23.1%)
	The number (%) of patients censored [a]	21 (80.8%)	20 (76.9%)
	Median time to event (95% CI) [b]	18.5 (10.0, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.641	
	HR (95% CI) [d]	0.75 (0.23, 2.48)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	4 (25.0%)	5 (23.8%)
	The number (%) of patients censored [a]	12 (75.0%)	16 (76.2%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.96 (0.26, 3.56)	
	P-value of subgroup*treatment interaction [e]	0.990	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	5 (6.2%)	3 (3.9%)
	The number (%) of patients censored [a]	76 (93.8%)	74 (96.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.203	
	HR (95% CI) [d]	2.47 (0.59, 10.37)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	0 (0.0%)	1 (3.8%)
	The number (%) of patients censored [a]	26 (100.0%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	NE (NE, NE)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	1 (6.3%)	1 (4.8%)
	The number (%) of patients censored [a]	15 (93.8%)	20 (95.2%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.560	
	HR (95% CI) [d]	2.24 (0.14, 35.90)	
	P-value of subgroup*treatment interaction [e]	0.999	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	31 (38.3%)	32 (41.6%)
	The number (%) of patients censored [a]	50 (61.7%)	45 (58.4%)
	Median time to event (95% CI) [b]	3.5 (1.7, 8.7)	5.4 (2.0, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.599	
	HR (95% CI) [d]	1.14 (0.69, 1.87)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	14 (53.8%)
	The number (%) of patients censored [a]	14 (53.8%)	12 (46.2%)
	Median time to event (95% CI) [b]	9.8 (1.5, 18.5)	4.9 (1.5, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.370	
	HR (95% CI) [d]	0.69 (0.30, 1.56)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	6 (37.5%)	9 (42.9%)
	The number (%) of patients censored [a]	10 (62.5%)	12 (57.1%)
	Median time to event (95% CI) [b]	13.1 (4.9, NE)	3.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.122	
	HR (95% CI) [d]	0.40 (0.12, 1.31)	
	P-value of subgroup*treatment interaction [e]	0.233	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	58 (71.6%)	48 (62.3%)
	The number (%) of patients censored [a]	23 (28.4%)	29 (37.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	3.1 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	1.82 (1.24, 2.68)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	20 (76.9%)	14 (53.8%)
	The number (%) of patients censored [a]	6 (23.1%)	12 (46.2%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.3)	5.6 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.008	
	HR (95% CI) [d]	2.48 (1.24, 4.97)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	12 (75.0%)	12 (57.1%)
	The number (%) of patients censored [a]	4 (25.0%)	9 (42.9%)
	Median time to event (95% CI) [b]	1.2 (0.8, 5.2)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.488	
	HR (95% CI) [d]	1.31 (0.58, 2.96)	
	P-value of subgroup*treatment interaction [e]	0.516	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	26 (32.1%)	25 (32.5%)
	The number (%) of patients censored [a]	55 (67.9%)	52 (67.5%)
	Median time to event (95% CI) [b]	17.1 (7.5, NE)	12.7 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.509	
	HR (95% CI) [d]	0.83 (0.48, 1.44)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	6 (23.1%)	6 (23.1%)
	The number (%) of patients censored [a]	20 (76.9%)	20 (76.9%)
	Median time to event (95% CI) [b]	NE (17.5, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.958	
	HR (95% CI) [d]	1.03 (0.33, 3.22)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	4 (25.0%)	4 (19.0%)
	The number (%) of patients censored [a]	12 (75.0%)	17 (81.0%)
	Median time to event (95% CI) [b]	24.7 (5.6, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.742	
	HR (95% CI) [d]	1.27 (0.31, 5.17)	
	P-value of subgroup*treatment interaction [e]	0.869	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	39 (48.1%)	43 (55.8%)
	The number (%) of patients censored [a]	42 (51.9%)	34 (44.2%)
	Median time to event (95% CI) [b]	6.5 (3.6, 9.3)	3.7 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.184	
	HR (95% CI) [d]	0.75 (0.48, 1.15)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	17 (65.4%)	17 (65.4%)
	The number (%) of patients censored [a]	9 (34.6%)	9 (34.6%)
	Median time to event (95% CI) [b]	2.9 (1.1, 15.5)	1.7 (0.9, 11.8)
	Nominal p-value for unstratified log-rank test [c]	0.601	
	HR (95% CI) [d]	0.83 (0.42, 1.64)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	5 (31.3%)	9 (42.9%)
	The number (%) of patients censored [a]	11 (68.8%)	12 (57.1%)
	Median time to event (95% CI) [b]	15.9 (1.5, NE)	6.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.189	
	HR (95% CI) [d]	0.47 (0.15, 1.48)	
	P-value of subgroup*treatment interaction [e]	0.757	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	9 (11.1%)	8 (10.4%)
	The number (%) of patients censored [a]	72 (88.9%)	69 (89.6%)
	Median time to event (95% CI) [b]	0.9 (0.7, 3.5)	1.4 (0.8, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.361	
	HR (95% CI) [d]	1.46 (0.55, 3.84)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	2 (7.7%)	1 (3.8%)
	The number (%) of patients censored [a]	24 (92.3%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.619	
	HR (95% CI) [d]	1.82 (0.16, 20.20)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	2 (12.5%)	4 (19.0%)
	The number (%) of patients censored [a]	14 (87.5%)	17 (81.0%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.260	
	HR (95% CI) [d]	0.38 (0.07, 2.13)	
	P-value of subgroup*treatment interaction [e]	0.428	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	28 (34.6%)	31 (40.3%)
	The number (%) of patients censored [a]	53 (65.4%)	46 (59.7%)
	Median time to event (95% CI) [b]	18.7 (7.2, NE)	10.3 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.488	
	HR (95% CI) [d]	0.84 (0.50, 1.40)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	11 (42.3%)	10 (38.5%)
	The number (%) of patients censored [a]	15 (57.7%)	16 (61.5%)
	Median time to event (95% CI) [b]	9.8 (2.9, NE)	13.0 (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.955	
	HR (95% CI) [d]	1.03 (0.43, 2.46)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	3 (18.8%)	3 (14.3%)
	The number (%) of patients censored [a]	13 (81.3%)	18 (85.7%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.800	
	HR (95% CI) [d]	1.23 (0.25, 6.10)	
	P-value of subgroup*treatment interaction [e]	0.780	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.4.2
Time to First Meaningful Deterioration for PGIC by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	18 (22.2%)	21 (27.3%)
	The number (%) of patients censored [a]	63 (77.8%)	56 (72.7%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.4 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.425	
	HR (95% CI) [d]	0.77 (0.41, 1.46)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	4 (15.4%)	4 (15.4%)
	The number (%) of patients censored [a]	22 (84.6%)	22 (84.6%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.742	
	HR (95% CI) [d]	1.25 (0.31, 4.99)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	1 (6.3%)	4 (19.0%)
	The number (%) of patients censored [a]	15 (93.8%)	17 (81.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.385	
	HR (95% CI) [d]	0.39 (0.04, 3.52)	
	P-value of subgroup*treatment interaction [e]	0.536	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.3
Time to First Meaningful Deterioration for PGIS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	8 (9.9%)	5 (6.5%)
	The number (%) of patients censored [a]	73 (90.1%)	72 (93.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.751	
	HR (95% CI) [d]	1.20 (0.39, 3.67)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	2 (7.7%)	3 (11.5%)
	The number (%) of patients censored [a]	24 (92.3%)	23 (88.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.517	
	HR (95% CI) [d]	0.56 (0.09, 3.35)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	1 (6.3%)	0 (0.0%)
	The number (%) of patients censored [a]	15 (93.8%)	21 (100.0%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.781	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	48 (59.3%)	54 (67.5%)
	The number (%) of patients censored [a]	33 (40.7%)	26 (32.5%)
	Median time to event (95% CI) [b]	4.9 (1.8, 7.2)	2.5 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.238	
	HR (95% CI) [d]	0.80 (0.54, 1.17)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	22 (50.0%)	19 (43.2%)
	The number (%) of patients censored [a]	22 (50.0%)	25 (56.8%)
	Median time to event (95% CI) [b]	3.2 (1.4, NE)	10.9 (2.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.713	
	HR (95% CI) [d]	1.12 (0.60, 2.11)	
	P-value of subgroup*treatment interaction [e]	0.302	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	38 (46.9%)	44 (55.0%)
	The number (%) of patients censored [a]	43 (53.1%)	36 (45.0%)
	Median time to event (95% CI) [b]	7.9 (4.3, NE)	5.4 (2.8, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.363	
	HR (95% CI) [d]	0.82 (0.53, 1.26)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	20 (45.5%)	25 (56.8%)
	The number (%) of patients censored [a]	24 (54.5%)	19 (43.2%)
	Median time to event (95% CI) [b]	6.4 (1.3, NE)	3.5 (1.5, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.216	
	HR (95% CI) [d]	0.68 (0.37, 1.27)	
	P-value of subgroup*treatment interaction [e]	0.643	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	49 (60.5%)	57 (71.3%)
	The number (%) of patients censored [a]	32 (39.5%)	23 (28.8%)
	Median time to event (95% CI) [b]	1.8 (1.4, 5.1)	4.1 (1.7, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.707	
	HR (95% CI) [d]	0.93 (0.64, 1.37)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	27 (61.4%)
	The number (%) of patients censored [a]	21 (47.7%)	17 (38.6%)
	Median time to event (95% CI) [b]	1.4 (0.9, 17.8)	2.5 (0.9, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.953	
	HR (95% CI) [d]	0.98 (0.56, 1.73)	
	P-value of subgroup*treatment interaction [e]	0.949	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	41 (50.6%)	36 (45.0%)
	The number (%) of patients censored [a]	40 (49.4%)	44 (55.0%)
	Median time to event (95% CI) [b]	8.8 (4.3, 11.4)	10.0 (5.1, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.938	
	HR (95% CI) [d]	1.02 (0.65, 1.60)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	18 (40.9%)	20 (45.5%)
	The number (%) of patients censored [a]	26 (59.1%)	24 (54.5%)
	Median time to event (95% CI) [b]	6.0 (3.0, NE)	4.9 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.579	
	HR (95% CI) [d]	0.83 (0.44, 1.59)	
	P-value of subgroup*treatment interaction [e]	0.520	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	45 (55.6%)	48 (60.0%)
	The number (%) of patients censored [a]	36 (44.4%)	32 (40.0%)
	Median time to event (95% CI) [b]	5.6 (2.8, 12.6)	3.1 (2.1, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.370	
	HR (95% CI) [d]	0.83 (0.55, 1.25)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	24 (54.5%)	31 (70.5%)
	The number (%) of patients censored [a]	20 (45.5%)	13 (29.5%)
	Median time to event (95% CI) [b]	3.4 (2.2, 4.6)	2.4 (1.4, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.305	
	HR (95% CI) [d]	0.76 (0.44, 1.29)	
	P-value of subgroup*treatment interaction [e]	0.824	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	46 (56.8%)	49 (61.3%)
	The number (%) of patients censored [a]	35 (43.2%)	31 (38.8%)
	Median time to event (95% CI) [b]	2.5 (1.4, 12.2)	3.5 (1.4, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.693	
	HR (95% CI) [d]	0.92 (0.61, 1.38)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	22 (50.0%)	28 (63.6%)
	The number (%) of patients censored [a]	22 (50.0%)	16 (36.4%)
	Median time to event (95% CI) [b]	3.5 (1.0, 21.5)	3.6 (0.9, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.438	
	HR (95% CI) [d]	0.80 (0.45, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.671	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	58 (71.6%)	62 (77.5%)
	The number (%) of patients censored [a]	23 (28.4%)	18 (22.5%)
	Median time to event (95% CI) [b]	1.7 (1.0, 2.3)	1.4 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.505	
	HR (95% CI) [d]	0.89 (0.62, 1.27)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	25 (56.8%)	30 (68.2%)
	The number (%) of patients censored [a]	19 (43.2%)	14 (31.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, 4.2)	1.4 (0.9, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.392	
	HR (95% CI) [d]	0.80 (0.46, 1.37)	
	P-value of subgroup*treatment interaction [e]	0.707	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	57 (70.4%)	56 (70.0%)
	The number (%) of patients censored [a]	24 (29.6%)	24 (30.0%)
	Median time to event (95% CI) [b]	1.8 (1.4, 2.8)	1.7 (1.1, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.980	
	HR (95% CI) [d]	0.99 (0.68, 1.44)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	23 (52.3%)
	The number (%) of patients censored [a]	21 (47.7%)	21 (47.7%)
	Median time to event (95% CI) [b]	1.4 (0.8, NE)	2.5 (1.4, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.470	
	HR (95% CI) [d]	1.25 (0.70, 2.23)	
	P-value of subgroup*treatment interaction [e]	0.506	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	42 (51.9%)	51 (63.8%)
	The number (%) of patients censored [a]	39 (48.1%)	29 (36.3%)
	Median time to event (95% CI) [b]	7.7 (2.5, 11.8)	2.8 (1.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.094	
	HR (95% CI) [d]	0.71 (0.47, 1.07)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	16 (36.4%)	25 (56.8%)
	The number (%) of patients censored [a]	28 (63.6%)	19 (43.2%)
	Median time to event (95% CI) [b]	17.8 (1.5, NE)	3.6 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.302	
	HR (95% CI) [d]	0.72 (0.38, 1.37)	
	P-value of subgroup*treatment interaction [e]	0.941	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	28 (34.6%)	46 (57.5%)
	The number (%) of patients censored [a]	53 (65.4%)	34 (42.5%)
	Median time to event (95% CI) [b]	NE (9.7, NE)	4.4 (2.4, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.46 (0.29, 0.74)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	15 (34.1%)	19 (43.2%)
	The number (%) of patients censored [a]	29 (65.9%)	25 (56.8%)
	Median time to event (95% CI) [b]	7.2 (3.1, NE)	5.8 (3.3, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.449	
	HR (95% CI) [d]	0.77 (0.39, 1.52)	
	P-value of subgroup*treatment interaction [e]	0.214	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	42 (51.9%)	44 (55.0%)
	The number (%) of patients censored [a]	39 (48.1%)	36 (45.0%)
	Median time to event (95% CI) [b]	5.3 (3.2, 14.4)	4.1 (2.7, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.486	
	HR (95% CI) [d]	0.86 (0.56, 1.31)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	17 (38.6%)	23 (52.3%)
	The number (%) of patients censored [a]	27 (61.4%)	21 (47.7%)
	Median time to event (95% CI) [b]	9.1 (1.4, 16.8)	4.4 (2.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.402	
	HR (95% CI) [d]	0.76 (0.40, 1.44)	
	P-value of subgroup*treatment interaction [e]	0.759	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	41 (50.6%)	49 (61.3%)
	The number (%) of patients censored [a]	40 (49.4%)	31 (38.8%)
	Median time to event (95% CI) [b]	4.2 (1.8, NE)	3.1 (1.4, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.202	
	HR (95% CI) [d]	0.77 (0.50, 1.16)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	19 (43.2%)
	The number (%) of patients censored [a]	21 (47.7%)	25 (56.8%)
	Median time to event (95% CI) [b]	2.8 (1.0, 3.8)	5.2 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	1.40 (0.76, 2.58)	
	P-value of subgroup*treatment interaction [e]	0.120	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	43 (53.1%)	51 (63.8%)
	The number (%) of patients censored [a]	38 (46.9%)	29 (36.3%)
	Median time to event (95% CI) [b]	3.1 (1.9, NE)	2.2 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.075	
	HR (95% CI) [d]	0.69 (0.46, 1.03)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	24 (54.5%)	21 (47.7%)
	The number (%) of patients censored [a]	20 (45.5%)	23 (52.3%)
	Median time to event (95% CI) [b]	2.1 (1.0, 4.6)	3.3 (1.5, 13.3)
	Nominal p-value for unstratified log-rank test [c]	0.525	
	HR (95% CI) [d]	1.21 (0.67, 2.18)	
	P-value of subgroup*treatment interaction [e]	0.107	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	57 (70.4%)	31 (38.8%)
	The number (%) of patients censored [a]	24 (29.6%)	49 (61.3%)
	Median time to event (95% CI) [b]	1.7 (1.0, 3.3)	10.1 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.54 (1.64, 3.95)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	27 (61.4%)	16 (36.4%)
	The number (%) of patients censored [a]	17 (38.6%)	28 (63.6%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.8)	NE (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	2.54 (1.37, 4.74)	
	P-value of subgroup*treatment interaction [e]	0.965	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	24 (29.6%)	26 (32.5%)
	The number (%) of patients censored [a]	57 (70.4%)	54 (67.5%)
	Median time to event (95% CI) [b]	19.0 (8.5, NE)	19.4 (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	0.72 (0.41, 1.27)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	18 (40.9%)	19 (43.2%)
	The number (%) of patients censored [a]	26 (59.1%)	25 (56.8%)
	Median time to event (95% CI) [b]	3.6 (1.3, NE)	4.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.938	
	HR (95% CI) [d]	1.03 (0.53, 1.99)	
	P-value of subgroup*treatment interaction [e]	0.609	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	49 (60.5%)	36 (45.0%)
	The number (%) of patients censored [a]	32 (39.5%)	44 (55.0%)
	Median time to event (95% CI) [b]	3.5 (1.8, 5.2)	7.0 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.106	
	HR (95% CI) [d]	1.42 (0.92, 2.19)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	21 (47.7%)	22 (50.0%)
	The number (%) of patients censored [a]	23 (52.3%)	22 (50.0%)
	Median time to event (95% CI) [b]	2.1 (1.0, 12.6)	5.0 (2.0, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.612	
	HR (95% CI) [d]	1.17 (0.64, 2.15)	
	P-value of subgroup*treatment interaction [e]	0.663	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	27 (33.3%)	23 (28.8%)
	The number (%) of patients censored [a]	54 (66.7%)	57 (71.3%)
	Median time to event (95% CI) [b]	18.5 (10.0, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.789	
	HR (95% CI) [d]	1.08 (0.62, 1.88)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	8 (18.2%)	14 (31.8%)
	The number (%) of patients censored [a]	36 (81.8%)	30 (68.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	0.51 (0.21, 1.22)	
	P-value of subgroup*treatment interaction [e]	0.159	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	5 (6.2%)	2 (2.5%)
	The number (%) of patients censored [a]	76 (93.8%)	78 (97.5%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.081	
	HR (95% CI) [d]	3.93 (0.76, 20.43)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	1 (2.3%)	3 (6.8%)
	The number (%) of patients censored [a]	43 (97.7%)	41 (93.2%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	3.1 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.095	
	HR (95% CI) [d]	0.16 (0.02, 1.73)	
	P-value of subgroup*treatment interaction [e]	0.033	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	36 (44.4%)	33 (41.3%)
	The number (%) of patients censored [a]	45 (55.6%)	47 (58.8%)
	Median time to event (95% CI) [b]	7.0 (3.1, 12.2)	7.0 (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.963	
	HR (95% CI) [d]	0.98 (0.61, 1.59)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	14 (31.8%)	22 (50.0%)
	The number (%) of patients censored [a]	30 (68.2%)	22 (50.0%)
	Median time to event (95% CI) [b]	4.2 (1.3, NE)	3.9 (1.5, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.315	
	HR (95% CI) [d]	0.70 (0.35, 1.39)	
	P-value of subgroup*treatment interaction [e]	0.333	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	65 (80.2%)	50 (62.5%)
	The number (%) of patients censored [a]	16 (19.8%)	30 (37.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.0)	2.9 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.24 (1.54, 3.28)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	26 (59.1%)	24 (54.5%)
	The number (%) of patients censored [a]	18 (40.9%)	20 (45.5%)
	Median time to event (95% CI) [b]	1.4 (0.8, 4.6)	3.5 (1.7, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.326	
	HR (95% CI) [d]	1.33 (0.76, 2.32)	
	P-value of subgroup*treatment interaction [e]	0.099	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	25 (30.9%)	24 (30.0%)
	The number (%) of patients censored [a]	56 (69.1%)	56 (70.0%)
	Median time to event (95% CI) [b]	17.5 (10.2, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.829	
	HR (95% CI) [d]	0.94 (0.54, 1.65)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	11 (25.0%)	11 (25.0%)
	The number (%) of patients censored [a]	33 (75.0%)	33 (75.0%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.739	
	HR (95% CI) [d]	0.86 (0.36, 2.04)	
	P-value of subgroup*treatment interaction [e]	0.917	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	39 (48.1%)	47 (58.8%)
	The number (%) of patients censored [a]	42 (51.9%)	33 (41.3%)
	Median time to event (95% CI) [b]	7.2 (3.5, 15.5)	3.5 (2.2, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.047	
	HR (95% CI) [d]	0.65 (0.42, 1.00)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	22 (50.0%)
	The number (%) of patients censored [a]	21 (47.7%)	22 (50.0%)
	Median time to event (95% CI) [b]	4.6 (1.4, 15.2)	4.2 (1.7, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.865	
	HR (95% CI) [d]	0.95 (0.53, 1.72)	
	P-value of subgroup*treatment interaction [e]	0.279	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	4 (4.9%)	10 (12.5%)
	The number (%) of patients censored [a]	77 (95.1%)	70 (87.5%)
	Median time to event (95% CI) [b]	7.2 (0.7, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.462	
	HR (95% CI) [d]	0.62 (0.19, 2.00)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	9 (20.5%)	3 (6.8%)
	The number (%) of patients censored [a]	35 (79.5%)	41 (93.2%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.431	
	HR (95% CI) [d]	1.68 (0.45, 6.29)	
	P-value of subgroup*treatment interaction [e]	0.254	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	28 (34.6%)	30 (37.5%)
	The number (%) of patients censored [a]	53 (65.4%)	50 (62.5%)
	Median time to event (95% CI) [b]	18.7 (9.0, NE)	12.4 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.680	
	HR (95% CI) [d]	0.90 (0.54, 1.51)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	15 (34.1%)	14 (31.8%)
	The number (%) of patients censored [a]	29 (65.9%)	30 (68.2%)
	Median time to event (95% CI) [b]	NE (2.3, NE)	15.4 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.839	
	HR (95% CI) [d]	1.08 (0.52, 2.24)	
	P-value of subgroup*treatment interaction [e]	0.770	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.5.2
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	22 (27.2%)	19 (23.8%)
	The number (%) of patients censored [a]	59 (72.8%)	61 (76.3%)
	Median time to event (95% CI) [b]	NE (5.8, NE)	6.5 (6.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.468	
	HR (95% CI) [d]	1.25 (0.68, 2.32)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	3 (6.8%)	10 (22.7%)
	The number (%) of patients censored [a]	41 (93.2%)	34 (77.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.075	
	HR (95% CI) [d]	0.32 (0.09, 1.20)	
	P-value of subgroup*treatment interaction [e]	0.048	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.3
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	6 (7.4%)	3 (3.8%)
	The number (%) of patients censored [a]	75 (92.6%)	77 (96.3%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.501	
	HR (95% CI) [d]	1.60 (0.40, 6.42)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	5 (11.4%)	5 (11.4%)
	The number (%) of patients censored [a]	39 (88.6%)	39 (88.6%)
	Median time to event (95% CI) [b]	NE (4.5, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.902	
	HR (95% CI) [d]	1.08 (0.31, 3.74)	
	P-value of subgroup*treatment interaction [e]	0.744	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	18 (50.0%)	9 (34.6%)
	The number (%) of patients censored [a]	18 (50.0%)	17 (65.4%)
	Median time to event (95% CI) [b]	6.0 (2.3, 15.2)	5.7 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	1.06 (0.47, 2.39)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	52 (58.4%)	64 (65.3%)
	The number (%) of patients censored [a]	37 (41.6%)	34 (34.7%)
	Median time to event (95% CI) [b]	2.4 (1.6, 7.2)	2.7 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.573	
	HR (95% CI) [d]	0.90 (0.63, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.522	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	14 (38.9%)	11 (42.3%)
	The number (%) of patients censored [a]	22 (61.1%)	15 (57.7%)
	Median time to event (95% CI) [b]	8.8 (6.4, NE)	4.4 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.352	
	HR (95% CI) [d]	0.68 (0.30, 1.54)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	44 (49.4%)	58 (59.2%)
	The number (%) of patients censored [a]	45 (50.6%)	40 (40.8%)
	Median time to event (95% CI) [b]	7.5 (2.4, 21.5)	4.9 (2.9, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.330	
	HR (95% CI) [d]	0.83 (0.56, 1.22)	
	P-value of subgroup*treatment interaction [e]	0.651	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	19 (52.8%)	12 (46.2%)
	The number (%) of patients censored [a]	17 (47.2%)	14 (53.8%)
	Median time to event (95% CI) [b]	1.9 (0.9, NE)	8.6 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.629	
	HR (95% CI) [d]	1.19 (0.57, 2.48)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	53 (59.6%)	72 (73.5%)
	The number (%) of patients censored [a]	36 (40.4%)	26 (26.5%)
	Median time to event (95% CI) [b]	1.5 (1.3, 2.8)	3.1 (1.5, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.581	
	HR (95% CI) [d]	0.91 (0.64, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.496	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	4 (15.4%)
	The number (%) of patients censored [a]	19 (52.8%)	22 (84.6%)
	Median time to event (95% CI) [b]	7.7 (3.2, 11.8)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.121	
	HR (95% CI) [d]	2.31 (0.78, 6.89)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	42 (47.2%)	52 (53.1%)
	The number (%) of patients censored [a]	47 (52.8%)	46 (46.9%)
	Median time to event (95% CI) [b]	9.0 (4.2, 12.5)	8.3 (4.4, 10.8)
	Nominal p-value for unstratified log-rank test [c]	0.432	
	HR (95% CI) [d]	0.85 (0.56, 1.28)	
	P-value of subgroup*treatment interaction [e]	0.107	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	13 (50.0%)
	The number (%) of patients censored [a]	19 (52.8%)	13 (50.0%)
	Median time to event (95% CI) [b]	4.9 (2.6, 13.1)	3.0 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.342	
	HR (95% CI) [d]	0.69 (0.33, 1.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	52 (58.4%)	66 (67.3%)
	The number (%) of patients censored [a]	37 (41.6%)	32 (32.7%)
	Median time to event (95% CI) [b]	4.2 (2.8, 6.9)	2.6 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.286	
	HR (95% CI) [d]	0.82 (0.57, 1.18)	
	P-value of subgroup*treatment interaction [e]	0.787	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	15 (41.7%)	10 (38.5%)
	The number (%) of patients censored [a]	21 (58.3%)	16 (61.5%)
	Median time to event (95% CI) [b]	3.8 (1.5, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.02 (0.46, 2.28)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	53 (59.6%)	67 (68.4%)
	The number (%) of patients censored [a]	36 (40.4%)	31 (31.6%)
	Median time to event (95% CI) [b]	1.8 (1.1, 4.8)	3.3 (1.6, 4.5)
	Nominal p-value for unstratified log-rank test [c]	0.573	
	HR (95% CI) [d]	0.90 (0.63, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.864	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	24 (66.7%)	12 (46.2%)
	The number (%) of patients censored [a]	12 (33.3%)	14 (53.8%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.4)	2.1 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.130	
	HR (95% CI) [d]	1.72 (0.86, 3.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	59 (66.3%)	80 (81.6%)
	The number (%) of patients censored [a]	30 (33.7%)	18 (18.4%)
	Median time to event (95% CI) [b]	1.7 (1.0, 2.3)	1.4 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.065	
	HR (95% CI) [d]	0.73 (0.52, 1.02)	
	P-value of subgroup*treatment interaction [e]	0.034	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	23 (63.9%)	15 (57.7%)
	The number (%) of patients censored [a]	13 (36.1%)	11 (42.3%)
	Median time to event (95% CI) [b]	1.7 (0.8, 3.1)	2.8 (1.2, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.546	
	HR (95% CI) [d]	1.23 (0.64, 2.38)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	57 (64.0%)	64 (65.3%)
	The number (%) of patients censored [a]	32 (36.0%)	34 (34.7%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.8)	1.6 (1.2, 2.6)
	Nominal p-value for unstratified log-rank test [c]	0.948	
	HR (95% CI) [d]	1.01 (0.71, 1.45)	
	P-value of subgroup*treatment interaction [e]	0.587	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	16 (44.4%)	11 (42.3%)
	The number (%) of patients censored [a]	20 (55.6%)	15 (57.7%)
	Median time to event (95% CI) [b]	8.8 (1.9, 17.8)	4.9 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.88 (0.40, 1.95)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	42 (47.2%)	65 (66.3%)
	The number (%) of patients censored [a]	47 (52.8%)	33 (33.7%)
	Median time to event (95% CI) [b]	6.5 (1.7, 15.5)	2.5 (1.9, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.052	
	HR (95% CI) [d]	0.68 (0.46, 1.01)	
	P-value of subgroup*treatment interaction [e]	0.527	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	12 (33.3%)	7 (26.9%)
	The number (%) of patients censored [a]	24 (66.7%)	19 (73.1%)
	Median time to event (95% CI) [b]	9.6 (3.6, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	0.99 (0.38, 2.57)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	31 (34.8%)	58 (59.2%)
	The number (%) of patients censored [a]	58 (65.2%)	40 (40.8%)
	Median time to event (95% CI) [b]	15.5 (9.7, NE)	4.9 (2.8, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.50 (0.32, 0.77)	
	P-value of subgroup*treatment interaction [e]	0.221	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	18 (50.0%)	12 (46.2%)
	The number (%) of patients censored [a]	18 (50.0%)	14 (53.8%)
	Median time to event (95% CI) [b]	5.3 (2.3, 10.8)	3.1 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.595	
	HR (95% CI) [d]	0.82 (0.39, 1.70)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	41 (46.1%)	55 (56.1%)
	The number (%) of patients censored [a]	48 (53.9%)	43 (43.9%)
	Median time to event (95% CI) [b]	7.2 (3.2, 16.8)	4.4 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.362	
	HR (95% CI) [d]	0.83 (0.55, 1.24)	
	P-value of subgroup*treatment interaction [e]	0.873	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	19 (52.8%)	7 (26.9%)
	The number (%) of patients censored [a]	17 (47.2%)	19 (73.1%)
	Median time to event (95% CI) [b]	3.1 (1.5, NE)	9.2 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.182	
	HR (95% CI) [d]	1.80 (0.75, 4.31)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	45 (50.6%)	61 (62.2%)
	The number (%) of patients censored [a]	44 (49.4%)	37 (37.8%)
	Median time to event (95% CI) [b]	3.8 (1.5, NE)	3.1 (1.7, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.273	
	HR (95% CI) [d]	0.81 (0.55, 1.19)	
	P-value of subgroup*treatment interaction [e]	0.095	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	20 (55.6%)	15 (57.7%)
	The number (%) of patients censored [a]	16 (44.4%)	11 (42.3%)
	Median time to event (95% CI) [b]	2.3 (1.7, 12.4)	1.4 (0.8, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.171	
	HR (95% CI) [d]	0.61 (0.31, 1.22)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	47 (52.8%)	57 (58.2%)
	The number (%) of patients censored [a]	42 (47.2%)	41 (41.8%)
	Median time to event (95% CI) [b]	2.8 (1.5, 19.4)	2.7 (1.7, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.494	
	HR (95% CI) [d]	0.87 (0.59, 1.28)	
	P-value of subgroup*treatment interaction [e]	0.466	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	25 (69.4%)	7 (26.9%)
	The number (%) of patients censored [a]	11 (30.6%)	19 (73.1%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.6)	10.1 (10.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	3.03 (1.30, 7.07)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	59 (66.3%)	40 (40.8%)
	The number (%) of patients censored [a]	30 (33.7%)	58 (59.2%)
	Median time to event (95% CI) [b]	1.7 (1.1, 3.6)	13.2 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.46 (1.64, 3.68)	
	P-value of subgroup*treatment interaction [e]	0.498	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	12 (33.3%)	5 (19.2%)
	The number (%) of patients censored [a]	24 (66.7%)	21 (80.8%)
	Median time to event (95% CI) [b]	19.0 (4.3, NE)	NE (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.832	
	HR (95% CI) [d]	1.12 (0.39, 3.26)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	30 (33.7%)	40 (40.8%)
	The number (%) of patients censored [a]	59 (66.3%)	58 (59.2%)
	Median time to event (95% CI) [b]	21.5 (7.9, NE)	8.7 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.286	
	HR (95% CI) [d]	0.77 (0.48, 1.25)	
	P-value of subgroup*treatment interaction [e]	0.457	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	22 (61.1%)	8 (30.8%)
	The number (%) of patients censored [a]	14 (38.9%)	18 (69.2%)
	Median time to event (95% CI) [b]	2.1 (1.1, 6.3)	NE (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.057	
	HR (95% CI) [d]	2.17 (0.95, 4.94)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	48 (53.9%)	50 (51.0%)
	The number (%) of patients censored [a]	41 (46.1%)	48 (49.0%)
	Median time to event (95% CI) [b]	3.5 (1.7, 5.2)	5.2 (2.1, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.405	
	HR (95% CI) [d]	1.18 (0.80, 1.76)	
	P-value of subgroup*treatment interaction [e]	0.214	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	8 (22.2%)	8 (30.8%)
	The number (%) of patients censored [a]	28 (77.8%)	18 (69.2%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	6.2 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.100	
	HR (95% CI) [d]	0.44 (0.16, 1.21)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	27 (30.3%)	29 (29.6%)
	The number (%) of patients censored [a]	62 (69.7%)	69 (70.4%)
	Median time to event (95% CI) [b]	NE (10.0, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.895	
	HR (95% CI) [d]	1.04 (0.61, 1.75)	
	P-value of subgroup*treatment interaction [e]	0.157	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	2 (5.6%)	0 (0.0%)
	The number (%) of patients censored [a]	34 (94.4%)	26 (100.0%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.260	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	4 (4.5%)	5 (5.1%)
	The number (%) of patients censored [a]	85 (95.5%)	93 (94.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.670	
	HR (95% CI) [d]	1.34 (0.36, 4.99)	
	P-value of subgroup*treatment interaction [e]	0.994	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	16 (44.4%)	6 (23.1%)
	The number (%) of patients censored [a]	20 (55.6%)	20 (76.9%)
	Median time to event (95% CI) [b]	4.2 (2.2, 12.6)	13.8 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.390	
	HR (95% CI) [d]	1.50 (0.58, 3.88)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	34 (38.2%)	49 (50.0%)
	The number (%) of patients censored [a]	55 (61.8%)	49 (50.0%)
	Median time to event (95% CI) [b]	6.3 (2.1, 18.5)	4.6 (1.7, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.288	
	HR (95% CI) [d]	0.79 (0.50, 1.23)	
	P-value of subgroup*treatment interaction [e]	0.187	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	26 (72.2%)	12 (46.2%)
	The number (%) of patients censored [a]	10 (27.8%)	14 (53.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.5)	5.1 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.038	
	HR (95% CI) [d]	2.04 (1.03, 4.07)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	65 (73.0%)	62 (63.3%)
	The number (%) of patients censored [a]	24 (27.0%)	36 (36.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.2)	3.1 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.90 (1.33, 2.70)	
	P-value of subgroup*treatment interaction [e]	0.894	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	9 (25.0%)	4 (15.4%)
	The number (%) of patients censored [a]	27 (75.0%)	22 (84.6%)
	Median time to event (95% CI) [b]	NE (3.9, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.510	
	HR (95% CI) [d]	1.48 (0.46, 4.83)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	27 (30.3%)	31 (31.6%)
	The number (%) of patients censored [a]	62 (69.7%)	67 (68.4%)
	Median time to event (95% CI) [b]	17.5 (10.2, NE)	NE (8.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.691	
	HR (95% CI) [d]	0.90 (0.54, 1.51)	
	P-value of subgroup*treatment interaction [e]	0.680	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	10 (38.5%)
	The number (%) of patients censored [a]	19 (52.8%)	16 (61.5%)
	Median time to event (95% CI) [b]	6.8 (2.9, 15.9)	5.0 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.846	
	HR (95% CI) [d]	0.92 (0.41, 2.07)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	45 (50.6%)	59 (60.2%)
	The number (%) of patients censored [a]	44 (49.4%)	39 (39.8%)
	Median time to event (95% CI) [b]	6.5 (3.5, 13.3)	3.1 (2.1, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.087	
	HR (95% CI) [d]	0.71 (0.48, 1.05)	
	P-value of subgroup*treatment interaction [e]	0.417	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	2 (5.6%)	0 (0.0%)
	The number (%) of patients censored [a]	34 (94.4%)	26 (100.0%)
	Median time to event (95% CI) [b]	NE (0.9, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	11 (12.4%)	13 (13.3%)
	The number (%) of patients censored [a]	78 (87.6%)	85 (86.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 7.2)	1.4 (0.8, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.95 (0.42, 2.12)	
	P-value of subgroup*treatment interaction [e]	0.991	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1

Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	14 (38.9%)	7 (26.9%)
	The number (%) of patients censored [a]	22 (61.1%)	19 (73.1%)
	Median time to event (95% CI) [b]	9.8 (3.9, NE)	NE (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.756	
	HR (95% CI) [d]	1.16 (0.46, 2.91)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	29 (32.6%)	37 (37.8%)
	The number (%) of patients censored [a]	60 (67.4%)	61 (62.2%)
	Median time to event (95% CI) [b]	NE (9.0, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.88 (0.54, 1.44)	
	P-value of subgroup*treatment interaction [e]	0.591	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.7.2

Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	4 (11.1%)	3 (11.5%)
	The number (%) of patients censored [a]	32 (88.9%)	23 (88.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.817	
	HR (95% CI) [d]	0.84 (0.19, 3.74)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	21 (23.6%)	26 (26.5%)
	The number (%) of patients censored [a]	68 (76.4%)	72 (73.5%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.912	
	HR (95% CI) [d]	0.97 (0.54, 1.72)	
	P-value of subgroup*treatment interaction [e]	0.835	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.3

Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	2 (5.6%)	1 (3.8%)
	The number (%) of patients censored [a]	34 (94.4%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.884	
	HR (95% CI) [d]	0.84 (0.08, 9.23)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	9 (10.1%)	7 (7.1%)
	The number (%) of patients censored [a]	80 (89.9%)	91 (92.9%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.601	
	HR (95% CI) [d]	1.30 (0.48, 3.49)	
	P-value of subgroup*treatment interaction [e]	0.756	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	3 (42.9%)
	The number (%) of patients censored [a]	4 (66.7%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.02 (0.17, 6.14)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	68 (57.1%)	70 (59.8%)
	The number (%) of patients censored [a]	51 (42.9%)	47 (40.2%)
	Median time to event (95% CI) [b]	4.1 (2.1, 6.3)	3.3 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.448	
	HR (95% CI) [d]	0.88 (0.63, 1.23)	
	P-value of subgroup*treatment interaction [e]	0.745	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (66.7%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	3.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.562	
	HR (95% CI) [d]	0.65 (0.12, 3.58)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	56 (47.1%)	65 (55.6%)
	The number (%) of patients censored [a]	63 (52.9%)	52 (44.4%)
	Median time to event (95% CI) [b]	7.5 (3.6, 20.1)	4.9 (2.8, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	0.79 (0.55, 1.13)	
	P-value of subgroup*treatment interaction [e]	0.746	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (66.7%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	4.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.608	
	HR (95% CI) [d]	0.69 (0.13, 3.78)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	70 (58.8%)	80 (68.4%)
	The number (%) of patients censored [a]	49 (41.2%)	37 (31.6%)
	Median time to event (95% CI) [b]	1.5 (1.4, 2.7)	3.3 (1.7, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.749	
	HR (95% CI) [d]	0.95 (0.69, 1.31)	
	P-value of subgroup*treatment interaction [e]	0.640	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	2 (28.6%)
	The number (%) of patients censored [a]	3 (50.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	3.1 (0.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.486	
	HR (95% CI) [d]	1.87 (0.31, 11.25)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	56 (47.1%)	54 (46.2%)
	The number (%) of patients censored [a]	63 (52.9%)	63 (53.8%)
	Median time to event (95% CI) [b]	7.8 (4.4, 11.8)	9.1 (4.7, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.657	
	HR (95% CI) [d]	0.92 (0.63, 1.34)	
	P-value of subgroup*treatment interaction [e]	0.323	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	2.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.311	
	HR (95% CI) [d]	0.47 (0.09, 2.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	67 (56.3%)	74 (63.2%)
	The number (%) of patients censored [a]	52 (43.7%)	43 (36.8%)
	Median time to event (95% CI) [b]	4.5 (2.8, 6.9)	3.0 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.215	
	HR (95% CI) [d]	0.81 (0.58, 1.13)	
	P-value of subgroup*treatment interaction [e]	0.426	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	1.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.428	
	HR (95% CI) [d]	0.58 (0.11, 2.99)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	66 (55.5%)	72 (61.5%)
	The number (%) of patients censored [a]	53 (44.5%)	45 (38.5%)
	Median time to event (95% CI) [b]	2.8 (1.4, 7.5)	3.6 (2.2, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.534	
	HR (95% CI) [d]	0.90 (0.64, 1.26)	
	P-value of subgroup*treatment interaction [e]	0.561	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	4 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	2 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	4.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.013	
	HR (95% CI) [d]	9.69 (1.04, 90.09)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	79 (66.4%)	88 (75.2%)
	The number (%) of patients censored [a]	40 (33.6%)	29 (24.8%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.2)	1.4 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.176	
	HR (95% CI) [d]	0.82 (0.60, 1.11)	
	P-value of subgroup*treatment interaction [e]	0.015	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (50.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	4.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.95 (0.19, 4.73)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	77 (64.7%)	75 (64.1%)
	The number (%) of patients censored [a]	42 (35.3%)	42 (35.9%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.6)	1.7 (1.4, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.668	
	HR (95% CI) [d]	1.07 (0.78, 1.48)	
	P-value of subgroup*treatment interaction [e]	0.909	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (66.7%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	4.6 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	1.03 (0.17, 6.20)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	56 (47.1%)	72 (61.5%)
	The number (%) of patients censored [a]	63 (52.9%)	45 (38.5%)
	Median time to event (95% CI) [b]	7.7 (2.5, 11.8)	2.8 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.045	
	HR (95% CI) [d]	0.70 (0.49, 1.00)	
	P-value of subgroup*treatment interaction [e]	0.747	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (83.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.477	
	HR (95% CI) [d]	0.45 (0.05, 4.33)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	42 (35.3%)	62 (53.0%)
	The number (%) of patients censored [a]	77 (64.7%)	55 (47.0%)
	Median time to event (95% CI) [b]	15.5 (9.6, NE)	4.9 (3.3, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	0.54 (0.37, 0.81)	
	P-value of subgroup*treatment interaction [e]	0.973	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	4 (57.1%)
	The number (%) of patients censored [a]	5 (83.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (5.3, NE)	2.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.118	
	HR (95% CI) [d]	0.20 (0.02, 1.84)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	58 (48.7%)	63 (53.8%)
	The number (%) of patients censored [a]	61 (51.3%)	54 (46.2%)
	Median time to event (95% CI) [b]	5.1 (3.1, 10.8)	4.4 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.432	
	HR (95% CI) [d]	0.87 (0.61, 1.24)	
	P-value of subgroup*treatment interaction [e]	0.209	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (50.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.833	
	HR (95% CI) [d]	0.90 (0.20, 4.03)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	61 (51.3%)	64 (54.7%)
	The number (%) of patients censored [a]	58 (48.7%)	53 (45.3%)
	Median time to event (95% CI) [b]	3.6 (1.8, 11.8)	4.1 (2.4, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.664	
	HR (95% CI) [d]	0.93 (0.65, 1.32)	
	P-value of subgroup*treatment interaction [e]	0.839	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (50.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	2.1 (2.1, NE)	3.6 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.678	
	HR (95% CI) [d]	1.49 (0.29, 7.56)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	64 (53.8%)	68 (58.1%)
	The number (%) of patients censored [a]	55 (46.2%)	49 (41.9%)
	Median time to event (95% CI) [b]	2.7 (1.7, 12.4)	2.3 (1.5, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	0.82 (0.59, 1.16)	
	P-value of subgroup*treatment interaction [e]	0.580	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	5 (83.3%)	2 (28.6%)
	The number (%) of patients censored [a]	1 (16.7%)	5 (71.4%)
	Median time to event (95% CI) [b]	1.5 (0.8, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	79 (66.4%)	45 (38.5%)
	The number (%) of patients censored [a]	40 (33.6%)	72 (61.5%)
	Median time to event (95% CI) [b]	1.7 (1.0, 2.9)	10.1 (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.43 (1.68, 3.50)	
	P-value of subgroup*treatment interaction [e]	0.150	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	2 (28.6%)
	The number (%) of patients censored [a]	3 (50.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	3.39 (0.56, 20.65)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	39 (32.8%)	43 (36.8%)
	The number (%) of patients censored [a]	80 (67.2%)	74 (63.2%)
	Median time to event (95% CI) [b]	19.0 (8.4, NE)	19.4 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.190	
	HR (95% CI) [d]	0.75 (0.48, 1.16)	
	P-value of subgroup*treatment interaction [e]	0.065	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	3 (42.9%)
	The number (%) of patients censored [a]	3 (50.0%)	4 (57.1%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.685	
	HR (95% CI) [d]	1.33 (0.27, 6.68)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	67 (56.3%)	55 (47.0%)
	The number (%) of patients censored [a]	52 (43.7%)	62 (53.0%)
	Median time to event (95% CI) [b]	3.0 (1.8, 5.0)	5.2 (3.3, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	1.32 (0.92, 1.89)	
	P-value of subgroup*treatment interaction [e]	0.656	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (83.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (3.1, NE)	8.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.956	
	HR (95% CI) [d]	0.93 (0.08, 10.93)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	34 (28.6%)	34 (29.1%)
	The number (%) of patients censored [a]	85 (71.4%)	83 (70.9%)
	Median time to event (95% CI) [b]	NE (13.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.691	
	HR (95% CI) [d]	0.91 (0.56, 1.46)	
	P-value of subgroup*treatment interaction [e]	0.632	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	6 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	6 (5.0%)	5 (4.3%)
	The number (%) of patients censored [a]	113 (95.0%)	112 (95.7%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.436	
	HR (95% CI) [d]	1.60 (0.49, 5.25)	
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	3 (42.9%)
	The number (%) of patients censored [a]	4 (66.7%)	4 (57.1%)
	Median time to event (95% CI) [b]	3.1 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.956	
	HR (95% CI) [d]	0.93 (0.15, 5.56)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	48 (40.3%)	52 (44.4%)
	The number (%) of patients censored [a]	71 (59.7%)	65 (55.6%)
	Median time to event (95% CI) [b]	7.0 (2.4, 12.2)	4.9 (2.8, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.436	
	HR (95% CI) [d]	0.85 (0.57, 1.27)	
	P-value of subgroup*treatment interaction [e]	0.535	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	3 (42.9%)
	The number (%) of patients censored [a]	3 (50.0%)	4 (57.1%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	8.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.337	
	HR (95% CI) [d]	2.37 (0.39, 14.37)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	88 (73.9%)	71 (60.7%)
	The number (%) of patients censored [a]	31 (26.1%)	46 (39.3%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.1)	3.0 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.86 (1.35, 2.54)	
	P-value of subgroup*treatment interaction [e]	0.891	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	2 (28.6%)
	The number (%) of patients censored [a]	5 (83.3%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (3.9, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	1.41 (0.09, 22.64)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	35 (29.4%)	33 (28.2%)
	The number (%) of patients censored [a]	84 (70.6%)	84 (71.8%)
	Median time to event (95% CI) [b]	24.7 (17.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.788	
	HR (95% CI) [d]	0.94 (0.58, 1.51)	
	P-value of subgroup*treatment interaction [e]	0.938	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	3.2 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.512	
	HR (95% CI) [d]	0.58 (0.11, 3.16)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	60 (50.4%)	64 (54.7%)
	The number (%) of patients censored [a]	59 (49.6%)	53 (45.3%)
	Median time to event (95% CI) [b]	6.8 (3.6, 10.8)	4.2 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.135	
	HR (95% CI) [d]	0.76 (0.54, 1.09)	
	P-value of subgroup*treatment interaction [e]	0.675	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	2 (28.6%)
	The number (%) of patients censored [a]	6 (100.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.157	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	13 (10.9%)	11 (9.4%)
	The number (%) of patients censored [a]	106 (89.1%)	106 (90.6%)
	Median time to event (95% CI) [b]	1.1 (0.8, 7.2)	1.5 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.434	
	HR (95% CI) [d]	1.33 (0.59, 2.99)	
	P-value of subgroup*treatment interaction [e]	0.991	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1

Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	1 (14.3%)
	The number (%) of patients censored [a]	5 (83.3%)	6 (85.7%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.757	
	HR (95% CI) [d]	1.55 (0.09, 25.33)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	42 (35.3%)	43 (36.8%)
	The number (%) of patients censored [a]	77 (64.7%)	74 (63.2%)
	Median time to event (95% CI) [b]	18.7 (8.8, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.717	
	HR (95% CI) [d]	0.92 (0.60, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.632	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.8.2

Time to First Meaningful Deterioration for PGIC by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	2 (28.6%)
	The number (%) of patients censored [a]	6 (100.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.312	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	25 (21.0%)	27 (23.1%)
	The number (%) of patients censored [a]	94 (79.0%)	90 (76.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.879	
	HR (95% CI) [d]	0.96 (0.55, 1.66)	
	P-value of subgroup*treatment interaction [e]	0.984	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.3

Time to First Meaningful Deterioration for PGIS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	6 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	11 (9.2%)	8 (6.8%)
	The number (%) of patients censored [a]	108 (90.8%)	109 (93.2%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.732	
	HR (95% CI) [d]	1.17 (0.47, 2.92)	
	P-value of subgroup*treatment interaction [e]	1.000	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	29 (69.0%)	32 (69.6%)
	The number (%) of patients censored [a]	13 (31.0%)	14 (30.4%)
	Median time to event (95% CI) [b]	1.8 (0.8, 3.6)	1.7 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.987	
	HR (95% CI) [d]	1.00 (0.60, 1.67)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	2 (28.6%)
	The number (%) of patients censored [a]	4 (44.4%)	5 (71.4%)
	Median time to event (95% CI) [b]	2.3 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.444	
	HR (95% CI) [d]	1.90 (0.37, 9.88)	
	P-value of subgroup*treatment interaction [e]	0.331	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	21 (50.0%)	28 (60.9%)
	The number (%) of patients censored [a]	21 (50.0%)	18 (39.1%)
	Median time to event (95% CI) [b]	7.5 (1.7, NE)	3.3 (1.5, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.140	
	HR (95% CI) [d]	0.65 (0.36, 1.17)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (55.6%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	19.4 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.564	
	HR (95% CI) [d]	1.64 (0.30, 9.01)	
	P-value of subgroup*treatment interaction [e]	0.316	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	27 (64.3%)	31 (67.4%)
	The number (%) of patients censored [a]	15 (35.7%)	15 (32.6%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.8)	1.7 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.943	
	HR (95% CI) [d]	1.02 (0.61, 1.72)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	3 (42.9%)
	The number (%) of patients censored [a]	4 (44.4%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.1 (0.8, NE)	10.6 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.401	
	HR (95% CI) [d]	2.04 (0.38, 10.93)	
	P-value of subgroup*treatment interaction [e]	0.492	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	24 (57.1%)	21 (45.7%)
	The number (%) of patients censored [a]	18 (42.9%)	25 (54.3%)
	Median time to event (95% CI) [b]	6.0 (3.2, 11.3)	9.1 (3.3, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.733	
	HR (95% CI) [d]	1.11 (0.61, 2.00)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (55.6%)	4 (57.1%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	8.3 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.656	
	HR (95% CI) [d]	1.49 (0.27, 8.20)	
	P-value of subgroup*treatment interaction [e]	0.678	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	29 (69.0%)	29 (63.0%)
	The number (%) of patients censored [a]	13 (31.0%)	17 (37.0%)
	Median time to event (95% CI) [b]	4.2 (2.8, 5.7)	2.7 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.724	
	HR (95% CI) [d]	0.91 (0.54, 1.52)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	6 (85.7%)
	The number (%) of patients censored [a]	4 (44.4%)	1 (14.3%)
	Median time to event (95% CI) [b]	7.9 (0.8, NE)	1.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	0.27 (0.08, 0.98)	
	P-value of subgroup*treatment interaction [e]	0.091	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	25 (59.5%)	27 (58.7%)
	The number (%) of patients censored [a]	17 (40.5%)	19 (41.3%)
	Median time to event (95% CI) [b]	1.8 (1.0, 7.5)	3.3 (1.0, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.883	
	HR (95% CI) [d]	1.04 (0.60, 1.80)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	6 (85.7%)
	The number (%) of patients censored [a]	3 (33.3%)	1 (14.3%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.1 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.512	
	HR (95% CI) [d]	0.68 (0.21, 2.28)	
	P-value of subgroup*treatment interaction [e]	0.445	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	28 (66.7%)	35 (76.1%)
	The number (%) of patients censored [a]	14 (33.3%)	11 (23.9%)
	Median time to event (95% CI) [b]	1.4 (0.8, 3.1)	1.2 (0.9, 3.2)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.93 (0.56, 1.54)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.762	
	HR (95% CI) [d]	0.83 (0.23, 2.97)	
	P-value of subgroup*treatment interaction [e]	0.770	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	26 (61.9%)	27 (58.7%)
	The number (%) of patients censored [a]	16 (38.1%)	19 (41.3%)
	Median time to event (95% CI) [b]	2.0 (1.1, 4.2)	2.1 (1.2, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.778	
	HR (95% CI) [d]	1.09 (0.63, 1.86)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	4 (57.1%)
	The number (%) of patients censored [a]	5 (55.6%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	5.5 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.539	
	HR (95% CI) [d]	0.66 (0.16, 2.70)	
	P-value of subgroup*treatment interaction [e]	0.551	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	21 (50.0%)	30 (65.2%)
	The number (%) of patients censored [a]	21 (50.0%)	16 (34.8%)
	Median time to event (95% CI) [b]	8.8 (1.5, 16.0)	2.3 (1.4, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.222	
	HR (95% CI) [d]	0.71 (0.40, 1.25)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.9 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.631	
	HR (95% CI) [d]	1.38 (0.38, 5.05)	
	P-value of subgroup*treatment interaction [e]	0.292	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	10 (23.8%)	25 (54.3%)
	The number (%) of patients censored [a]	32 (76.2%)	21 (45.7%)
	Median time to event (95% CI) [b]	NE (9.6, NE)	3.1 (1.4, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.29 (0.14, 0.62)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	3 (33.3%)	3 (42.9%)
	The number (%) of patients censored [a]	6 (66.7%)	4 (57.1%)
	Median time to event (95% CI) [b]	7.2 (1.9, NE)	6.3 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.739	
	HR (95% CI) [d]	0.76 (0.15, 3.79)	
	P-value of subgroup*treatment interaction [e]	0.283	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	20 (47.6%)	26 (56.5%)
	The number (%) of patients censored [a]	22 (52.4%)	20 (43.5%)
	Median time to event (95% CI) [b]	5.1 (2.5, NE)	3.6 (1.4, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.275	
	HR (95% CI) [d]	0.72 (0.40, 1.29)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	3 (42.9%)
	The number (%) of patients censored [a]	3 (33.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.9 (0.8, NE)	9.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.057	
	HR (95% CI) [d]	6.22 (0.73, 52.69)	
	P-value of subgroup*treatment interaction [e]	0.049	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	22 (52.4%)	26 (56.5%)
	The number (%) of patients censored [a]	20 (47.6%)	20 (43.5%)
	Median time to event (95% CI) [b]	3.6 (1.7, NE)	3.1 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.706	
	HR (95% CI) [d]	0.90 (0.51, 1.59)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (44.4%)	3 (42.9%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	2.1 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.338	
	HR (95% CI) [d]	0.53 (0.14, 1.99)	
	P-value of subgroup*treatment interaction [e]	0.506	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	24 (57.1%)	26 (56.5%)
	The number (%) of patients censored [a]	18 (42.9%)	20 (43.5%)
	Median time to event (95% CI) [b]	2.3 (1.3, 6.9)	2.2 (1.4, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.747	
	HR (95% CI) [d]	0.91 (0.52, 1.59)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (44.4%)	2 (28.6%)
	Median time to event (95% CI) [b]	1.0 (0.7, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.333	
	HR (95% CI) [d]	0.52 (0.15, 1.85)	
	P-value of subgroup*treatment interaction [e]	0.520	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	30 (71.4%)	19 (41.3%)
	The number (%) of patients censored [a]	12 (28.6%)	27 (58.7%)
	Median time to event (95% CI) [b]	1.7 (0.8, 2.8)	5.8 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	2.64 (1.48, 4.72)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	8 (88.9%)	2 (28.6%)
	The number (%) of patients censored [a]	1 (11.1%)	5 (71.4%)
	Median time to event (95% CI) [b]	2.9 (0.8, 5.8)	NE (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.040	
	HR (95% CI) [d]	4.49 (0.94, 21.49)	
	P-value of subgroup*treatment interaction [e]	0.602	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	12 (28.6%)	21 (45.7%)
	The number (%) of patients censored [a]	30 (71.4%)	25 (54.3%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	4.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.093	
	HR (95% CI) [d]	0.55 (0.27, 1.12)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	3 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	6 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	4.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.555	
	HR (95% CI) [d]	0.64 (0.14, 2.88)	
	P-value of subgroup*treatment interaction [e]	0.962	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	26 (61.9%)	23 (50.0%)
	The number (%) of patients censored [a]	16 (38.1%)	23 (50.0%)
	Median time to event (95% CI) [b]	1.7 (1.0, 5.1)	2.6 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.376	
	HR (95% CI) [d]	1.29 (0.73, 2.26)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.3 (0.7, NE)	2.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.421	
	HR (95% CI) [d]	1.68 (0.47, 5.98)	
	P-value of subgroup*treatment interaction [e]	0.677	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	10 (23.8%)	13 (28.3%)
	The number (%) of patients censored [a]	32 (76.2%)	33 (71.7%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (5.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.637	
	HR (95% CI) [d]	0.82 (0.36, 1.87)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	0 (0.0%)	4 (57.1%)
	The number (%) of patients censored [a]	9 (100.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	3.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.989	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	2 (4.8%)	2 (4.3%)
	The number (%) of patients censored [a]	40 (95.2%)	44 (95.7%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.895	
	HR (95% CI) [d]	1.14 (0.16, 8.15)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	9 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	15 (35.7%)	20 (43.5%)
	The number (%) of patients censored [a]	27 (64.3%)	26 (56.5%)
	Median time to event (95% CI) [b]	7.0 (1.7, NE)	3.3 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.460	
	HR (95% CI) [d]	0.77 (0.39, 1.51)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (55.6%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.2 (1.0, NE)	4.0 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.143	
	HR (95% CI) [d]	3.62 (0.62, 21.04)	
	P-value of subgroup*treatment interaction [e]	0.114	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	30 (71.4%)	26 (56.5%)
	The number (%) of patients censored [a]	12 (28.6%)	20 (43.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.5)	3.1 (1.4, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.23 (1.31, 3.82)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	8 (88.9%)	4 (57.1%)
	The number (%) of patients censored [a]	1 (11.1%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.7, 1.2)	2.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.080	
	HR (95% CI) [d]	2.99 (0.84, 10.70)	
	P-value of subgroup*treatment interaction [e]	0.492	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	11 (26.2%)	16 (34.8%)
	The number (%) of patients censored [a]	31 (73.8%)	30 (65.2%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	8.7 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.282	
	HR (95% CI) [d]	0.66 (0.31, 1.42)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	3 (33.3%)	2 (28.6%)
	The number (%) of patients censored [a]	6 (66.7%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.834	
	HR (95% CI) [d]	0.82 (0.13, 5.07)	
	P-value of subgroup*treatment interaction [e]	0.830	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	23 (54.8%)	28 (60.9%)
	The number (%) of patients censored [a]	19 (45.2%)	18 (39.1%)
	Median time to event (95% CI) [b]	5.0 (2.9, 9.6)	3.1 (1.4, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.227	
	HR (95% CI) [d]	0.71 (0.41, 1.24)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	2.8 (0.8, NE)	2.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.71 (0.20, 2.53)	
	P-value of subgroup*treatment interaction [e]	0.753	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	6 (14.3%)	5 (10.9%)
	The number (%) of patients censored [a]	36 (85.7%)	41 (89.1%)
	Median time to event (95% CI) [b]	0.8 (0.7, NE)	1.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.026	
	HR (95% CI) [d]	4.89 (1.11, 21.50)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	1 (11.1%)	0 (0.0%)
	The number (%) of patients censored [a]	8 (88.9%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1

Time to First Meaningful Deterioration for EQ-VAS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	20 (47.6%)	20 (43.5%)
	The number (%) of patients censored [a]	22 (52.4%)	26 (56.5%)
	Median time to event (95% CI) [b]	8.8 (3.9, 15.5)	12.4 (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.885	
	HR (95% CI) [d]	1.05 (0.56, 1.96)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	0 (0.0%)
	The number (%) of patients censored [a]	4 (44.4%)	7 (100.0%)
	Median time to event (95% CI) [b]	7.2 (0.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.025	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.985	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.9.2

Time to First Meaningful Deterioration for PGIC by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	12 (28.6%)	12 (26.1%)
	The number (%) of patients censored [a]	30 (71.4%)	34 (73.9%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	6.4 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.973	
	HR (95% CI) [d]	0.99 (0.44, 2.22)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	2 (22.2%)	2 (28.6%)
	The number (%) of patients censored [a]	7 (77.8%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.919	
	HR (95% CI) [d]	0.90 (0.13, 6.43)	
	P-value of subgroup*treatment interaction [e]	0.891	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.3

Time to First Meaningful Deterioration for PGIS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	7 (16.7%)	4 (8.7%)
	The number (%) of patients censored [a]	35 (83.3%)	42 (91.3%)
	Median time to event (95% CI) [b]	6.3 (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	1.43 (0.41, 4.92)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	1 (11.1%)	0 (0.0%)
	The number (%) of patients censored [a]	8 (88.9%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (4.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.995	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	14 (48.3%)	18 (51.4%)
	The number (%) of patients censored [a]	15 (51.7%)	17 (48.6%)
	Median time to event (95% CI) [b]	6.0 (1.6, NE)	5.6 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.961	
	HR (95% CI) [d]	0.99 (0.49, 1.99)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	56 (58.3%)	55 (62.5%)
	The number (%) of patients censored [a]	40 (41.7%)	33 (37.5%)
	Median time to event (95% CI) [b]	3.6 (1.8, 6.3)	3.1 (1.5, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.266	
	HR (95% CI) [d]	0.81 (0.56, 1.18)	
	P-value of subgroup*treatment interaction [e]	0.667	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	11 (37.9%)	19 (54.3%)
	The number (%) of patients censored [a]	18 (62.1%)	16 (45.7%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	5.6 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.265	
	HR (95% CI) [d]	0.66 (0.31, 1.38)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	47 (49.0%)	49 (55.7%)
	The number (%) of patients censored [a]	49 (51.0%)	39 (44.3%)
	Median time to event (95% CI) [b]	7.4 (2.4, 20.1)	4.9 (2.4, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.274	
	HR (95% CI) [d]	0.80 (0.54, 1.20)	
	P-value of subgroup*treatment interaction [e]	0.733	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	14 (48.3%)	23 (65.7%)
	The number (%) of patients censored [a]	15 (51.7%)	12 (34.3%)
	Median time to event (95% CI) [b]	8.4 (1.7, NE)	3.7 (1.6, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.228	
	HR (95% CI) [d]	0.67 (0.34, 1.30)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	58 (60.4%)	60 (68.2%)
	The number (%) of patients censored [a]	38 (39.6%)	28 (31.8%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.9)	2.6 (1.2, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.926	
	HR (95% CI) [d]	1.02 (0.71, 1.47)	
	P-value of subgroup*treatment interaction [e]	0.303	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	14 (48.3%)	13 (37.1%)
	The number (%) of patients censored [a]	15 (51.7%)	22 (62.9%)
	Median time to event (95% CI) [b]	7.3 (4.1, 15.5)	14.0 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.365	
	HR (95% CI) [d]	1.42 (0.66, 3.03)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	45 (46.9%)	42 (47.7%)
	The number (%) of patients censored [a]	51 (53.1%)	46 (52.3%)
	Median time to event (95% CI) [b]	8.8 (4.2, 11.8)	9.1 (4.2, 10.8)
	Nominal p-value for unstratified log-rank test [c]	0.498	
	HR (95% CI) [d]	0.87 (0.57, 1.32)	
	P-value of subgroup*treatment interaction [e]	0.275	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	13 (44.8%)	23 (65.7%)
	The number (%) of patients censored [a]	16 (55.2%)	12 (34.3%)
	Median time to event (95% CI) [b]	6.4 (2.8, NE)	2.2 (1.0, 7.3)
	Nominal p-value for unstratified log-rank test [c]	0.077	
	HR (95% CI) [d]	0.54 (0.27, 1.08)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	56 (58.3%)	55 (62.5%)
	The number (%) of patients censored [a]	40 (41.7%)	33 (37.5%)
	Median time to event (95% CI) [b]	4.2 (2.6, 6.9)	3.1 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.575	
	HR (95% CI) [d]	0.90 (0.62, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.174	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.10.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	15 (51.7%)	25 (71.4%)
	The number (%) of patients censored [a]	14 (48.3%)	10 (28.6%)
	Median time to event (95% CI) [b]	3.8 (1.5, NE)	3.1 (0.9, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.58 (0.30, 1.14)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	53 (55.2%)	51 (58.0%)
	The number (%) of patients censored [a]	43 (44.8%)	37 (42.0%)
	Median time to event (95% CI) [b]	2.2 (1.1, 4.8)	3.6 (1.4, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.953	
	HR (95% CI) [d]	0.99 (0.67, 1.45)	
	P-value of subgroup*treatment interaction [e]	0.333	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	16 (55.2%)	24 (68.6%)
	The number (%) of patients censored [a]	13 (44.8%)	11 (31.4%)
	Median time to event (95% CI) [b]	1.8 (0.8, NE)	1.6 (0.9, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.502	
	HR (95% CI) [d]	0.81 (0.43, 1.53)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	67 (69.8%)	67 (76.1%)
	The number (%) of patients censored [a]	29 (30.2%)	21 (23.9%)
	Median time to event (95% CI) [b]	1.3 (0.9, 1.7)	1.2 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.340	
	HR (95% CI) [d]	0.86 (0.61, 1.20)	
	P-value of subgroup*treatment interaction [e]	0.801	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	19 (65.5%)	25 (71.4%)
	The number (%) of patients censored [a]	10 (34.5%)	10 (28.6%)
	Median time to event (95% CI) [b]	2.2 (0.8, 11.2)	1.4 (0.9, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	0.84 (0.46, 1.54)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	61 (63.5%)	53 (60.2%)
	The number (%) of patients censored [a]	35 (36.5%)	35 (39.8%)
	Median time to event (95% CI) [b]	1.5 (1.1, 2.6)	2.1 (1.4, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.354	
	HR (95% CI) [d]	1.19 (0.82, 1.72)	
	P-value of subgroup*treatment interaction [e]	0.374	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	10 (34.5%)	20 (57.1%)
	The number (%) of patients censored [a]	19 (65.5%)	15 (42.9%)
	Median time to event (95% CI) [b]	15.5 (2.5, NE)	2.7 (1.4, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.080	
	HR (95% CI) [d]	0.51 (0.24, 1.10)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	48 (50.0%)	56 (63.6%)
	The number (%) of patients censored [a]	48 (50.0%)	32 (36.4%)
	Median time to event (95% CI) [b]	6.5 (1.8, 9.8)	2.8 (2.1, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.149	
	HR (95% CI) [d]	0.76 (0.51, 1.11)	
	P-value of subgroup*treatment interaction [e]	0.272	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	9 (31.0%)	21 (60.0%)
	The number (%) of patients censored [a]	20 (69.0%)	14 (40.0%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	4.9 (1.4, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.020	
	HR (95% CI) [d]	0.41 (0.19, 0.89)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	34 (35.4%)	43 (48.9%)
	The number (%) of patients censored [a]	62 (64.6%)	45 (51.1%)
	Median time to event (95% CI) [b]	15.5 (7.2, NE)	5.0 (3.3, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	0.62 (0.39, 0.97)	
	P-value of subgroup*treatment interaction [e]	0.305	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	12 (41.4%)	19 (54.3%)
	The number (%) of patients censored [a]	17 (58.6%)	16 (45.7%)
	Median time to event (95% CI) [b]	14.4 (3.5, NE)	4.6 (3.1, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	0.66 (0.32, 1.37)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	47 (49.0%)	47 (53.4%)
	The number (%) of patients censored [a]	49 (51.0%)	41 (46.6%)
	Median time to event (95% CI) [b]	5.1 (2.6, 9.1)	4.1 (2.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.639	
	HR (95% CI) [d]	0.91 (0.61, 1.36)	
	P-value of subgroup*treatment interaction [e]	0.423	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	15 (51.7%)	19 (54.3%)
	The number (%) of patients censored [a]	14 (48.3%)	16 (45.7%)
	Median time to event (95% CI) [b]	4.2 (1.0, NE)	3.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.98 (0.50, 1.93)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	49 (51.0%)	48 (54.5%)
	The number (%) of patients censored [a]	47 (49.0%)	40 (45.5%)
	Median time to event (95% CI) [b]	3.2 (1.8, 13.6)	4.9 (2.1, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.663	
	HR (95% CI) [d]	0.92 (0.62, 1.37)	
	P-value of subgroup*treatment interaction [e]	0.938	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	10 (34.5%)	17 (48.6%)
	The number (%) of patients censored [a]	19 (65.5%)	18 (51.4%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	6.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.246	
	HR (95% CI) [d]	0.63 (0.29, 1.38)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	57 (59.4%)	54 (61.4%)
	The number (%) of patients censored [a]	39 (40.6%)	34 (38.6%)
	Median time to event (95% CI) [b]	2.3 (1.6, 3.7)	1.9 (1.4, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.463	
	HR (95% CI) [d]	0.86 (0.59, 1.25)	
	P-value of subgroup*treatment interaction [e]	0.539	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoeaby Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	20 (69.0%)	15 (42.9%)
	The number (%) of patients censored [a]	9 (31.0%)	20 (57.1%)
	Median time to event (95% CI) [b]	1.7 (0.8, 2.9)	7.4 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.019	
	HR (95% CI) [d]	2.23 (1.13, 4.42)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	64 (66.7%)	31 (35.2%)
	The number (%) of patients censored [a]	32 (33.3%)	57 (64.8%)
	Median time to event (95% CI) [b]	1.6 (1.0, 3.3)	NE (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.74 (1.78, 4.21)	
	P-value of subgroup*treatment interaction [e]	0.709	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	11 (37.9%)	18 (51.4%)
	The number (%) of patients censored [a]	18 (62.1%)	17 (48.6%)
	Median time to event (95% CI) [b]	16.1 (3.6, NE)	3.8 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.41 (0.18, 0.93)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	31 (32.3%)	27 (30.7%)
	The number (%) of patients censored [a]	65 (67.7%)	61 (69.3%)
	Median time to event (95% CI) [b]	21.5 (7.9, NE)	19.4 (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	1.00 (0.59, 1.68)	
	P-value of subgroup*treatment interaction [e]	0.170	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	13 (44.8%)	18 (51.4%)
	The number (%) of patients censored [a]	16 (55.2%)	17 (48.6%)
	Median time to event (95% CI) [b]	3.0 (1.5, NE)	3.8 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.607	
	HR (95% CI) [d]	0.83 (0.40, 1.72)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	57 (59.4%)	40 (45.5%)
	The number (%) of patients censored [a]	39 (40.6%)	48 (54.5%)
	Median time to event (95% CI) [b]	2.9 (1.7, 4.6)	5.4 (3.0, 17.1)
	Nominal p-value for unstratified log-rank test [c]	0.041	
	HR (95% CI) [d]	1.52 (1.01, 2.28)	
	P-value of subgroup*treatment interaction [e]	0.172	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	8 (27.6%)	14 (40.0%)
	The number (%) of patients censored [a]	21 (72.4%)	21 (60.0%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	0.57 (0.24, 1.36)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	27 (28.1%)	23 (26.1%)
	The number (%) of patients censored [a]	69 (71.9%)	65 (73.9%)
	Median time to event (95% CI) [b]	NE (18.5, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.914	
	HR (95% CI) [d]	1.03 (0.59, 1.80)	
	P-value of subgroup*treatment interaction [e]	0.306	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.10.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	3 (10.3%)	3 (8.6%)
	The number (%) of patients censored [a]	26 (89.7%)	32 (91.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.534	
	HR (95% CI) [d]	1.68 (0.34, 8.33)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	3 (3.1%)	2 (2.3%)
	The number (%) of patients censored [a]	93 (96.9%)	86 (97.7%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.560	
	HR (95% CI) [d]	1.69 (0.28, 10.17)	
	P-value of subgroup*treatment interaction [e]	0.975	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.10.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	12 (41.4%)	20 (57.1%)
	The number (%) of patients censored [a]	17 (58.6%)	15 (42.9%)
	Median time to event (95% CI) [b]	4.2 (1.7, NE)	2.8 (1.5, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	0.59 (0.28, 1.24)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	38 (39.6%)	34 (38.6%)
	The number (%) of patients censored [a]	58 (60.4%)	54 (61.4%)
	Median time to event (95% CI) [b]	7.0 (3.1, 12.6)	8.8 (3.3, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.795	
	HR (95% CI) [d]	1.06 (0.66, 1.70)	
	P-value of subgroup*treatment interaction [e]	0.135	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	23 (79.3%)	22 (62.9%)
	The number (%) of patients censored [a]	6 (20.7%)	13 (37.1%)
	Median time to event (95% CI) [b]	0.8 (0.7, 0.8)	1.7 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.44 (1.34, 4.47)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	68 (70.8%)	51 (58.0%)
	The number (%) of patients censored [a]	28 (29.2%)	37 (42.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.3 (2.0, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	1.76 (1.22, 2.53)	
	P-value of subgroup*treatment interaction [e]	0.241	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	5 (17.2%)	9 (25.7%)
	The number (%) of patients censored [a]	24 (82.8%)	26 (74.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.626	
	HR (95% CI) [d]	0.76 (0.25, 2.28)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	31 (32.3%)	26 (29.5%)
	The number (%) of patients censored [a]	65 (67.7%)	62 (70.5%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.722	
	HR (95% CI) [d]	0.91 (0.54, 1.54)	
	P-value of subgroup*treatment interaction [e]	0.756	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	11 (37.9%)	25 (71.4%)
	The number (%) of patients censored [a]	18 (62.1%)	10 (28.6%)
	Median time to event (95% CI) [b]	15.5 (3.2, NE)	2.8 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.012	
	HR (95% CI) [d]	0.41 (0.20, 0.84)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	51 (53.1%)	43 (48.9%)
	The number (%) of patients censored [a]	45 (46.9%)	45 (51.1%)
	Median time to event (95% CI) [b]	6.5 (3.1, 9.3)	4.9 (3.1, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.743	
	HR (95% CI) [d]	0.93 (0.62, 1.40)	
	P-value of subgroup*treatment interaction [e]	0.059	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	2 (6.9%)	6 (17.1%)
	The number (%) of patients censored [a]	27 (93.1%)	29 (82.9%)
	Median time to event (95% CI) [b]	0.9 (0.7, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.749	
	HR (95% CI) [d]	1.23 (0.24, 6.24)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	11 (11.5%)	7 (8.0%)
	The number (%) of patients censored [a]	85 (88.5%)	81 (92.0%)
	Median time to event (95% CI) [b]	1.7 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.953	
	HR (95% CI) [d]	1.02 (0.40, 2.64)	
	P-value of subgroup*treatment interaction [e]	0.943	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.10.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	6 (20.7%)	13 (37.1%)
	The number (%) of patients censored [a]	23 (79.3%)	22 (62.9%)
	Median time to event (95% CI) [b]	NE (15.5, NE)	10.5 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.200	
	HR (95% CI) [d]	0.53 (0.20, 1.42)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	37 (38.5%)	31 (35.2%)
	The number (%) of patients censored [a]	59 (61.5%)	57 (64.8%)
	Median time to event (95% CI) [b]	18.7 (7.2, NE)	13.0 (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.801	
	HR (95% CI) [d]	1.07 (0.66, 1.72)	
	P-value of subgroup*treatment interaction [e]	0.255	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.10.4
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	4 (13.8%)	11 (31.4%)
	The number (%) of patients censored [a]	25 (86.2%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.202	
	HR (95% CI) [d]	0.48 (0.15, 1.51)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	21 (21.9%)	18 (20.5%)
	The number (%) of patients censored [a]	75 (78.1%)	70 (79.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.718	
	HR (95% CI) [d]	1.12 (0.59, 2.13)	
	P-value of subgroup*treatment interaction [e]	0.223	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.10.5
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	1 (3.4%)	4 (11.4%)
	The number (%) of patients censored [a]	28 (96.6%)	31 (88.6%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.424	
	HR (95% CI) [d]	0.42 (0.05, 3.76)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	10 (10.4%)	4 (4.5%)
	The number (%) of patients censored [a]	86 (89.6%)	84 (95.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.332	
	HR (95% CI) [d]	1.76 (0.55, 5.62)	
	P-value of subgroup*treatment interaction [e]	0.254	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEXRun Date: 01MAY2026

Table 7.3.1.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	13 (44.8%)	11 (42.3%)
	The number (%) of patients censored [a]	16 (55.2%)	15 (57.7%)
	Median time to event (95% CI) [b]	9.8 (1.7, NE)	10.9 (2.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.991	
	HR (95% CI) [d]	1.01 (0.45, 2.28)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	21 (67.7%)	23 (74.2%)
	The number (%) of patients censored [a]	10 (32.3%)	8 (25.8%)
	Median time to event (95% CI) [b]	5.4 (1.0, 7.7)	1.7 (0.9, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.175	
	HR (95% CI) [d]	0.67 (0.37, 1.22)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	36 (55.4%)	39 (58.2%)
	The number (%) of patients censored [a]	29 (44.6%)	28 (41.8%)
	Median time to event (95% CI) [b]	2.3 (1.6, 6.3)	3.9 (1.7, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.930	
	HR (95% CI) [d]	1.02 (0.65, 1.61)	
	P-value of subgroup*treatment interaction [e]	0.477	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	12 (41.4%)	14 (53.8%)
	The number (%) of patients censored [a]	17 (58.6%)	12 (46.2%)
	Median time to event (95% CI) [b]	20.1 (2.1, NE)	2.6 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	0.55 (0.25, 1.19)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	19 (61.3%)	17 (54.8%)
	The number (%) of patients censored [a]	12 (38.7%)	14 (45.2%)
	Median time to event (95% CI) [b]	3.6 (1.4, NE)	5.1 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.797	
	HR (95% CI) [d]	0.92 (0.48, 1.77)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	27 (41.5%)	38 (56.7%)
	The number (%) of patients censored [a]	38 (58.5%)	29 (43.3%)
	Median time to event (95% CI) [b]	7.5 (3.6, NE)	5.4 (3.5, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.550	
	HR (95% CI) [d]	0.86 (0.52, 1.41)	
	P-value of subgroup*treatment interaction [e]	0.514	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	11 (37.9%)	16 (61.5%)
	The number (%) of patients censored [a]	18 (62.1%)	10 (38.5%)
	Median time to event (95% CI) [b]	17.8 (1.5, NE)	3.7 (0.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.052	
	HR (95% CI) [d]	0.46 (0.21, 1.02)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	23 (74.2%)	20 (64.5%)
	The number (%) of patients censored [a]	8 (25.8%)	11 (35.5%)
	Median time to event (95% CI) [b]	1.3 (0.9, 5.1)	1.7 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.706	
	HR (95% CI) [d]	1.13 (0.62, 2.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	38 (58.5%)	48 (71.6%)
	The number (%) of patients censored [a]	27 (41.5%)	19 (28.4%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.7)	3.3 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.625	
	HR (95% CI) [d]	1.12 (0.73, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.144	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	8 (27.6%)	9 (34.6%)
	The number (%) of patients censored [a]	21 (72.4%)	17 (65.4%)
	Median time to event (95% CI) [b]	NE (7.3, NE)	10.0 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	0.60 (0.23, 1.57)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	20 (64.5%)	13 (41.9%)
	The number (%) of patients censored [a]	11 (35.5%)	18 (58.1%)
	Median time to event (95% CI) [b]	4.1 (3.0, 12.2)	5.6 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.628	
	HR (95% CI) [d]	1.19 (0.59, 2.40)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	31 (47.7%)	34 (50.7%)
	The number (%) of patients censored [a]	34 (52.3%)	33 (49.3%)
	Median time to event (95% CI) [b]	6.0 (4.2, 11.4)	9.1 (4.4, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.617	
	HR (95% CI) [d]	1.13 (0.70, 1.85)	
	P-value of subgroup*treatment interaction [e]	0.242	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	16 (55.2%)	19 (73.1%)
	The number (%) of patients censored [a]	13 (44.8%)	7 (26.9%)
	Median time to event (95% CI) [b]	1.8 (0.9, NE)	2.1 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.147	
	HR (95% CI) [d]	0.60 (0.30, 1.22)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	21 (67.7%)	16 (51.6%)
	The number (%) of patients censored [a]	10 (32.3%)	15 (48.4%)
	Median time to event (95% CI) [b]	4.2 (2.8, 8.4)	7.0 (2.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.827	
	HR (95% CI) [d]	1.07 (0.56, 2.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	32 (49.2%)	44 (65.7%)
	The number (%) of patients censored [a]	33 (50.8%)	23 (34.3%)
	Median time to event (95% CI) [b]	5.1 (2.8, 12.6)	2.7 (1.8, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.259	
	HR (95% CI) [d]	0.77 (0.49, 1.21)	
	P-value of subgroup*treatment interaction [e]	0.298	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	14 (48.3%)	19 (73.1%)
	The number (%) of patients censored [a]	15 (51.7%)	7 (26.9%)
	Median time to event (95% CI) [b]	3.8 (0.8, NE)	2.4 (0.8, 4.5)
	Nominal p-value for unstratified log-rank test [c]	0.156	
	HR (95% CI) [d]	0.62 (0.31, 1.23)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	19 (61.3%)	22 (71.0%)
	The number (%) of patients censored [a]	12 (38.7%)	9 (29.0%)
	Median time to event (95% CI) [b]	3.2 (1.0, 12.2)	1.4 (0.9, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.078	
	HR (95% CI) [d]	0.57 (0.30, 1.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	35 (53.8%)	36 (53.7%)
	The number (%) of patients censored [a]	30 (46.2%)	31 (46.3%)
	Median time to event (95% CI) [b]	2.2 (1.4, 16.1)	4.9 (3.1, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.343	
	HR (95% CI) [d]	1.25 (0.78, 1.99)	
	P-value of subgroup*treatment interaction [e]	0.065	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	16 (55.2%)	18 (69.2%)
	The number (%) of patients censored [a]	13 (44.8%)	8 (30.8%)
	Median time to event (95% CI) [b]	3.9 (1.7, NE)	1.4 (0.8, 1.6)
	Nominal p-value for unstratified log-rank test [c]	0.023	
	HR (95% CI) [d]	0.46 (0.23, 0.92)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	22 (71.0%)	24 (77.4%)
	The number (%) of patients censored [a]	9 (29.0%)	7 (22.6%)
	Median time to event (95% CI) [b]	1.3 (0.8, 1.8)	1.2 (0.9, 3.2)
	Nominal p-value for unstratified log-rank test [c]	0.506	
	HR (95% CI) [d]	0.82 (0.46, 1.46)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	45 (69.2%)	50 (74.6%)
	The number (%) of patients censored [a]	20 (30.8%)	17 (25.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.6)	1.6 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.554	
	HR (95% CI) [d]	1.14 (0.76, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.095	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	19 (65.5%)	20 (76.9%)
	The number (%) of patients censored [a]	10 (34.5%)	6 (23.1%)
	Median time to event (95% CI) [b]	2.9 (1.1, 4.2)	1.4 (0.8, 1.7)
	Nominal p-value for unstratified log-rank test [c]	0.007	
	HR (95% CI) [d]	0.41 (0.21, 0.80)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	25 (80.6%)	17 (54.8%)
	The number (%) of patients censored [a]	6 (19.4%)	14 (45.2%)
	Median time to event (95% CI) [b]	1.4 (0.9, 2.0)	2.1 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.176	
	HR (95% CI) [d]	1.52 (0.82, 2.83)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	36 (55.4%)	42 (62.7%)
	The number (%) of patients censored [a]	29 (44.6%)	25 (37.3%)
	Median time to event (95% CI) [b]	1.8 (0.9, 4.5)	3.4 (1.3, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.456	
	HR (95% CI) [d]	1.19 (0.76, 1.88)	
	P-value of subgroup*treatment interaction [e]	0.014	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	9 (31.0%)	11 (42.3%)
	The number (%) of patients censored [a]	20 (69.0%)	15 (57.7%)
	Median time to event (95% CI) [b]	17.8 (7.8, NE)	6.3 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.047	
	HR (95% CI) [d]	0.39 (0.15, 1.02)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	16 (51.6%)	20 (64.5%)
	The number (%) of patients censored [a]	15 (48.4%)	11 (35.5%)
	Median time to event (95% CI) [b]	4.3 (1.4, NE)	1.4 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	0.67 (0.34, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	33 (50.8%)	45 (67.2%)
	The number (%) of patients censored [a]	32 (49.2%)	22 (32.8%)
	Median time to event (95% CI) [b]	4.4 (1.4, 9.1)	2.8 (2.1, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	0.95 (0.60, 1.49)	
	P-value of subgroup*treatment interaction [e]	0.227	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	9 (31.0%)	14 (53.8%)
	The number (%) of patients censored [a]	20 (69.0%)	12 (46.2%)
	Median time to event (95% CI) [b]	NE (5.3, NE)	2.8 (1.4, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.031	
	HR (95% CI) [d]	0.40 (0.17, 0.95)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	18 (58.1%)
	The number (%) of patients censored [a]	18 (58.1%)	13 (41.9%)
	Median time to event (95% CI) [b]	12.2 (3.5, NE)	4.4 (1.4, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.020	
	HR (95% CI) [d]	0.44 (0.21, 0.90)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	21 (32.3%)	33 (49.3%)
	The number (%) of patients censored [a]	44 (67.7%)	34 (50.7%)
	Median time to event (95% CI) [b]	11.4 (6.7, NE)	6.7 (3.7, 18.5)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	0.70 (0.40, 1.21)	
	P-value of subgroup*treatment interaction [e]	0.403	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	12 (41.4%)	12 (46.2%)
	The number (%) of patients censored [a]	17 (58.6%)	14 (53.8%)
	Median time to event (95% CI) [b]	10.8 (3.1, NE)	4.4 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.198	
	HR (95% CI) [d]	0.59 (0.26, 1.33)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	16 (51.6%)	20 (64.5%)
	The number (%) of patients censored [a]	15 (48.4%)	11 (35.5%)
	Median time to event (95% CI) [b]	4.2 (1.5, NE)	1.2 (0.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.089	
	HR (95% CI) [d]	0.56 (0.29, 1.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	31 (47.7%)	35 (52.2%)
	The number (%) of patients censored [a]	34 (52.3%)	32 (47.8%)
	Median time to event (95% CI) [b]	4.0 (1.7, 14.4)	4.6 (3.3, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.648	
	HR (95% CI) [d]	1.12 (0.69, 1.82)	
	P-value of subgroup*treatment interaction [e]	0.207	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	13 (44.8%)	15 (57.7%)
	The number (%) of patients censored [a]	16 (55.2%)	11 (42.3%)
	Median time to event (95% CI) [b]	8.8 (1.4, NE)	2.6 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.231	
	HR (95% CI) [d]	0.64 (0.30, 1.35)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	19 (61.3%)	13 (41.9%)
	The number (%) of patients censored [a]	12 (38.7%)	18 (58.1%)
	Median time to event (95% CI) [b]	3.4 (0.9, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.360	
	HR (95% CI) [d]	1.39 (0.69, 2.82)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	32 (49.2%)	40 (59.7%)
	The number (%) of patients censored [a]	33 (50.8%)	27 (40.3%)
	Median time to event (95% CI) [b]	3.6 (1.6, 13.6)	4.1 (1.7, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.675	
	HR (95% CI) [d]	0.91 (0.57, 1.45)	
	P-value of subgroup*treatment interaction [e]	0.306	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	13 (44.8%)	17 (65.4%)
	The number (%) of patients censored [a]	16 (55.2%)	9 (34.6%)
	Median time to event (95% CI) [b]	12.4 (1.7, NE)	1.1 (0.8, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.011	
	HR (95% CI) [d]	0.39 (0.18, 0.83)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	21 (67.7%)	14 (45.2%)
	The number (%) of patients censored [a]	10 (32.3%)	17 (54.8%)
	Median time to event (95% CI) [b]	2.2 (1.3, 3.7)	2.2 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.599	
	HR (95% CI) [d]	1.19 (0.60, 2.35)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	33 (50.8%)	41 (61.2%)
	The number (%) of patients censored [a]	32 (49.2%)	26 (38.8%)
	Median time to event (95% CI) [b]	2.3 (1.4, NE)	2.8 (1.5, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.654	
	HR (95% CI) [d]	0.89 (0.57, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.098	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	15 (51.7%)	13 (50.0%)
	The number (%) of patients censored [a]	14 (48.3%)	13 (50.0%)
	Median time to event (95% CI) [b]	1.7 (1.0, NE)	6.0 (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.863	
	HR (95% CI) [d]	1.07 (0.50, 2.30)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	23 (74.2%)	11 (35.5%)
	The number (%) of patients censored [a]	8 (25.8%)	20 (64.5%)
	Median time to event (95% CI) [b]	2.1 (1.0, 4.4)	NE (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	2.15 (1.04, 4.42)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	46 (70.8%)	23 (34.3%)
	The number (%) of patients censored [a]	19 (29.2%)	44 (65.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.4)	NE (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	4.17 (2.51, 6.93)	
	P-value of subgroup*treatment interaction [e]	0.012	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	8 (27.6%)	9 (34.6%)
	The number (%) of patients censored [a]	21 (72.4%)	17 (65.4%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	5.2 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.117	
	HR (95% CI) [d]	0.46 (0.17, 1.24)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	13 (41.9%)
	The number (%) of patients censored [a]	18 (58.1%)	18 (58.1%)
	Median time to event (95% CI) [b]	21.5 (3.6, NE)	3.1 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.231	
	HR (95% CI) [d]	0.62 (0.28, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	21 (32.3%)	23 (34.3%)
	The number (%) of patients censored [a]	44 (67.7%)	44 (65.7%)
	Median time to event (95% CI) [b]	16.1 (5.1, NE)	19.4 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.714	
	HR (95% CI) [d]	1.12 (0.61, 2.04)	
	P-value of subgroup*treatment interaction [e]	0.167	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	15 (51.7%)	9 (34.6%)
	The number (%) of patients censored [a]	14 (48.3%)	17 (65.4%)
	Median time to event (95% CI) [b]	4.6 (1.7, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.465	
	HR (95% CI) [d]	1.36 (0.59, 3.13)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	17 (54.8%)	13 (41.9%)
	The number (%) of patients censored [a]	14 (45.2%)	18 (58.1%)
	Median time to event (95% CI) [b]	6.9 (1.4, NE)	7.0 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.89 (0.42, 1.86)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	38 (58.5%)	36 (53.7%)
	The number (%) of patients censored [a]	27 (41.5%)	31 (46.3%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	5.0 (2.4, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.011	
	HR (95% CI) [d]	1.81 (1.14, 2.87)	
	P-value of subgroup*treatment interaction [e]	0.330	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	9 (31.0%)	8 (30.8%)
	The number (%) of patients censored [a]	20 (69.0%)	18 (69.2%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.768	
	HR (95% CI) [d]	0.86 (0.33, 2.24)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	6 (19.4%)
	The number (%) of patients censored [a]	18 (58.1%)	25 (80.6%)
	Median time to event (95% CI) [b]	18.5 (3.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	1.71 (0.64, 4.56)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	13 (20.0%)	23 (34.3%)
	The number (%) of patients censored [a]	52 (80.0%)	44 (65.7%)
	Median time to event (95% CI) [b]	NE (13.3, NE)	NE (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.141	
	HR (95% CI) [d]	0.60 (0.31, 1.19)	
	P-value of subgroup*treatment interaction [e]	0.203	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	1 (3.4%)	0 (0.0%)
	The number (%) of patients censored [a]	28 (96.6%)	26 (100.0%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	NE (NE, NE)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	0 (0.0%)	1 (3.2%)
	The number (%) of patients censored [a]	31 (100.0%)	30 (96.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.456	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	5 (7.7%)	4 (6.0%)
	The number (%) of patients censored [a]	60 (92.3%)	63 (94.0%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.283	
	HR (95% CI) [d]	2.04 (0.55, 7.64)	
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	12 (41.4%)	12 (46.2%)
	The number (%) of patients censored [a]	17 (58.6%)	14 (53.8%)
	Median time to event (95% CI) [b]	7.0 (2.2, NE)	6.3 (0.9, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.311	
	HR (95% CI) [d]	0.66 (0.29, 1.47)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	14 (45.2%)	15 (48.4%)
	The number (%) of patients censored [a]	17 (54.8%)	16 (51.6%)
	Median time to event (95% CI) [b]	8.4 (1.4, 18.5)	3.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.133	
	HR (95% CI) [d]	0.55 (0.25, 1.22)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	24 (36.9%)	28 (41.8%)
	The number (%) of patients censored [a]	41 (63.1%)	39 (58.2%)
	Median time to event (95% CI) [b]	3.8 (1.7, 9.8)	5.4 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.540	
	HR (95% CI) [d]	1.19 (0.68, 2.08)	
	P-value of subgroup*treatment interaction [e]	0.314	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	21 (72.4%)	18 (69.2%)
	The number (%) of patients censored [a]	8 (27.6%)	8 (30.8%)
	Median time to event (95% CI) [b]	1.5 (0.8, 3.2)	1.7 (0.8, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.863	
	HR (95% CI) [d]	1.06 (0.56, 1.99)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	26 (83.9%)	18 (58.1%)
	The number (%) of patients censored [a]	5 (16.1%)	13 (41.9%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.3)	2.9 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.019	
	HR (95% CI) [d]	2.05 (1.12, 3.75)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	44 (67.7%)	38 (56.7%)
	The number (%) of patients censored [a]	21 (32.3%)	29 (43.3%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	4.9 (2.0, 8.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.38 (1.52, 3.73)	
	P-value of subgroup*treatment interaction [e]	0.087	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	4 (13.8%)	8 (30.8%)
	The number (%) of patients censored [a]	25 (86.2%)	18 (69.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	7.4 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.081	
	HR (95% CI) [d]	0.35 (0.11, 1.20)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	13 (41.9%)	11 (35.5%)
	The number (%) of patients censored [a]	18 (58.1%)	20 (64.5%)
	Median time to event (95% CI) [b]	17.5 (3.9, NE)	12.7 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.394	
	HR (95% CI) [d]	0.70 (0.31, 1.60)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	19 (29.2%)	16 (23.9%)
	The number (%) of patients censored [a]	46 (70.8%)	51 (76.1%)
	Median time to event (95% CI) [b]	17.1 (5.6, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.240	
	HR (95% CI) [d]	1.49 (0.76, 2.90)	
	P-value of subgroup*treatment interaction [e]	0.063	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	14 (48.3%)	16 (61.5%)
	The number (%) of patients censored [a]	15 (51.7%)	10 (38.5%)
	Median time to event (95% CI) [b]	6.8 (3.2, NE)	2.8 (0.8, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.023	
	HR (95% CI) [d]	0.43 (0.21, 0.91)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	23 (74.2%)	17 (54.8%)
	The number (%) of patients censored [a]	8 (25.8%)	14 (45.2%)
	Median time to event (95% CI) [b]	3.0 (1.5, 5.6)	3.7 (1.7, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.565	
	HR (95% CI) [d]	1.20 (0.64, 2.26)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	25 (38.5%)	36 (53.7%)
	The number (%) of patients censored [a]	40 (61.5%)	31 (46.3%)
	Median time to event (95% CI) [b]	9.6 (6.9, 15.5)	4.9 (2.5, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.144	
	HR (95% CI) [d]	0.68 (0.41, 1.14)	
	P-value of subgroup*treatment interaction [e]	0.054	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	3 (10.3%)	3 (11.5%)
	The number (%) of patients censored [a]	26 (89.7%)	23 (88.5%)
	Median time to event (95% CI) [b]	7.2 (0.8, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.917	
	HR (95% CI) [d]	0.89 (0.17, 4.60)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	3 (9.7%)	3 (9.7%)
	The number (%) of patients censored [a]	28 (90.3%)	28 (90.3%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	2.2 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.874	
	HR (95% CI) [d]	1.14 (0.23, 5.73)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	7 (10.8%)	7 (10.4%)
	The number (%) of patients censored [a]	58 (89.2%)	60 (89.6%)
	Median time to event (95% CI) [b]	1.0 (0.1, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.904	
	HR (95% CI) [d]	0.91 (0.32, 2.62)	
	P-value of subgroup*treatment interaction [e]	0.986	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	6 (20.7%)	10 (38.5%)
	The number (%) of patients censored [a]	23 (79.3%)	16 (61.5%)
	Median time to event (95% CI) [b]	NE (18.7, NE)	10.5 (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.110	
	HR (95% CI) [d]	0.43 (0.15, 1.25)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	15 (48.4%)	12 (38.7%)
	The number (%) of patients censored [a]	16 (51.6%)	19 (61.3%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.738	
	HR (95% CI) [d]	1.14 (0.53, 2.44)	
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.1.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	The number (%) of patients with an event [a]	22 (33.8%)	22 (32.8%)
	The number (%) of patients censored [a]	43 (66.2%)	45 (67.2%)
	Median time to event (95% CI) [b]	9.8 (7.2, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.623	
	HR (95% CI) [d]	1.16 (0.64, 2.10)	
	P-value of subgroup*treatment interaction [e]	0.256	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.1.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	11 (37.9%)	13 (50.0%)
	The number (%) of patients censored [a]	18 (62.1%)	13 (50.0%)
	Median time to event (95% CI) [b]	18.6 (1.7, NE)	5.8 (0.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.188	
	HR (95% CI) [d]	0.58 (0.26, 1.30)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	12 (38.7%)	12 (38.7%)
	The number (%) of patients censored [a]	19 (61.3%)	19 (61.3%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.708	
	HR (95% CI) [d]	0.86 (0.38, 1.91)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	27 (41.5%)	23 (34.3%)
	The number (%) of patients censored [a]	38 (58.5%)	44 (65.7%)
	Median time to event (95% CI) [b]	9.1 (3.3, 11.8)	19.4 (9.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.078	
	HR (95% CI) [d]	1.65 (0.94, 2.89)	
	P-value of subgroup*treatment interaction [e]	0.122	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	2 (6.9%)	7 (26.9%)
	The number (%) of patients censored [a]	27 (93.1%)	19 (73.1%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (4.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.042	
	HR (95% CI) [d]	0.23 (0.05, 1.09)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	6 (19.4%)	7 (22.6%)
	The number (%) of patients censored [a]	25 (80.6%)	24 (77.4%)
	Median time to event (95% CI) [b]	NE (5.8, NE)	6.5 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.890	
	HR (95% CI) [d]	0.93 (0.30, 2.88)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	17 (26.2%)	15 (22.4%)
	The number (%) of patients censored [a]	48 (73.8%)	52 (77.6%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	6.4 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.309	
	HR (95% CI) [d]	1.44 (0.71, 2.92)	
	P-value of subgroup*treatment interaction [e]	0.111	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	26
	The number (%) of patients with an event [a]	1 (3.4%)	1 (3.8%)
	The number (%) of patients censored [a]	28 (96.6%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.784	
	HR (95% CI) [d]	0.68 (0.04, 10.88)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	31	31
	The number (%) of patients with an event [a]	2 (6.5%)	4 (12.9%)
	The number (%) of patients censored [a]	29 (93.5%)	27 (87.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.282	
	HR (95% CI) [d]	0.41 (0.07, 2.22)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.1.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	65	67
	The number (%) of patients with an event [a]	8 (12.3%)	3 (4.5%)
	The number (%) of patients censored [a]	57 (87.7%)	64 (95.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.131	
	HR (95% CI) [d]	2.67 (0.71, 10.10)	
	P-value of subgroup*treatment interaction [e]	0.249	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	14 (46.7%)	24 (68.6%)
	The number (%) of patients censored [a]	16 (53.3%)	11 (31.4%)
	Median time to event (95% CI) [b]	4.9 (1.7, NE)	1.4 (0.9, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.065	
	HR (95% CI) [d]	0.54 (0.28, 1.06)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	56 (58.9%)	49 (55.1%)
	The number (%) of patients censored [a]	39 (41.1%)	40 (44.9%)
	Median time to event (95% CI) [b]	4.1 (1.8, 7.2)	4.2 (2.5, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.768	
	HR (95% CI) [d]	1.06 (0.72, 1.56)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.095	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	13 (43.3%)	23 (65.7%)
	The number (%) of patients censored [a]	17 (56.7%)	12 (34.3%)
	Median time to event (95% CI) [b]	7.4 (1.7, NE)	2.4 (1.4, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.127	
	HR (95% CI) [d]	0.59 (0.30, 1.18)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	45 (47.4%)	46 (51.7%)
	The number (%) of patients censored [a]	50 (52.6%)	43 (48.3%)
	Median time to event (95% CI) [b]	7.9 (3.6, 21.5)	5.8 (3.1, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.547	
	HR (95% CI) [d]	0.88 (0.58, 1.33)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.300	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	17 (56.7%)	28 (80.0%)
	The number (%) of patients censored [a]	13 (43.3%)	7 (20.0%)
	Median time to event (95% CI) [b]	1.4 (0.8, NE)	2.5 (0.9, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.406	
	HR (95% CI) [d]	0.77 (0.42, 1.42)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	55 (57.9%)	56 (62.9%)
	The number (%) of patients censored [a]	40 (42.1%)	33 (37.1%)
	Median time to event (95% CI) [b]	1.8 (1.4, 3.2)	3.7 (2.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.919	
	HR (95% CI) [d]	1.02 (0.70, 1.48)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.500	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	12 (40.0%)	14 (40.0%)
	The number (%) of patients censored [a]	18 (60.0%)	21 (60.0%)
	Median time to event (95% CI) [b]	10.4 (3.2, NE)	10.8 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.983	
	HR (95% CI) [d]	0.99 (0.46, 2.15)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	47 (49.5%)	42 (47.2%)
	The number (%) of patients censored [a]	48 (50.5%)	47 (52.8%)
	Median time to event (95% CI) [b]	7.8 (4.3, 11.8)	9.1 (4.4, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.769	
	HR (95% CI) [d]	0.94 (0.62, 1.43)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.907	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	14 (46.7%)	23 (65.7%)
	The number (%) of patients censored [a]	16 (53.3%)	12 (34.3%)
	Median time to event (95% CI) [b]	6.4 (2.8, NE)	2.2 (1.5, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.060	
	HR (95% CI) [d]	0.53 (0.27, 1.04)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	55 (57.9%)	56 (62.9%)
	The number (%) of patients censored [a]	40 (42.1%)	33 (37.1%)
	Median time to event (95% CI) [b]	3.6 (2.6, 6.9)	3.5 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.564	
	HR (95% CI) [d]	0.90 (0.62, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.169	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	12 (40.0%)	21 (60.0%)
	The number (%) of patients censored [a]	18 (60.0%)	14 (40.0%)
	Median time to event (95% CI) [b]	3.8 (0.8, NE)	3.3 (0.9, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.404	
	HR (95% CI) [d]	0.74 (0.36, 1.51)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	56 (58.9%)	56 (62.9%)
	The number (%) of patients censored [a]	39 (41.1%)	33 (37.1%)
	Median time to event (95% CI) [b]	2.4 (1.4, 7.5)	3.5 (1.6, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.734	
	HR (95% CI) [d]	0.94 (0.65, 1.36)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.482	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	18 (60.0%)	29 (82.9%)
	The number (%) of patients censored [a]	12 (40.0%)	6 (17.1%)
	Median time to event (95% CI) [b]	0.9 (0.8, 5.7)	1.1 (0.9, 1.4)
	Nominal p-value for unstratified log-rank test [c]	0.229	
	HR (95% CI) [d]	0.70 (0.38, 1.29)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	65 (68.4%)	63 (70.8%)
	The number (%) of patients censored [a]	30 (31.6%)	26 (29.2%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.2)	1.9 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.747	
	HR (95% CI) [d]	0.95 (0.67, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.371	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	19 (54.3%)
	The number (%) of patients censored [a]	15 (50.0%)	16 (45.7%)
	Median time to event (95% CI) [b]	3.2 (0.9, NE)	2.1 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.556	
	HR (95% CI) [d]	0.81 (0.41, 1.64)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	65 (68.4%)	60 (67.4%)
	The number (%) of patients censored [a]	30 (31.6%)	29 (32.6%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.9)	1.7 (1.0, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.527	
	HR (95% CI) [d]	1.12 (0.78, 1.59)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.502	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	12 (40.0%)	22 (62.9%)
	The number (%) of patients censored [a]	18 (60.0%)	13 (37.1%)
	Median time to event (95% CI) [b]	16.0 (1.7, NE)	3.0 (1.8, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.190	
	HR (95% CI) [d]	0.62 (0.30, 1.29)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	46 (48.4%)	54 (60.7%)
	The number (%) of patients censored [a]	49 (51.6%)	35 (39.3%)
	Median time to event (95% CI) [b]	6.5 (2.4, 11.8)	2.8 (1.9, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.73 (0.49, 1.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.767	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	11 (36.7%)	22 (62.9%)
	The number (%) of patients censored [a]	19 (63.3%)	13 (37.1%)
	Median time to event (95% CI) [b]	15.5 (1.5, NE)	3.1 (1.2, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.44 (0.21, 0.94)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	32 (33.7%)	43 (48.3%)
	The number (%) of patients censored [a]	63 (66.3%)	46 (51.7%)
	Median time to event (95% CI) [b]	NE (7.7, NE)	6.7 (3.7, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.028	
	HR (95% CI) [d]	0.60 (0.38, 0.95)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.474	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	16 (45.7%)
	The number (%) of patients censored [a]	15 (50.0%)	19 (54.3%)
	Median time to event (95% CI) [b]	5.1 (2.5, NE)	6.0 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.693	
	HR (95% CI) [d]	1.15 (0.57, 2.33)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	44 (46.3%)	51 (57.3%)
	The number (%) of patients censored [a]	51 (53.7%)	38 (42.7%)
	Median time to event (95% CI) [b]	7.2 (3.2, 14.4)	4.1 (2.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.123	
	HR (95% CI) [d]	0.73 (0.49, 1.09)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.277	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	11 (36.7%)	20 (57.1%)
	The number (%) of patients censored [a]	19 (63.3%)	15 (42.9%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	3.5 (1.8, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.180	
	HR (95% CI) [d]	0.60 (0.29, 1.28)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	53 (55.8%)	48 (53.9%)
	The number (%) of patients censored [a]	42 (44.2%)	41 (46.1%)
	Median time to event (95% CI) [b]	3.1 (1.5, 4.2)	3.5 (1.4, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.839	
	HR (95% CI) [d]	1.04 (0.71, 1.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.166	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	23 (65.7%)
	The number (%) of patients censored [a]	15 (50.0%)	12 (34.3%)
	Median time to event (95% CI) [b]	3.1 (1.4, NE)	1.7 (1.2, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.438	
	HR (95% CI) [d]	0.77 (0.40, 1.48)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	52 (54.7%)	49 (55.1%)
	The number (%) of patients censored [a]	43 (45.3%)	40 (44.9%)
	Median time to event (95% CI) [b]	2.4 (1.8, 12.4)	2.6 (1.0, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	0.87 (0.59, 1.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.764	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	23 (76.7%)	11 (31.4%)
	The number (%) of patients censored [a]	7 (23.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	1.4 (0.8, 2.9)	10.1 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.49 (1.68, 7.25)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	61 (64.2%)	36 (40.4%)
	The number (%) of patients censored [a]	34 (35.8%)	53 (59.6%)
	Median time to event (95% CI) [b]	1.6 (1.0, 3.3)	13.2 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.28 (1.51, 3.46)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.252	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	8 (26.7%)	11 (31.4%)
	The number (%) of patients censored [a]	22 (73.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.716	
	HR (95% CI) [d]	0.85 (0.34, 2.10)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	34 (35.8%)	34 (38.2%)
	The number (%) of patients censored [a]	61 (64.2%)	55 (61.8%)
	Median time to event (95% CI) [b]	19.0 (7.0, 27.9)	8.7 (4.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.375	
	HR (95% CI) [d]	0.80 (0.50, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.933	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	14 (46.7%)	17 (48.6%)
	The number (%) of patients censored [a]	16 (53.3%)	18 (51.4%)
	Median time to event (95% CI) [b]	1.8 (1.5, NE)	4.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.786	
	HR (95% CI) [d]	1.10 (0.54, 2.23)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	56 (58.9%)	41 (46.1%)
	The number (%) of patients censored [a]	39 (41.1%)	48 (53.9%)
	Median time to event (95% CI) [b]	3.5 (2.1, 5.0)	6.5 (3.5, 17.1)
	Nominal p-value for unstratified log-rank test [c]	0.075	
	HR (95% CI) [d]	1.44 (0.96, 2.15)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.445	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	7 (23.3%)	13 (37.1%)
	The number (%) of patients censored [a]	23 (76.7%)	22 (62.9%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	5.3 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.141	
	HR (95% CI) [d]	0.51 (0.20, 1.28)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	28 (29.5%)	24 (27.0%)
	The number (%) of patients censored [a]	67 (70.5%)	65 (73.0%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.782	
	HR (95% CI) [d]	1.08 (0.63, 1.86)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.137	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	1 (3.3%)	3 (8.6%)
	The number (%) of patients censored [a]	29 (96.7%)	32 (91.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.890	
	HR (95% CI) [d]	1.18 (0.11, 13.16)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	5 (5.3%)	2 (2.2%)
	The number (%) of patients censored [a]	90 (94.7%)	87 (97.8%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.221	
	HR (95% CI) [d]	2.68 (0.52, 13.80)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.490	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	10 (33.3%)	14 (40.0%)
	The number (%) of patients censored [a]	20 (66.7%)	21 (60.0%)
	Median time to event (95% CI) [b]	3.5 (1.4, NE)	6.3 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.959	
	HR (95% CI) [d]	0.98 (0.43, 2.21)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	40 (42.1%)	41 (46.1%)
	The number (%) of patients censored [a]	55 (57.9%)	48 (53.9%)
	Median time to event (95% CI) [b]	7.0 (2.4, 12.6)	4.9 (2.0, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.399	
	HR (95% CI) [d]	0.82 (0.53, 1.28)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.686	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	23 (76.7%)	19 (54.3%)
	The number (%) of patients censored [a]	7 (23.3%)	16 (45.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.2)	3.1 (1.3, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.55 (1.36, 4.77)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	68 (71.6%)	55 (61.8%)
	The number (%) of patients censored [a]	27 (28.4%)	34 (38.2%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.0 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	1.71 (1.20, 2.45)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.344	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	7 (23.3%)	11 (31.4%)
	The number (%) of patients censored [a]	23 (76.7%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.204	
	HR (95% CI) [d]	0.54 (0.21, 1.42)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	29 (30.5%)	24 (27.0%)
	The number (%) of patients censored [a]	66 (69.5%)	65 (73.0%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.667	
	HR (95% CI) [d]	1.13 (0.65, 1.94)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.168	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	13 (43.3%)	19 (54.3%)
	The number (%) of patients censored [a]	17 (56.7%)	16 (45.7%)
	Median time to event (95% CI) [b]	7.9 (2.8, NE)	4.2 (2.1, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.189	
	HR (95% CI) [d]	0.61 (0.30, 1.27)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	49 (51.6%)	50 (56.2%)
	The number (%) of patients censored [a]	46 (48.4%)	39 (43.8%)
	Median time to event (95% CI) [b]	6.8 (3.5, 10.8)	3.5 (2.2, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.234	
	HR (95% CI) [d]	0.79 (0.53, 1.17)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.598	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	5 (16.7%)	2 (5.7%)
	The number (%) of patients censored [a]	25 (83.3%)	33 (94.3%)
	Median time to event (95% CI) [b]	0.9 (0.7, NE)	1.4 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.154	
	HR (95% CI) [d]	3.23 (0.60, 17.45)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	8 (8.4%)	11 (12.4%)
	The number (%) of patients censored [a]	87 (91.6%)	78 (87.6%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.579	
	HR (95% CI) [d]	0.76 (0.31, 1.89)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.216	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	10 (33.3%)	14 (40.0%)
	The number (%) of patients censored [a]	20 (66.7%)	21 (60.0%)
	Median time to event (95% CI) [b]	18.7 (3.9, NE)	5.1 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.453	
	HR (95% CI) [d]	0.73 (0.31, 1.70)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	33 (34.7%)	30 (33.7%)
	The number (%) of patients censored [a]	62 (65.3%)	59 (66.3%)
	Median time to event (95% CI) [b]	NE (8.8, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.865	
	HR (95% CI) [d]	1.04 (0.63, 1.71)	
	P-value of subgroup*treatment interaction [e]	0.521	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.2.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	15 (50.0%)	8 (22.9%)
	The number (%) of patients censored [a]	15 (50.0%)	27 (77.1%)
	Median time to event (95% CI) [b]	3.5 (1.5, NE)	15.9 (15.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.007	
	HR (95% CI) [d]	3.24 (1.32, 7.98)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	35 (36.8%)	40 (44.9%)
	The number (%) of patients censored [a]	60 (63.2%)	49 (55.1%)
	Median time to event (95% CI) [b]	11.8 (4.2, NE)	9.7 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.351	
	HR (95% CI) [d]	0.80 (0.51, 1.26)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.008	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	8 (26.7%)	11 (31.4%)
	The number (%) of patients censored [a]	22 (73.3%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	6.4 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.366	
	HR (95% CI) [d]	0.66 (0.26, 1.64)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	17 (17.9%)	18 (20.2%)
	The number (%) of patients censored [a]	78 (82.1%)	71 (79.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.927	
	HR (95% CI) [d]	1.03 (0.53, 2.01)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.462	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	30	35
	The number (%) of patients with an event [a]	2 (6.7%)	2 (5.7%)
	The number (%) of patients censored [a]	28 (93.3%)	33 (94.3%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	0.82 (0.11, 6.22)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	95	89
	The number (%) of patients with an event [a]	9 (9.5%)	6 (6.7%)
	The number (%) of patients censored [a]	86 (90.5%)	83 (93.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.678	
	HR (95% CI) [d]	1.25 (0.44, 3.50)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.2.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.840	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	58 (59.2%)	55 (57.3%)
	The number (%) of patients censored [a]	40 (40.8%)	41 (42.7%)
	Median time to event (95% CI) [b]	5.0 (2.1, 7.7)	3.7 (2.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.610	
	HR (95% CI) [d]	0.91 (0.63, 1.32)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	18 (64.3%)
	The number (%) of patients censored [a]	15 (55.6%)	10 (35.7%)
	Median time to event (95% CI) [b]	2.3 (1.0, NE)	2.6 (1.1, 10.9)
	Nominal p-value for unstratified log-rank test [c]	0.633	
	HR (95% CI) [d]	0.83 (0.40, 1.74)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.809	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	47 (48.0%)	54 (56.3%)
	The number (%) of patients censored [a]	51 (52.0%)	42 (43.8%)
	Median time to event (95% CI) [b]	8.8 (5.3, 21.5)	4.4 (2.6, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.111	
	HR (95% CI) [d]	0.73 (0.49, 1.08)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	11 (40.7%)	15 (53.6%)
	The number (%) of patients censored [a]	16 (59.3%)	13 (46.4%)
	Median time to event (95% CI) [b]	4.3 (1.0, NE)	5.1 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.718	
	HR (95% CI) [d]	1.15 (0.53, 2.52)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.383	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	59 (60.2%)	65 (67.7%)
	The number (%) of patients censored [a]	39 (39.8%)	31 (32.3%)
	Median time to event (95% CI) [b]	1.7 (1.3, 5.1)	3.5 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.576	
	HR (95% CI) [d]	0.91 (0.64, 1.30)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	19 (67.9%)
	The number (%) of patients censored [a]	14 (51.9%)	9 (32.1%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.4)	3.1 (0.9, 7.8)
	Nominal p-value for unstratified log-rank test [c]	0.664	
	HR (95% CI) [d]	1.16 (0.57, 2.39)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.592	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	53 (54.1%)	44 (45.8%)
	The number (%) of patients censored [a]	45 (45.9%)	52 (54.2%)
	Median time to event (95% CI) [b]	7.7 (4.2, 11.3)	10.0 (4.4, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.998	
	HR (95% CI) [d]	1.00 (0.67, 1.50)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	6 (22.2%)	12 (42.9%)
	The number (%) of patients censored [a]	21 (77.8%)	16 (57.1%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	9.1 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	0.70 (0.26, 1.90)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.391	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	62 (63.3%)	64 (66.7%)
	The number (%) of patients censored [a]	36 (36.7%)	32 (33.3%)
	Median time to event (95% CI) [b]	4.2 (2.8, 6.4)	2.4 (1.9, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.157	
	HR (95% CI) [d]	0.78 (0.55, 1.10)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	7 (25.9%)	15 (53.6%)
	The number (%) of patients censored [a]	20 (74.1%)	13 (46.4%)
	Median time to event (95% CI) [b]	22.4 (2.1, NE)	8.4 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	0.55 (0.21, 1.44)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.657	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	53 (54.1%)	59 (61.5%)
	The number (%) of patients censored [a]	45 (45.9%)	37 (38.5%)
	Median time to event (95% CI) [b]	3.6 (1.5, 12.2)	3.3 (1.6, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.269	
	HR (95% CI) [d]	0.81 (0.56, 1.18)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	15 (55.6%)	18 (64.3%)
	The number (%) of patients censored [a]	12 (44.4%)	10 (35.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	3.6 (0.9, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.604	
	HR (95% CI) [d]	1.21 (0.59, 2.44)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.273	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	67 (68.4%)	69 (71.9%)
	The number (%) of patients censored [a]	31 (31.6%)	27 (28.1%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.2)	1.4 (0.9, 2.7)
	Nominal p-value for unstratified log-rank test [c]	0.479	
	HR (95% CI) [d]	0.89 (0.64, 1.25)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	16 (59.3%)	23 (82.1%)
	The number (%) of patients censored [a]	11 (40.7%)	5 (17.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.6)	1.1 (0.9, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.85 (0.45, 1.61)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.822	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	71 (72.4%)	64 (66.7%)
	The number (%) of patients censored [a]	27 (27.6%)	32 (33.3%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.4)	1.5 (1.2, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.737	
	HR (95% CI) [d]	1.06 (0.76, 1.49)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	9 (33.3%)	15 (53.6%)
	The number (%) of patients censored [a]	18 (66.7%)	13 (46.4%)
	Median time to event (95% CI) [b]	3.2 (1.4, NE)	4.9 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.818	
	HR (95% CI) [d]	0.90 (0.39, 2.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.607	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	48 (49.0%)	57 (59.4%)
	The number (%) of patients censored [a]	50 (51.0%)	39 (40.6%)
	Median time to event (95% CI) [b]	7.7 (2.8, 15.5)	2.8 (1.9, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.076	
	HR (95% CI) [d]	0.71 (0.48, 1.04)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	10 (37.0%)	19 (67.9%)
	The number (%) of patients censored [a]	17 (63.0%)	9 (32.1%)
	Median time to event (95% CI) [b]	11.8 (1.0, NE)	2.6 (1.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.502	
	HR (95% CI) [d]	0.77 (0.35, 1.68)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.867	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	36 (36.7%)	50 (52.1%)
	The number (%) of patients censored [a]	62 (63.3%)	46 (47.9%)
	Median time to event (95% CI) [b]	NE (7.7, NE)	4.9 (2.8, 8.0)
	Nominal p-value for unstratified log-rank test [c]	0.004	
	HR (95% CI) [d]	0.53 (0.35, 0.82)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	7 (25.9%)	15 (53.6%)
	The number (%) of patients censored [a]	20 (74.1%)	13 (46.4%)
	Median time to event (95% CI) [b]	15.5 (3.1, NE)	5.0 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.326	
	HR (95% CI) [d]	0.62 (0.24, 1.62)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.667	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	51 (52.0%)	52 (54.2%)
	The number (%) of patients censored [a]	47 (48.0%)	44 (45.8%)
	Median time to event (95% CI) [b]	5.3 (3.2, 10.8)	4.4 (3.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.335	
	HR (95% CI) [d]	0.83 (0.56, 1.22)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	8 (29.6%)	15 (53.6%)
	The number (%) of patients censored [a]	19 (70.4%)	13 (46.4%)
	Median time to event (95% CI) [b]	4.0 (1.0, NE)	3.6 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.658	
	HR (95% CI) [d]	0.83 (0.35, 1.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.915	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	51 (52.0%)	57 (59.4%)
	The number (%) of patients censored [a]	47 (48.0%)	39 (40.6%)
	Median time to event (95% CI) [b]	4.1 (1.6, NE)	2.4 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.133	
	HR (95% CI) [d]	0.75 (0.52, 1.10)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	11 (39.3%)
	The number (%) of patients censored [a]	14 (51.9%)	17 (60.7%)
	Median time to event (95% CI) [b]	2.1 (1.4, 4.0)	14.5 (4.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.018	
	HR (95% CI) [d]	2.64 (1.15, 6.02)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.021	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	55 (56.1%)	57 (59.4%)
	The number (%) of patients censored [a]	43 (43.9%)	39 (40.6%)
	Median time to event (95% CI) [b]	2.5 (1.8, 12.4)	2.1 (1.4, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.199	
	HR (95% CI) [d]	0.78 (0.54, 1.13)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	15 (53.6%)
	The number (%) of patients censored [a]	15 (55.6%)	13 (46.4%)
	Median time to event (95% CI) [b]	1.9 (1.0, NE)	3.5 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.702	
	HR (95% CI) [d]	1.16 (0.54, 2.48)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.430	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	71 (72.4%)	39 (40.6%)
	The number (%) of patients censored [a]	27 (27.6%)	57 (59.4%)
	Median time to event (95% CI) [b]	1.7 (1.1, 2.8)	7.4 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.28 (1.54, 3.38)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	8 (28.6%)
	The number (%) of patients censored [a]	14 (51.9%)	20 (71.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 3.3)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	3.76 (1.51, 9.36)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.203	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	37 (37.8%)	36 (37.5%)
	The number (%) of patients censored [a]	61 (62.2%)	60 (62.5%)
	Median time to event (95% CI) [b]	16.1 (6.9, NE)	6.5 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.290	
	HR (95% CI) [d]	0.78 (0.49, 1.24)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	5 (18.5%)	9 (32.1%)
	The number (%) of patients censored [a]	22 (81.5%)	19 (67.9%)
	Median time to event (95% CI) [b]	27.9 (2.4, NE)	19.4 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.473	
	HR (95% CI) [d]	0.65 (0.20, 2.12)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.963	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	58 (59.2%)	46 (47.9%)
	The number (%) of patients censored [a]	40 (40.8%)	50 (52.1%)
	Median time to event (95% CI) [b]	3.6 (2.1, 5.2)	5.2 (2.4, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.431	
	HR (95% CI) [d]	1.17 (0.79, 1.72)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	12 (42.9%)
	The number (%) of patients censored [a]	15 (55.6%)	16 (57.1%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.3)	15.2 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.046	
	HR (95% CI) [d]	2.30 (1.00, 5.33)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.099	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	31 (31.6%)	28 (29.2%)
	The number (%) of patients censored [a]	67 (68.4%)	68 (70.8%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.705	
	HR (95% CI) [d]	0.91 (0.54, 1.51)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	4 (14.8%)	9 (32.1%)
	The number (%) of patients censored [a]	23 (85.2%)	19 (67.9%)
	Median time to event (95% CI) [b]	NE (4.9, NE)	NE (5.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.819	
	HR (95% CI) [d]	0.87 (0.26, 2.87)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.699	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	6 (6.1%)	5 (5.2%)
	The number (%) of patients censored [a]	92 (93.9%)	91 (94.8%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.411	
	HR (95% CI) [d]	1.64 (0.50, 5.39)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	27 (100.0%)	28 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	44 (44.9%)	43 (44.8%)
	The number (%) of patients censored [a]	54 (55.1%)	53 (55.2%)
	Median time to event (95% CI) [b]	6.3 (2.2, 12.2)	4.9 (2.0, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.502	
	HR (95% CI) [d]	0.86 (0.56, 1.32)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	6 (22.2%)	12 (42.9%)
	The number (%) of patients censored [a]	21 (77.8%)	16 (57.1%)
	Median time to event (95% CI) [b]	27.9 (1.2, NE)	13.8 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.482	
	HR (95% CI) [d]	0.68 (0.24, 1.96)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.942	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	78 (79.6%)	60 (62.5%)
	The number (%) of patients censored [a]	20 (20.4%)	36 (37.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	2.7 (1.4, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.82 (1.30, 2.56)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	13 (48.1%)	14 (50.0%)
	The number (%) of patients censored [a]	14 (51.9%)	14 (50.0%)
	Median time to event (95% CI) [b]	1.1 (0.8, 3.8)	5.1 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.071	
	HR (95% CI) [d]	2.01 (0.93, 4.34)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.998	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	30 (30.6%)	25 (26.0%)
	The number (%) of patients censored [a]	68 (69.4%)	71 (74.0%)
	Median time to event (95% CI) [b]	24.7 (17.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	0.97 (0.57, 1.65)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	6 (22.2%)	10 (35.7%)
	The number (%) of patients censored [a]	21 (77.8%)	18 (64.3%)
	Median time to event (95% CI) [b]	NE (1.5, NE)	NE (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.964	
	HR (95% CI) [d]	1.02 (0.37, 2.83)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.874	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	52 (53.1%)	53 (55.2%)
	The number (%) of patients censored [a]	46 (46.9%)	43 (44.8%)
	Median time to event (95% CI) [b]	6.9 (3.5, 13.3)	3.5 (2.8, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.156	
	HR (95% CI) [d]	0.76 (0.52, 1.11)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	10 (37.0%)	16 (57.1%)
	The number (%) of patients censored [a]	17 (63.0%)	12 (42.9%)
	Median time to event (95% CI) [b]	6.8 (2.5, NE)	3.7 (1.0, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.530	
	HR (95% CI) [d]	0.77 (0.35, 1.71)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.920	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	9 (9.2%)	10 (10.4%)
	The number (%) of patients censored [a]	89 (90.8%)	86 (89.6%)
	Median time to event (95% CI) [b]	2.2 (0.8, NE)	1.4 (0.8, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.503	
	HR (95% CI) [d]	0.72 (0.29, 1.80)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	4 (14.8%)	3 (10.7%)
	The number (%) of patients censored [a]	23 (85.2%)	25 (89.3%)
	Median time to event (95% CI) [b]	1.2 (0.1, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.234	
	HR (95% CI) [d]	2.44 (0.54, 11.06)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.175	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	38 (38.8%)	34 (35.4%)
	The number (%) of patients censored [a]	60 (61.2%)	62 (64.6%)
	Median time to event (95% CI) [b]	18.7 (8.8, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.911	
	HR (95% CI) [d]	0.97 (0.61, 1.55)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	5 (18.5%)	10 (35.7%)
	The number (%) of patients censored [a]	22 (81.5%)	18 (64.3%)
	Median time to event (95% CI) [b]	NE (2.3, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.783	
	HR (95% CI) [d]	0.86 (0.29, 2.53)	
	P-value of subgroup*treatment interaction [e]	0.657	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.3.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	38 (38.8%)	40 (41.7%)
	The number (%) of patients censored [a]	60 (61.2%)	56 (58.3%)
	Median time to event (95% CI) [b]	11.4 (4.3, NE)	16.1 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.625	
	HR (95% CI) [d]	0.89 (0.57, 1.39)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	12 (44.4%)	8 (28.6%)
	The number (%) of patients censored [a]	15 (55.6%)	20 (71.4%)
	Median time to event (95% CI) [b]	2.8 (1.7, NE)	15.9 (15.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	2.04 (0.81, 5.16)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.076	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	22 (22.4%)	24 (25.0%)
	The number (%) of patients censored [a]	76 (77.6%)	72 (75.0%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.389	
	HR (95% CI) [d]	0.77 (0.43, 1.38)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	3 (11.1%)	5 (17.9%)
	The number (%) of patients censored [a]	24 (88.9%)	23 (82.1%)
	Median time to event (95% CI) [b]	NE (3.3, NE)	NE (6.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	1.62 (0.39, 6.82)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.398	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	98	96
	The number (%) of patients with an event [a]	9 (9.2%)	5 (5.2%)
	The number (%) of patients censored [a]	89 (90.8%)	91 (94.8%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.643	
	HR (95% CI) [d]	1.29 (0.43, 3.86)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	27	28
	The number (%) of patients with an event [a]	2 (7.4%)	3 (10.7%)
	The number (%) of patients censored [a]	25 (92.6%)	25 (89.3%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.485	
	HR (95% CI) [d]	1.88 (0.31, 11.32)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.3.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.778	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	46 (56.8%)	52 (67.5%)
	The number (%) of patients censored [a]	35 (43.2%)	25 (32.5%)
	Median time to event (95% CI) [b]	2.4 (1.4, 6.0)	2.7 (1.4, 3.9)
	Nominal p-value for unstratified log-rank test [c]	0.255	
	HR (95% CI) [d]	0.80 (0.53, 1.19)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	14 (53.8%)
	The number (%) of patients censored [a]	11 (42.3%)	12 (46.2%)
	Median time to event (95% CI) [b]	6.3 (1.8, 15.5)	5.6 (1.6, 14.0)
	Nominal p-value for unstratified log-rank test [c]	0.834	
	HR (95% CI) [d]	0.92 (0.44, 1.93)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	7 (43.8%)	7 (33.3%)
	The number (%) of patients censored [a]	9 (56.3%)	14 (66.7%)
	Median time to event (95% CI) [b]	15.2 (2.4, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.839	
	HR (95% CI) [d]	1.12 (0.39, 3.20)	
	P-value of subgroup*treatment interaction [e]	0.775	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	36 (44.4%)	43 (55.8%)
	The number (%) of patients censored [a]	45 (55.6%)	34 (44.2%)
	Median time to event (95% CI) [b]	7.4 (3.5, NE)	3.7 (2.2, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.239	
	HR (95% CI) [d]	0.77 (0.49, 1.20)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	16 (61.5%)	14 (53.8%)
	The number (%) of patients censored [a]	10 (38.5%)	12 (46.2%)
	Median time to event (95% CI) [b]	3.6 (0.9, 8.8)	5.6 (1.6, 14.0)
	Nominal p-value for unstratified log-rank test [c]	0.649	
	HR (95% CI) [d]	1.18 (0.57, 2.43)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	6 (37.5%)	12 (57.1%)
	The number (%) of patients censored [a]	10 (62.5%)	9 (42.9%)
	Median time to event (95% CI) [b]	21.5 (2.4, NE)	5.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	0.45 (0.17, 1.22)	
	P-value of subgroup*treatment interaction [e]	0.290	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	48 (59.3%)	49 (63.6%)
	The number (%) of patients censored [a]	33 (40.7%)	28 (36.4%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.4)	3.8 (1.6, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.538	
	HR (95% CI) [d]	1.14 (0.76, 1.70)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	18 (69.2%)
	The number (%) of patients censored [a]	11 (42.3%)	8 (30.8%)
	Median time to event (95% CI) [b]	3.2 (0.9, 8.4)	3.5 (0.9, 7.8)
	Nominal p-value for unstratified log-rank test [c]	0.880	
	HR (95% CI) [d]	0.94 (0.47, 1.86)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	7 (43.8%)	17 (81.0%)
	The number (%) of patients censored [a]	9 (56.3%)	4 (19.0%)
	Median time to event (95% CI) [b]	17.8 (1.0, NE)	3.1 (0.8, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.017	
	HR (95% CI) [d]	0.35 (0.14, 0.87)	
	P-value of subgroup*treatment interaction [e]	0.075	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	37 (45.7%)	34 (44.2%)
	The number (%) of patients censored [a]	44 (54.3%)	43 (55.8%)
	Median time to event (95% CI) [b]	7.8 (3.4, NE)	5.9 (3.5, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.931	
	HR (95% CI) [d]	0.98 (0.61, 1.56)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	14 (53.8%)
	The number (%) of patients censored [a]	14 (53.8%)	12 (46.2%)
	Median time to event (95% CI) [b]	11.3 (4.1, 15.5)	9.1 (4.9, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.363	
	HR (95% CI) [d]	0.69 (0.31, 1.53)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	8 (38.1%)
	The number (%) of patients censored [a]	8 (50.0%)	13 (61.9%)
	Median time to event (95% CI) [b]	7.3 (3.1, NE)	14.0 (1.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.924	
	HR (95% CI) [d]	1.05 (0.39, 2.82)	
	P-value of subgroup*treatment interaction [e]	0.947	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	41 (50.6%)	49 (63.6%)
	The number (%) of patients censored [a]	40 (49.4%)	28 (36.4%)
	Median time to event (95% CI) [b]	5.1 (2.8, 9.8)	2.2 (1.7, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	0.71 (0.47, 1.08)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	17 (65.4%)
	The number (%) of patients censored [a]	11 (42.3%)	9 (34.6%)
	Median time to event (95% CI) [b]	3.6 (2.3, 18.5)	4.2 (2.2, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.479	
	HR (95% CI) [d]	0.77 (0.37, 1.58)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	11 (68.8%)	13 (61.9%)
	The number (%) of patients censored [a]	5 (31.3%)	8 (38.1%)
	Median time to event (95% CI) [b]	4.3 (1.0, 13.1)	3.3 (1.4, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.751	
	HR (95% CI) [d]	0.87 (0.38, 1.99)	
	P-value of subgroup*treatment interaction [e]	0.820	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	40 (49.4%)	45 (58.4%)
	The number (%) of patients censored [a]	41 (50.6%)	32 (41.6%)
	Median time to event (95% CI) [b]	2.2 (1.4, NE)	3.6 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.774	
	HR (95% CI) [d]	0.94 (0.61, 1.44)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	15 (57.7%)	16 (61.5%)
	The number (%) of patients censored [a]	11 (42.3%)	10 (38.5%)
	Median time to event (95% CI) [b]	3.6 (1.0, NE)	4.9 (2.2, 7.1)
	Nominal p-value for unstratified log-rank test [c]	0.750	
	HR (95% CI) [d]	0.89 (0.44, 1.80)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	11 (68.8%)	16 (76.2%)
	The number (%) of patients censored [a]	5 (31.3%)	5 (23.8%)
	Median time to event (95% CI) [b]	2.4 (1.0, 21.5)	1.4 (0.8, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.175	
	HR (95% CI) [d]	0.57 (0.25, 1.30)	
	P-value of subgroup*treatment interaction [e]	0.563	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	53 (65.4%)	58 (75.3%)
	The number (%) of patients censored [a]	28 (34.6%)	19 (24.7%)
	Median time to event (95% CI) [b]	1.5 (0.8, 2.3)	1.2 (0.9, 1.6)
	Nominal p-value for unstratified log-rank test [c]	0.142	
	HR (95% CI) [d]	0.76 (0.52, 1.11)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	19 (73.1%)	18 (69.2%)
	The number (%) of patients censored [a]	7 (26.9%)	8 (30.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.8)	4.1 (0.9, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.182	
	HR (95% CI) [d]	1.56 (0.81, 3.00)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	9 (56.3%)	16 (76.2%)
	The number (%) of patients censored [a]	7 (43.8%)	5 (23.8%)
	Median time to event (95% CI) [b]	2.3 (0.8, NE)	2.1 (0.8, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.138	
	HR (95% CI) [d]	0.54 (0.24, 1.24)	
	P-value of subgroup*treatment interaction [e]	0.088	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	54 (66.7%)	48 (62.3%)
	The number (%) of patients censored [a]	27 (33.3%)	29 (37.7%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.8)	2.1 (1.4, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.416	
	HR (95% CI) [d]	1.18 (0.80, 1.74)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	14 (53.8%)	17 (65.4%)
	The number (%) of patients censored [a]	12 (46.2%)	9 (34.6%)
	Median time to event (95% CI) [b]	2.0 (1.0, NE)	1.6 (0.8, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.574	
	HR (95% CI) [d]	0.81 (0.40, 1.66)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	10 (62.5%)	14 (66.7%)
	The number (%) of patients censored [a]	6 (37.5%)	7 (33.3%)
	Median time to event (95% CI) [b]	2.2 (0.8, 3.1)	1.3 (0.8, 3.4)
	Nominal p-value for unstratified log-rank test [c]	0.780	
	HR (95% CI) [d]	0.89 (0.39, 2.02)	
	P-value of subgroup*treatment interaction [e]	0.616	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	39 (48.1%)	49 (63.6%)
	The number (%) of patients censored [a]	42 (51.9%)	28 (36.4%)
	Median time to event (95% CI) [b]	4.4 (1.8, 9.8)	2.4 (1.6, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.140	
	HR (95% CI) [d]	0.73 (0.48, 1.11)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	17 (65.4%)
	The number (%) of patients censored [a]	14 (53.8%)	9 (34.6%)
	Median time to event (95% CI) [b]	8.8 (1.4, NE)	2.5 (1.7, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.106	
	HR (95% CI) [d]	0.53 (0.24, 1.16)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	5 (31.3%)	10 (47.6%)
	The number (%) of patients censored [a]	11 (68.8%)	11 (52.4%)
	Median time to event (95% CI) [b]	17.8 (0.8, NE)	6.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.446	
	HR (95% CI) [d]	0.66 (0.22, 1.95)	
	P-value of subgroup*treatment interaction [e]	0.805	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	27 (33.3%)	42 (54.5%)
	The number (%) of patients censored [a]	54 (66.7%)	35 (45.5%)
	Median time to event (95% CI) [b]	NE (7.7, NE)	4.9 (2.1, 8.0)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	0.51 (0.32, 0.84)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	11 (42.3%)	12 (46.2%)
	The number (%) of patients censored [a]	15 (57.7%)	14 (53.8%)
	Median time to event (95% CI) [b]	11.4 (3.5, NE)	5.8 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.525	
	HR (95% CI) [d]	0.76 (0.33, 1.74)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	5 (31.3%)	11 (52.4%)
	The number (%) of patients censored [a]	11 (68.8%)	10 (47.6%)
	Median time to event (95% CI) [b]	NE (1.5, NE)	4.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.182	
	HR (95% CI) [d]	0.49 (0.17, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.568	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	38 (46.9%)	42 (54.5%)
	The number (%) of patients censored [a]	43 (53.1%)	35 (45.5%)
	Median time to event (95% CI) [b]	5.1 (3.1, 9.1)	3.5 (2.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.555	
	HR (95% CI) [d]	0.88 (0.57, 1.36)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	15 (57.7%)
	The number (%) of patients censored [a]	14 (53.8%)	11 (42.3%)
	Median time to event (95% CI) [b]	9.1 (1.8, NE)	6.0 (0.9, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.163	
	HR (95% CI) [d]	0.57 (0.26, 1.26)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	10 (47.6%)
	The number (%) of patients censored [a]	8 (50.0%)	11 (52.4%)
	Median time to event (95% CI) [b]	6.6 (1.1, NE)	4.4 (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.936	
	HR (95% CI) [d]	0.96 (0.37, 2.47)	
	P-value of subgroup*treatment interaction [e]	0.751	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	43 (53.1%)	46 (59.7%)
	The number (%) of patients censored [a]	38 (46.9%)	31 (40.3%)
	Median time to event (95% CI) [b]	2.8 (1.4, 13.6)	2.6 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.513	
	HR (95% CI) [d]	0.88 (0.58, 1.33)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	13 (50.0%)
	The number (%) of patients censored [a]	14 (53.8%)	13 (50.0%)
	Median time to event (95% CI) [b]	4.1 (1.8, NE)	5.6 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.936	
	HR (95% CI) [d]	1.02 (0.46, 2.23)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	9 (42.9%)
	The number (%) of patients censored [a]	8 (50.0%)	12 (57.1%)
	Median time to event (95% CI) [b]	4.1 (1.4, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.926	
	HR (95% CI) [d]	1.04 (0.40, 2.70)	
	P-value of subgroup*treatment interaction [e]	0.972	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	43 (53.1%)	46 (59.7%)
	The number (%) of patients censored [a]	38 (46.9%)	31 (40.3%)
	Median time to event (95% CI) [b]	2.4 (1.7, 6.9)	2.2 (1.4, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.401	
	HR (95% CI) [d]	0.83 (0.55, 1.26)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	14 (53.8%)	15 (57.7%)
	The number (%) of patients censored [a]	12 (46.2%)	11 (42.3%)
	Median time to event (95% CI) [b]	2.3 (1.0, NE)	6.5 (0.9, 13.3)
	Nominal p-value for unstratified log-rank test [c]	0.688	
	HR (95% CI) [d]	0.85 (0.41, 1.78)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	9 (56.3%)	11 (52.4%)
	The number (%) of patients censored [a]	7 (43.8%)	10 (47.6%)
	Median time to event (95% CI) [b]	3.1 (1.0, 19.4)	2.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.584	
	HR (95% CI) [d]	0.77 (0.32, 1.88)	
	P-value of subgroup*treatment interaction [e]	0.981	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	52 (64.2%)	23 (29.9%)
	The number (%) of patients censored [a]	29 (35.8%)	54 (70.1%)
	Median time to event (95% CI) [b]	2.1 (1.0, 3.6)	13.2 (10.1, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.10 (1.89, 5.08)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	17 (65.4%)	11 (42.3%)
	The number (%) of patients censored [a]	9 (34.6%)	15 (57.7%)
	Median time to event (95% CI) [b]	1.8 (0.8, 5.8)	6.2 (2.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.035	
	HR (95% CI) [d]	2.24 (1.04, 4.80)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	13 (81.3%)	13 (61.9%)
	The number (%) of patients censored [a]	3 (18.8%)	8 (38.1%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.045	
	HR (95% CI) [d]	2.23 (1.01, 4.91)	
	P-value of subgroup*treatment interaction [e]	0.591	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	27 (33.3%)	33 (42.9%)
	The number (%) of patients censored [a]	54 (66.7%)	44 (57.1%)
	Median time to event (95% CI) [b]	16.1 (5.1, NE)	5.2 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	0.67 (0.40, 1.12)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	10 (38.5%)	7 (26.9%)
	The number (%) of patients censored [a]	16 (61.5%)	19 (73.1%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.521	
	HR (95% CI) [d]	1.37 (0.52, 3.61)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	4 (25.0%)	5 (23.8%)
	The number (%) of patients censored [a]	12 (75.0%)	16 (76.2%)
	Median time to event (95% CI) [b]	27.9 (1.4, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.591	
	HR (95% CI) [d]	0.64 (0.12, 3.31)	
	P-value of subgroup*treatment interaction [e]	0.401	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	40 (49.4%)	39 (50.6%)
	The number (%) of patients censored [a]	41 (50.6%)	38 (49.4%)
	Median time to event (95% CI) [b]	3.5 (1.7, 5.2)	5.0 (2.6, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.353	
	HR (95% CI) [d]	1.24 (0.79, 1.92)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	21 (80.8%)	11 (42.3%)
	The number (%) of patients censored [a]	5 (19.2%)	15 (57.7%)
	Median time to event (95% CI) [b]	2.9 (1.3, 5.1)	17.1 (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.017	
	HR (95% CI) [d]	2.43 (1.14, 5.19)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	8 (38.1%)
	The number (%) of patients censored [a]	8 (50.0%)	13 (61.9%)
	Median time to event (95% CI) [b]	5.0 (1.0, NE)	5.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.950	
	HR (95% CI) [d]	0.97 (0.36, 2.58)	
	P-value of subgroup*treatment interaction [e]	0.221	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	25 (30.9%)	26 (33.8%)
	The number (%) of patients censored [a]	56 (69.1%)	51 (66.2%)
	Median time to event (95% CI) [b]	13.3 (6.9, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.524	
	HR (95% CI) [d]	0.84 (0.48, 1.45)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	5 (19.2%)	6 (23.1%)
	The number (%) of patients censored [a]	21 (80.8%)	20 (76.9%)
	Median time to event (95% CI) [b]	18.5 (10.0, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.641	
	HR (95% CI) [d]	0.75 (0.23, 2.48)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	4 (25.0%)	5 (23.8%)
	The number (%) of patients censored [a]	12 (75.0%)	16 (76.2%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.96 (0.26, 3.56)	
	P-value of subgroup*treatment interaction [e]	0.990	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	5 (6.2%)	3 (3.9%)
	The number (%) of patients censored [a]	76 (93.8%)	74 (96.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.203	
	HR (95% CI) [d]	2.47 (0.59, 10.37)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	0 (0.0%)	1 (3.8%)
	The number (%) of patients censored [a]	26 (100.0%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	1 (6.3%)	1 (4.8%)
	The number (%) of patients censored [a]	15 (93.8%)	20 (95.2%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.560	
	HR (95% CI) [d]	2.24 (0.14, 35.90)	
	P-value of subgroup*treatment interaction [e]	0.999	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	31 (38.3%)	32 (41.6%)
	The number (%) of patients censored [a]	50 (61.7%)	45 (58.4%)
	Median time to event (95% CI) [b]	3.5 (1.7, 8.7)	5.4 (2.0, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.599	
	HR (95% CI) [d]	1.14 (0.69, 1.87)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	12 (46.2%)	14 (53.8%)
	The number (%) of patients censored [a]	14 (53.8%)	12 (46.2%)
	Median time to event (95% CI) [b]	9.8 (1.5, 18.5)	4.9 (1.5, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.370	
	HR (95% CI) [d]	0.69 (0.30, 1.56)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	6 (37.5%)	9 (42.9%)
	The number (%) of patients censored [a]	10 (62.5%)	12 (57.1%)
	Median time to event (95% CI) [b]	13.1 (4.9, NE)	3.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.122	
	HR (95% CI) [d]	0.40 (0.12, 1.31)	
	P-value of subgroup*treatment interaction [e]	0.233	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.4.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	58 (71.6%)	48 (62.3%)
	The number (%) of patients censored [a]	23 (28.4%)	29 (37.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	3.1 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	1.82 (1.24, 2.68)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	20 (76.9%)	14 (53.8%)
	The number (%) of patients censored [a]	6 (23.1%)	12 (46.2%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.3)	5.6 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.008	
	HR (95% CI) [d]	2.48 (1.24, 4.97)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.4.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	12 (75.0%)	12 (57.1%)
	The number (%) of patients censored [a]	4 (25.0%)	9 (42.9%)
	Median time to event (95% CI) [b]	1.2 (0.8, 5.2)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.488	
	HR (95% CI) [d]	1.31 (0.58, 2.96)	
	P-value of subgroup*treatment interaction [e]	0.516	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.4.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	26 (32.1%)	25 (32.5%)
	The number (%) of patients censored [a]	55 (67.9%)	52 (67.5%)
	Median time to event (95% CI) [b]	17.1 (7.5, NE)	12.7 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.509	
	HR (95% CI) [d]	0.83 (0.48, 1.44)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	6 (23.1%)	6 (23.1%)
	The number (%) of patients censored [a]	20 (76.9%)	20 (76.9%)
	Median time to event (95% CI) [b]	NE (17.5, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.958	
	HR (95% CI) [d]	1.03 (0.33, 3.22)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	4 (25.0%)	4 (19.0%)
	The number (%) of patients censored [a]	12 (75.0%)	17 (81.0%)
	Median time to event (95% CI) [b]	24.7 (5.6, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.742	
	HR (95% CI) [d]	1.27 (0.31, 5.17)	
	P-value of subgroup*treatment interaction [e]	0.869	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	39 (48.1%)	43 (55.8%)
	The number (%) of patients censored [a]	42 (51.9%)	34 (44.2%)
	Median time to event (95% CI) [b]	6.5 (3.6, 9.3)	3.7 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.184	
	HR (95% CI) [d]	0.75 (0.48, 1.15)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	17 (65.4%)	17 (65.4%)
	The number (%) of patients censored [a]	9 (34.6%)	9 (34.6%)
	Median time to event (95% CI) [b]	2.9 (1.1, 15.5)	1.7 (0.9, 11.8)
	Nominal p-value for unstratified log-rank test [c]	0.601	
	HR (95% CI) [d]	0.83 (0.42, 1.64)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	5 (31.3%)	9 (42.9%)
	The number (%) of patients censored [a]	11 (68.8%)	12 (57.1%)
	Median time to event (95% CI) [b]	15.9 (1.5, NE)	6.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.189	
	HR (95% CI) [d]	0.47 (0.15, 1.48)	
	P-value of subgroup*treatment interaction [e]	0.757	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	9 (11.1%)	8 (10.4%)
	The number (%) of patients censored [a]	72 (88.9%)	69 (89.6%)
	Median time to event (95% CI) [b]	0.9 (0.7, 3.5)	1.4 (0.8, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.361	
	HR (95% CI) [d]	1.46 (0.55, 3.84)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	2 (7.7%)	1 (3.8%)
	The number (%) of patients censored [a]	24 (92.3%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.619	
	HR (95% CI) [d]	1.82 (0.16, 20.20)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	2 (12.5%)	4 (19.0%)
	The number (%) of patients censored [a]	14 (87.5%)	17 (81.0%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.260	
	HR (95% CI) [d]	0.38 (0.07, 2.13)	
	P-value of subgroup*treatment interaction [e]	0.428	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	28 (34.6%)	31 (40.3%)
	The number (%) of patients censored [a]	53 (65.4%)	46 (59.7%)
	Median time to event (95% CI) [b]	18.7 (7.2, NE)	10.3 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.488	
	HR (95% CI) [d]	0.84 (0.50, 1.40)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	11 (42.3%)	10 (38.5%)
	The number (%) of patients censored [a]	15 (57.7%)	16 (61.5%)
	Median time to event (95% CI) [b]	9.8 (2.9, NE)	13.0 (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.955	
	HR (95% CI) [d]	1.03 (0.43, 2.46)	
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.4.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	The number (%) of patients with an event [a]	3 (18.8%)	3 (14.3%)
	The number (%) of patients censored [a]	13 (81.3%)	18 (85.7%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.800	
	HR (95% CI) [d]	1.23 (0.25, 6.10)	
	P-value of subgroup*treatment interaction [e]	0.780	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.4.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	34 (42.0%)	31 (40.3%)
	The number (%) of patients censored [a]	47 (58.0%)	46 (59.7%)
	Median time to event (95% CI) [b]	7.0 (3.5, 13.2)	15.9 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.509	
	HR (95% CI) [d]	1.17 (0.72, 1.91)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	7 (26.9%)	10 (38.5%)
	The number (%) of patients censored [a]	19 (73.1%)	16 (61.5%)
	Median time to event (95% CI) [b]	NE (9.6, NE)	16.1 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.341	
	HR (95% CI) [d]	0.63 (0.24, 1.66)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.4.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	8 (50.0%)	7 (33.3%)
	The number (%) of patients censored [a]	8 (50.0%)	14 (66.7%)
	Median time to event (95% CI) [b]	4.1 (1.5, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.285	
	HR (95% CI) [d]	1.73 (0.62, 4.80)	
	P-value of subgroup*treatment interaction [e]	0.338	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	18 (22.2%)	21 (27.3%)
	The number (%) of patients censored [a]	63 (77.8%)	56 (72.7%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.4 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.425	
	HR (95% CI) [d]	0.77 (0.41, 1.46)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	4 (15.4%)	4 (15.4%)
	The number (%) of patients censored [a]	22 (84.6%)	22 (84.6%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.742	
	HR (95% CI) [d]	1.25 (0.31, 4.99)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	1 (6.3%)	4 (19.0%)
	The number (%) of patients censored [a]	15 (93.8%)	17 (81.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.385	
	HR (95% CI) [d]	0.39 (0.04, 3.52)	
	P-value of subgroup*treatment interaction [e]	0.536	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	77
	The number (%) of patients with an event [a]	8 (9.9%)	5 (6.5%)
	The number (%) of patients censored [a]	73 (90.1%)	72 (93.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.751	
	HR (95% CI) [d]	1.20 (0.39, 3.67)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	26	26
	The number (%) of patients with an event [a]	2 (7.7%)	3 (11.5%)
	The number (%) of patients censored [a]	24 (92.3%)	23 (88.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.517	
	HR (95% CI) [d]	0.56 (0.09, 3.35)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.4.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	16	21
	The number (%) of patients with an event [a]	1 (6.3%)	0 (0.0%)
	The number (%) of patients censored [a]	15 (93.8%)	21 (100.0%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.781	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	48 (59.3%)	54 (67.5%)
	The number (%) of patients censored [a]	33 (40.7%)	26 (32.5%)
	Median time to event (95% CI) [b]	4.9 (1.8, 7.2)	2.5 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.238	
	HR (95% CI) [d]	0.80 (0.54, 1.17)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	22 (50.0%)	19 (43.2%)
	The number (%) of patients censored [a]	22 (50.0%)	25 (56.8%)
	Median time to event (95% CI) [b]	3.2 (1.4, NE)	10.9 (2.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.713	
	HR (95% CI) [d]	1.12 (0.60, 2.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.302	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	38 (46.9%)	44 (55.0%)
	The number (%) of patients censored [a]	43 (53.1%)	36 (45.0%)
	Median time to event (95% CI) [b]	7.9 (4.3, NE)	5.4 (2.8, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.363	
	HR (95% CI) [d]	0.82 (0.53, 1.26)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	20 (45.5%)	25 (56.8%)
	The number (%) of patients censored [a]	24 (54.5%)	19 (43.2%)
	Median time to event (95% CI) [b]	6.4 (1.3, NE)	3.5 (1.5, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.216	
	HR (95% CI) [d]	0.68 (0.37, 1.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.643	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	49 (60.5%)	57 (71.3%)
	The number (%) of patients censored [a]	32 (39.5%)	23 (28.8%)
	Median time to event (95% CI) [b]	1.8 (1.4, 5.1)	4.1 (1.7, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.707	
	HR (95% CI) [d]	0.93 (0.64, 1.37)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	27 (61.4%)
	The number (%) of patients censored [a]	21 (47.7%)	17 (38.6%)
	Median time to event (95% CI) [b]	1.4 (0.9, 17.8)	2.5 (0.9, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.953	
	HR (95% CI) [d]	0.98 (0.56, 1.73)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.949	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	41 (50.6%)	36 (45.0%)
	The number (%) of patients censored [a]	40 (49.4%)	44 (55.0%)
	Median time to event (95% CI) [b]	8.8 (4.3, 11.4)	10.0 (5.1, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.938	
	HR (95% CI) [d]	1.02 (0.65, 1.60)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	18 (40.9%)	20 (45.5%)
	The number (%) of patients censored [a]	26 (59.1%)	24 (54.5%)
	Median time to event (95% CI) [b]	6.0 (3.0, NE)	4.9 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.579	
	HR (95% CI) [d]	0.83 (0.44, 1.59)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.520	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	45 (55.6%)	48 (60.0%)
	The number (%) of patients censored [a]	36 (44.4%)	32 (40.0%)
	Median time to event (95% CI) [b]	5.6 (2.8, 12.6)	3.1 (2.1, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.370	
	HR (95% CI) [d]	0.83 (0.55, 1.25)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	24 (54.5%)	31 (70.5%)
	The number (%) of patients censored [a]	20 (45.5%)	13 (29.5%)
	Median time to event (95% CI) [b]	3.4 (2.2, 4.6)	2.4 (1.4, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.305	
	HR (95% CI) [d]	0.76 (0.44, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.824	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	46 (56.8%)	49 (61.3%)
	The number (%) of patients censored [a]	35 (43.2%)	31 (38.8%)
	Median time to event (95% CI) [b]	2.5 (1.4, 12.2)	3.5 (1.4, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.693	
	HR (95% CI) [d]	0.92 (0.61, 1.38)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	22 (50.0%)	28 (63.6%)
	The number (%) of patients censored [a]	22 (50.0%)	16 (36.4%)
	Median time to event (95% CI) [b]	3.5 (1.0, 21.5)	3.6 (0.9, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.438	
	HR (95% CI) [d]	0.80 (0.45, 1.42)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.671	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	58 (71.6%)	62 (77.5%)
	The number (%) of patients censored [a]	23 (28.4%)	18 (22.5%)
	Median time to event (95% CI) [b]	1.7 (1.0, 2.3)	1.4 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.505	
	HR (95% CI) [d]	0.89 (0.62, 1.27)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	25 (56.8%)	30 (68.2%)
	The number (%) of patients censored [a]	19 (43.2%)	14 (31.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, 4.2)	1.4 (0.9, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.392	
	HR (95% CI) [d]	0.80 (0.46, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.707	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	57 (70.4%)	56 (70.0%)
	The number (%) of patients censored [a]	24 (29.6%)	24 (30.0%)
	Median time to event (95% CI) [b]	1.8 (1.4, 2.8)	1.7 (1.1, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.980	
	HR (95% CI) [d]	0.99 (0.68, 1.44)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	23 (52.3%)
	The number (%) of patients censored [a]	21 (47.7%)	21 (47.7%)
	Median time to event (95% CI) [b]	1.4 (0.8, NE)	2.5 (1.4, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.470	
	HR (95% CI) [d]	1.25 (0.70, 2.23)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.506	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	42 (51.9%)	51 (63.8%)
	The number (%) of patients censored [a]	39 (48.1%)	29 (36.3%)
	Median time to event (95% CI) [b]	7.7 (2.5, 11.8)	2.8 (1.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.094	
	HR (95% CI) [d]	0.71 (0.47, 1.07)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	16 (36.4%)	25 (56.8%)
	The number (%) of patients censored [a]	28 (63.6%)	19 (43.2%)
	Median time to event (95% CI) [b]	17.8 (1.5, NE)	3.6 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.302	
	HR (95% CI) [d]	0.72 (0.38, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.941	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	28 (34.6%)	46 (57.5%)
	The number (%) of patients censored [a]	53 (65.4%)	34 (42.5%)
	Median time to event (95% CI) [b]	NE (9.7, NE)	4.4 (2.4, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.46 (0.29, 0.74)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	15 (34.1%)	19 (43.2%)
	The number (%) of patients censored [a]	29 (65.9%)	25 (56.8%)
	Median time to event (95% CI) [b]	7.2 (3.1, NE)	5.8 (3.3, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.449	
	HR (95% CI) [d]	0.77 (0.39, 1.52)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.214	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	42 (51.9%)	44 (55.0%)
	The number (%) of patients censored [a]	39 (48.1%)	36 (45.0%)
	Median time to event (95% CI) [b]	5.3 (3.2, 14.4)	4.1 (2.7, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.486	
	HR (95% CI) [d]	0.86 (0.56, 1.31)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	17 (38.6%)	23 (52.3%)
	The number (%) of patients censored [a]	27 (61.4%)	21 (47.7%)
	Median time to event (95% CI) [b]	9.1 (1.4, 16.8)	4.4 (2.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.402	
	HR (95% CI) [d]	0.76 (0.40, 1.44)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.759	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	41 (50.6%)	49 (61.3%)
	The number (%) of patients censored [a]	40 (49.4%)	31 (38.8%)
	Median time to event (95% CI) [b]	4.2 (1.8, NE)	3.1 (1.4, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.202	
	HR (95% CI) [d]	0.77 (0.50, 1.16)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	19 (43.2%)
	The number (%) of patients censored [a]	21 (47.7%)	25 (56.8%)
	Median time to event (95% CI) [b]	2.8 (1.0, 3.8)	5.2 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	1.40 (0.76, 2.58)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.120	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	43 (53.1%)	51 (63.8%)
	The number (%) of patients censored [a]	38 (46.9%)	29 (36.3%)
	Median time to event (95% CI) [b]	3.1 (1.9, NE)	2.2 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.075	
	HR (95% CI) [d]	0.69 (0.46, 1.03)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	24 (54.5%)	21 (47.7%)
	The number (%) of patients censored [a]	20 (45.5%)	23 (52.3%)
	Median time to event (95% CI) [b]	2.1 (1.0, 4.6)	3.3 (1.5, 13.3)
	Nominal p-value for unstratified log-rank test [c]	0.525	
	HR (95% CI) [d]	1.21 (0.67, 2.18)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.107	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	57 (70.4%)	31 (38.8%)
	The number (%) of patients censored [a]	24 (29.6%)	49 (61.3%)
	Median time to event (95% CI) [b]	1.7 (1.0, 3.3)	10.1 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.54 (1.64, 3.95)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	27 (61.4%)	16 (36.4%)
	The number (%) of patients censored [a]	17 (38.6%)	28 (63.6%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.8)	NE (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	2.54 (1.37, 4.74)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.965	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	24 (29.6%)	26 (32.5%)
	The number (%) of patients censored [a]	57 (70.4%)	54 (67.5%)
	Median time to event (95% CI) [b]	19.0 (8.5, NE)	19.4 (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	0.72 (0.41, 1.27)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	18 (40.9%)	19 (43.2%)
	The number (%) of patients censored [a]	26 (59.1%)	25 (56.8%)
	Median time to event (95% CI) [b]	3.6 (1.3, NE)	4.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.938	
	HR (95% CI) [d]	1.03 (0.53, 1.99)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.609	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	49 (60.5%)	36 (45.0%)
	The number (%) of patients censored [a]	32 (39.5%)	44 (55.0%)
	Median time to event (95% CI) [b]	3.5 (1.8, 5.2)	7.0 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.106	
	HR (95% CI) [d]	1.42 (0.92, 2.19)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	21 (47.7%)	22 (50.0%)
	The number (%) of patients censored [a]	23 (52.3%)	22 (50.0%)
	Median time to event (95% CI) [b]	2.1 (1.0, 12.6)	5.0 (2.0, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.612	
	HR (95% CI) [d]	1.17 (0.64, 2.15)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.663	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	27 (33.3%)	23 (28.8%)
	The number (%) of patients censored [a]	54 (66.7%)	57 (71.3%)
	Median time to event (95% CI) [b]	18.5 (10.0, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.789	
	HR (95% CI) [d]	1.08 (0.62, 1.88)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	8 (18.2%)	14 (31.8%)
	The number (%) of patients censored [a]	36 (81.8%)	30 (68.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	0.51 (0.21, 1.22)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.159	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	5 (6.2%)	2 (2.5%)
	The number (%) of patients censored [a]	76 (93.8%)	78 (97.5%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.081	
	HR (95% CI) [d]	3.93 (0.76, 20.43)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	1 (2.3%)	3 (6.8%)
	The number (%) of patients censored [a]	43 (97.7%)	41 (93.2%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	3.1 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.095	
	HR (95% CI) [d]	0.16 (0.02, 1.73)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.033	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	36 (44.4%)	33 (41.3%)
	The number (%) of patients censored [a]	45 (55.6%)	47 (58.8%)
	Median time to event (95% CI) [b]	7.0 (3.1, 12.2)	7.0 (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.963	
	HR (95% CI) [d]	0.98 (0.61, 1.59)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	14 (31.8%)	22 (50.0%)
	The number (%) of patients censored [a]	30 (68.2%)	22 (50.0%)
	Median time to event (95% CI) [b]	4.2 (1.3, NE)	3.9 (1.5, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.315	
	HR (95% CI) [d]	0.70 (0.35, 1.39)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.333	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	65 (80.2%)	50 (62.5%)
	The number (%) of patients censored [a]	16 (19.8%)	30 (37.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.0)	2.9 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.24 (1.54, 3.28)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	26 (59.1%)	24 (54.5%)
	The number (%) of patients censored [a]	18 (40.9%)	20 (45.5%)
	Median time to event (95% CI) [b]	1.4 (0.8, 4.6)	3.5 (1.7, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.326	
	HR (95% CI) [d]	1.33 (0.76, 2.32)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.099	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	25 (30.9%)	24 (30.0%)
	The number (%) of patients censored [a]	56 (69.1%)	56 (70.0%)
	Median time to event (95% CI) [b]	17.5 (10.2, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.829	
	HR (95% CI) [d]	0.94 (0.54, 1.65)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	11 (25.0%)	11 (25.0%)
	The number (%) of patients censored [a]	33 (75.0%)	33 (75.0%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.739	
	HR (95% CI) [d]	0.86 (0.36, 2.04)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.917	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	39 (48.1%)	47 (58.8%)
	The number (%) of patients censored [a]	42 (51.9%)	33 (41.3%)
	Median time to event (95% CI) [b]	7.2 (3.5, 15.5)	3.5 (2.2, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.047	
	HR (95% CI) [d]	0.65 (0.42, 1.00)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	23 (52.3%)	22 (50.0%)
	The number (%) of patients censored [a]	21 (47.7%)	22 (50.0%)
	Median time to event (95% CI) [b]	4.6 (1.4, 15.2)	4.2 (1.7, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.865	
	HR (95% CI) [d]	0.95 (0.53, 1.72)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.279	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	4 (4.9%)	10 (12.5%)
	The number (%) of patients censored [a]	77 (95.1%)	70 (87.5%)
	Median time to event (95% CI) [b]	7.2 (0.7, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.462	
	HR (95% CI) [d]	0.62 (0.19, 2.00)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	9 (20.5%)	3 (6.8%)
	The number (%) of patients censored [a]	35 (79.5%)	41 (93.2%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.431	
	HR (95% CI) [d]	1.68 (0.45, 6.29)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.254	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	28 (34.6%)	30 (37.5%)
	The number (%) of patients censored [a]	53 (65.4%)	50 (62.5%)
	Median time to event (95% CI) [b]	18.7 (9.0, NE)	12.4 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.680	
	HR (95% CI) [d]	0.90 (0.54, 1.51)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	15 (34.1%)	14 (31.8%)
	The number (%) of patients censored [a]	29 (65.9%)	30 (68.2%)
	Median time to event (95% CI) [b]	NE (2.3, NE)	15.4 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.839	
	HR (95% CI) [d]	1.08 (0.52, 2.24)	
	P-value of subgroup*treatment interaction [e]	0.770	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.5.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	32 (39.5%)	31 (38.8%)
	The number (%) of patients censored [a]	49 (60.5%)	49 (61.3%)
	Median time to event (95% CI) [b]	11.8 (7.0, NE)	19.4 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.817	
	HR (95% CI) [d]	1.06 (0.64, 1.73)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	18 (40.9%)	17 (38.6%)
	The number (%) of patients censored [a]	26 (59.1%)	27 (61.4%)
	Median time to event (95% CI) [b]	3.5 (1.6, NE)	15.9 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.717	
	HR (95% CI) [d]	1.12 (0.57, 2.20)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.885	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	22 (27.2%)	19 (23.8%)
	The number (%) of patients censored [a]	59 (72.8%)	61 (76.3%)
	Median time to event (95% CI) [b]	NE (5.8, NE)	6.5 (6.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.468	
	HR (95% CI) [d]	1.25 (0.68, 2.32)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	3 (6.8%)	10 (22.7%)
	The number (%) of patients censored [a]	41 (93.2%)	34 (77.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.075	
	HR (95% CI) [d]	0.32 (0.09, 1.20)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.048	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	80
	The number (%) of patients with an event [a]	6 (7.4%)	3 (3.8%)
	The number (%) of patients censored [a]	75 (92.6%)	77 (96.3%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.501	
	HR (95% CI) [d]	1.60 (0.40, 6.42)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	44
	The number (%) of patients with an event [a]	5 (11.4%)	5 (11.4%)
	The number (%) of patients censored [a]	39 (88.6%)	39 (88.6%)
	Median time to event (95% CI) [b]	NE (4.5, NE)	NE (4.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.902	
	HR (95% CI) [d]	1.08 (0.31, 3.74)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.5.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.744	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	18 (50.0%)	9 (34.6%)
	The number (%) of patients censored [a]	18 (50.0%)	17 (65.4%)
	Median time to event (95% CI) [b]	6.0 (2.3, 15.2)	5.7 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	1.06 (0.47, 2.39)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	52 (58.4%)	64 (65.3%)
	The number (%) of patients censored [a]	37 (41.6%)	34 (34.7%)
	Median time to event (95% CI) [b]	2.4 (1.6, 7.2)	2.7 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.573	
	HR (95% CI) [d]	0.90 (0.63, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.522	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	14 (38.9%)	11 (42.3%)
	The number (%) of patients censored [a]	22 (61.1%)	15 (57.7%)
	Median time to event (95% CI) [b]	8.8 (6.4, NE)	4.4 (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.352	
	HR (95% CI) [d]	0.68 (0.30, 1.54)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	44 (49.4%)	58 (59.2%)
	The number (%) of patients censored [a]	45 (50.6%)	40 (40.8%)
	Median time to event (95% CI) [b]	7.5 (2.4, 21.5)	4.9 (2.9, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.330	
	HR (95% CI) [d]	0.83 (0.56, 1.22)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.651	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	19 (52.8%)	12 (46.2%)
	The number (%) of patients censored [a]	17 (47.2%)	14 (53.8%)
	Median time to event (95% CI) [b]	1.9 (0.9, NE)	8.6 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.629	
	HR (95% CI) [d]	1.19 (0.57, 2.48)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	53 (59.6%)	72 (73.5%)
	The number (%) of patients censored [a]	36 (40.4%)	26 (26.5%)
	Median time to event (95% CI) [b]	1.5 (1.3, 2.8)	3.1 (1.5, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.581	
	HR (95% CI) [d]	0.91 (0.64, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.496	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	4 (15.4%)
	The number (%) of patients censored [a]	19 (52.8%)	22 (84.6%)
	Median time to event (95% CI) [b]	7.7 (3.2, 11.8)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.121	
	HR (95% CI) [d]	2.31 (0.78, 6.89)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	42 (47.2%)	52 (53.1%)
	The number (%) of patients censored [a]	47 (52.8%)	46 (46.9%)
	Median time to event (95% CI) [b]	9.0 (4.2, 12.5)	8.3 (4.4, 10.8)
	Nominal p-value for unstratified log-rank test [c]	0.432	
	HR (95% CI) [d]	0.85 (0.56, 1.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.107	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	13 (50.0%)
	The number (%) of patients censored [a]	19 (52.8%)	13 (50.0%)
	Median time to event (95% CI) [b]	4.9 (2.6, 13.1)	3.0 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.342	
	HR (95% CI) [d]	0.69 (0.33, 1.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	52 (58.4%)	66 (67.3%)
	The number (%) of patients censored [a]	37 (41.6%)	32 (32.7%)
	Median time to event (95% CI) [b]	4.2 (2.8, 6.9)	2.6 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.286	
	HR (95% CI) [d]	0.82 (0.57, 1.18)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.787	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	15 (41.7%)	10 (38.5%)
	The number (%) of patients censored [a]	21 (58.3%)	16 (61.5%)
	Median time to event (95% CI) [b]	3.8 (1.5, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.02 (0.46, 2.28)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	53 (59.6%)	67 (68.4%)
	The number (%) of patients censored [a]	36 (40.4%)	31 (31.6%)
	Median time to event (95% CI) [b]	1.8 (1.1, 4.8)	3.3 (1.6, 4.5)
	Nominal p-value for unstratified log-rank test [c]	0.573	
	HR (95% CI) [d]	0.90 (0.63, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.864	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	24 (66.7%)	12 (46.2%)
	The number (%) of patients censored [a]	12 (33.3%)	14 (53.8%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.4)	2.1 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.130	
	HR (95% CI) [d]	1.72 (0.86, 3.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	59 (66.3%)	80 (81.6%)
	The number (%) of patients censored [a]	30 (33.7%)	18 (18.4%)
	Median time to event (95% CI) [b]	1.7 (1.0, 2.3)	1.4 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.065	
	HR (95% CI) [d]	0.73 (0.52, 1.02)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.034	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	23 (63.9%)	15 (57.7%)
	The number (%) of patients censored [a]	13 (36.1%)	11 (42.3%)
	Median time to event (95% CI) [b]	1.7 (0.8, 3.1)	2.8 (1.2, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.546	
	HR (95% CI) [d]	1.23 (0.64, 2.38)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	57 (64.0%)	64 (65.3%)
	The number (%) of patients censored [a]	32 (36.0%)	34 (34.7%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.8)	1.6 (1.2, 2.6)
	Nominal p-value for unstratified log-rank test [c]	0.948	
	HR (95% CI) [d]	1.01 (0.71, 1.45)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.587	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	16 (44.4%)	11 (42.3%)
	The number (%) of patients censored [a]	20 (55.6%)	15 (57.7%)
	Median time to event (95% CI) [b]	8.8 (1.9, 17.8)	4.9 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.88 (0.40, 1.95)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	42 (47.2%)	65 (66.3%)
	The number (%) of patients censored [a]	47 (52.8%)	33 (33.7%)
	Median time to event (95% CI) [b]	6.5 (1.7, 15.5)	2.5 (1.9, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.052	
	HR (95% CI) [d]	0.68 (0.46, 1.01)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.527	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	12 (33.3%)	7 (26.9%)
	The number (%) of patients censored [a]	24 (66.7%)	19 (73.1%)
	Median time to event (95% CI) [b]	9.6 (3.6, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	0.99 (0.38, 2.57)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	31 (34.8%)	58 (59.2%)
	The number (%) of patients censored [a]	58 (65.2%)	40 (40.8%)
	Median time to event (95% CI) [b]	15.5 (9.7, NE)	4.9 (2.8, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.50 (0.32, 0.77)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.221	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	18 (50.0%)	12 (46.2%)
	The number (%) of patients censored [a]	18 (50.0%)	14 (53.8%)
	Median time to event (95% CI) [b]	5.3 (2.3, 10.8)	3.1 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.595	
	HR (95% CI) [d]	0.82 (0.39, 1.70)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	41 (46.1%)	55 (56.1%)
	The number (%) of patients censored [a]	48 (53.9%)	43 (43.9%)
	Median time to event (95% CI) [b]	7.2 (3.2, 16.8)	4.4 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.362	
	HR (95% CI) [d]	0.83 (0.55, 1.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.873	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	19 (52.8%)	7 (26.9%)
	The number (%) of patients censored [a]	17 (47.2%)	19 (73.1%)
	Median time to event (95% CI) [b]	3.1 (1.5, NE)	9.2 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.182	
	HR (95% CI) [d]	1.80 (0.75, 4.31)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	45 (50.6%)	61 (62.2%)
	The number (%) of patients censored [a]	44 (49.4%)	37 (37.8%)
	Median time to event (95% CI) [b]	3.8 (1.5, NE)	3.1 (1.7, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.273	
	HR (95% CI) [d]	0.81 (0.55, 1.19)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.095	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	20 (55.6%)	15 (57.7%)
	The number (%) of patients censored [a]	16 (44.4%)	11 (42.3%)
	Median time to event (95% CI) [b]	2.3 (1.7, 12.4)	1.4 (0.8, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.171	
	HR (95% CI) [d]	0.61 (0.31, 1.22)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	47 (52.8%)	57 (58.2%)
	The number (%) of patients censored [a]	42 (47.2%)	41 (41.8%)
	Median time to event (95% CI) [b]	2.8 (1.5, 19.4)	2.7 (1.7, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.494	
	HR (95% CI) [d]	0.87 (0.59, 1.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.466	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	25 (69.4%)	7 (26.9%)
	The number (%) of patients censored [a]	11 (30.6%)	19 (73.1%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.6)	10.1 (10.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	3.03 (1.30, 7.07)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	59 (66.3%)	40 (40.8%)
	The number (%) of patients censored [a]	30 (33.7%)	58 (59.2%)
	Median time to event (95% CI) [b]	1.7 (1.1, 3.6)	13.2 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.46 (1.64, 3.68)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.498	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	12 (33.3%)	5 (19.2%)
	The number (%) of patients censored [a]	24 (66.7%)	21 (80.8%)
	Median time to event (95% CI) [b]	19.0 (4.3, NE)	NE (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.832	
	HR (95% CI) [d]	1.12 (0.39, 3.26)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	30 (33.7%)	40 (40.8%)
	The number (%) of patients censored [a]	59 (66.3%)	58 (59.2%)
	Median time to event (95% CI) [b]	21.5 (7.9, NE)	8.7 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.286	
	HR (95% CI) [d]	0.77 (0.48, 1.25)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.457	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	22 (61.1%)	8 (30.8%)
	The number (%) of patients censored [a]	14 (38.9%)	18 (69.2%)
	Median time to event (95% CI) [b]	2.1 (1.1, 6.3)	NE (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.057	
	HR (95% CI) [d]	2.17 (0.95, 4.94)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	48 (53.9%)	50 (51.0%)
	The number (%) of patients censored [a]	41 (46.1%)	48 (49.0%)
	Median time to event (95% CI) [b]	3.5 (1.7, 5.2)	5.2 (2.1, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.405	
	HR (95% CI) [d]	1.18 (0.80, 1.76)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.214	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	8 (22.2%)	8 (30.8%)
	The number (%) of patients censored [a]	28 (77.8%)	18 (69.2%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	6.2 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.100	
	HR (95% CI) [d]	0.44 (0.16, 1.21)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	27 (30.3%)	29 (29.6%)
	The number (%) of patients censored [a]	62 (69.7%)	69 (70.4%)
	Median time to event (95% CI) [b]	NE (10.0, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.895	
	HR (95% CI) [d]	1.04 (0.61, 1.75)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.157	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	2 (5.6%)	0 (0.0%)
	The number (%) of patients censored [a]	34 (94.4%)	26 (100.0%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.260	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	4 (4.5%)	5 (5.1%)
	The number (%) of patients censored [a]	85 (95.5%)	93 (94.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.670	
	HR (95% CI) [d]	1.34 (0.36, 4.99)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.994	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	16 (44.4%)	6 (23.1%)
	The number (%) of patients censored [a]	20 (55.6%)	20 (76.9%)
	Median time to event (95% CI) [b]	4.2 (2.2, 12.6)	13.8 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.390	
	HR (95% CI) [d]	1.50 (0.58, 3.88)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	34 (38.2%)	49 (50.0%)
	The number (%) of patients censored [a]	55 (61.8%)	49 (50.0%)
	Median time to event (95% CI) [b]	6.3 (2.1, 18.5)	4.6 (1.7, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.288	
	HR (95% CI) [d]	0.79 (0.50, 1.23)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.187	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	26 (72.2%)	12 (46.2%)
	The number (%) of patients censored [a]	10 (27.8%)	14 (53.8%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.5)	5.1 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.038	
	HR (95% CI) [d]	2.04 (1.03, 4.07)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	65 (73.0%)	62 (63.3%)
	The number (%) of patients censored [a]	24 (27.0%)	36 (36.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.2)	3.1 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.90 (1.33, 2.70)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.894	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	9 (25.0%)	4 (15.4%)
	The number (%) of patients censored [a]	27 (75.0%)	22 (84.6%)
	Median time to event (95% CI) [b]	NE (3.9, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.510	
	HR (95% CI) [d]	1.48 (0.46, 4.83)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	27 (30.3%)	31 (31.6%)
	The number (%) of patients censored [a]	62 (69.7%)	67 (68.4%)
	Median time to event (95% CI) [b]	17.5 (10.2, NE)	NE (8.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.691	
	HR (95% CI) [d]	0.90 (0.54, 1.51)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.680	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	10 (38.5%)
	The number (%) of patients censored [a]	19 (52.8%)	16 (61.5%)
	Median time to event (95% CI) [b]	6.8 (2.9, 15.9)	5.0 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.846	
	HR (95% CI) [d]	0.92 (0.41, 2.07)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	45 (50.6%)	59 (60.2%)
	The number (%) of patients censored [a]	44 (49.4%)	39 (39.8%)
	Median time to event (95% CI) [b]	6.5 (3.5, 13.3)	3.1 (2.1, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.087	
	HR (95% CI) [d]	0.71 (0.48, 1.05)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.417	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	2 (5.6%)	0 (0.0%)
	The number (%) of patients censored [a]	34 (94.4%)	26 (100.0%)
	Median time to event (95% CI) [b]	NE (0.9, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	11 (12.4%)	13 (13.3%)
	The number (%) of patients censored [a]	78 (87.6%)	85 (86.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 7.2)	1.4 (0.8, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.95 (0.42, 2.12)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.991	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	14 (38.9%)	7 (26.9%)
	The number (%) of patients censored [a]	22 (61.1%)	19 (73.1%)
	Median time to event (95% CI) [b]	9.8 (3.9, NE)	NE (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.756	
	HR (95% CI) [d]	1.16 (0.46, 2.91)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	29 (32.6%)	37 (37.8%)
	The number (%) of patients censored [a]	60 (67.4%)	61 (62.2%)
	Median time to event (95% CI) [b]	NE (9.0, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.88 (0.54, 1.44)	
	P-value of subgroup*treatment interaction [e]	0.591	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.6.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	17 (47.2%)	9 (34.6%)
	The number (%) of patients censored [a]	19 (52.8%)	17 (65.4%)
	Median time to event (95% CI) [b]	9.6 (3.3, 18.6)	15.9 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.974	
	HR (95% CI) [d]	1.01 (0.44, 2.33)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	33 (37.1%)	39 (39.8%)
	The number (%) of patients censored [a]	56 (62.9%)	59 (60.2%)
	Median time to event (95% CI) [b]	11.4 (4.1, NE)	16.1 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.866	
	HR (95% CI) [d]	1.04 (0.65, 1.65)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.6.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.902	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	4 (11.1%)	3 (11.5%)
	The number (%) of patients censored [a]	32 (88.9%)	23 (88.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.817	
	HR (95% CI) [d]	0.84 (0.19, 3.74)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	21 (23.6%)	26 (26.5%)
	The number (%) of patients censored [a]	68 (76.4%)	72 (73.5%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.912	
	HR (95% CI) [d]	0.97 (0.54, 1.72)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.835	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	36	26
	The number (%) of patients with an event [a]	2 (5.6%)	1 (3.8%)
	The number (%) of patients censored [a]	34 (94.4%)	25 (96.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.884	
	HR (95% CI) [d]	0.84 (0.08, 9.23)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	89	98
	The number (%) of patients with an event [a]	9 (10.1%)	7 (7.1%)
	The number (%) of patients censored [a]	80 (89.9%)	91 (92.9%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.601	
	HR (95% CI) [d]	1.30 (0.48, 3.49)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.6.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.756	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	3 (42.9%)
	The number (%) of patients censored [a]	4 (66.7%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.02 (0.17, 6.14)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	68 (57.1%)	70 (59.8%)
	The number (%) of patients censored [a]	51 (42.9%)	47 (40.2%)
	Median time to event (95% CI) [b]	4.1 (2.1, 6.3)	3.3 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.448	
	HR (95% CI) [d]	0.88 (0.63, 1.23)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.745	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (66.7%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	3.2 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.562	
	HR (95% CI) [d]	0.65 (0.12, 3.58)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	56 (47.1%)	65 (55.6%)
	The number (%) of patients censored [a]	63 (52.9%)	52 (44.4%)
	Median time to event (95% CI) [b]	7.5 (3.6, 20.1)	4.9 (2.8, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	0.79 (0.55, 1.13)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.746	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (66.7%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	4.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.608	
	HR (95% CI) [d]	0.69 (0.13, 3.78)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	70 (58.8%)	80 (68.4%)
	The number (%) of patients censored [a]	49 (41.2%)	37 (31.6%)
	Median time to event (95% CI) [b]	1.5 (1.4, 2.7)	3.3 (1.7, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.749	
	HR (95% CI) [d]	0.95 (0.69, 1.31)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.640	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	2 (28.6%)
	The number (%) of patients censored [a]	3 (50.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	3.1 (0.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.486	
	HR (95% CI) [d]	1.87 (0.31, 11.25)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	56 (47.1%)	54 (46.2%)
	The number (%) of patients censored [a]	63 (52.9%)	63 (53.8%)
	Median time to event (95% CI) [b]	7.8 (4.4, 11.8)	9.1 (4.7, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.657	
	HR (95% CI) [d]	0.92 (0.63, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.323	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	2.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.311	
	HR (95% CI) [d]	0.47 (0.09, 2.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	67 (56.3%)	74 (63.2%)
	The number (%) of patients censored [a]	52 (43.7%)	43 (36.8%)
	Median time to event (95% CI) [b]	4.5 (2.8, 6.9)	3.0 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.215	
	HR (95% CI) [d]	0.81 (0.58, 1.13)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.426	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	1.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.428	
	HR (95% CI) [d]	0.58 (0.11, 2.99)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	66 (55.5%)	72 (61.5%)
	The number (%) of patients censored [a]	53 (44.5%)	45 (38.5%)
	Median time to event (95% CI) [b]	2.8 (1.4, 7.5)	3.6 (2.2, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.534	
	HR (95% CI) [d]	0.90 (0.64, 1.26)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.561	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	4 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	2 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	4.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.013	
	HR (95% CI) [d]	9.69 (1.04, 90.09)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	79 (66.4%)	88 (75.2%)
	The number (%) of patients censored [a]	40 (33.6%)	29 (24.8%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.2)	1.4 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.176	
	HR (95% CI) [d]	0.82 (0.60, 1.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.015	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (50.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	4.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.95 (0.19, 4.73)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	77 (64.7%)	75 (64.1%)
	The number (%) of patients censored [a]	42 (35.3%)	42 (35.9%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.6)	1.7 (1.4, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.668	
	HR (95% CI) [d]	1.07 (0.78, 1.48)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.909	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (66.7%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	4.6 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	1.03 (0.17, 6.20)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	56 (47.1%)	72 (61.5%)
	The number (%) of patients censored [a]	63 (52.9%)	45 (38.5%)
	Median time to event (95% CI) [b]	7.7 (2.5, 11.8)	2.8 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.045	
	HR (95% CI) [d]	0.70 (0.49, 1.00)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.747	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (83.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.477	
	HR (95% CI) [d]	0.45 (0.05, 4.33)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	42 (35.3%)	62 (53.0%)
	The number (%) of patients censored [a]	77 (64.7%)	55 (47.0%)
	Median time to event (95% CI) [b]	15.5 (9.6, NE)	4.9 (3.3, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	0.54 (0.37, 0.81)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.973	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	4 (57.1%)
	The number (%) of patients censored [a]	5 (83.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (5.3, NE)	2.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.118	
	HR (95% CI) [d]	0.20 (0.02, 1.84)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	58 (48.7%)	63 (53.8%)
	The number (%) of patients censored [a]	61 (51.3%)	54 (46.2%)
	Median time to event (95% CI) [b]	5.1 (3.1, 10.8)	4.4 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.432	
	HR (95% CI) [d]	0.87 (0.61, 1.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.209	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (50.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.833	
	HR (95% CI) [d]	0.90 (0.20, 4.03)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	61 (51.3%)	64 (54.7%)
	The number (%) of patients censored [a]	58 (48.7%)	53 (45.3%)
	Median time to event (95% CI) [b]	3.6 (1.8, 11.8)	4.1 (2.4, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.664	
	HR (95% CI) [d]	0.93 (0.65, 1.32)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.839	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (50.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	2.1 (2.1, NE)	3.6 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.678	
	HR (95% CI) [d]	1.49 (0.29, 7.56)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	64 (53.8%)	68 (58.1%)
	The number (%) of patients censored [a]	55 (46.2%)	49 (41.9%)
	Median time to event (95% CI) [b]	2.7 (1.7, 12.4)	2.3 (1.5, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	0.82 (0.59, 1.16)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.580	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	5 (83.3%)	2 (28.6%)
	The number (%) of patients censored [a]	1 (16.7%)	5 (71.4%)
	Median time to event (95% CI) [b]	1.5 (0.8, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	79 (66.4%)	45 (38.5%)
	The number (%) of patients censored [a]	40 (33.6%)	72 (61.5%)
	Median time to event (95% CI) [b]	1.7 (1.0, 2.9)	10.1 (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.43 (1.68, 3.50)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.150	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	2 (28.6%)
	The number (%) of patients censored [a]	3 (50.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	3.39 (0.56, 20.65)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	39 (32.8%)	43 (36.8%)
	The number (%) of patients censored [a]	80 (67.2%)	74 (63.2%)
	Median time to event (95% CI) [b]	19.0 (8.4, NE)	19.4 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.190	
	HR (95% CI) [d]	0.75 (0.48, 1.16)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.065	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	3 (42.9%)
	The number (%) of patients censored [a]	3 (50.0%)	4 (57.1%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.685	
	HR (95% CI) [d]	1.33 (0.27, 6.68)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	67 (56.3%)	55 (47.0%)
	The number (%) of patients censored [a]	52 (43.7%)	62 (53.0%)
	Median time to event (95% CI) [b]	3.0 (1.8, 5.0)	5.2 (3.3, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.125	
	HR (95% CI) [d]	1.32 (0.92, 1.89)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.656	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (83.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (3.1, NE)	8.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.956	
	HR (95% CI) [d]	0.93 (0.08, 10.93)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	34 (28.6%)	34 (29.1%)
	The number (%) of patients censored [a]	85 (71.4%)	83 (70.9%)
	Median time to event (95% CI) [b]	NE (13.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.691	
	HR (95% CI) [d]	0.91 (0.56, 1.46)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.632	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	6 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	6 (5.0%)	5 (4.3%)
	The number (%) of patients censored [a]	113 (95.0%)	112 (95.7%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.436	
	HR (95% CI) [d]	1.60 (0.49, 5.25)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	3 (42.9%)
	The number (%) of patients censored [a]	4 (66.7%)	4 (57.1%)
	Median time to event (95% CI) [b]	3.1 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.956	
	HR (95% CI) [d]	0.93 (0.15, 5.56)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	48 (40.3%)	52 (44.4%)
	The number (%) of patients censored [a]	71 (59.7%)	65 (55.6%)
	Median time to event (95% CI) [b]	7.0 (2.4, 12.2)	4.9 (2.8, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.436	
	HR (95% CI) [d]	0.85 (0.57, 1.27)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.535	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	3 (50.0%)	3 (42.9%)
	The number (%) of patients censored [a]	3 (50.0%)	4 (57.1%)
	Median time to event (95% CI) [b]	0.8 (0.8, NE)	8.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.337	
	HR (95% CI) [d]	2.37 (0.39, 14.37)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	88 (73.9%)	71 (60.7%)
	The number (%) of patients censored [a]	31 (26.1%)	46 (39.3%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.1)	3.0 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.86 (1.35, 2.54)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.891	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	2 (28.6%)
	The number (%) of patients censored [a]	5 (83.3%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (3.9, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	1.41 (0.09, 22.64)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	35 (29.4%)	33 (28.2%)
	The number (%) of patients censored [a]	84 (70.6%)	84 (71.8%)
	Median time to event (95% CI) [b]	24.7 (17.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.788	
	HR (95% CI) [d]	0.94 (0.58, 1.51)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.938	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	2 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	3.2 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.512	
	HR (95% CI) [d]	0.58 (0.11, 3.16)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	60 (50.4%)	64 (54.7%)
	The number (%) of patients censored [a]	59 (49.6%)	53 (45.3%)
	Median time to event (95% CI) [b]	6.8 (3.6, 10.8)	4.2 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.135	
	HR (95% CI) [d]	0.76 (0.54, 1.09)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.675	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	2 (28.6%)
	The number (%) of patients censored [a]	6 (100.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.157	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	13 (10.9%)	11 (9.4%)
	The number (%) of patients censored [a]	106 (89.1%)	106 (90.6%)
	Median time to event (95% CI) [b]	1.1 (0.8, 7.2)	1.5 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.434	
	HR (95% CI) [d]	1.33 (0.59, 2.99)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.991	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	1 (14.3%)
	The number (%) of patients censored [a]	5 (83.3%)	6 (85.7%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.757	
	HR (95% CI) [d]	1.55 (0.09, 25.33)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	42 (35.3%)	43 (36.8%)
	The number (%) of patients censored [a]	77 (64.7%)	74 (63.2%)
	Median time to event (95% CI) [b]	18.7 (8.8, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.717	
	HR (95% CI) [d]	0.92 (0.60, 1.42)	
	P-value of subgroup*treatment interaction [e]	0.632	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.7.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	1 (16.7%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (83.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	2.8 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	0.86 (0.09, 8.50)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	49 (41.2%)	45 (38.5%)
	The number (%) of patients censored [a]	70 (58.8%)	72 (61.5%)
	Median time to event (95% CI) [b]	11.4 (4.1, 22.4)	16.1 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.583	
	HR (95% CI) [d]	1.12 (0.74, 1.67)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.655	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	2 (28.6%)
	The number (%) of patients censored [a]	6 (100.0%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.312	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	25 (21.0%)	27 (23.1%)
	The number (%) of patients censored [a]	94 (79.0%)	90 (76.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.879	
	HR (95% CI) [d]	0.96 (0.55, 1.66)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.984	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	6	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	6 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	119	117
	The number (%) of patients with an event [a]	11 (9.2%)	8 (6.8%)
	The number (%) of patients censored [a]	108 (90.8%)	109 (93.2%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.732	
	HR (95% CI) [d]	1.17 (0.47, 2.92)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.7.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	29 (69.0%)	32 (69.6%)
	The number (%) of patients censored [a]	13 (31.0%)	14 (30.4%)
	Median time to event (95% CI) [b]	1.8 (0.8, 3.6)	1.7 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.987	
	HR (95% CI) [d]	1.00 (0.60, 1.67)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	2 (28.6%)
	The number (%) of patients censored [a]	4 (44.4%)	5 (71.4%)
	Median time to event (95% CI) [b]	2.3 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.444	
	HR (95% CI) [d]	1.90 (0.37, 9.88)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.331	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	21 (50.0%)	28 (60.9%)
	The number (%) of patients censored [a]	21 (50.0%)	18 (39.1%)
	Median time to event (95% CI) [b]	7.5 (1.7, NE)	3.3 (1.5, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.140	
	HR (95% CI) [d]	0.65 (0.36, 1.17)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (55.6%)	4 (57.1%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	19.4 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.564	
	HR (95% CI) [d]	1.64 (0.30, 9.01)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.316	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	27 (64.3%)	31 (67.4%)
	The number (%) of patients censored [a]	15 (35.7%)	15 (32.6%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.8)	1.7 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.943	
	HR (95% CI) [d]	1.02 (0.61, 1.72)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	3 (42.9%)
	The number (%) of patients censored [a]	4 (44.4%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.1 (0.8, NE)	10.6 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.401	
	HR (95% CI) [d]	2.04 (0.38, 10.93)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.492	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	24 (57.1%)	21 (45.7%)
	The number (%) of patients censored [a]	18 (42.9%)	25 (54.3%)
	Median time to event (95% CI) [b]	6.0 (3.2, 11.3)	9.1 (3.3, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.733	
	HR (95% CI) [d]	1.11 (0.61, 2.00)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (55.6%)	4 (57.1%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	8.3 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.656	
	HR (95% CI) [d]	1.49 (0.27, 8.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.678	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	29 (69.0%)	29 (63.0%)
	The number (%) of patients censored [a]	13 (31.0%)	17 (37.0%)
	Median time to event (95% CI) [b]	4.2 (2.8, 5.7)	2.7 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.724	
	HR (95% CI) [d]	0.91 (0.54, 1.52)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	6 (85.7%)
	The number (%) of patients censored [a]	4 (44.4%)	1 (14.3%)
	Median time to event (95% CI) [b]	7.9 (0.8, NE)	1.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	0.27 (0.08, 0.98)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.091	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	25 (59.5%)	27 (58.7%)
	The number (%) of patients censored [a]	17 (40.5%)	19 (41.3%)
	Median time to event (95% CI) [b]	1.8 (1.0, 7.5)	3.3 (1.0, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.883	
	HR (95% CI) [d]	1.04 (0.60, 1.80)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	6 (85.7%)
	The number (%) of patients censored [a]	3 (33.3%)	1 (14.3%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.1 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.512	
	HR (95% CI) [d]	0.68 (0.21, 2.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.445	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	28 (66.7%)	35 (76.1%)
	The number (%) of patients censored [a]	14 (33.3%)	11 (23.9%)
	Median time to event (95% CI) [b]	1.4 (0.8, 3.1)	1.2 (0.9, 3.2)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.93 (0.56, 1.54)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.762	
	HR (95% CI) [d]	0.83 (0.23, 2.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.770	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	26 (61.9%)	27 (58.7%)
	The number (%) of patients censored [a]	16 (38.1%)	19 (41.3%)
	Median time to event (95% CI) [b]	2.0 (1.1, 4.2)	2.1 (1.2, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.778	
	HR (95% CI) [d]	1.09 (0.63, 1.86)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	4 (57.1%)
	The number (%) of patients censored [a]	5 (55.6%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	5.5 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.539	
	HR (95% CI) [d]	0.66 (0.16, 2.70)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.551	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	21 (50.0%)	30 (65.2%)
	The number (%) of patients censored [a]	21 (50.0%)	16 (34.8%)
	Median time to event (95% CI) [b]	8.8 (1.5, 16.0)	2.3 (1.4, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.222	
	HR (95% CI) [d]	0.71 (0.40, 1.25)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.9 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.631	
	HR (95% CI) [d]	1.38 (0.38, 5.05)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.292	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	10 (23.8%)	25 (54.3%)
	The number (%) of patients censored [a]	32 (76.2%)	21 (45.7%)
	Median time to event (95% CI) [b]	NE (9.6, NE)	3.1 (1.4, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.29 (0.14, 0.62)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	3 (33.3%)	3 (42.9%)
	The number (%) of patients censored [a]	6 (66.7%)	4 (57.1%)
	Median time to event (95% CI) [b]	7.2 (1.9, NE)	6.3 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.739	
	HR (95% CI) [d]	0.76 (0.15, 3.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.283	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	20 (47.6%)	26 (56.5%)
	The number (%) of patients censored [a]	22 (52.4%)	20 (43.5%)
	Median time to event (95% CI) [b]	5.1 (2.5, NE)	3.6 (1.4, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.275	
	HR (95% CI) [d]	0.72 (0.40, 1.29)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	3 (42.9%)
	The number (%) of patients censored [a]	3 (33.3%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.9 (0.8, NE)	9.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.057	
	HR (95% CI) [d]	6.22 (0.73, 52.69)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.049	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	22 (52.4%)	26 (56.5%)
	The number (%) of patients censored [a]	20 (47.6%)	20 (43.5%)
	Median time to event (95% CI) [b]	3.6 (1.7, NE)	3.1 (1.4, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.706	
	HR (95% CI) [d]	0.90 (0.51, 1.59)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	4 (57.1%)
	The number (%) of patients censored [a]	4 (44.4%)	3 (42.9%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	2.1 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.338	
	HR (95% CI) [d]	0.53 (0.14, 1.99)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.506	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	24 (57.1%)	26 (56.5%)
	The number (%) of patients censored [a]	18 (42.9%)	20 (43.5%)
	Median time to event (95% CI) [b]	2.3 (1.3, 6.9)	2.2 (1.4, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.747	
	HR (95% CI) [d]	0.91 (0.52, 1.59)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	5 (71.4%)
	The number (%) of patients censored [a]	4 (44.4%)	2 (28.6%)
	Median time to event (95% CI) [b]	1.0 (0.7, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.333	
	HR (95% CI) [d]	0.52 (0.15, 1.85)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.520	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	30 (71.4%)	19 (41.3%)
	The number (%) of patients censored [a]	12 (28.6%)	27 (58.7%)
	Median time to event (95% CI) [b]	1.7 (0.8, 2.8)	5.8 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	2.64 (1.48, 4.72)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	8 (88.9%)	2 (28.6%)
	The number (%) of patients censored [a]	1 (11.1%)	5 (71.4%)
	Median time to event (95% CI) [b]	2.9 (0.8, 5.8)	NE (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.040	
	HR (95% CI) [d]	4.49 (0.94, 21.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.602	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	12 (28.6%)	21 (45.7%)
	The number (%) of patients censored [a]	30 (71.4%)	25 (54.3%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	4.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.093	
	HR (95% CI) [d]	0.55 (0.27, 1.12)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	3 (33.3%)	5 (71.4%)
	The number (%) of patients censored [a]	6 (66.7%)	2 (28.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	4.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.555	
	HR (95% CI) [d]	0.64 (0.14, 2.88)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.962	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.8.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	26 (61.9%)	23 (50.0%)
	The number (%) of patients censored [a]	16 (38.1%)	23 (50.0%)
	Median time to event (95% CI) [b]	1.7 (1.0, 5.1)	2.6 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.376	
	HR (95% CI) [d]	1.29 (0.73, 2.26)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.3 (0.7, NE)	2.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.421	
	HR (95% CI) [d]	1.68 (0.47, 5.98)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.677	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	10 (23.8%)	13 (28.3%)
	The number (%) of patients censored [a]	32 (76.2%)	33 (71.7%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (5.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.637	
	HR (95% CI) [d]	0.82 (0.36, 1.87)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	0 (0.0%)	4 (57.1%)
	The number (%) of patients censored [a]	9 (100.0%)	3 (42.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	3.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.989	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	2 (4.8%)	2 (4.3%)
	The number (%) of patients censored [a]	40 (95.2%)	44 (95.7%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.895	
	HR (95% CI) [d]	1.14 (0.16, 8.15)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	9 (100.0%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	15 (35.7%)	20 (43.5%)
	The number (%) of patients censored [a]	27 (64.3%)	26 (56.5%)
	Median time to event (95% CI) [b]	7.0 (1.7, NE)	3.3 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.460	
	HR (95% CI) [d]	0.77 (0.39, 1.51)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	4 (44.4%)	3 (42.9%)
	The number (%) of patients censored [a]	5 (55.6%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.2 (1.0, NE)	4.0 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.143	
	HR (95% CI) [d]	3.62 (0.62, 21.04)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.114	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	30 (71.4%)	26 (56.5%)
	The number (%) of patients censored [a]	12 (28.6%)	20 (43.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.5)	3.1 (1.4, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.23 (1.31, 3.82)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	8 (88.9%)	4 (57.1%)
	The number (%) of patients censored [a]	1 (11.1%)	3 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.7, 1.2)	2.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.080	
	HR (95% CI) [d]	2.99 (0.84, 10.70)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.492	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	11 (26.2%)	16 (34.8%)
	The number (%) of patients censored [a]	31 (73.8%)	30 (65.2%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	8.7 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.282	
	HR (95% CI) [d]	0.66 (0.31, 1.42)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	3 (33.3%)	2 (28.6%)
	The number (%) of patients censored [a]	6 (66.7%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.834	
	HR (95% CI) [d]	0.82 (0.13, 5.07)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.830	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	23 (54.8%)	28 (60.9%)
	The number (%) of patients censored [a]	19 (45.2%)	18 (39.1%)
	Median time to event (95% CI) [b]	5.0 (2.9, 9.6)	3.1 (1.4, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.227	
	HR (95% CI) [d]	0.71 (0.41, 1.24)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	6 (66.7%)	4 (57.1%)
	The number (%) of patients censored [a]	3 (33.3%)	3 (42.9%)
	Median time to event (95% CI) [b]	2.8 (0.8, NE)	2.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.615	
	HR (95% CI) [d]	0.71 (0.20, 2.53)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.753	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	6 (14.3%)	5 (10.9%)
	The number (%) of patients censored [a]	36 (85.7%)	41 (89.1%)
	Median time to event (95% CI) [b]	0.8 (0.7, NE)	1.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.026	
	HR (95% CI) [d]	4.89 (1.11, 21.50)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	1 (11.1%)	0 (0.0%)
	The number (%) of patients censored [a]	8 (88.9%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.8.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	20 (47.6%)	20 (43.5%)
	The number (%) of patients censored [a]	22 (52.4%)	26 (56.5%)
	Median time to event (95% CI) [b]	8.8 (3.9, 15.5)	12.4 (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.885	
	HR (95% CI) [d]	1.05 (0.56, 1.96)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	5 (55.6%)	0 (0.0%)
	The number (%) of patients censored [a]	4 (44.4%)	7 (100.0%)
	Median time to event (95% CI) [b]	7.2 (0.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.025	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.985	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.8.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	15 (35.7%)	17 (37.0%)
	The number (%) of patients censored [a]	27 (64.3%)	29 (63.0%)
	Median time to event (95% CI) [b]	9.1 (4.2, NE)	15.9 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.962	
	HR (95% CI) [d]	0.98 (0.49, 1.97)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	7 (77.8%)	3 (42.9%)
	The number (%) of patients censored [a]	2 (22.2%)	4 (57.1%)
	Median time to event (95% CI) [b]	1.0 (0.2, 3.3)	19.4 (0.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.047	
	HR (95% CI) [d]	4.47 (0.89, 22.59)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.019	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.5
Time to First Meaningful Deterioration for PGIC by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	12 (28.6%)	12 (26.1%)
	The number (%) of patients censored [a]	30 (71.4%)	34 (73.9%)
	Median time to event (95% CI) [b]	NE (5.0, NE)	6.4 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.973	
	HR (95% CI) [d]	0.99 (0.44, 2.22)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	2 (22.2%)	2 (28.6%)
	The number (%) of patients censored [a]	7 (77.8%)	5 (71.4%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.919	
	HR (95% CI) [d]	0.90 (0.13, 6.43)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.5
Time to First Meaningful Deterioration for PGIC by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.891	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.6
Time to First Meaningful Deterioration for PGIS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	42	46
	The number (%) of patients with an event [a]	7 (16.7%)	4 (8.7%)
	The number (%) of patients censored [a]	35 (83.3%)	42 (91.3%)
	Median time to event (95% CI) [b]	6.3 (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	1.43 (0.41, 4.92)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	9	7
	The number (%) of patients with an event [a]	1 (11.1%)	0 (0.0%)
	The number (%) of patients censored [a]	8 (88.9%)	7 (100.0%)
	Median time to event (95% CI) [b]	NE (4.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	NE (NE, NE)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.8.6
Time to First Meaningful Deterioration for PGIS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.995	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	14 (48.3%)	18 (51.4%)
	The number (%) of patients censored [a]	15 (51.7%)	17 (48.6%)
	Median time to event (95% CI) [b]	6.0 (1.6, NE)	5.6 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.961	
	HR (95% CI) [d]	0.99 (0.49, 1.99)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	56 (58.3%)	55 (62.5%)
	The number (%) of patients censored [a]	40 (41.7%)	33 (37.5%)
	Median time to event (95% CI) [b]	3.6 (1.8, 6.3)	3.1 (1.5, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.266	
	HR (95% CI) [d]	0.81 (0.56, 1.18)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.667	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	11 (37.9%)	19 (54.3%)
	The number (%) of patients censored [a]	18 (62.1%)	16 (45.7%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	5.6 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.265	
	HR (95% CI) [d]	0.66 (0.31, 1.38)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	47 (49.0%)	49 (55.7%)
	The number (%) of patients censored [a]	49 (51.0%)	39 (44.3%)
	Median time to event (95% CI) [b]	7.4 (2.4, 20.1)	4.9 (2.4, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.274	
	HR (95% CI) [d]	0.80 (0.54, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.733	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	14 (48.3%)	23 (65.7%)
	The number (%) of patients censored [a]	15 (51.7%)	12 (34.3%)
	Median time to event (95% CI) [b]	8.4 (1.7, NE)	3.7 (1.6, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.228	
	HR (95% CI) [d]	0.67 (0.34, 1.30)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	58 (60.4%)	60 (68.2%)
	The number (%) of patients censored [a]	38 (39.6%)	28 (31.8%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.9)	2.6 (1.2, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.926	
	HR (95% CI) [d]	1.02 (0.71, 1.47)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.303	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	14 (48.3%)	13 (37.1%)
	The number (%) of patients censored [a]	15 (51.7%)	22 (62.9%)
	Median time to event (95% CI) [b]	7.3 (4.1, 15.5)	14.0 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.365	
	HR (95% CI) [d]	1.42 (0.66, 3.03)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	45 (46.9%)	42 (47.7%)
	The number (%) of patients censored [a]	51 (53.1%)	46 (52.3%)
	Median time to event (95% CI) [b]	8.8 (4.2, 11.8)	9.1 (4.2, 10.8)
	Nominal p-value for unstratified log-rank test [c]	0.498	
	HR (95% CI) [d]	0.87 (0.57, 1.32)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.275	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	13 (44.8%)	23 (65.7%)
	The number (%) of patients censored [a]	16 (55.2%)	12 (34.3%)
	Median time to event (95% CI) [b]	6.4 (2.8, NE)	2.2 (1.0, 7.3)
	Nominal p-value for unstratified log-rank test [c]	0.077	
	HR (95% CI) [d]	0.54 (0.27, 1.08)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	56 (58.3%)	55 (62.5%)
	The number (%) of patients censored [a]	40 (41.7%)	33 (37.5%)
	Median time to event (95% CI) [b]	4.2 (2.6, 6.9)	3.1 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.575	
	HR (95% CI) [d]	0.90 (0.62, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.174	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	15 (51.7%)	25 (71.4%)
	The number (%) of patients censored [a]	14 (48.3%)	10 (28.6%)
	Median time to event (95% CI) [b]	3.8 (1.5, NE)	3.1 (0.9, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.58 (0.30, 1.14)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	53 (55.2%)	51 (58.0%)
	The number (%) of patients censored [a]	43 (44.8%)	37 (42.0%)
	Median time to event (95% CI) [b]	2.2 (1.1, 4.8)	3.6 (1.4, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.953	
	HR (95% CI) [d]	0.99 (0.67, 1.45)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.333	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	16 (55.2%)	24 (68.6%)
	The number (%) of patients censored [a]	13 (44.8%)	11 (31.4%)
	Median time to event (95% CI) [b]	1.8 (0.8, NE)	1.6 (0.9, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.502	
	HR (95% CI) [d]	0.81 (0.43, 1.53)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	67 (69.8%)	67 (76.1%)
	The number (%) of patients censored [a]	29 (30.2%)	21 (23.9%)
	Median time to event (95% CI) [b]	1.3 (0.9, 1.7)	1.2 (0.9, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.340	
	HR (95% CI) [d]	0.86 (0.61, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.801	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	19 (65.5%)	25 (71.4%)
	The number (%) of patients censored [a]	10 (34.5%)	10 (28.6%)
	Median time to event (95% CI) [b]	2.2 (0.8, 11.2)	1.4 (0.9, 2.8)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	0.84 (0.46, 1.54)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	61 (63.5%)	53 (60.2%)
	The number (%) of patients censored [a]	35 (36.5%)	35 (39.8%)
	Median time to event (95% CI) [b]	1.5 (1.1, 2.6)	2.1 (1.4, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.354	
	HR (95% CI) [d]	1.19 (0.82, 1.72)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.374	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	10 (34.5%)	20 (57.1%)
	The number (%) of patients censored [a]	19 (65.5%)	15 (42.9%)
	Median time to event (95% CI) [b]	15.5 (2.5, NE)	2.7 (1.4, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.080	
	HR (95% CI) [d]	0.51 (0.24, 1.10)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	48 (50.0%)	56 (63.6%)
	The number (%) of patients censored [a]	48 (50.0%)	32 (36.4%)
	Median time to event (95% CI) [b]	6.5 (1.8, 9.8)	2.8 (2.1, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.149	
	HR (95% CI) [d]	0.76 (0.51, 1.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.272	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	9 (31.0%)	21 (60.0%)
	The number (%) of patients censored [a]	20 (69.0%)	14 (40.0%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	4.9 (1.4, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.020	
	HR (95% CI) [d]	0.41 (0.19, 0.89)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	34 (35.4%)	43 (48.9%)
	The number (%) of patients censored [a]	62 (64.6%)	45 (51.1%)
	Median time to event (95% CI) [b]	15.5 (7.2, NE)	5.0 (3.3, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	0.62 (0.39, 0.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.305	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	12 (41.4%)	19 (54.3%)
	The number (%) of patients censored [a]	17 (58.6%)	16 (45.7%)
	Median time to event (95% CI) [b]	14.4 (3.5, NE)	4.6 (3.1, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	0.66 (0.32, 1.37)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	47 (49.0%)	47 (53.4%)
	The number (%) of patients censored [a]	49 (51.0%)	41 (46.6%)
	Median time to event (95% CI) [b]	5.1 (2.6, 9.1)	4.1 (2.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.639	
	HR (95% CI) [d]	0.91 (0.61, 1.36)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.423	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	15 (51.7%)	19 (54.3%)
	The number (%) of patients censored [a]	14 (48.3%)	16 (45.7%)
	Median time to event (95% CI) [b]	4.2 (1.0, NE)	3.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.946	
	HR (95% CI) [d]	0.98 (0.50, 1.93)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	49 (51.0%)	48 (54.5%)
	The number (%) of patients censored [a]	47 (49.0%)	40 (45.5%)
	Median time to event (95% CI) [b]	3.2 (1.8, 13.6)	4.9 (2.1, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.663	
	HR (95% CI) [d]	0.92 (0.62, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.938	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	10 (34.5%)	17 (48.6%)
	The number (%) of patients censored [a]	19 (65.5%)	18 (51.4%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	6.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.246	
	HR (95% CI) [d]	0.63 (0.29, 1.38)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	57 (59.4%)	54 (61.4%)
	The number (%) of patients censored [a]	39 (40.6%)	34 (38.6%)
	Median time to event (95% CI) [b]	2.3 (1.6, 3.7)	1.9 (1.4, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.463	
	HR (95% CI) [d]	0.86 (0.59, 1.25)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.539	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	20 (69.0%)	15 (42.9%)
	The number (%) of patients censored [a]	9 (31.0%)	20 (57.1%)
	Median time to event (95% CI) [b]	1.7 (0.8, 2.9)	7.4 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.019	
	HR (95% CI) [d]	2.23 (1.13, 4.42)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	64 (66.7%)	31 (35.2%)
	The number (%) of patients censored [a]	32 (33.3%)	57 (64.8%)
	Median time to event (95% CI) [b]	1.6 (1.0, 3.3)	NE (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.74 (1.78, 4.21)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.709	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	11 (37.9%)	18 (51.4%)
	The number (%) of patients censored [a]	18 (62.1%)	17 (48.6%)
	Median time to event (95% CI) [b]	16.1 (3.6, NE)	3.8 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.41 (0.18, 0.93)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	31 (32.3%)	27 (30.7%)
	The number (%) of patients censored [a]	65 (67.7%)	61 (69.3%)
	Median time to event (95% CI) [b]	21.5 (7.9, NE)	19.4 (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.994	
	HR (95% CI) [d]	1.00 (0.59, 1.68)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.170	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	13 (44.8%)	18 (51.4%)
	The number (%) of patients censored [a]	16 (55.2%)	17 (48.6%)
	Median time to event (95% CI) [b]	3.0 (1.5, NE)	3.8 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.607	
	HR (95% CI) [d]	0.83 (0.40, 1.72)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	57 (59.4%)	40 (45.5%)
	The number (%) of patients censored [a]	39 (40.6%)	48 (54.5%)
	Median time to event (95% CI) [b]	2.9 (1.7, 4.6)	5.4 (3.0, 17.1)
	Nominal p-value for unstratified log-rank test [c]	0.041	
	HR (95% CI) [d]	1.52 (1.01, 2.28)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.172	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	8 (27.6%)	14 (40.0%)
	The number (%) of patients censored [a]	21 (72.4%)	21 (60.0%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	0.57 (0.24, 1.36)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	27 (28.1%)	23 (26.1%)
	The number (%) of patients censored [a]	69 (71.9%)	65 (73.9%)
	Median time to event (95% CI) [b]	NE (18.5, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.914	
	HR (95% CI) [d]	1.03 (0.59, 1.80)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.306	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	3 (10.3%)	3 (8.6%)
	The number (%) of patients censored [a]	26 (89.7%)	32 (91.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.534	
	HR (95% CI) [d]	1.68 (0.34, 8.33)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	3 (3.1%)	2 (2.3%)
	The number (%) of patients censored [a]	93 (96.9%)	86 (97.7%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.560	
	HR (95% CI) [d]	1.69 (0.28, 10.17)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.975	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	12 (41.4%)	20 (57.1%)
	The number (%) of patients censored [a]	17 (58.6%)	15 (42.9%)
	Median time to event (95% CI) [b]	4.2 (1.7, NE)	2.8 (1.5, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	0.59 (0.28, 1.24)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	38 (39.6%)	34 (38.6%)
	The number (%) of patients censored [a]	58 (60.4%)	54 (61.4%)
	Median time to event (95% CI) [b]	7.0 (3.1, 12.6)	8.8 (3.3, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.795	
	HR (95% CI) [d]	1.06 (0.66, 1.70)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.135	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	23 (79.3%)	22 (62.9%)
	The number (%) of patients censored [a]	6 (20.7%)	13 (37.1%)
	Median time to event (95% CI) [b]	0.8 (0.7, 0.8)	1.7 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.44 (1.34, 4.47)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	68 (70.8%)	51 (58.0%)
	The number (%) of patients censored [a]	28 (29.2%)	37 (42.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.3 (2.0, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	1.76 (1.22, 2.53)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.241	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	5 (17.2%)	9 (25.7%)
	The number (%) of patients censored [a]	24 (82.8%)	26 (74.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.626	
	HR (95% CI) [d]	0.76 (0.25, 2.28)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	31 (32.3%)	26 (29.5%)
	The number (%) of patients censored [a]	65 (67.7%)	62 (70.5%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.722	
	HR (95% CI) [d]	0.91 (0.54, 1.54)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.756	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	11 (37.9%)	25 (71.4%)
	The number (%) of patients censored [a]	18 (62.1%)	10 (28.6%)
	Median time to event (95% CI) [b]	15.5 (3.2, NE)	2.8 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.012	
	HR (95% CI) [d]	0.41 (0.20, 0.84)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	51 (53.1%)	43 (48.9%)
	The number (%) of patients censored [a]	45 (46.9%)	45 (51.1%)
	Median time to event (95% CI) [b]	6.5 (3.1, 9.3)	4.9 (3.1, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.743	
	HR (95% CI) [d]	0.93 (0.62, 1.40)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.059	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	2 (6.9%)	6 (17.1%)
	The number (%) of patients censored [a]	27 (93.1%)	29 (82.9%)
	Median time to event (95% CI) [b]	0.9 (0.7, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.749	
	HR (95% CI) [d]	1.23 (0.24, 6.24)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	11 (11.5%)	7 (8.0%)
	The number (%) of patients censored [a]	85 (88.5%)	81 (92.0%)
	Median time to event (95% CI) [b]	1.7 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.953	
	HR (95% CI) [d]	1.02 (0.40, 2.64)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.943	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	6 (20.7%)	13 (37.1%)
	The number (%) of patients censored [a]	23 (79.3%)	22 (62.9%)
	Median time to event (95% CI) [b]	NE (15.5, NE)	10.5 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.200	
	HR (95% CI) [d]	0.53 (0.20, 1.42)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	37 (38.5%)	31 (35.2%)
	The number (%) of patients censored [a]	59 (61.5%)	57 (64.8%)
	Median time to event (95% CI) [b]	18.7 (7.2, NE)	13.0 (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.801	
	HR (95% CI) [d]	1.07 (0.66, 1.72)	
	P-value of subgroup*treatment interaction [e]	0.255	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.3.9.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	8 (27.6%)	18 (51.4%)
	The number (%) of patients censored [a]	21 (72.4%)	17 (48.6%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	5.8 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.206	
	HR (95% CI) [d]	0.58 (0.25, 1.35)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	42 (43.8%)	30 (34.1%)
	The number (%) of patients censored [a]	54 (56.3%)	58 (65.9%)
	Median time to event (95% CI) [b]	9.6 (4.1, 18.6)	15.9 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.254	
	HR (95% CI) [d]	1.31 (0.82, 2.09)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.115	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	4 (13.8%)	11 (31.4%)
	The number (%) of patients censored [a]	25 (86.2%)	24 (68.6%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.202	
	HR (95% CI) [d]	0.48 (0.15, 1.51)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	21 (21.9%)	18 (20.5%)
	The number (%) of patients censored [a]	75 (78.1%)	70 (79.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.718	
	HR (95% CI) [d]	1.12 (0.59, 2.13)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.223	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	29	35
	The number (%) of patients with an event [a]	1 (3.4%)	4 (11.4%)
	The number (%) of patients censored [a]	28 (96.6%)	31 (88.6%)
	Median time to event (95% CI) [b]	NE (5.1, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.424	
	HR (95% CI) [d]	0.42 (0.05, 3.76)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	96	88
	The number (%) of patients with an event [a]	10 (10.4%)	4 (4.5%)
	The number (%) of patients censored [a]	86 (89.6%)	84 (95.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.332	
	HR (95% CI) [d]	1.76 (0.55, 5.62)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.9.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.254	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	26 (59.1%)	33 (63.5%)
	The number (%) of patients censored [a]	18 (40.9%)	19 (36.5%)
	Median time to event (95% CI) [b]	3.6 (1.5, 7.7)	3.0 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.464	
	HR (95% CI) [d]	0.82 (0.49, 1.38)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	44 (54.3%)	40 (55.6%)
	The number (%) of patients censored [a]	37 (45.7%)	32 (44.4%)
	Median time to event (95% CI) [b]	4.9 (1.7, 7.7)	4.2 (1.7, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.793	
	HR (95% CI) [d]	0.95 (0.62, 1.46)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.563	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	20 (45.5%)	29 (55.8%)
	The number (%) of patients censored [a]	24 (54.5%)	23 (44.2%)
	Median time to event (95% CI) [b]	7.9 (3.6, NE)	4.9 (2.9, 19.4)
	Nominal p-value for unstratified log-rank test [c]	0.191	
	HR (95% CI) [d]	0.68 (0.39, 1.21)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	38 (46.9%)	40 (55.6%)
	The number (%) of patients censored [a]	43 (53.1%)	32 (44.4%)
	Median time to event (95% CI) [b]	7.5 (3.0, 21.5)	5.1 (2.1, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.388	
	HR (95% CI) [d]	0.82 (0.53, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.621	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	24 (54.5%)	34 (65.4%)
	The number (%) of patients censored [a]	20 (45.5%)	18 (34.6%)
	Median time to event (95% CI) [b]	2.7 (1.1, NE)	3.7 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.424	
	HR (95% CI) [d]	0.81 (0.48, 1.37)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	48 (59.3%)	50 (69.4%)
	The number (%) of patients censored [a]	33 (40.7%)	22 (30.6%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.5)	2.8 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.977	
	HR (95% CI) [d]	1.01 (0.68, 1.51)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.523	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	25 (56.8%)	25 (48.1%)
	The number (%) of patients censored [a]	19 (43.2%)	27 (51.9%)
	Median time to event (95% CI) [b]	5.0 (3.4, 11.4)	5.6 (3.6, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.753	
	HR (95% CI) [d]	1.09 (0.63, 1.90)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	34 (42.0%)	31 (43.1%)
	The number (%) of patients censored [a]	47 (58.0%)	41 (56.9%)
	Median time to event (95% CI) [b]	9.0 (6.0, 15.5)	10.2 (5.1, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.601	
	HR (95% CI) [d]	0.88 (0.54, 1.44)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.673	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	27 (61.4%)	33 (63.5%)
	The number (%) of patients censored [a]	17 (38.6%)	19 (36.5%)
	Median time to event (95% CI) [b]	4.9 (2.3, 9.8)	2.7 (1.7, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.372	
	HR (95% CI) [d]	0.79 (0.48, 1.32)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	42 (51.9%)	46 (63.9%)
	The number (%) of patients censored [a]	39 (48.1%)	26 (36.1%)
	Median time to event (95% CI) [b]	4.2 (2.8, 13.1)	2.9 (2.1, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.183	
	HR (95% CI) [d]	0.75 (0.49, 1.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.856	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	26 (59.1%)	36 (69.2%)
	The number (%) of patients censored [a]	18 (40.9%)	16 (30.8%)
	Median time to event (95% CI) [b]	1.8 (1.1, 16.1)	2.9 (0.9, 3.6)
	Nominal p-value for unstratified log-rank test [c]	0.308	
	HR (95% CI) [d]	0.77 (0.46, 1.27)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	42 (51.9%)	41 (56.9%)
	The number (%) of patients censored [a]	39 (48.1%)	31 (43.1%)
	Median time to event (95% CI) [b]	3.6 (1.4, 12.2)	4.4 (2.8, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.981	
	HR (95% CI) [d]	1.00 (0.65, 1.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.349	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	27 (61.4%)	39 (75.0%)
	The number (%) of patients censored [a]	17 (38.6%)	13 (25.0%)
	Median time to event (95% CI) [b]	1.6 (0.9, 5.7)	1.4 (0.9, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.152	
	HR (95% CI) [d]	0.70 (0.43, 1.15)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	56 (69.1%)	53 (73.6%)
	The number (%) of patients censored [a]	25 (30.9%)	19 (26.4%)
	Median time to event (95% CI) [b]	1.4 (0.8, 1.8)	1.4 (0.9, 2.4)
	Nominal p-value for unstratified log-rank test [c]	0.834	
	HR (95% CI) [d]	0.97 (0.66, 1.41)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.310	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	33 (75.0%)	34 (65.4%)
	The number (%) of patients censored [a]	11 (25.0%)	18 (34.6%)
	Median time to event (95% CI) [b]	1.1 (0.8, 1.7)	3.1 (1.5, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.088	
	HR (95% CI) [d]	1.52 (0.93, 2.48)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	47 (58.0%)	45 (62.5%)
	The number (%) of patients censored [a]	34 (42.0%)	27 (37.5%)
	Median time to event (95% CI) [b]	2.4 (1.4, 3.5)	1.4 (1.2, 2.2)
	Nominal p-value for unstratified log-rank test [c]	0.464	
	HR (95% CI) [d]	0.86 (0.57, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.072	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	23 (52.3%)	32 (61.5%)
	The number (%) of patients censored [a]	21 (47.7%)	20 (38.5%)
	Median time to event (95% CI) [b]	7.7 (2.8, 11.8)	2.4 (1.7, 3.6)
	Nominal p-value for unstratified log-rank test [c]	0.048	
	HR (95% CI) [d]	0.58 (0.34, 1.00)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	35 (43.2%)	44 (61.1%)
	The number (%) of patients censored [a]	46 (56.8%)	28 (38.9%)
	Median time to event (95% CI) [b]	4.3 (1.5, NE)	4.1 (2.1, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.247	
	HR (95% CI) [d]	0.77 (0.49, 1.21)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.477	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	12 (27.3%)	25 (48.1%)
	The number (%) of patients censored [a]	32 (72.7%)	27 (51.9%)
	Median time to event (95% CI) [b]	NE (11.4, NE)	5.0 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.013	
	HR (95% CI) [d]	0.43 (0.21, 0.85)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	31 (38.3%)	40 (55.6%)
	The number (%) of patients censored [a]	50 (61.7%)	32 (44.4%)
	Median time to event (95% CI) [b]	12.2 (5.3, NE)	4.4 (2.4, 8.0)
	Nominal p-value for unstratified log-rank test [c]	0.039	
	HR (95% CI) [d]	0.61 (0.38, 0.98)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.357	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	23 (52.3%)	25 (48.1%)
	The number (%) of patients censored [a]	21 (47.7%)	27 (51.9%)
	Median time to event (95% CI) [b]	5.3 (3.5, 16.8)	4.4 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.952	
	HR (95% CI) [d]	0.98 (0.56, 1.73)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	36 (44.4%)	42 (58.3%)
	The number (%) of patients censored [a]	45 (55.6%)	30 (41.7%)
	Median time to event (95% CI) [b]	4.5 (2.3, 14.4)	3.5 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.154	
	HR (95% CI) [d]	0.72 (0.46, 1.13)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.404	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	26 (59.1%)	29 (55.8%)
	The number (%) of patients censored [a]	18 (40.9%)	23 (44.2%)
	Median time to event (95% CI) [b]	1.7 (1.0, 11.8)	5.0 (1.4, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.580	
	HR (95% CI) [d]	1.16 (0.68, 1.99)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	38 (46.9%)	39 (54.2%)
	The number (%) of patients censored [a]	43 (53.1%)	33 (45.8%)
	Median time to event (95% CI) [b]	4.1 (2.0, NE)	3.4 (1.6, 14.5)
	Nominal p-value for unstratified log-rank test [c]	0.381	
	HR (95% CI) [d]	0.82 (0.52, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.336	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	24 (54.5%)	29 (55.8%)
	The number (%) of patients censored [a]	20 (45.5%)	23 (44.2%)
	Median time to event (95% CI) [b]	2.1 (1.3, NE)	2.1 (1.0, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.477	
	HR (95% CI) [d]	0.82 (0.47, 1.41)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	43 (53.1%)	43 (59.7%)
	The number (%) of patients censored [a]	38 (46.9%)	29 (40.3%)
	Median time to event (95% CI) [b]	2.8 (1.9, 6.9)	2.3 (1.5, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.453	
	HR (95% CI) [d]	0.85 (0.55, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.950	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	28 (63.6%)	18 (34.6%)
	The number (%) of patients censored [a]	16 (36.4%)	34 (65.4%)
	Median time to event (95% CI) [b]	1.7 (1.0, 3.7)	NE (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.78 (1.53, 5.05)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	56 (69.1%)	29 (40.3%)
	The number (%) of patients censored [a]	25 (30.9%)	43 (59.7%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.9)	13.2 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.42 (1.54, 3.80)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.800	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	17 (38.6%)	24 (46.2%)
	The number (%) of patients censored [a]	27 (61.4%)	28 (53.8%)
	Median time to event (95% CI) [b]	16.1 (4.4, NE)	5.8 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.101	
	HR (95% CI) [d]	0.59 (0.32, 1.11)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	25 (30.9%)	21 (29.2%)
	The number (%) of patients censored [a]	56 (69.1%)	51 (70.8%)
	Median time to event (95% CI) [b]	21.5 (7.0, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.802	
	HR (95% CI) [d]	1.08 (0.60, 1.94)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.182	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	28 (63.6%)	26 (50.0%)
	The number (%) of patients censored [a]	16 (36.4%)	26 (50.0%)
	Median time to event (95% CI) [b]	2.3 (1.3, 4.6)	5.0 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.167	
	HR (95% CI) [d]	1.46 (0.85, 2.49)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	42 (51.9%)	32 (44.4%)
	The number (%) of patients censored [a]	39 (48.1%)	40 (55.6%)
	Median time to event (95% CI) [b]	3.5 (1.7, 6.9)	6.5 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.312	
	HR (95% CI) [d]	1.27 (0.80, 2.01)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.791	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	16 (36.4%)	13 (25.0%)
	The number (%) of patients censored [a]	28 (63.6%)	39 (75.0%)
	Median time to event (95% CI) [b]	13.3 (6.9, NE)	NE (6.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.562	
	HR (95% CI) [d]	1.24 (0.59, 2.59)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	19 (23.5%)	24 (33.3%)
	The number (%) of patients censored [a]	62 (76.5%)	48 (66.7%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.227	
	HR (95% CI) [d]	0.69 (0.38, 1.26)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.176	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	4 (9.1%)	2 (3.8%)
	The number (%) of patients censored [a]	40 (90.9%)	50 (96.2%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.294	
	HR (95% CI) [d]	2.42 (0.44, 13.28)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	2 (2.5%)	3 (4.2%)
	The number (%) of patients censored [a]	79 (97.5%)	69 (95.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.937	
	HR (95% CI) [d]	0.93 (0.16, 5.58)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.451	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	20 (45.5%)	25 (48.1%)
	The number (%) of patients censored [a]	24 (54.5%)	27 (51.9%)
	Median time to event (95% CI) [b]	3.1 (1.5, 18.5)	3.9 (1.5, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.778	
	HR (95% CI) [d]	0.92 (0.51, 1.66)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	30 (37.0%)	30 (41.7%)
	The number (%) of patients censored [a]	51 (63.0%)	42 (58.3%)
	Median time to event (95% CI) [b]	7.0 (3.5, 12.2)	6.3 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.613	
	HR (95% CI) [d]	0.87 (0.52, 1.46)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.921	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	33 (75.0%)	32 (61.5%)
	The number (%) of patients censored [a]	11 (25.0%)	20 (38.5%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.3)	3.1 (1.7, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.008	
	HR (95% CI) [d]	1.97 (1.20, 3.25)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	58 (71.6%)	42 (58.3%)
	The number (%) of patients censored [a]	23 (28.4%)	30 (41.7%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.2)	2.7 (1.4, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.004	
	HR (95% CI) [d]	1.80 (1.21, 2.69)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.991	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	18 (40.9%)	18 (34.6%)
	The number (%) of patients censored [a]	26 (59.1%)	34 (65.4%)
	Median time to event (95% CI) [b]	17.1 (3.9, NE)	12.7 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.897	
	HR (95% CI) [d]	1.05 (0.54, 2.02)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	18 (22.2%)	17 (23.6%)
	The number (%) of patients censored [a]	63 (77.8%)	55 (76.4%)
	Median time to event (95% CI) [b]	24.7 (24.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.773	
	HR (95% CI) [d]	0.91 (0.47, 1.76)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.807	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	24 (54.5%)	28 (53.8%)
	The number (%) of patients censored [a]	20 (45.5%)	24 (46.2%)
	Median time to event (95% CI) [b]	4.0 (1.7, 13.3)	4.9 (3.1, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.794	
	HR (95% CI) [d]	0.93 (0.54, 1.60)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	38 (46.9%)	41 (56.9%)
	The number (%) of patients censored [a]	43 (53.1%)	31 (43.1%)
	Median time to event (95% CI) [b]	6.9 (4.1, 15.5)	3.5 (2.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.055	
	HR (95% CI) [d]	0.65 (0.41, 1.01)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.10.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.337	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.10.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	6 (13.6%)	6 (11.5%)
	The number (%) of patients censored [a]	38 (86.4%)	46 (88.5%)
	Median time to event (95% CI) [b]	1.2 (0.1, NE)	0.8 (0.7, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.318	
	HR (95% CI) [d]	0.55 (0.18, 1.75)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	7 (8.6%)	7 (9.7%)
	The number (%) of patients censored [a]	74 (91.4%)	65 (90.3%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	3.2 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.451	
	HR (95% CI) [d]	1.46 (0.51, 4.20)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.10.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.181	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

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Table 7.3.10.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	13 (29.5%)	19 (36.5%)
	The number (%) of patients censored [a]	31 (70.5%)	33 (63.5%)
	Median time to event (95% CI) [b]	NE (9.1, NE)	NE (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.309	
	HR (95% CI) [d]	0.69 (0.34, 1.41)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	30 (37.0%)	25 (34.7%)
	The number (%) of patients censored [a]	51 (63.0%)	47 (65.3%)
	Median time to event (95% CI) [b]	9.8 (5.1, NE)	13.0 (10.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.644	
	HR (95% CI) [d]	1.14 (0.67, 1.94)	
	P-value of subgroup*treatment interaction [e]	0.221	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
Data Source: ADSL ADQS ADRBC ADEX

Table 7.3.10.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	16 (36.4%)	18 (34.6%)
	The number (%) of patients censored [a]	28 (63.6%)	34 (65.4%)
	Median time to event (95% CI) [b]	11.8 (6.4, NE)	15.9 (9.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.823	
	HR (95% CI) [d]	0.92 (0.47, 1.81)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	34 (42.0%)	30 (41.7%)
	The number (%) of patients censored [a]	47 (58.0%)	42 (58.3%)
	Median time to event (95% CI) [b]	7.0 (2.8, NE)	16.1 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.528	
	HR (95% CI) [d]	1.17 (0.72, 1.91)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.3.10.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.614	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.5
Time to First Meaningful Deterioration for PGIC by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	9 (20.5%)	12 (23.1%)
	The number (%) of patients censored [a]	35 (79.5%)	40 (76.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	0.78 (0.33, 1.85)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	16 (19.8%)	17 (23.6%)
	The number (%) of patients censored [a]	65 (80.2%)	55 (76.4%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.852	
	HR (95% CI) [d]	0.94 (0.47, 1.86)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.5
Time to First Meaningful Deterioration for PGIC by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.948	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.6
Time to First Meaningful Deterioration for PGIS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	44	52
	The number (%) of patients with an event [a]	5 (11.4%)	3 (5.8%)
	The number (%) of patients censored [a]	39 (88.6%)	49 (94.2%)
	Median time to event (95% CI) [b]	6.3 (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.592	
	HR (95% CI) [d]	1.48 (0.35, 6.18)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel	81	72
	The number (%) of patients with an event [a]	6 (7.4%)	5 (6.9%)
	The number (%) of patients censored [a]	75 (92.6%)	67 (93.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.948	
	HR (95% CI) [d]	1.04 (0.32, 3.42)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.3.10.6
Time to First Meaningful Deterioration for PGIS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

Subgroup	Parameter	SG (N=125)	TPC (N=124)
	P-value of subgroup*treatment interaction [e]	0.736	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Figure 1.3.1.1
Observed Mean Change from Baseline in EORTC QLQ-C30 Global Health Status/QoL by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

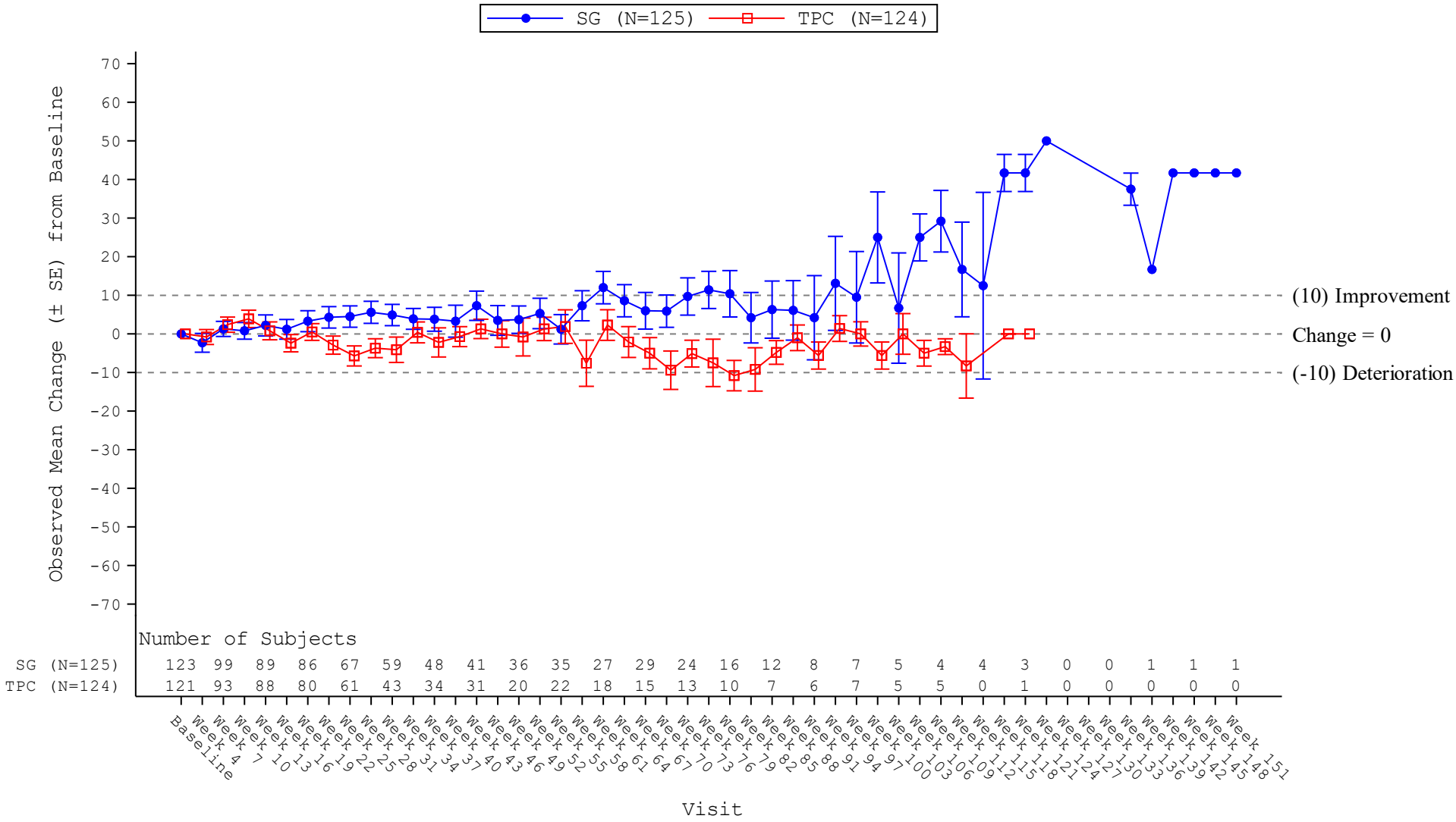


Figure 1.3.1.2
Observed Mean Change from Baseline in EORTC QLQ-C30 Physical Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

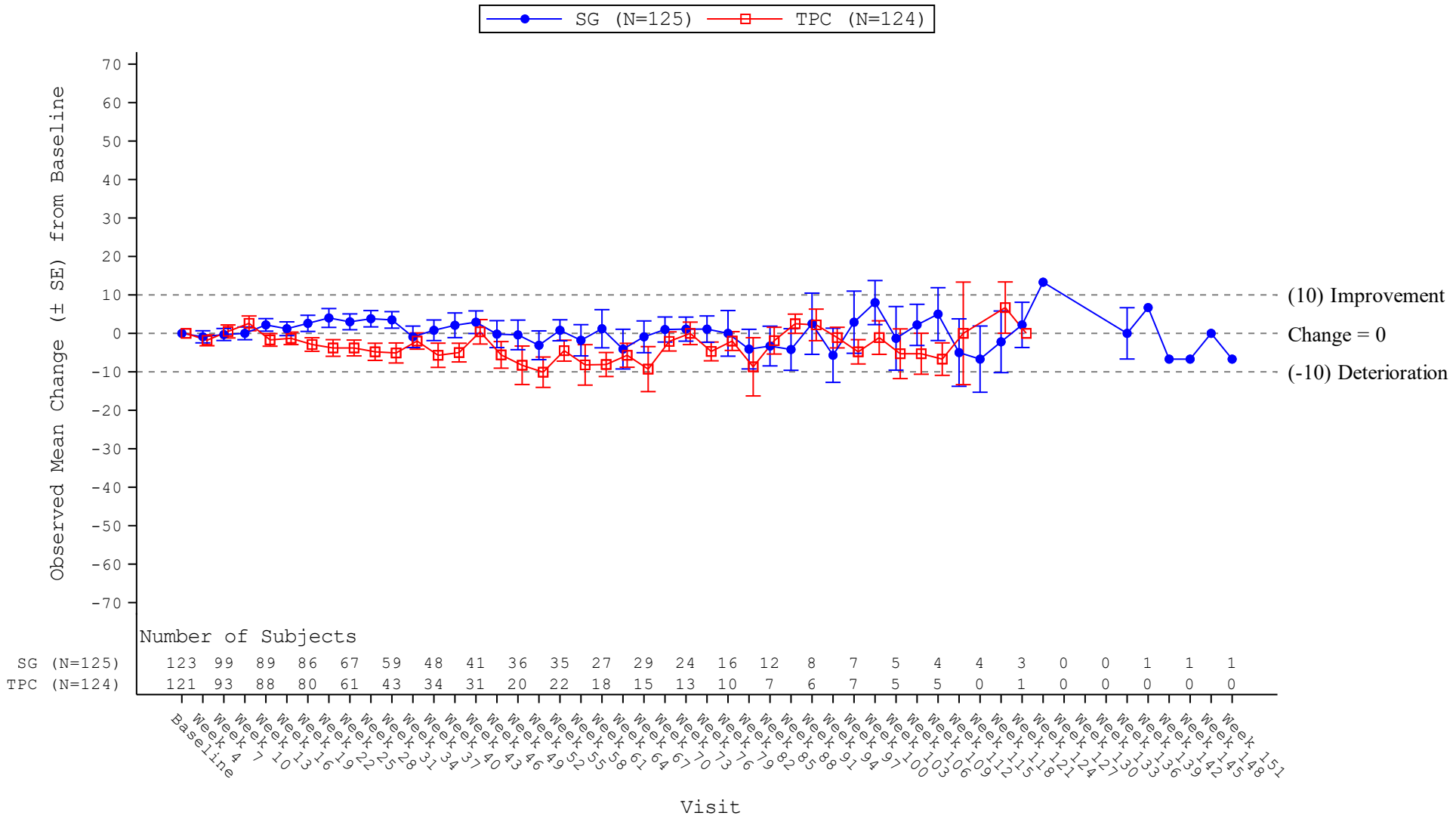


Figure 1.3.1.3
Observed Mean Change from Baseline in EORTC QLQ-C30 Role Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

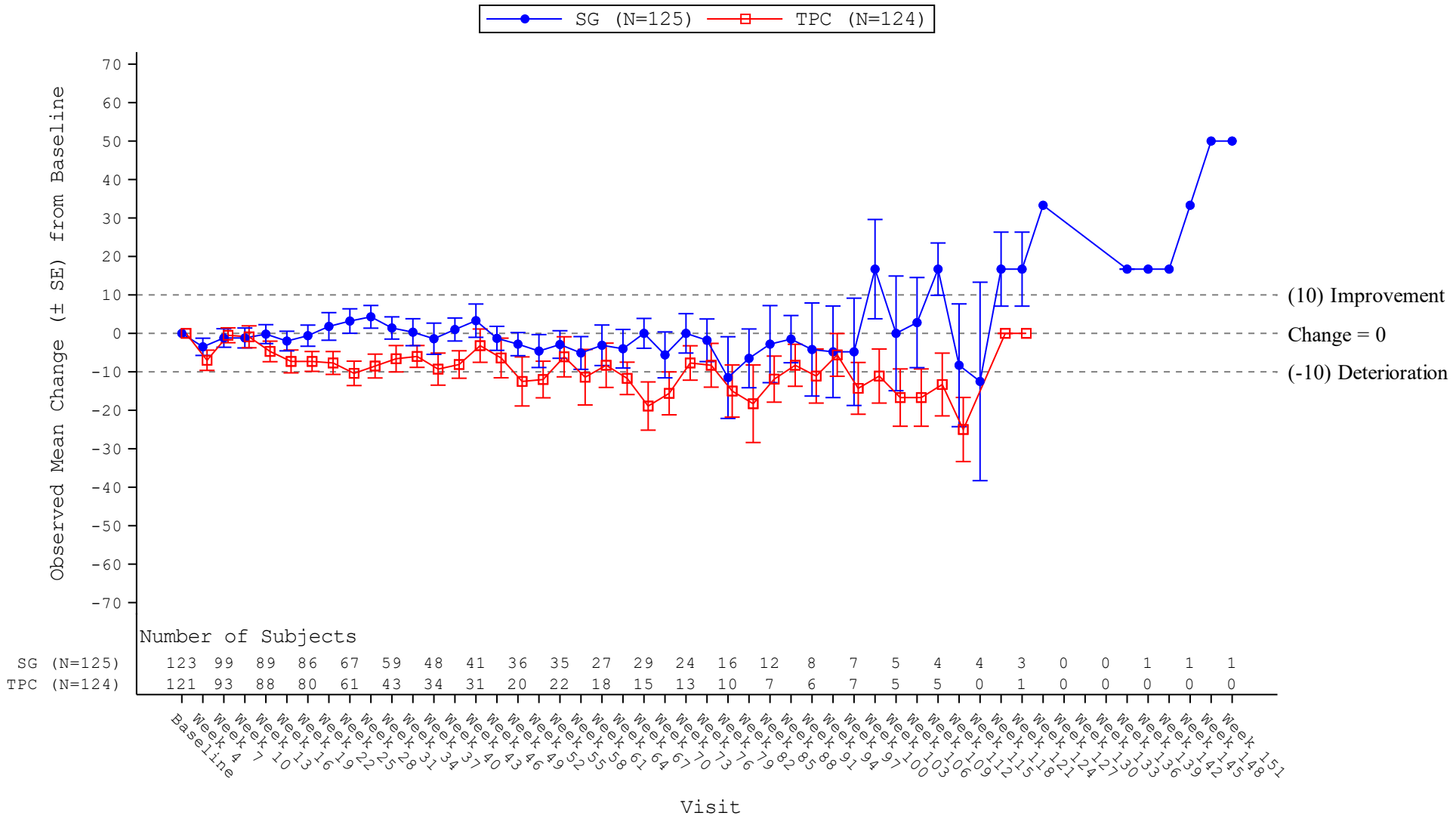


Figure 1.3.1.4
Observed Mean Change from Baseline in EORTC QLQ-C30 Emotional Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

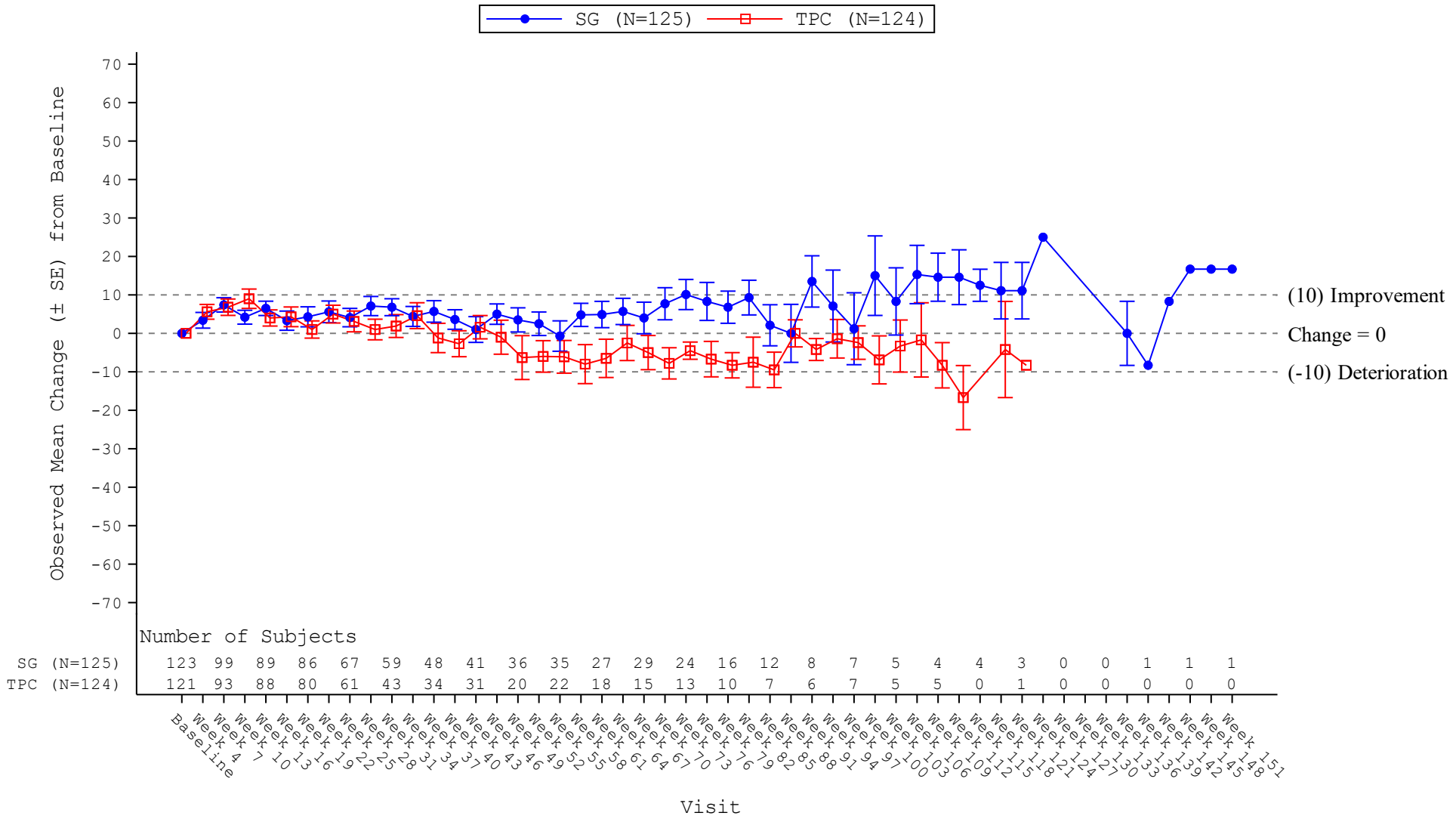


Figure 1.3.1.5
Observed Mean Change from Baseline in EORTC QLQ-C30 Cognitive Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

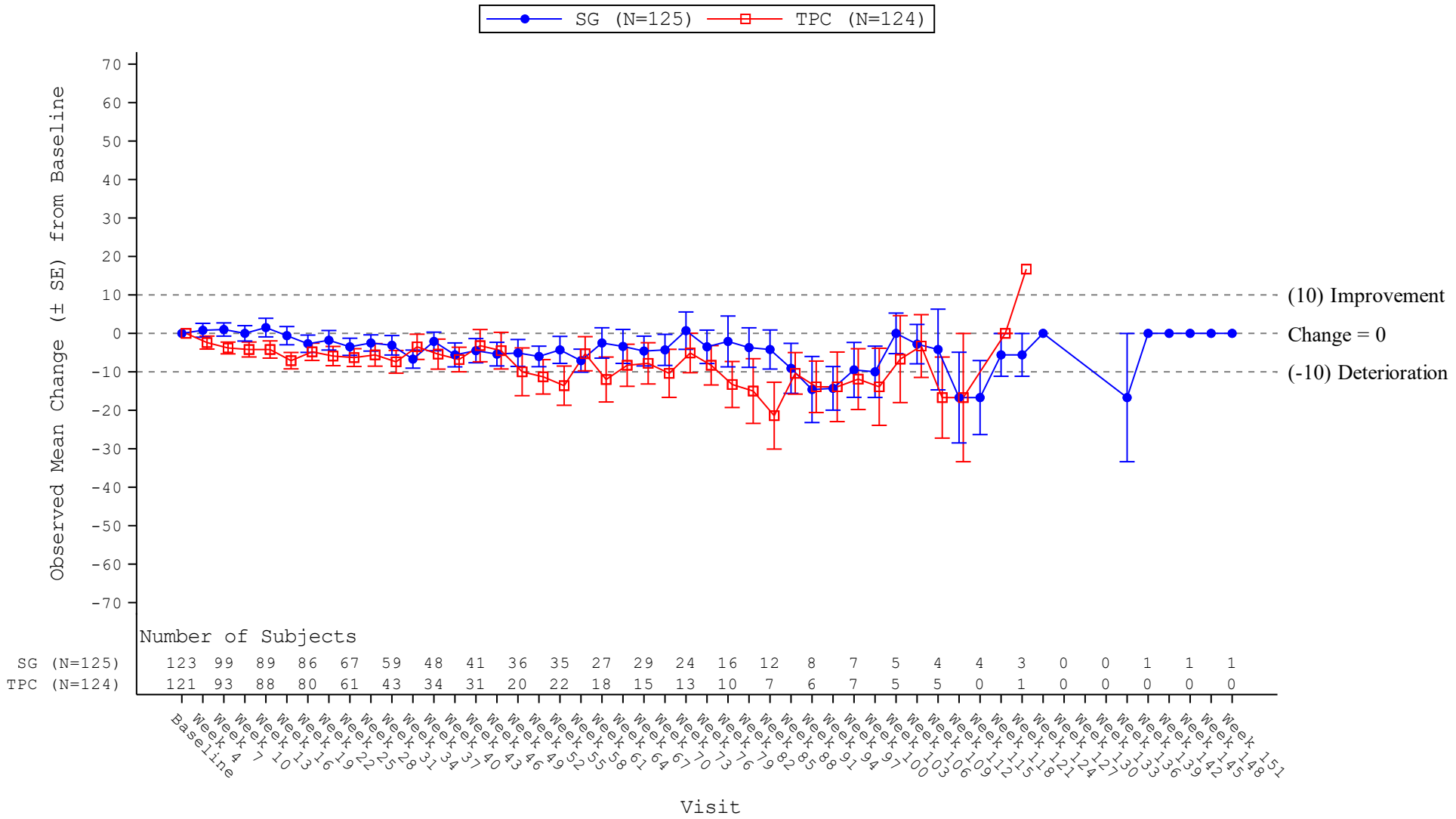


Figure 1.3.1.6
Observed Mean Change from Baseline in EORTC QLQ-C30 Social Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

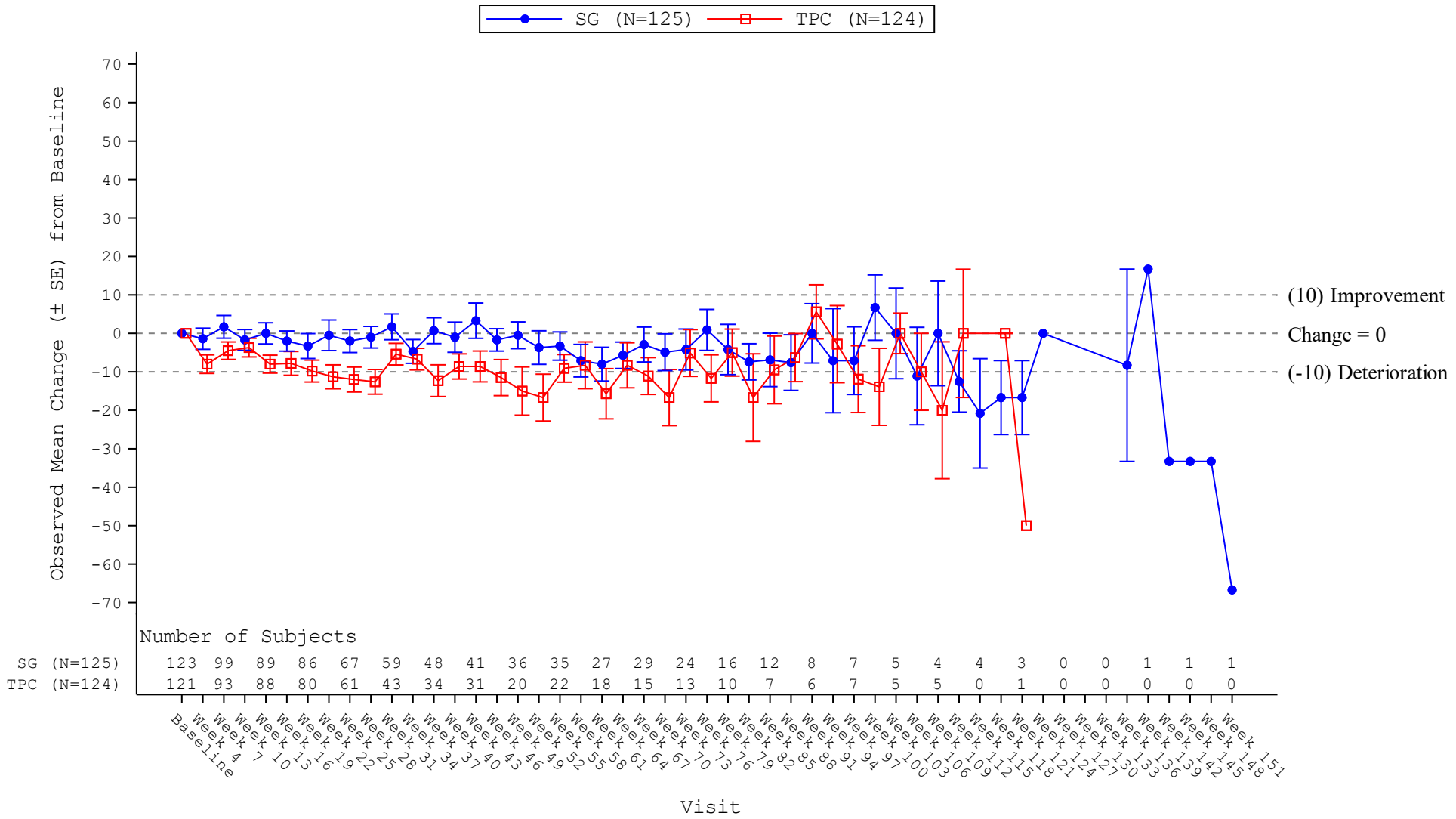


Figure 1.3.1.7
Observed Mean Change from Baseline in EORTC QLQ-C30 Fatigue by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

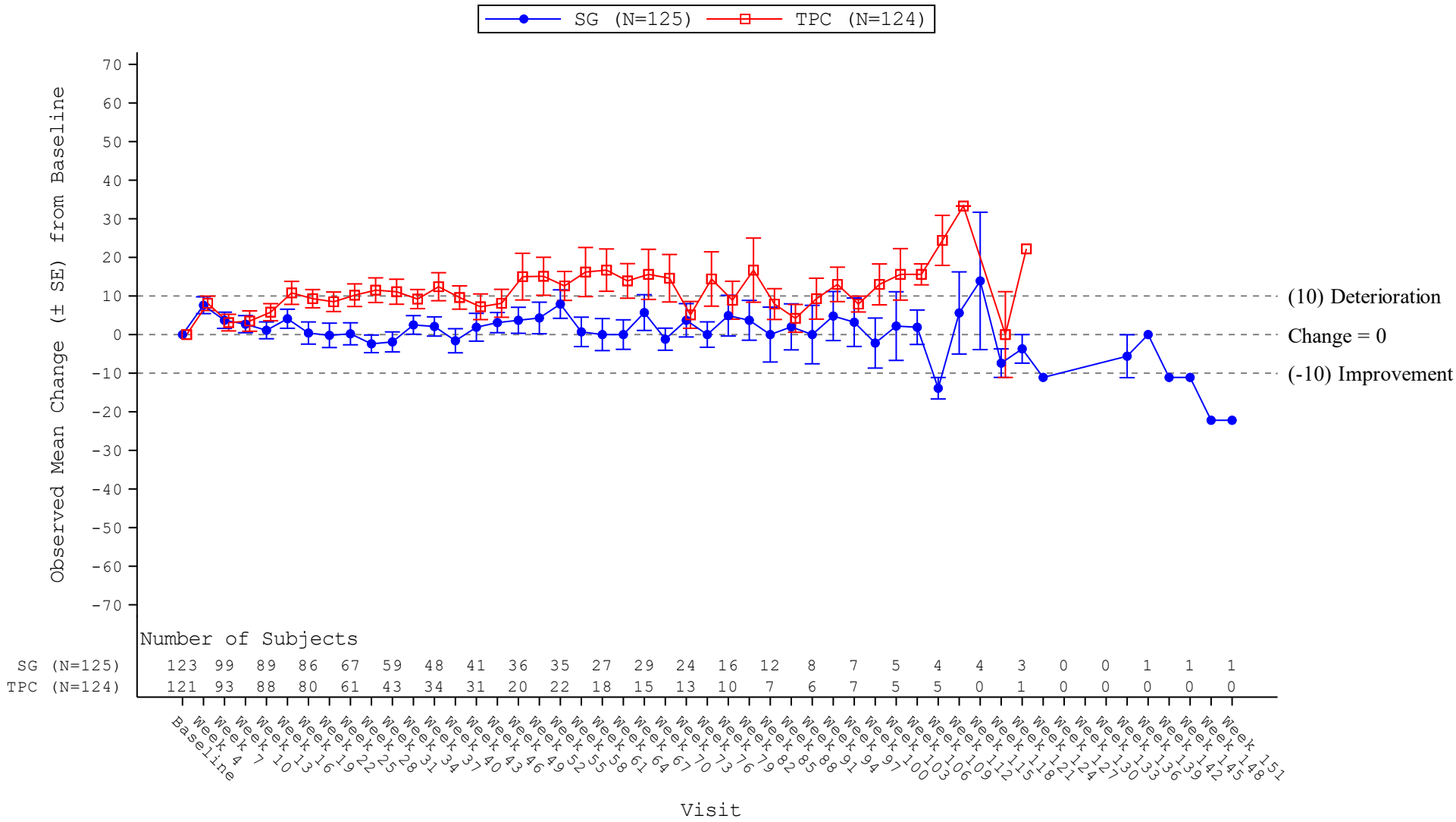


Figure 1.3.1.8
Observed Mean Change from Baseline in EORTC QLQ-C30 Nausea and Vomiting by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

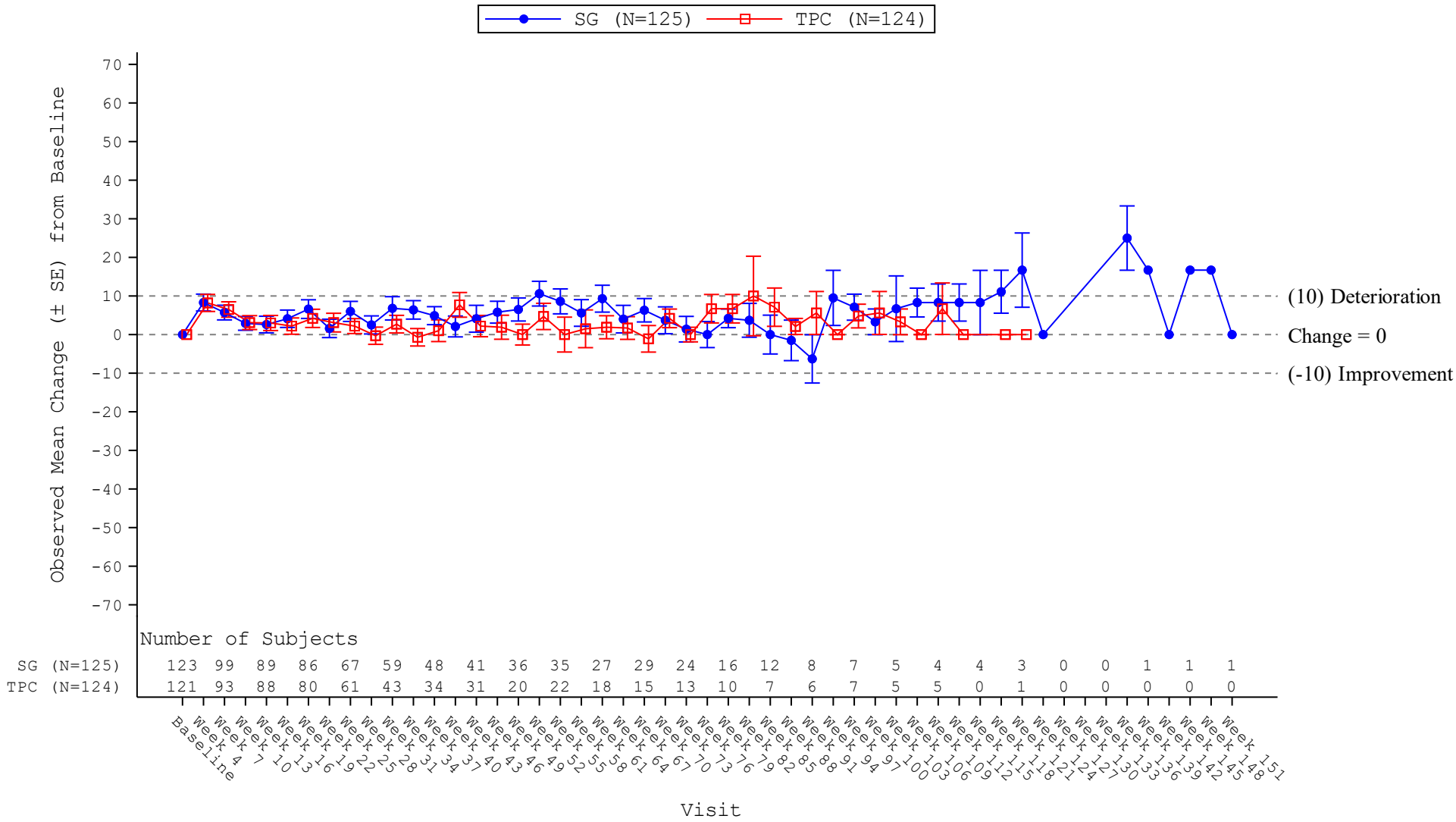


Figure 1.3.1.9
Observed Mean Change from Baseline in EORTC QLQ-C30 Pain by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

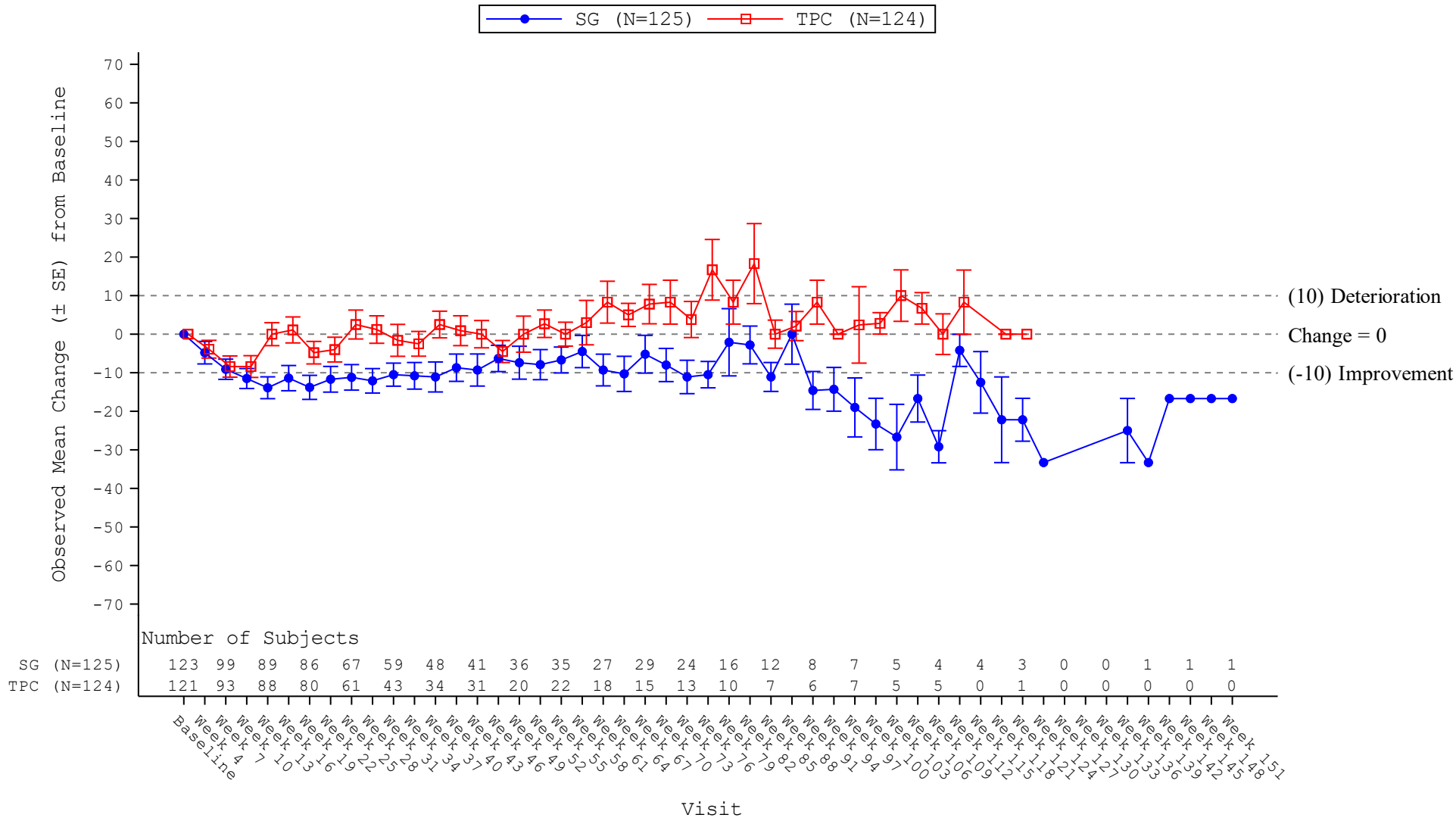


Figure 1.3.1.10
Observed Mean Change from Baseline in EORTC QLQ-C30 Dyspnea by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

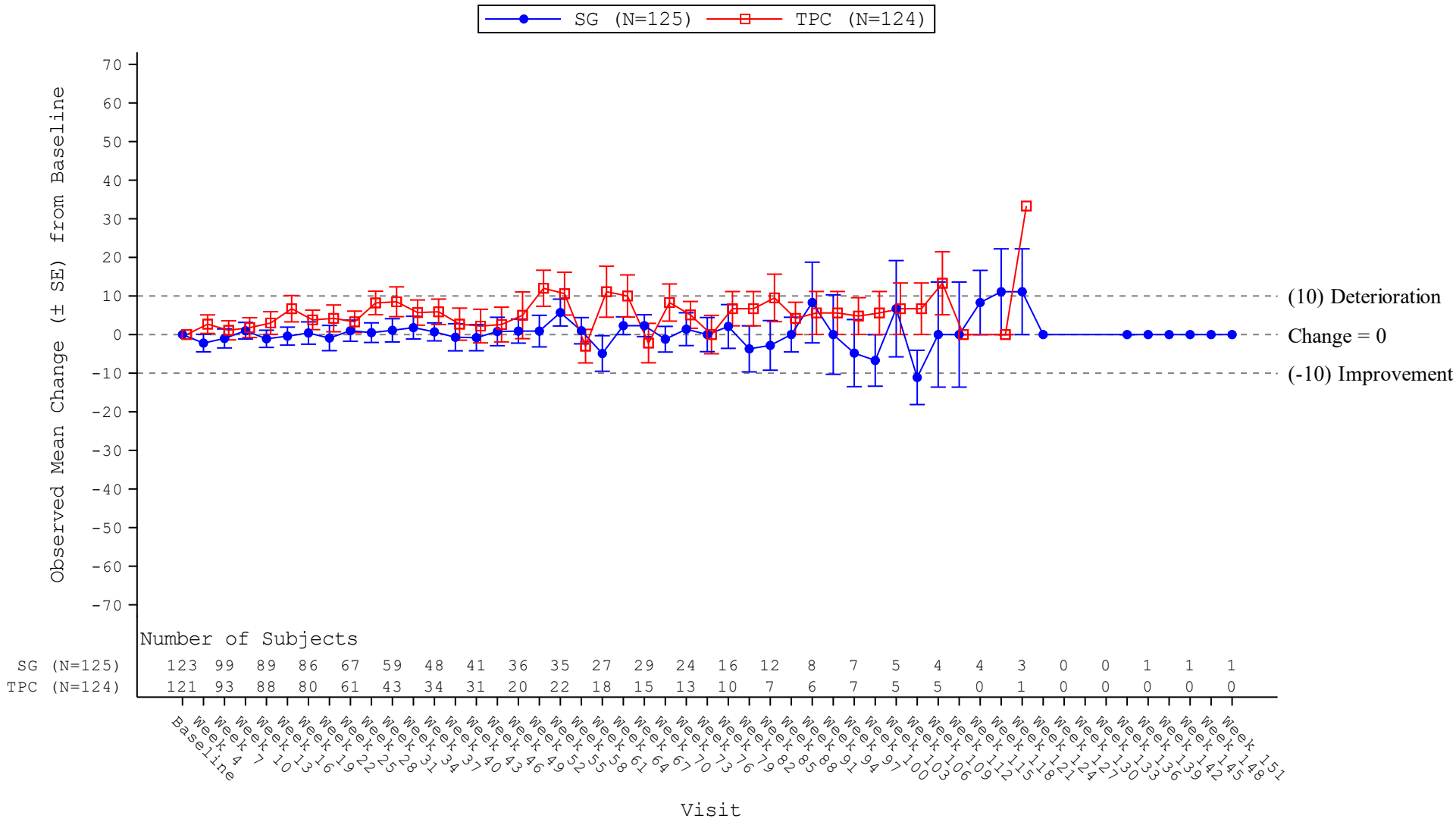


Figure 1.3.1.11
Observed Mean Change from Baseline in EORTC QLQ-C30 Insomnia by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

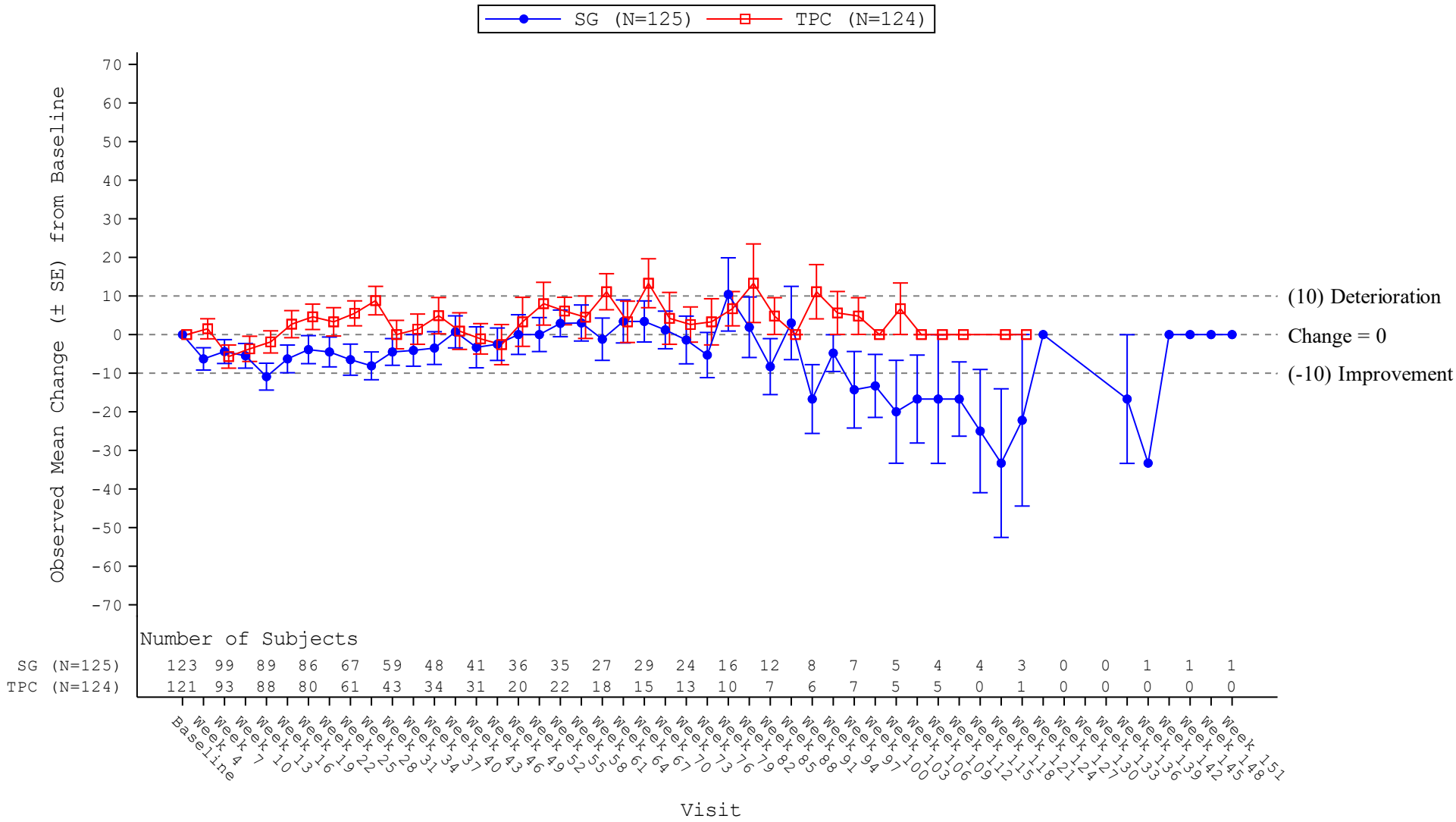


Figure 1.3.1.12
Observed Mean Change from Baseline in EORTC QLQ-C30 Appetite Loss by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

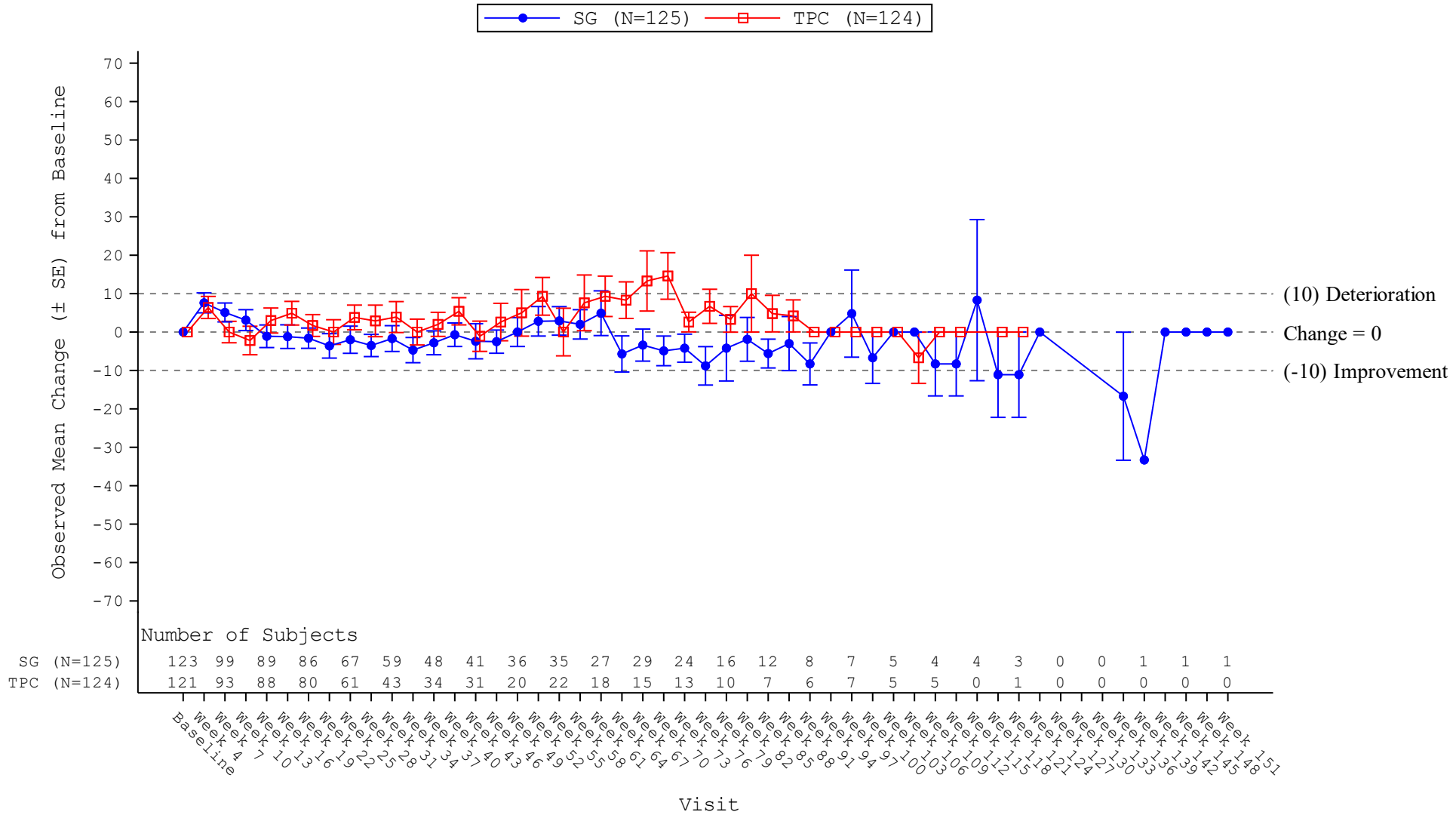

SG (N=125)
TPC (N=124)
Observed Mean Change (± SE) from Baseline
70
60
50
40
30
20
10
0
-10
-20
-30
-40
-50
-60
-70
(10) Deterioration
Change = 0
(-10) Improvement
Number of Subjects
SG (N=125) 123 99 89 86 67 59 48 41 36 35 27 29 24 16 12 8 7 5 4 4 3 0 0 1 1 1
TPC (N=124) 121 93 88 80 61 43 34 31 20 22 18 15 13 10 7 6 7 5 5 0 1 0 0 0 0 0
Baseline
week 4
week 7
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Figure 1.3.1.13
Observed Mean Change from Baseline in EORTC QLQ-C30 Constipation by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

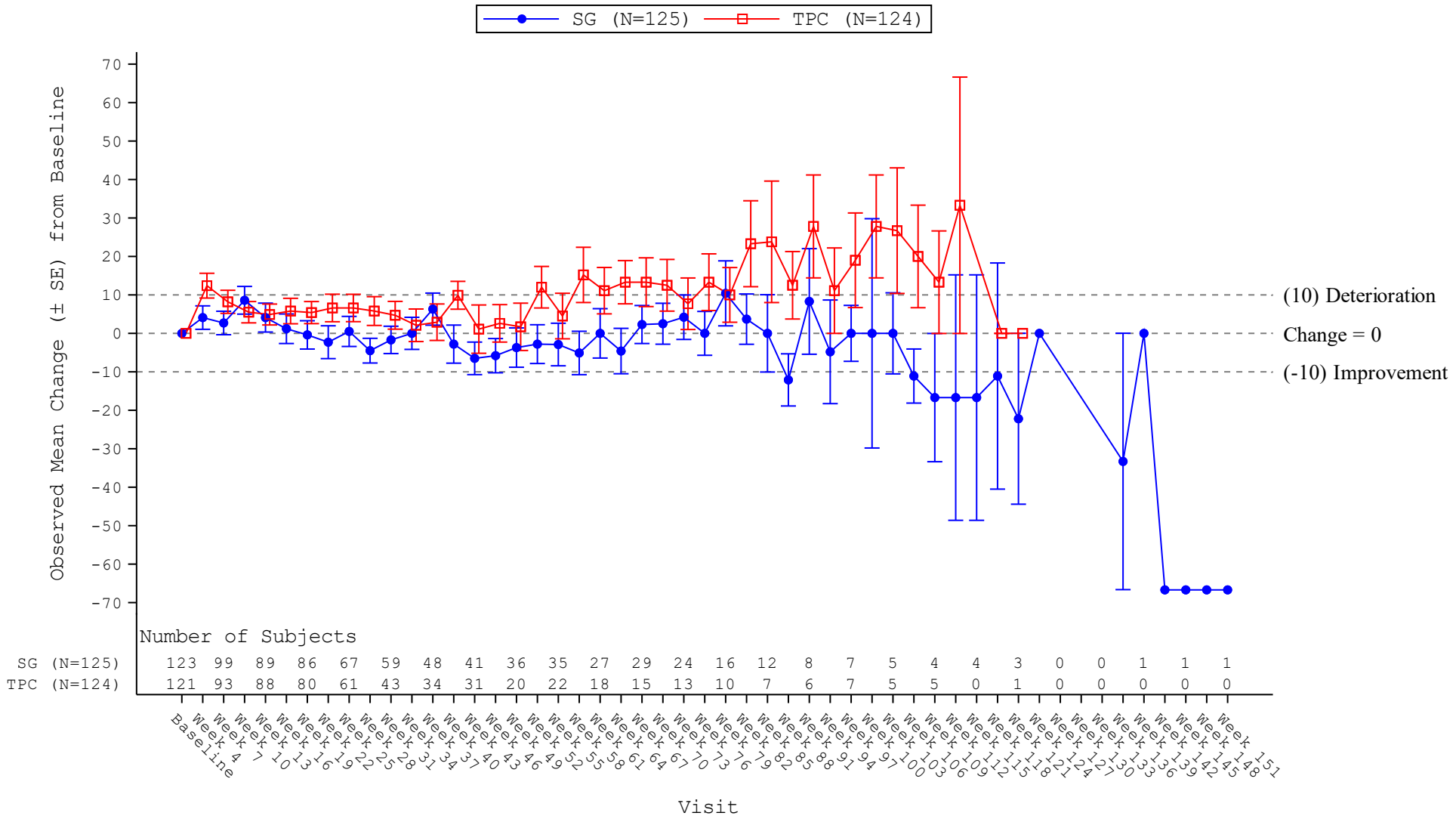


Figure 1.3.1.14
Observed Mean Change from Baseline in EORTC QLQ-C30 Diarrhea by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

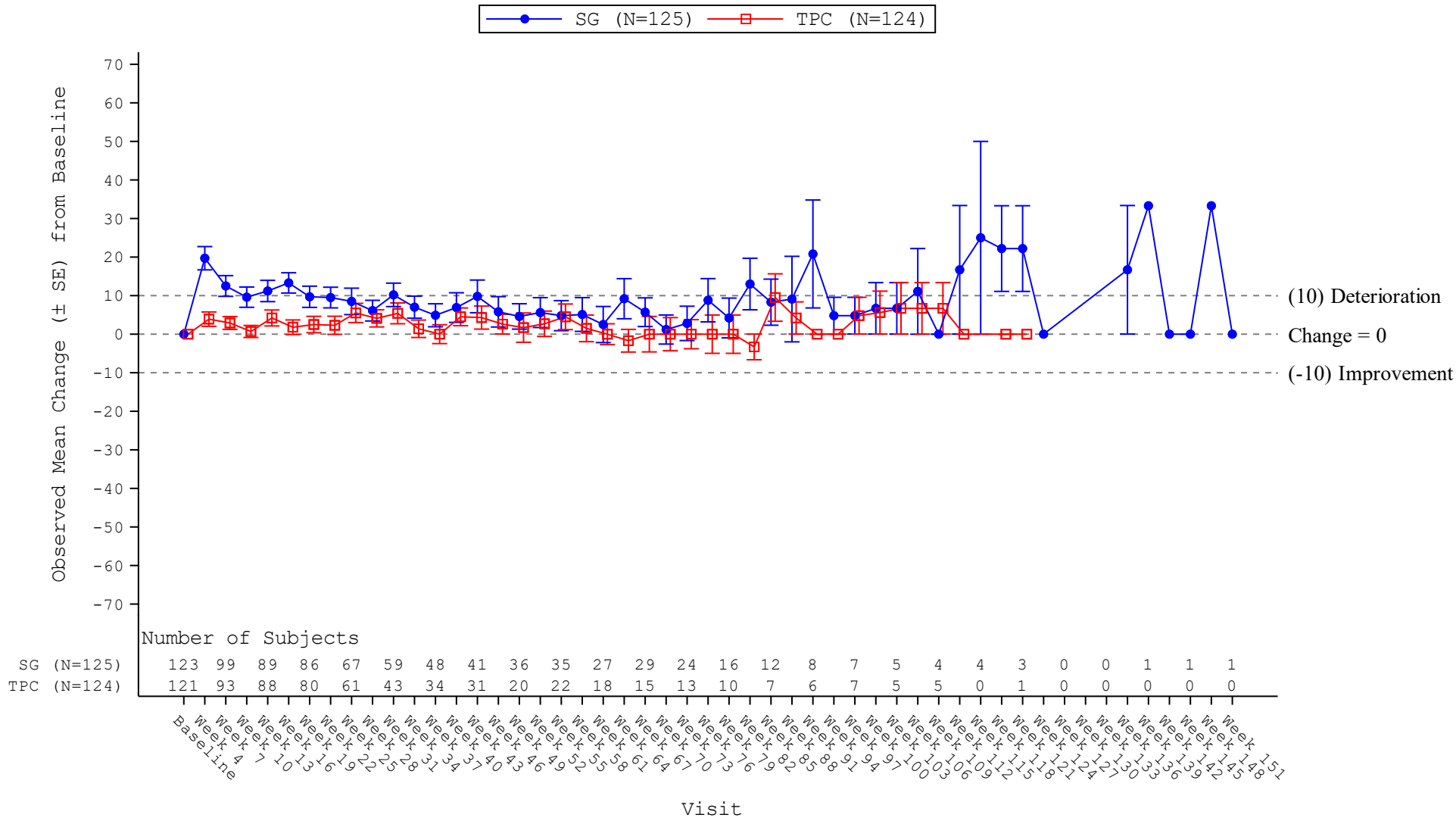


Figure 1.3.1.15
Observed Mean Change from Baseline in EORTC QLQ-C30 Financial Difficulties by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

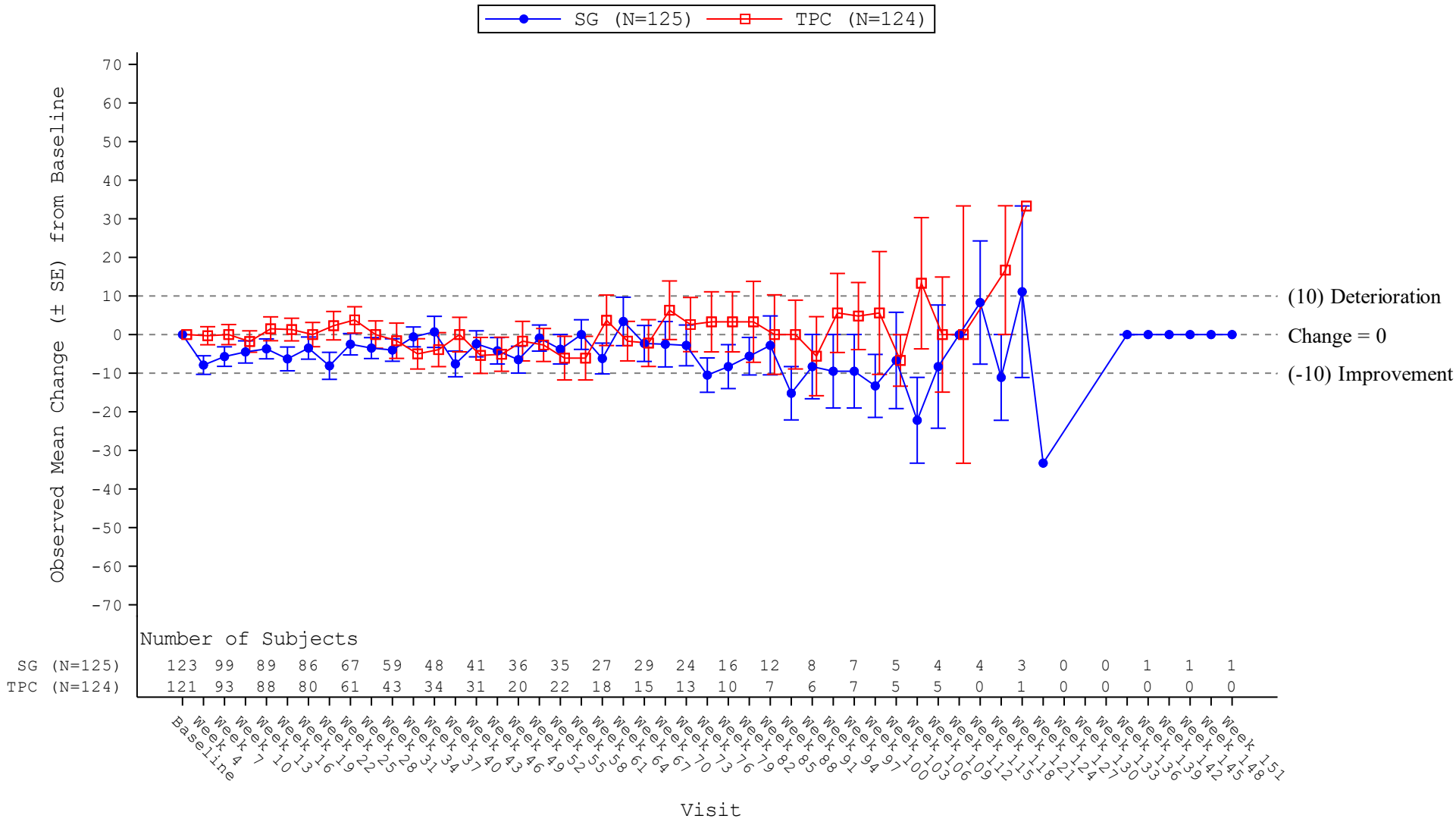


Figure 1.3.2.1
Observed Mean Change from Baseline in EORTC QLQ-BR23 Body Image by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

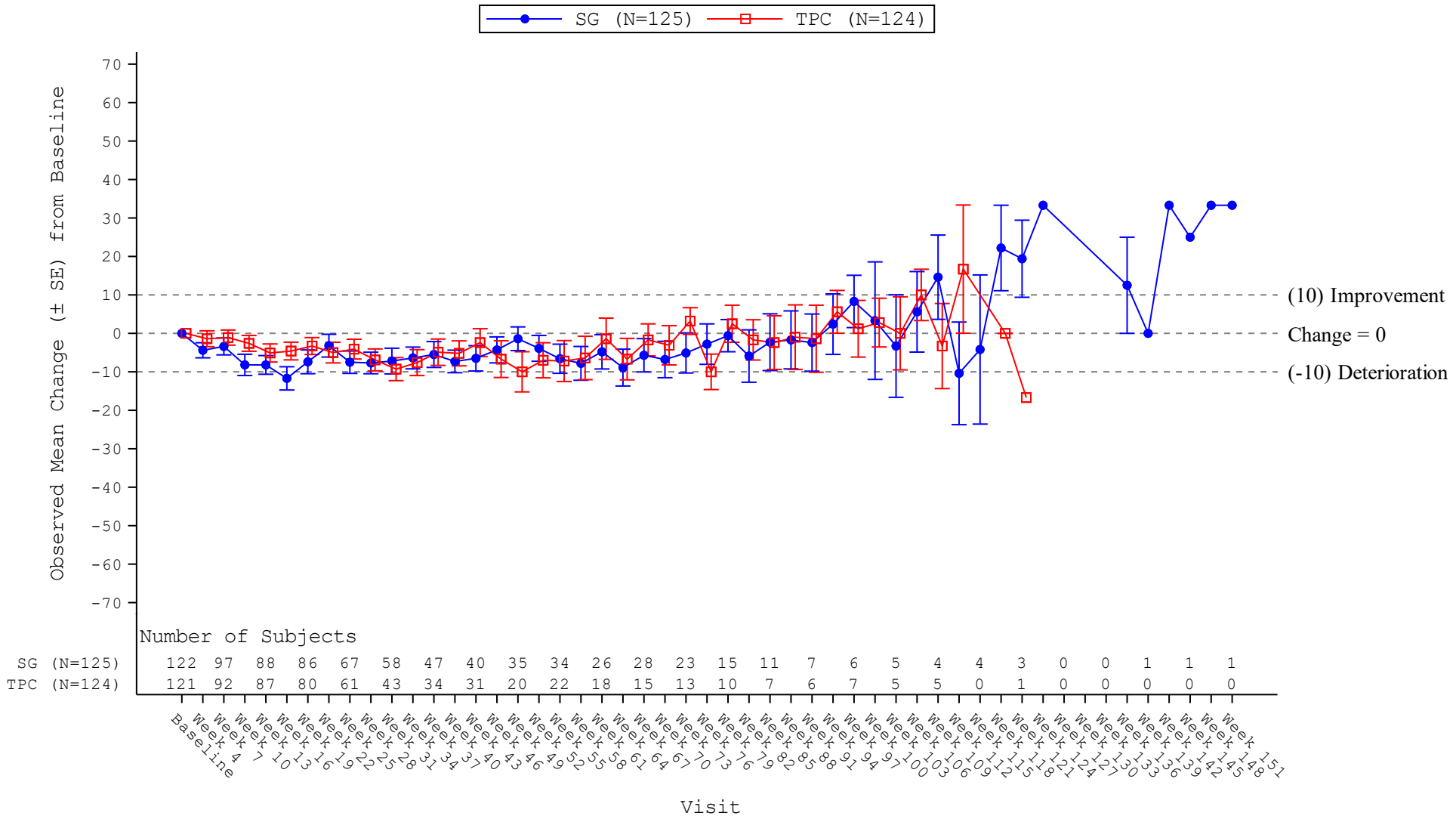


Figure 1.3.2.2
Observed Mean Change from Baseline in EORTC QLQ-BR23 Sexual Function by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

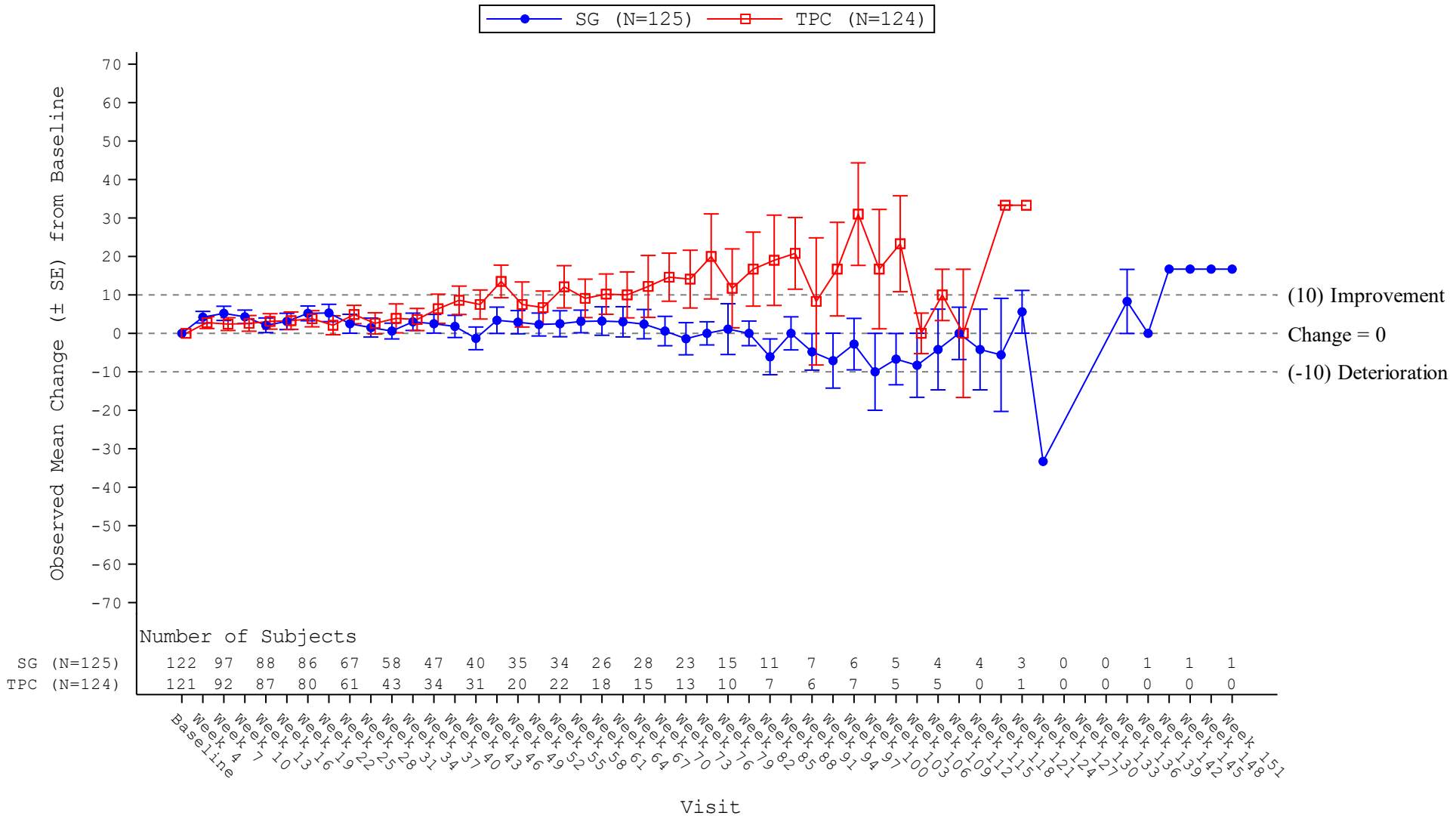


Figure 1.3.2.3
Observed Mean Change from Baseline in EORTC QLQ-BR23 Sexual Enjoyment by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

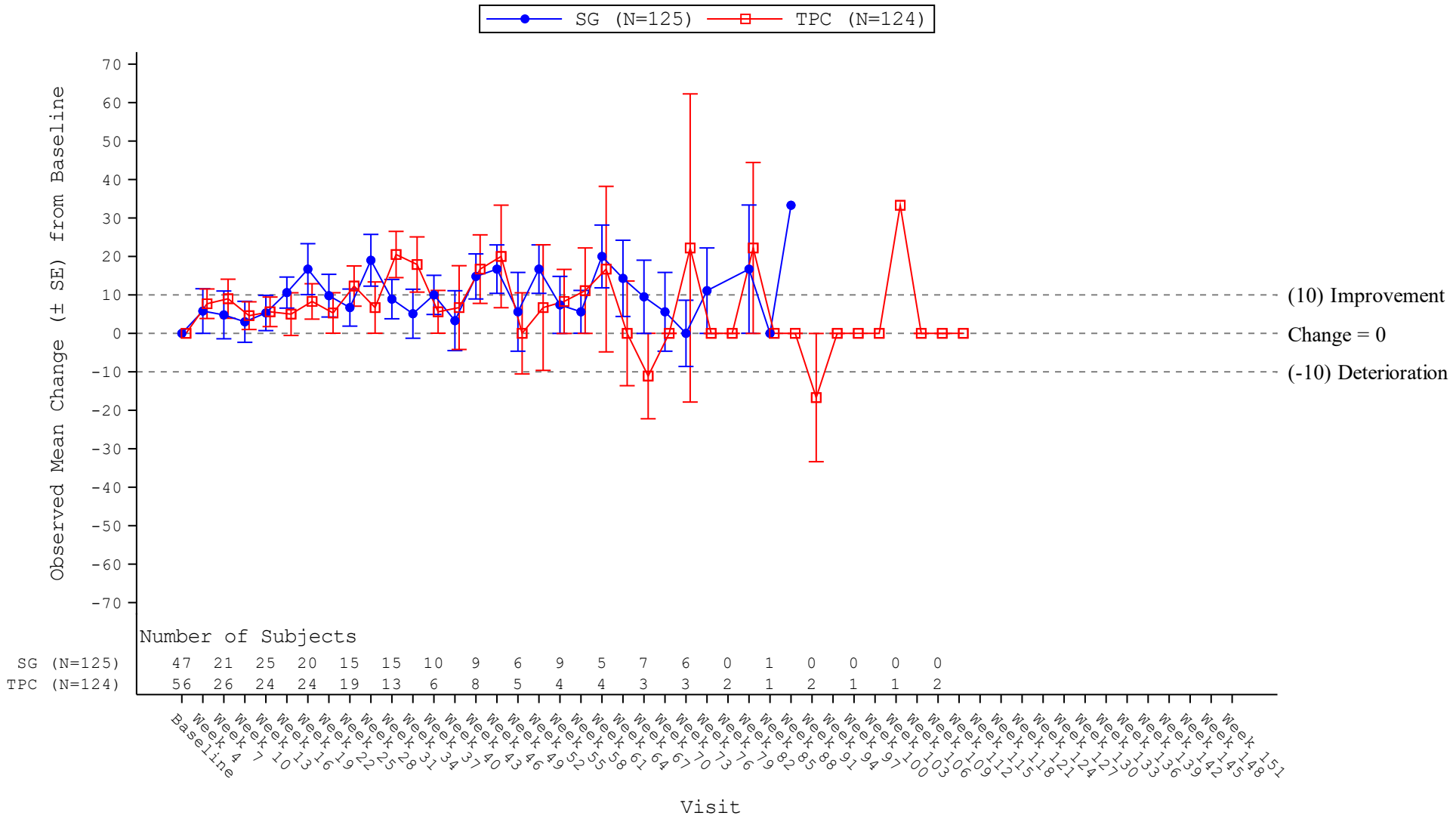


Figure 1.3.2.4
Observed Mean Change from Baseline in EORTC QLQ-BR23 Future Perspective by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

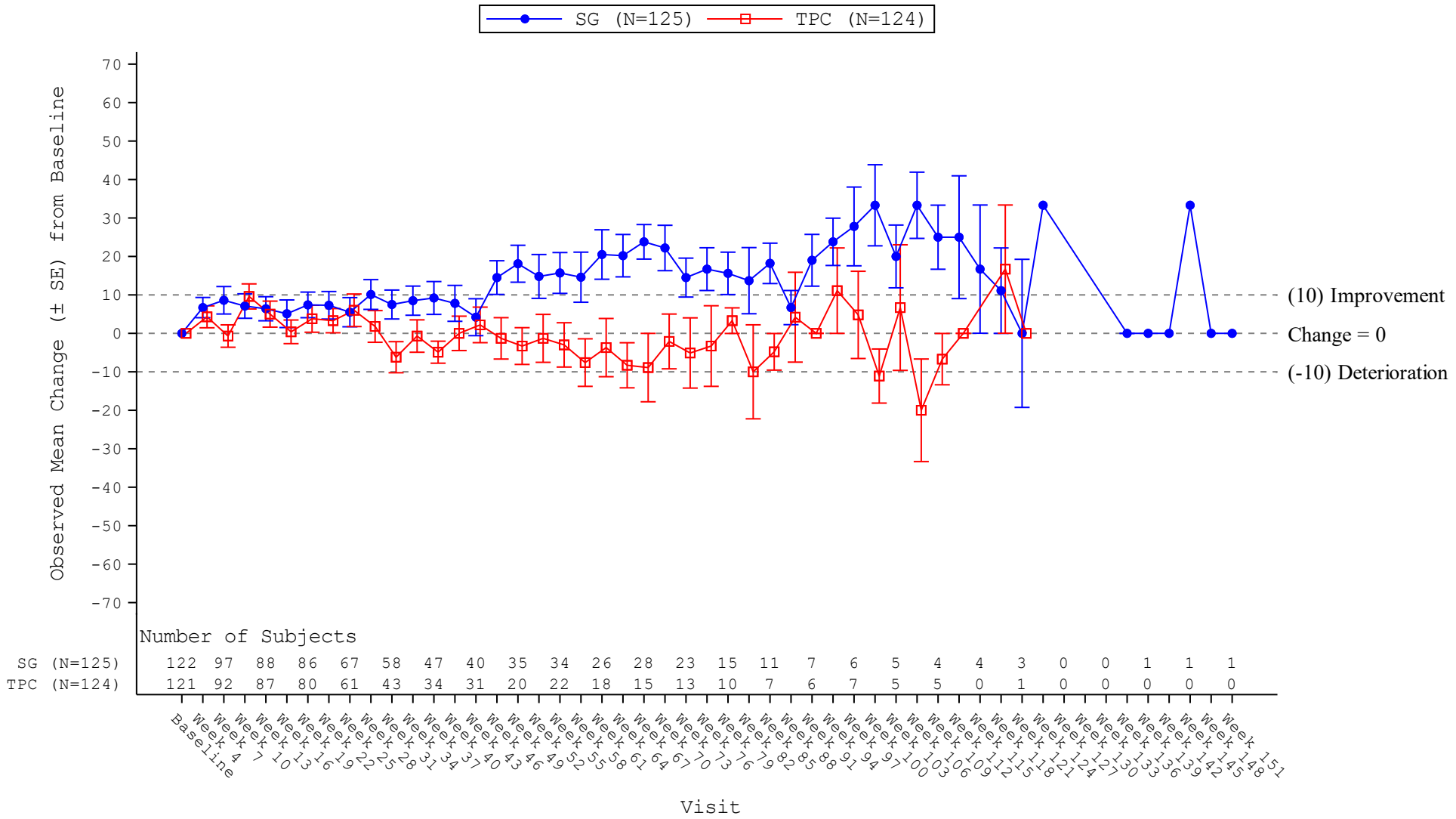


Figure 1.3.2.5
Observed Mean Change from Baseline in EORTC QLQ-BR23 Systemic Therapy Side Effects by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

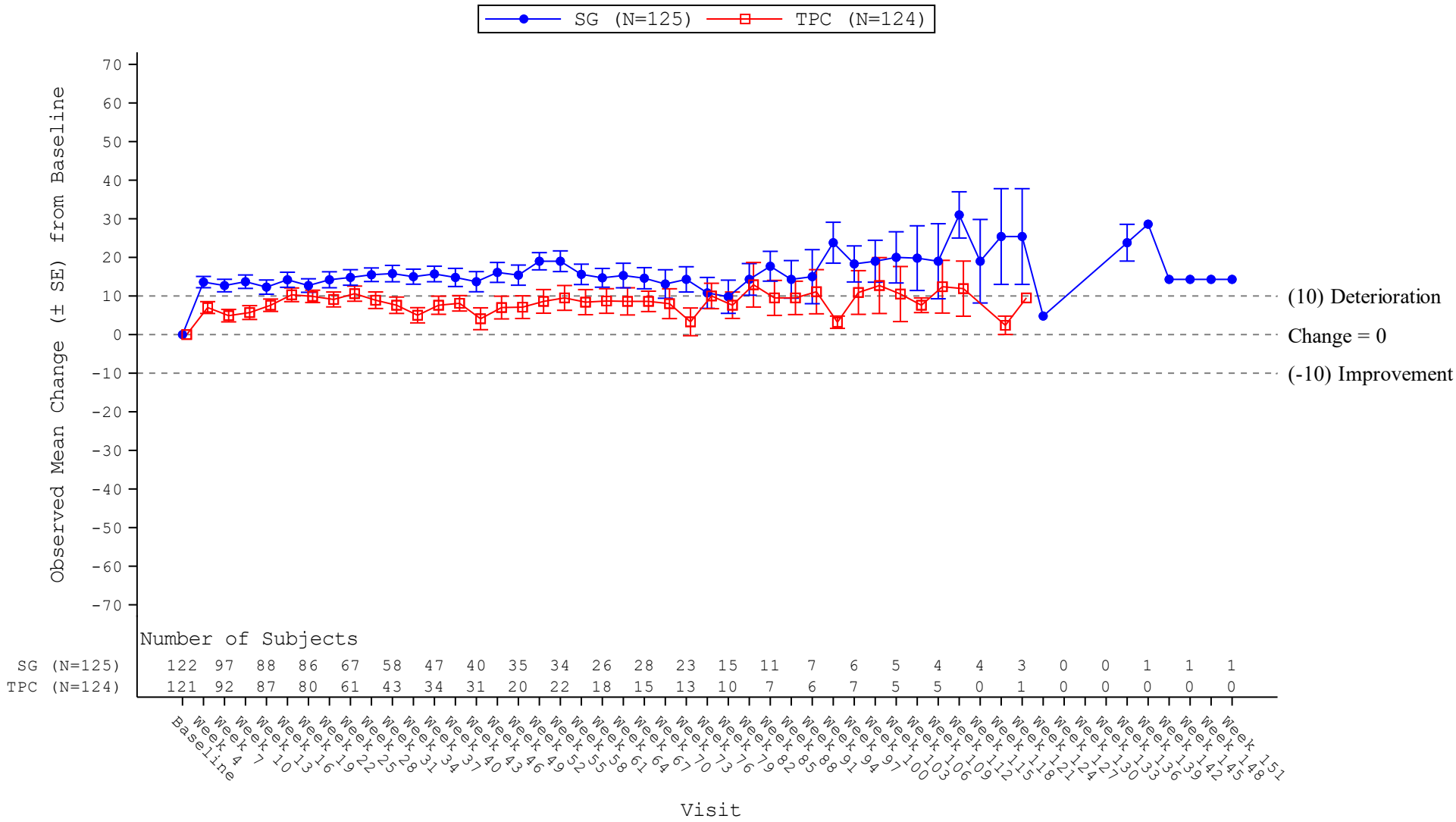


Figure 1.3.2.6
Observed Mean Change from Baseline in EORTC QLQ-BR23 Breast Symptoms by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

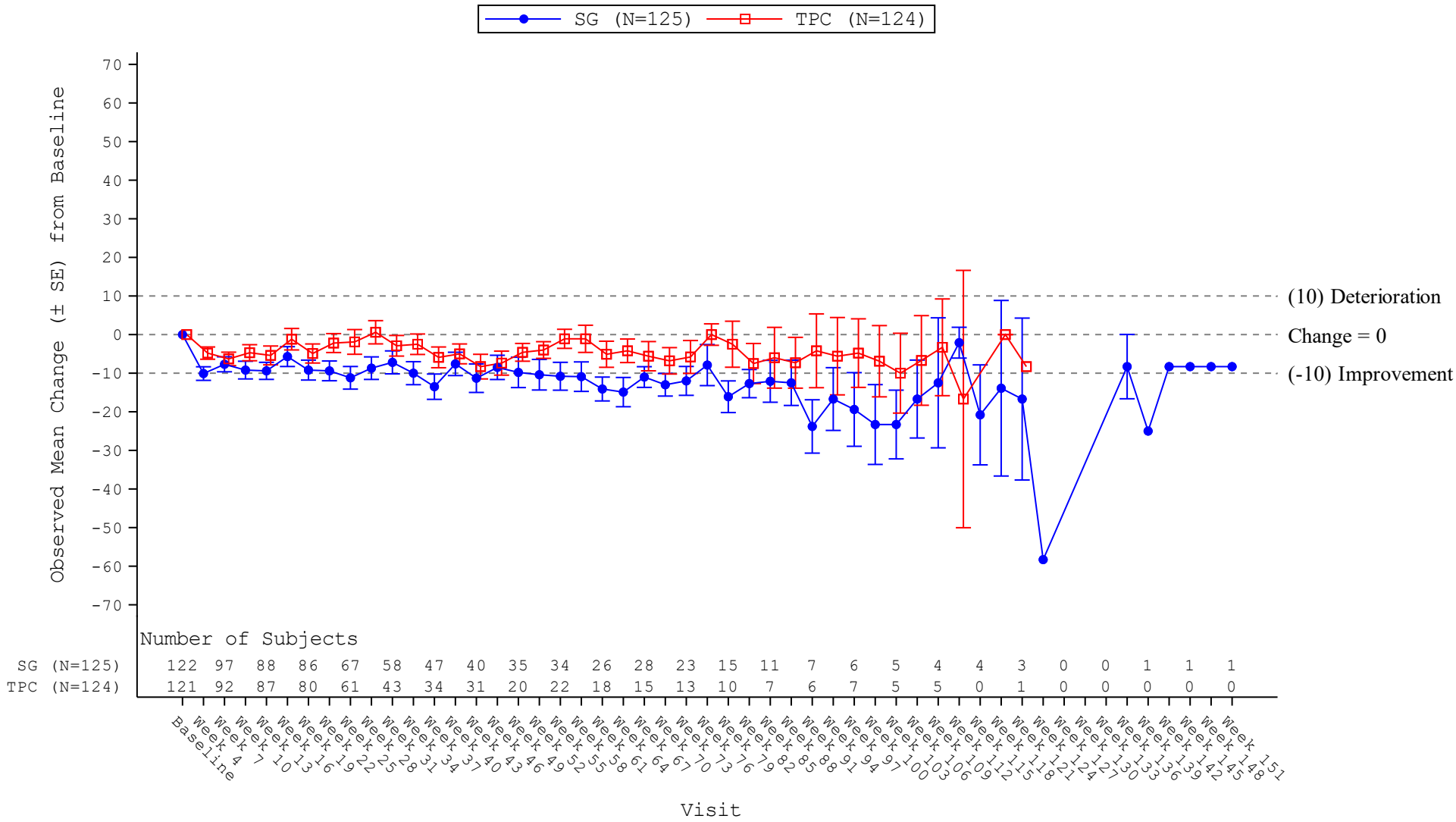


Figure 1.3.2.7
Observed Mean Change from Baseline in EORTC QLQ-BR23 Arm Symptoms by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

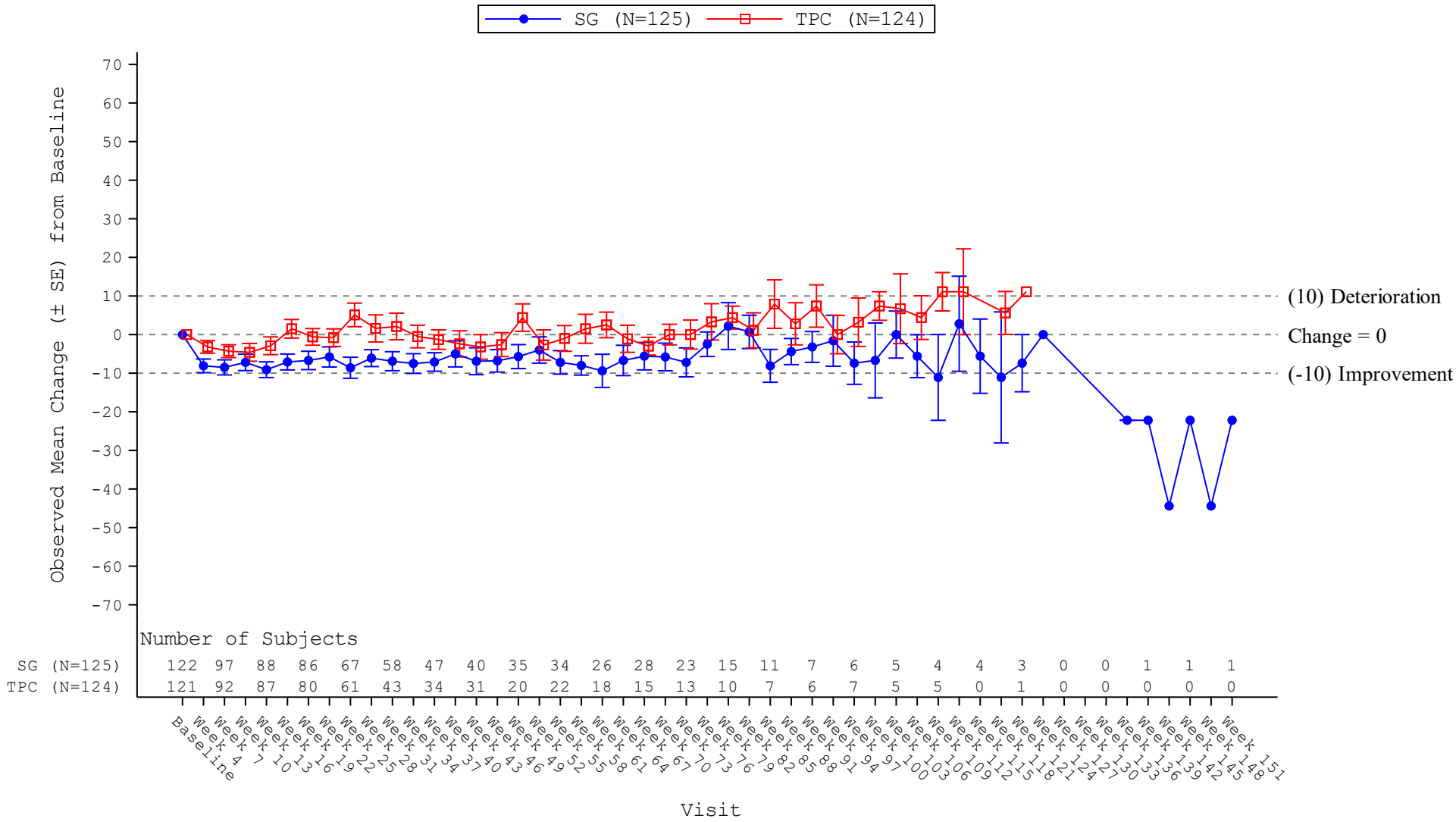


Figure 1.3.2.8
Observed Mean Change from Baseline in EORTC QLQ-BR23 Upset by Hair Loss by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

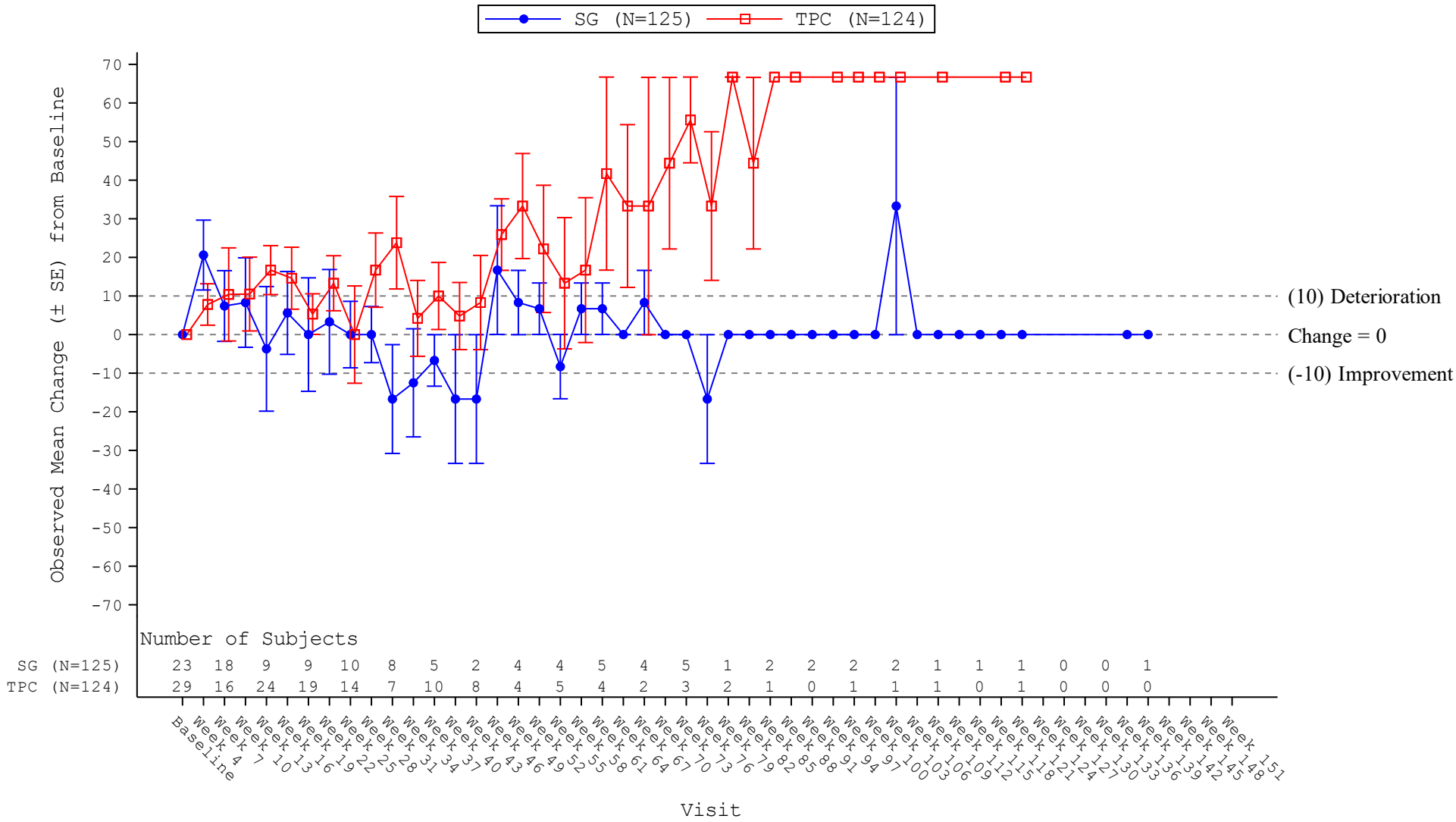


Figure 1.3.3
Observed Mean Change from Baseline in EQ-VAS by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)

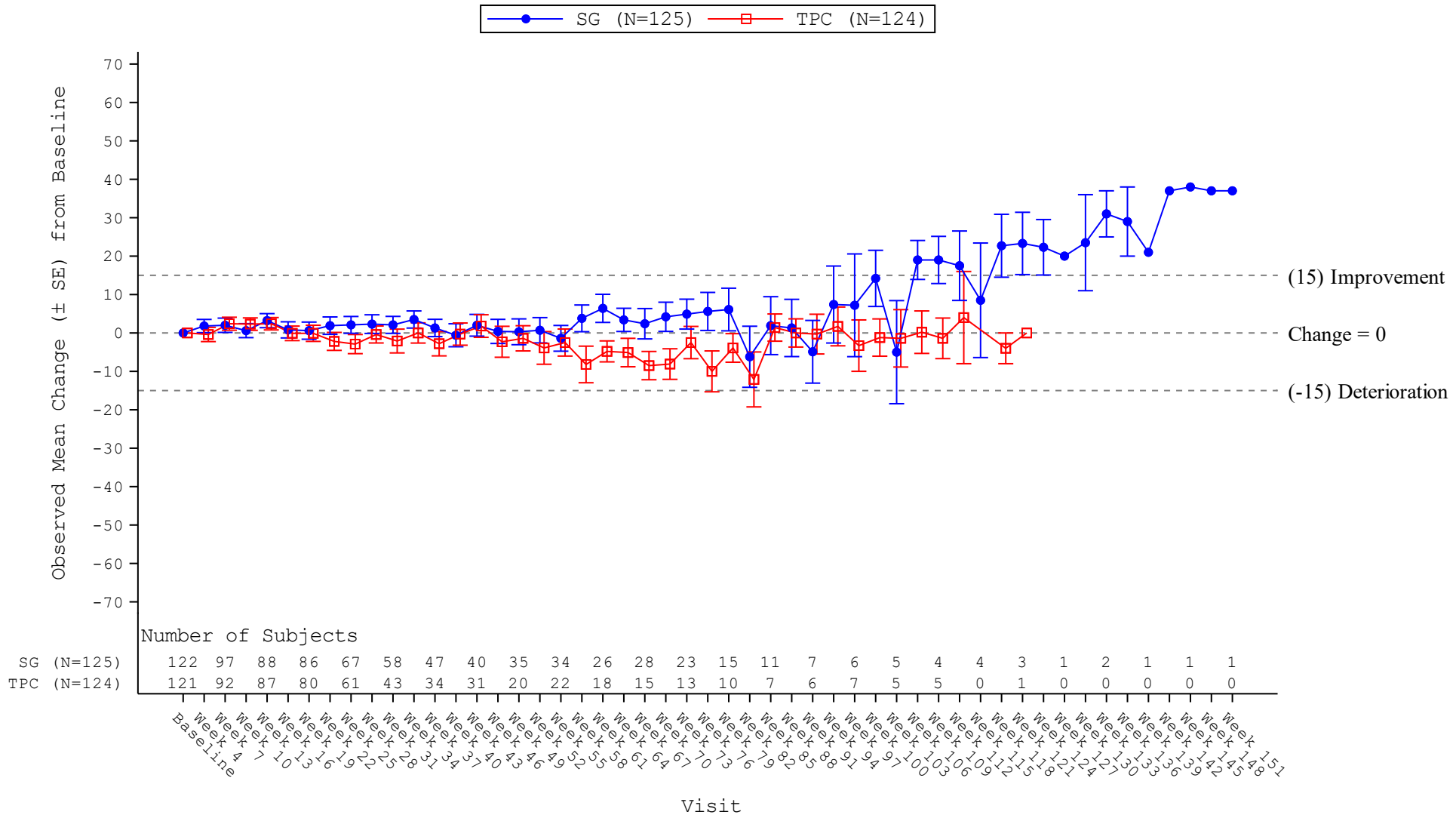
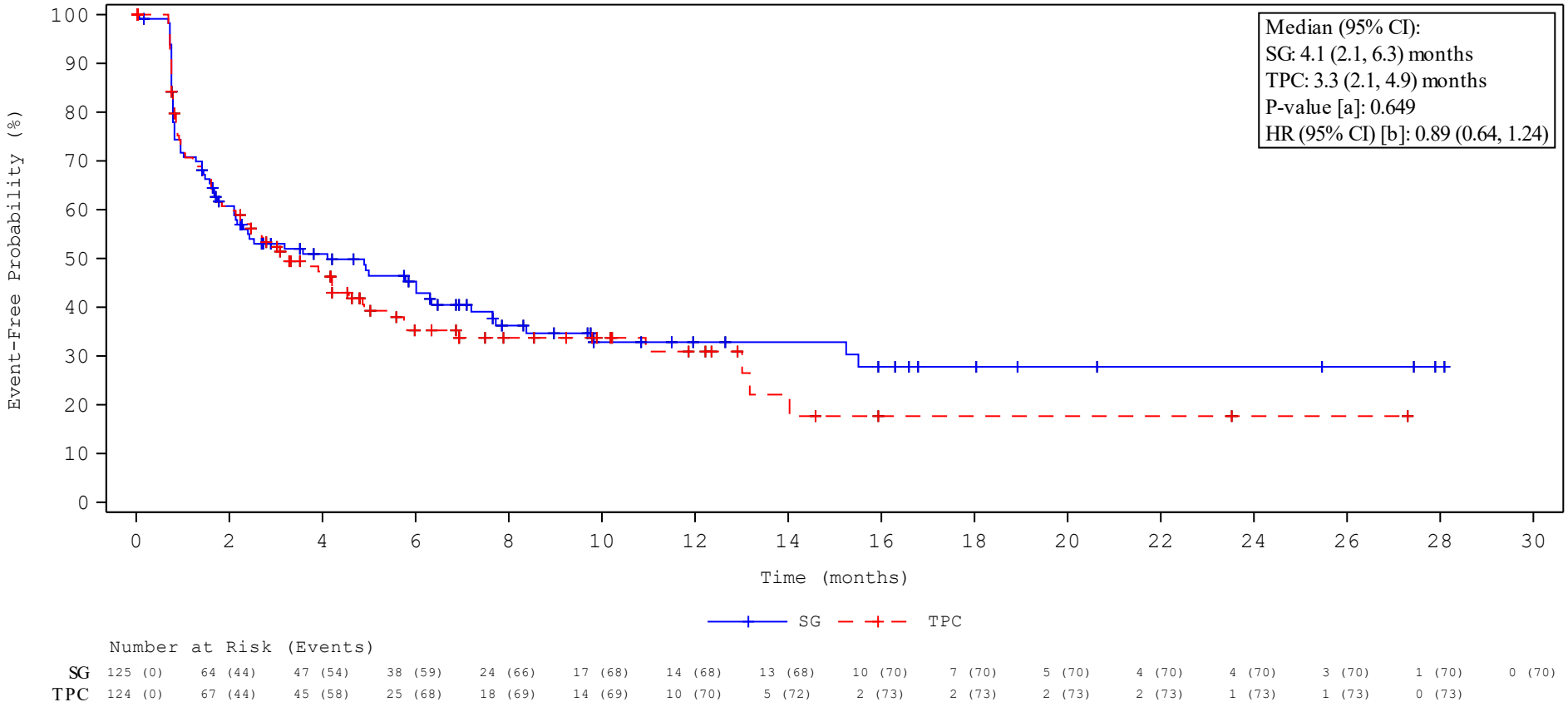


Figure 2.3.1.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



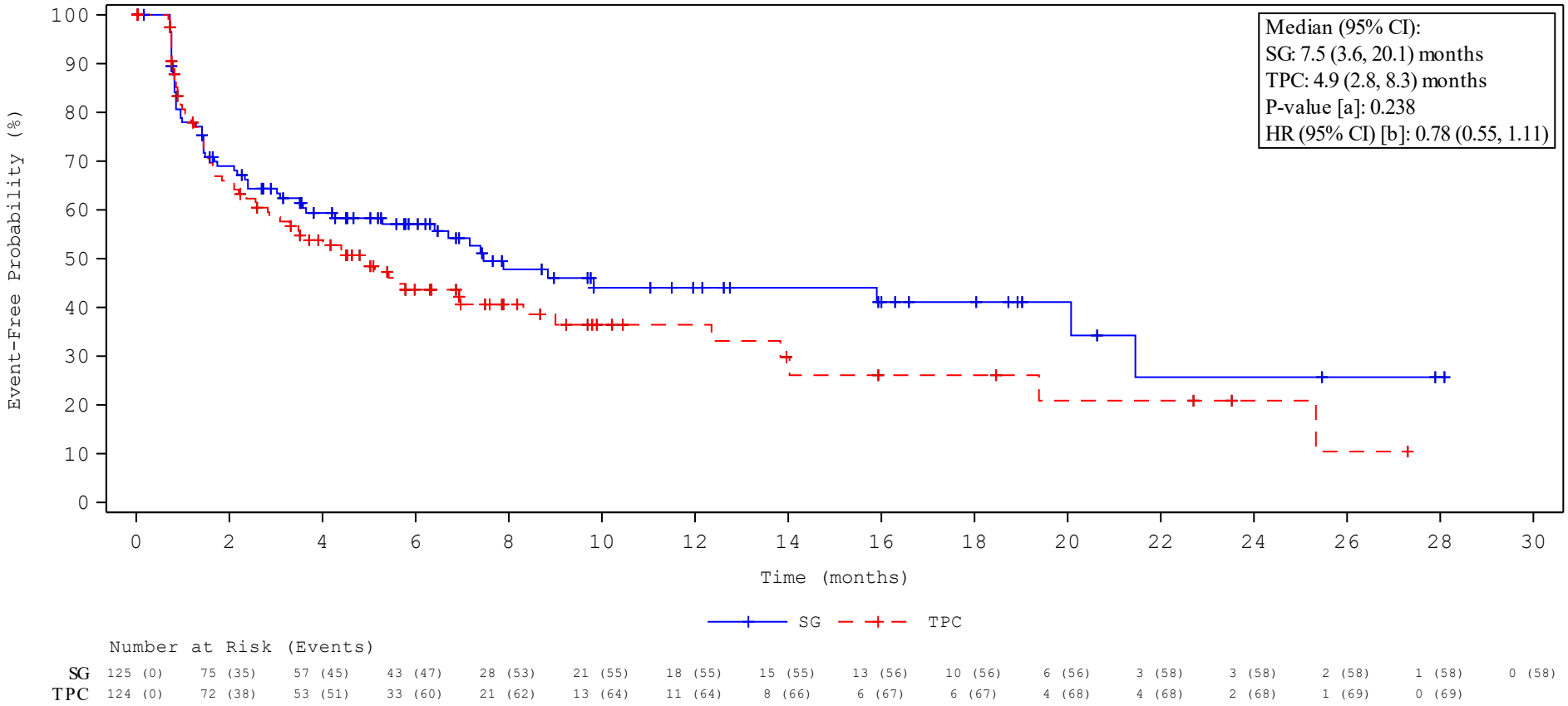
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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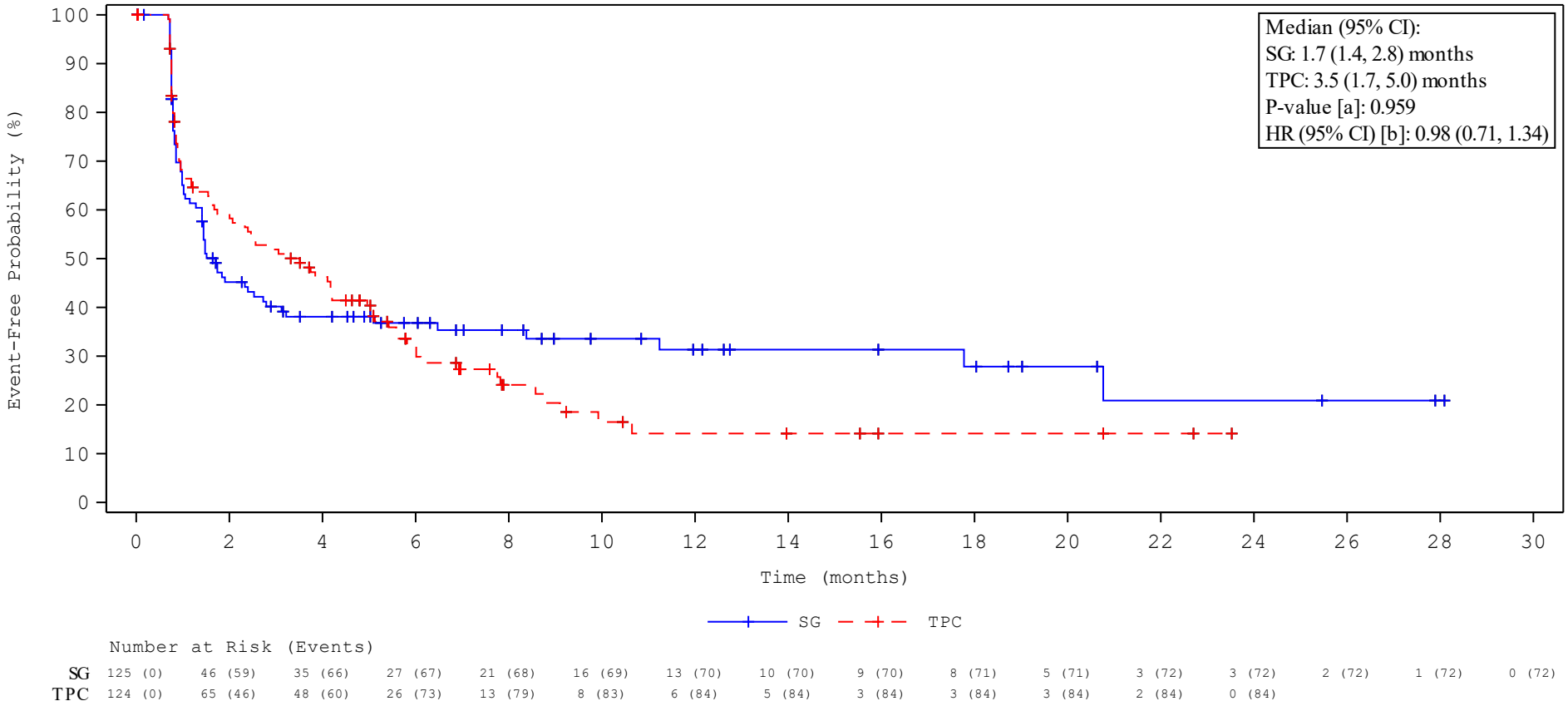
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Figure 2.3.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Physical Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



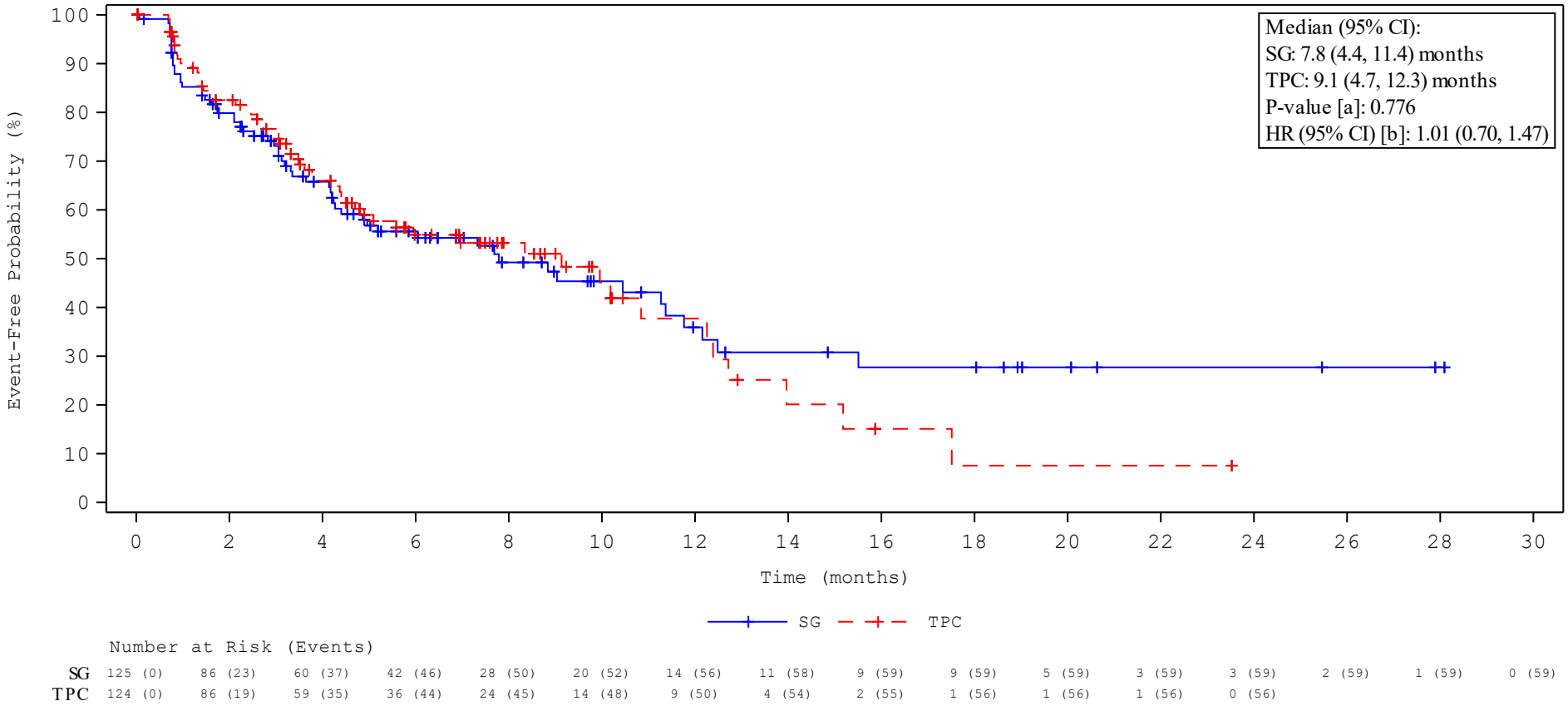
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



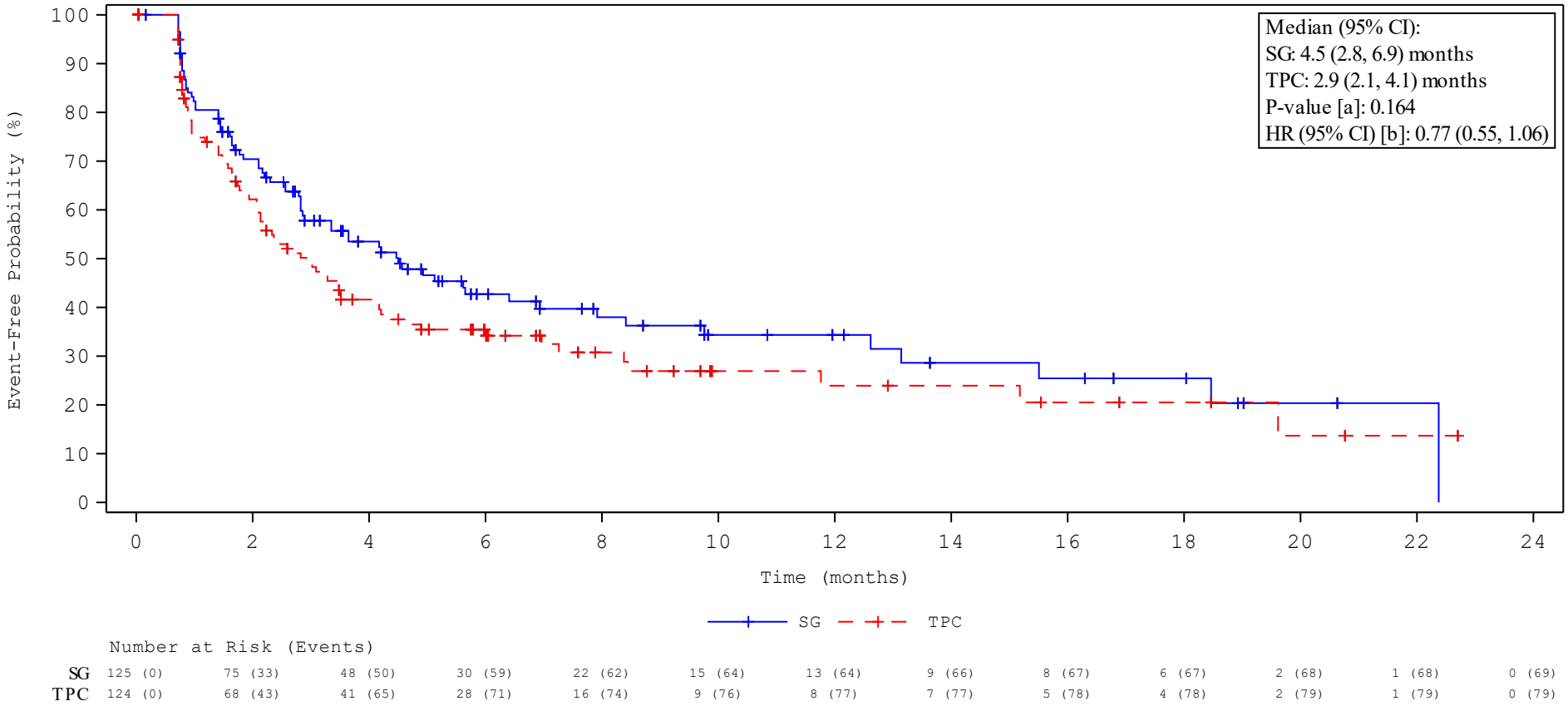
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Emotional Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



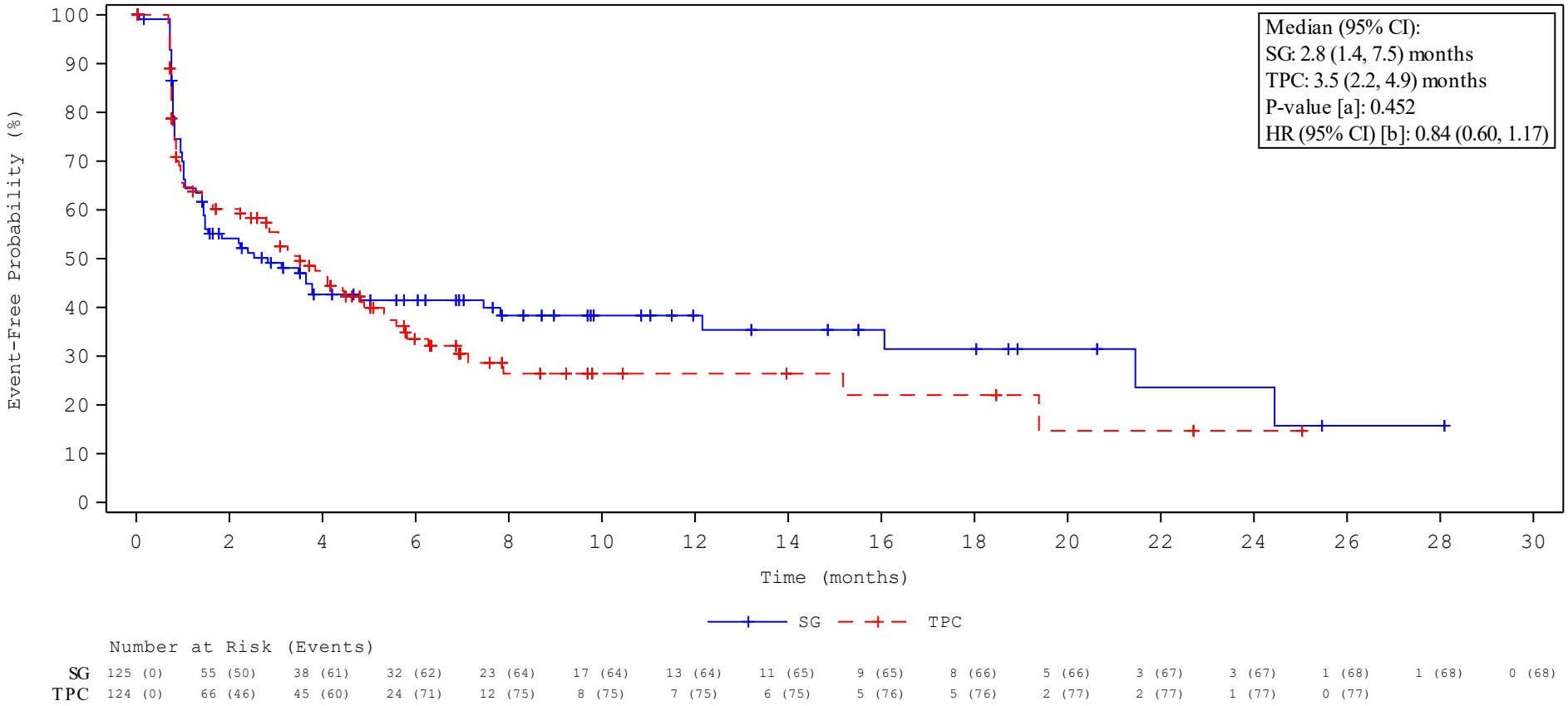
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



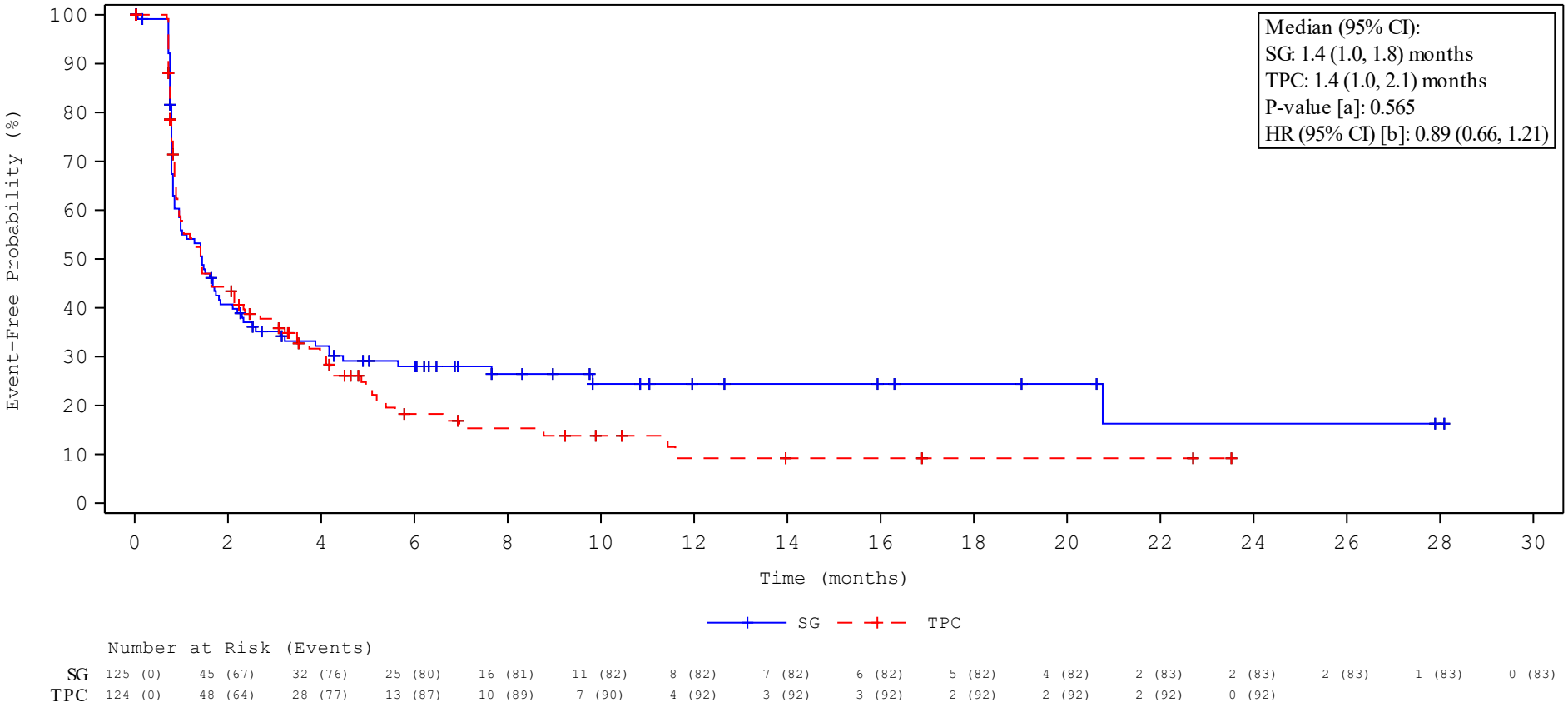
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.6
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



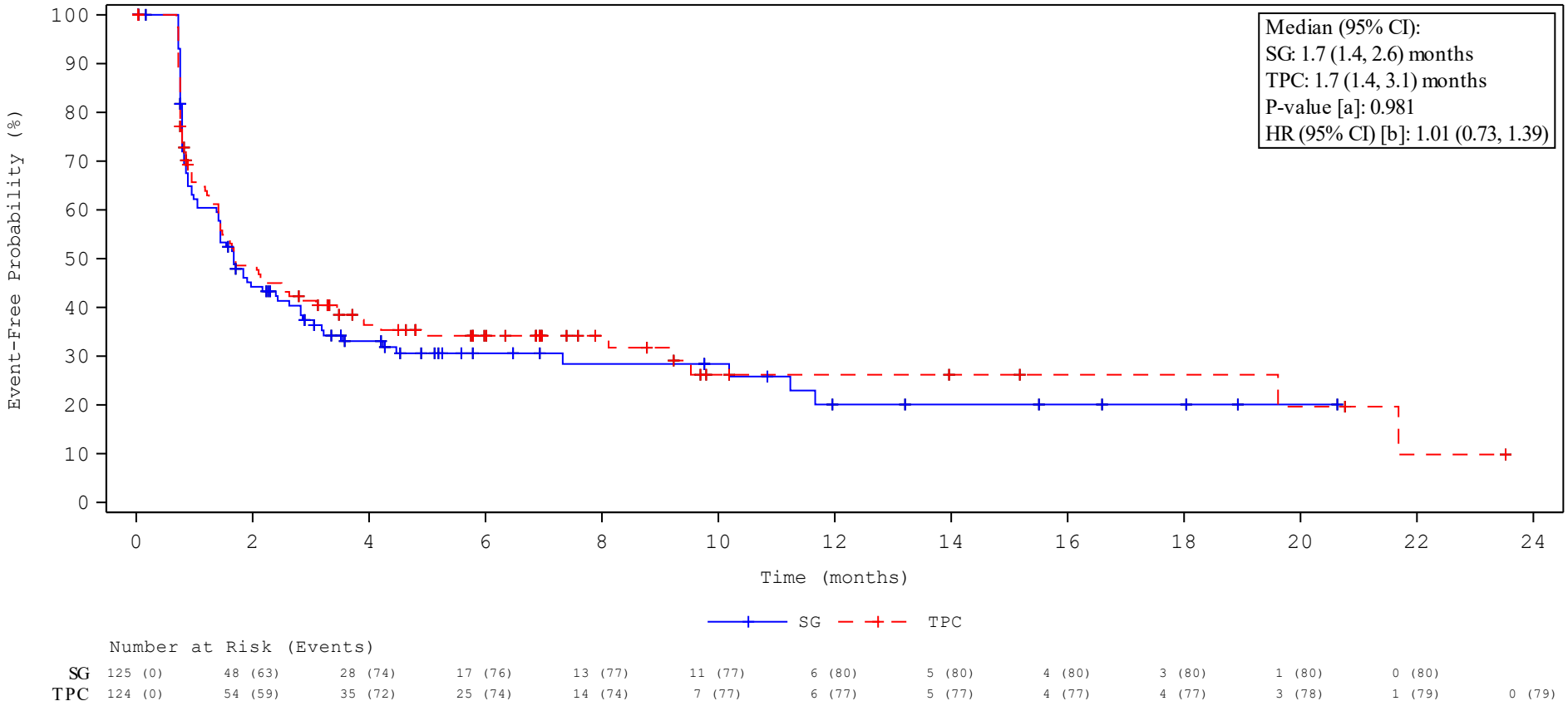
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.7
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



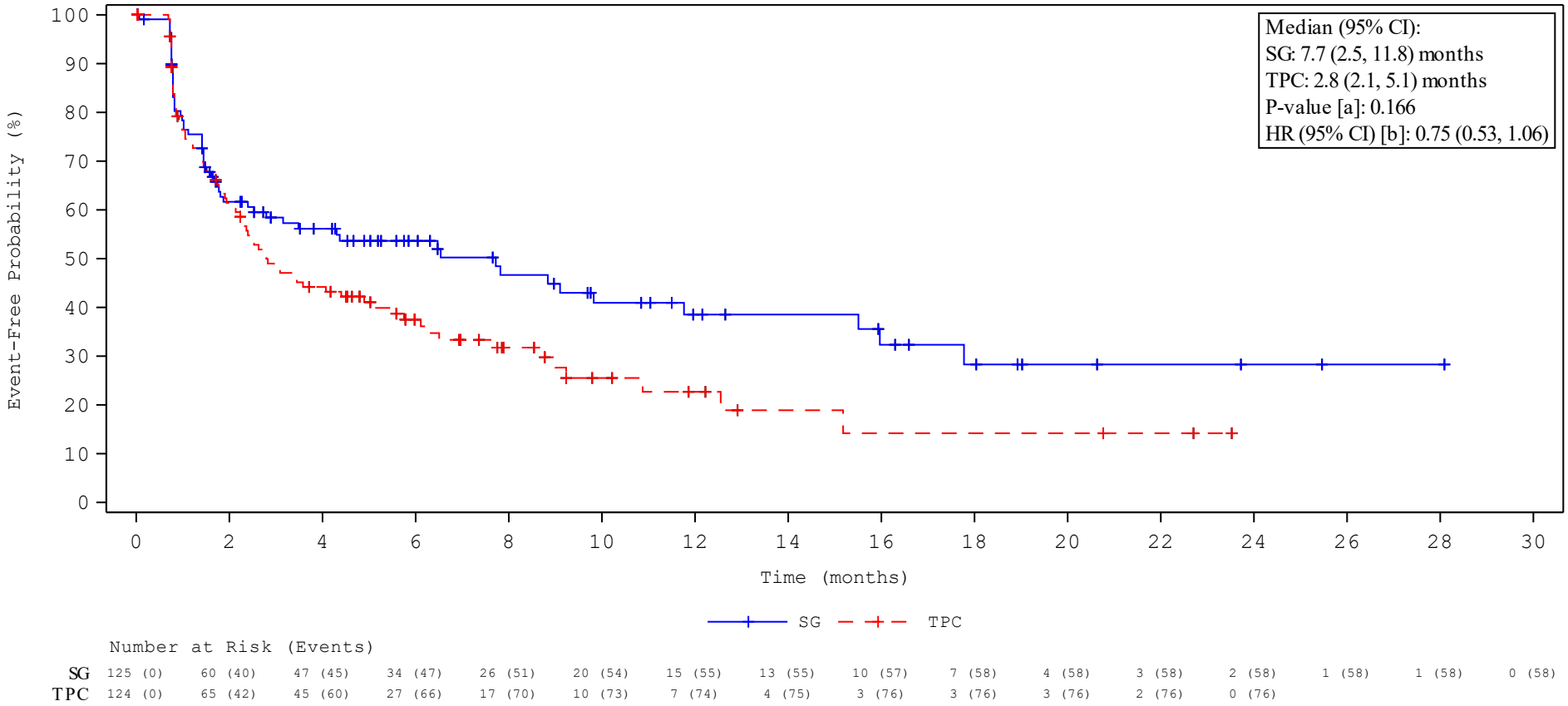
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.8
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



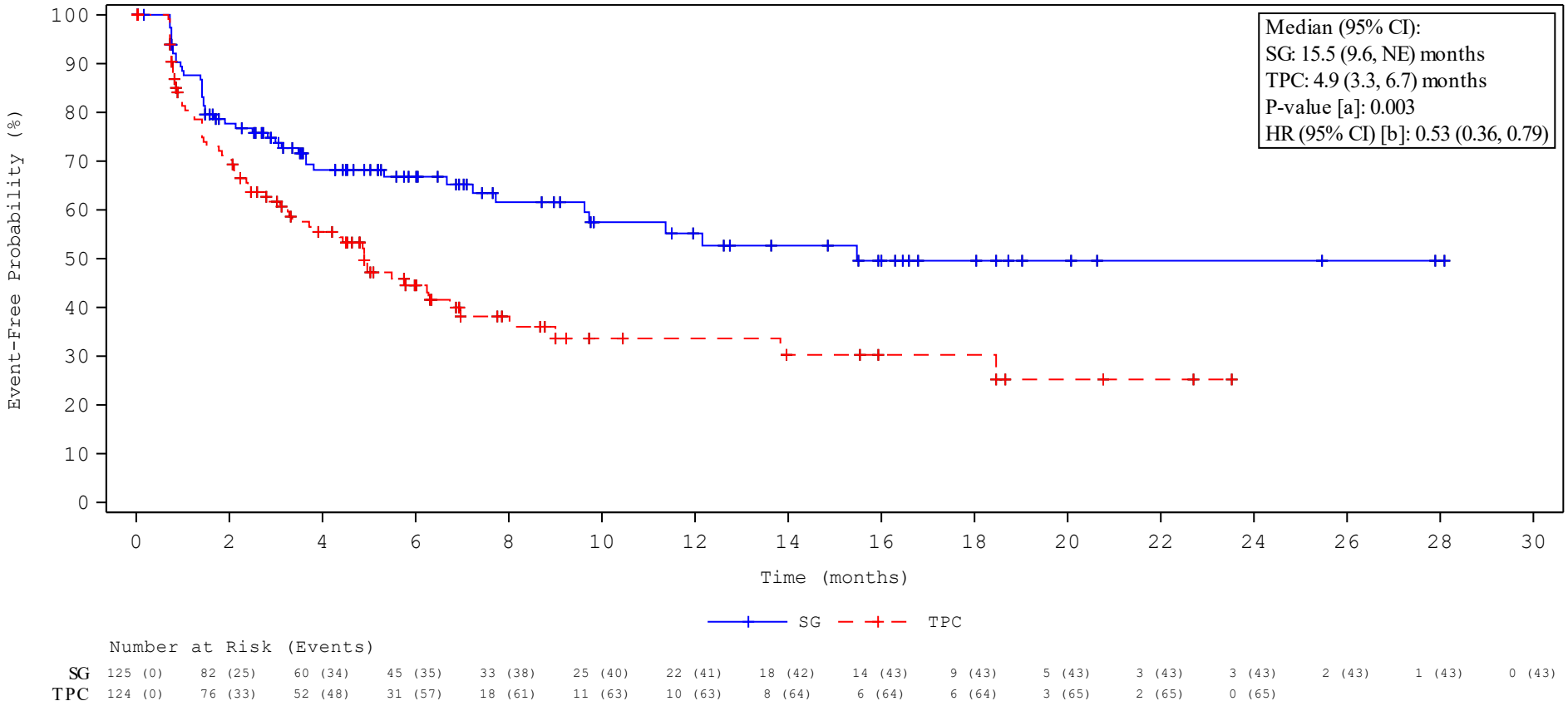
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.9
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Pain by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



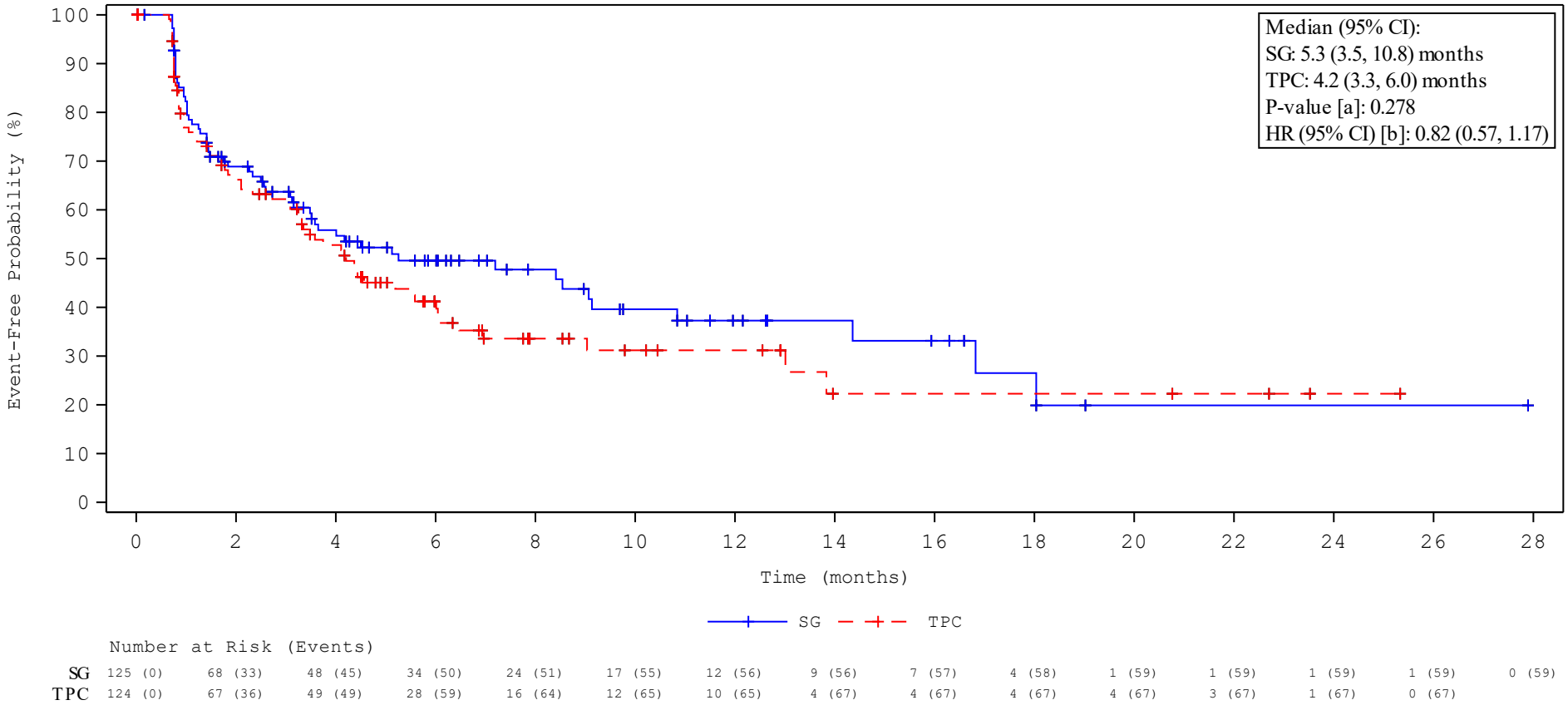
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.10
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Dyspnea by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



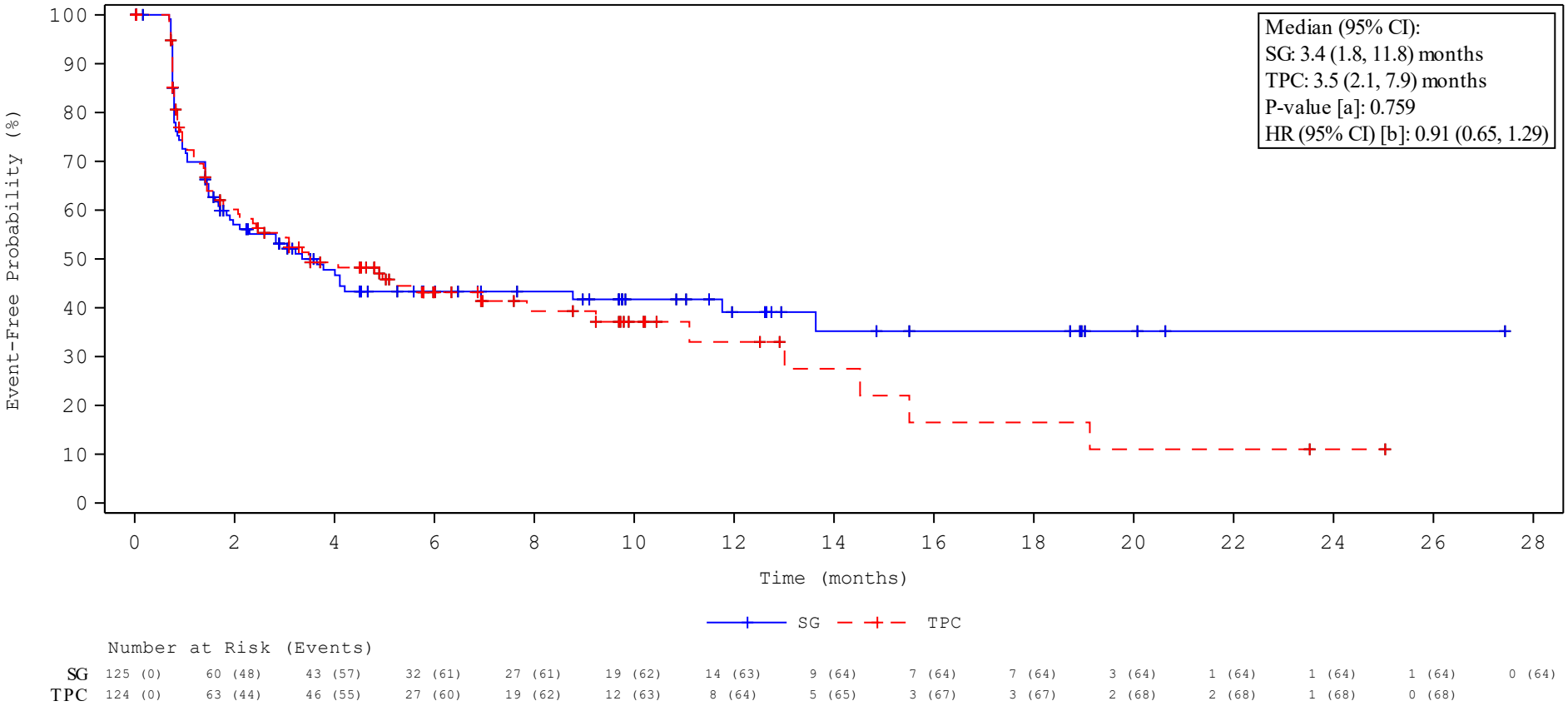
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.11
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Insomnia by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



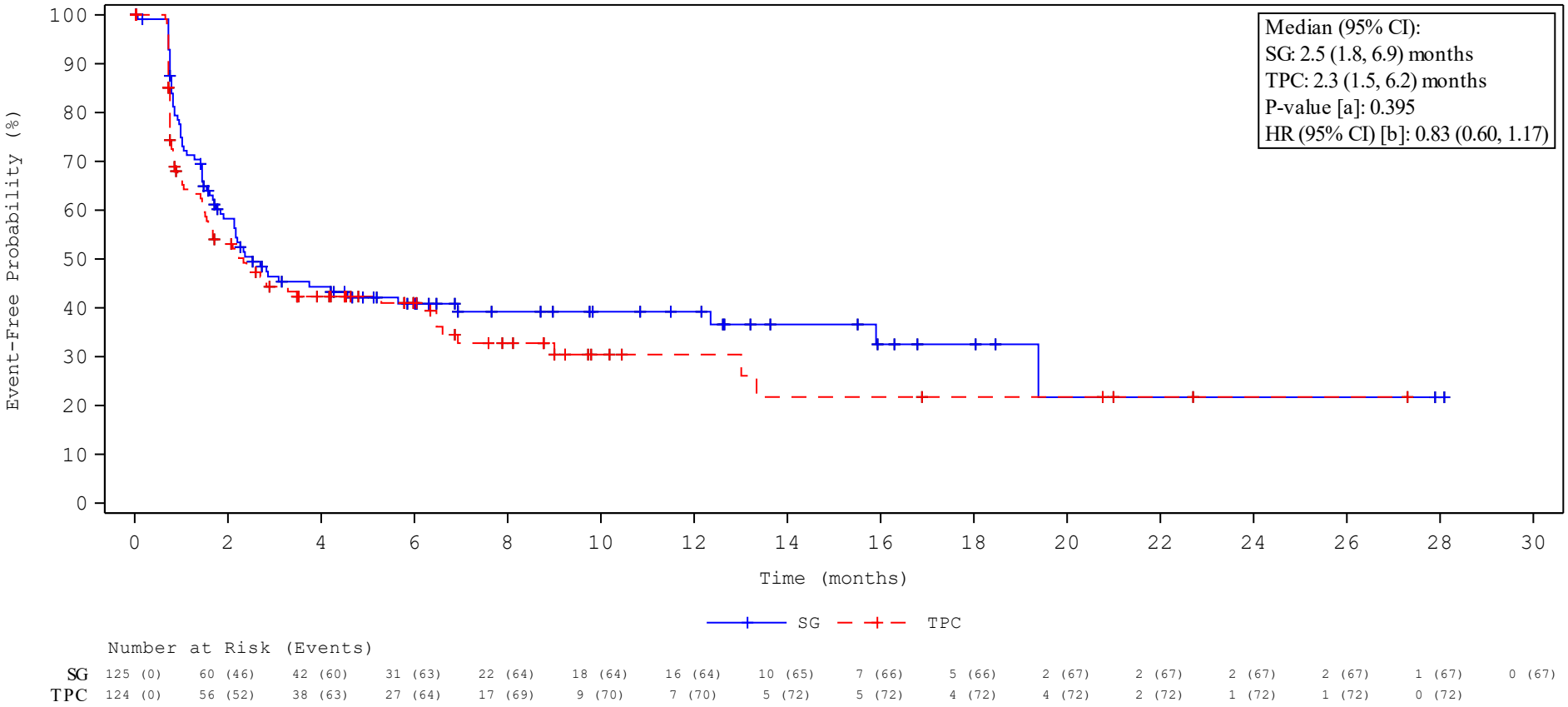
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.12
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Appetite Loss by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



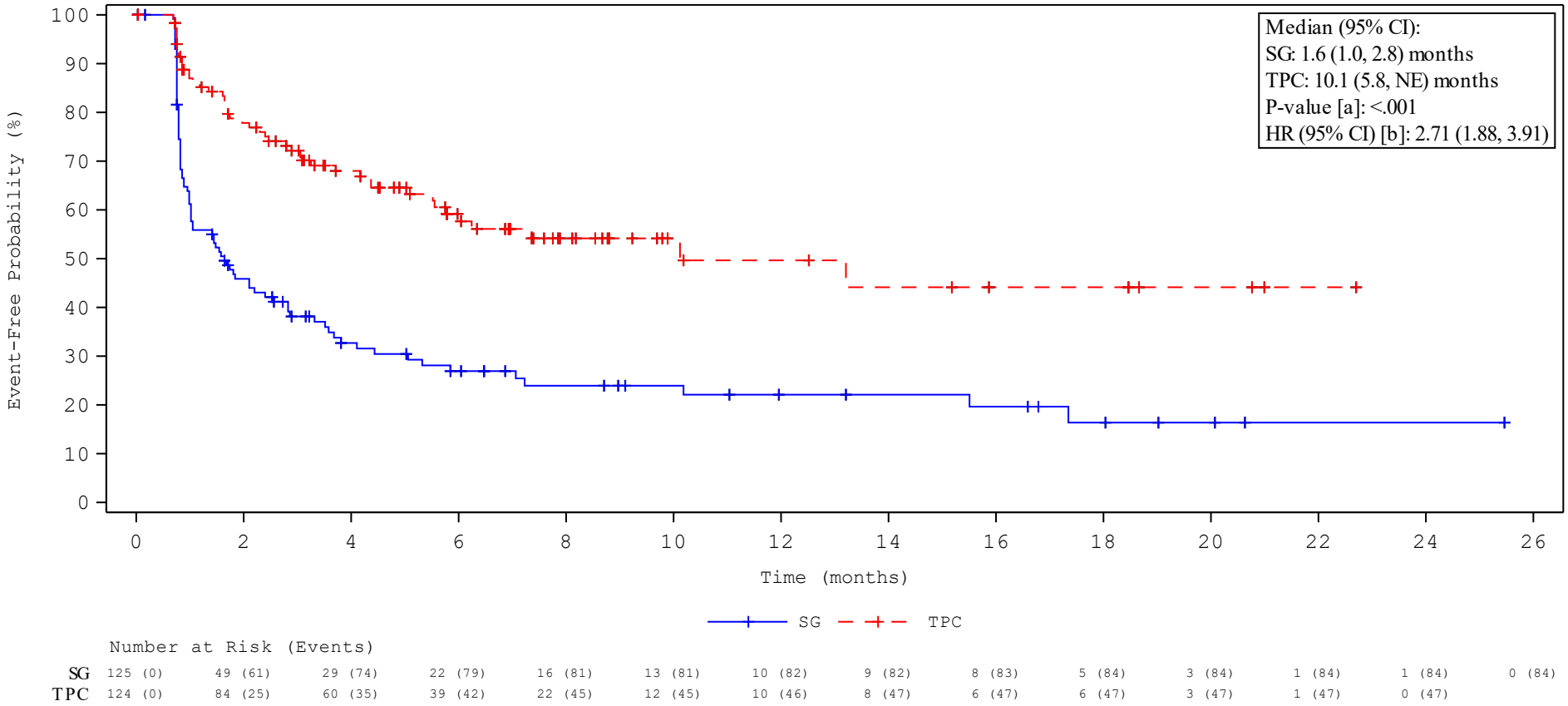
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.13
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Constipation by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



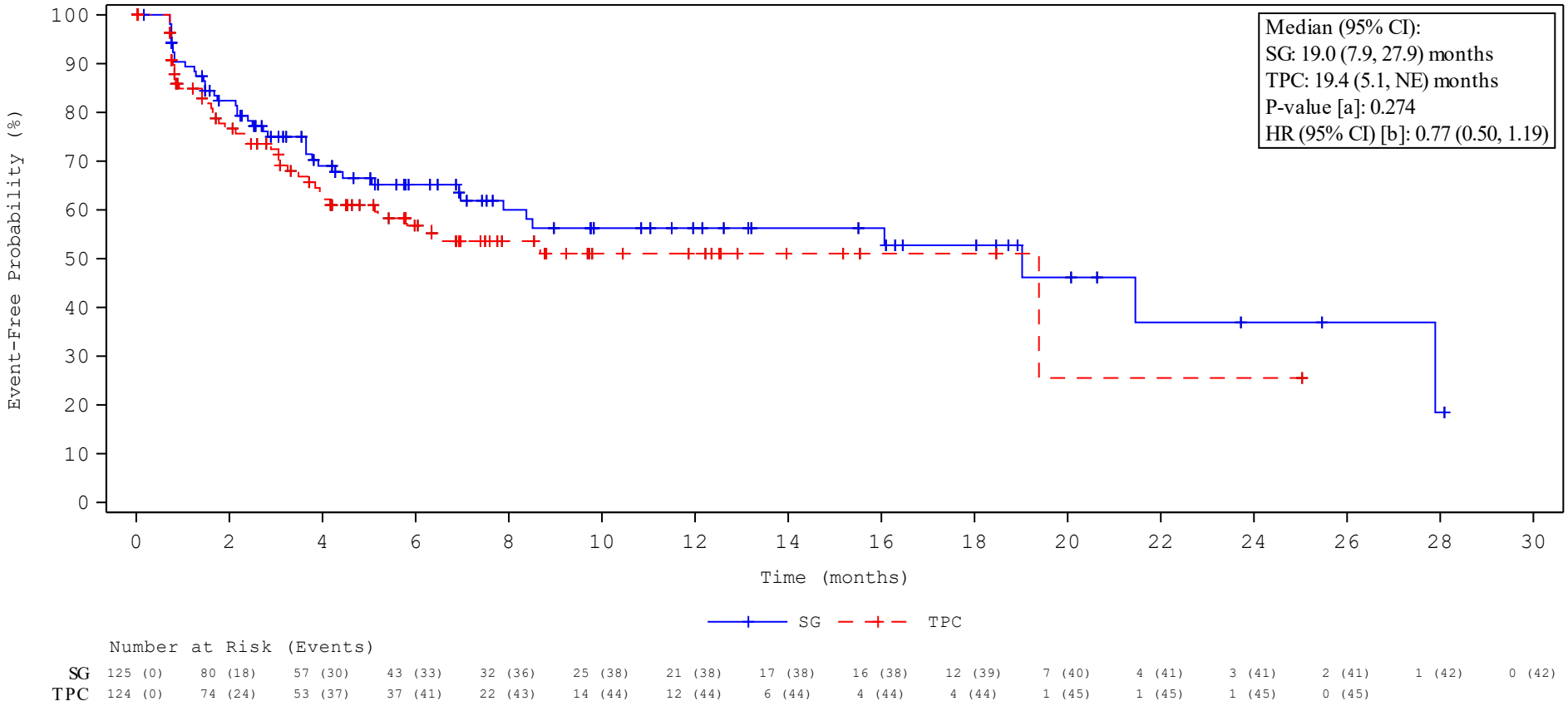
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.14
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



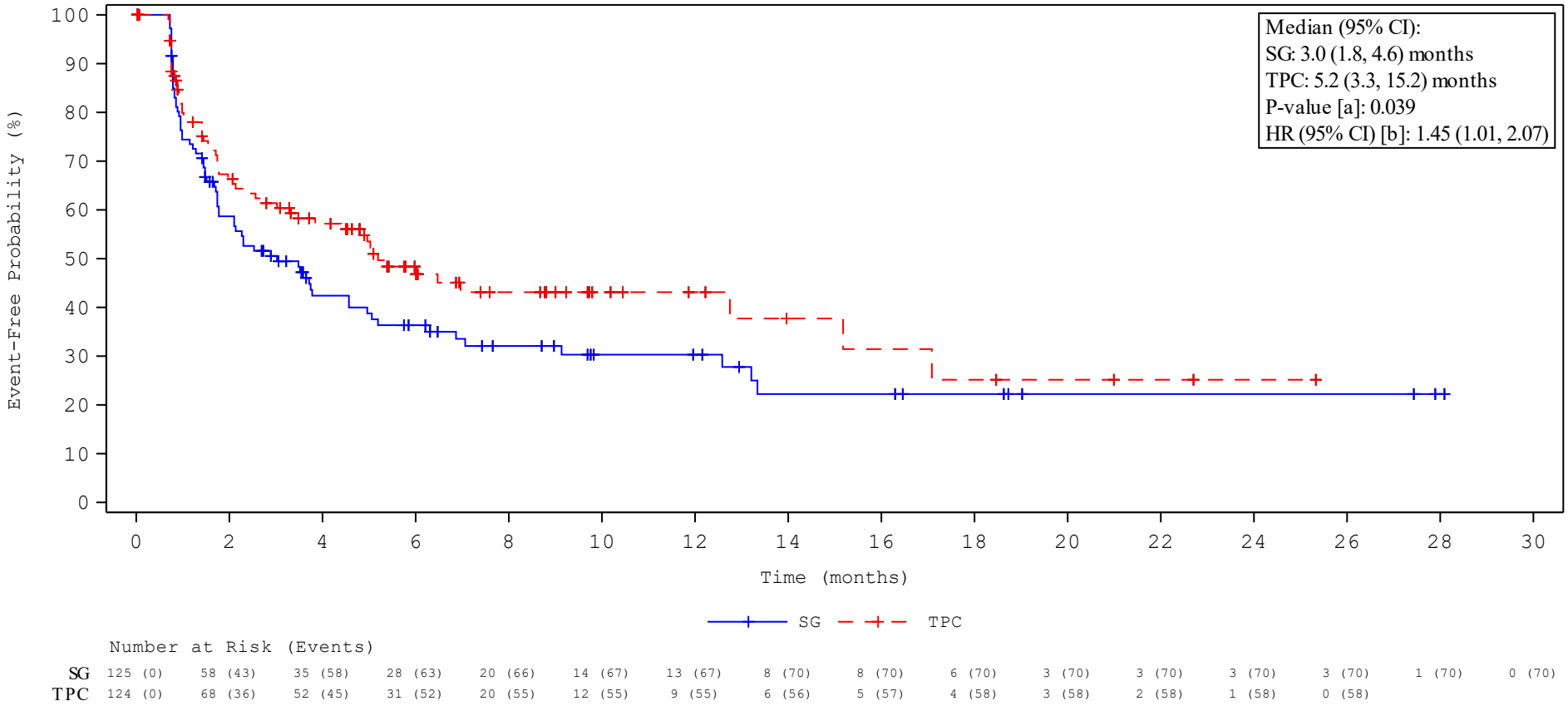
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.1.15
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Financial Difficulties by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



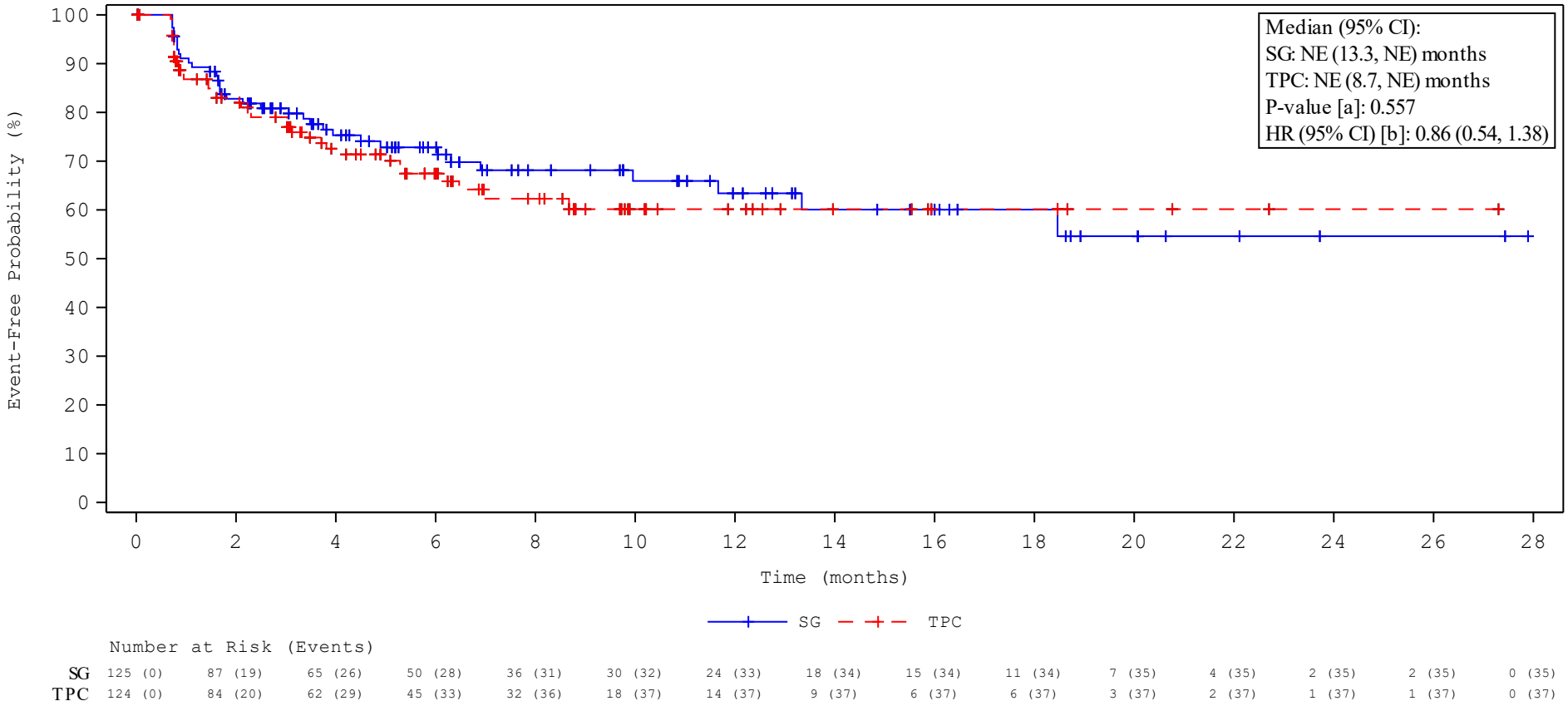
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Body Image by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



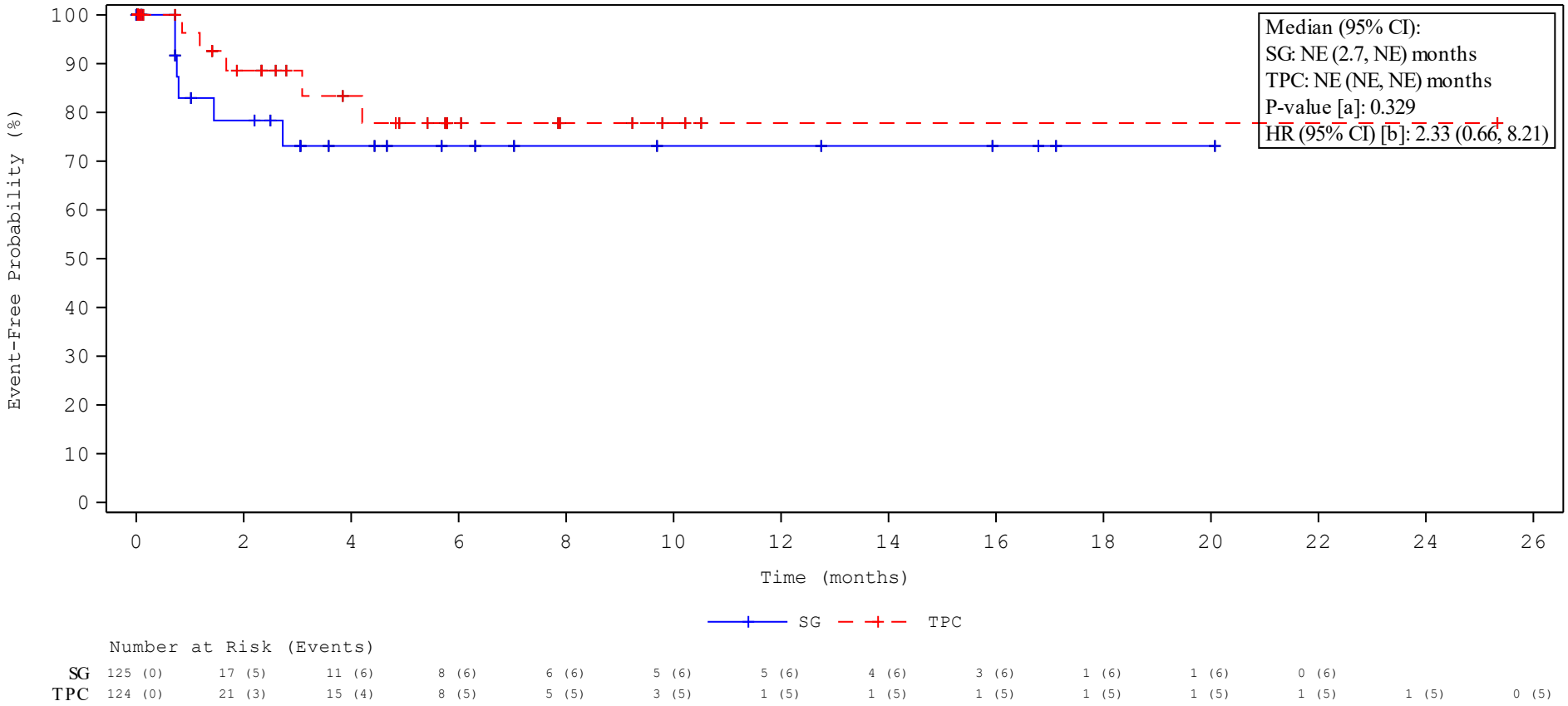
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Function by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



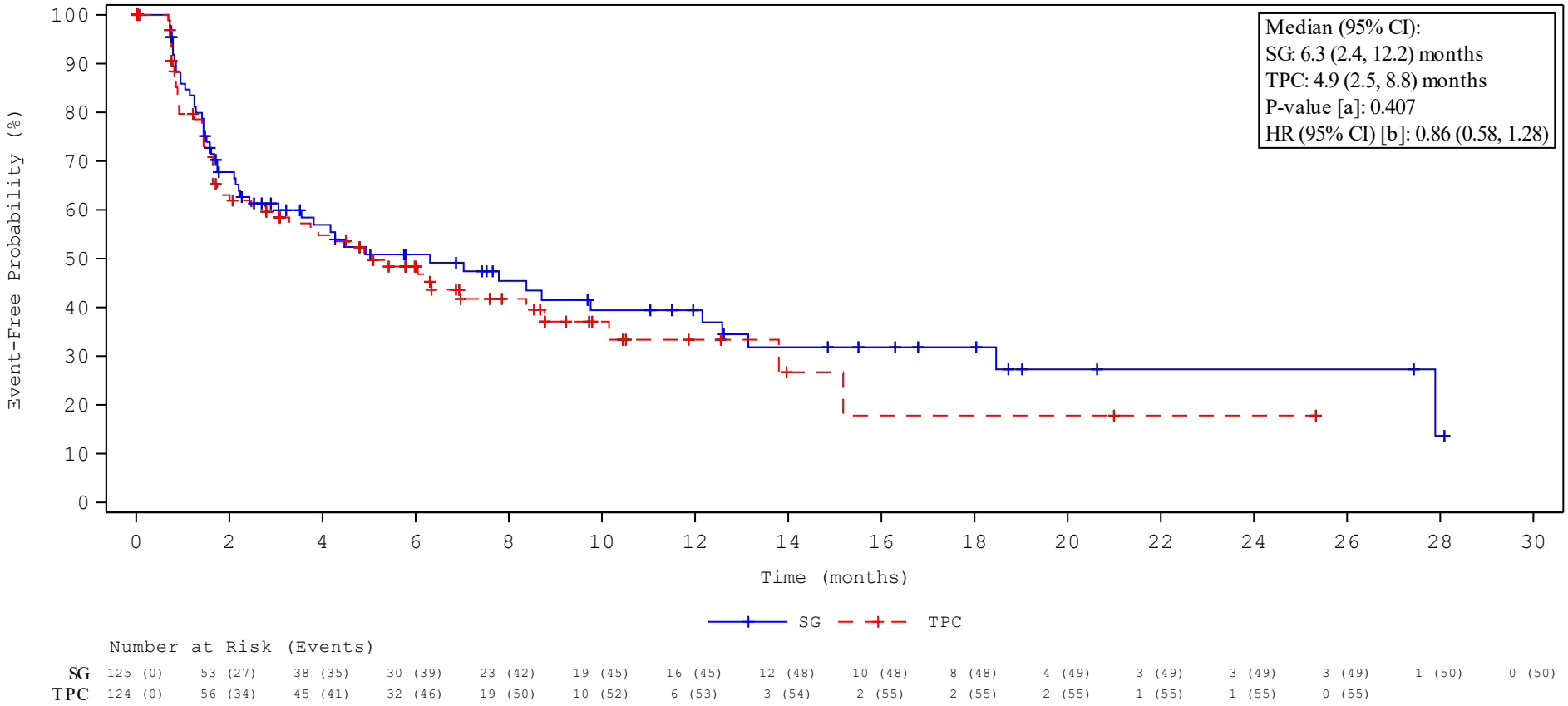
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Enjoyment by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



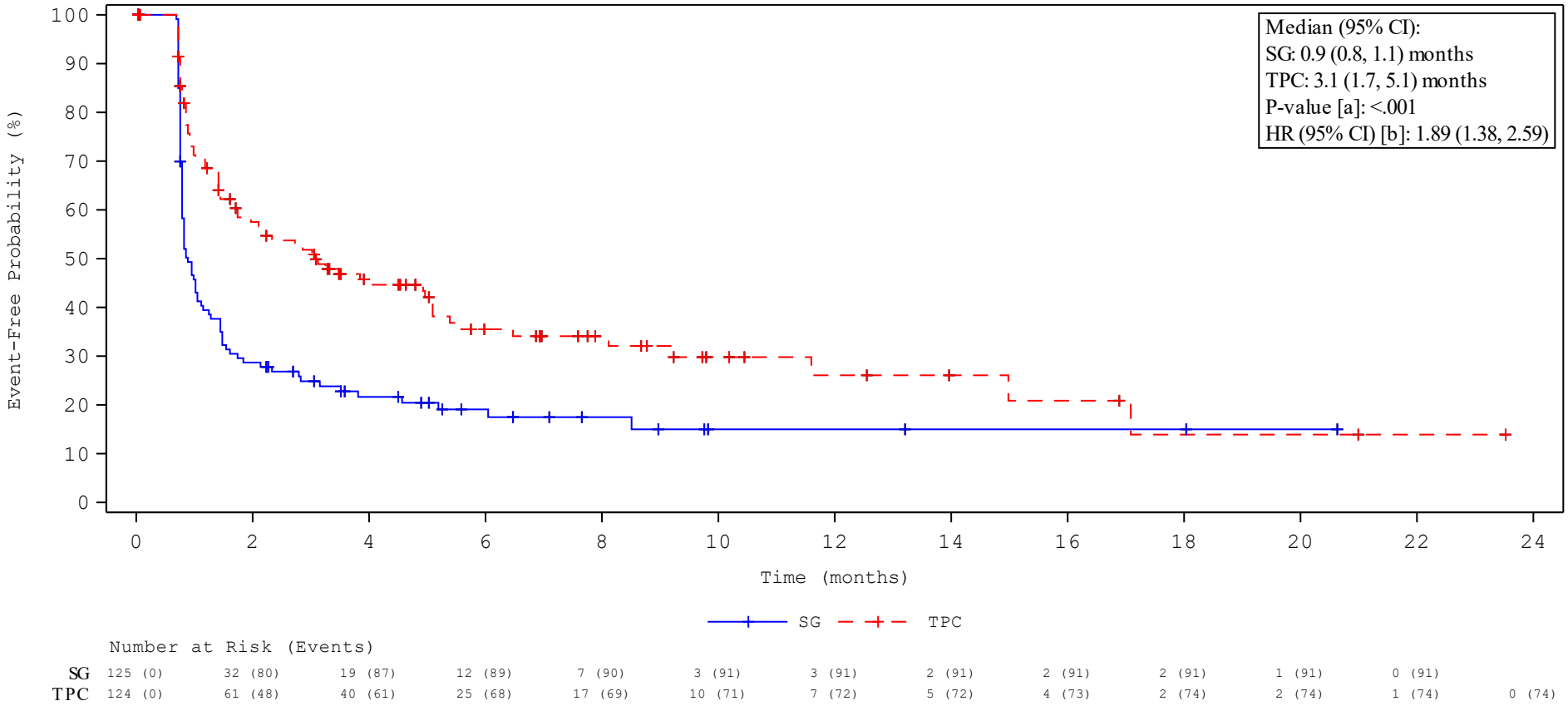
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Future Perspective by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



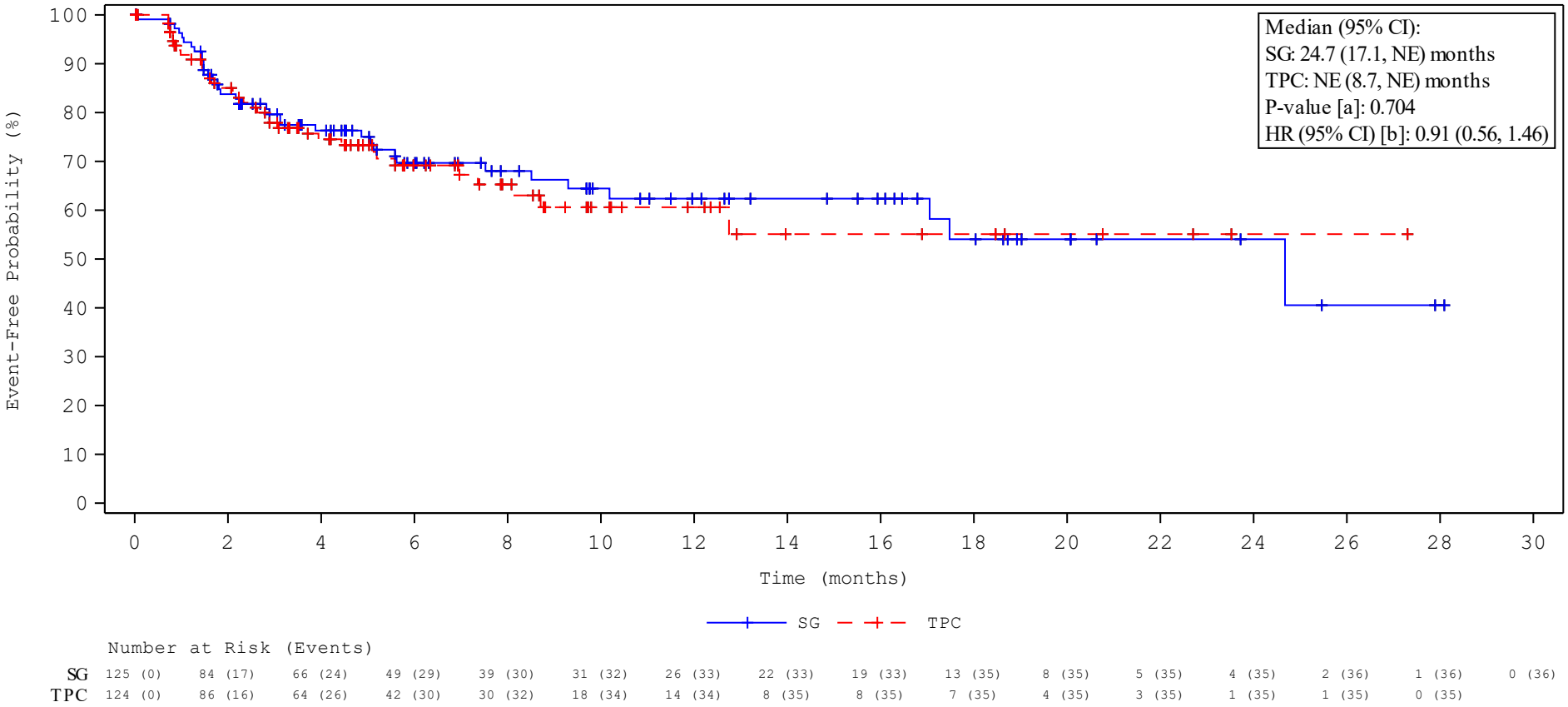
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Systemic Therapy Side Effects by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



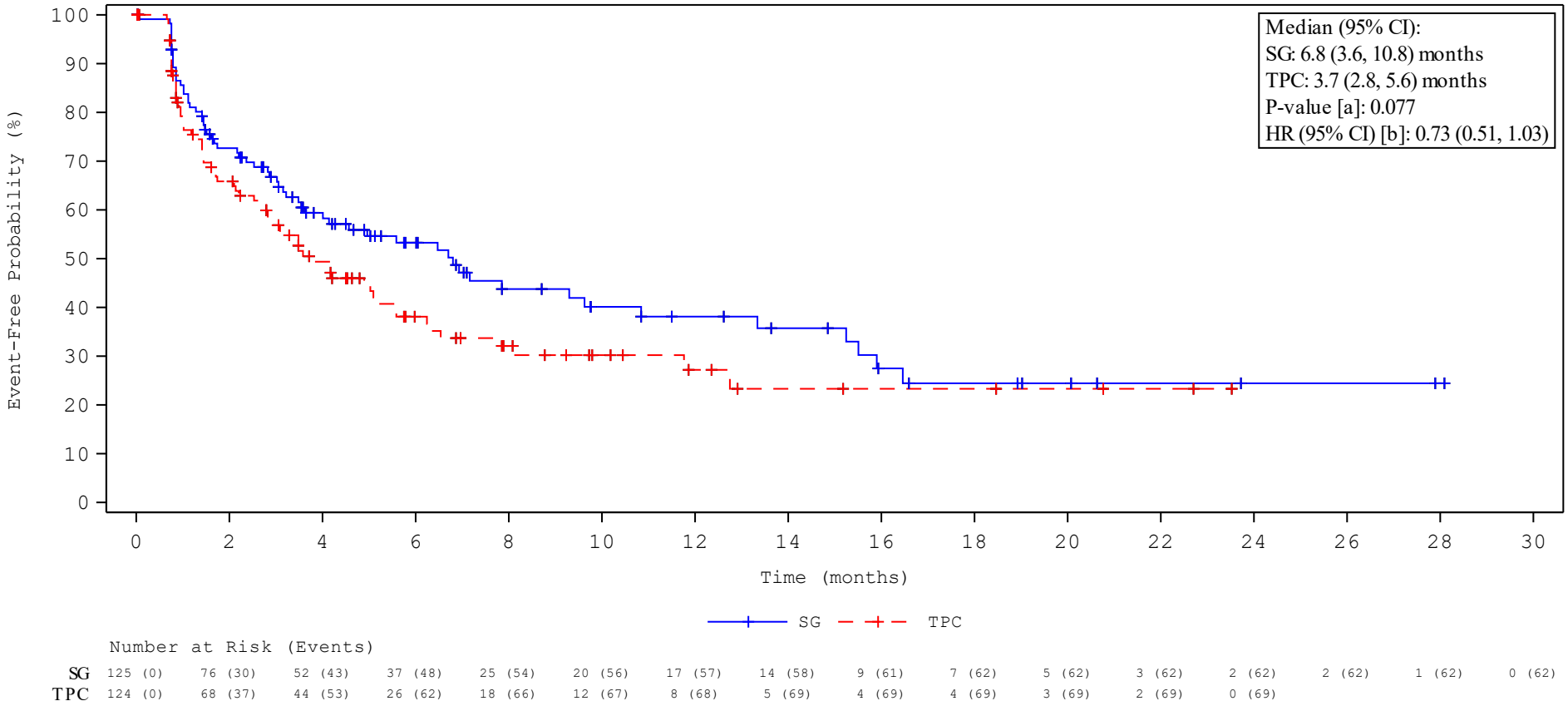
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.6
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Breast Symptoms by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



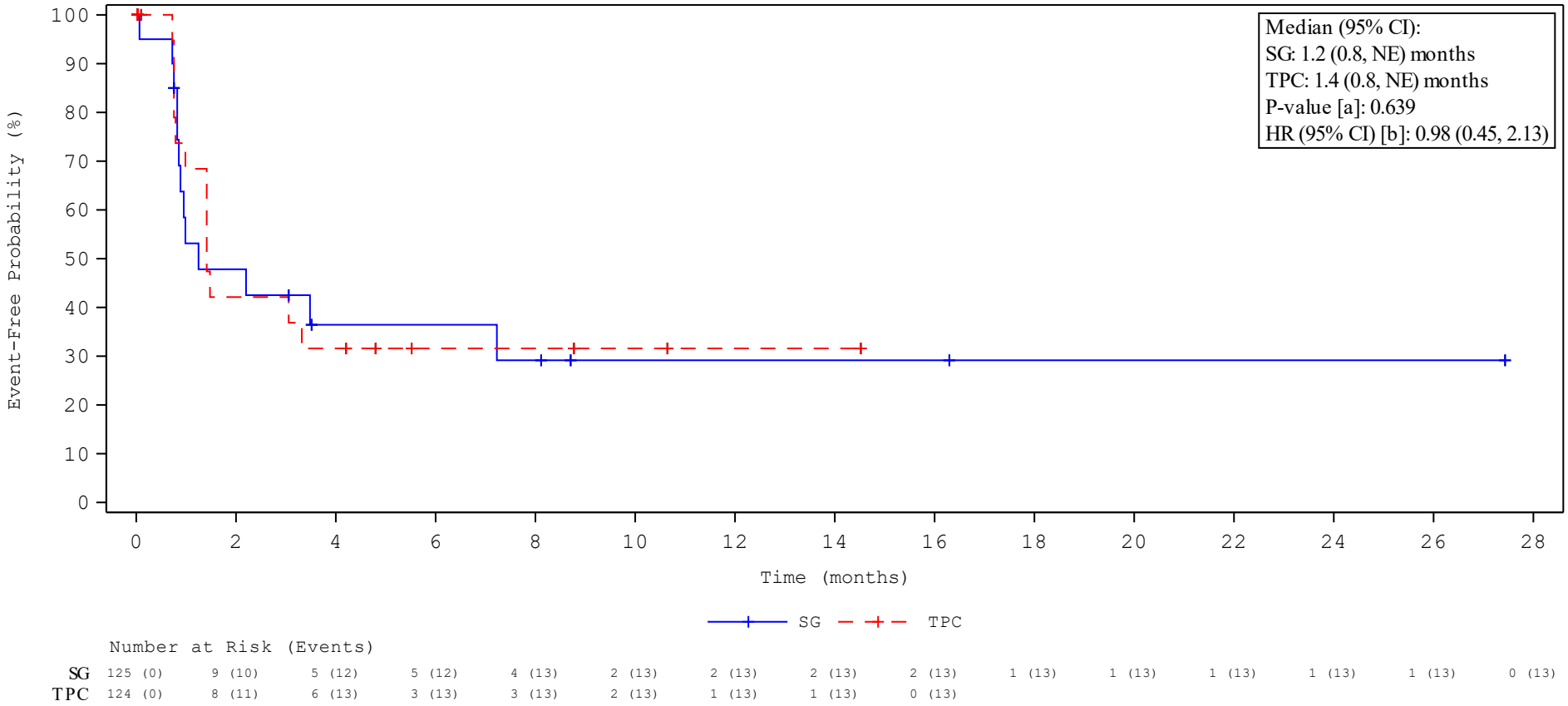
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.7
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Arm Symptoms by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



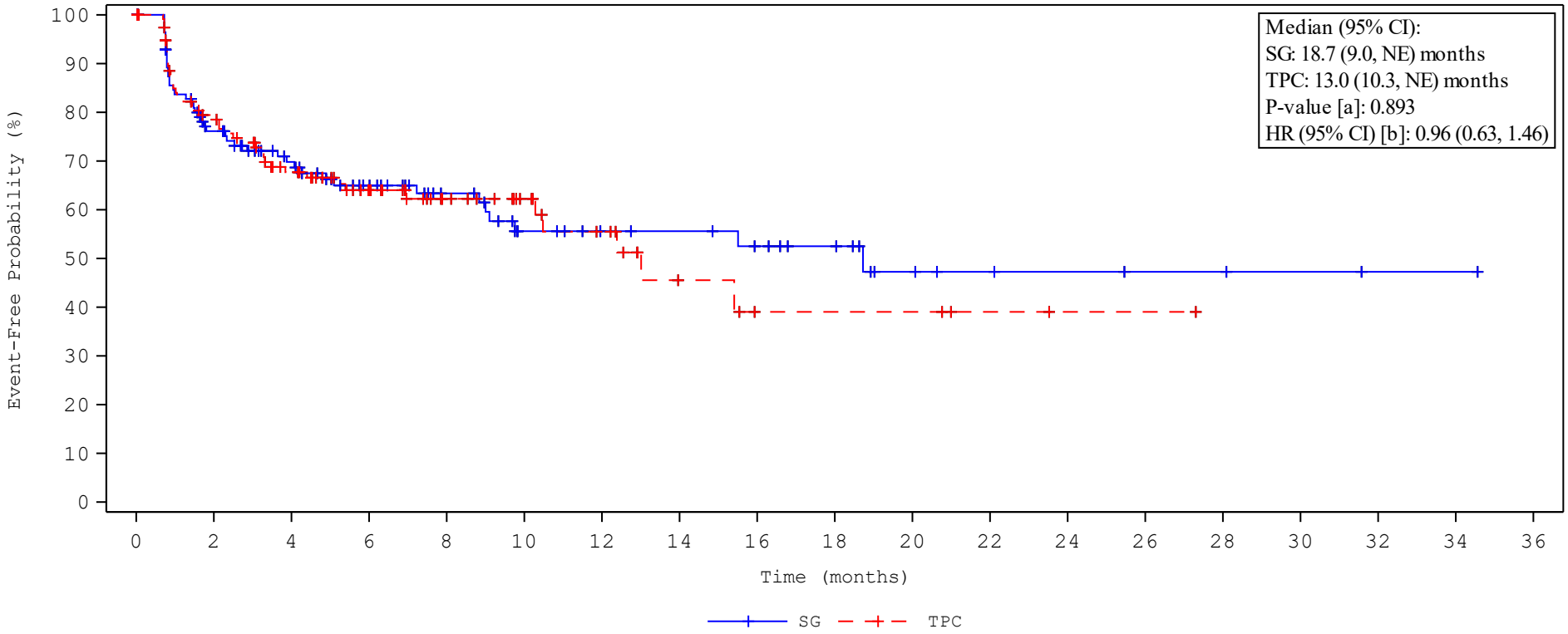
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.2.8
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Upset by Hair Loss by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



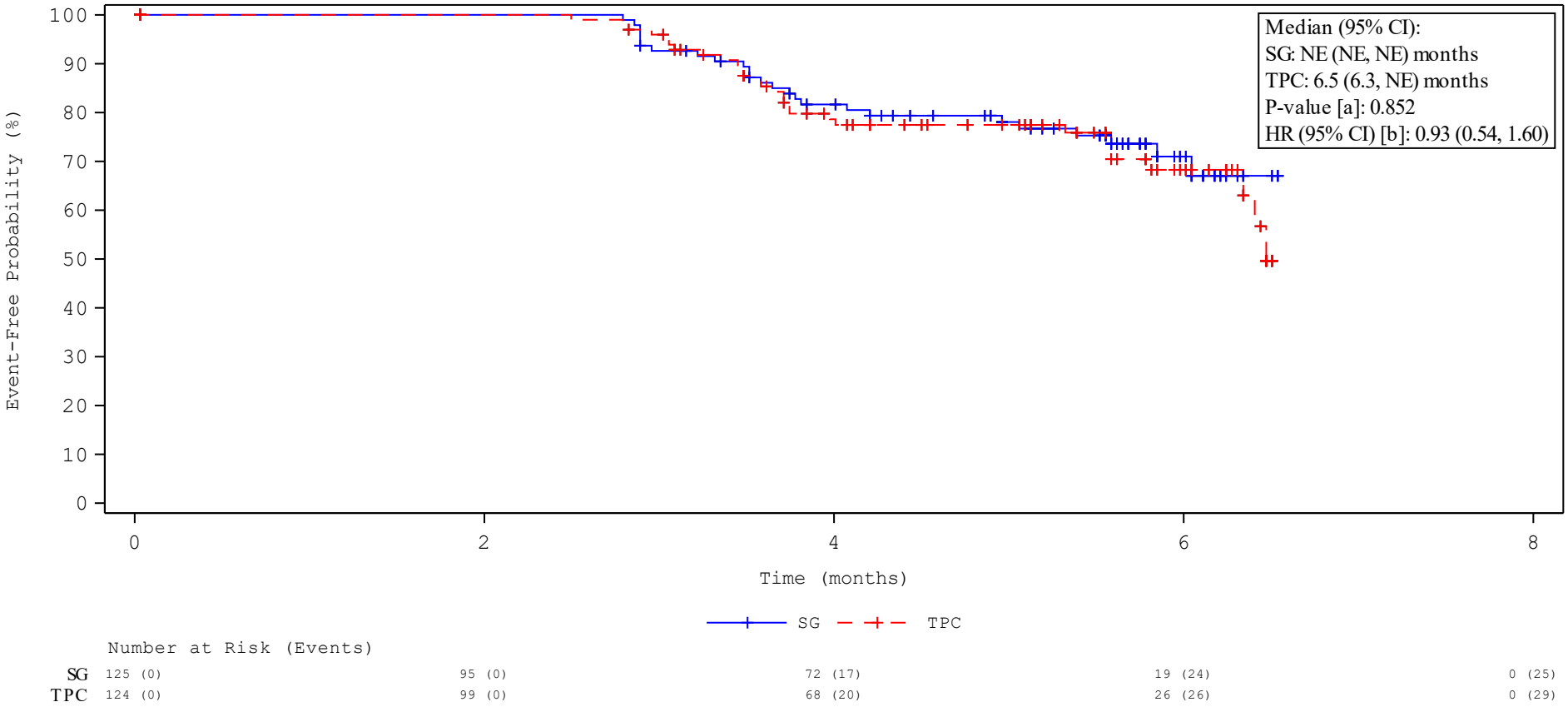
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EQ-VAS by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



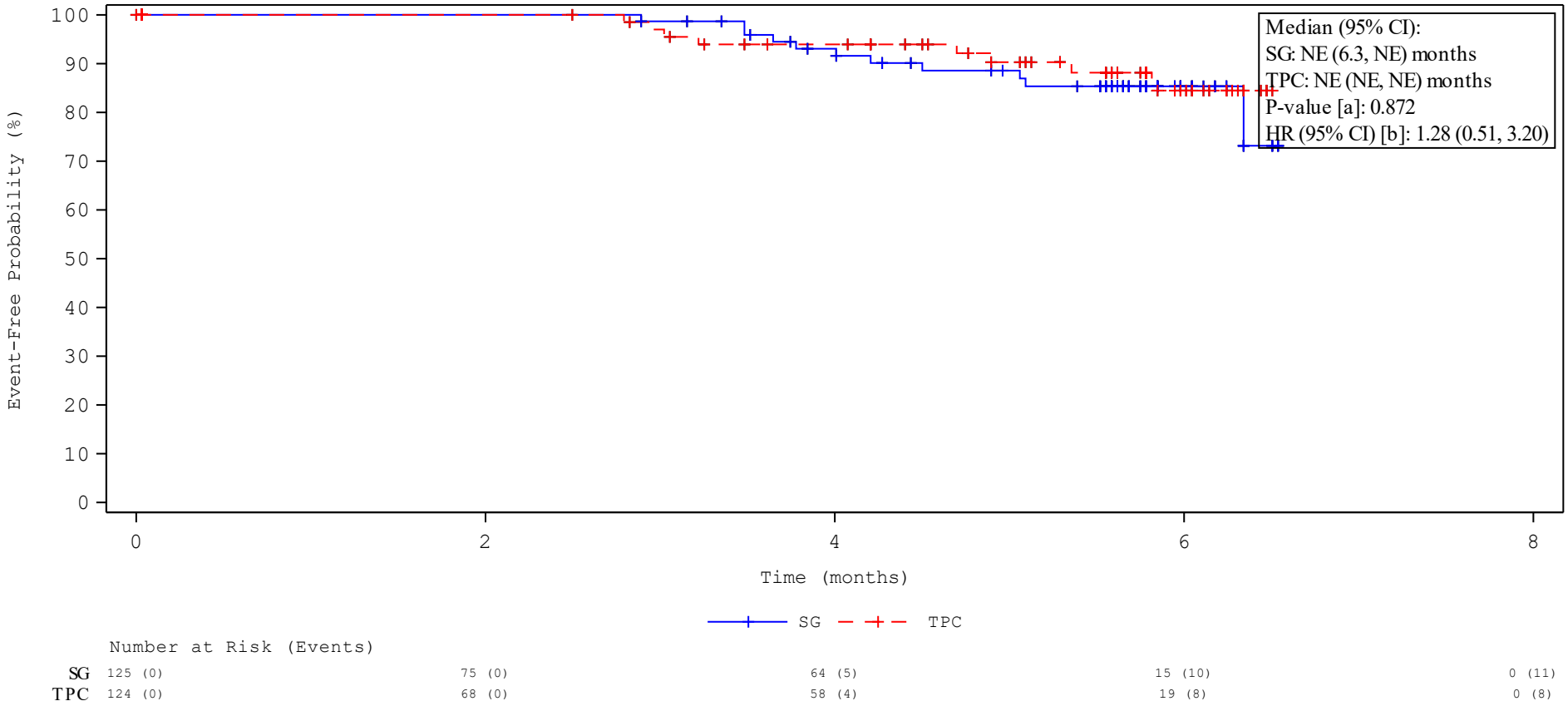
Note: The response threshold for EQ-VAS is ≥15 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Figure 2.3.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIC by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



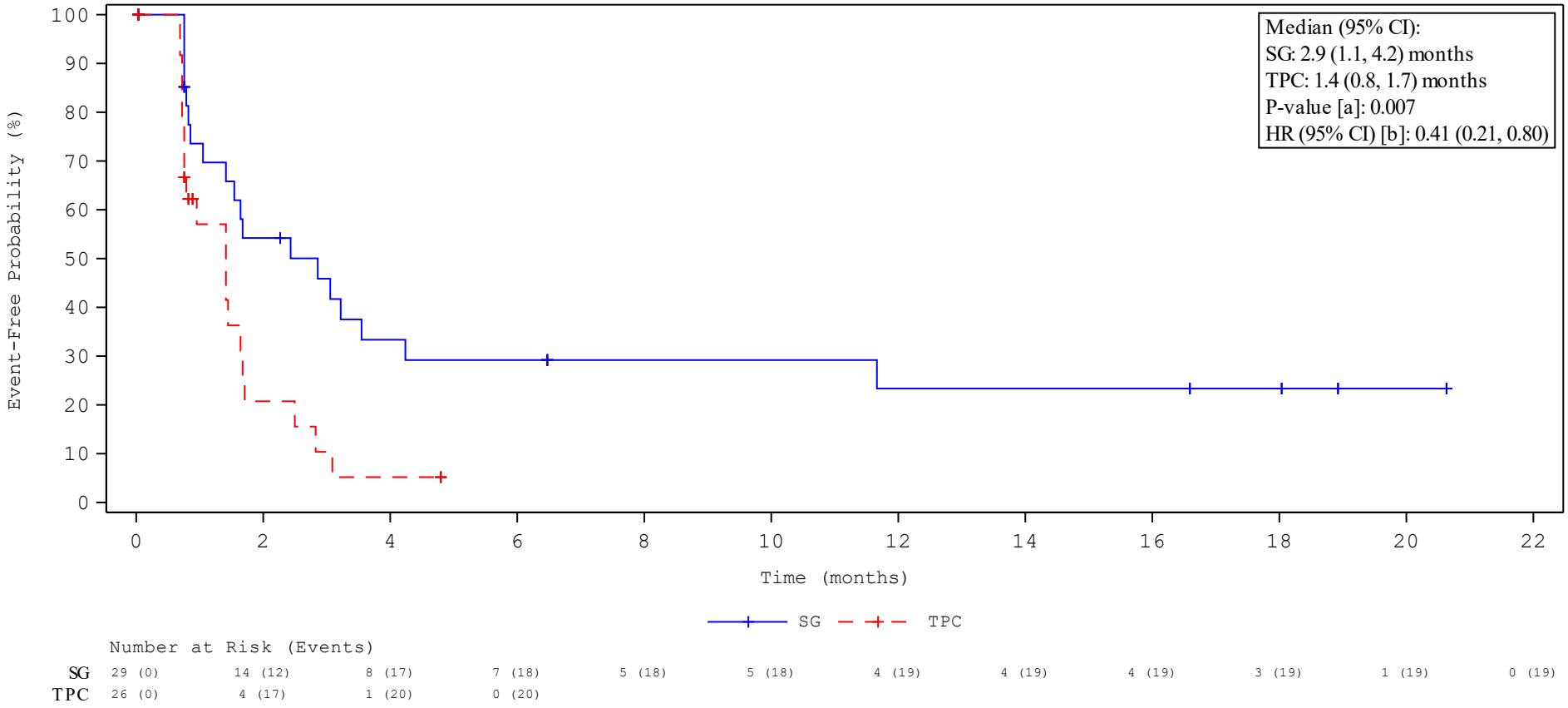
Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.3.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIS by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



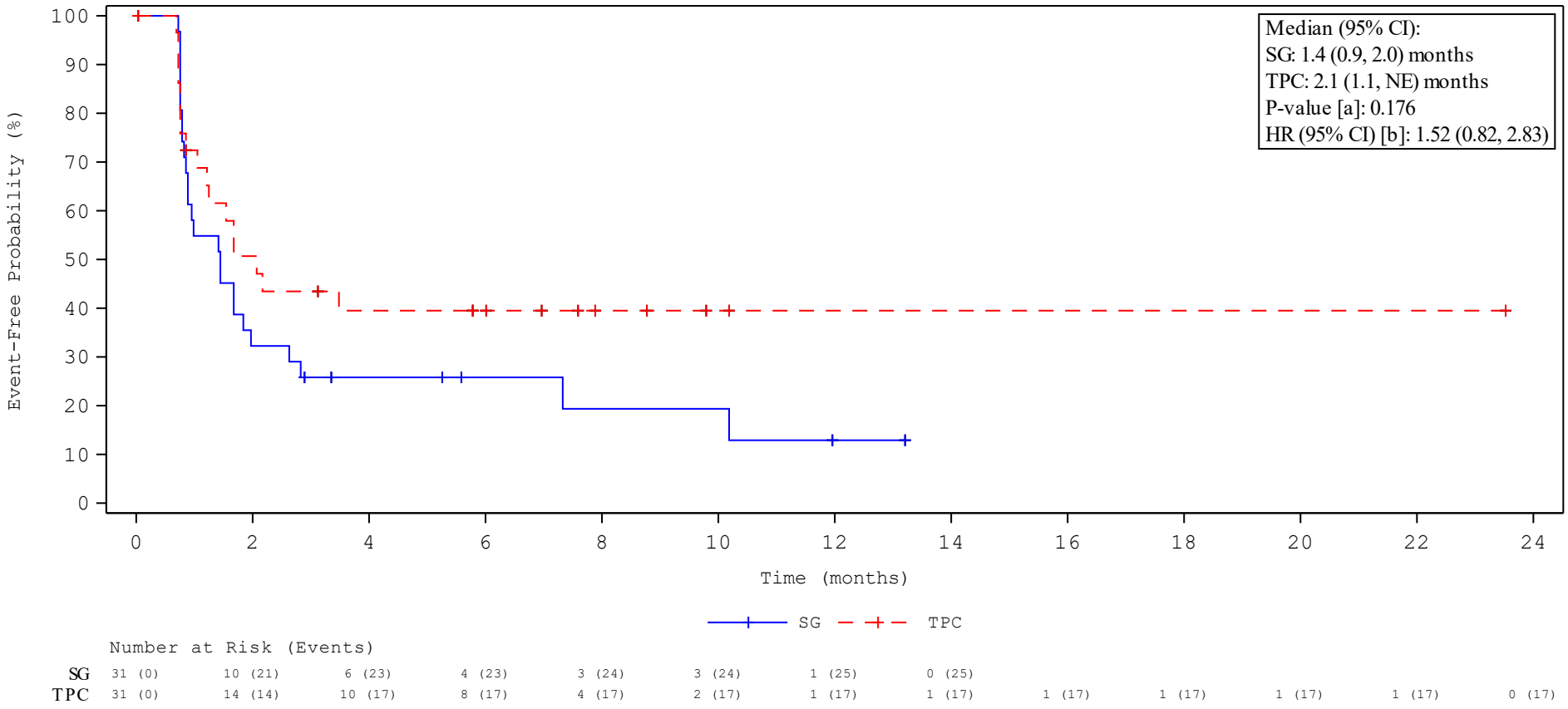
Note: 'Very poor' and 'poor' are classified as responders.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.3.1.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group (Disease-free Interval = De novo)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



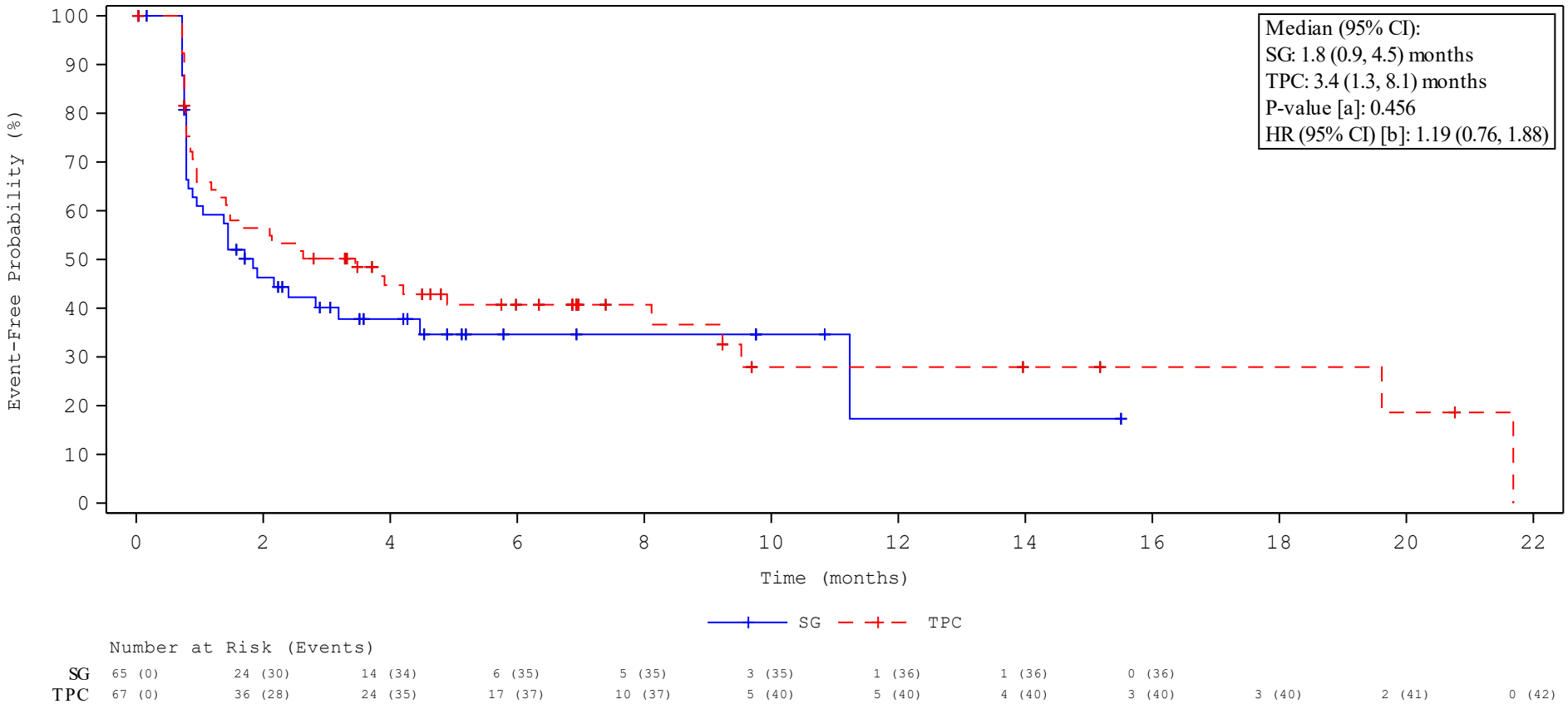
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.3.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group (Disease-free Interval = Recurrent Disease within 6 to 12 Months)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



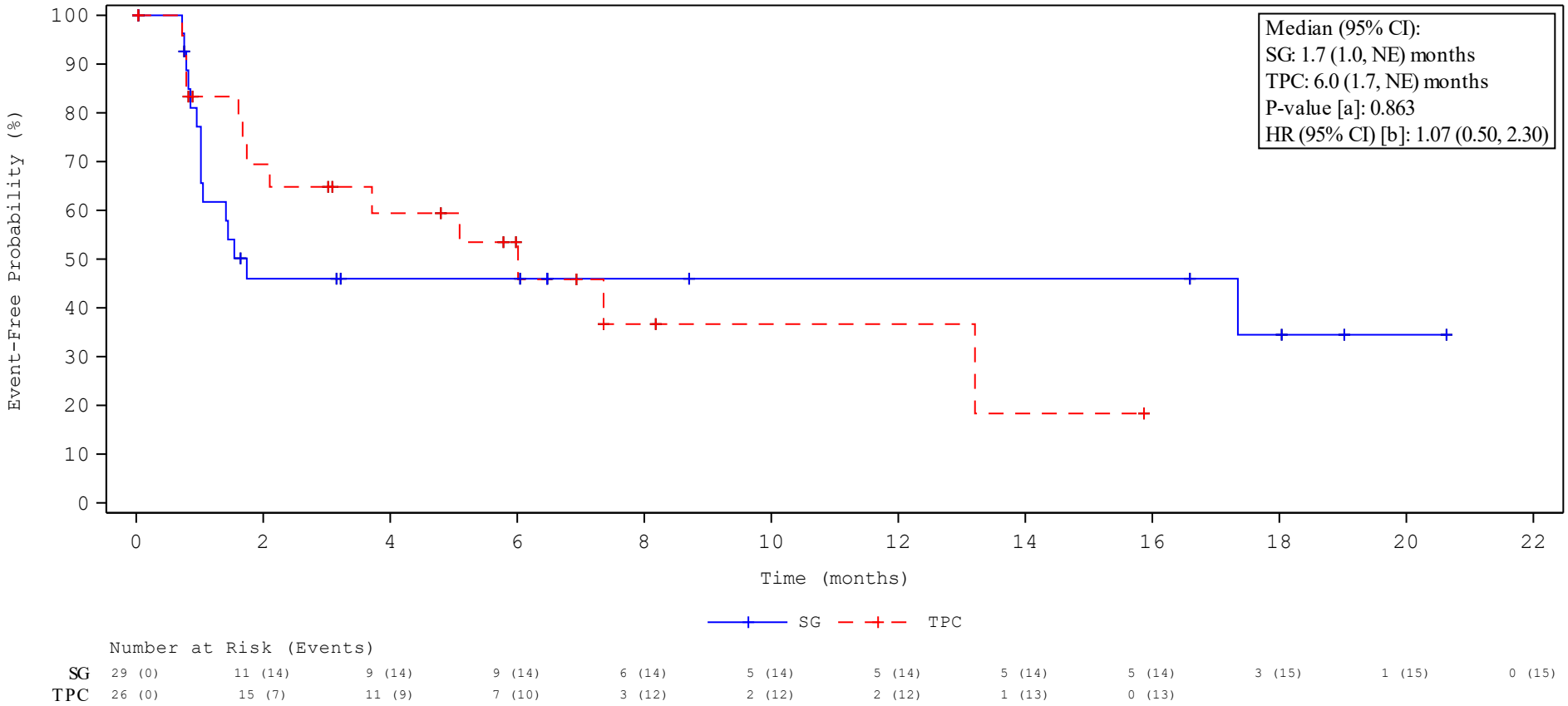
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.3.1.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group (Disease-free Interval = Recurrent Disease Occurring > 12 Months)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



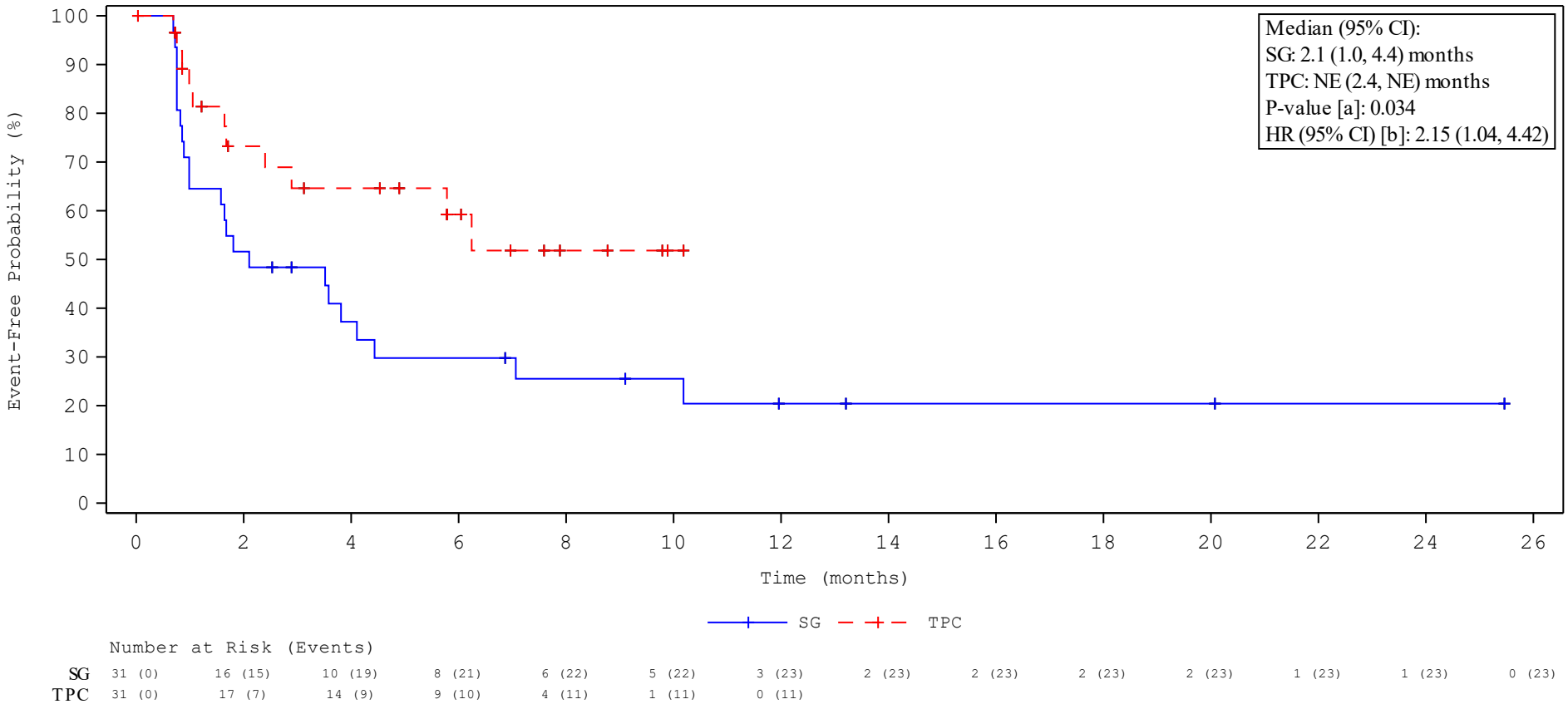
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.3.2.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group (Disease-free Interval = De novo)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



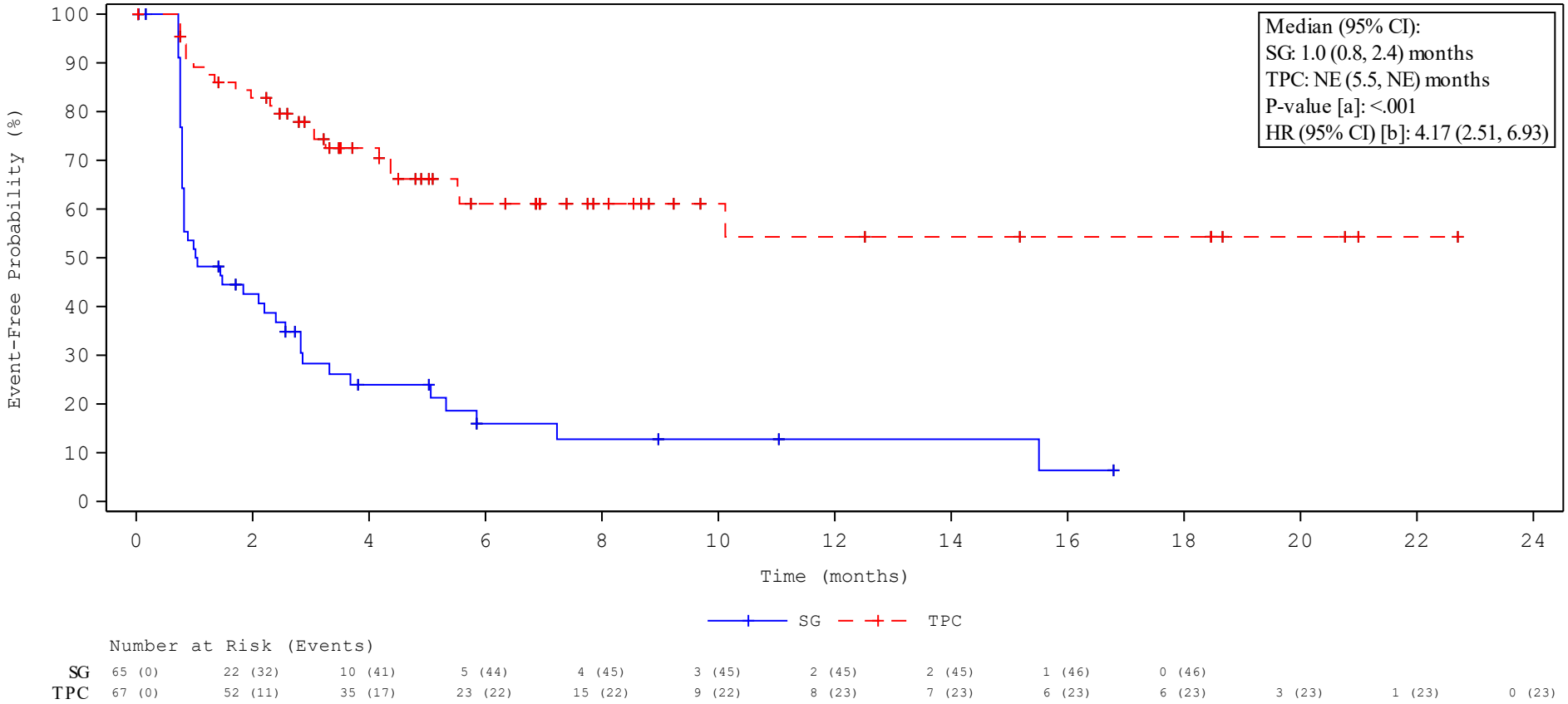
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.2.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group (Disease-free Interval = Recurrent Disease within 6 to 12 Months)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



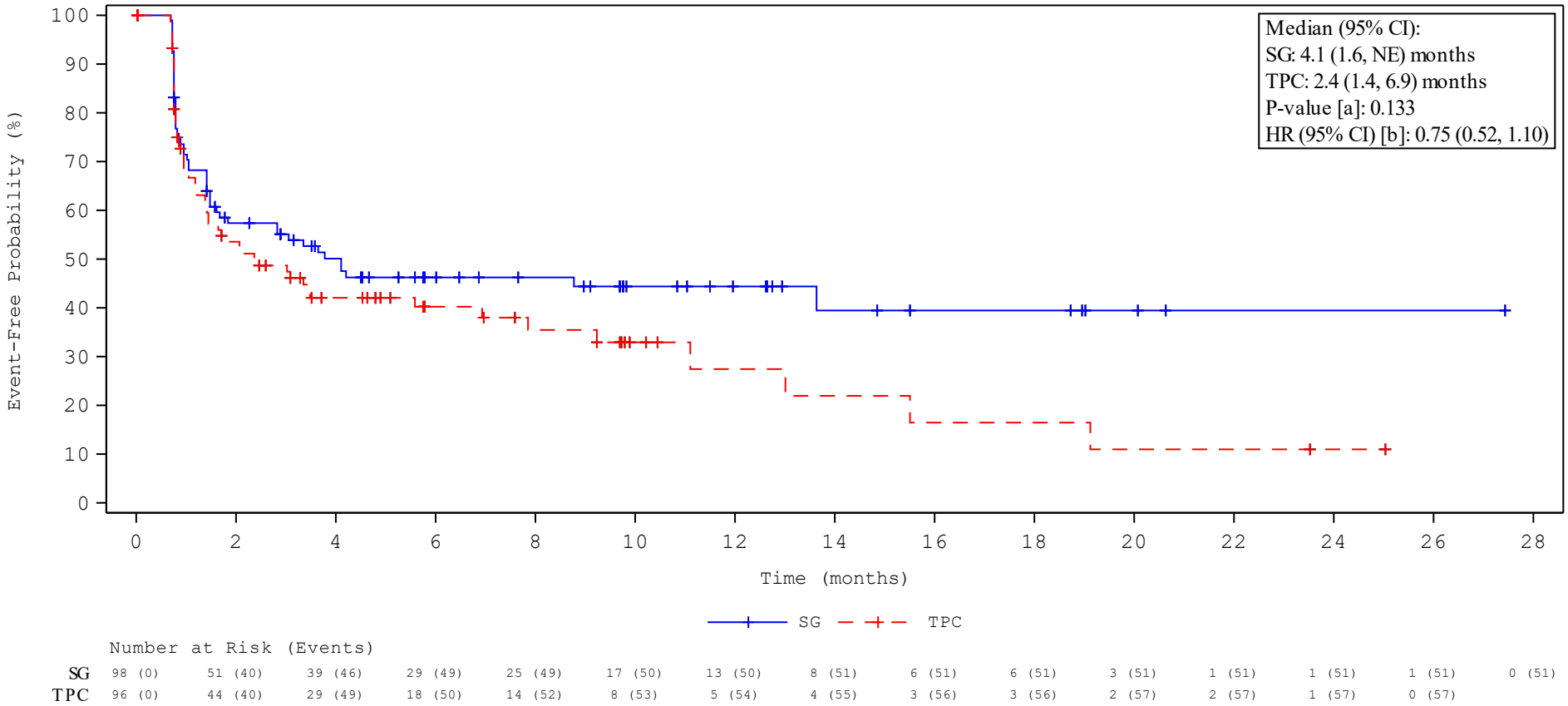
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.3.2.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group (Disease-free Interval = Recurrent Disease Occurring > 12 Months)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



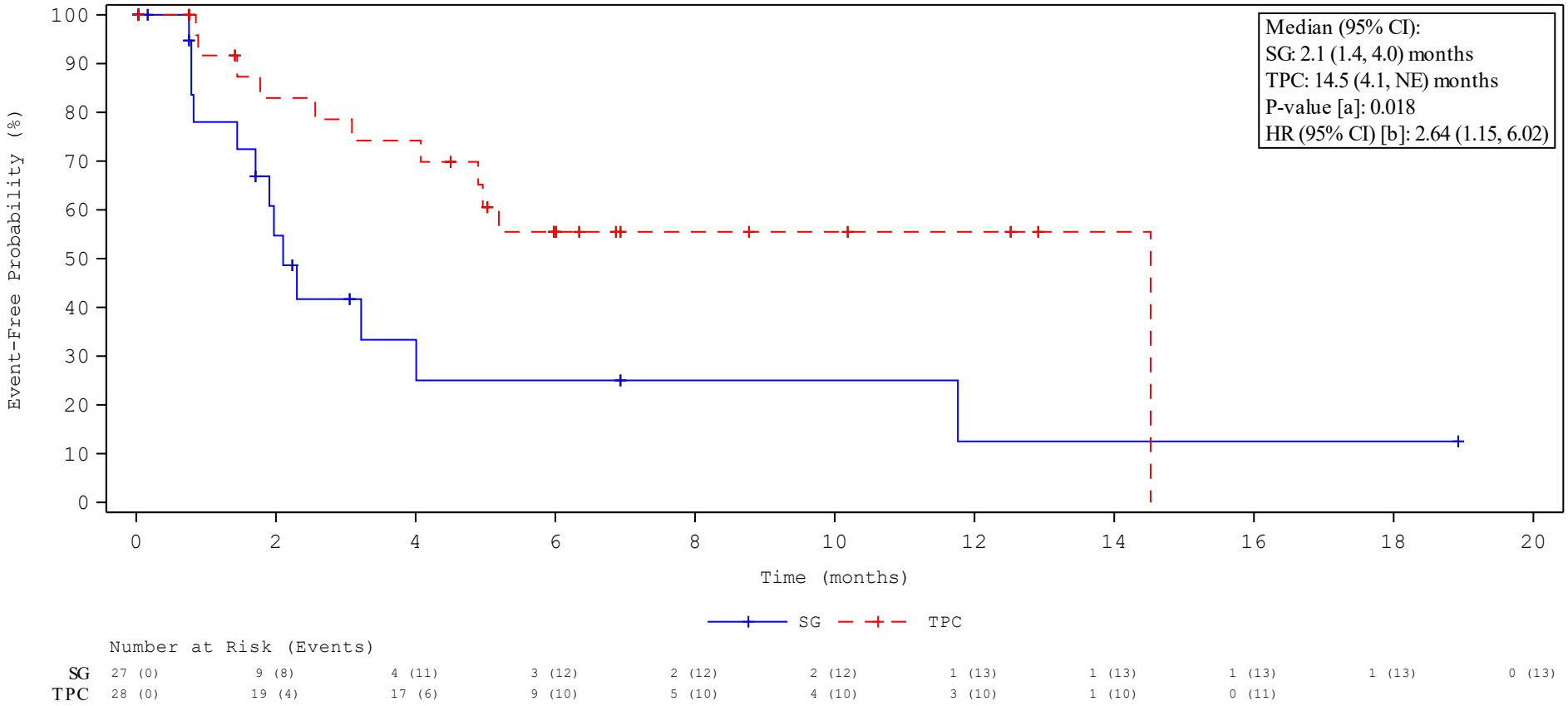
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.3.4.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Appetite Loss by Treatment Group (Age Group = <65 Years)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



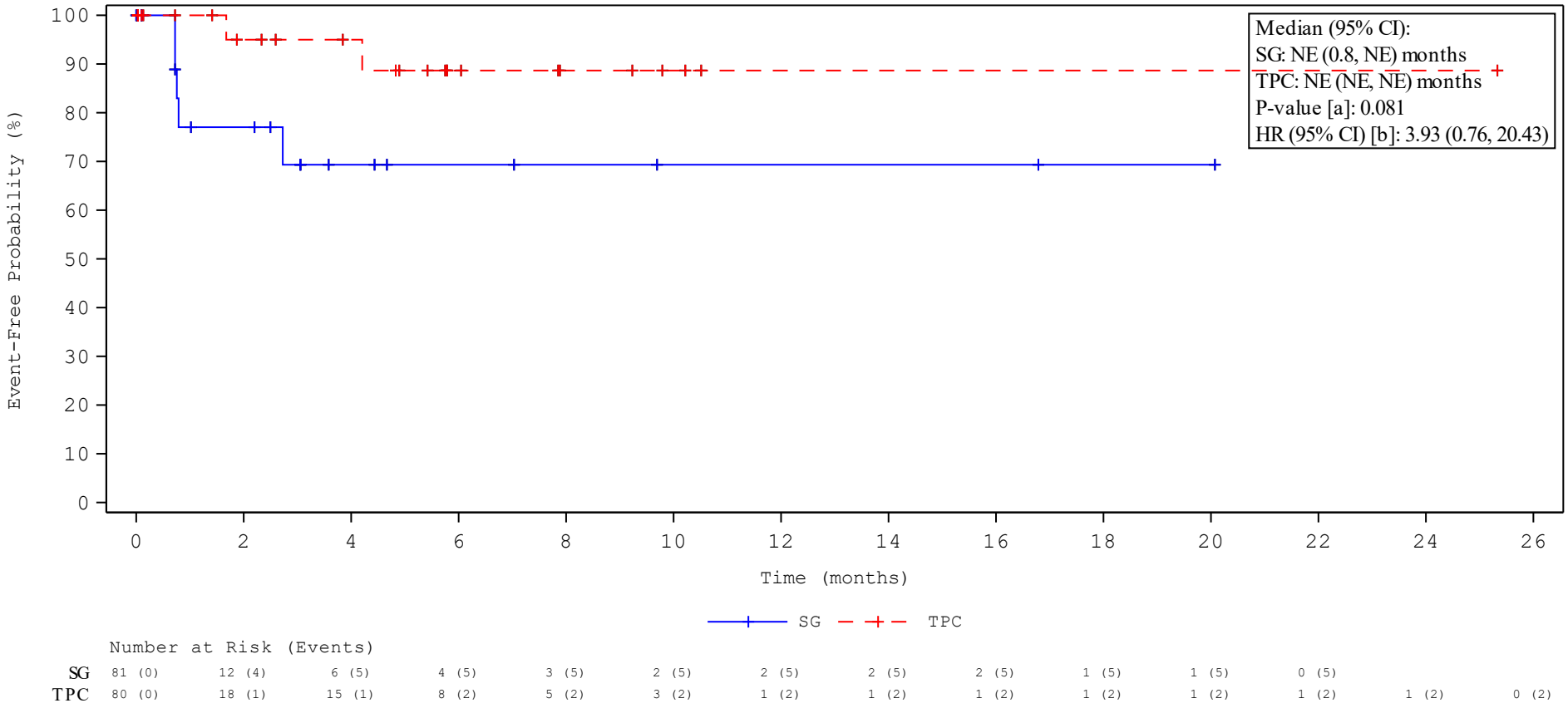
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.4.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Appetite Loss by Treatment Group (Age Group = ≥65 Years)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



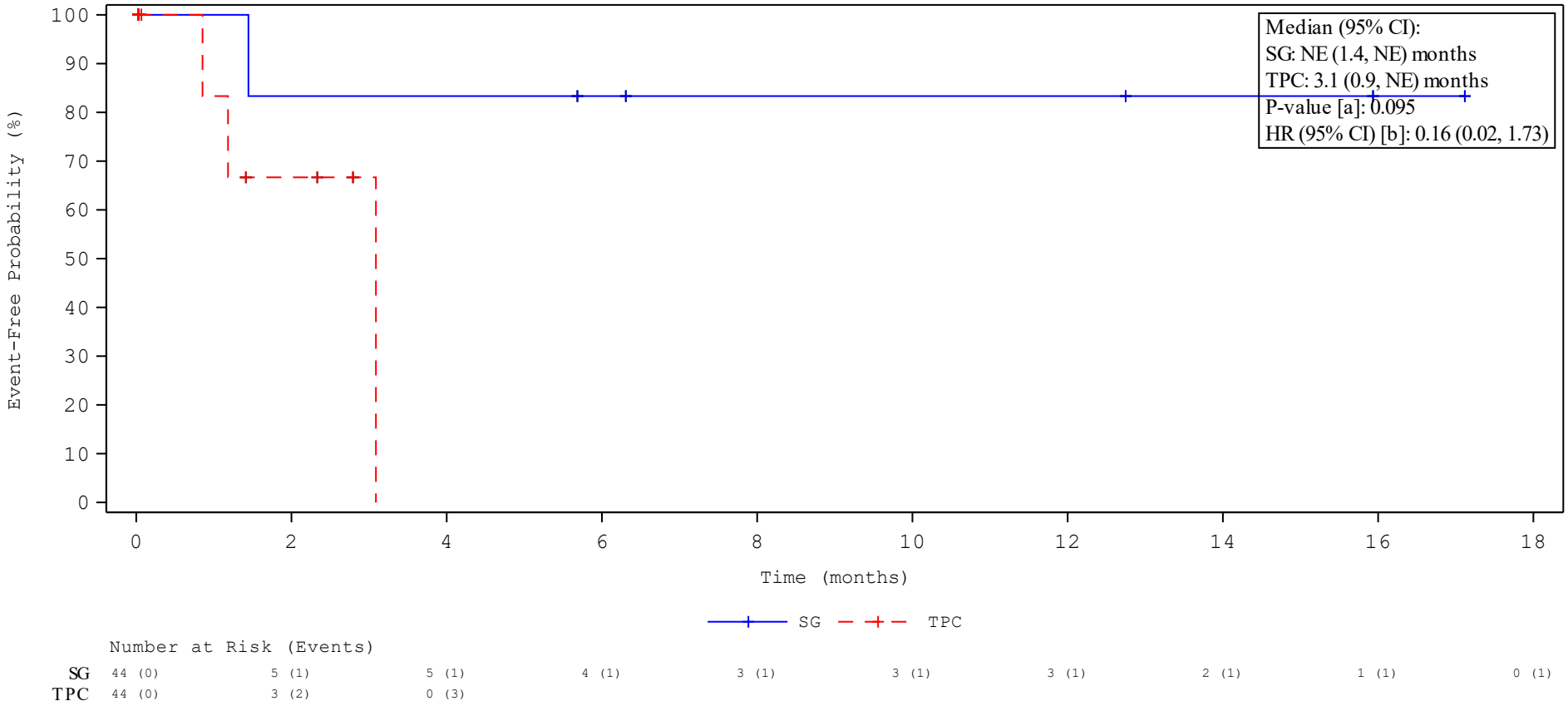
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.5.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Enjoyment by Treatment Group (Baseline ECOG = 0)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



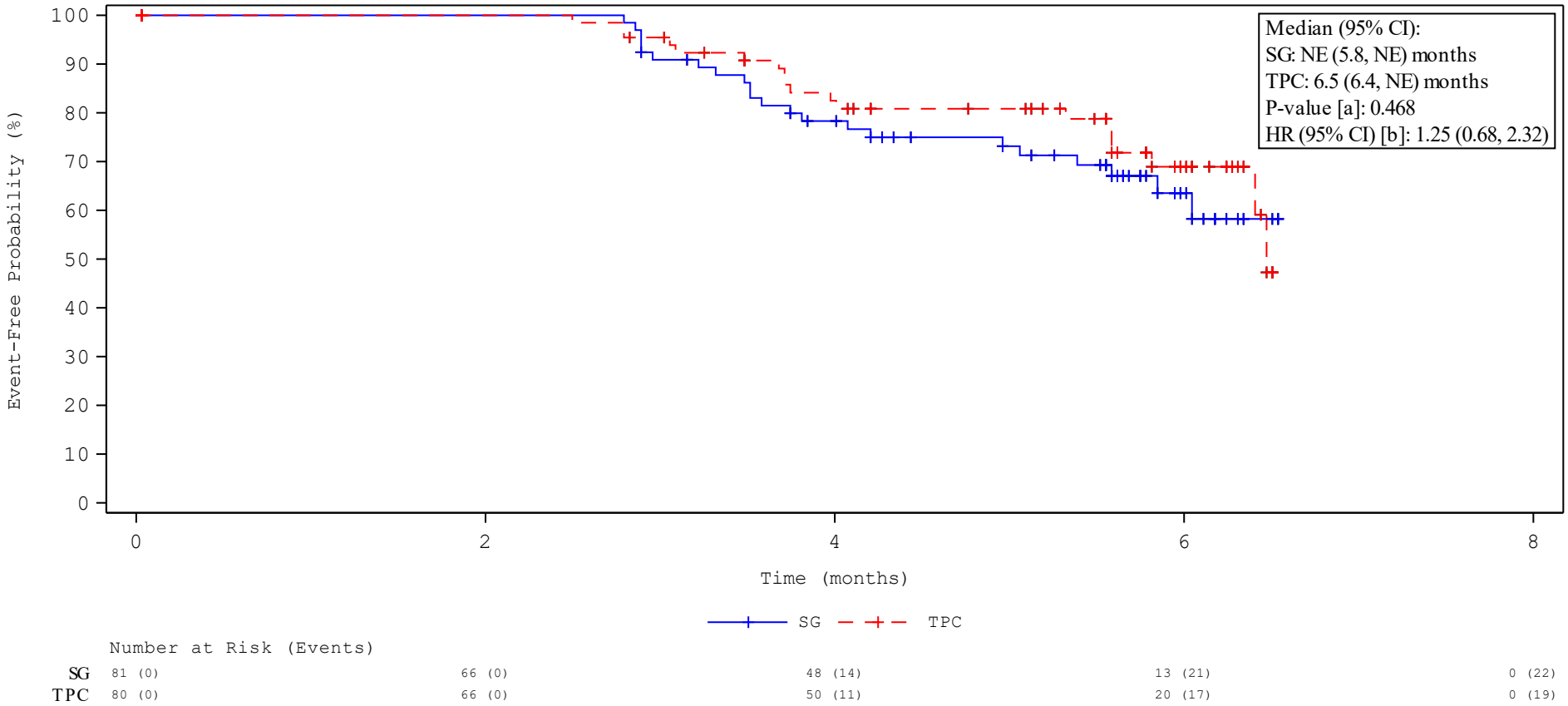
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.5.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Enjoyment by Treatment Group (Baseline ECOG = 1)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



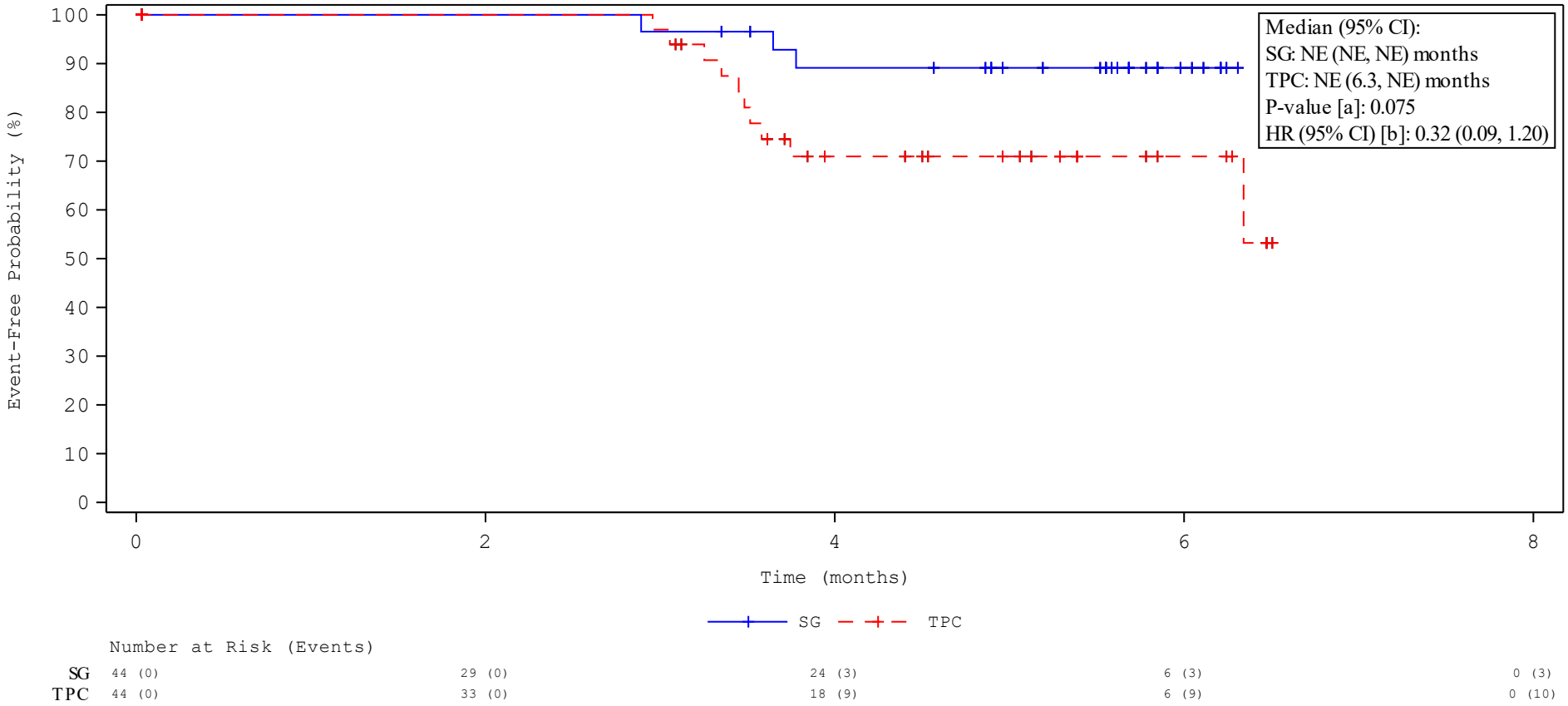
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.6.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIC by Treatment Group (Baseline ECOG = 0)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



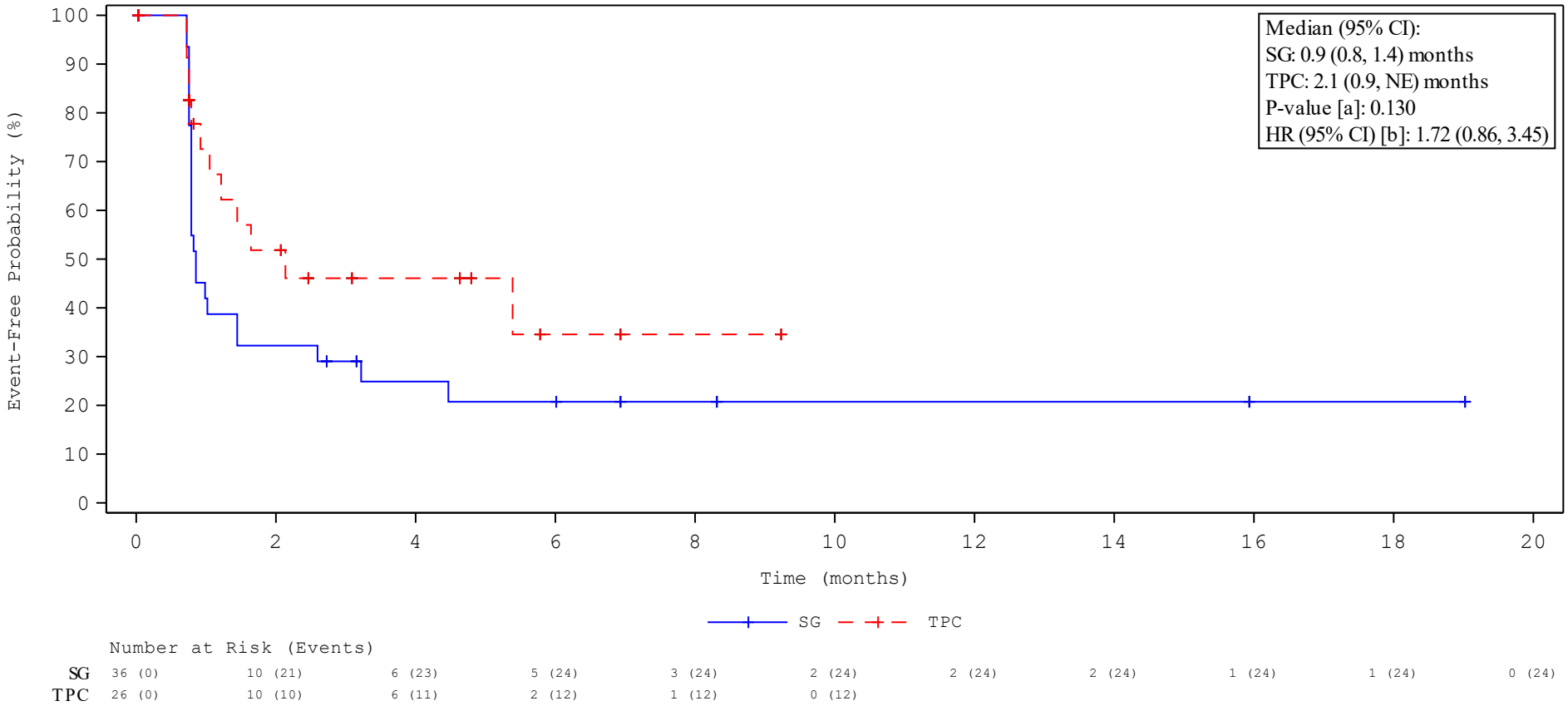
Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; HR = hazard ratio; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.6.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIC by Treatment Group (Baseline ECOG = 1)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



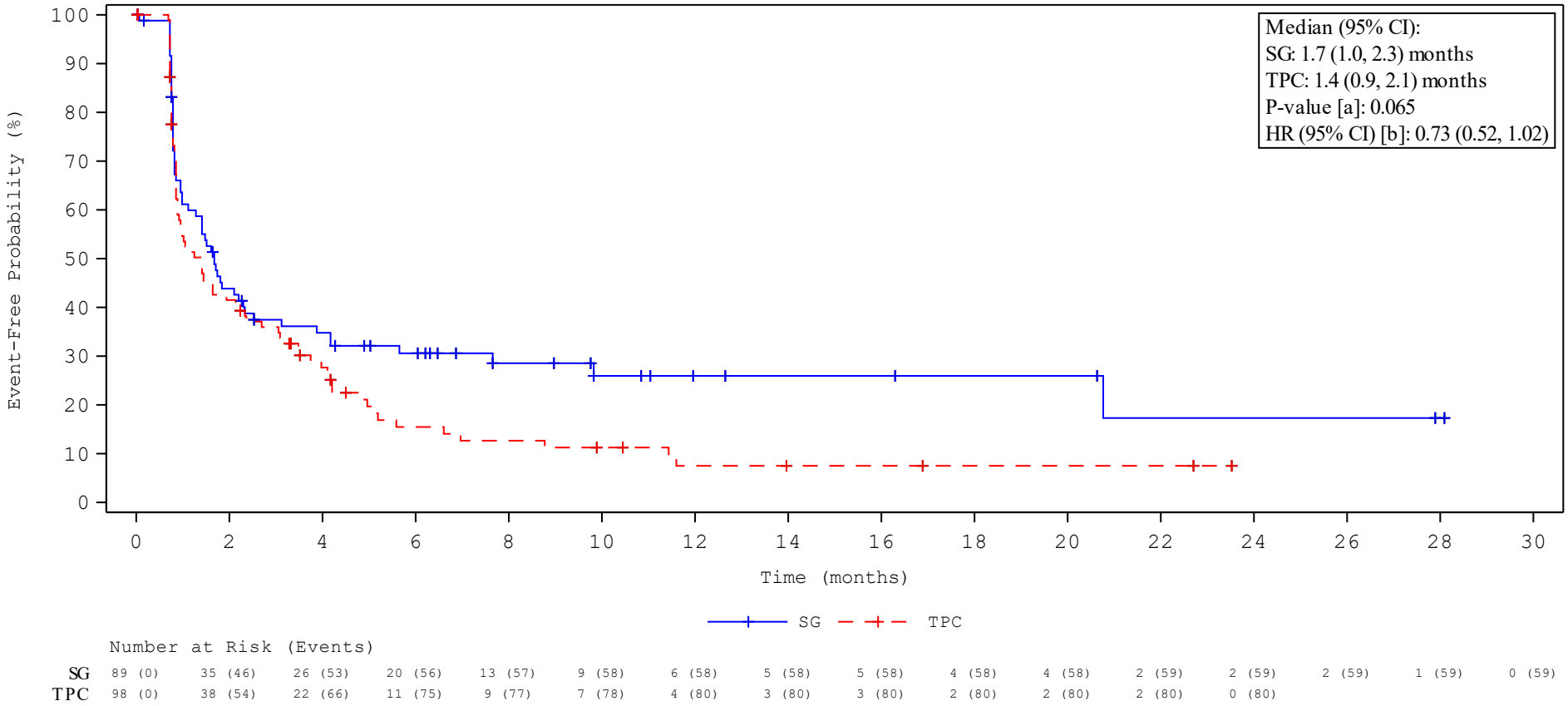
Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; HR = hazard ratio; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.7.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group (Liver Metastasis = Yes)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



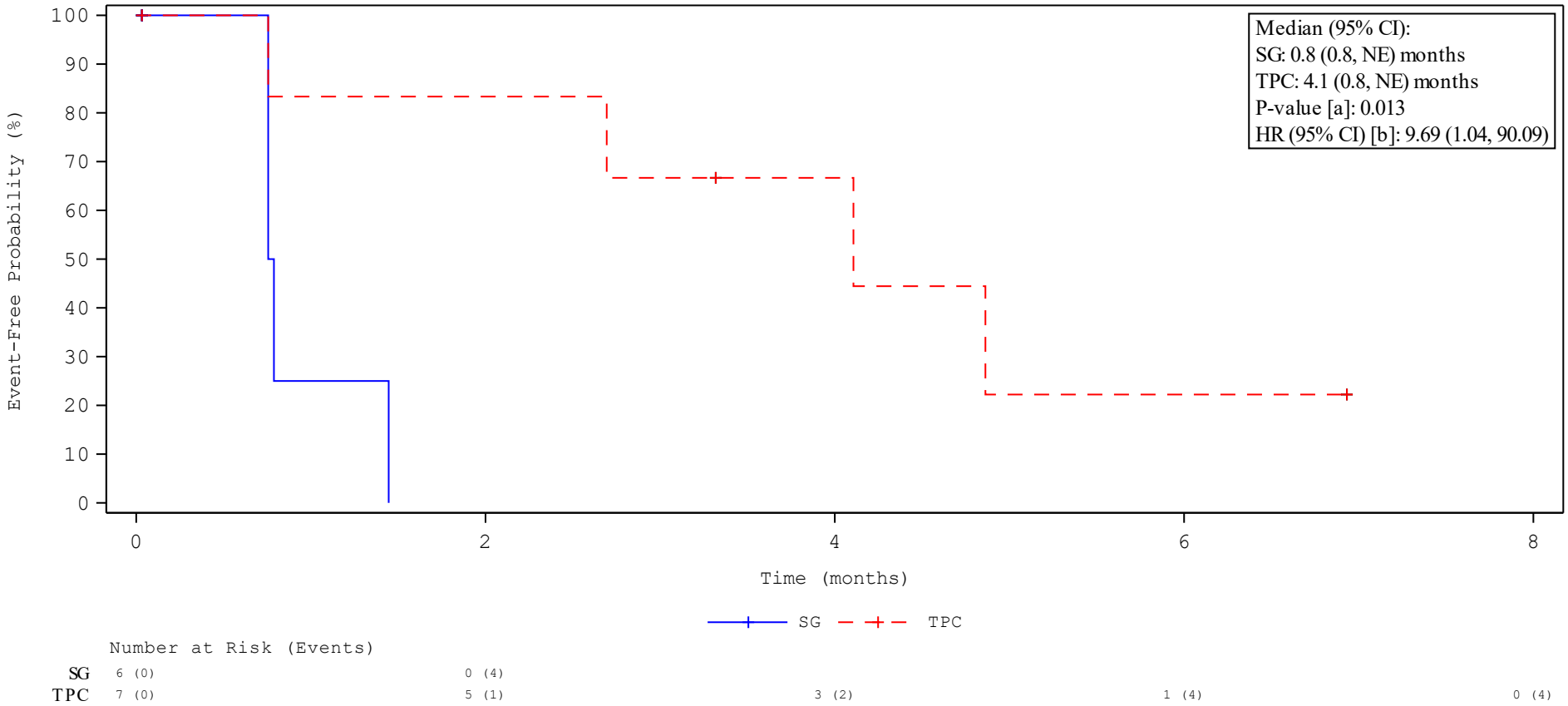
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.7.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group (Liver Metastasis = No)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



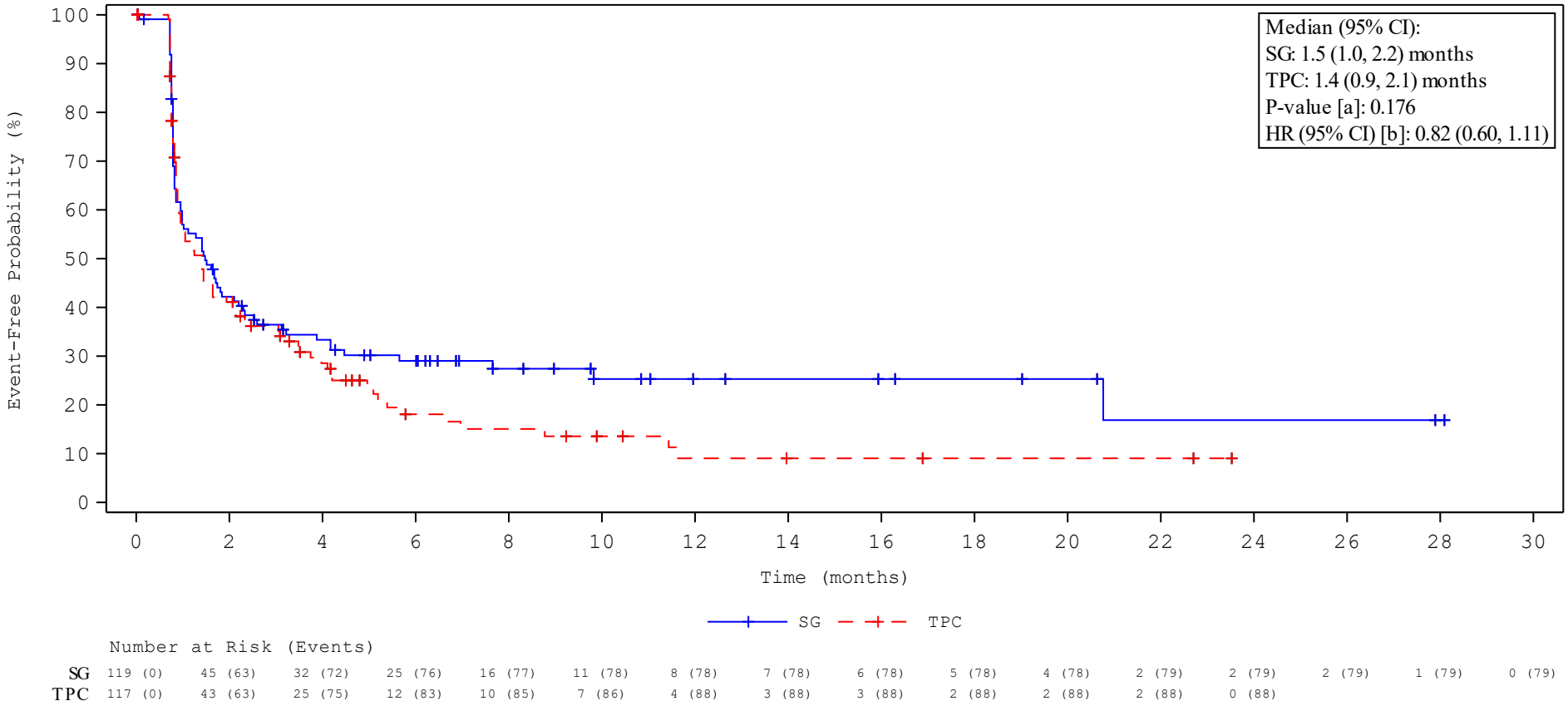
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.8.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group (Brain Metastasis = Yes)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



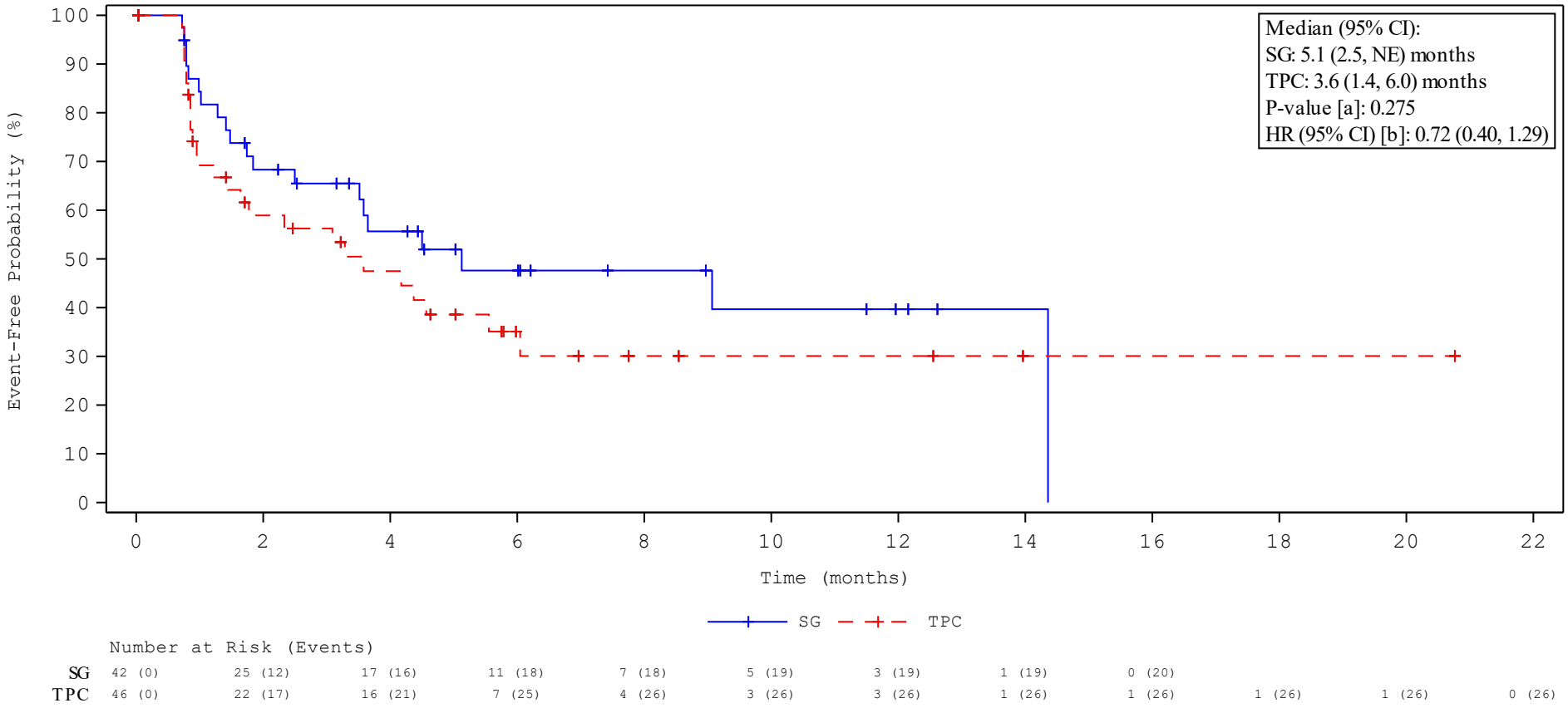
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.8.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group (Brain Metastasis = No)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



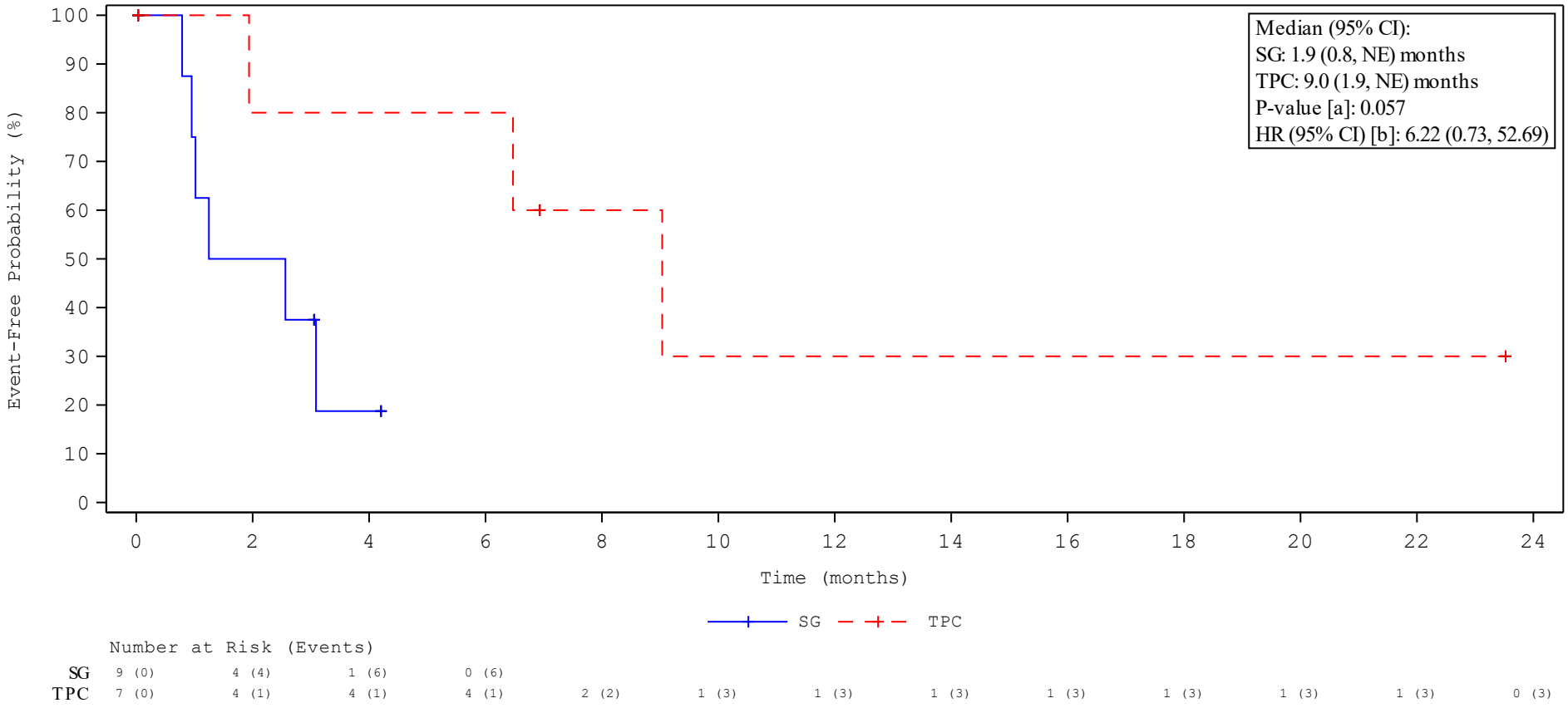
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.3.9.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Insomnia by Treatment Group (BRCA1/2 Status = Wild-type)
(mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

1. Statistical Analysis for German Submission of ASCENT-03

2. TFLs

Population: Triple-negative breast cancer (mTNBC)

Sub-Populations:
— Excluding patients preselected to receive nab-paclitaxel

Data Cut Date: 22 APR 2026
Report Date: 11 June 2026

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4. Disposition And Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel

4.1. Table 1.1.1: Participant Disposition — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Screened			346
mITT	177	169	346
Randomized but not Treated	2	3	5
Safety Analysis Set	175	166	341
Study Treatment Completion Status (Randomized Phase)			
Continuing Study Treatment	20 (11.3%)	5 (3.0%)	25 (7.2%)
Discontinued Study Treatment	157 (88.7%)	164 (97.0%)	321 (92.8%)
Adverse Event	9 (5.1%)	17 (10.1%)	26 (7.5%)
Pregnancy	0	0	0
Investigator's Discretion	9 (5.1%)	6 (3.6%)	15 (4.3%)
Non-Compliance with Study Drug	0	0	0
Subject Decision	13 (7.3%)	14 (8.3%)	27 (7.8%)
Study Terminated by Sponsor	0	0	0
Progressive Disease	121 (68.4%)	126 (74.6%)	247 (71.4%)
Lost to Follow-Up	0	0	0
Death	5 (2.8%)	1 (0.6%)	6 (1.7%)
Received Study Treatment in Crossover Phase		78 (46.2%)	
Study Completion Status			
Continuing Study	63 (35.6%)	46 (27.2%)	109 (31.5%)
Discontinued Study	114 (64.4%)	123 (72.8%)	237 (68.5%)
Death	107 (60.5%)	112 (66.3%)	219 (63.3%)
Withdrew Consent	7 (4.0%)	11 (6.5%)	18 (5.2%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Lost to Follow-Up	0	0	0
Study Terminated by Sponsor	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Screened Population: Participants who have signed an informed consent and participated in the screening procedures at site to assess eligibility.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug.
Denominator of percentages is the number of participants in each treatment group.
Randomized Phase excludes crossover phase when participants in TPC arm started to receive SG.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table1.Disposition of participants.R

4.2. Table 1.1.2: Demographic and Baseline Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Age (years)			
N	177	169	346
Mean (Sd)	56.3 (12.1)	53.7 (12.1)	55.1 (12.2)
Median	55.0	52.0	54.0
Q1, Q3	48.0, 64.0	45.0, 63.0	46.0, 63.8
Min, Max	28.0, 84.0	28.0, 86.0	28.0, 86.0
Age Group			
< 65	133 (75.1%)	131 (77.5%)	264 (76.3%)
>= 65	44 (24.9%)	38 (22.5%)	82 (23.7%)
Sex at Birth			
F	177 (100.0%)	168 (99.4%)	345 (99.7%)
M	0	1 (0.6%)	1 (0.3%)
Race			
AMERICAN INDIAN OR ALASKA NATIVE	6 (3.4%)	11 (6.5%)	17 (4.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
ASIAN	38 (21.5%)	38 (22.5%)	76 (22.0%)
BLACK OR AFRICAN AMERICAN	5 (2.8%)	5 (3.0%)	10 (2.9%)
NOT REPORTED	5 (2.8%)	3 (1.8%)	8 (2.3%)
OTHER	8 (4.5%)	8 (4.7%)	16 (4.6%)
WHITE	115 (65.0%)	104 (61.5%)	219 (63.3%)
Ethnicity			
HISPANIC OR LATINO	46 (26.0%)	50 (29.6%)	96 (27.7%)
NOT HISPANIC OR LATINO	128 (72.3%)	117 (69.2%)	245 (70.8%)
NOT REPORTED	3 (1.7%)	2 (1.2%)	5 (1.4%)
Region			
Rest of the World	121 (68.4%)	117 (69.2%)	238 (68.8%)
US/Canada/Western Europe	56 (31.6%)	52 (30.8%)	108 (31.2%)
Country			
Argentina	10 (5.6%)	12 (7.1%)	22 (6.4%)
Australia	4 (2.3%)	0	4 (1.2%)
Belgium	2 (1.1%)	3 (1.8%)	5 (1.4%)
Brazil	18 (10.2%)	15 (8.9%)	33 (9.5%)
Canada	5 (2.8%)	1 (0.6%)	6 (1.7%)
Chile	4 (2.3%)	5 (3.0%)	9 (2.6%)
China	2 (1.1%)	5 (3.0%)	7 (2.0%)
Czech Republic	3 (1.7%)	2 (1.2%)	5 (1.4%)
France	10 (5.6%)	6 (3.6%)	16 (4.6%)
Germany	7 (4.0%)	3 (1.8%)	10 (2.9%)
Hong Kong	1 (0.6%)	1 (0.6%)	2 (0.6%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hungary	3 (1.7%)	4 (2.4%)	7 (2.0%)
Israel	9 (5.1%)	5 (3.0%)	14 (4.0%)
Italy	10 (5.6%)	12 (7.1%)	22 (6.4%)
Japan	20 (11.3%)	15 (8.9%)	35 (10.1%)
Korea, Republic of	12 (6.8%)	9 (5.3%)	21 (6.1%)
Malaysia	3 (1.7%)	4 (2.4%)	7 (2.0%)
Mexico	12 (6.8%)	16 (9.5%)	28 (8.1%)
Netherlands	4 (2.3%)	2 (1.2%)	6 (1.7%)
Poland	1 (0.6%)	0	1 (0.3%)
South Africa	4 (2.3%)	5 (3.0%)	9 (2.6%)
Spain	7 (4.0%)	10 (5.9%)	17 (4.9%)
Turkey	15 (8.5%)	14 (8.3%)	29 (8.4%)
United States	11 (6.2%)	11 (6.5%)	22 (6.4%)
Austria	0	2 (1.2%)	2 (0.6%)
Romania	0	1 (0.6%)	1 (0.3%)
Slovakia	0	2 (1.2%)	2 (0.6%)
Taiwan	0	2 (1.2%)	2 (0.6%)
United Kingdom	0	2 (1.2%)	2 (0.6%)
Weight (kg)			
N	177	169	346
Mean (Sd)	70.4 (15.9)	67.7 (13.8)	69.1 (15.0)
Median	68.8	66.8	68.0
Q1, Q3	59.0, 80.0	56.0, 77.0	58.0, 79.3
Min, Max	38.1, 131.4	42.0, 113.0	38.1, 131.4

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Height (cm)			
N	177	169	346
Mean (Sd)	160.9 (7.5)	160.7 (7.0)	160.8 (7.3)
Median	161.0	160.0	160.9
Q1, Q3	156.2, 166.0	155.0, 166.0	156.0, 166.0
Min, Max	140.0, 180.0	145.0, 183.0	140.0, 183.0
BMI (kg/m2)			
N	177	169	346
Mean (Sd)	27.2 (5.9)	26.2 (5.2)	26.7 (5.6)
Median	26.2	25.4	26.0
Q1, Q3	22.9, 30.9	22.3, 29.3	22.7, 30.1
Min, Max	14.1, 54.8	16.8, 44.1	14.1, 54.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Age (in years) was collected on the date of first study drug administration (Day 1) if dosed, or randomization if not dosed.
Not Permitted = local regulators did not allow collection of race or ethnicity information or participant refused to provide information.
*Body Mass Index (BMI) (kg/m^2) = [Weight (kg) / Height (cm)^2]*10,000*
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table2.Demographic and Baseline Characteristics.R

4.3. Table 1.1.3: Other Baseline Disease Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Baseline ECOG Score			
0	116 (65.5%)	106 (62.7%)	222 (64.2%)
1	61 (34.5%)	63 (37.3%)	124 (35.8%)
UGT1A1 Genotype			
*1/*1	76 (42.9%)	78 (46.2%)	154 (44.5%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
*1/*28	68 (38.4%)	55 (32.5%)	123 (35.5%)
*1/*6	10 (5.6%)	7 (4.1%)	17 (4.9%)
*28/*28	14 (7.9%)	18 (10.7%)	32 (9.2%)
*28/*37	2 (1.1%)	0 (0.0%)	2 (0.6%)
*6/*28	1 (0.6%)	2 (1.2%)	3 (0.9%)
*6/*6	1 (0.6%)	1 (0.6%)	2 (0.6%)
Missing/Not Done	5 (2.8%)	6 (3.6%)	11 (3.2%)
*1/*37	0 (0.0%)	1 (0.6%)	1 (0.3%)
*27/*28	0 (0.0%)	1 (0.6%)	1 (0.3%)
Menopausal Status (Females Only)			
Post-menopausal	140 (79.1%)	119 (70.8%)	259 (75.1%)
Pre-menopausal	37 (20.9%)	49 (29.2%)	86 (24.9%)
BRCA1 Mutation Status			
Mutant	11 (6.2%)	8 (4.7%)	19 (5.5%)
Unknown	99 (55.9%)	95 (56.2%)	194 (56.1%)
Wild Type	67 (37.9%)	66 (39.1%)	133 (38.4%)
BRCA2 Mutation Status			
Mutant	3 (1.7%)	3 (1.8%)	6 (1.7%)
Unknown	99 (55.9%)	99 (58.6%)	198 (57.2%)
Wild Type	75 (42.4%)	67 (39.6%)	142 (41.0%)
BRCA1/2 Mutation Status			
Mutant	12 (6.8%)	10 (5.9%)	22 (6.4%)
Unknown	99 (55.9%)	94 (55.6%)	193 (55.8%)
Wild Type	66 (37.3%)	65 (38.5%)	131 (37.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
PD-L1 CPS			
1 to <10	108 (61.0%)	110 (65.1%)	218 (63.0%)
<1	67 (37.9%)	59 (34.9%)	126 (36.4%)
>=10	1 (0.6%)	0 (0.0%)	1 (0.3%)
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Estrogen Receptor Status			
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Negative (< 1%)	175 (98.9%)	169 (100.0%)	344 (99.4%)
Positive (>= 1%)	1 (0.6%)	0 (0.0%)	1 (0.3%)
Progesterone Receptor Status			
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Negative (< 1%)	176 (99.4%)	169 (100.0%)	345 (99.7%)
HER2 Status			
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Negative	176 (99.4%)	169 (100.0%)	345 (99.7%)
Disease Stratification			
De novo	55 (31.1%)	49 (29.0%)	104 (30.1%)
Recurrent disease occurring > 12 months	88 (49.7%)	86 (50.9%)	174 (50.3%)
Recurrent disease within 6 to 12 months	34 (19.2%)	34 (20.1%)	68 (19.7%)
Pre-selected TPC Prior to Randomization			
Gemcitabine/Carboplatin	125 (70.6%)	124 (73.4%)	249 (72.0%)
Taxane	52 (29.4%)	45 (26.6%)	97 (28.0%)
Breast Cancer Stage at Initial Diagnosis			
STAGE 1	27 (15.3%)	20 (11.8%)	47 (13.6%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
STAGE 2	60 (33.9%)	61 (36.1%)	121 (35.0%)
STAGE 3	40 (22.6%)	42 (24.9%)	82 (23.7%)
STAGE 4	50 (28.2%)	46 (27.2%)	96 (27.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subtype of Cancer at Initial Diagnosis			
HR+/HER2+	3 (1.7%)	3 (1.8%)	6 (1.7%)
HR+/HER2-	22 (12.4%)	23 (13.6%)	45 (13.0%)
HR-/HER2+	3 (1.7%)	0 (0.0%)	3 (0.9%)
HR-/HER2- (TNBC)	148 (83.6%)	141 (83.4%)	289 (83.5%)
Missing	1 (0.6%)	2 (1.2%)	3 (0.9%)
Disease Status at Screening			
Locally advanced and Inoperable	4 (2.3%)	5 (3.0%)	9 (2.6%)
Metastatic	173 (97.7%)	164 (97.0%)	337 (97.4%)
Site of Metastasis at Screening			
Bone	63 (35.6%)	51 (30.2%)	114 (32.9%)
Brain	8 (4.5%)	9 (5.3%)	17 (4.9%)
Liver	47 (26.6%)	39 (23.1%)	86 (24.9%)
Lung	106 (59.9%)	103 (60.9%)	209 (60.4%)
Lymph Node	116 (65.5%)	107 (63.3%)	223 (64.5%)
Other	55 (31.1%)	59 (34.9%)	114 (32.9%)
Time from Locally Advanced and Inoperable or Metastatic Disease to Randomization (months) [a]			
N	176	169	345
Mean (StD)	2.2 (1.60)	2.5 (2.10)	2.3 (1.87)
Median	1.8	1.8	1.8

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Q1, Q3	1.3, 2.5	1.3, 2.9	1.3, 2.7
Min, Max	0.5, 14.3	0.1, 13.2	0.1, 14.3

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages for other baseline characteristics is the number of participants in each treatment group.
[a] Mutant denotes participant is either BRCA1 or BRCA2 mutant, or both mutant. Wild type denotes participant is both BRCA1 and BRCA2 wild type. Unknown denotes participant is BRCA1 unknown and BRCA2 wild type or unknown, or participant is BRCA1 wild type or unknown and BRCA2 unknown.
PD-L1 CPS (combined positive score) and TNBC status were collected centrally.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table3.Other Baseline Disease Characteristics.R

4.4. Table 1.1.4: Medical History by System Organ Class and Preferred Term — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Number (%) of Participants with Any Medical History	160 (90.4%)	151 (89.3%)	311 (89.9%)
Blood and lymphatic system disorders	12 (6.8%)	17 (10.1%)	29 (8.4%)
Anaemia	10 (5.6%)	14 (8.3%)	24 (6.9%)
Lymphopenia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Coagulopathy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Increased tendency to bruise	1 (0.6%)	0 (0.0%)	1 (6.9%)
Leukopenia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lymphadenopathy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Neutropenia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Thrombocytopenia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Thrombocytosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac disorders	12 (6.8%)	15 (8.9%)	27 (8.4%)
Atrial fibrillation	2 (1.1%)	2 (1.2%)	4 (6.9%)
Sinus tachycardia	2 (1.1%)	2 (1.2%)	4 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Tachycardia	3 (1.7%)	1 (0.6%)	4 (6.9%)
Arrhythmia	2 (1.1%)	1 (0.6%)	3 (6.9%)
Ventricular extrasystoles	0 (0.0%)	3 (1.8%)	3 (6.9%)
Cardiomyopathy	1 (0.6%)	1 (0.6%)	2 (6.9%)
Angina pectoris	0 (0.0%)	1 (0.6%)	1 (6.9%)
Arrhythmia supraventricular	1 (0.6%)	0 (0.0%)	1 (6.9%)
Arteriosclerosis coronary artery	0 (0.0%)	1 (0.6%)	1 (6.9%)
Bradycardia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac failure chronic	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac failure congestive	1 (0.6%)	0 (0.0%)	1 (6.9%)
Carditis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Myocardial infarction	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pericardial effusion	0 (0.0%)	1 (0.6%)	1 (6.9%)
Sinus bradycardia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Supraventricular extrasystoles	0 (0.0%)	1 (0.6%)	1 (6.9%)
Congenital, familial and genetic disorders	3 (1.7%)	8 (4.7%)	11 (8.4%)
Congenital neuropathy	2 (1.1%)	0 (0.0%)	2 (6.9%)
Adenomatous polyposis coli	0 (0.0%)	1 (0.6%)	1 (6.9%)
Coarctation of the aorta	0 (0.0%)	1 (0.6%)	1 (6.9%)
Congenital musculoskeletal disorder of limbs	0 (0.0%)	1 (0.6%)	1 (6.9%)
Developmental hip dysplasia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Factor V Leiden mutation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Kidney duplex	0 (0.0%)	1 (0.6%)	1 (6.9%)
Renal fusion anomaly	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Thalassaemia sickle cell	0 (0.0%)	1 (0.6%)	1 (6.9%)
Venous angioma of brain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Ear and labyrinth disorders	8 (4.5%)	3 (1.8%)	11 (8.4%)
Vertigo	2 (1.1%)	2 (1.2%)	4 (6.9%)
Deafness	2 (1.1%)	0 (0.0%)	2 (6.9%)
Hypoacusis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Cholesteatoma	1 (0.6%)	0 (0.0%)	1 (6.9%)
Meniere's disease	0 (0.0%)	1 (0.6%)	1 (6.9%)
Sudden hearing loss	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vertigo positional	1 (0.6%)	0 (0.0%)	1 (6.9%)
Endocrine disorders	25 (14.1%)	25 (14.8%)	50 (8.4%)
Hypothyroidism	16 (9.0%)	18 (10.7%)	34 (6.9%)
Hyperthyroidism	2 (1.1%)	5 (3.0%)	7 (6.9%)
Autoimmune thyroiditis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Hyperparathyroidism	1 (0.6%)	1 (0.6%)	2 (6.9%)
Thyroid disorder	2 (1.1%)	0 (0.0%)	2 (6.9%)
Thyroid mass	2 (1.1%)	0 (0.0%)	2 (6.9%)
Autoimmune hypothyroidism	1 (0.6%)	0 (0.0%)	1 (6.9%)
Goitre	0 (0.0%)	1 (0.6%)	1 (6.9%)
Eye disorders	16 (9.0%)	10 (5.9%)	26 (8.4%)
Cataract	3 (1.7%)	3 (1.8%)	6 (6.9%)
Dry eye	2 (1.1%)	4 (2.4%)	6 (6.9%)
Myopia	2 (1.1%)	3 (1.8%)	5 (6.9%)
Glaucoma	1 (0.6%)	2 (1.2%)	3 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Presbyopia	2 (1.1%)	1 (0.6%)	3 (6.9%)
Astigmatism	0 (0.0%)	2 (1.2%)	2 (6.9%)
Conjunctivitis allergic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Eye pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Fuchs' syndrome	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hypermetropia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Macular degeneration	1 (0.6%)	0 (0.0%)	1 (6.9%)
Macular oedema	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pterygium	1 (0.6%)	0 (0.0%)	1 (6.9%)
Retinal haemorrhage	1 (0.6%)	0 (0.0%)	1 (6.9%)
Retinal vein occlusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Strabismus	0 (0.0%)	1 (0.6%)	1 (6.9%)
Vision blurred	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gastrointestinal disorders	42 (23.7%)	43 (25.4%)	85 (8.4%)
Constipation	9 (5.1%)	14 (8.3%)	23 (6.9%)
Gastrooesophageal reflux disease	10 (5.6%)	7 (4.1%)	17 (6.9%)
Nausea	2 (1.1%)	8 (4.7%)	10 (6.9%)
Abdominal pain upper	3 (1.7%)	3 (1.8%)	6 (6.9%)
Hiatus hernia	3 (1.7%)	2 (1.2%)	5 (6.9%)
Diarrhoea	2 (1.1%)	2 (1.2%)	4 (6.9%)
Irritable bowel syndrome	2 (1.1%)	2 (1.2%)	4 (6.9%)
Colitis ulcerative	1 (0.6%)	2 (1.2%)	3 (6.9%)
Dyspepsia	2 (1.1%)	1 (0.6%)	3 (6.9%)
Gastric ulcer	2 (1.1%)	1 (0.6%)	3 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Gastritis	1 (0.6%)	2 (1.2%)	3 (6.9%)
Tooth loss	2 (1.1%)	1 (0.6%)	3 (6.9%)
Abdominal pain	1 (0.6%)	1 (0.6%)	2 (6.9%)
Coeliac disease	1 (0.6%)	1 (0.6%)	2 (6.9%)
Crohn's disease	0 (0.0%)	2 (1.2%)	2 (6.9%)
Dysphagia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Haemorrhoids	1 (0.6%)	1 (0.6%)	2 (6.9%)
Large intestine polyp	2 (1.1%)	0 (0.0%)	2 (6.9%)
Umbilical hernia	0 (0.0%)	2 (1.2%)	2 (6.9%)
Abdominal discomfort	0 (0.0%)	1 (0.6%)	1 (6.9%)
Abdominal distension	1 (0.6%)	0 (0.0%)	1 (6.9%)
Anal incontinence	1 (0.6%)	0 (0.0%)	1 (6.9%)
Anal sphincter atony	1 (0.6%)	0 (0.0%)	1 (6.9%)
Ascites	1 (0.6%)	0 (0.0%)	1 (6.9%)
Chronic gastritis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Diverticulum	0 (0.0%)	1 (0.6%)	1 (6.9%)
Diverticulum intestinal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Food poisoning	0 (0.0%)	1 (0.6%)	1 (6.9%)
Gastrointestinal disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gastrointestinal pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Haemorrhoidal haemorrhage	1 (0.6%)	0 (0.0%)	1 (6.9%)
Inguinal hernia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lumbar hernia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Mucosal prolapse syndrome	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Obstructive pancreatitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Oral pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pancreatitis chronic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Periodontal disease	1 (0.6%)	0 (0.0%)	1 (6.9%)
Stomatitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tongue pigmentation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vomiting	1 (0.6%)	0 (0.0%)	1 (6.9%)
General disorders and administration site conditions	21 (11.9%)	20 (11.8%)	41 (8.4%)
Fatigue	7 (4.0%)	6 (3.6%)	13 (6.9%)
Pain	3 (1.7%)	4 (2.4%)	7 (6.9%)
Asthenia	2 (1.1%)	4 (2.4%)	6 (6.9%)
Chest pain	2 (1.1%)	4 (2.4%)	6 (6.9%)
Oedema peripheral	4 (2.3%)	1 (0.6%)	5 (6.9%)
Peripheral swelling	1 (0.6%)	1 (0.6%)	2 (6.9%)
Pyrexia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Axillary pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Drug intolerance	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gait disturbance	0 (0.0%)	1 (0.6%)	1 (6.9%)
Non-cardiac chest pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Oedema	0 (0.0%)	1 (0.6%)	1 (6.9%)
Supraclavicular fossa pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hepatobiliary disorders	15 (8.5%)	8 (4.7%)	23 (8.4%)
Cholelithiasis	5 (2.8%)	5 (3.0%)	10 (6.9%)
Hepatic function abnormal	3 (1.7%)	1 (0.6%)	4 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hepatic steatosis	2 (1.1%)	1 (0.6%)	3 (6.9%)
Cholecystitis chronic	2 (1.1%)	0 (0.0%)	2 (6.9%)
Hyperbilirubinaemia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Autoimmune hepatitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Biliary fistula	1 (0.6%)	0 (0.0%)	1 (6.9%)
Cholangitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cholecystitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hypertransaminasaemia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Jaundice cholestatic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Liver disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Metabolic dysfunction-associated steatohepatitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Immune system disorders	17 (9.6%)	21 (12.4%)	38 (8.4%)
Drug hypersensitivity	5 (2.8%)	12 (7.1%)	17 (6.9%)
Seasonal allergy	8 (4.5%)	7 (4.1%)	15 (6.9%)
Contrast media allergy	2 (1.1%)	1 (0.6%)	3 (6.9%)
Hypersensitivity	1 (0.6%)	1 (0.6%)	2 (6.9%)
Allergy to arthropod sting	1 (0.6%)	0 (0.0%)	1 (6.9%)
Food allergy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Iodine allergy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Rubber sensitivity	0 (0.0%)	1 (0.6%)	1 (6.9%)
Secondary immunodeficiency	0 (0.0%)	1 (0.6%)	1 (6.9%)
Infections and infestations	24 (13.6%)	20 (11.8%)	44 (8.4%)
COVID-19	5 (2.8%)	1 (0.6%)	6 (6.9%)
Appendicitis	5 (2.8%)	0 (0.0%)	5 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Urinary tract infection	1 (0.6%)	4 (2.4%)	5 (6.9%)
Herpes zoster	3 (1.7%)	1 (0.6%)	4 (6.9%)
Pneumonia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Empyema	1 (0.6%)	1 (0.6%)	2 (6.9%)
Labyrinthitis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Rhinitis	0 (0.0%)	2 (1.2%)	2 (6.9%)
American trypanosomiasis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Anal abscess	0 (0.0%)	1 (0.6%)	1 (6.9%)
Breast abscess	0 (0.0%)	1 (0.6%)	1 (6.9%)
Conjunctivitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Dengue fever	0 (0.0%)	1 (0.6%)	1 (6.9%)
Erysipelas	1 (0.6%)	0 (0.0%)	1 (6.9%)
Furuncle	0 (0.0%)	1 (0.6%)	1 (6.9%)
Genital herpes	0 (0.0%)	1 (0.6%)	1 (6.9%)
Gingivitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
HIV infection	0 (0.0%)	1 (0.6%)	1 (6.9%)
Helicobacter infection	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hepatitis B	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hepatitis viral	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lung abscess	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nosocomial infection	1 (0.6%)	0 (0.0%)	1 (6.9%)
Periodontitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Peritonitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pyelonephritis acute	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Rash pustular	0 (0.0%)	1 (0.6%)	1 (6.9%)
Skin candida	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tonsillitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tuberculosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Upper respiratory tract infection	0 (0.0%)	1 (0.6%)	1 (6.9%)
Viral pericarditis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Injury, poisoning and procedural complications	10 (5.6%)	1 (0.6%)	11 (8.4%)
Pelvic fracture	2 (1.1%)	0 (0.0%)	2 (6.9%)
Ankle fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Compression fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Contusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Femur fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Foot fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Humerus fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint dislocation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Neck injury	1 (0.6%)	0 (0.0%)	1 (6.9%)
Postoperative ileus	1 (0.6%)	0 (0.0%)	1 (6.9%)
Procedural pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Radiation skin injury	1 (0.6%)	0 (0.0%)	1 (6.9%)
Upper limb fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Wound complication	1 (0.6%)	0 (0.0%)	1 (6.9%)
Investigations	26 (14.7%)	22 (13.0%)	48 (8.4%)
Aspartate aminotransferase increased	10 (5.6%)	5 (3.0%)	15 (6.9%)
Blood alkaline phosphatase increased	8 (4.5%)	2 (1.2%)	10 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Blood cholesterol increased	3 (1.7%)	5 (3.0%)	8 (6.9%)
Alanine aminotransferase increased	4 (2.3%)	1 (0.6%)	5 (6.9%)
Blood lactate dehydrogenase increased	2 (1.1%)	3 (1.8%)	5 (6.9%)
Hepatic enzyme increased	2 (1.1%)	1 (0.6%)	3 (6.9%)
Arthroscopy	1 (0.6%)	1 (0.6%)	2 (6.9%)
Blood bilirubin increased	1 (0.6%)	1 (0.6%)	2 (6.9%)
Blood glucose increased	1 (0.6%)	1 (0.6%)	2 (6.9%)
Blood triglycerides increased	0 (0.0%)	2 (1.2%)	2 (6.9%)
Blood uric acid increased	0 (0.0%)	2 (1.2%)	2 (6.9%)
Gamma-glutamyltransferase increased	1 (0.6%)	1 (0.6%)	2 (6.9%)
Alpha 1 foetoprotein abnormal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Bile acids increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Biopsy breast	1 (0.6%)	0 (0.0%)	1 (6.9%)
Biopsy liver	1 (0.6%)	0 (0.0%)	1 (6.9%)
Biopsy lung	0 (0.0%)	1 (0.6%)	1 (6.9%)
Biopsy skin	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood albumin decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Blood chloride increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood glucose abnormal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Blood potassium increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood pressure increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood sodium increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood urea increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac murmur functional	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Ejection fraction decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Electrocardiogram QT shortened	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hepatitis B core antibody positive	1 (0.6%)	0 (0.0%)	1 (6.9%)
Liver function test abnormal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Low density lipoprotein increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lymph node palpable	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lymphocyte count decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Platelet count decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Transaminases increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Weight decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
White blood cells urine positive	0 (0.0%)	1 (0.6%)	1 (6.9%)
Metabolism and nutrition disorders	54 (30.5%)	41 (24.3%)	95 (8.4%)
Diabetes mellitus	16 (9.0%)	7 (4.1%)	23 (6.9%)
Dyslipidaemia	13 (7.3%)	7 (4.1%)	20 (6.9%)
Hypercholesterolaemia	13 (7.3%)	4 (2.4%)	17 (6.9%)
Type 2 diabetes mellitus	5 (2.8%)	6 (3.6%)	11 (6.9%)
Hyperlipidaemia	3 (1.7%)	4 (2.4%)	7 (6.9%)
Hyperglycaemia	3 (1.7%)	3 (1.8%)	6 (6.9%)
Hypoalbuminaemia	2 (1.1%)	3 (1.8%)	5 (6.9%)
Vitamin D deficiency	2 (1.1%)	3 (1.8%)	5 (6.9%)
Decreased appetite	1 (0.6%)	3 (1.8%)	4 (6.9%)
Hypertriglyceridaemia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Hyponatraemia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Obesity	2 (1.1%)	2 (1.2%)	4 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Glucose tolerance impaired	2 (1.1%)	1 (0.6%)	3 (6.9%)
Hypercalcaemia	1 (0.6%)	2 (1.2%)	3 (6.9%)
Hypomagnesaemia	1 (0.6%)	2 (1.2%)	3 (6.9%)
Hyperuricaemia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Insulin resistance	2 (1.1%)	0 (0.0%)	2 (6.9%)
Lactose intolerance	2 (1.1%)	0 (0.0%)	2 (6.9%)
Food intolerance	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gout	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hypocalcaemia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hypoglycaemia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Malnutrition	0 (0.0%)	1 (0.6%)	1 (6.9%)
Sarcopenic obesity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tetany	0 (0.0%)	1 (0.6%)	1 (6.9%)
Vitamin B12 deficiency	1 (0.6%)	0 (0.0%)	1 (6.9%)
Musculoskeletal and connective tissue disorders	54 (30.5%)	43 (25.4%)	97 (8.4%)
Back pain	13 (7.3%)	12 (7.1%)	25 (6.9%)
Arthralgia	13 (7.3%)	10 (5.9%)	23 (6.9%)
Osteoarthritis	4 (2.3%)	9 (5.3%)	13 (6.9%)
Osteoporosis	7 (4.0%)	4 (2.4%)	11 (6.9%)
Pain in extremity	6 (3.4%)	3 (1.8%)	9 (6.9%)
Bone pain	4 (2.3%)	3 (1.8%)	7 (6.9%)
Intervertebral disc protrusion	5 (2.8%)	1 (0.6%)	6 (6.9%)
Arthritis	2 (1.1%)	3 (1.8%)	5 (6.9%)
Musculoskeletal chest pain	0 (0.0%)	5 (3.0%)	5 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Osteopenia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Fibromyalgia	3 (1.7%)	0 (0.0%)	3 (6.9%)
Groin pain	1 (0.6%)	1 (0.6%)	2 (6.9%)
Muscle spasms	1 (0.6%)	1 (0.6%)	2 (6.9%)
Muscular weakness	1 (0.6%)	1 (0.6%)	2 (6.9%)
Myalgia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Neck pain	1 (0.6%)	1 (0.6%)	2 (6.9%)
Rheumatoid arthritis	1 (0.6%)	1 (0.6%)	2 (6.9%)
Axillary mass	1 (0.6%)	0 (0.0%)	1 (6.9%)
Foot deformity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Intervertebral disc compression	1 (0.6%)	0 (0.0%)	1 (6.9%)
Intervertebral disc degeneration	0 (0.0%)	1 (0.6%)	1 (6.9%)
Jaw cyst	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint contracture	0 (0.0%)	1 (0.6%)	1 (6.9%)
Musculoskeletal pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Rheumatic disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sacral pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Scoliosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Spinal osteoarthritis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Trigger finger	0 (0.0%)	1 (0.6%)	1 (6.9%)
Vertebral foraminal stenosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (13.6%)	35 (20.7%)	59 (8.4%)
Cancer pain	12 (6.8%)	11 (6.5%)	23 (6.9%)
Uterine leiomyoma	2 (1.1%)	7 (4.1%)	9 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Tumour pain	4 (2.3%)	4 (2.4%)	8 (6.9%)
Breast cancer	2 (1.1%)	4 (2.4%)	6 (6.9%)
Basal cell carcinoma	3 (1.7%)	1 (0.6%)	4 (6.9%)
Tumour ulceration	2 (1.1%)	0 (0.0%)	2 (6.9%)
Cervix carcinoma	0 (0.0%)	1 (0.6%)	1 (6.9%)
Colorectal adenoma	0 (0.0%)	1 (0.6%)	1 (6.9%)
Dysplastic naevus	0 (0.0%)	1 (0.6%)	1 (6.9%)
Follicular lymphoma	0 (0.0%)	1 (0.6%)	1 (6.9%)
Haemangioma of liver	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hormone receptor positive breast cancer	0 (0.0%)	1 (0.6%)	1 (6.9%)
Infected neoplasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Intraductal papillary mucinous neoplasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lymphangiosis carcinomatosa	0 (0.0%)	1 (0.6%)	1 (6.9%)
Mediastinum neoplasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Metastases to bone	0 (0.0%)	1 (0.6%)	1 (6.9%)
Ovarian cancer	1 (0.6%)	0 (0.0%)	1 (6.9%)
Ovarian cancer recurrent	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pituitary tumour benign	0 (0.0%)	1 (0.6%)	1 (6.9%)
Prolactin-producing pituitary tumour	1 (0.6%)	0 (0.0%)	1 (6.9%)
Squamous cell carcinoma of skin	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tumour exudation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tumour inflammation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Tumour thrombosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Nervous system disorders	28 (15.8%)	34 (20.1%)	62 (8.4%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Headache	6 (3.4%)	6 (3.6%)	12 (6.9%)
Peripheral sensory neuropathy	5 (2.8%)	5 (3.0%)	10 (6.9%)
Migraine	5 (2.8%)	4 (2.4%)	9 (6.9%)
Neuropathy peripheral	6 (3.4%)	3 (1.8%)	9 (6.9%)
Epilepsy	1 (0.6%)	2 (1.2%)	3 (6.9%)
Polyneuropathy	1 (0.6%)	2 (1.2%)	3 (6.9%)
Cerebrovascular accident	2 (1.1%)	0 (0.0%)	2 (6.9%)
Cervicobrachial syndrome	1 (0.6%)	1 (0.6%)	2 (6.9%)
Paraesthesia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Presyncope	2 (1.1%)	0 (0.0%)	2 (6.9%)
Sciatica	0 (0.0%)	2 (1.2%)	2 (6.9%)
Amnesia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Brain fog	0 (0.0%)	1 (0.6%)	1 (6.9%)
Carotid arteriosclerosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Cerebral small vessel ischaemic disease	0 (0.0%)	1 (0.6%)	1 (6.9%)
Complex regional pain syndrome	0 (0.0%)	1 (0.6%)	1 (6.9%)
Essential tremor	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hydromyelia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hypoaesthesia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Intercostal neuralgia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nervous system disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Neurotoxicity	0 (0.0%)	1 (0.6%)	1 (6.9%)
Peripheral motor neuropathy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Petit mal epilepsy	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Restless legs syndrome	0 (0.0%)	1 (0.6%)	1 (6.9%)
Spinal cord compression	0 (0.0%)	1 (0.6%)	1 (6.9%)
Syncope	1 (0.6%)	0 (0.0%)	1 (6.9%)
Taste disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Trigeminal neuralgia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Trigeminal neuropathy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Psychiatric disorders	37 (20.9%)	34 (20.1%)	71 (8.4%)
Insomnia	17 (9.6%)	13 (7.7%)	30 (6.9%)
Anxiety	13 (7.3%)	14 (8.3%)	27 (6.9%)
Depression	13 (7.3%)	12 (7.1%)	25 (6.9%)
Bipolar disorder	1 (0.6%)	1 (0.6%)	2 (6.9%)
Burnout syndrome	0 (0.0%)	2 (1.2%)	2 (6.9%)
Schizophrenia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Affective disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Anxiety disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Attention deficit hyperactivity disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Claustrophobia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Generalised anxiety disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Irritability	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nightmare	1 (0.6%)	0 (0.0%)	1 (6.9%)
Post-traumatic stress disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sleep disorder due to general medical condition, insomnia type	0 (0.0%)	1 (0.6%)	1 (6.9%)
Suicidal ideation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Renal and urinary disorders	10 (5.6%)	4 (2.4%)	14 (8.4%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Urinary incontinence	3 (1.7%)	0 (0.0%)	3 (6.9%)
Chronic kidney disease	2 (1.1%)	0 (0.0%)	2 (6.9%)
Nephrolithiasis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Stress urinary incontinence	1 (0.6%)	1 (0.6%)	2 (6.9%)
Calculus bladder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Haematuria	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hydronephrosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
IgA nephropathy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pollakiuria	1 (0.6%)	0 (0.0%)	1 (6.9%)
Proteinuria	1 (0.6%)	0 (0.0%)	1 (6.9%)
Renal colic	0 (0.0%)	1 (0.6%)	1 (6.9%)
Urge incontinence	1 (0.6%)	0 (0.0%)	1 (6.9%)
Reproductive system and breast disorders	17 (9.6%)	17 (10.1%)	34 (8.4%)
Breast pain	11 (6.2%)	8 (4.7%)	19 (6.9%)
Menopausal symptoms	2 (1.1%)	1 (0.6%)	3 (6.9%)
Ovarian cyst	2 (1.1%)	1 (0.6%)	3 (6.9%)
Amenorrhoea	1 (0.6%)	0 (0.0%)	1 (6.9%)
Breast discomfort	1 (0.6%)	0 (0.0%)	1 (6.9%)
Breast mass	0 (0.0%)	1 (0.6%)	1 (6.9%)
Breast ulceration	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cervical dysplasia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Endometriosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Menstrual disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Premenstrual dysphoric disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Rectocele	1 (0.6%)	0 (0.0%)	1 (6.9%)
Uterovaginal prolapse	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vaginal prolapse	0 (0.0%)	1 (0.6%)	1 (6.9%)
Respiratory, thoracic and mediastinal disorders	41 (23.2%)	40 (23.7%)	81 (8.4%)
Cough	19 (10.7%)	20 (11.8%)	39 (6.9%)
Dyspnoea	7 (4.0%)	8 (4.7%)	15 (6.9%)
Rhinitis allergic	8 (4.5%)	6 (3.6%)	14 (6.9%)
Asthma	7 (4.0%)	5 (3.0%)	12 (6.9%)
Pleural effusion	1 (0.6%)	5 (3.0%)	6 (6.9%)
Dysphonia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Productive cough	2 (1.1%)	0 (0.0%)	2 (6.9%)
Sleep apnoea syndrome	1 (0.6%)	1 (0.6%)	2 (6.9%)
Bronchial hyperreactivity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Bronchospasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Chronic obstructive pulmonary disease	1 (0.6%)	0 (0.0%)	1 (6.9%)
Dyspnoea exertional	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hyperventilation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Nasal septum deviation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Oropharyngeal pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pleuritic pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pulmonary arterial hypertension	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pulmonary artery thrombosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pulmonary embolism	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pulmonary hypertension	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Pulmonary mass	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pulmonary toxicity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pulmonary venous thrombosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sinus congestion	0 (0.0%)	1 (0.6%)	1 (6.9%)
Tracheal mass	1 (0.6%)	0 (0.0%)	1 (6.9%)
Skin and subcutaneous tissue disorders	18 (10.2%)	8 (4.7%)	26 (8.4%)
Dermatitis atopic	2 (1.1%)	1 (0.6%)	3 (6.9%)
Dry skin	1 (0.6%)	2 (1.2%)	3 (6.9%)
Dermatitis contact	2 (1.1%)	0 (0.0%)	2 (6.9%)
Eczema	1 (0.6%)	1 (0.6%)	2 (6.9%)
Pruritus	2 (1.1%)	0 (0.0%)	2 (6.9%)
Actinic keratosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Alopecia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Dermatitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Dermatitis acneiform	0 (0.0%)	1 (0.6%)	1 (6.9%)
Dermatitis allergic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Erythema	1 (0.6%)	0 (0.0%)	1 (6.9%)
Henoch-Schonlein purpura	0 (0.0%)	1 (0.6%)	1 (6.9%)
Nail bed bleeding	1 (0.6%)	0 (0.0%)	1 (6.9%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.0%)	1 (0.6%)	1 (6.9%)
Psoriasis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Rash	0 (0.0%)	1 (0.6%)	1 (6.9%)
Rash erythematous	1 (0.6%)	0 (0.0%)	1 (6.9%)
Skin mass	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Skin ulcer	1 (0.6%)	0 (0.0%)	1 (6.9%)
Xeroderma	1 (0.6%)	0 (0.0%)	1 (6.9%)
Social circumstances	5 (2.8%)	4 (2.4%)	9 (8.4%)
Edentulous	2 (1.1%)	0 (0.0%)	2 (6.9%)
Menopause	1 (0.6%)	1 (0.6%)	2 (6.9%)
Postmenopause	0 (0.0%)	2 (1.2%)	2 (6.9%)
Ex-tobacco user	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint prosthesis user	1 (0.6%)	0 (0.0%)	1 (6.9%)
Orthodontic appliance user	0 (0.0%)	1 (0.6%)	1 (6.9%)
Surgical and medical procedures	46 (26.0%)	33 (19.5%)	79 (8.4%)
Hysterectomy	14 (7.9%)	7 (4.1%)	21 (6.9%)
Cholecystectomy	11 (6.2%)	5 (3.0%)	16 (6.9%)
Caesarean section	5 (2.8%)	3 (1.8%)	8 (6.9%)
Female sterilisation	3 (1.7%)	4 (2.4%)	7 (6.9%)
Salpingo-oophorectomy bilateral	2 (1.1%)	3 (1.8%)	5 (6.9%)
Appendicectomy	4 (2.3%)	0 (0.0%)	4 (6.9%)
Tonsillectomy	1 (0.6%)	3 (1.8%)	4 (6.9%)
Breast conserving surgery	2 (1.1%)	1 (0.6%)	3 (6.9%)
Hysterosalpingo-oophorectomy	3 (1.7%)	0 (0.0%)	3 (6.9%)
Mastectomy	3 (1.7%)	0 (0.0%)	3 (6.9%)
Cardiac pacemaker insertion	2 (1.1%)	0 (0.0%)	2 (6.9%)
Central venous catheterisation	2 (1.1%)	0 (0.0%)	2 (6.9%)
Corneal transplant	2 (1.1%)	0 (0.0%)	2 (6.9%)
Fracture treatment	1 (0.6%)	1 (0.6%)	2 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hip arthroplasty	0 (0.0%)	2 (1.2%)	2 (6.9%)
Knee arthroplasty	2 (1.1%)	0 (0.0%)	2 (6.9%)
Oophorectomy	2 (1.1%)	0 (0.0%)	2 (6.9%)
Ovarian cystectomy	0 (0.0%)	2 (1.2%)	2 (6.9%)
Thyroidectomy	1 (0.6%)	1 (0.6%)	2 (6.9%)
Aortic valve replacement	1 (0.6%)	0 (0.0%)	1 (6.9%)
Axillary lymphadenectomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Breast reconstruction	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cartilage operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cataract operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Constipation prophylaxis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Corneal operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Eye excision	0 (0.0%)	1 (0.6%)	1 (6.9%)
Eye prosthesis insertion	0 (0.0%)	1 (0.6%)	1 (6.9%)
Gastric ulcer surgery	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gastrointestinal disorder prophylaxis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hernia repair	1 (0.6%)	0 (0.0%)	1 (6.9%)
Implantable cardiac monitor insertion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint arthroplasty	0 (0.0%)	1 (0.6%)	1 (6.9%)
Knee operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lung operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lymphadenectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Mammoplasty	0 (0.0%)	1 (0.6%)	1 (6.9%)
Metabolic surgery	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Myomectomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Myopia correction	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nasal septal operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Oophorectomy bilateral	1 (0.6%)	0 (0.0%)	1 (6.9%)
Ovarian operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Peptic ulcer repair	1 (0.6%)	0 (0.0%)	1 (6.9%)
Radical mastectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Red blood cell transfusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Retinal operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Salpingo-oophorectomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Salpingo-oophorectomy unilateral	0 (0.0%)	1 (0.6%)	1 (6.9%)
Skin graft	1 (0.6%)	0 (0.0%)	1 (6.9%)
Spinal operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sterilisation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Surgery	1 (0.6%)	0 (0.0%)	1 (6.9%)
Synovectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Thrombectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Thyroid nodule removal	0 (0.0%)	1 (0.6%)	1 (6.9%)
Tracheostomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Transfusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Varicose vein operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vascular access placement	1 (0.6%)	0 (0.0%)	1 (6.9%)
Wisdom teeth removal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vascular disorders	69 (39.0%)	53 (31.4%)	122 (8.4%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hypertension	59 (33.3%)	49 (29.0%)	108 (6.9%)
Lymphoedema	4 (2.3%)	4 (2.4%)	8 (6.9%)
Deep vein thrombosis	4 (2.3%)	2 (1.2%)	6 (6.9%)
Varicose vein	3 (1.7%)	2 (1.2%)	5 (6.9%)
Peripheral venous disease	3 (1.7%)	0 (0.0%)	3 (6.9%)
Hot flush	1 (0.6%)	1 (0.6%)	2 (6.9%)
Aneurysm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Orthostatic hypotension	1 (0.6%)	0 (0.0%)	1 (6.9%)
Raynaud's phenomenon	1 (0.6%)	0 (0.0%)	1 (6.9%)
White coat hypertension	0 (0.0%)	1 (0.6%)	1 (6.9%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Medical history was coded according to MedDRA Version 27.1.
Participants may report >=1 medical history per system organ class or preferred term. At each level of summarization, a participant was counted once if the participant reported 1 or more medical history.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table4.Summary of Medical History.R

4.5. Table 1.1.5: Summary of Prior Systemic Therapy — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Patients with Prior Systemic Therapy	117 (66.1%)	118 (69.8%)	235 (67.9%)
Number of Prior Regimens			
1	62 (35.0%)	65 (38.5%)	127 (36.7%)
2	37 (20.9%)	38 (22.5%)	75 (21.7%)
3	17 (9.6%)	11 (6.5%)	28 (8.1%)
4	1 (0.6%)	4 (2.4%)	5 (1.4%)
Regimen Setting			

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
ADJUVANT	85 (48.0%)	73 (43.2%)	158 (45.7%)
NEO-ADJUVANT	32 (18.1%)	44 (26.0%)	76 (22.0%)
METASTATIC	0 (0.0%)	1 (0.6%)	1 (0.3%)
Best Response to Prior Therapy			
Complete Remission	18 (10.2%)	19 (11.2%)	37 (10.7%)
Partial Remission	14 (7.9%)	14 (8.3%)	28 (8.1%)
Stable Disease	7 (4.0%)	10 (5.9%)	17 (4.9%)
Progressive Disease	7 (4.0%)	13 (7.7%)	20 (5.8%)
Unevaluable	6 (3.4%)	5 (3.0%)	11 (3.2%)
Not Available	40 (22.6%)	29 (17.2%)	69 (19.9%)
Unknown	25 (14.1%)	28 (16.6%)	53 (15.3%)
Progression After Prior Therapy			
Yes	97 (54.8%)	94 (55.6%)	191 (55.2%)
No	20 (11.3%)	24 (14.2%)	44 (12.7%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table5.Summary of Prior Systemic Therapy.R

4.6. Table 1.1.6: Prior Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Participants with Any Prior Anti-Cancer Therapy, n (%)	117 (66.1%)	118 (69.8%)	235 (67.9%)
Prior Neoadjuvant or Adjuvant Anti-cancer Therapy [a]			
Yes	117 (66.1%)	117 (69.2%)	234 (67.6%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Taxanes	101 (57.1%)	102 (60.4%)	203 (58.7%)
Anthracyclines	93 (52.5%)	97 (57.4%)	190 (54.9%)
Platinum	23 (13.0%)	21 (12.4%)	44 (12.7%)
Anti-PD-1/PD-L1 agents	9 (5.1%)	5 (3.0%)	14 (4.0%)
Capecitabine	33 (18.6%)	31 (18.3%)	64 (18.5%)
PARP inhibitors	1 (0.6%)	0	1 (0.3%)
Other	107 (60.5%)	103 (60.9%)	210 (60.7%)
No	0	1 (0.6%)	1 (0.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
[a] Participants can receive multiple categories of prior neoadjuvant or adjuvant anti-cancer therapy.
Participants who received any prior neoadjuvant or adjuvant anti-cancer therapy will be summarized as "Yes".
Participants who received prior anti-cancer therapy but did not receive any prior neoadjuvant/adjuvant anti-cancer therapy will be summarized as "No".
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table6.Prior Anti-Cancer Therapy.R

4.7. Table 1.1.7: Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Participants with Any Subsequent Anti Cancer Therapy, n (%)	108 (61.0%)	125 (74.0%)	233 (67.3%)
Taxanes	46 (26.0%)	22 (13.0%)	68 (19.7%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.6%)	1 (0.3%)
DOCETAXEL	4 (2.3%)	5 (3.0%)	9 (2.6%)
PACLITAXEL	37 (20.9%)	14 (8.3%)	51 (14.7%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	7 (4.0%)	3 (1.8%)	10 (2.9%)
Anthracyclines	22 (12.4%)	18 (10.7%)	40 (11.6%)
DOXORUBICIN	6 (3.4%)	7 (4.1%)	13 (3.8%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
DOXORUBICIN HYDROCHLORIDE	1 (0.6%)	4 (2.4%)	5 (1.4%)
EPIRUBICIN	7 (4.0%)	4 (2.4%)	11 (3.2%)
EPIRUBICIN HYDROCHLORIDE	2 (1.1%)	0	2 (0.6%)
LIPOSOMAL DOXORUBICIN	2 (1.1%)	1 (0.6%)	3 (0.9%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	5 (2.8%)	2 (1.2%)	7 (2.0%)
Platinum	50 (28.2%)	27 (16.0%)	77 (22.3%)
CARBOPLATIN	44 (24.9%)	23 (13.6%)	67 (19.4%)
CISPLATIN	6 (3.4%)	4 (2.4%)	10 (2.9%)
Anti-PD-1/PD-L1 agents	9 (5.1%)	10 (5.9%)	19 (5.5%)
ATEZOLIZUMAB	1 (0.6%)	2 (1.2%)	3 (0.9%)
PEMBROLIZUMAB	8 (4.5%)	6 (3.6%)	14 (4.0%)
SINTILIMAB	0	1 (0.6%)	1 (0.3%)
TISLELIZUMAB	0	1 (0.6%)	1 (0.3%)
PARP inhibitors	4 (2.3%)	3 (1.8%)	7 (2.0%)
OLAPARIB	4 (2.3%)	2 (1.2%)	6 (1.7%)
TALAZOPARIB	0	1 (0.6%)	1 (0.3%)
ADC	26 (14.7%)	110 (65.1%)	136 (39.3%)
SACITUZUMAB GOVITECAN	3 (1.7%)	109 (64.5%)	112 (32.4%)
TRASTUZUMAB DERUXTECAN	21 (11.9%)	21 (12.4%)	42 (12.1%)
TRASTUZUMAB DERUXTECAN NXKI	2 (1.1%)	0	2 (0.6%)
Other	82 (46.3%)	72 (42.6%)	154 (44.5%)
ABBV 400	1 (0.6%)	0	1 (0.3%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.6%)	0	1 (0.3%)
BEVACIZUMAB	7 (4.0%)	3 (1.8%)	10 (2.9%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
CAPECITABINE	31 (17.5%)	35 (20.7%)	66 (19.1%)
CATEQUENTINIB HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
CHLORINE DIOXIDE	0	1 (0.6%)	1 (0.3%)
CYCLOPHOSPHAMIDE	12 (6.8%)	12 (7.1%)	24 (6.9%)
ERIBULIN	27 (15.3%)	19 (11.2%)	46 (13.3%)
ERIBULIN MESILATE	7 (4.0%)	10 (5.9%)	17 (4.9%)
ETOPOSIDE	0	1 (0.6%)	1 (0.3%)
FLUOROURACIL	3 (1.7%)	3 (1.8%)	6 (1.7%)
GEMCITABINE	23 (13.0%)	13 (7.7%)	36 (10.4%)
GEMCITABINE HYDROCHLORIDE	9 (5.1%)	6 (3.6%)	15 (4.3%)
GEN 1047	0	1 (0.6%)	1 (0.3%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	4 (2.3%)	1 (0.6%)	5 (1.4%)
IMC 002	0	1 (0.6%)	1 (0.3%)
INVESTIGATIONAL DRUG	2 (1.1%)	3 (1.8%)	5 (1.4%)
IXABEPILONE	0	1 (0.6%)	1 (0.3%)
LAROTRECTINIB	0	1 (0.6%)	1 (0.3%)
METHOTREXATE	2 (1.1%)	3 (1.8%)	5 (1.4%)
NADUNOLIMAB	1 (0.6%)	0	1 (0.3%)
NATURAL KILLER CELLS	1 (0.6%)	0	1 (0.3%)
NIVOLUMAB	0	4 (2.4%)	4 (1.2%)
ONDANSETRON	1 (0.6%)	0	1 (0.3%)
PEGYLATED LIPOSOMAL DOXORUBICIN	0	1 (0.6%)	1 (0.3%)
PERTUZUMAB	1 (0.6%)	0	1 (0.3%)
PROGESTERONE	0	1 (0.6%)	1 (0.3%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
REPOTRECTINIB	0	1 (0.6%)	1 (0.3%)
RUCAPARIB	0	1 (0.6%)	1 (0.3%)
TALAZOPARIB TOSYLATE	0	1 (0.6%)	1 (0.3%)
TRASTUZUMAB	1 (0.6%)	0	1 (0.3%)
TUCATINIB	1 (0.6%)	0	1 (0.3%)
TUMOR-INFILTRATING LYMPHOCYTES	0	1 (0.6%)	1 (0.3%)
VINORELBINE	7 (4.0%)	5 (3.0%)	12 (3.5%)
VINORELBINE TARTRATE	4 (2.3%)	4 (2.4%)	8 (2.3%)
XMT 1660	1 (0.6%)	0	1 (0.3%)
ZEN 3694	0	1 (0.6%)	1 (0.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table10.Subsequent Anti cancer by preferred drug name.R

4.8. Table 1.1.8: First Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Participants with First Subsequent Anti Cancer Therapy, n (%)	108 (61.0%)	124 (73.4%)	232 (67.1%)
Taxanes	37 (20.9%)	5 (3.0%)	42 (12.1%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.6%)	1 (0.3%)
DOCETAXEL	2 (1.1%)	1 (0.6%)	3 (0.9%)
PACLITAXEL	30 (16.9%)	2 (1.2%)	32 (9.2%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	5 (2.8%)	1 (0.6%)	6 (1.7%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Anthracyclines	7 (4.0%)	2 (1.2%)	9 (2.6%)
DOXORUBICIN	1 (0.6%)	0	1 (0.3%)
EPIRUBICIN	2 (1.1%)	2 (1.2%)	4 (1.2%)
EPIRUBICIN HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
LIPOSOMAL DOXORUBICIN	1 (0.6%)	0	1 (0.3%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	2 (1.1%)	0	2 (0.6%)
Platinum	36 (20.3%)	2 (1.2%)	38 (11.0%)
CARBOPLATIN	30 (16.9%)	2 (1.2%)	32 (9.2%)
CISPLATIN	6 (3.4%)	0	6 (1.7%)
Anti-PD-1/PD-L1 agents	6 (3.4%)	2 (1.2%)	8 (2.3%)
ATEZOLIZUMAB	1 (0.6%)	1 (0.6%)	2 (0.6%)
PEMBROLIZUMAB	5 (2.8%)	0	5 (1.4%)
SINTILIMAB	0	1 (0.6%)	1 (0.3%)
PARP inhibitors	3 (1.7%)	2 (1.2%)	5 (1.4%)
OLAPARIB	3 (1.7%)	1 (0.6%)	4 (1.2%)
TALAZOPARIB	0	1 (0.6%)	1 (0.3%)
ADC	11 (6.2%)	101 (59.8%)	112 (32.4%)
SACITUZUMAB GOVITECAN	2 (1.1%)	99 (58.6%)	101 (29.2%)
TRASTUZUMAB DERUXTECAN	7 (4.0%)	2 (1.2%)	9 (2.6%)
TRASTUZUMAB DERUXTECAN NXKI	2 (1.1%)	0	2 (0.6%)
Other	64 (36.2%)	15 (8.9%)	79 (22.8%)
ABBV 400	1 (0.6%)	0	1 (0.3%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.6%)	0	1 (0.3%)
BEVACIZUMAB	5 (2.8%)	0	5 (1.4%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
CAPECITABINE	17 (9.6%)	10 (5.9%)	27 (7.8%)
CYCLOPHOSPHAMIDE	4 (2.3%)	1 (0.6%)	5 (1.4%)
ERIBULIN	15 (8.5%)	1 (0.6%)	16 (4.6%)
ERIBULIN MESILATE	2 (1.1%)	0	2 (0.6%)
GEMCITABINE	18 (10.2%)	1 (0.6%)	19 (5.5%)
GEMCITABINE HYDROCHLORIDE	4 (2.3%)	1 (0.6%)	5 (1.4%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (0.6%)	0	1 (0.3%)
INVESTIGATIONAL DRUG	1 (0.6%)	0	1 (0.3%)
LAROTRECTINIB	0	1 (0.6%)	1 (0.3%)
NADUNOLIMAB	1 (0.6%)	0	1 (0.3%)
NATURAL KILLER CELLS	1 (0.6%)	0	1 (0.3%)
PERTUZUMAB	1 (0.6%)	0	1 (0.3%)
TRASTUZUMAB	1 (0.6%)	0	1 (0.3%)
VINORELBINE	2 (1.1%)	0	2 (0.6%)
VINORELBINE TARTRATE	1 (0.6%)	0	1 (0.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 22 APR 2026.

Source: Disposition and Characteristics/Table11.First Subsequent Anti cancer therapy by Preferred drug name.R

5. Efficacy - mITT — Excluding patients preselected to receive nab-paclitaxel

5.1. Table 1.1.1: Observation Period (Months) for Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	SG (N=177)	TPC (N=169)	Total (N=346)
Observation Period (months)			
N	177	169	346
Mean (SD)	19.4 (9.7)	18.4 (9.1)	18.9 (9.4)
Median	20.8	19.6	19.8
Q1, Q3	12.1, 26.5	11.5, 25.3	11.6, 25.8
Min, Max	0.5, 40.8	0, 36.1	0, 40.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Observation period is defined as time from randomisation to death date or the last date known alive.
Data Cut Date: 22 APR 2026.

5.2. Table 1.1.2: Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events (Death)	111 (62.7%)	117 (69.2%)
Number (%) of Participants Censored	66 (37.3%)	52 (30.8%)
Ongoing [a]	63 (35.6%)	46 (27.2%)
Discontinued Study	3 (1.7%)	6 (3.6%)
Kaplan-Meier Estimate of OS (Months) (95% CI) [b]		
Q1	12.68 (10.32, 15.34)	11.73 (9.66, 14.03)
Median	20.90 (18.10, 25.46)	19.78 (17.84, 22.44)
Q3	36.57 (32.95, NR)	29.17 (27.27, NR)
Absolute Difference in Median OS, SG vs TPC (Months)	1.12	

Parameter	SG (N=177)	TPC (N=169)
Kaplan-Meier Estimate of OS Rate (95% CI) [b]		
At 12 Months	0.762 (0.692, 0.818)	0.742 (0.668, 0.801)
At 18 Months	0.578 (0.502, 0.648)	0.573 (0.494, 0.644)
At 24 Months	0.447 (0.372, 0.520)	0.388 (0.312, 0.463)
At 30 Months	0.336 (0.257, 0.415)	0.243 (0.172, 0.322)
At 36 Months	0.292 (0.207, 0.383)	0.135 (0.041, 0.284)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.1778	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.833 (0.641, 1.081)	
Duration of OS Follow-up (Months) [e]		
N	177	169
Mean (StD)	19.40 (9.680)	18.44 (9.051)
Median	20.80	19.65
Q1, Q3	12.06, 26.55	11.47, 25.30
Min, Max	0.53, 40.80	0.03, 36.07
>=12 Months	133 (75.1%)	123 (72.8%)
>=18 Months	100 (56.5%)	95 (56.2%)
>=24 Months	64 (36.2%)	49 (29.0%)
>=30 Months	23 (13.0%)	19 (11.2%)
>=36 Months	6 (3.4%)	1 (0.6%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice; NR = Not Reached; IWRS = Interactive Web Response System.
[a] Ongoing participants are those who have not discontinued participation in the study by the data cutoff date.
[b] OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Based on Kaplan-Meier estimates with 95% CI using the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test, adjusted for randomization stratification factors (IWRS).
[d] Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
[e] Duration of OS follow-up (months) = (date of death or censoring - date of randomization + 1) / 30.4375.
Data Cut Date: 22 APR 2026.

5.3. Table 1.1.3: Subgroup Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.6271
Number (%) of Participants with Events (Death)	34 (61.8%)	38 (77.6%)	
Number (%) of Participants Censored	21 (38.2%)	11 (22.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (16.62, 28.62)	19.38 (13.11, 22.64)	
Log-Rank Test p-value (unstratified)	0.1789		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.728 (0.458, 1.159)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Death)	23 (67.6%)	25 (73.5%)	
Number (%) of Participants Censored	11 (32.4%)	9 (26.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.64 (15.93, 26.55)	16.99 (13.70, 21.75)	
Log-Rank Test p-value (unstratified)	0.4632		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.809 (0.459, 1.427)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Death)	54 (61.4%)	54 (62.8%)	
Number (%) of Participants Censored	34 (38.6%)	32 (37.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.71, 28.25)	21.26 (18.10, 27.56)	
Log-Rank Test p-value (unstratified)	0.7494		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.939 (0.643, 1.373)		

	SG (N=177)	TPC (N=169)	Interaction
Geographic region			
US/Canada/Western Europe	56	52	0.9285
Number (%) of Participants with Events (Death)	39 (69.6%)	37 (71.2%)	
Number (%) of Participants Censored	17 (30.4%)	15 (28.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.86 (17.51, 26.55)	18.43 (13.50, 24.41)	
Log-Rank Test p-value (unstratified)	0.3241		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.797 (0.506, 1.255)		
Rest of the world	121	117	
Number (%) of Participants with Events (Death)	72 (59.5%)	80 (68.4%)	
Number (%) of Participants Censored	49 (40.5%)	37 (31.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.90 (17.41, 25.53)	19.91 (17.22, 22.93)	
Log-Rank Test p-value (unstratified)	0.3298		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.853 (0.620, 1.174)		
Age group			
< 65	133	131	0.8477
Number (%) of Participants with Events (Death)	84 (63.2%)	90 (68.7%)	
Number (%) of Participants Censored	49 (36.8%)	41 (31.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.29 (18.20, 25.46)	19.75 (17.22, 22.64)	
Log-Rank Test p-value (unstratified)	0.3185		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.859 (0.638, 1.158)		
>= 65	44	38	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Death)	27 (61.4%)	27 (71.1%)	
Number (%) of Participants Censored	17 (38.6%)	11 (28.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.59 (11.40, 36.57)	19.24 (14.55, 24.74)	
Log-Rank Test p-value (unstratified)	0.4760		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.476, 1.414)		
Race			
White	115	104	0.6222
Number (%) of Participants with Events (Death)	77 (67.0%)	75 (72.1%)	
Number (%) of Participants Censored	38 (33.0%)	29 (27.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.14 (16.95, 24.02)	18.73 (15.41, 22.51)	
Log-Rank Test p-value (unstratified)	0.3552		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.860 (0.625, 1.183)		
Asian	38	38	
Number (%) of Participants with Events (Death)	18 (47.4%)	23 (60.5%)	
Number (%) of Participants Censored	20 (52.6%)	15 (39.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (17.71, NR)	22.93 (19.78, 26.91)	
Log-Rank Test p-value (unstratified)	0.5731		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.837 (0.451, 1.552)		
Other	19	24	
Number (%) of Participants with Events (Death)	12 (63.2%)	17 (70.8%)	
Number (%) of Participants Censored	7 (36.8%)	7 (29.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (13.31, NR)	14.85 (10.51, 19.61)	
Log-Rank Test p-value (unstratified)	0.3030		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.677 (0.321, 1.428)		
Baseline ECOG status			
0	116	106	0.6675
Number (%) of Participants with Events (Death)	64 (55.2%)	64 (60.4%)	
Number (%) of Participants Censored	52 (44.8%)	42 (39.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	25.49 (20.14, 29.17)	22.51 (19.65, 27.89)	
Log-Rank Test p-value (unstratified)	0.5036		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.888 (0.628, 1.257)		
1	61	63	
Number (%) of Participants with Events (Death)	47 (77.0%)	53 (84.1%)	
Number (%) of Participants Censored	14 (23.0%)	10 (15.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	16.95 (12.68, 20.80)	15.15 (10.55, 18.33)	
Log-Rank Test p-value (unstratified)	0.2475		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.791 (0.531, 1.178)		
Physician's choice of chemotherapy			
Taxane	52	45	0.0148
Number (%) of Participants with Events (Death)	26 (50.0%)	36 (80.0%)	
Number (%) of Participants Censored	26 (50.0%)	9 (20.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	28.68 (20.86, NR)	18.33 (14.03, 24.38)	
Log-Rank Test p-value (unstratified)	0.0058		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.497 (0.299, 0.824)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Death)	85 (68.0%)	81 (65.3%)	
Number (%) of Participants Censored	40 (32.0%)	43 (34.7%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	19.09 (16.62, 22.14)	19.91 (18.00, 22.93)	
Log-Rank Test p-value (unstratified)	0.8031		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.040 (0.766, 1.411)		
History of liver metastasis			
Yes	47	39	0.8802
Number (%) of Participants with Events (Death)	38 (80.9%)	33 (84.6%)	
Number (%) of Participants Censored	9 (19.1%)	6 (15.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.80 (11.20, 19.09)	14.03 (7.69, 16.99)	
Log-Rank Test p-value (unstratified)	0.4040		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.818 (0.510, 1.311)		
No	130	130	
Number (%) of Participants with Events (Death)	73 (56.2%)	84 (64.6%)	
Number (%) of Participants Censored	57 (43.8%)	46 (35.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	24.02 (20.14, 28.68)	21.49 (19.38, 24.74)	
Log-Rank Test p-value (unstratified)	0.2206		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.822 (0.599, 1.126)		
History of brain metastasis			
Yes	8	9	0.5777
Number (%) of Participants with Events (Death)	7 (87.5%)	9 (100.0%)	
Number (%) of Participants Censored	1 (12.5%)	0	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.48 (0.85, 26.55)	13.50 (0.16, 21.06)	
Log-Rank Test p-value (unstratified)	0.2149		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.516 (0.178, 1.493)		
No	169	160	
Number (%) of Participants with Events (Death)	104 (61.5%)	108 (67.5%)	
Number (%) of Participants Censored	65 (38.5%)	52 (32.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.90 (18.10, 25.53)	20.24 (17.84, 22.93)	
Log-Rank Test p-value (unstratified)	0.2629		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.857 (0.654, 1.123)		
PD-L1 Status			
CPS < 1	67	59	0.4509
Number (%) of Participants with Events (Death)	41 (61.2%)	44 (74.6%)	
Number (%) of Participants Censored	26 (38.8%)	15 (25.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (15.34, 28.25)	19.84 (13.50, 22.93)	
Log-Rank Test p-value (unstratified)	0.1395		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.725 (0.473, 1.112)		

	SG (N=177)	TPC (N=169)	Interaction
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Death)	69 (63.3%)	73 (66.4%)	
Number (%) of Participants Censored	40 (36.7%)	37 (33.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.29 (17.71, 26.09)	19.75 (17.22, 23.23)	
Log-Rank Test p-value (unstratified)	0.5272		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.899 (0.645, 1.252)		
BRCA 1/2 status			
Wild-Type	66	65	0.0867
Number (%) of Participants with Events (Death)	42 (63.6%)	46 (70.8%)	
Number (%) of Participants Censored	24 (36.4%)	19 (29.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.99 (16.26, 25.46)	19.06 (13.70, 24.38)	
Log-Rank Test p-value (unstratified)	0.2781		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.791 (0.519, 1.206)		
Mutant	12	10	
Number (%) of Participants with Events (Death)	8 (66.7%)	4 (40.0%)	
Number (%) of Participants Censored	4 (33.3%)	6 (60.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.55 (3.15, NR)	31.77 (7.72, NR)	
Log-Rank Test p-value (unstratified)	0.1266		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.516 (0.741, 8.538)		
Menopausal status			
Pre-menopausal	37	49	0.4978

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Death)	24 (64.9%)	35 (71.4%)	
Number (%) of Participants Censored	13 (35.1%)	14 (28.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.17 (12.75, 23.52)	19.75 (15.01, 23.23)	
Log-Rank Test p-value (unstratified)	0.9740		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.008 (0.599, 1.695)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Death)	87 (62.1%)	82 (68.9%)	
Number (%) of Participants Censored	53 (37.9%)	37 (31.1%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.74, 26.55)	19.65 (16.23, 22.93)	
Log-Rank Test p-value (unstratified)	0.1499		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.801 (0.591, 1.084)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Median OS from Kaplan-Meier estimate. 95% CI based on log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
Log-rank test is unstratified.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Participants with unknown BRCA 1/2 status were excluded from that subgroup.
Disease stratification and geographic region are collected from IWRS.
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5.4. Table 1.1.4: Follow-up Duration (Months) for PFS and Tumor Response by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	SG (N=177)	TPC (N=169)	Total (N=346)
Follow-up duration (months) for Progression-Free Survival by Blinded Independent Central Review (BICR) [a]			

Statistic	SG (N=177)	TPC (N=169)	Total (N=346)
N	177	169	346
Mean (SD)	9.4 (8.3)	7.1 (6.6)	8.3 (7.6)
Median	7	5.5	5.7
Q1, Q3	3, 15.1	2.8, 8.4	2.9, 11.1
Min, Max	0, 37.6	0, 31.9	0, 37.6
Tumor Response by Blinded Independent Central Review (BICR), n (%)			
CR	16 (9.0%)	11 (6.5%)	27 (7.8%)
PR	85 (48.0%)	76 (45.0%)	161 (46.5%)
SD	48 (27.1%)	52 (30.8%)	100 (28.9%)
PD	16 (9.0%)	18 (10.7%)	34 (9.8%)
NE	1 (0.6%)	1 (0.6%)	2 (0.6%)
NON-CR/NON-PD	1 (0.6%)	1 (0.6%)	2 (0.6%)
Missing/NE	10 (5.6%)	10 (5.9%)	20 (5.8%)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; BICR = blinded independent central review; IWRS = Interactive Web Response System; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE = not evaluable; NON-CR/NON-PD = non-complete response/non-progressive disease (applicable to non-measurable disease).
[a] Observation period for PFS is defined as time from randomisation to the event or censoring date of progression-free survival.
Tumour response assessed by BICR per RECIST v1.1; confirmed responses only.
Data Cut Date: 22 APR 2026.

5.5. Table 1.1.5: Analysis of PFS by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events	118 (66.7%)	120 (71.0%)
Disease Progression (PD)	105 (59.3%)	115 (68.0%)
Death	13 (7.3%)	5 (3.0%)
Number (%) of Participants Censored	59 (33.3%)	49 (29.0%)
PD after Starting New Anti-Cancer Therapy	1 (0.6%)	1 (0.6%)

Parameter	SG (N=177)	TPC (N=169)
PD right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	2 (1.1%)	3 (1.8%)
Death after Starting New Anti-Cancer Therapy	19 (10.7%)	18 (10.7%)
Death right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	3 (1.7%)	5 (3.0%)
No PD and No Death without New Anti-Cancer Therapy	21 (11.9%)	11 (6.5%)
No PD and No Death with New Anti-Cancer Therapy	12 (6.8%)	6 (3.6%)
No Baseline or Postbaseline Evaluable Assessment [a]	1 (0.6%)	5 (3.0%)
Kaplan-Meier Estimate of PFS (Months) (95% CI) [b]		
Q1	4.17 (3.15, 4.93)	4.14 (3.06, 4.34)
Median	8.77 (7.16, 11.10)	6.93 (5.59, 8.28)
Q3	18.07 (15.21, 31.93)	12.32 (8.80, 15.18)
Absolute Difference in Median PFS, SG vs TPC (Months)	1.84	
Kaplan-Meier Estimate of PFS Rate (95% CI) [c]		
At 3 Months	0.831 (0.765, 0.880)	0.824 (0.754, 0.876)
At 6 Months	0.637 (0.557, 0.707)	0.543 (0.458, 0.620)
At 9 Months	0.498 (0.416, 0.574)	0.322 (0.244, 0.402)
At 12 Months	0.411 (0.331, 0.489)	0.253 (0.181, 0.331)
At 18 Months	0.267 (0.195, 0.343)	0.107 (0.058, 0.174)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [d]	0.0022	
Stratified Hazard Ratio of SG vs TPC (95% CI) [e]	0.664 (0.510, 0.864)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
[a] Censoring due to no baseline or no postbaseline evaluable assessment does not include death events before the second scheduled postbaseline visit.
[b] PFS (months) = (date of event or censoring − date of randomisation + 1) / 30.4375. The 95% CI is based on the log-log transformation.
[c] PFS rate is the proportion of participants alive without progressive disease (PD). The 95% CI is based on the log-log transformation.
[d] The two-sided p-value is from stratified log-rank test.
[e] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.6. Table 1.1.6: Analysis of PFS by BICR – Subgroup — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.3960
Number (%) of Participants with Events	37 (67.3%)	40 (81.6%)	
Disease Progression (PD)	32 (58.2%)	39 (79.6%)	
Death	5 (9.1%)	1 (2.0%)	
Number (%) of Participants Censored	18 (32.7%)	9 (18.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (5.52, 15.21)	5.42 (4.14, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.543 (0.342, 0.861)		
p-value (Log-Rank Test, Unstratified)	0.0085		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events	27 (79.4%)	24 (70.6%)	
Disease Progression (PD)	26 (76.5%)	24 (70.6%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	7 (20.6%)	10 (29.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (5.39, 9.92)	6.74 (5.52, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.681 (0.387, 1.200)		
p-value (Log-Rank Test, Unstratified)	0.1801		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events	54 (61.4%)	56 (65.1%)	
Disease Progression (PD)	47 (53.4%)	52 (60.5%)	
Death	7 (8.0%)	4 (4.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	34 (38.6%)	30 (34.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.76 (7.13, 13.86)	8.31 (5.59, 11.07)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.768 (0.526, 1.121)		
p-value (Log-Rank Test, Unstratified)	0.1698		
Geographic region			
US/Canada/Western Europe	56	52	0.4178
Number (%) of Participants with Events	34 (60.7%)	32 (61.5%)	
Disease Progression (PD)	32 (57.1%)	32 (61.5%)	
Death	2 (3.6%)	0	
Number (%) of Participants Censored	22 (39.3%)	20 (38.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (7.26, 15.21)	6.87 (5.39, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.578 (0.353, 0.945)		
p-value (Log-Rank Test, Unstratified)	0.0264		
Rest of the world	121	117	
Number (%) of Participants with Events	84 (69.4%)	88 (75.2%)	
Disease Progression (PD)	73 (60.3%)	83 (70.9%)	
Death	11 (9.1%)	5 (4.3%)	
Number (%) of Participants Censored	37 (30.6%)	29 (24.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.93, 12.32)	7.13 (5.49, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.735 (0.543, 0.995)		
p-value (Log-Rank Test, Unstratified)	0.0453		

	SG (N=177)	TPC (N=169)	Interaction
Age group			
< 65	133	131	0.2461
Number (%) of Participants with Events	91 (68.4%)	95 (72.5%)	
Disease Progression (PD)	84 (63.2%)	92 (70.2%)	
Death	7 (5.3%)	3 (2.3%)	
Number (%) of Participants Censored	42 (31.6%)	36 (27.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.77 (7.13, 11.10)	6.93 (5.49, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.641 (0.479, 0.858)		
p-value (Log-Rank Test, Unstratified)	0.0026		
>= 65	44	38	
Number (%) of Participants with Events	27 (61.4%)	25 (65.8%)	
Disease Progression (PD)	21 (47.7%)	23 (60.5%)	
Death	6 (13.6%)	2 (5.3%)	
Number (%) of Participants Censored	17 (38.6%)	13 (34.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.72 (4.30, 15.21)	8.38 (5.42, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.888 (0.507, 1.557)		
p-value (Log-Rank Test, Unstratified)	0.6762		
Race			
White	115	104	0.8271
Number (%) of Participants with Events	77 (67.0%)	68 (65.4%)	
Disease Progression (PD)	70 (60.9%)	64 (61.5%)	
Death	7 (6.1%)	4 (3.8%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	38 (33.0%)	36 (34.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (6.93, 10.32)	6.93 (5.42, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.737 (0.530, 1.025)		
p-value (Log-Rank Test, Unstratified)	0.0685		
Asian	38	38	
Number (%) of Participants with Events	26 (68.4%)	32 (84.2%)	
Disease Progression (PD)	22 (57.9%)	32 (84.2%)	
Death	4 (10.5%)	0	
Number (%) of Participants Censored	12 (31.6%)	6 (15.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.92 (6.90, 15.31)	7.06 (4.21, 8.57)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.586 (0.345, 0.994)		
p-value (Log-Rank Test, Unstratified)	0.0450		
Other	19	24	
Number (%) of Participants with Events	12 (63.2%)	17 (70.8%)	
Disease Progression (PD)	11 (57.9%)	16 (66.7%)	
Death	1 (5.3%)	1 (4.2%)	
Number (%) of Participants Censored	7 (36.8%)	7 (29.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.15 (5.52, 18.00)	7.13 (4.40, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.728 (0.343, 1.542)		
p-value (Log-Rank Test, Unstratified)	0.4095		
Baseline ECOG status			

	SG (N=177)	TPC (N=169)	Interaction
0	116	106	0.3855
Number (%) of Participants with Events	72 (62.1%)	76 (71.7%)	
Disease Progression (PD)	66 (56.9%)	74 (69.8%)	
Death	6 (5.2%)	2 (1.9%)	
Number (%) of Participants Censored	44 (37.9%)	30 (28.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.32 (9.59, 15.21)	8.15 (6.87, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.608 (0.439, 0.844)		
p-value (Log-Rank Test, Unstratified)	0.0026		
1	61	63	
Number (%) of Participants with Events	46 (75.4%)	44 (69.8%)	
Disease Progression (PD)	39 (63.9%)	41 (65.1%)	
Death	7 (11.5%)	3 (4.8%)	
Number (%) of Participants Censored	15 (24.6%)	19 (30.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.17, 7.13)	5.39 (4.14, 6.90)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.866 (0.569, 1.318)		
p-value (Log-Rank Test, Unstratified)	0.5002		
Physician's choice of chemotherapy			
Taxane	52	45	0.0048
Number (%) of Participants with Events	31 (59.6%)	36 (80.0%)	
Disease Progression (PD)	29 (55.8%)	34 (75.6%)	
Death	2 (3.8%)	2 (4.4%)	
Number (%) of Participants Censored	21 (40.4%)	9 (20.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (7.13, 15.34)	5.39 (3.06, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.334 (0.198, 0.563)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events	87 (69.6%)	84 (67.7%)	
Disease Progression (PD)	76 (60.8%)	81 (65.3%)	
Death	11 (8.8%)	3 (2.4%)	
Number (%) of Participants Censored	38 (30.4%)	40 (32.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (6.90, 9.92)	8.08 (5.65, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.851 (0.629, 1.152)		
p-value (Log-Rank Test, Unstratified)	0.2970		
History of liver metastasis			
Yes	47	39	0.1897
Number (%) of Participants with Events	38 (80.9%)	28 (71.8%)	
Disease Progression (PD)	34 (72.3%)	24 (61.5%)	
Death	4 (8.5%)	4 (10.3%)	
Number (%) of Participants Censored	9 (19.1%)	11 (28.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.16 (3.88, 9.59)	4.17 (2.76, 4.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.513 (0.307, 0.858)		
p-value (Log-Rank Test, Unstratified)	0.0098		
No	130	130	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events	80 (61.5%)	92 (70.8%)	
Disease Progression (PD)	71 (54.6%)	91 (70.0%)	
Death	9 (6.9%)	1 (0.8%)	
Number (%) of Participants Censored	50 (38.5%)	38 (29.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.92 (7.23, 15.08)	8.28 (6.93, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.675 (0.498, 0.916)		
p-value (Log-Rank Test, Unstratified)	0.0110		
History of brain metastasis			
Yes	8	9	0.4203
Number (%) of Participants with Events	7 (87.5%)	6 (66.7%)	
Disease Progression (PD)	6 (75.0%)	5 (55.6%)	
Death	1 (12.5%)	1 (11.1%)	
Number (%) of Participants Censored	1 (12.5%)	3 (33.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (0.85, 8.54)	8.08 (0.16, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.904 (0.289, 2.830)		
p-value (Log-Rank Test, Unstratified)	0.8623		
No	169	160	
Number (%) of Participants with Events	111 (65.7%)	114 (71.2%)	
Disease Progression (PD)	99 (58.6%)	110 (68.8%)	
Death	12 (7.1%)	4 (2.5%)	
Number (%) of Participants Censored	58 (34.3%)	46 (28.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	9.72 (7.23, 12.45)	6.93 (5.55, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.675 (0.518, 0.880)		
p-value (Log-Rank Test, Unstratified)	0.0034		
PD-L1 Status			
CPS < 1	67	59	0.3808
Number (%) of Participants with Events	47 (70.1%)	37 (62.7%)	
Disease Progression (PD)	41 (61.2%)	36 (61.0%)	
Death	6 (9.0%)	1 (1.7%)	
Number (%) of Participants Censored	20 (29.9%)	22 (37.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.93, 12.45)	7.06 (4.34, 12.35)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.532, 1.268)		
p-value (Log-Rank Test, Unstratified)	0.3741		
CPS ≥ 1	109	110	
Number (%) of Participants with Events	71 (65.1%)	83 (75.5%)	
Disease Progression (PD)	64 (58.7%)	79 (71.8%)	
Death	7 (6.4%)	4 (3.6%)	
Number (%) of Participants Censored	38 (34.9%)	27 (24.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (6.90, 15.08)	6.90 (5.55, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.629 (0.455, 0.868)		
p-value (Log-Rank Test, Unstratified)	0.0044		
BRCA 1/2 status			
Wild-Type	66	65	0.1697

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events	43 (65.2%)	46 (70.8%)	
Disease Progression (PD)	39 (59.1%)	45 (69.2%)	
Death	4 (6.1%)	1 (1.5%)	
Number (%) of Participants Censored	23 (34.8%)	19 (29.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.23 (4.53, 11.10)	5.52 (4.07, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.635 (0.417, 0.968)		
p-value (Log-Rank Test, Unstratified)	0.0332		
Mutant	12	10	
Number (%) of Participants with Events	9 (75.0%)	7 (70.0%)	
Disease Progression (PD)	7 (58.3%)	7 (70.0%)	
Death	2 (16.7%)	0	
Number (%) of Participants Censored	3 (25.0%)	3 (30.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.26 (1.51, 19.32)	10.84 (2.89, 16.59)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.355 (0.497, 3.693)		
p-value (Log-Rank Test, Unstratified)	0.5511		
Menopausal status			
Pre-menopausal	37	49	0.9804
Number (%) of Participants with Events	25 (67.6%)	37 (75.5%)	
Disease Progression (PD)	23 (62.2%)	36 (73.5%)	
Death	2 (5.4%)	1 (2.0%)	
Number (%) of Participants Censored	12 (32.4%)	12 (24.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	6.93 (5.52, 15.08)	5.62 (4.21, 7.79)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.719 (0.431, 1.199)		
p-value (Log-Rank Test, Unstratified)	0.2048		
Post-menopausal	140	119	
Number (%) of Participants with Events	93 (66.4%)	82 (68.9%)	
Disease Progression (PD)	82 (58.6%)	78 (65.5%)	
Death	11 (7.9%)	4 (3.4%)	
Number (%) of Participants Censored	47 (33.6%)	37 (31.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.59 (7.26, 12.32)	8.11 (5.62, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.678 (0.501, 0.918)		
p-value (Log-Rank Test, Unstratified)	0.0110		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Intent-to-treat (ITT) Analysis Set includes all participants who were randomised in the study.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS (months) = (date of events or censoring − date of randomisation + 1) / 30.4375. 95% CI based on log-log transformation. Median PFS from Kaplan-Meier estimate.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5.7. Table 1.1.7: Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events	129 (72.9%)	137 (81.1%)
Disease Progression (PD)	68 (38.4%)	97 (57.4%)

Parameter	SG (N=177)	TPC (N=169)
Death	61 (34.5%)	40 (23.7%)
Number (%) of Participants Censored	48 (27.1%)	32 (18.9%)
Alive Without PFS2 Event and Without Second Next-Line Therapy	10 (5.6%)	9 (5.3%)
Alive Without PFS2 Event and With Second Next-Line Therapy	6 (3.4%)	6 (3.6%)
Discontinued Study	0	0
No Baseline or Postbaseline Evaluable Assessment	0	0
Kaplan-Meier Estimate of PFS2 (Months) (95% CI) [a]		
Q1	9.95 (7.43, 11.40)	9.10 (7.16, 10.05)
Median	16.00 (13.80, 20.90)	13.21 (11.47, 14.75)
Q3	28.09 (25.46, 30.65)	20.67 (18.92, 23.52)
Absolute Difference in Median PFS2, SG vs TPC (Months)	2.79	
Kaplan-Meier Estimate of PFS2 Rate (95% CI) [b]		
At 3 Months	0.960 (0.919, 0.981)	0.964 (0.922, 0.984)
At 6 Months	0.847 (0.785, 0.893)	0.874 (0.813, 0.916)
At 9 Months	0.773 (0.704, 0.828)	0.759 (0.686, 0.817)
At 12 Months	0.657 (0.582, 0.723)	0.543 (0.464, 0.616)
At 18 Months	0.457 (0.381, 0.529)	0.331 (0.259, 0.404)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [c]	0.0035	
Stratified Hazard Ratio of SG vs TPC (95% CI) [d]	0.692 (0.540, 0.887)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first. Next line therapy is defined as the first new systemic anti-cancer therapy (including crossover treatment) initiated after discontinuation of study treatment regardless of end of treatment reason.
[a] Quantile of PFS2 is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.8. Table 1.1.8: Subgroup Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.2844
Number (%) of Participants with Events	47 (85.5%)	46 (93.9%)	
Disease Progression (PD)	42 (76.4%)	45 (91.8%)	
Death	5 (9.1%)	1 (2.0%)	
Number (%) of Participants Censored	8 (14.5%)	3 (6.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.59 (4.27, 10.32)	5.39 (3.98, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.599 (0.393, 0.913)		
p-value (Log-Rank Test, Unstratified)	0.0157		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events	30 (88.2%)	29 (85.3%)	
Disease Progression (PD)	29 (85.3%)	29 (85.3%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	4 (11.8%)	5 (14.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.37, 9.92)	5.63 (4.90, 7.20)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.560 (0.328, 0.957)		
p-value (Log-Rank Test, Unstratified)	0.0320		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events	78 (88.6%)	76 (88.4%)	
Disease Progression (PD)	71 (80.7%)	72 (83.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Death	7 (8.0%)	4 (4.7%)	
Number (%) of Participants Censored	10 (11.4%)	10 (11.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (4.30, 9.30)	6.34 (4.34, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.849 (0.617, 1.168)		
p-value (Log-Rank Test, Unstratified)	0.3132		
Geographic region			
US/Canada/Western Europe	56	52	0.4060
Number (%) of Participants with Events	49 (87.5%)	45 (86.5%)	
Disease Progression (PD)	47 (83.9%)	45 (86.5%)	
Death	2 (3.6%)	0	
Number (%) of Participants Censored	7 (12.5%)	7 (13.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.92 (5.22, 9.30)	5.49 (2.99, 6.41)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.616 (0.406, 0.933)		
p-value (Log-Rank Test, Unstratified)	0.0206		
Rest of the world	121	117	
Number (%) of Participants with Events	106 (87.6%)	106 (90.6%)	
Disease Progression (PD)	95 (78.5%)	101 (86.3%)	
Death	11 (9.1%)	5 (4.3%)	
Number (%) of Participants Censored	15 (12.4%)	11 (9.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.97 (4.70, 9.07)	5.63 (4.53, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.758 (0.577, 0.996)		

	SG (N=177)	TPC (N=169)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0461		
Age group			
< 65	133	131	0.2954
Number (%) of Participants with Events	119 (89.5%)	117 (89.3%)	
Disease Progression (PD)	112 (84.2%)	114 (87.0%)	
Death	7 (5.3%)	3 (2.3%)	
Number (%) of Participants Censored	14 (10.5%)	14 (10.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.15 (5.55, 8.77)	5.50 (4.21, 6.74)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.674 (0.520, 0.874)		
p-value (Log-Rank Test, Unstratified)	0.0027		
>= 65	44	38	
Number (%) of Participants with Events	36 (81.8%)	34 (89.5%)	
Disease Progression (PD)	30 (68.2%)	32 (84.2%)	
Death	6 (13.6%)	2 (5.3%)	
Number (%) of Participants Censored	8 (18.2%)	4 (10.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.74 (2.89, 9.72)	6.41 (4.53, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.897 (0.555, 1.450)		
p-value (Log-Rank Test, Unstratified)	0.6566		
Race			
White	115	104	0.9230
Number (%) of Participants with Events	103 (89.6%)	90 (86.5%)	
Disease Progression (PD)	96 (83.5%)	86 (82.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Death	7 (6.1%)	4 (3.8%)	
Number (%) of Participants Censored	12 (10.4%)	14 (13.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.93 (4.93, 8.34)	5.49 (4.21, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.729 (0.547, 0.971)		
p-value (Log-Rank Test, Unstratified)	0.0295		
Asian	38	38	
Number (%) of Participants with Events	32 (84.2%)	37 (97.4%)	
Disease Progression (PD)	28 (73.7%)	37 (97.4%)	
Death	4 (10.5%)	0	
Number (%) of Participants Censored	6 (15.8%)	1 (2.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.59 (3.88, 13.63)	5.55 (4.04, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.646 (0.398, 1.048)		
p-value (Log-Rank Test, Unstratified)	0.0740		
Other	19	24	
Number (%) of Participants with Events	16 (84.2%)	21 (87.5%)	
Disease Progression (PD)	15 (78.9%)	20 (83.3%)	
Death	1 (5.3%)	1 (4.2%)	
Number (%) of Participants Censored	3 (15.8%)	3 (12.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.36 (2.33, 12.71)	6.01 (4.24, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.796 (0.411, 1.541)		
p-value (Log-Rank Test, Unstratified)	0.5021		

	SG (N=177)	TPC (N=169)	Interaction
Baseline ECOG status			
0	116	106	0.9597
Number (%) of Participants with Events	98 (84.5%)	93 (87.7%)	
Disease Progression (PD)	92 (79.3%)	91 (85.8%)	
Death	6 (5.2%)	2 (1.9%)	
Number (%) of Participants Censored	18 (15.5%)	13 (12.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.07 (6.93, 10.28)	6.87 (5.49, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.691 (0.518, 0.921)		
p-value (Log-Rank Test, Unstratified)	0.0113		
1	61	63	
Number (%) of Participants with Events	57 (93.4%)	58 (92.1%)	
Disease Progression (PD)	50 (82.0%)	55 (87.3%)	
Death	7 (11.5%)	3 (4.8%)	
Number (%) of Participants Censored	4 (6.6%)	5 (7.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.42 (3.29, 6.14)	4.40 (3.19, 5.52)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.771 (0.531, 1.120)		
p-value (Log-Rank Test, Unstratified)	0.1693		
Physician's choice of chemotherapy			
Taxane	52	45	0.0154
Number (%) of Participants with Events	41 (78.8%)	40 (88.9%)	
Disease Progression (PD)	39 (75.0%)	38 (84.4%)	
Death	2 (3.8%)	2 (4.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	11 (21.2%)	5 (11.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (4.53, 13.63)	4.21 (2.89, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.408 (0.254, 0.655)		
p-value (Log-Rank Test, Unstratified)	0.0001		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events	114 (91.2%)	111 (89.5%)	
Disease Progression (PD)	103 (82.4%)	108 (87.1%)	
Death	11 (8.8%)	3 (2.4%)	
Number (%) of Participants Censored	11 (8.8%)	13 (10.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.90 (5.22, 8.34)	5.70 (5.32, 6.90)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.847 (0.651, 1.102)		
p-value (Log-Rank Test, Unstratified)	0.2160		
History of liver metastasis			
Yes	47	39	0.0260
Number (%) of Participants with Events	43 (91.5%)	35 (89.7%)	
Disease Progression (PD)	39 (83.0%)	31 (79.5%)	
Death	4 (8.5%)	4 (10.3%)	
Number (%) of Participants Censored	4 (8.5%)	4 (10.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.88 (3.15, 8.31)	3.30 (2.20, 4.17)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.476 (0.296, 0.764)		
p-value (Log-Rank Test, Unstratified)	0.0017		

	SG (N=177)	TPC (N=169)	Interaction
No	130	130	
Number (%) of Participants with Events	112 (86.2%)	116 (89.2%)	
Disease Progression (PD)	103 (79.2%)	115 (88.5%)	
Death	9 (6.9%)	1 (0.8%)	
Number (%) of Participants Censored	18 (13.8%)	14 (10.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.23 (5.55, 9.30)	6.87 (5.59, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.580, 0.983)		
p-value (Log-Rank Test, Unstratified)	0.0358		
History of brain metastasis			
Yes	8	9	0.8713
Number (%) of Participants with Events	8 (100.0%)	9 (100.0%)	
Disease Progression (PD)	7 (87.5%)	8 (88.9%)	
Death	1 (12.5%)	1 (11.1%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.72 (0.85, 8.54)	3.19 (0.16, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.704 (0.260, 1.902)		
p-value (Log-Rank Test, Unstratified)	0.4864		
No	169	160	
Number (%) of Participants with Events	147 (87.0%)	142 (88.8%)	
Disease Progression (PD)	135 (79.9%)	138 (86.2%)	
Death	12 (7.1%)	4 (2.5%)	
Number (%) of Participants Censored	22 (13.0%)	18 (11.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (5.55, 8.77)	5.60 (4.90, 6.74)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.719 (0.569, 0.909)		
p-value (Log-Rank Test, Unstratified)	0.0055		
PD-L1 Status			
CPS < 1	67	59	0.8275
Number (%) of Participants with Events	56 (83.6%)	51 (86.4%)	
Disease Progression (PD)	50 (74.6%)	50 (84.7%)	
Death	6 (9.0%)	1 (1.7%)	
Number (%) of Participants Censored	11 (16.4%)	8 (13.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.15 (5.36, 9.76)	5.42 (4.07, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.711 (0.485, 1.042)		
p-value (Log-Rank Test, Unstratified)	0.0788		
CPS ≥ 1	109	110	
Number (%) of Participants with Events	99 (90.8%)	100 (90.9%)	
Disease Progression (PD)	92 (84.4%)	96 (87.3%)	
Death	7 (6.4%)	4 (3.6%)	
Number (%) of Participants Censored	10 (9.2%)	10 (9.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.29 (4.37, 8.74)	5.65 (4.90, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.732 (0.551, 0.972)		
p-value (Log-Rank Test, Unstratified)	0.0301		
BRCA 1/2 status			

	SG (N=177)	TPC (N=169)	Interaction
Wild-Type	66	65	0.1008
Number (%) of Participants with Events	60 (90.9%)	58 (89.2%)	
Disease Progression (PD)	56 (84.8%)	57 (87.7%)	
Death	4 (6.1%)	1 (1.5%)	
Number (%) of Participants Censored	6 (9.1%)	7 (10.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.37 (4.17, 7.66)	4.88 (3.06, 5.65)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.731 (0.507, 1.053)		
p-value (Log-Rank Test, Unstratified)	0.0920		
Mutant	12	10	
Number (%) of Participants with Events	12 (100.0%)	8 (80.0%)	
Disease Progression (PD)	10 (83.3%)	8 (80.0%)	
Death	2 (16.7%)	0	
Number (%) of Participants Censored	0	2 (20.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.20 (1.51, 9.30)	9.00 (2.89, 16.59)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.526 (0.618, 3.771)		
p-value (Log-Rank Test, Unstratified)	0.3560		
Menopausal status			
Pre-menopausal	37	49	0.5220
Number (%) of Participants with Events	34 (91.9%)	44 (89.8%)	
Disease Progression (PD)	32 (86.5%)	43 (87.8%)	
Death	2 (5.4%)	1 (2.0%)	
Number (%) of Participants Censored	3 (8.1%)	5 (10.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.85 (4.27, 8.74)	5.42 (4.17, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.783 (0.498, 1.230)		
p-value (Log-Rank Test, Unstratified)	0.2893		
Post-menopausal	140	119	
Number (%) of Participants with Events	121 (86.4%)	106 (89.1%)	
Disease Progression (PD)	110 (78.6%)	102 (85.7%)	
Death	11 (7.9%)	4 (3.4%)	
Number (%) of Participants Censored	19 (13.6%)	13 (10.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.26 (5.36, 9.26)	5.65 (4.40, 7.13)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.691 (0.530, 0.901)		
p-value (Log-Rank Test, Unstratified)	0.0059		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from an unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5.9. Table 1.1.9: Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events	145 (81.9%)	152 (89.9%)
First Subsequent Therapy	108 (61.0%)	125 (74.0%)

Parameter	SG (N=177)	TPC (N=169)
Death	37 (20.9%)	27 (16.0%)
Number (%) of Participants Censored	32 (18.1%)	17 (10.1%)
Kaplan-Meier Estimate of TFST (Months) (95% CI) [a]		
Q1	5.39 (4.37, 6.41)	4.96 (3.94, 5.75)
Median	11.40 (9.13, 12.94)	7.66 (6.60, 9.13)
Q3	20.14 (17.97, 25.07)	12.48 (10.84, 15.34)
Absolute Difference in Median TFST, SG vs TPC (Months)	3.75	
Kaplan-Meier Estimate of TFST Rate (95% CI) [b]		
At 3 Months	0.893 (0.837, 0.930)	0.893 (0.835, 0.931)
At 6 Months	0.711 (0.638, 0.772)	0.673 (0.596, 0.738)
At 9 Months	0.586 (0.510, 0.655)	0.440 (0.363, 0.513)
At 12 Months	0.455 (0.380, 0.527)	0.271 (0.206, 0.340)
At 18 Months	0.317 (0.249, 0.386)	0.163 (0.111, 0.223)
At 24 Months	0.194 (0.139, 0.256)	0.105 (0.064, 0.158)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.0004	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.661 (0.524, 0.833)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomization to the start date of the first subsequent anti-cancer therapy after discontinuation of randomized treatment, or death due to any cause.
[a] Quantile of TFST is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] TFST rate is the proportion of participants alive without any subsequent therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d]Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
Data Cut Date: 22 APR 2026.

5.10. Table 1.1.10: Subgroup Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.1562
Number (%) of Participants with Events	44 (80.0%)	48 (98.0%)	
First Subsequent Therapy	32 (58.2%)	38 (77.6%)	
Death	12 (21.8%)	10 (20.4%)	
Number (%) of Participants Censored	11 (20.0%)	1 (2.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	13.04 (8.15, 16.85)	6.47 (4.99, 7.85)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.471 (0.309, 0.718)		
p-value (Log-Rank Test, Unstratified)	0.0004		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events	30 (88.2%)	29 (85.3%)	
First Subsequent Therapy	24 (70.6%)	25 (73.5%)	
Death	6 (17.6%)	4 (11.8%)	
Number (%) of Participants Censored	4 (11.8%)	5 (14.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.79 (6.74, 13.01)	7.39 (6.11, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.728 (0.435, 1.219)		
p-value (Log-Rank Test, Unstratified)	0.2248		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events	71 (80.7%)	75 (87.2%)	
First Subsequent Therapy	52 (59.1%)	62 (72.1%)	

	SG (N=177)	TPC (N=169)	Interaction
Death	19 (21.6%)	13 (15.1%)	
Number (%) of Participants Censored	17 (19.3%)	11 (12.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.32 (8.08, 14.09)	9.13 (7.16, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.785 (0.566, 1.088)		
p-value (Log-Rank Test, Unstratified)	0.1451		
Geographic region			
US/Canada/Western Europe	56	52	0.6031
Number (%) of Participants with Events	51 (91.1%)	49 (94.2%)	
First Subsequent Therapy	40 (71.4%)	42 (80.8%)	
Death	11 (19.6%)	7 (13.5%)	
Number (%) of Participants Censored	5 (8.9%)	3 (5.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.43 (8.57, 13.86)	6.75 (5.59, 8.44)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.611 (0.410, 0.911)		
p-value (Log-Rank Test, Unstratified)	0.0147		
Rest of the world	121	117	
Number (%) of Participants with Events	94 (77.7%)	103 (88.0%)	
First Subsequent Therapy	68 (56.2%)	83 (70.9%)	
Death	26 (21.5%)	20 (17.1%)	
Number (%) of Participants Censored	27 (22.3%)	14 (12.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.24 (8.87, 14.13)	7.98 (6.77, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.707 (0.533, 0.937)		

	SG (N=177)	TPC (N=169)	Interaction
p-value (Log-Rank Test, Unstratified)	0.0153		
Age group			
< 65	133	131	0.9357
Number (%) of Participants with Events	110 (82.7%)	116 (88.5%)	
First Subsequent Therapy	88 (66.2%)	99 (75.6%)	
Death	22 (16.5%)	17 (13.0%)	
Number (%) of Participants Censored	23 (17.3%)	15 (11.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.79 (9.33, 14.13)	7.39 (6.34, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.670 (0.515, 0.871)		
p-value (Log-Rank Test, Unstratified)	0.0026		
>= 65	44	38	
Number (%) of Participants with Events	35 (79.5%)	36 (94.7%)	
First Subsequent Therapy	20 (45.5%)	26 (68.4%)	
Death	15 (34.1%)	10 (26.3%)	
Number (%) of Participants Censored	9 (20.5%)	2 (5.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.74 (4.73, 14.09)	8.33 (6.24, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.718 (0.448, 1.151)		
p-value (Log-Rank Test, Unstratified)	0.1675		
Race			
White	115	104	0.6149
Number (%) of Participants with Events	99 (86.1%)	93 (89.4%)	
First Subsequent Therapy	74 (64.3%)	75 (72.1%)	

	SG (N=177)	TPC (N=169)	Interaction
Death	25 (21.7%)	18 (17.3%)	
Number (%) of Participants Censored	16 (13.9%)	11 (10.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.38 (8.87, 12.75)	7.59 (6.11, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.741 (0.558, 0.985)		
p-value (Log-Rank Test, Unstratified)	0.0388		
Asian	38	38	
Number (%) of Participants with Events	27 (71.1%)	35 (92.1%)	
First Subsequent Therapy	22 (57.9%)	33 (86.8%)	
Death	5 (13.2%)	2 (5.3%)	
Number (%) of Participants Censored	11 (28.9%)	3 (7.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	12.32 (4.90, 18.46)	8.13 (6.21, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.577 (0.344, 0.968)		
p-value (Log-Rank Test, Unstratified)	0.0359		
Other	19	24	
Number (%) of Participants with Events	15 (78.9%)	21 (87.5%)	
First Subsequent Therapy	9 (47.4%)	15 (62.5%)	
Death	6 (31.6%)	6 (25.0%)	
Number (%) of Participants Censored	4 (21.1%)	3 (12.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.52 (7.26, 18.76)	9.26 (6.34, 11.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.520 (0.261, 1.034)		
p-value (Log-Rank Test, Unstratified)	0.0594		

	SG (N=177)	TPC (N=169)	Interaction
Baseline ECOG status			
0	116	106	0.8353
Number (%) of Participants with Events	92 (79.3%)	92 (86.8%)	
First Subsequent Therapy	71 (61.2%)	81 (76.4%)	
Death	21 (18.1%)	11 (10.4%)	
Number (%) of Participants Censored	24 (20.7%)	14 (13.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.09 (11.24, 16.85)	9.30 (7.39, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.681 (0.509, 0.912)		
p-value (Log-Rank Test, Unstratified)	0.0094		
1	61	63	
Number (%) of Participants with Events	53 (86.9%)	60 (95.2%)	
First Subsequent Therapy	37 (60.7%)	44 (69.8%)	
Death	16 (26.2%)	16 (25.4%)	
Number (%) of Participants Censored	8 (13.1%)	3 (4.8%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.26 (4.80, 10.15)	6.24 (5.29, 7.20)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.712 (0.489, 1.036)		
p-value (Log-Rank Test, Unstratified)	0.0744		
Physician's choice of chemotherapy			
Taxane	52	45	0.0170
Number (%) of Participants with Events	40 (76.9%)	43 (95.6%)	
First Subsequent Therapy	31 (59.6%)	33 (73.3%)	
Death	9 (17.3%)	10 (22.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	12 (23.1%)	2 (4.4%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	15.87 (11.66, 18.96)	7.59 (5.59, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.387 (0.246, 0.609)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events	105 (84.0%)	109 (87.9%)	
First Subsequent Therapy	77 (61.6%)	92 (74.2%)	
Death	28 (22.4%)	17 (13.7%)	
Number (%) of Participants Censored	20 (16.0%)	15 (12.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.69 (7.43, 11.40)	7.79 (6.54, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.627, 1.074)		
p-value (Log-Rank Test, Unstratified)	0.1494		
History of liver metastasis			
Yes	47	39	0.1611
Number (%) of Participants with Events	42 (89.4%)	38 (97.4%)	
First Subsequent Therapy	29 (61.7%)	28 (71.8%)	
Death	13 (27.7%)	10 (25.6%)	
Number (%) of Participants Censored	5 (10.6%)	1 (2.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.87 (4.86, 9.76)	5.13 (3.91, 6.01)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.531 (0.338, 0.835)		
p-value (Log-Rank Test, Unstratified)	0.0054		

	SG (N=177)	TPC (N=169)	Interaction
No	130	130	
Number (%) of Participants with Events	103 (79.2%)	114 (87.7%)	
First Subsequent Therapy	79 (60.8%)	97 (74.6%)	
Death	24 (18.5%)	17 (13.1%)	
Number (%) of Participants Censored	27 (20.8%)	16 (12.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	12.68 (10.38, 16.03)	9.13 (7.62, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.694 (0.530, 0.908)		
p-value (Log-Rank Test, Unstratified)	0.0075		
History of brain metastasis			
Yes	8	9	0.5508
Number (%) of Participants with Events	8 (100.0%)	9 (100.0%)	
First Subsequent Therapy	7 (87.5%)	6 (66.7%)	
Death	1 (12.5%)	3 (33.3%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	6.85 (0.85, 11.24)	7.20 (0.16, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.813 (0.301, 2.198)		
p-value (Log-Rank Test, Unstratified)	0.6824		
No	169	160	
Number (%) of Participants with Events	137 (81.1%)	143 (89.4%)	
First Subsequent Therapy	101 (59.8%)	119 (74.4%)	
Death	36 (21.3%)	24 (15.0%)	
Number (%) of Participants Censored	32 (18.9%)	17 (10.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.60 (9.33, 14.09)	7.69 (6.60, 9.36)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.677 (0.534, 0.858)		
p-value (Log-Rank Test, Unstratified)	0.0012		
PD-L1 Status			
CPS < 1	67	59	0.5150
Number (%) of Participants with Events	53 (79.1%)	54 (91.5%)	
First Subsequent Therapy	41 (61.2%)	44 (74.6%)	
Death	12 (17.9%)	10 (16.9%)	
Number (%) of Participants Censored	14 (20.9%)	5 (8.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.60 (9.03, 14.09)	7.13 (5.59, 8.48)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.620 (0.423, 0.908)		
p-value (Log-Rank Test, Unstratified)	0.0131		
CPS ≥ 1	109	110	
Number (%) of Participants with Events	91 (83.5%)	98 (89.1%)	
First Subsequent Therapy	67 (61.5%)	81 (73.6%)	
Death	24 (22.0%)	17 (15.5%)	
Number (%) of Participants Censored	18 (16.5%)	12 (10.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.74 (7.26, 14.13)	7.98 (6.60, 9.69)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.725 (0.543, 0.968)		
p-value (Log-Rank Test, Unstratified)	0.0285		
BRCA 1/2 status			

	SG (N=177)	TPC (N=169)	Interaction
Wild-Type	66	65	0.0829
Number (%) of Participants with Events	60 (90.9%)	60 (92.3%)	
First Subsequent Therapy	46 (69.7%)	50 (76.9%)	
Death	14 (21.2%)	10 (15.4%)	
Number (%) of Participants Censored	6 (9.1%)	5 (7.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.73 (6.74, 14.92)	6.24 (5.36, 7.85)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.657 (0.457, 0.944)		
p-value (Log-Rank Test, Unstratified)	0.0225		
Mutant	12	10	
Number (%) of Participants with Events	11 (91.7%)	8 (80.0%)	
First Subsequent Therapy	8 (66.7%)	7 (70.0%)	
Death	3 (25.0%)	1 (10.0%)	
Number (%) of Participants Censored	1 (8.3%)	2 (20.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.33 (3.15, 16.79)	11.27 (4.99, 16.62)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.454 (0.582, 3.629)		
p-value (Log-Rank Test, Unstratified)	0.4202		
Menopausal status			
Pre-menopausal	37	49	0.2556
Number (%) of Participants with Events	31 (83.8%)	42 (85.7%)	
First Subsequent Therapy	28 (75.7%)	38 (77.6%)	
Death	3 (8.1%)	4 (8.2%)	
Number (%) of Participants Censored	6 (16.2%)	7 (14.3%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.03 (5.85, 12.68)	6.74 (6.21, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.863 (0.542, 1.375)		
p-value (Log-Rank Test, Unstratified)	0.5382		
Post-menopausal	140	119	
Number (%) of Participants with Events	114 (81.4%)	109 (91.6%)	
First Subsequent Therapy	80 (57.1%)	86 (72.3%)	
Death	34 (24.3%)	23 (19.3%)	
Number (%) of Participants Censored	26 (18.6%)	10 (8.4%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.60 (9.33, 14.13)	7.98 (6.80, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.629 (0.482, 0.820)		
p-value (Log-Rank Test, Unstratified)	0.0006		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomisation to the start date of the first subsequent anti-cancer therapy after discontinuation of randomised treatment, or death due to any cause.
TFST rate is the proportion of participants alive without any subsequent therapy.
Hazard ratio and 95% CIs calculated using unstratified Cox proportional hazards model. Efron method used to handle ties. Reference arm = TPC.
Log-rank p-value is from an unstratified log-rank test.
Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Data Cut Date: 22 APR 2026.

6. Safety - mSAF — Excluding patients preselected to receive nab-paclitaxel

6.1. Table 1.1.1: Summary of Treatment Exposure - Treatment Duration (months) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	Gemcitabine (N=122)	Carboplatin (N=122)	Gem/Carbo (N=122)	Taxane (N=44)	Any TPC (N=166)
Total Duration of Exposure to Study Drug						
Duration (months)						
N	175	122	122	122	44	166
Mean (StD)	10.44 (8.777)	8.15 (7.306)	7.23 (6.016)	7.15 (5.986)	5.44 (4.341)	6.70 (5.636)
Median	8.08	6.09	5.77	5.77	4.76	5.42
Q1, Q3	3.73, 17.69	3.76, 9.68	3.50, 9.49	3.50, 9.20	2.17, 7.68	2.82, 8.39
Min, Max	0.20, 40.74	0.03, 33.84	0.03, 31.28	0.03, 31.28	0.03, 17.91	0.03, 31.28
Cumulative Number (%) of Participants						
Exposed to Study Drug						
>= 3 months, n, (%)	140 (80.0%)	95 (77.9%)	95 (77.9%)	95 (77.9%)	28 (63.6%)	123 (74.1%)
>= 6 months, n, (%)	102 (58.3%)	62 (50.8%)	58 (47.5%)	58 (47.5%)	16 (36.4%)	74 (44.6%)
>= 12 months, n, (%)	58 (33.1%)	24 (19.7%)	18 (14.8%)	17 (13.9%)	3 (6.8%)	20 (12.0%)
>= 24 months, n, (%)	16 (9.1%)	8 (6.6%)	5 (4.1%)	5 (4.1%)	0 (0.0%)	5 (3.0%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, Gem = gemcitabine, Carbo = carboplatin.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug. Taxane includes participants who have received Paclitaxel. TPC column includes participants who have received any of Gem, Carbo or Paclitaxel.
Duration of exposure to study drug (months) = (last dosing date − first dosing date + 1)/30.4375.
Data Cut Date: 22 APR 2026.

6.2. Table 1.1.2: Observation Period (Months) for Safety — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Total (N=341)
Observation Period (months) for Safety [a]			
N	175	166	341
Mean (StD)	11.31 (8.623)	8.45 (6.703)	9.92 (7.868)
Median	9.07	6.59	7.46
Q1, Q3	4.71, 18.68	3.90, 10.34	4.50, 13.21
Min, Max	0.46, 40.77	0.10, 33.84	0.10, 40.77

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
[a] Observation period is defined as the time from first dose until Data cutoff date, study treatment discontinuation +30 days for any AE and any serious AE, or death, whichever comes first and stops the collection of endpoint data.
Data Cut Date: 22 APR 2026.

6.3. Table 1.1.3: Analysis of Time to First Treatment-Emergent Adverse Event (TEAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	175 (100.0%)	163 (98.2%)
Patients (%) Without Events (Censored)	0 (0.0%)	3 (1.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.10 (0.10, 0.16)	0.18 (0.10, 0.23)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.246 (1.002, 1.548)
p-value		0.0424

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.

	SG (N=175)	TPC (N=166)

Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.4. Table 1.1.4: Subgroup Analysis of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.5106
De novo			
Total Patients	55	48	
Patients (%) With Events	55 (100.0%)	47 (97.9%)	
Patients (%) Without Events (Censored)	0	1 (2.1%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.16)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.239 (0.831, 1.848)	
p-value		0.2759	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	34 (100.0%)	33 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.21 (0.10, 0.26)	0.20 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.003 (0.616, 1.633)	
p-value		0.9957	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	86 (100.0%)	83 (97.6%)	
Patients (%) Without Events (Censored)	0	2 (2.4%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.417 (1.037, 1.935)	
p-value		0.0271	
Geographic region			0.4926
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	55 (100.0%)	49 (98.0%)	
Patients (%) Without Events (Censored)	0	1 (2.0%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.07, 0.20)	0.18 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.165 (0.790, 1.719)	
p-value		0.4318	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	120 (100.0%)	114 (98.3%)	
Patients (%) Without Events (Censored)	0	2 (1.7%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.20)	0.18 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.316 (1.008, 1.717)	
p-value		0.0384	
Age group			0.6875
< 65			
Total Patients	132	128	
Patients (%) With Events	132 (100.0%)	125 (97.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	0	3 (2.3%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.262 (0.984, 1.620)	
p-value		0.0681	
>= 65			
Total Patients	43	38	
Patients (%) With Events	43 (100.0%)	38 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.13 (0.07, 0.20)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.167 (0.746, 1.824)	
p-value		0.4318	
Race			0.9199
White			
Total Patients	114	101	
Patients (%) With Events	114 (100.0%)	98 (97.0%)	
Patients (%) Without Events (Censored)	0	3 (3.0%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.13, 0.23)	
Hazard Ratio (95% CI)		1.220 (0.929, 1.603)	
p-value		0.1311	
Asian			
Total Patients	38	38	
Patients (%) With Events	38 (100.0%)	38 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.10 (0.07, 0.20)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.273 (0.789, 2.054)	
p-value		0.3570	
Other			
Total Patients	18	24	
Patients (%) With Events	18 (100.0%)	24 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.07, 0.26)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.120 (0.594, 2.112)	
p-value		0.6710	
Baseline ECOG status			0.7199
0			
Total Patients	115	104	
Patients (%) With Events	115 (100.0%)	102 (98.1%)	
Patients (%) Without Events (Censored)	0	2 (1.9%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.20)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.270 (0.967, 1.668)	
p-value		0.0842	
1			
Total Patients	60	62	
Patients (%) With Events	60 (100.0%)	61 (98.4%)	
Patients (%) Without Events (Censored)	0	1 (1.6%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.23)	0.20 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.194 (0.832, 1.714)	
p-value		0.3083	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.9140
Taxane			
Total Patients	51	44	
Patients (%) With Events	51 (100.0%)	42 (95.5%)	
Patients (%) Without Events (Censored)	0	2 (4.5%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.26)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.267 (0.826, 1.944)	
p-value		0.2754	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	124 (100.0%)	121 (99.2%)	
Patients (%) Without Events (Censored)	0	1 (0.8%)	
Median Time to First TEAE, months (95% CI)	0.11 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.244 (0.965, 1.604)	
p-value		0.0771	
History of liver metastasis			0.6446
Yes			
Total Patients	47	37	
Patients (%) With Events	47 (100.0%)	34 (91.9%)	
Patients (%) Without Events (Censored)	0	3 (8.1%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.13 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.287 (0.819, 2.023)	
p-value		0.2383	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	128 (100.0%)	129 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.215 (0.947, 1.558)	
p-value		0.1155	
History of brain metastasis			0.3238
Yes			
Total Patients	8	9	
Patients (%) With Events	8 (100.0%)	9 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.03, 0.26)	0.20 (0.03, 1.64)	
Hazard Ratio (95% CI)		1.754 (0.633, 4.859)	
p-value		0.2560	
No			
Total Patients	167	157	
Patients (%) With Events	167 (100.0%)	154 (98.1%)	
Patients (%) Without Events (Censored)	0	3 (1.9%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.16)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.216 (0.973, 1.519)	
p-value		0.0758	
PD-L1 Status			0.6591
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	66 (100.0%)	57 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.13)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.403 (0.966, 2.037)	
p-value		0.0634	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	109 (100.0%)	106 (97.2%)	
Patients (%) Without Events (Censored)	0	3 (2.8%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.183 (0.902, 1.551)	
p-value		0.2338	
BRCA 1/2 status			0.4180
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	65 (100.0%)	61 (96.8%)	
Patients (%) Without Events (Censored)	0	2 (3.2%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.23)	0.23 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.219 (0.856, 1.735)	
p-value		0.2506	
Mutant			
Total Patients	12	10	
Patients (%) With Events	12 (100.0%)	10 (100.0%)	
Patients (%) Without Events (Censored)	0	0	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.18 (0.07, 0.26)	0.10 (0.03, 0.26)	
Hazard Ratio (95% CI)		0.834 (0.351, 1.984)	
p-value		0.5450	
Menopausal status			0.5787
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	37 (100.0%)	48 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.23)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.418 (0.905, 2.222)	
p-value		0.1343	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	138 (100.0%)	114 (97.4%)	
Patients (%) Without Events (Censored)	0	3 (2.6%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.202 (0.935, 1.546)	
p-value		0.1285	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.5. Table 1.1.5: Analysis of Time to First Serious Treatment-Emergent Adverse Event (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	52 (29.7%)	53 (31.9%)
Patients (%) Without Events (Censored)	123 (70.3%)	113 (68.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	18.92 (12.22, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.827 (0.561, 1.218)
p-value		0.3285

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.6. Table 1.1.6: Subgroup Analysis of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.5313
De novo			
Total Patients	55	48	
Patients (%) With Events	20 (36.4%)	15 (31.2%)	
Patients (%) Without Events (Censored)	35 (63.6%)	33 (68.8%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (13.14, NR)	NR (5.98, NR)	
Hazard Ratio (95% CI)		1.005 (0.507, 1.990)	
p-value		0.9925	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	9 (26.5%)	7 (21.2%)	
Patients (%) Without Events (Censored)	25 (73.5%)	26 (78.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.10, NR)	29.01 (NR, NR)	
Hazard Ratio (95% CI)		1.107 (0.407, 3.010)	
p-value		0.8416	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	23 (26.7%)	31 (36.5%)	
Patients (%) Without Events (Censored)	63 (73.3%)	54 (63.5%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (6.90, NR)	
Hazard Ratio (95% CI)		0.651 (0.378, 1.124)	
p-value		0.1183	
Geographic region			0.4227
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	18 (32.7%)	14 (28.0%)	
Patients (%) Without Events (Censored)	37 (67.3%)	36 (72.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	12.22 (12.22, NR)	
Hazard Ratio (95% CI)		1.101 (0.545, 2.227)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.8008	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	34 (28.3%)	39 (33.6%)	
Patients (%) Without Events (Censored)	86 (71.7%)	77 (66.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.733 (0.460, 1.170)	
p-value		0.1897	
Age group			0.0250
< 65			
Total Patients	132	128	
Patients (%) With Events	33 (25.0%)	42 (32.8%)	
Patients (%) Without Events (Censored)	99 (75.0%)	86 (67.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	29.01 (9.76, NR)	
Hazard Ratio (95% CI)		0.627 (0.395, 0.995)	
p-value		0.0449	
>= 65			
Total Patients	43	38	
Patients (%) With Events	19 (44.2%)	11 (28.9%)	
Patients (%) Without Events (Censored)	24 (55.8%)	27 (71.1%)	
Median Time to First Serious TEAE, months (95% CI)	11.40 (1.31, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		1.737 (0.822, 3.672)	
p-value		0.1457	
Race			0.2438

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
White			
Total Patients	114	101	
Patients (%) With Events	32 (28.1%)	34 (33.7%)	
Patients (%) Without Events (Censored)	82 (71.9%)	67 (66.3%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.750 (0.460, 1.220)	
p-value		0.2391	
Asian			
Total Patients	38	38	
Patients (%) With Events	9 (23.7%)	12 (31.6%)	
Patients (%) Without Events (Censored)	29 (76.3%)	26 (68.4%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.666 (0.276, 1.603)	
p-value		0.3608	
Other			
Total Patients	18	24	
Patients (%) With Events	10 (55.6%)	7 (29.2%)	
Patients (%) Without Events (Censored)	8 (44.4%)	17 (70.8%)	
Median Time to First Serious TEAE, months (95% CI)	12.11 (0.66, NR)	29.01 (5.62, NR)	
Hazard Ratio (95% CI)		1.826 (0.683, 4.882)	
p-value		0.2261	
Baseline ECOG status			0.8151
0			
Total Patients	115	104	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	31 (27.0%)	32 (30.8%)	
Patients (%) Without Events (Censored)	84 (73.0%)	72 (69.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (18.92, NR)	
Hazard Ratio (95% CI)		0.798 (0.485, 1.315)	
p-value		0.3697	
1			
Total Patients	60	62	
Patients (%) With Events	21 (35.0%)	21 (33.9%)	
Patients (%) Without Events (Censored)	39 (65.0%)	41 (66.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	12.22 (7.36, NR)	
Hazard Ratio (95% CI)		0.918 (0.496, 1.697)	
p-value		0.7801	
The physician's choice of chemotherapy selected prior to randomization			0.6262
Taxane			
Total Patients	51	44	
Patients (%) With Events	12 (23.5%)	8 (18.2%)	
Patients (%) Without Events (Censored)	39 (76.5%)	36 (81.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.234 (0.504, 3.024)	
p-value		0.6547	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	40 (32.3%)	45 (36.9%)	
Patients (%) Without Events (Censored)	84 (67.7%)	77 (63.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	18.92 (9.10, NR)	
Hazard Ratio (95% CI)		0.792 (0.515, 1.217)	
p-value		0.2824	
History of liver metastasis			0.5796
Yes			
Total Patients	47	37	
Patients (%) With Events	18 (38.3%)	12 (32.4%)	
Patients (%) Without Events (Censored)	29 (61.7%)	25 (67.6%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (5.36, NR)	12.22 (3.06, NR)	
Hazard Ratio (95% CI)		0.938 (0.439, 2.005)	
p-value		0.8391	
No			
Total Patients	128	129	
Patients (%) With Events	34 (26.6%)	41 (31.8%)	
Patients (%) Without Events (Censored)	94 (73.4%)	88 (68.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	29.01 (18.92, NR)	
Hazard Ratio (95% CI)		0.756 (0.477, 1.196)	
p-value		0.2299	
History of brain metastasis			0.6554
Yes			
Total Patients	8	9	
Patients (%) With Events	4 (50.0%)	4 (44.4%)	
Patients (%) Without Events (Censored)	4 (50.0%)	5 (55.6%)	
Median Time to First Serious TEAE, months (95% CI)	6.46 (0.26, NR)	NR (0.03, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.990 (0.247, 3.965)	
p-value		0.9881	
No			
Total Patients	167	157	
Patients (%) With Events	48 (28.7%)	49 (31.2%)	
Patients (%) Without Events (Censored)	119 (71.3%)	108 (68.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		0.810 (0.541, 1.212)	
p-value		0.2995	
PD-L1 Status			0.0194
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	17 (25.8%)	25 (43.9%)	
Patients (%) Without Events (Censored)	49 (74.2%)	32 (56.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	12.22 (4.63, NR)	
Hazard Ratio (95% CI)		0.454 (0.242, 0.852)	
p-value		0.0111	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	35 (32.1%)	28 (25.7%)	
Patients (%) Without Events (Censored)	74 (67.9%)	81 (74.3%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	31.47 (NR, NR)	
Hazard Ratio (95% CI)		1.211 (0.733, 1.999)	
p-value		0.4575	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
BRCA 1/2 status			0.0379
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	15 (23.1%)	15 (23.8%)	
Patients (%) Without Events (Censored)	50 (76.9%)	48 (76.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (12.22, NR)	
Hazard Ratio (95% CI)		0.819 (0.398, 1.685)	
p-value		0.5828	
Mutant			
Total Patients	12	10	
Patients (%) With Events	6 (50.0%)	2 (20.0%)	
Patients (%) Without Events (Censored)	6 (50.0%)	8 (80.0%)	
Median Time to First Serious TEAE, months (95% CI)	10.41 (0.23, NR)	23.97 (18.92, NR)	
Hazard Ratio (95% CI)		7.220 (0.859, 60.652)	
p-value		0.0342	
Menopausal status			0.9128
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	9 (24.3%)	14 (29.2%)	
Patients (%) Without Events (Censored)	28 (75.7%)	34 (70.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	29.01 (7.36, NR)	
Hazard Ratio (95% CI)		0.816 (0.346, 1.924)	
p-value		0.6393	
Post-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	138	117	
Patients (%) With Events	43 (31.2%)	39 (33.3%)	
Patients (%) Without Events (Censored)	95 (68.8%)	78 (66.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		0.829 (0.534, 1.285)	
p-value		0.3935	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
NC = Not Calculable: the hazard ratio and 95% CI are not estimable by the Cox model.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.7. Table 1.1.7: Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	120 (68.6%)	127 (76.5%)
Patients (%) Without Events (Censored)	55 (31.4%)	39 (23.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.61 (0.95, 3.52)	1.71 (1.15, 2.27)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.820 (0.636, 1.057)
p-value		0.1165

	SG (N=175)	TPC (N=166)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.8. Table 1.1.8: Subgroup Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.6251
De novo			
Total Patients	55	48	
Patients (%) With Events	38 (69.1%)	32 (66.7%)	
Patients (%) Without Events (Censored)	17 (30.9%)	16 (33.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.72, 3.48)	1.97 (0.85, 3.48)	
Hazard Ratio (95% CI)		1.063 (0.662, 1.707)	
p-value		0.7987	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	25 (73.5%)	29 (87.9%)	
Patients (%) Without Events (Censored)	9 (26.5%)	4 (12.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.79 (0.43, 4.14)	0.95 (0.85, 1.64)	
Hazard Ratio (95% CI)		0.809 (0.467, 1.403)	
p-value		0.4232	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	57 (66.3%)	66 (77.6%)	
Patients (%) Without Events (Censored)	29 (33.7%)	19 (22.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.52 (0.95, 6.28)	1.84 (1.35, 2.99)	
Hazard Ratio (95% CI)		0.724 (0.504, 1.040)	
p-value		0.0750	
Geographic region			0.8294
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	35 (63.6%)	35 (70.0%)	
Patients (%) Without Events (Censored)	20 (36.4%)	15 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.38 (0.92, 21.39)	1.97 (1.05, 3.48)	
Hazard Ratio (95% CI)		0.875 (0.545, 1.405)	
p-value		0.5676	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	85 (70.8%)	92 (79.3%)	
Patients (%) Without Events (Censored)	35 (29.2%)	24 (20.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.77 (0.72, 3.68)	1.64 (0.95, 2.30)	
Hazard Ratio (95% CI)		0.806 (0.596, 1.088)	
p-value		0.1482	
Age group			0.1315
< 65			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	132	128	
Patients (%) With Events	86 (65.2%)	97 (75.8%)	
Patients (%) Without Events (Censored)	46 (34.8%)	31 (24.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.56 (1.25, 4.83)	1.64 (0.99, 2.30)	
Hazard Ratio (95% CI)		0.744 (0.555, 0.999)	
p-value		0.0453	
>= 65			
Total Patients	43	38	
Patients (%) With Events	34 (79.1%)	30 (78.9%)	
Patients (%) Without Events (Censored)	9 (20.9%)	8 (21.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.66 (0.43, 1.61)	1.71 (0.92, 3.81)	
Hazard Ratio (95% CI)		1.105 (0.667, 1.832)	
p-value		0.7147	
Race			0.2193
White			
Total Patients	114	101	
Patients (%) With Events	71 (62.3%)	77 (76.2%)	
Patients (%) Without Events (Censored)	43 (37.7%)	24 (23.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.37 (1.25, 6.41)	1.61 (1.05, 2.33)	
Hazard Ratio (95% CI)		0.712 (0.514, 0.987)	
p-value		0.0393	
Asian			
Total Patients	38	38	
Patients (%) With Events	29 (76.3%)	27 (71.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	9 (23.7%)	11 (28.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.56, 5.39)	1.77 (0.92, 5.39)	
Hazard Ratio (95% CI)		1.093 (0.643, 1.860)	
p-value		0.7812	
Other			
Total Patients	18	24	
Patients (%) With Events	17 (94.4%)	22 (91.7%)	
Patients (%) Without Events (Censored)	1 (5.6%)	2 (8.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.43 (0.30, 0.69)	0.97 (0.72, 3.88)	
Hazard Ratio (95% CI)		1.133 (0.575, 2.234)	
p-value		0.7354	
Baseline ECOG status			0.9737
0			
Total Patients	115	104	
Patients (%) With Events	76 (66.1%)	80 (76.9%)	
Patients (%) Without Events (Censored)	39 (33.9%)	24 (23.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.72, 3.68)	1.84 (1.15, 2.50)	
Hazard Ratio (95% CI)		0.856 (0.623, 1.176)	
p-value		0.3197	
1			
Total Patients	60	62	
Patients (%) With Events	44 (73.3%)	47 (75.8%)	
Patients (%) Without Events (Censored)	16 (26.7%)	15 (24.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.07 (0.89, 5.39)	1.41 (0.76, 2.63)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.770 (0.503, 1.177)	
p-value		0.2221	
The physician's choice of chemotherapy selected prior to randomization			0.0016
Taxane			
Total Patients	51	44	
Patients (%) With Events	33 (64.7%)	18 (40.9%)	
Patients (%) Without Events (Censored)	18 (35.3%)	26 (59.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, 6.41)	7.79 (2.27, NR)	
Hazard Ratio (95% CI)		1.789 (1.003, 3.191)	
p-value		0.0459	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	87 (70.2%)	109 (89.3%)	
Patients (%) Without Events (Censored)	37 (29.8%)	13 (10.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.51 (0.72, 3.68)	1.18 (0.95, 1.77)	
Hazard Ratio (95% CI)		0.633 (0.473, 0.847)	
p-value		0.0017	
History of liver metastasis			0.6855
Yes			
Total Patients	47	37	
Patients (%) With Events	33 (70.2%)	27 (73.0%)	
Patients (%) Without Events (Censored)	14 (29.8%)	10 (27.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.49, 3.81)	1.41 (0.92, 2.99)	
Hazard Ratio (95% CI)		0.928 (0.552, 1.560)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.7536	
No			
Total Patients	128	129	
Patients (%) With Events	87 (68.0%)	100 (77.5%)	
Patients (%) Without Events (Censored)	41 (32.0%)	29 (22.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.91 (0.95, 4.14)	1.77 (1.15, 2.37)	
Hazard Ratio (95% CI)		0.786 (0.587, 1.053)	
p-value		0.1002	
History of brain metastasis			0.9351
Yes			
Total Patients	8	9	
Patients (%) With Events	6 (75.0%)	8 (88.9%)	
Patients (%) Without Events (Censored)	2 (25.0%)	1 (11.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.84 (0.20, NR)	1.64 (0.07, 2.50)	
Hazard Ratio (95% CI)		0.813 (0.276, 2.394)	
p-value		0.7050	
No			
Total Patients	167	157	
Patients (%) With Events	114 (68.3%)	119 (75.8%)	
Patients (%) Without Events (Censored)	53 (31.7%)	38 (24.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.61 (0.95, 3.58)	1.71 (1.05, 2.37)	
Hazard Ratio (95% CI)		0.821 (0.632, 1.066)	
p-value		0.1310	
PD-L1 Status			0.2789

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	43 (65.2%)	47 (82.5%)	
Patients (%) Without Events (Censored)	23 (34.8%)	10 (17.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.59 (0.72, 4.14)	1.41 (0.95, 2.17)	
Hazard Ratio (95% CI)		0.709 (0.465, 1.081)	
p-value		0.1047	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	77 (70.6%)	80 (73.4%)	
Patients (%) Without Events (Censored)	32 (29.4%)	29 (26.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.95, 3.68)	1.84 (0.99, 3.02)	
Hazard Ratio (95% CI)		0.893 (0.650, 1.229)	
p-value		0.4732	
BRCA 1/2 status			0.0104
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	44 (67.7%)	44 (69.8%)	
Patients (%) Without Events (Censored)	21 (32.3%)	19 (30.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.92, 4.83)	1.41 (0.92, 3.09)	
Hazard Ratio (95% CI)		0.813 (0.532, 1.243)	
p-value		0.3363	
Mutant			
Total Patients	12	10	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	11 (91.7%)	7 (70.0%)	
Patients (%) Without Events (Censored)	1 (8.3%)	3 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.48 (0.23, 0.95)	3.48 (0.72, NR)	
Hazard Ratio (95% CI)		3.539 (1.278, 9.802)	
p-value		0.0109	
Menopausal status			0.8252
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	24 (64.9%)	35 (72.9%)	
Patients (%) Without Events (Censored)	13 (35.1%)	13 (27.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.20 (0.72, 8.05)	1.84 (0.95, 3.02)	
Hazard Ratio (95% CI)		0.855 (0.507, 1.439)	
p-value		0.5470	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	96 (69.6%)	92 (78.6%)	
Patients (%) Without Events (Censored)	42 (30.4%)	25 (21.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.59 (0.95, 3.68)	1.61 (0.99, 2.50)	
Hazard Ratio (95% CI)		0.788 (0.589, 1.056)	
p-value		0.1019	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.9. Table 1.1.9: Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Number of patients at risk	175 (100.0%)	166 (100.0%)
Number of patients with events	9 (5.1%)	29 (17.5%)
Sacituzumab Govitecan	9 (5.1%)	0
Paclitaxel	0	6 (3.6%)
Gemcitabine	0	12 (7.2%)
Carboplatin	0	22 (13.3%)
Number of patients censored	166 (94.9%)	137 (82.5%)
Probability of being event-free [a] [95% CI] [b] at:		
Month 3	96.5 [92.4, 98.4]	94.9 [90.0, 97.4]
Month 6	95.1 [90.5, 97.5]	90.8 [84.6, 94.6]
Month 9	95.1 [90.5, 97.5]	79.8 [70.4, 86.6]
Month 12	95.1 [90.5, 97.5]	71.2 [57.6, 81.1]
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	28.32 (14.55, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.213 (0.100, 0.456)
p-value		<0.0001

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[a] Estimated from the Kaplan-Meier method.
[b] Calculated using the log-log transformation (Brookmeyer-Crowley method).

	SG (N=175)	TPC (N=166)

[c] Median 95% CI based on Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties. p-value is from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm in the Safety Analysis Set.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.10. Table 1.1.10: Subgroup Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.3878
De novo			
Total Patients	55	48	
Patients (%) With Events	5 (9.1%)	7 (14.6%)	
Patients (%) Without Events (Censored)	50 (90.9%)	41 (85.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.505 (0.157, 1.629)	
p-value		0.2450	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	1 (2.9%)	4 (12.1%)	
Patients (%) Without Events (Censored)	33 (97.1%)	29 (87.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.73, NR)	
Hazard Ratio (95% CI)		0.155 (0.016, 1.475)	
p-value		0.0683	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	3 (3.5%)	18 (21.2%)	
Patients (%) Without Events (Censored)	83 (96.5%)	67 (78.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (12.06, NR)	
Hazard Ratio (95% CI)		0.125 (0.037, 0.430)	
p-value		0.0001	
Geographic region			0.7623
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	3 (5.5%)	10 (20.0%)	
Patients (%) Without Events (Censored)	52 (94.5%)	40 (80.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.93, NR)	
Hazard Ratio (95% CI)		0.211 (0.058, 0.770)	
p-value		0.0095	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	6 (5.0%)	19 (16.4%)	
Patients (%) Without Events (Censored)	114 (95.0%)	97 (83.6%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.214 (0.084, 0.545)	
p-value		0.0004	
Age group			0.0134
< 65			
Total Patients	132	128	
Patients (%) With Events	4 (3.0%)	24 (18.8%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	128 (97.0%)	104 (81.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (12.06, NR)	
Hazard Ratio (95% CI)		0.103 (0.035, 0.301)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	5 (11.6%)	5 (13.2%)	
Patients (%) Without Events (Censored)	38 (88.4%)	33 (86.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (19.61, NR)	
Hazard Ratio (95% CI)		0.862 (0.243, 3.058)	
p-value		0.8175	
Race			0.0652
White			
Total Patients	114	101	
Patients (%) With Events	4 (3.5%)	22 (21.8%)	
Patients (%) Without Events (Censored)	110 (96.5%)	79 (78.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.73, NR)	
Hazard Ratio (95% CI)		0.113 (0.039, 0.333)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	3 (7.9%)	
Patients (%) Without Events (Censored)	34 (89.5%)	35 (92.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.054 (0.229, 4.846)	
p-value		0.9457	
Other			
Total Patients	18	24	
Patients (%) With Events	1 (5.6%)	4 (16.7%)	
Patients (%) Without Events (Censored)	17 (94.4%)	20 (83.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	14.55 (14.55, NR)	
Hazard Ratio (95% CI)		0.222 (0.023, 2.137)	
p-value		0.1607	
Baseline ECOG status			0.4610
0			
Total Patients	115	104	
Patients (%) With Events	7 (6.1%)	19 (18.3%)	
Patients (%) Without Events (Censored)	108 (93.9%)	85 (81.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.244 (0.101, 0.589)	
p-value		0.0007	
1			
Total Patients	60	62	
Patients (%) With Events	2 (3.3%)	10 (16.1%)	
Patients (%) Without Events (Censored)	58 (96.7%)	52 (83.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (8.48, NR)	
Hazard Ratio (95% CI)		0.141 (0.030, 0.658)	
p-value		0.0041	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.4691
Taxane			
Total Patients	51	44	
Patients (%) With Events	4 (7.8%)	6 (13.6%)	
Patients (%) Without Events (Censored)	47 (92.2%)	38 (86.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.450 (0.126, 1.611)	
p-value		0.2086	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	5 (4.0%)	23 (18.9%)	
Patients (%) Without Events (Censored)	119 (96.0%)	99 (81.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.163 (0.061, 0.434)	
p-value		<0.0001	
History of liver metastasis			0.0902
Yes			
Total Patients	47	37	
Patients (%) With Events	0	3 (8.1%)	
Patients (%) Without Events (Censored)	47 (100.0%)	34 (91.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.44, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0060	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	9 (7.0%)	26 (20.2%)	
Patients (%) Without Events (Censored)	119 (93.0%)	103 (79.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.270 (0.125, 0.583)	
p-value		0.0004	
History of brain metastasis			0.9279
Yes			
Total Patients	8	9	
Patients (%) With Events	1 (12.5%)	4 (44.4%)	
Patients (%) Without Events (Censored)	7 (87.5%)	5 (55.6%)	
Median Time to Discontinuation, months (95% CI)	NR (1.58, NR)	8.57 (0.20, NR)	
Hazard Ratio (95% CI)		0.269 (0.030, 2.409)	
p-value		0.2077	
No			
Total Patients	167	157	
Patients (%) With Events	8 (4.8%)	25 (15.9%)	
Patients (%) Without Events (Censored)	159 (95.2%)	132 (84.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.210 (0.094, 0.473)	
p-value		<0.0001	
PD-L1 Status			0.0048
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	1 (1.5%)	16 (28.1%)	
Patients (%) Without Events (Censored)	65 (98.5%)	41 (71.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	12.06 (8.48, NR)	
Hazard Ratio (95% CI)		0.034 (0.005, 0.262)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	8 (7.3%)	13 (11.9%)	
Patients (%) Without Events (Censored)	101 (92.7%)	96 (88.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (14.55, NR)	
Hazard Ratio (95% CI)		0.490 (0.200, 1.200)	
p-value		0.1115	
BRCA 1/2 status			0.6009
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	3 (4.6%)	7 (11.1%)	
Patients (%) Without Events (Censored)	62 (95.4%)	56 (88.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (28.32, NR)	
Hazard Ratio (95% CI)		0.339 (0.087, 1.313)	
p-value		0.1004	
Mutant			
Total Patients	12	10	
Patients (%) With Events	1 (8.3%)	2 (20.0%)	
Patients (%) Without Events (Censored)	11 (91.7%)	8 (80.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (6.93, NR)	
Hazard Ratio (95% CI)		0.953 (0.060, 15.255)	
p-value		0.9731	
Menopausal status			0.7487
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	1 (2.7%)	7 (14.6%)	
Patients (%) Without Events (Censored)	36 (97.3%)	41 (85.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.148 (0.018, 1.221)	
p-value		0.0413	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	8 (5.8%)	22 (18.8%)	
Patients (%) Without Events (Censored)	130 (94.2%)	95 (81.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	28.32 (11.93, NR)	
Hazard Ratio (95% CI)		0.214 (0.094, 0.489)	
p-value		0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. NC = Not Calculable (HR is NC when one treatment arm has zero events; log-rank p-value remains valid).
Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
Data Cut Date: 22 APR 2026.

6.11. Table 1.1.11: Analysis of Time to First TEAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Blood and lymphatic system disorders		
Total Patients	175	166
Patients (%) With Events	133 (76.0%)	136 (81.9%)
Patients (%) Without Events (Censored)	42 (24.0%)	30 (18.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.72 (0.69, 0.92)	0.72 (0.69, 0.95)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.852 (0.670, 1.084)
p-value		0.1732
Anaemia		
Total Patients	175	166
Patients (%) With Events	68 (38.9%)	95 (57.2%)
Patients (%) Without Events (Censored)	107 (61.1%)	71 (42.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (10.32, NR)	2.73 (2.10, 4.30)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.534 (0.390, 0.732)
p-value		0.0001
Febrile neutropenia		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	3 (1.8%)
Patients (%) Without Events (Censored)	167 (95.4%)	163 (98.2%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.570 (0.682, 9.687)
p-value		0.1478
Leukopenia		
Total Patients	175	166
Patients (%) With Events	48 (27.4%)	56 (33.7%)
Patients (%) Without Events (Censored)	127 (72.6%)	110 (66.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	29.90 (29.90, NR)	15.90 (9.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.724 (0.491, 1.067)
p-value		0.0997
Lymphopenia		
Total Patients	175	166
Patients (%) With Events	24 (13.7%)	24 (14.5%)
Patients (%) Without Events (Censored)	151 (86.3%)	142 (85.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.868 (0.491, 1.534)
p-value		0.6234
Neutropenia		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	116 (66.3%)	116 (69.9%)
Patients (%) Without Events (Censored)	59 (33.7%)	50 (30.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 2.60)	1.25 (0.92, 1.87)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.910 (0.703, 1.179)
p-value		0.4435
Thrombocytopenia		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	71 (42.8%)
Patients (%) Without Events (Censored)	170 (97.1%)	95 (57.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	6.93 (5.39, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.045 (0.018, 0.113)
p-value		<0.0001
Cardiac disorders		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	15 (9.0%)
Patients (%) Without Events (Censored)	157 (89.7%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.017 (0.509, 2.031)
p-value		0.9616
Ear and labyrinth disorders		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	7 (4.2%)
Patients (%) Without Events (Censored)	168 (96.0%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.889 (0.311, 2.541)
p-value		0.8263
Eye disorders		
Total Patients	175	166
Patients (%) With Events	29 (16.6%)	11 (6.6%)
Patients (%) Without Events (Censored)	146 (83.4%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (21.98, NR)	NR (26.84, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.106 (1.045, 4.244)
p-value		0.0332
Dry eye		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	2 (1.2%)
Patients (%) Without Events (Censored)	165 (94.3%)	164 (98.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.746 (0.812, 17.276)
p-value		0.0698
Gastrointestinal disorders		
Total Patients	175	166
Patients (%) With Events	162 (92.6%)	119 (71.7%)
Patients (%) Without Events (Censored)	13 (7.4%)	47 (28.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.26 (0.16, 0.30)	0.80 (0.39, 1.74)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.849 (1.454, 2.350)
p-value		<0.0001
Abdominal distension		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	5 (3.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.837 (0.238, 2.941)
p-value		0.7813
Abdominal pain		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	29 (16.6%)	12 (7.2%)
Patients (%) Without Events (Censored)	146 (83.4%)	154 (92.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.203 (1.121, 4.330)
p-value		0.0190
Abdominal pain upper		
Total Patients	175	166
Patients (%) With Events	16 (9.1%)	10 (6.0%)
Patients (%) Without Events (Censored)	159 (90.9%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.423 (0.644, 3.144)
p-value		0.3806
Constipation		
Total Patients	175	166
Patients (%) With Events	73 (41.7%)	50 (30.1%)
Patients (%) Without Events (Censored)	102 (58.3%)	116 (69.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (6.05, NR)	NR (14.75, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.427 (0.995, 2.047)
p-value		0.0519
Diarrhoea		
Total Patients	175	166
Patients (%) With Events	102 (58.3%)	38 (22.9%)
Patients (%) Without Events (Censored)	73 (41.7%)	128 (77.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	3.32 (1.25, 7.33)	30.42 (20.96, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.229 (2.222, 4.692)
p-value		<0.0001
Dyspepsia		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	7 (4.2%)
Patients (%) Without Events (Censored)	161 (92.0%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.527 (0.608, 3.836)
p-value		0.3636
Gastrooesophageal reflux disease		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	3 (1.8%)
Patients (%) Without Events (Censored)	164 (93.7%)	163 (98.2%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.088 (0.857, 11.127)
p-value		0.0696
Nausea		
Total Patients	175	166
Patients (%) With Events	111 (63.4%)	70 (42.2%)
Patients (%) Without Events (Censored)	64 (36.6%)	96 (57.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.53 (0.95, 3.98)	15.54 (9.23, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.750 (1.297, 2.362)
p-value		0.0002
Stomatitis		
Total Patients	175	166
Patients (%) With Events	30 (17.1%)	8 (4.8%)
Patients (%) Without Events (Censored)	145 (82.9%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.282 (1.500, 7.179)
p-value		0.0016
Vomiting		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	53 (30.3%)	28 (16.9%)
Patients (%) Without Events (Censored)	122 (69.7%)	138 (83.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (21.13, NR)	33.58 (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.739 (1.099, 2.754)
p-value		0.0167
General disorders and administration site conditions		
Total Patients	175	166
Patients (%) With Events	120 (68.6%)	101 (60.8%)
Patients (%) Without Events (Censored)	55 (31.4%)	65 (39.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.81 (1.35, 2.86)	3.55 (1.94, 4.44)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.170 (0.897, 1.525)
p-value		0.2482
Chest pain		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	3 (1.8%)
Patients (%) Without Events (Censored)	166 (94.9%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		2.479 (0.667, 9.212)
p-value		0.1611
Fatigue		
Total Patients	175	166
Patients (%) With Events	91 (52.0%)	82 (49.4%)
Patients (%) Without Events (Censored)	84 (48.0%)	84 (50.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	4.90 (2.53, NR)	7.26 (3.78, 17.51)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.070 (0.793, 1.442)
p-value		0.6619
Malaise		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	5 (3.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.854 (0.633, 5.431)
p-value		0.2527
Oedema peripheral		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	13 (7.8%)
Patients (%) Without Events (Censored)	157 (89.7%)	153 (92.2%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.123 (0.547, 2.305)
p-value		0.7516
Pain		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	4 (2.4%)
Patients (%) Without Events (Censored)	168 (96.0%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.428 (0.412, 4.947)
p-value		0.5721
Pyrexia		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	21 (12.7%)
Patients (%) Without Events (Censored)	154 (88.0%)	145 (87.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.784 (0.425, 1.444)
p-value		0.4331
Hepatobiliary disorders		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	11 (6.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (25.56, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.658 (0.271, 1.602)
p-value		0.3534
Immune system disorders		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	6 (3.6%)
Patients (%) Without Events (Censored)	168 (96.0%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.008 (0.337, 3.012)
p-value		0.9885
Infections and infestations		
Total Patients	175	166
Patients (%) With Events	105 (60.0%)	85 (51.2%)
Patients (%) Without Events (Censored)	70 (40.0%)	81 (48.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	6.57 (4.76, 7.69)	5.75 (4.37, 9.23)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.041 (0.780, 1.391)
p-value		0.7803
Bronchitis		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	2 (1.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.237 (0.683, 15.345)
p-value		0.1180
COVID-19		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	9 (5.4%)
Patients (%) Without Events (Censored)	164 (93.7%)	157 (94.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.967 (0.399, 2.346)
p-value		0.9411
Influenza		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	6 (3.6%)
Patients (%) Without Events (Censored)	164 (93.7%)	160 (96.4%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.180 (0.429, 3.243)
p-value		0.7478
Nasopharyngitis		
Total Patients	175	166
Patients (%) With Events	16 (9.1%)	9 (5.4%)
Patients (%) Without Events (Censored)	159 (90.9%)	157 (94.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.234 (0.539, 2.824)
p-value		0.6181
Pneumonia		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	11 (6.6%)
Patients (%) Without Events (Censored)	165 (94.3%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.586 (0.245, 1.402)
p-value		0.2249
Upper respiratory tract infection		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	11 (6.6%)
Patients (%) Without Events (Censored)	154 (88.0%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (26.02, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.493 (0.717, 3.107)
p-value		0.2807
Urinary tract infection		
Total Patients	175	166
Patients (%) With Events	23 (13.1%)	26 (15.7%)
Patients (%) Without Events (Censored)	152 (86.9%)	140 (84.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.709 (0.402, 1.250)
p-value		0.2326
Injury, poisoning and procedural complications		
Total Patients	175	166
Patients (%) With Events	19 (10.9%)	30 (18.1%)
Patients (%) Without Events (Censored)	156 (89.1%)	136 (81.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	33.58 (18.83, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.461 (0.256, 0.828)
p-value		0.0081
Infusion related reaction		
Total Patients	175	166
Patients (%) With Events	3 (1.7%)	10 (6.0%)
Patients (%) Without Events (Censored)	172 (98.3%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.232 (0.062, 0.863)
p-value		0.0184
Investigations		
Total Patients	175	166
Patients (%) With Events	76 (43.4%)	79 (47.6%)
Patients (%) Without Events (Censored)	99 (56.6%)	87 (52.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	19.35 (7.85, NR)	7.16 (3.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.747 (0.544, 1.026)
p-value		0.0733
Alanine aminotransferase increased		
Total Patients	175	166
Patients (%) With Events	35 (20.0%)	59 (35.5%)
Patients (%) Without Events (Censored)	140 (80.0%)	107 (64.5%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (11.76, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.437 (0.286, 0.666)
p-value		0.0001
Aspartate aminotransferase increased		
Total Patients	175	166
Patients (%) With Events	32 (18.3%)	48 (28.9%)
Patients (%) Without Events (Censored)	143 (81.7%)	118 (71.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.524 (0.334, 0.822)
p-value		0.0043
Blood alkaline phosphatase increased		
Total Patients	175	166
Patients (%) With Events	25 (14.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	150 (85.7%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.974 (0.967, 4.032)
p-value		0.0572
Blood creatinine increased		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	5 (3.0%)
Patients (%) Without Events (Censored)	169 (96.6%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.073 (0.327, 3.518)
p-value		0.9086
Gamma-glutamyltransferase increased		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	10 (6.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.861 (0.357, 2.074)
p-value		0.7403
Weight decreased		
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	6 (3.6%)
Patients (%) Without Events (Censored)	158 (90.3%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		2.618 (1.030, 6.656)
p-value		0.0357
Metabolism and nutrition disorders		
Total Patients	175	166
Patients (%) With Events	76 (43.4%)	57 (34.3%)
Patients (%) Without Events (Censored)	99 (56.6%)	109 (65.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	12.88 (7.13, NR)	15.44 (12.32, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.264 (0.896, 1.784)
p-value		0.1812
Decreased appetite		
Total Patients	175	166
Patients (%) With Events	35 (20.0%)	22 (13.3%)
Patients (%) Without Events (Censored)	140 (80.0%)	144 (86.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.423 (0.833, 2.429)
p-value		0.1947
Hyperglycaemia		
Total Patients	175	166
Patients (%) With Events	15 (8.6%)	16 (9.6%)
Patients (%) Without Events (Censored)	160 (91.4%)	150 (90.4%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.823 (0.405, 1.670)
p-value		0.5862
Hyperkalaemia		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	4 (2.4%)
Patients (%) Without Events (Censored)	169 (96.6%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.335 (0.376, 4.737)
p-value		0.6540
Hypoalbuminaemia		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	4 (2.4%)
Patients (%) Without Events (Censored)	168 (96.0%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.574 (0.459, 5.396)
p-value		0.4669
Hypocalcaemia		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	8 (4.8%)
Patients (%) Without Events (Censored)	165 (94.3%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (26.48, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.009 (0.394, 2.580)
p-value		0.9837
Hypokalaemia		
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	11 (6.6%)
Patients (%) Without Events (Censored)	158 (90.3%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.313 (0.611, 2.823)
p-value		0.4861
Hypomagnesaemia		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	10 (6.0%)
Patients (%) Without Events (Censored)	163 (93.1%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.19, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.859 (0.366, 2.017)
p-value		0.7259
Hyponatraemia		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	8 (4.8%)
Patients (%) Without Events (Censored)	164 (93.7%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.304 (0.525, 3.242)
p-value		0.5669
Musculoskeletal and connective tissue disorders		
Total Patients	175	166
Patients (%) With Events	69 (39.4%)	63 (38.0%)
Patients (%) Without Events (Censored)	106 (60.6%)	103 (62.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.13 (10.41, NR)	13.50 (8.77, 22.60)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.854 (0.604, 1.210)
p-value		0.3738
Arthralgia		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	19 (11.4%)
Patients (%) Without Events (Censored)	157 (89.7%)	147 (88.6%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (22.60, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.676 (0.349, 1.307)
p-value		0.2409
Back pain		
Total Patients	175	166
Patients (%) With Events	19 (10.9%)	18 (10.8%)
Patients (%) Without Events (Censored)	156 (89.1%)	148 (89.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	30.36 (19.68, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.821 (0.428, 1.576)
p-value		0.5524
Bone pain		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	1 (0.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	165 (99.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		7.197 (0.907, 57.089)
p-value		0.0293
Muscle spasms		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	4 (2.4%)
Patients (%) Without Events (Censored)	169 (96.6%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.94, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.939 (0.256, 3.444)
p-value		0.9246
Myalgia		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	18 (10.8%)
Patients (%) Without Events (Censored)	161 (92.0%)	148 (89.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.608 (0.299, 1.235)
p-value		0.1645
Pain in extremity		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	14 (8.4%)
Patients (%) Without Events (Censored)	168 (96.0%)	152 (91.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.383 (0.153, 0.957)
p-value		0.0333
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	2 (1.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.808 (0.587, 13.440)
p-value		0.1778
Nervous system disorders		
Total Patients	175	166
Patients (%) With Events	70 (40.0%)	68 (41.0%)
Patients (%) Without Events (Censored)	105 (60.0%)	98 (59.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.29 (10.64, NR)	12.58 (6.44, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.844 (0.603, 1.182)
p-value		0.3244
Dizziness		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	164 (93.7%)	155 (93.4%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.828 (0.357, 1.920)
p-value		0.6604
Dysgeusia		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	12 (7.2%)
Patients (%) Without Events (Censored)	161 (92.0%)	154 (92.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.046 (0.483, 2.267)
p-value		0.9088
Headache		
Total Patients	175	166
Patients (%) With Events	30 (17.1%)	26 (15.7%)
Patients (%) Without Events (Censored)	145 (82.9%)	140 (84.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	36.86 (36.86, NR)	NR (25.40, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.916 (0.537, 1.562)
p-value		0.7483
Neuropathy peripheral		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	15 (9.0%)
Patients (%) Without Events (Censored)	167 (95.4%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.422 (0.178, 0.998)
p-value		0.0430
Peripheral sensory neuropathy		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	15 (9.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.270 (0.098, 0.745)
p-value		0.0068
Psychiatric disorders		
Total Patients	175	166
Patients (%) With Events	27 (15.4%)	20 (12.0%)
Patients (%) Without Events (Censored)	148 (84.6%)	146 (88.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	37.13 (37.13, NR)	NR (28.32, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.132 (0.629, 2.038)
p-value		0.6780
Anxiety		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	6 (3.6%)
Patients (%) Without Events (Censored)	169 (96.6%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.851 (0.273, 2.648)
p-value		0.7801
Depression		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	2 (1.2%)
Patients (%) Without Events (Censored)	163 (93.1%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		5.111 (1.139, 22.941)
p-value		0.0179
Insomnia		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	7 (4.2%)
Patients (%) Without Events (Censored)	164 (93.7%)	159 (95.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	37.13 (37.13, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.180 (0.444, 3.136)
p-value		0.7392
Renal and urinary disorders		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	14 (8.4%)
Patients (%) Without Events (Censored)	154 (88.0%)	152 (91.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.296 (0.657, 2.557)
p-value		0.4540
Reproductive system and breast disorders		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	17 (10.2%)
Patients (%) Without Events (Censored)	154 (88.0%)	149 (89.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.988 (0.519, 1.882)
p-value		0.9700
Breast pain		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	164 (93.7%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.773 (0.333, 1.796)
p-value		0.5480
Respiratory, thoracic and mediastinal disorders		
Total Patients	175	166
Patients (%) With Events	67 (38.3%)	51 (30.7%)
Patients (%) Without Events (Censored)	108 (61.7%)	115 (69.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	15.41 (10.68, NR)	22.05 (11.60, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.147 (0.795, 1.656)
p-value		0.4606
Cough		
Total Patients	175	166
Patients (%) With Events	34 (19.4%)	15 (9.0%)
Patients (%) Without Events (Censored)	141 (80.6%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (23.92, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.857 (1.008, 3.421)
p-value		0.0437
Dyspnoea		
Total Patients	175	166
Patients (%) With Events	19 (10.9%)	22 (13.3%)
Patients (%) Without Events (Censored)	156 (89.1%)	144 (86.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (22.05, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.740 (0.399, 1.371)
p-value		0.3374
Oropharyngeal pain		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	5 (3.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.805 (0.616, 5.291)
p-value		0.2747
Pulmonary embolism		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	6 (3.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	160 (96.4%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.359 (0.483, 3.827)
p-value		0.5596
Rhinorrhoea		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	2 (1.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.051 (0.645, 14.436)
p-value		0.1392
Skin and subcutaneous tissue disorders		
Total Patients	175	166
Patients (%) With Events	120 (68.6%)	67 (40.4%)
Patients (%) Without Events (Censored)	55 (31.4%)	99 (59.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.95 (0.72, 1.35)	17.08 (6.21, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.458 (1.819, 3.323)
p-value		<0.0001
Alopecia		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	97 (55.4%)	34 (20.5%)
Patients (%) Without Events (Censored)	78 (44.6%)	132 (79.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.38 (0.92, 5.32)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.821 (2.581, 5.657)
p-value		<0.0001
Dry skin		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	3 (1.8%)
Patients (%) Without Events (Censored)	166 (94.9%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (23.56, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.239 (0.597, 8.392)
p-value		0.2203
Eczema		
Total Patients	175	166
Patients (%) With Events	3 (1.7%)	7 (4.2%)
Patients (%) Without Events (Censored)	172 (98.3%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.370 (0.095, 1.439)
p-value		0.1356
Pruritus		
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	7 (4.2%)
Patients (%) Without Events (Censored)	158 (90.3%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (25.72, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.956 (0.806, 4.745)
p-value		0.1309
Rash		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	15 (9.0%)
Patients (%) Without Events (Censored)	154 (88.0%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.187 (0.609, 2.312)
p-value		0.6141
Urticaria		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	5 (3.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	161 (97.0%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.599 (0.169, 2.126)
p-value		0.4235
Vascular disorders		
Total Patients	175	166
Patients (%) With Events	29 (16.6%)	28 (16.9%)
Patients (%) Without Events (Censored)	146 (83.4%)	138 (83.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	25.56 (18.73, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.815 (0.482, 1.377)
p-value		0.4439
Hot flush		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	4 (2.4%)
Patients (%) Without Events (Censored)	165 (94.3%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.130 (0.665, 6.828)
p-value		0.1925

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=175)	TPC (N=166)

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.12. Table 1.1.12.1: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
History of brain metastasis			0.3742
Yes			
Total Patients	8	9	
Patients (%) With Events	1 (12.5%)	0 (0.0%)	
Patients (%) Without Events (Censored)	7 (87.5%)	9 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (5.06, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.3613	
No			
Total Patients	167	157	
Patients (%) With Events	28 (16.8%)	11 (7.0%)	
Patients (%) Without Events (Censored)	139 (83.2%)	146 (93.0%)	
Median Time to First TEAE, months (95% CI)	NR (21.98, NR)	NR (26.84, NR)	
Hazard Ratio (95% CI)		2.015 (0.996, 4.076)	
p-value		0.0469	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.13. Table 1.1.12.2: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.2400
De novo			
Total Patients	55	48	
Patients (%) With Events	52 (94.5%)	31 (64.6%)	
Patients (%) Without Events (Censored)	3 (5.5%)	17 (35.4%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.36)	0.76 (0.30, 5.19)	
Hazard Ratio (95% CI)		2.332 (1.478, 3.679)	
p-value		0.0002	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	30 (88.2%)	24 (72.7%)	
Patients (%) Without Events (Censored)	4 (11.8%)	9 (27.3%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.38 (0.16, 1.45)	0.95 (0.26, 3.29)	
Hazard Ratio (95% CI)		1.292 (0.749, 2.229)	
p-value		0.3484	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	80 (93.0%)	64 (75.3%)	
Patients (%) Without Events (Censored)	6 (7.0%)	21 (24.7%)	
Median Time to First TEAE, months (95% CI)	0.21 (0.10, 0.30)	0.82 (0.20, 2.04)	
Hazard Ratio (95% CI)		1.873 (1.338, 2.621)	
p-value		0.0002	
Geographic region			0.6345
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	52 (94.5%)	36 (72.0%)	
Patients (%) Without Events (Censored)	3 (5.5%)	14 (28.0%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.36)	0.90 (0.30, 2.89)	
Hazard Ratio (95% CI)		2.279 (1.470, 3.534)	
p-value		0.0002	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	110 (91.7%)	83 (71.6%)	
Patients (%) Without Events (Censored)	10 (8.3%)	33 (28.4%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.74 (0.30, 2.04)	
Hazard Ratio (95% CI)		1.737 (1.300, 2.320)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0001	
Age group			0.2301
< 65			
Total Patients	132	128	
Patients (%) With Events	121 (91.7%)	90 (70.3%)	
Patients (%) Without Events (Censored)	11 (8.3%)	38 (29.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.36)	0.77 (0.30, 1.74)	
Hazard Ratio (95% CI)		1.699 (1.290, 2.238)	
p-value		0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	41 (95.3%)	29 (76.3%)	
Patients (%) Without Events (Censored)	2 (4.7%)	9 (23.7%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.26)	1.08 (0.26, 5.03)	
Hazard Ratio (95% CI)		2.767 (1.638, 4.674)	
p-value		0.0001	
Race			0.4510
White			
Total Patients	114	101	
Patients (%) With Events	105 (92.1%)	69 (68.3%)	
Patients (%) Without Events (Censored)	9 (7.9%)	32 (31.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	1.61 (0.72, 3.29)	
Hazard Ratio (95% CI)		2.001 (1.470, 2.723)	
p-value		<0.0001	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Asian			
Total Patients	38	38	
Patients (%) With Events	36 (94.7%)	26 (68.4%)	
Patients (%) Without Events (Censored)	2 (5.3%)	12 (31.6%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.36)	0.28 (0.10, 7.59)	
Hazard Ratio (95% CI)		1.714 (1.022, 2.874)	
p-value		0.0325	
Other			
Total Patients	18	24	
Patients (%) With Events	16 (88.9%)	21 (87.5%)	
Patients (%) Without Events (Censored)	2 (11.1%)	3 (12.5%)	
Median Time to First TEAE, months (95% CI)	0.31 (0.07, 0.59)	0.59 (0.10, 0.82)	
Hazard Ratio (95% CI)		1.398 (0.721, 2.709)	
p-value		0.3261	
Baseline ECOG status			0.6508
0			
Total Patients	115	104	
Patients (%) With Events	105 (91.3%)	73 (70.2%)	
Patients (%) Without Events (Censored)	10 (8.7%)	31 (29.8%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.13, 0.36)	0.90 (0.30, 2.89)	
Hazard Ratio (95% CI)		1.893 (1.399, 2.562)	
p-value		<0.0001	
1			
Total Patients	60	62	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	57 (95.0%)	46 (74.2%)	
Patients (%) Without Events (Censored)	3 (5.0%)	16 (25.8%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.30)	0.72 (0.23, 2.73)	
Hazard Ratio (95% CI)		1.803 (1.214, 2.678)	
p-value		0.0029	
The physician's choice of chemotherapy selected prior to randomization			0.1004
Taxane			
Total Patients	51	44	
Patients (%) With Events	49 (96.1%)	24 (54.5%)	
Patients (%) Without Events (Censored)	2 (3.9%)	20 (45.5%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.10, 0.43)	2.89 (0.26, NR)	
Hazard Ratio (95% CI)		2.663 (1.614, 4.392)	
p-value		0.0001	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	113 (91.1%)	95 (77.9%)	
Patients (%) Without Events (Censored)	11 (8.9%)	27 (22.1%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.30)	0.72 (0.30, 1.05)	
Hazard Ratio (95% CI)		1.638 (1.243, 2.160)	
p-value		0.0003	
History of liver metastasis			0.8623
Yes			
Total Patients	47	37	
Patients (%) With Events	44 (93.6%)	25 (67.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	3 (6.4%)	12 (32.4%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.33)	0.33 (0.10, 3.29)	
Hazard Ratio (95% CI)		1.659 (1.010, 2.723)	
p-value		0.0364	
No			
Total Patients	128	129	
Patients (%) With Events	118 (92.2%)	94 (72.9%)	
Patients (%) Without Events (Censored)	10 (7.8%)	35 (27.1%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	0.95 (0.43, 2.04)	
Hazard Ratio (95% CI)		1.883 (1.430, 2.480)	
p-value		<0.0001	
History of brain metastasis			0.7348
Yes			
Total Patients	8	9	
Patients (%) With Events	8 (100.0%)	7 (77.8%)	
Patients (%) Without Events (Censored)	0 (0.0%)	2 (22.2%)	
Median Time to First TEAE, months (95% CI)	0.28 (0.07, 0.53)	2.73 (0.03, NR)	
Hazard Ratio (95% CI)		2.889 (0.843, 9.901)	
p-value		0.0750	
No			
Total Patients	167	157	
Patients (%) With Events	154 (92.2%)	112 (71.3%)	
Patients (%) Without Events (Censored)	13 (7.8%)	45 (28.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.30)	0.79 (0.39, 1.74)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.827 (1.428, 2.337)	
p-value		<0.0001	
PD-L1 Status			0.8168
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	63 (95.5%)	44 (77.2%)	
Patients (%) Without Events (Censored)	3 (4.5%)	13 (22.8%)	
Median Time to First TEAE, months (95% CI)	0.28 (0.10, 0.36)	0.76 (0.13, 3.29)	
Hazard Ratio (95% CI)		1.828 (1.234, 2.706)	
p-value		0.0020	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	99 (90.8%)	75 (68.8%)	
Patients (%) Without Events (Censored)	10 (9.2%)	34 (31.2%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.30)	0.82 (0.39, 1.61)	
Hazard Ratio (95% CI)		1.880 (1.387, 2.548)	
p-value		<0.0001	
BRCA 1/2 status			0.0284
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	62 (95.4%)	42 (66.7%)	
Patients (%) Without Events (Censored)	3 (4.6%)	21 (33.3%)	
Median Time to First TEAE, months (95% CI)	0.30 (0.13, 0.36)	1.87 (0.36, 4.57)	
Hazard Ratio (95% CI)		2.313 (1.545, 3.463)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		<0.0001	
Mutant			
Total Patients	12	10	
Patients (%) With Events	9 (75.0%)	9 (90.0%)	
Patients (%) Without Events (Censored)	3 (25.0%)	1 (10.0%)	
Median Time to First TEAE, months (95% CI)	0.38 (0.13, 5.39)	0.30 (0.03, 3.52)	
Hazard Ratio (95% CI)		0.739 (0.293, 1.867)	
p-value		0.5190	
Menopausal status			0.9291
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	34 (91.9%)	34 (70.8%)	
Patients (%) Without Events (Censored)	3 (8.1%)	14 (29.2%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.49)	0.72 (0.13, 3.29)	
Hazard Ratio (95% CI)		1.765 (1.086, 2.868)	
p-value		0.0195	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	128 (92.8%)	84 (71.8%)	
Patients (%) Without Events (Censored)	10 (7.2%)	33 (28.2%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	0.85 (0.43, 2.37)	
Hazard Ratio (95% CI)		1.898 (1.435, 2.510)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.14. Table 1.1.12.3: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Injury, poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.1028
De novo			
Total Patients	55	48	
Patients (%) With Events	9 (16.4%)	10 (20.8%)	
Patients (%) Without Events (Censored)	46 (83.6%)	38 (79.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.586 (0.228, 1.501)	
p-value		0.2624	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	0 (0.0%)	4 (12.1%)	
Patients (%) Without Events (Censored)	34 (100.0%)	29 (87.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0297	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	10 (11.6%)	16 (18.8%)	
Patients (%) Without Events (Censored)	76 (88.4%)	69 (81.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.83, NR)	
Hazard Ratio (95% CI)		0.497 (0.223, 1.106)	
p-value		0.0807	
Geographic region			0.5841
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	7 (12.7%)	12 (24.0%)	
Patients (%) Without Events (Censored)	48 (87.3%)	38 (76.0%)	
Median Time to First TEAE, months (95% CI)	NR (17.68, NR)	18.83 (11.76, NR)	
Hazard Ratio (95% CI)		0.317 (0.118, 0.850)	
p-value		0.0173	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	12 (10.0%)	18 (15.5%)	
Patients (%) Without Events (Censored)	108 (90.0%)	98 (84.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.92, NR)	
Hazard Ratio (95% CI)		0.545 (0.260, 1.143)	
p-value		0.1033	
Age group			0.9554

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
< 65			
Total Patients	132	128	
Patients (%) With Events	12 (9.1%)	18 (14.1%)	
Patients (%) Without Events (Censored)	120 (90.9%)	110 (85.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		0.512 (0.245, 1.070)	
p-value		0.0703	
>= 65			
Total Patients	43	38	
Patients (%) With Events	7 (16.3%)	12 (31.6%)	
Patients (%) Without Events (Censored)	36 (83.7%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	NR (9.95, NR)	18.83 (11.76, NR)	
Hazard Ratio (95% CI)		0.433 (0.167, 1.124)	
p-value		0.0776	
Race			0.5653
White			
Total Patients	114	101	
Patients (%) With Events	13 (11.4%)	16 (15.8%)	
Patients (%) Without Events (Censored)	101 (88.6%)	85 (84.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	18.92 (18.83, NR)	
Hazard Ratio (95% CI)		0.521 (0.247, 1.101)	
p-value		0.0830	
Asian			
Total Patients	38	38	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	4 (10.5%)	11 (28.9%)	
Patients (%) Without Events (Censored)	34 (89.5%)	27 (71.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (7.03, NR)	
Hazard Ratio (95% CI)		0.325 (0.102, 1.037)	
p-value		0.0463	
Other			
Total Patients	18	24	
Patients (%) With Events	1 (5.6%)	2 (8.3%)	
Patients (%) Without Events (Censored)	17 (94.4%)	22 (91.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		0.445 (0.038, 5.183)	
p-value		0.5084	
Baseline ECOG status			0.7433
0			
Total Patients	115	104	
Patients (%) With Events	11 (9.6%)	18 (17.3%)	
Patients (%) Without Events (Censored)	104 (90.4%)	86 (82.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.83, NR)	
Hazard Ratio (95% CI)		0.411 (0.191, 0.886)	
p-value		0.0196	
1			
Total Patients	60	62	
Patients (%) With Events	8 (13.3%)	12 (19.4%)	
Patients (%) Without Events (Censored)	52 (86.7%)	50 (80.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.573 (0.232, 1.414)	
p-value		0.2215	
The physician's choice of chemotherapy selected prior to randomization			0.7730
Taxane			
Total Patients	51	44	
Patients (%) With Events	6 (11.8%)	8 (18.2%)	
Patients (%) Without Events (Censored)	45 (88.2%)	36 (81.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.498 (0.168, 1.473)	
p-value		0.2016	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	13 (10.5%)	22 (18.0%)	
Patients (%) Without Events (Censored)	111 (89.5%)	100 (82.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.83, NR)	
Hazard Ratio (95% CI)		0.462 (0.230, 0.928)	
p-value		0.0264	
History of liver metastasis			0.3748
Yes			
Total Patients	47	37	
Patients (%) With Events	5 (10.6%)	3 (8.1%)	
Patients (%) Without Events (Censored)	42 (89.4%)	34 (91.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (11.76, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.669 (0.137, 3.262)	
p-value		0.6168	
No			
Total Patients	128	129	
Patients (%) With Events	14 (10.9%)	27 (20.9%)	
Patients (%) Without Events (Censored)	114 (89.1%)	102 (79.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.83, NR)	
Hazard Ratio (95% CI)		0.426 (0.221, 0.820)	
p-value		0.0088	
History of brain metastasis			0.4280
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	2 (22.2%)	
Patients (%) Without Events (Censored)	6 (75.0%)	7 (77.8%)	
Median Time to First TEAE, months (95% CI)	NR (1.58, NR)	NR (0.07, NR)	
Hazard Ratio (95% CI)		1.070 (0.151, 7.607)	
p-value		0.9458	
No			
Total Patients	167	157	
Patients (%) With Events	17 (10.2%)	28 (17.8%)	
Patients (%) Without Events (Censored)	150 (89.8%)	129 (82.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (18.83, NR)	
Hazard Ratio (95% CI)		0.430 (0.232, 0.795)	
p-value		0.0058	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
PD-L1 Status			0.8866
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	8 (12.1%)	12 (21.1%)	
Patients (%) Without Events (Censored)	58 (87.9%)	45 (78.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	18.92 (11.76, NR)	
Hazard Ratio (95% CI)		0.424 (0.170, 1.056)	
p-value		0.0583	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	11 (10.1%)	18 (16.5%)	
Patients (%) Without Events (Censored)	98 (89.9%)	91 (83.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		0.492 (0.229, 1.056)	
p-value		0.0640	
Menopausal status			0.5740
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	5 (13.5%)	9 (18.8%)	
Patients (%) Without Events (Censored)	32 (86.5%)	39 (81.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		0.745 (0.243, 2.283)	
p-value		0.6065	
Post-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	138	117	
Patients (%) With Events	14 (10.1%)	21 (17.9%)	
Patients (%) Without Events (Censored)	124 (89.9%)	96 (82.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	18.92 (18.83, NR)	
Hazard Ratio (95% CI)		0.416 (0.208, 0.830)	
p-value		0.0105	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.15. Table 1.1.12.4: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.8177
De novo			
Total Patients	55	48	
Patients (%) With Events	40 (72.7%)	23 (47.9%)	
Patients (%) Without Events (Censored)	15 (27.3%)	25 (52.1%)	
Median Time to First TEAE, months (95% CI)	0.79 (0.56, 1.41)	6.21 (1.91, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.174 (1.294, 3.653)	
p-value		0.0028	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	20 (58.8%)	10 (30.3%)	
Patients (%) Without Events (Censored)	14 (41.2%)	23 (69.7%)	
Median Time to First TEAE, months (95% CI)	1.51 (0.72, NR)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.494 (1.162, 5.353)	
p-value		0.0152	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	60 (69.8%)	34 (40.0%)	
Patients (%) Without Events (Censored)	26 (30.2%)	51 (60.0%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.66, 1.35)	17.08 (5.09, NR)	
Hazard Ratio (95% CI)		2.651 (1.733, 4.057)	
p-value		<0.0001	
Geographic region			0.3001
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	37 (67.3%)	22 (44.0%)	
Patients (%) Without Events (Censored)	18 (32.7%)	28 (56.0%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.76, 3.02)	5.09 (2.37, NR)	
Hazard Ratio (95% CI)		2.107 (1.238, 3.586)	
p-value		0.0053	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	83 (69.2%)	45 (38.8%)	
Patients (%) Without Events (Censored)	37 (30.8%)	71 (61.2%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.59, 1.12)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.600 (1.802, 3.751)	
p-value		<0.0001	
Age group			0.2004
< 65			
Total Patients	132	128	
Patients (%) With Events	96 (72.7%)	49 (38.3%)	
Patients (%) Without Events (Censored)	36 (27.3%)	79 (61.7%)	
Median Time to First TEAE, months (95% CI)	0.87 (0.72, 1.15)	23.56 (6.47, NR)	
Hazard Ratio (95% CI)		2.702 (1.910, 3.823)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	24 (55.8%)	18 (47.4%)	
Patients (%) Without Events (Censored)	19 (44.2%)	20 (52.6%)	
Median Time to First TEAE, months (95% CI)	1.48 (0.62, NR)	5.45 (1.97, NR)	
Hazard Ratio (95% CI)		1.791 (0.966, 3.321)	
p-value		0.0618	
Race			0.6006
White			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	114	101	
Patients (%) With Events	74 (64.9%)	33 (32.7%)	
Patients (%) Without Events (Censored)	40 (35.1%)	68 (67.3%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.76, 1.74)	NR (17.08, NR)	
Hazard Ratio (95% CI)		2.943 (1.948, 4.449)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	32 (84.2%)	23 (60.5%)	
Patients (%) Without Events (Censored)	6 (15.8%)	15 (39.5%)	
Median Time to First TEAE, months (95% CI)	0.57 (0.49, 0.92)	2.86 (0.49, NR)	
Hazard Ratio (95% CI)		1.944 (1.121, 3.370)	
p-value		0.0166	
Other			
Total Patients	18	24	
Patients (%) With Events	12 (66.7%)	8 (33.3%)	
Patients (%) Without Events (Censored)	6 (33.3%)	16 (66.7%)	
Median Time to First TEAE, months (95% CI)	1.05 (0.53, 15.93)	23.56 (2.43, NR)	
Hazard Ratio (95% CI)		3.396 (1.318, 8.748)	
p-value		0.0074	
Baseline ECOG status			0.7391
0			
Total Patients	115	104	
Patients (%) With Events	82 (71.3%)	46 (44.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	33 (28.7%)	58 (55.8%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.69, 1.41)	17.08 (5.09, NR)	
Hazard Ratio (95% CI)		2.365 (1.643, 3.404)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	38 (63.3%)	21 (33.9%)	
Patients (%) Without Events (Censored)	22 (36.7%)	41 (66.1%)	
Median Time to First TEAE, months (95% CI)	0.85 (0.72, 2.20)	NR (3.38, NR)	
Hazard Ratio (95% CI)		2.613 (1.527, 4.471)	
p-value		0.0003	
The physician's choice of chemotherapy selected prior to randomization			0.0475
Taxane			
Total Patients	51	44	
Patients (%) With Events	35 (68.6%)	22 (50.0%)	
Patients (%) Without Events (Censored)	16 (31.4%)	22 (50.0%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.20)	3.29 (0.92, NR)	
Hazard Ratio (95% CI)		1.539 (0.901, 2.628)	
p-value		0.1101	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	85 (68.5%)	45 (36.9%)	
Patients (%) Without Events (Censored)	39 (31.5%)	77 (63.1%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.69, 1.15)	23.56 (6.74, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.918 (2.025, 4.206)	
p-value		<0.0001	
History of liver metastasis			0.7401
Yes			
Total Patients	47	37	
Patients (%) With Events	29 (61.7%)	12 (32.4%)	
Patients (%) Without Events (Censored)	18 (38.3%)	25 (67.6%)	
Median Time to First TEAE, months (95% CI)	1.48 (0.66, 9.43)	NR (3.02, NR)	
Hazard Ratio (95% CI)		2.226 (1.134, 4.369)	
p-value		0.0167	
No			
Total Patients	128	129	
Patients (%) With Events	91 (71.1%)	55 (42.6%)	
Patients (%) Without Events (Censored)	37 (28.9%)	74 (57.4%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 1.12)	17.08 (5.45, NR)	
Hazard Ratio (95% CI)		2.599 (1.853, 3.646)	
p-value		<0.0001	
History of brain metastasis			0.7721
Yes			
Total Patients	8	9	
Patients (%) With Events	5 (62.5%)	3 (33.3%)	
Patients (%) Without Events (Censored)	3 (37.5%)	6 (66.7%)	
Median Time to First TEAE, months (95% CI)	2.89 (0.13, NR)	NR (0.36, NR)	
Hazard Ratio (95% CI)		1.936 (0.459, 8.173)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.3600	
No			
Total Patients	167	157	
Patients (%) With Events	115 (68.9%)	64 (40.8%)	
Patients (%) Without Events (Censored)	52 (31.1%)	93 (59.2%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 1.15)	17.08 (6.21, NR)	
Hazard Ratio (95% CI)		2.482 (1.823, 3.378)	
p-value		<0.0001	
PD-L1 Status			0.9357
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	47 (71.2%)	26 (45.6%)	
Patients (%) Without Events (Censored)	19 (28.8%)	31 (54.4%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.59, 1.41)	6.54 (4.73, NR)	
Hazard Ratio (95% CI)		2.444 (1.504, 3.973)	
p-value		0.0002	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	73 (67.0%)	41 (37.6%)	
Patients (%) Without Events (Censored)	36 (33.0%)	68 (62.4%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 1.41)	NR (6.21, NR)	
Hazard Ratio (95% CI)		2.430 (1.653, 3.571)	
p-value		<0.0001	
BRCA 1/2 status			0.1401

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	47 (72.3%)	28 (44.4%)	
Patients (%) Without Events (Censored)	18 (27.7%)	35 (55.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.49, 1.41)	6.47 (2.37, NR)	
Hazard Ratio (95% CI)		2.281 (1.424, 3.653)	
p-value		0.0005	
Mutant			
Total Patients	12	10	
Patients (%) With Events	6 (50.0%)	7 (70.0%)	
Patients (%) Without Events (Censored)	6 (50.0%)	3 (30.0%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.56, NR)	10.17 (0.07, NR)	
Hazard Ratio (95% CI)		0.994 (0.316, 3.125)	
p-value		0.9928	
Menopausal status			0.6996
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	28 (75.7%)	21 (43.8%)	
Patients (%) Without Events (Censored)	9 (24.3%)	27 (56.2%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.46, 1.41)	23.56 (3.48, NR)	
Hazard Ratio (95% CI)		2.678 (1.498, 4.787)	
p-value		0.0006	
Post-menopausal			
Total Patients	138	117	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	92 (66.7%)	46 (39.3%)	
Patients (%) Without Events (Censored)	46 (33.3%)	71 (60.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 1.41)	17.08 (5.45, NR)	
Hazard Ratio (95% CI)		2.445 (1.712, 3.492)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.16. Table 1.1.12.5: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Anaemia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.0816
De novo			
Total Patients	55	48	
Patients (%) With Events	23 (41.8%)	21 (43.8%)	
Patients (%) Without Events (Censored)	32 (58.2%)	27 (56.2%)	
Median Time to First TEAE, months (95% CI)	NR (3.65, NR)	6.47 (2.33, NR)	
Hazard Ratio (95% CI)		0.882 (0.484, 1.607)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.6704	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	14 (41.2%)	17 (51.5%)	
Patients (%) Without Events (Censored)	20 (58.8%)	16 (48.5%)	
Median Time to First TEAE, months (95% CI)	10.68 (5.13, NR)	4.34 (1.71, NR)	
Hazard Ratio (95% CI)		0.575 (0.278, 1.187)	
p-value		0.1303	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	31 (36.0%)	57 (67.1%)	
Patients (%) Without Events (Censored)	55 (64.0%)	28 (32.9%)	
Median Time to First TEAE, months (95% CI)	NR (10.74, NR)	2.14 (1.12, 2.56)	
Hazard Ratio (95% CI)		0.394 (0.253, 0.612)	
p-value		<0.0001	
Geographic region			0.8971
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	16 (29.1%)	22 (44.0%)	
Patients (%) Without Events (Censored)	39 (70.9%)	28 (56.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	4.34 (2.33, NR)	
Hazard Ratio (95% CI)		0.591 (0.310, 1.127)	
p-value		0.1046	
Rest of the world			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	120	116	
Patients (%) With Events	52 (43.3%)	73 (62.9%)	
Patients (%) Without Events (Censored)	68 (56.7%)	43 (37.1%)	
Median Time to First TEAE, months (95% CI)	10.74 (6.93, NR)	2.23 (1.71, 3.02)	
Hazard Ratio (95% CI)		0.516 (0.359, 0.740)	
p-value		0.0003	
Age group			0.6671
< 65			
Total Patients	132	128	
Patients (%) With Events	53 (40.2%)	71 (55.5%)	
Patients (%) Without Events (Censored)	79 (59.8%)	57 (44.5%)	
Median Time to First TEAE, months (95% CI)	NR (10.32, NR)	3.02 (2.20, 5.52)	
Hazard Ratio (95% CI)		0.541 (0.377, 0.777)	
p-value		0.0008	
>= 65			
Total Patients	43	38	
Patients (%) With Events	15 (34.9%)	24 (63.2%)	
Patients (%) Without Events (Censored)	28 (65.1%)	14 (36.8%)	
Median Time to First TEAE, months (95% CI)	NR (2.79, NR)	2.10 (0.92, 4.34)	
Hazard Ratio (95% CI)		0.504 (0.264, 0.963)	
p-value		0.0339	
Race			0.9948
White			
Total Patients	114	101	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	48 (42.1%)	62 (61.4%)	
Patients (%) Without Events (Censored)	66 (57.9%)	39 (38.6%)	
Median Time to First TEAE, months (95% CI)	10.74 (4.90, NR)	2.30 (1.64, 3.94)	
Hazard Ratio (95% CI)		0.524 (0.358, 0.766)	
p-value		0.0008	
Asian			
Total Patients	38	38	
Patients (%) With Events	11 (28.9%)	19 (50.0%)	
Patients (%) Without Events (Censored)	27 (71.1%)	19 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	6.47 (1.87, NR)	
Hazard Ratio (95% CI)		0.532 (0.250, 1.132)	
p-value		0.0934	
Other			
Total Patients	18	24	
Patients (%) With Events	8 (44.4%)	14 (58.3%)	
Patients (%) Without Events (Censored)	10 (55.6%)	10 (41.7%)	
Median Time to First TEAE, months (95% CI)	10.68 (2.10, NR)	2.30 (1.64, 4.63)	
Hazard Ratio (95% CI)		0.435 (0.177, 1.067)	
p-value		0.0625	
Baseline ECOG status			0.1142
0			
Total Patients	115	104	
Patients (%) With Events	39 (33.9%)	61 (58.7%)	
Patients (%) Without Events (Censored)	76 (66.1%)	43 (41.3%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.73 (2.10, 5.26)	
Hazard Ratio (95% CI)		0.448 (0.299, 0.673)	
p-value		0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	29 (48.3%)	34 (54.8%)	
Patients (%) Without Events (Censored)	31 (51.7%)	28 (45.2%)	
Median Time to First TEAE, months (95% CI)	9.63 (2.14, NR)	3.02 (0.99, NR)	
Hazard Ratio (95% CI)		0.701 (0.420, 1.169)	
p-value		0.1720	
The physician's choice of chemotherapy selected prior to randomization			0.0003
Taxane			
Total Patients	51	44	
Patients (%) With Events	22 (43.1%)	12 (27.3%)	
Patients (%) Without Events (Censored)	29 (56.9%)	32 (72.7%)	
Median Time to First TEAE, months (95% CI)	NR (2.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.600 (0.789, 3.247)	
p-value		0.1912	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	46 (37.1%)	83 (68.0%)	
Patients (%) Without Events (Censored)	78 (62.9%)	39 (32.0%)	
Median Time to First TEAE, months (95% CI)	NR (10.68, NR)	2.10 (1.64, 2.63)	
Hazard Ratio (95% CI)		0.380 (0.264, 0.548)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		<0.0001	
History of liver metastasis			0.5671
Yes			
Total Patients	47	37	
Patients (%) With Events	16 (34.0%)	19 (51.4%)	
Patients (%) Without Events (Censored)	31 (66.0%)	18 (48.6%)	
Median Time to First TEAE, months (95% CI)	NR (4.17, NR)	1.84 (0.99, NR)	
Hazard Ratio (95% CI)		0.478 (0.242, 0.946)	
p-value		0.0311	
No			
Total Patients	128	129	
Patients (%) With Events	52 (40.6%)	76 (58.9%)	
Patients (%) Without Events (Censored)	76 (59.4%)	53 (41.1%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.09, NR)	2.76 (2.10, 4.34)	
Hazard Ratio (95% CI)		0.558 (0.391, 0.797)	
p-value		0.0011	
History of brain metastasis			0.1305
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	6 (66.7%)	
Patients (%) Without Events (Censored)	6 (75.0%)	3 (33.3%)	
Median Time to First TEAE, months (95% CI)	NR (2.14, NR)	1.41 (0.26, NR)	
Hazard Ratio (95% CI)		0.147 (0.028, 0.771)	
p-value		0.0106	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
No			
Total Patients	167	157	
Patients (%) With Events	66 (39.5%)	89 (56.7%)	
Patients (%) Without Events (Censored)	101 (60.5%)	68 (43.3%)	
Median Time to First TEAE, months (95% CI)	NR (10.32, NR)	2.76 (2.14, 4.63)	
Hazard Ratio (95% CI)		0.562 (0.407, 0.776)	
p-value		0.0004	
PD-L1 Status			0.0222
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	21 (31.8%)	38 (66.7%)	
Patients (%) Without Events (Censored)	45 (68.2%)	19 (33.3%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.23 (0.95, 4.34)	
Hazard Ratio (95% CI)		0.325 (0.189, 0.559)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	47 (43.1%)	57 (52.3%)	
Patients (%) Without Events (Censored)	62 (56.9%)	52 (47.7%)	
Median Time to First TEAE, months (95% CI)	10.74 (4.17, NR)	2.76 (2.10, NR)	
Hazard Ratio (95% CI)		0.704 (0.476, 1.040)	
p-value		0.0770	
BRCA 1/2 status			0.0649
Wild-Type			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	65	63	
Patients (%) With Events	16 (24.6%)	29 (46.0%)	
Patients (%) Without Events (Censored)	49 (75.4%)	34 (54.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	5.26 (2.10, NR)	
Hazard Ratio (95% CI)		0.435 (0.236, 0.803)	
p-value		0.0062	
Mutant			
Total Patients	12	10	
Patients (%) With Events	5 (41.7%)	3 (30.0%)	
Patients (%) Without Events (Censored)	7 (58.3%)	7 (70.0%)	
Median Time to First TEAE, months (95% CI)	10.74 (0.95, NR)	NR (2.23, NR)	
Hazard Ratio (95% CI)		1.600 (0.378, 6.764)	
p-value		0.5194	
Menopausal status			0.6756
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	13 (35.1%)	24 (50.0%)	
Patients (%) Without Events (Censored)	24 (64.9%)	24 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (4.17, NR)	5.26 (1.94, NR)	
Hazard Ratio (95% CI)		0.602 (0.306, 1.183)	
p-value		0.1343	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	55 (39.9%)	70 (59.8%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	83 (60.1%)	47 (40.2%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	2.30 (1.84, 3.29)	
Hazard Ratio (95% CI)		0.512 (0.358, 0.733)	
p-value		0.0002	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.17. Table 1.1.12.6: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Abdominal pain (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Age group			0.2639
< 65			
Total Patients	132	128	
Patients (%) With Events	23 (17.4%)	11 (8.6%)	
Patients (%) Without Events (Censored)	109 (82.6%)	117 (91.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (19.02, NR)	
Hazard Ratio (95% CI)		1.880 (0.913, 3.872)	
p-value		0.0820	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
>= 65			
Total Patients	43	38	
Patients (%) With Events	6 (14.0%)	1 (2.6%)	
Patients (%) Without Events (Censored)	37 (86.0%)	37 (97.4%)	
Median Time to First TEAE, months (95% CI)	NR (16.69, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.032 (0.718, 50.671)	
p-value		0.0607	
Baseline ECOG status			0.3559
0			
Total Patients	115	104	
Patients (%) With Events	21 (18.3%)	10 (9.6%)	
Patients (%) Without Events (Censored)	94 (81.7%)	94 (90.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (19.02, NR)	
Hazard Ratio (95% CI)		1.815 (0.852, 3.866)	
p-value		0.1173	
1			
Total Patients	60	62	
Patients (%) With Events	8 (13.3%)	2 (3.2%)	
Patients (%) Without Events (Censored)	52 (86.7%)	60 (96.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.306 (0.914, 20.280)	
p-value		0.0446	
History of liver metastasis			0.0180
Yes			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	47	37	
Patients (%) With Events	9 (19.1%)	0 (0.0%)	
Patients (%) Without Events (Censored)	38 (80.9%)	37 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0102	
No			
Total Patients	128	129	
Patients (%) With Events	20 (15.6%)	12 (9.3%)	
Patients (%) Without Events (Censored)	108 (84.4%)	117 (90.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.637 (0.798, 3.361)	
p-value		0.1761	
History of brain metastasis			0.9999
Yes			
Total Patients	8	9	
Patients (%) With Events	0 (0.0%)	0 (0.0%)	
Patients (%) Without Events (Censored)	8 (100.0%)	9 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		1.0000	
No			
Total Patients	167	157	
Patients (%) With Events	29 (17.4%)	12 (7.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	138 (82.6%)	145 (92.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.200 (1.119, 4.325)	
p-value		0.0192	
PD-L1 Status			0.5661
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	8 (12.1%)	2 (3.5%)	
Patients (%) Without Events (Censored)	58 (87.9%)	55 (96.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (19.02, NR)	
Hazard Ratio (95% CI)		3.001 (0.632, 14.262)	
p-value		0.1473	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	21 (19.3%)	10 (9.2%)	
Patients (%) Without Events (Censored)	88 (80.7%)	99 (90.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.131 (1.002, 4.532)	
p-value		0.0445	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.18. Table 1.1.12.7: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Diarrhoea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.0274
De novo			
Total Patients	55	48	
Patients (%) With Events	32 (58.2%)	15 (31.2%)	
Patients (%) Without Events (Censored)	23 (41.8%)	33 (68.8%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.72, NR)	NR (6.21, NR)	
Hazard Ratio (95% CI)		2.372 (1.279, 4.397)	
p-value		0.0049	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	16 (47.1%)	9 (27.3%)	
Patients (%) Without Events (Censored)	18 (52.9%)	24 (72.7%)	
Median Time to First TEAE, months (95% CI)	13.54 (1.97, NR)	23.56 (NR, NR)	
Hazard Ratio (95% CI)		1.681 (0.739, 3.826)	
p-value		0.2132	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	54 (62.8%)	14 (16.5%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	32 (37.2%)	71 (83.5%)	
Median Time to First TEAE, months (95% CI)	2.50 (0.59, 6.54)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		5.430 (3.007, 9.802)	
p-value		<0.0001	
Geographic region			0.3091
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	41 (74.5%)	12 (24.0%)	
Patients (%) Without Events (Censored)	14 (25.5%)	38 (76.0%)	
Median Time to First TEAE, months (95% CI)	0.89 (0.46, 2.60)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.341 (2.274, 8.287)	
p-value		<0.0001	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	61 (50.8%)	26 (22.4%)	
Patients (%) Without Events (Censored)	59 (49.2%)	90 (77.6%)	
Median Time to First TEAE, months (95% CI)	5.39 (2.50, NR)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		2.764 (1.744, 4.379)	
p-value		<0.0001	
Age group			0.9487
< 65			
Total Patients	132	128	
Patients (%) With Events	74 (56.1%)	26 (20.3%)	
Patients (%) Without Events (Censored)	58 (43.9%)	102 (79.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	4.57 (1.97, 13.54)	23.56 (20.96, NR)	
Hazard Ratio (95% CI)		3.258 (2.082, 5.100)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	28 (65.1%)	12 (31.6%)	
Patients (%) Without Events (Censored)	15 (34.9%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	0.53 (0.33, 3.61)	NR (3.52, NR)	
Hazard Ratio (95% CI)		3.270 (1.645, 6.501)	
p-value		0.0004	
Race			0.4702
White			
Total Patients	114	101	
Patients (%) With Events	66 (57.9%)	20 (19.8%)	
Patients (%) Without Events (Censored)	48 (42.1%)	81 (80.2%)	
Median Time to First TEAE, months (95% CI)	4.37 (1.22, 11.56)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.568 (2.161, 5.890)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	18 (47.4%)	10 (26.3%)	
Patients (%) Without Events (Censored)	20 (52.6%)	28 (73.7%)	
Median Time to First TEAE, months (95% CI)	17.35 (0.46, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.102 (0.963, 4.588)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0569	
Other			
Total Patients	18	24	
Patients (%) With Events	13 (72.2%)	7 (29.2%)	
Patients (%) Without Events (Censored)	5 (27.8%)	17 (70.8%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.30, 3.25)	23.56 (3.29, NR)	
Hazard Ratio (95% CI)		4.459 (1.681, 11.830)	
p-value		0.0011	
Baseline ECOG status			0.7472
0			
Total Patients	115	104	
Patients (%) With Events	63 (54.8%)	21 (20.2%)	
Patients (%) Without Events (Censored)	52 (45.2%)	83 (79.8%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.58, 16.82)	30.42 (23.56, NR)	
Hazard Ratio (95% CI)		3.361 (2.048, 5.517)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	39 (65.0%)	17 (27.4%)	
Patients (%) Without Events (Censored)	21 (35.0%)	45 (72.6%)	
Median Time to First TEAE, months (95% CI)	1.74 (0.66, 4.90)	20.96 (NR, NR)	
Hazard Ratio (95% CI)		3.126 (1.765, 5.538)	
p-value		<0.0001	
The physician's choice of chemotherapy selected prior to randomization			0.7423

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Taxane			
Total Patients	51	44	
Patients (%) With Events	31 (60.8%)	10 (22.7%)	
Patients (%) Without Events (Censored)	20 (39.2%)	34 (77.3%)	
Median Time to First TEAE, months (95% CI)	1.74 (0.72, 17.35)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.005 (1.466, 6.163)	
p-value		0.0017	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	71 (57.3%)	28 (23.0%)	
Patients (%) Without Events (Censored)	53 (42.7%)	94 (77.0%)	
Median Time to First TEAE, months (95% CI)	3.52 (1.58, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.339 (2.153, 5.180)	
p-value		<0.0001	
History of liver metastasis			0.4113
Yes			
Total Patients	47	37	
Patients (%) With Events	28 (59.6%)	6 (16.2%)	
Patients (%) Without Events (Censored)	19 (40.4%)	31 (83.8%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.36, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.476 (1.846, 10.854)	
p-value		0.0003	
No			
Total Patients	128	129	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	74 (57.8%)	32 (24.8%)	
Patients (%) Without Events (Censored)	54 (42.2%)	97 (75.2%)	
Median Time to First TEAE, months (95% CI)	4.37 (1.97, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.042 (2.007, 4.613)	
p-value		<0.0001	
History of brain metastasis			0.2851
Yes			
Total Patients	8	9	
Patients (%) With Events	6 (75.0%)	1 (11.1%)	
Patients (%) Without Events (Censored)	2 (25.0%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	1.61 (0.10, 6.54)	NR (2.50, NR)	
Hazard Ratio (95% CI)		11.033 (1.300, 93.603)	
p-value		0.0066	
No			
Total Patients	167	157	
Patients (%) With Events	96 (57.5%)	37 (23.6%)	
Patients (%) Without Events (Censored)	71 (42.5%)	120 (76.4%)	
Median Time to First TEAE, months (95% CI)	3.52 (1.25, 11.04)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.079 (2.105, 4.505)	
p-value		<0.0001	
PD-L1 Status			0.8120
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	38 (57.6%)	12 (21.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	28 (42.4%)	45 (78.9%)	
Median Time to First TEAE, months (95% CI)	3.52 (0.89, 17.35)	NR (23.56, NR)	
Hazard Ratio (95% CI)		3.545 (1.847, 6.802)	
p-value		0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	64 (58.7%)	26 (23.9%)	
Patients (%) Without Events (Censored)	45 (41.3%)	83 (76.1%)	
Median Time to First TEAE, months (95% CI)	3.06 (1.05, 7.33)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.230 (2.031, 5.136)	
p-value		<0.0001	
BRCA 1/2 status			0.1718
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	43 (66.2%)	10 (15.9%)	
Patients (%) Without Events (Censored)	22 (33.8%)	53 (84.1%)	
Median Time to First TEAE, months (95% CI)	2.27 (0.89, 4.53)	20.96 (20.96, NR)	
Hazard Ratio (95% CI)		5.345 (2.678, 10.669)	
p-value		<0.0001	
Mutant			
Total Patients	12	10	
Patients (%) With Events	7 (58.3%)	5 (50.0%)	
Patients (%) Without Events (Censored)	5 (41.7%)	5 (50.0%)	
Median Time to First TEAE, months (95% CI)	3.86 (0.26, NR)	23.56 (0.03, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.010 (0.579, 6.983)	
p-value		0.2752	
Menopausal status			0.3879
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	17 (45.9%)	11 (22.9%)	
Patients (%) Without Events (Censored)	20 (54.1%)	37 (77.1%)	
Median Time to First TEAE, months (95% CI)	NR (1.25, NR)	23.56 (23.56, NR)	
Hazard Ratio (95% CI)		2.613 (1.194, 5.718)	
p-value		0.0125	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	85 (61.6%)	26 (22.2%)	
Patients (%) Without Events (Censored)	53 (38.4%)	91 (77.8%)	
Median Time to First TEAE, months (95% CI)	2.60 (0.92, 5.39)	30.42 (20.96, NR)	
Hazard Ratio (95% CI)		3.586 (2.307, 5.572)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
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6.19. Table 1.1.12.8: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Nausea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.6227
De novo			
Total Patients	55	48	
Patients (%) With Events	41 (74.5%)	20 (41.7%)	
Patients (%) Without Events (Censored)	14 (25.5%)	28 (58.3%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.26, 3.48)	NR (1.61, NR)	
Hazard Ratio (95% CI)		2.249 (1.311, 3.857)	
p-value		0.0024	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	17 (50.0%)	12 (36.4%)	
Patients (%) Without Events (Censored)	17 (50.0%)	21 (63.6%)	
Median Time to First TEAE, months (95% CI)	9.43 (0.49, NR)	NR (3.09, NR)	
Hazard Ratio (95% CI)		1.448 (0.690, 3.040)	
p-value		0.3227	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	53 (61.6%)	38 (44.7%)	
Patients (%) Without Events (Censored)	33 (38.4%)	47 (55.3%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.33, 7.20)	9.82 (3.09, NR)	
Hazard Ratio (95% CI)		1.660 (1.093, 2.521)	
p-value		0.0160	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Geographic region			0.8277
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	41 (74.5%)	25 (50.0%)	
Patients (%) Without Events (Censored)	14 (25.5%)	25 (50.0%)	
Median Time to First TEAE, months (95% CI)	1.18 (0.26, 2.89)	9.23 (1.41, NR)	
Hazard Ratio (95% CI)		1.866 (1.134, 3.072)	
p-value		0.0126	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	70 (58.3%)	45 (38.8%)	
Patients (%) Without Events (Censored)	50 (41.7%)	71 (61.2%)	
Median Time to First TEAE, months (95% CI)	3.48 (1.02, 6.47)	NR (9.33, NR)	
Hazard Ratio (95% CI)		1.692 (1.162, 2.463)	
p-value		0.0051	
Age group			0.9811
< 65			
Total Patients	132	128	
Patients (%) With Events	83 (62.9%)	53 (41.4%)	
Patients (%) Without Events (Censored)	49 (37.1%)	75 (58.6%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.59, 5.09)	NR (6.11, NR)	
Hazard Ratio (95% CI)		1.737 (1.230, 2.453)	
p-value		0.0015	
>= 65			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	43	38	
Patients (%) With Events	28 (65.1%)	17 (44.7%)	
Patients (%) Without Events (Censored)	15 (34.9%)	21 (55.3%)	
Median Time to First TEAE, months (95% CI)	2.33 (0.49, 3.48)	9.82 (3.09, NR)	
Hazard Ratio (95% CI)		1.921 (1.043, 3.536)	
p-value		0.0321	
Race			0.7952
White			
Total Patients	114	101	
Patients (%) With Events	73 (64.0%)	43 (42.6%)	
Patients (%) Without Events (Censored)	41 (36.0%)	58 (57.4%)	
Median Time to First TEAE, months (95% CI)	2.92 (0.82, 4.47)	15.54 (3.29, NR)	
Hazard Ratio (95% CI)		1.703 (1.167, 2.483)	
p-value		0.0051	
Asian			
Total Patients	38	38	
Patients (%) With Events	21 (55.3%)	12 (31.6%)	
Patients (%) Without Events (Censored)	17 (44.7%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	3.19 (0.16, NR)	NR (9.33, NR)	
Hazard Ratio (95% CI)		1.945 (0.954, 3.968)	
p-value		0.0582	
Other			
Total Patients	18	24	
Patients (%) With Events	13 (72.2%)	14 (58.3%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	5 (27.8%)	10 (41.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.16, 5.59)	1.74 (0.30, NR)	
Hazard Ratio (95% CI)		1.478 (0.691, 3.161)	
p-value		0.3106	
Baseline ECOG status			0.3371
0			
Total Patients	115	104	
Patients (%) With Events	73 (63.5%)	42 (40.4%)	
Patients (%) Without Events (Censored)	42 (36.5%)	62 (59.6%)	
Median Time to First TEAE, months (95% CI)	2.92 (0.59, 4.47)	NR (9.23, NR)	
Hazard Ratio (95% CI)		1.963 (1.342, 2.871)	
p-value		0.0004	
1			
Total Patients	60	62	
Patients (%) With Events	38 (63.3%)	28 (45.2%)	
Patients (%) Without Events (Censored)	22 (36.7%)	34 (54.8%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.36, 5.39)	9.82 (1.05, NR)	
Hazard Ratio (95% CI)		1.438 (0.880, 2.348)	
p-value		0.1364	
The physician's choice of chemotherapy selected prior to randomization			0.2199
Taxane			
Total Patients	51	44	
Patients (%) With Events	31 (60.8%)	12 (27.3%)	
Patients (%) Without Events (Censored)	20 (39.2%)	32 (72.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	2.83 (0.95, 5.09)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.586 (1.327, 5.039)	
p-value		0.0036	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	80 (64.5%)	58 (47.5%)	
Patients (%) Without Events (Censored)	44 (35.5%)	64 (52.5%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.36, 4.47)	9.33 (3.09, NR)	
Hazard Ratio (95% CI)		1.590 (1.133, 2.232)	
p-value		0.0065	
History of liver metastasis			0.8984
Yes			
Total Patients	47	37	
Patients (%) With Events	33 (70.2%)	16 (43.2%)	
Patients (%) Without Events (Censored)	14 (29.8%)	21 (56.8%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.16, 3.48)	9.23 (0.30, NR)	
Hazard Ratio (95% CI)		1.761 (0.967, 3.210)	
p-value		0.0594	
No			
Total Patients	128	129	
Patients (%) With Events	78 (60.9%)	54 (41.9%)	
Patients (%) Without Events (Censored)	50 (39.1%)	75 (58.1%)	
Median Time to First TEAE, months (95% CI)	3.06 (1.48, 5.59)	15.54 (6.11, NR)	
Hazard Ratio (95% CI)		1.712 (1.209, 2.425)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0021	
History of brain metastasis			0.4261
Yes			
Total Patients	8	9	
Patients (%) With Events	5 (62.5%)	2 (22.2%)	
Patients (%) Without Events (Censored)	3 (37.5%)	7 (77.8%)	
Median Time to First TEAE, months (95% CI)	4.88 (0.10, NR)	NR (0.10, NR)	
Hazard Ratio (95% CI)		2.472 (0.450, 13.571)	
p-value		0.2771	
No			
Total Patients	167	157	
Patients (%) With Events	106 (63.5%)	68 (43.3%)	
Patients (%) Without Events (Censored)	61 (36.5%)	89 (56.7%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.99, 3.98)	15.54 (6.11, NR)	
Hazard Ratio (95% CI)		1.708 (1.259, 2.318)	
p-value		0.0005	
PD-L1 Status			0.8555
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	39 (59.1%)	23 (40.4%)	
Patients (%) Without Events (Censored)	27 (40.9%)	34 (59.6%)	
Median Time to First TEAE, months (95% CI)	3.58 (0.53, 10.28)	15.54 (3.29, NR)	
Hazard Ratio (95% CI)		1.669 (0.995, 2.797)	
p-value		0.0500	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	72 (66.1%)	47 (43.1%)	
Patients (%) Without Events (Censored)	37 (33.9%)	62 (56.9%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.49, 3.88)	9.82 (3.25, NR)	
Hazard Ratio (95% CI)		1.815 (1.255, 2.624)	
p-value		0.0012	
BRCA 1/2 status			0.8955
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	39 (60.0%)	27 (42.9%)	
Patients (%) Without Events (Censored)	26 (40.0%)	36 (57.1%)	
Median Time to First TEAE, months (95% CI)	3.19 (0.59, 7.23)	9.33 (3.09, NR)	
Hazard Ratio (95% CI)		1.644 (1.006, 2.689)	
p-value		0.0459	
Mutant			
Total Patients	12	10	
Patients (%) With Events	6 (50.0%)	4 (40.0%)	
Patients (%) Without Events (Censored)	6 (50.0%)	6 (60.0%)	
Median Time to First TEAE, months (95% CI)	7.20 (0.13, NR)	15.54 (0.03, NR)	
Hazard Ratio (95% CI)		1.469 (0.413, 5.228)	
p-value		0.5479	
Menopausal status			0.6501
Pre-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	37	48	
Patients (%) With Events	25 (67.6%)	23 (47.9%)	
Patients (%) Without Events (Censored)	12 (32.4%)	25 (52.1%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.16, 5.09)	6.11 (0.82, NR)	
Hazard Ratio (95% CI)		1.598 (0.905, 2.819)	
p-value		0.0975	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	86 (62.3%)	46 (39.3%)	
Patients (%) Without Events (Censored)	52 (37.7%)	71 (60.7%)	
Median Time to First TEAE, months (95% CI)	2.83 (0.99, 4.47)	15.54 (9.23, NR)	
Hazard Ratio (95% CI)		1.882 (1.314, 2.694)	
p-value		0.0004	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.20. Table 1.1.12.9: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Vomiting (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.1316
De novo			
Total Patients	55	48	
Patients (%) With Events	19 (34.5%)	8 (16.7%)	
Patients (%) Without Events (Censored)	36 (65.5%)	40 (83.3%)	
Median Time to First TEAE, months (95% CI)	NR (15.01, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.032 (0.883, 4.681)	
p-value		0.0888	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	11 (32.4%)	2 (6.1%)	
Patients (%) Without Events (Censored)	23 (67.6%)	31 (93.9%)	
Median Time to First TEAE, months (95% CI)	NR (8.31, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.542 (1.227, 25.042)	
p-value		0.0122	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	23 (26.7%)	18 (21.2%)	
Patients (%) Without Events (Censored)	63 (73.3%)	67 (78.8%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.220 (0.658, 2.263)	
p-value		0.5260	
Geographic region			0.1264

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	22 (40.0%)	7 (14.0%)	
Patients (%) Without Events (Censored)	33 (60.0%)	43 (86.0%)	
Median Time to First TEAE, months (95% CI)	21.13 (4.60, NR)	NR (9.89, NR)	
Hazard Ratio (95% CI)		2.990 (1.275, 7.011)	
p-value		0.0081	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	31 (25.8%)	21 (18.1%)	
Patients (%) Without Events (Censored)	89 (74.2%)	95 (81.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.348 (0.773, 2.351)	
p-value		0.2894	
Age group			0.3494
< 65			
Total Patients	132	128	
Patients (%) With Events	40 (30.3%)	23 (18.0%)	
Patients (%) Without Events (Censored)	92 (69.7%)	105 (82.0%)	
Median Time to First TEAE, months (95% CI)	NR (21.13, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.521 (0.908, 2.545)	
p-value		0.1080	
>= 65			
Total Patients	43	38	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	13 (30.2%)	5 (13.2%)	
Patients (%) Without Events (Censored)	30 (69.8%)	33 (86.8%)	
Median Time to First TEAE, months (95% CI)	NR (3.29, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.680 (0.954, 7.526)	
p-value		0.0514	
Race			0.8837
White			
Total Patients	114	101	
Patients (%) With Events	36 (31.6%)	21 (20.8%)	
Patients (%) Without Events (Censored)	78 (68.4%)	80 (79.2%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.462 (0.853, 2.507)	
p-value		0.1647	
Asian			
Total Patients	38	38	
Patients (%) With Events	6 (15.8%)	3 (7.9%)	
Patients (%) Without Events (Censored)	32 (84.2%)	35 (92.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.040 (0.509, 8.169)	
p-value		0.3045	
Other			
Total Patients	18	24	
Patients (%) With Events	6 (33.3%)	4 (16.7%)	
Patients (%) Without Events (Censored)	12 (66.7%)	20 (83.3%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (4.63, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.682 (0.468, 6.049)	
p-value		0.4212	
Baseline ECOG status			0.7357
0			
Total Patients	115	104	
Patients (%) With Events	33 (28.7%)	18 (17.3%)	
Patients (%) Without Events (Censored)	82 (71.3%)	86 (82.7%)	
Median Time to First TEAE, months (95% CI)	NR (21.13, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.636 (0.920, 2.909)	
p-value		0.0898	
1			
Total Patients	60	62	
Patients (%) With Events	20 (33.3%)	10 (16.1%)	
Patients (%) Without Events (Censored)	40 (66.7%)	52 (83.9%)	
Median Time to First TEAE, months (95% CI)	NR (8.31, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.893 (0.879, 4.074)	
p-value		0.0971	
The physician's choice of chemotherapy selected prior to randomization			0.5335
Taxane			
Total Patients	51	44	
Patients (%) With Events	15 (29.4%)	5 (11.4%)	
Patients (%) Without Events (Censored)	36 (70.6%)	39 (88.6%)	
Median Time to First TEAE, months (95% CI)	NR (21.13, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.469 (0.889, 6.857)	
p-value		0.0725	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	38 (30.6%)	23 (18.9%)	
Patients (%) Without Events (Censored)	86 (69.4%)	99 (81.1%)	
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.618 (0.963, 2.719)	
p-value		0.0660	
History of liver metastasis			0.1788
Yes			
Total Patients	47	37	
Patients (%) With Events	12 (25.5%)	8 (21.6%)	
Patients (%) Without Events (Censored)	35 (74.5%)	29 (78.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	9.89 (NR, NR)	
Hazard Ratio (95% CI)		1.048 (0.420, 2.615)	
p-value		0.9201	
No			
Total Patients	128	129	
Patients (%) With Events	41 (32.0%)	20 (15.5%)	
Patients (%) Without Events (Censored)	87 (68.0%)	109 (84.5%)	
Median Time to First TEAE, months (95% CI)	NR (15.01, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		2.046 (1.197, 3.497)	
p-value		0.0074	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
History of brain metastasis			0.2874
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	3 (33.3%)	
Patients (%) Without Events (Censored)	6 (75.0%)	6 (66.7%)	
Median Time to First TEAE, months (95% CI)	NR (0.30, NR)	NR (0.03, NR)	
Hazard Ratio (95% CI)		0.664 (0.111, 3.980)	
p-value		0.6519	
No			
Total Patients	167	157	
Patients (%) With Events	51 (30.5%)	25 (15.9%)	
Patients (%) Without Events (Censored)	116 (69.5%)	132 (84.1%)	
Median Time to First TEAE, months (95% CI)	NR (21.13, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		1.863 (1.153, 3.011)	
p-value		0.0098	
PD-L1 Status			0.3456
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	16 (24.2%)	10 (17.5%)	
Patients (%) Without Events (Censored)	50 (75.8%)	47 (82.5%)	
Median Time to First TEAE, months (95% CI)	NR (21.13, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.305 (0.591, 2.881)	
p-value		0.5095	
CPS ≥ 1			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	109	109	
Patients (%) With Events	37 (33.9%)	18 (16.5%)	
Patients (%) Without Events (Censored)	72 (66.1%)	91 (83.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	33.58 (NR, NR)	
Hazard Ratio (95% CI)		2.059 (1.171, 3.622)	
p-value		0.0104	
Menopausal status			0.5183
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	16 (43.2%)	10 (20.8%)	
Patients (%) Without Events (Censored)	21 (56.8%)	38 (79.2%)	
Median Time to First TEAE, months (95% CI)	15.01 (3.52, NR)	33.58 (8.15, NR)	
Hazard Ratio (95% CI)		2.373 (1.045, 5.389)	
p-value		0.0331	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	37 (26.8%)	18 (15.4%)	
Patients (%) Without Events (Censored)	101 (73.2%)	99 (84.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.673 (0.951, 2.943)	
p-value		0.0709	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.21. Table 1.1.12.10: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alanine aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.7039
De novo			
Total Patients	55	48	
Patients (%) With Events	12 (21.8%)	16 (33.3%)	
Patients (%) Without Events (Censored)	43 (78.2%)	32 (66.7%)	
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	NR (6.01, NR)	
Hazard Ratio (95% CI)		0.476 (0.220, 1.032)	
p-value		0.0552	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	7 (20.6%)	15 (45.5%)	
Patients (%) Without Events (Censored)	27 (79.4%)	18 (54.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.16, NR)	7.16 (1.64, NR)	
Hazard Ratio (95% CI)		0.272 (0.105, 0.708)	
p-value		0.0049	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	86	85	
Patients (%) With Events	16 (18.6%)	28 (32.9%)	
Patients (%) Without Events (Censored)	70 (81.4%)	57 (67.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.466 (0.251, 0.865)	
p-value		0.0133	
Geographic region			0.6197
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	8 (14.5%)	15 (30.0%)	
Patients (%) Without Events (Censored)	47 (85.5%)	35 (70.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (6.60, NR)	
Hazard Ratio (95% CI)		0.369 (0.154, 0.887)	
p-value		0.0210	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	27 (22.5%)	44 (37.9%)	
Patients (%) Without Events (Censored)	93 (77.5%)	72 (62.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (6.87, NR)	
Hazard Ratio (95% CI)		0.468 (0.289, 0.759)	
p-value		0.0017	
Age group			0.4603
< 65			
Total Patients	132	128	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	32 (24.2%)	50 (39.1%)	
Patients (%) Without Events (Censored)	100 (75.8%)	78 (60.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (6.87, NR)	
Hazard Ratio (95% CI)		0.450 (0.286, 0.706)	
p-value		0.0004	
>= 65			
Total Patients	43	38	
Patients (%) With Events	3 (7.0%)	9 (23.7%)	
Patients (%) Without Events (Censored)	40 (93.0%)	29 (76.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.280 (0.076, 1.034)	
p-value		0.0412	
Race			0.2310
White			
Total Patients	114	101	
Patients (%) With Events	25 (21.9%)	37 (36.6%)	
Patients (%) Without Events (Censored)	89 (78.1%)	64 (63.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (6.87, NR)	
Hazard Ratio (95% CI)		0.464 (0.278, 0.775)	
p-value		0.0028	
Asian			
Total Patients	38	38	
Patients (%) With Events	6 (15.8%)	10 (26.3%)	
Patients (%) Without Events (Censored)	32 (84.2%)	28 (73.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.456 (0.162, 1.279)	
p-value		0.1270	
Other			
Total Patients	18	24	
Patients (%) With Events	2 (11.1%)	12 (50.0%)	
Patients (%) Without Events (Censored)	16 (88.9%)	12 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	4.14 (0.99, NR)	
Hazard Ratio (95% CI)		0.128 (0.028, 0.595)	
p-value		0.0024	
Baseline ECOG status			0.1056
0			
Total Patients	115	104	
Patients (%) With Events	22 (19.1%)	43 (41.3%)	
Patients (%) Without Events (Censored)	93 (80.9%)	61 (58.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (6.60, NR)	
Hazard Ratio (95% CI)		0.342 (0.203, 0.574)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	13 (21.7%)	16 (25.8%)	
Patients (%) Without Events (Censored)	47 (78.3%)	46 (74.2%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.733 (0.351, 1.532)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.4116	
The physician's choice of chemotherapy selected prior to randomization			0.0046
Taxane			
Total Patients	51	44	
Patients (%) With Events	11 (21.6%)	5 (11.4%)	
Patients (%) Without Events (Censored)	40 (78.4%)	39 (88.6%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.389 (0.469, 4.114)	
p-value		0.5474	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	24 (19.4%)	54 (44.3%)	
Patients (%) Without Events (Censored)	100 (80.6%)	68 (55.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (3.22, NR)	
Hazard Ratio (95% CI)		0.335 (0.207, 0.544)	
p-value		<0.0001	
History of liver metastasis			0.4962
Yes			
Total Patients	47	37	
Patients (%) With Events	14 (29.8%)	15 (40.5%)	
Patients (%) Without Events (Censored)	33 (70.2%)	22 (59.5%)	
Median Time to First TEAE, months (95% CI)	NR (6.24, NR)	11.76 (1.35, NR)	
Hazard Ratio (95% CI)		0.476 (0.224, 1.009)	
p-value		0.0482	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
No			
Total Patients	128	129	
Patients (%) With Events	21 (16.4%)	44 (34.1%)	
Patients (%) Without Events (Censored)	107 (83.6%)	85 (65.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.380 (0.225, 0.642)	
p-value		0.0002	
History of brain metastasis			0.1833
Yes			
Total Patients	8	9	
Patients (%) With Events	3 (37.5%)	2 (22.2%)	
Patients (%) Without Events (Censored)	5 (62.5%)	7 (77.8%)	
Median Time to First TEAE, months (95% CI)	5.49 (3.48, NR)	NR (0.95, NR)	
Hazard Ratio (95% CI)		1.186 (0.194, 7.244)	
p-value		0.8531	
No			
Total Patients	167	157	
Patients (%) With Events	32 (19.2%)	57 (36.3%)	
Patients (%) Without Events (Censored)	135 (80.8%)	100 (63.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.410 (0.264, 0.635)	
p-value		<0.0001	
PD-L1 Status			0.6152
CPS < 1			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	66	57	
Patients (%) With Events	14 (21.2%)	24 (42.1%)	
Patients (%) Without Events (Censored)	52 (78.8%)	33 (57.9%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	11.76 (6.01, NR)	
Hazard Ratio (95% CI)		0.378 (0.195, 0.736)	
p-value		0.0031	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	21 (19.3%)	35 (32.1%)	
Patients (%) Without Events (Censored)	88 (80.7%)	74 (67.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.485 (0.281, 0.836)	
p-value		0.0080	
Menopausal status			0.7633
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	10 (27.0%)	20 (41.7%)	
Patients (%) Without Events (Censored)	27 (73.0%)	28 (58.3%)	
Median Time to First TEAE, months (95% CI)	NR (11.14, NR)	7.16 (4.14, NR)	
Hazard Ratio (95% CI)		0.435 (0.196, 0.969)	
p-value		0.0373	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	25 (18.1%)	38 (32.5%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	113 (81.9%)	79 (67.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.442 (0.266, 0.735)	
p-value		0.0013	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.22. Table 1.1.12.11: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Aspartate aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.9404
De novo			
Total Patients	55	48	
Patients (%) With Events	11 (20.0%)	14 (29.2%)	
Patients (%) Without Events (Censored)	44 (80.0%)	34 (70.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.535 (0.240, 1.193)	
p-value		0.1218	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	7 (20.6%)	10 (30.3%)	
Patients (%) Without Events (Censored)	27 (79.4%)	23 (69.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (7.16, NR)	
Hazard Ratio (95% CI)		0.595 (0.225, 1.577)	
p-value		0.2929	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	14 (16.3%)	24 (28.2%)	
Patients (%) Without Events (Censored)	72 (83.7%)	61 (71.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.475 (0.245, 0.921)	
p-value		0.0246	
Geographic region			0.8090
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	7 (12.7%)	9 (18.0%)	
Patients (%) Without Events (Censored)	48 (87.3%)	41 (82.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.616 (0.229, 1.659)	
p-value		0.3324	
Rest of the world			
Total Patients	120	116	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	25 (20.8%)	39 (33.6%)	
Patients (%) Without Events (Censored)	95 (79.2%)	77 (66.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.507 (0.305, 0.840)	
p-value		0.0074	
Age group			0.1807
< 65			
Total Patients	132	128	
Patients (%) With Events	30 (22.7%)	40 (31.2%)	
Patients (%) Without Events (Censored)	102 (77.3%)	88 (68.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.581 (0.360, 0.936)	
p-value		0.0244	
>= 65			
Total Patients	43	38	
Patients (%) With Events	2 (4.7%)	8 (21.1%)	
Patients (%) Without Events (Censored)	41 (95.3%)	30 (78.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.210 (0.045, 0.990)	
p-value		0.0294	
Race			0.4297
White			
Total Patients	114	101	
Patients (%) With Events	23 (20.2%)	28 (27.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	91 (79.8%)	73 (72.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.596 (0.342, 1.039)	
p-value		0.0654	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	10 (26.3%)	
Patients (%) Without Events (Censored)	34 (89.5%)	28 (73.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.307 (0.095, 0.994)	
p-value		0.0378	
Other			
Total Patients	18	24	
Patients (%) With Events	3 (16.7%)	10 (41.7%)	
Patients (%) Without Events (Censored)	15 (83.3%)	14 (58.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (2.30, NR)	
Hazard Ratio (95% CI)		0.314 (0.086, 1.147)	
p-value		0.0641	
Baseline ECOG status			0.0644
0			
Total Patients	115	104	
Patients (%) With Events	18 (15.7%)	34 (32.7%)	
Patients (%) Without Events (Censored)	97 (84.3%)	70 (67.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.390 (0.220, 0.692)	
p-value		0.0009	
1			
Total Patients	60	62	
Patients (%) With Events	14 (23.3%)	14 (22.6%)	
Patients (%) Without Events (Censored)	46 (76.7%)	48 (77.4%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.853 (0.402, 1.810)	
p-value		0.6831	
The physician's choice of chemotherapy selected prior to randomization			0.0566
Taxane			
Total Patients	51	44	
Patients (%) With Events	9 (17.6%)	5 (11.4%)	
Patients (%) Without Events (Censored)	42 (82.4%)	39 (88.6%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.187 (0.387, 3.644)	
p-value		0.7628	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	23 (18.5%)	43 (35.2%)	
Patients (%) Without Events (Censored)	101 (81.5%)	79 (64.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.436 (0.263, 0.725)	
p-value		0.0010	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
History of liver metastasis			0.9059
Yes			
Total Patients	47	37	
Patients (%) With Events	12 (25.5%)	14 (37.8%)	
Patients (%) Without Events (Censored)	35 (74.5%)	23 (62.2%)	
Median Time to First TEAE, months (95% CI)	NR (8.31, NR)	NR (1.91, NR)	
Hazard Ratio (95% CI)		0.429 (0.193, 0.955)	
p-value		0.0339	
No			
Total Patients	128	129	
Patients (%) With Events	20 (15.6%)	34 (26.4%)	
Patients (%) Without Events (Censored)	108 (84.4%)	95 (73.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.509 (0.292, 0.887)	
p-value		0.0153	
History of brain metastasis			0.2680
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	1 (11.1%)	
Patients (%) Without Events (Censored)	6 (75.0%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	NR (3.68, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		1.758 (0.158, 19.572)	
p-value		0.6419	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	167	157	
Patients (%) With Events	30 (18.0%)	47 (29.9%)	
Patients (%) Without Events (Censored)	137 (82.0%)	110 (70.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.499 (0.314, 0.791)	
p-value		0.0026	
PD-L1 Status			0.6479
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	12 (18.2%)	18 (31.6%)	
Patients (%) Without Events (Censored)	54 (81.8%)	39 (68.4%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.459 (0.220, 0.957)	
p-value		0.0340	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	20 (18.3%)	30 (27.5%)	
Patients (%) Without Events (Censored)	89 (81.7%)	79 (72.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.585 (0.332, 1.031)	
p-value		0.0606	
BRCA 1/2 status			0.7892
Wild-Type			
Total Patients	65	63	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	10 (15.4%)	14 (22.2%)	
Patients (%) Without Events (Censored)	55 (84.6%)	49 (77.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.597 (0.264, 1.349)	
p-value		0.2106	
Mutant			
Total Patients	12	10	
Patients (%) With Events	1 (8.3%)	2 (20.0%)	
Patients (%) Without Events (Censored)	11 (91.7%)	8 (80.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (0.72, NR)	
Hazard Ratio (95% CI)		0.452 (0.041, 4.988)	
p-value		0.4998	
Menopausal status			0.4068
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	7 (18.9%)	18 (37.5%)	
Patients (%) Without Events (Censored)	30 (81.1%)	30 (62.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.58, NR)	NR (4.14, NR)	
Hazard Ratio (95% CI)		0.390 (0.159, 0.954)	
p-value		0.0329	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	25 (18.1%)	29 (24.8%)	
Patients (%) Without Events (Censored)	113 (81.9%)	88 (75.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.616 (0.360, 1.055)	
p-value		0.0754	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.23. Table 1.1.12.12: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Cough (SOC: Respiratory, thoracic and mediastinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Age group			0.0481
< 65			
Total Patients	132	128	
Patients (%) With Events	23 (17.4%)	13 (10.2%)	
Patients (%) Without Events (Censored)	109 (82.6%)	115 (89.8%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.334 (0.672, 2.648)	
p-value		0.4081	
>= 65			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	43	38	
Patients (%) With Events	11 (25.6%)	2 (5.3%)	
Patients (%) Without Events (Censored)	32 (74.4%)	36 (94.7%)	
Median Time to First TEAE, months (95% CI)	15.34 (10.61, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.772 (1.277, 26.081)	
p-value		0.0099	
Race			0.7945
White			
Total Patients	114	101	
Patients (%) With Events	29 (25.4%)	12 (11.9%)	
Patients (%) Without Events (Censored)	85 (74.6%)	89 (88.1%)	
Median Time to First TEAE, months (95% CI)	23.92 (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.884 (0.959, 3.699)	
p-value		0.0613	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	1 (2.6%)	
Patients (%) Without Events (Censored)	34 (89.5%)	37 (97.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.118 (0.342, 28.397)	
p-value		0.2886	
Other			
Total Patients	18	24	
Patients (%) With Events	1 (5.6%)	1 (4.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	17 (94.4%)	23 (95.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (10.55, NR)	
Hazard Ratio (95% CI)		1.118 (0.070, 17.952)	
p-value		0.9372	
Baseline ECOG status			0.5867
0			
Total Patients	115	104	
Patients (%) With Events	27 (23.5%)	13 (12.5%)	
Patients (%) Without Events (Censored)	88 (76.5%)	91 (87.5%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.748 (0.900, 3.396)	
p-value		0.0950	
1			
Total Patients	60	62	
Patients (%) With Events	7 (11.7%)	2 (3.2%)	
Patients (%) Without Events (Censored)	53 (88.3%)	60 (96.8%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.554 (0.519, 12.559)	
p-value		0.2327	
The physician's choice of chemotherapy selected prior to randomization			0.4461
Taxane			
Total Patients	51	44	
Patients (%) With Events	9 (17.6%)	4 (9.1%)	
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.406 (0.423, 4.673)	
p-value		0.5761	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	25 (20.2%)	11 (9.0%)	
Patients (%) Without Events (Censored)	99 (79.8%)	111 (91.0%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.102 (1.032, 4.282)	
p-value		0.0364	
History of liver metastasis			0.1202
Yes			
Total Patients	47	37	
Patients (%) With Events	6 (12.8%)	4 (10.8%)	
Patients (%) Without Events (Censored)	41 (87.2%)	33 (89.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	10.32 (10.32, NR)	
Hazard Ratio (95% CI)		0.870 (0.237, 3.194)	
p-value		0.8337	
No			
Total Patients	128	129	
Patients (%) With Events	28 (21.9%)	11 (8.5%)	
Patients (%) Without Events (Censored)	100 (78.1%)	118 (91.5%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.303 (1.143, 4.639)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0163	
History of brain metastasis			0.7431
Yes			
Total Patients	8	9	
Patients (%) With Events	1 (12.5%)	1 (11.1%)	
Patients (%) Without Events (Censored)	7 (87.5%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	NR (2.99, NR)	NR (7.59, NR)	
Hazard Ratio (95% CI)		1.155 (0.072, 18.594)	
p-value		0.9191	
No			
Total Patients	167	157	
Patients (%) With Events	33 (19.8%)	14 (8.9%)	
Patients (%) Without Events (Censored)	134 (80.2%)	143 (91.1%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.909 (1.018, 3.581)	
p-value		0.0402	
Menopausal status			0.2225
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	3 (8.1%)	4 (8.3%)	
Patients (%) Without Events (Censored)	34 (91.9%)	44 (91.7%)	
Median Time to First TEAE, months (95% CI)	NR (17.91, NR)	NR (10.55, NR)	
Hazard Ratio (95% CI)		0.713 (0.154, 3.305)	
p-value		0.6642	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	31 (22.5%)	11 (9.4%)	
Patients (%) Without Events (Censored)	107 (77.5%)	106 (90.6%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.139 (1.073, 4.266)	
p-value		0.0270	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.24. Table 1.1.12.13: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alopecia (SOC: Skin and subcutaneous tissue disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.8149
De novo			
Total Patients	55	48	
Patients (%) With Events	34 (61.8%)	13 (27.1%)	
Patients (%) Without Events (Censored)	21 (38.2%)	35 (72.9%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 5.32)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.128 (1.645, 5.949)	
p-value		0.0003	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	16 (47.1%)	5 (15.2%)	
Patients (%) Without Events (Censored)	18 (52.9%)	28 (84.8%)	
Median Time to First TEAE, months (95% CI)	NR (0.85, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.148 (1.516, 11.347)	
p-value		0.0026	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	47 (54.7%)	16 (18.8%)	
Patients (%) Without Events (Censored)	39 (45.3%)	69 (81.2%)	
Median Time to First TEAE, months (95% CI)	1.35 (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.217 (2.384, 7.456)	
p-value		<0.0001	
Geographic region			0.2706
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	31 (56.4%)	13 (26.0%)	
Patients (%) Without Events (Censored)	24 (43.6%)	37 (74.0%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.85, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.025 (1.578, 5.798)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0005	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	66 (55.0%)	21 (18.1%)	
Patients (%) Without Events (Censored)	54 (45.0%)	95 (81.9%)	
Median Time to First TEAE, months (95% CI)	1.35 (0.79, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.263 (2.603, 6.981)	
p-value		<0.0001	
Age group			0.0380
< 65			
Total Patients	132	128	
Patients (%) With Events	78 (59.1%)	22 (17.2%)	
Patients (%) Without Events (Censored)	54 (40.9%)	106 (82.8%)	
Median Time to First TEAE, months (95% CI)	1.18 (0.82, 5.06)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.862 (3.024, 7.818)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	19 (44.2%)	12 (31.6%)	
Patients (%) Without Events (Censored)	24 (55.8%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.76, NR)	NR (5.09, NR)	
Hazard Ratio (95% CI)		1.981 (0.957, 4.100)	
p-value		0.0622	
Race			0.5725

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
White			
Total Patients	114	101	
Patients (%) With Events	59 (51.8%)	15 (14.9%)	
Patients (%) Without Events (Censored)	55 (48.2%)	86 (85.1%)	
Median Time to First TEAE, months (95% CI)	1.64 (0.95, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.015 (2.839, 8.856)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	27 (71.1%)	13 (34.2%)	
Patients (%) Without Events (Censored)	11 (28.9%)	25 (65.8%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.49, 1.38)	NR (5.45, NR)	
Hazard Ratio (95% CI)		2.931 (1.502, 5.718)	
p-value		0.0010	
Other			
Total Patients	18	24	
Patients (%) With Events	9 (50.0%)	4 (16.7%)	
Patients (%) Without Events (Censored)	9 (50.0%)	20 (83.3%)	
Median Time to First TEAE, months (95% CI)	2.20 (0.56, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.103 (1.258, 13.385)	
p-value		0.0113	
Baseline ECOG status			0.7689
0			
Total Patients	115	104	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	65 (56.5%)	23 (22.1%)	
Patients (%) Without Events (Censored)	50 (43.5%)	81 (77.9%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.89, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.647 (2.262, 5.879)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	32 (53.3%)	11 (17.7%)	
Patients (%) Without Events (Censored)	28 (46.7%)	51 (82.3%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.79, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.135 (2.077, 8.230)	
p-value		<0.0001	
The physician's choice of chemotherapy selected prior to randomization			0.0037
Taxane			
Total Patients	51	44	
Patients (%) With Events	29 (56.9%)	16 (36.4%)	
Patients (%) Without Events (Censored)	22 (43.1%)	28 (63.6%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.72, NR)	NR (1.84, NR)	
Hazard Ratio (95% CI)		1.717 (0.931, 3.164)	
p-value		0.0788	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	68 (54.8%)	18 (14.8%)	
Patients (%) Without Events (Censored)	56 (45.2%)	104 (85.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	1.38 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.693 (3.378, 9.596)	
p-value		<0.0001	
History of liver metastasis			0.9479
Yes			
Total Patients	47	37	
Patients (%) With Events	23 (48.9%)	6 (16.2%)	
Patients (%) Without Events (Censored)	24 (51.1%)	31 (83.8%)	
Median Time to First TEAE, months (95% CI)	5.32 (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.570 (1.451, 8.783)	
p-value		0.0031	
No			
Total Patients	128	129	
Patients (%) With Events	74 (57.8%)	28 (21.7%)	
Patients (%) Without Events (Censored)	54 (42.2%)	101 (78.3%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.85, 3.02)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.961 (2.558, 6.135)	
p-value		<0.0001	
History of brain metastasis			0.6580
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	1 (11.1%)	
Patients (%) Without Events (Censored)	6 (75.0%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	NR (0.49, NR)	NR (2.30, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.962 (0.177, 21.779)	
p-value		0.5759	
No			
Total Patients	167	157	
Patients (%) With Events	95 (56.9%)	33 (21.0%)	
Patients (%) Without Events (Censored)	72 (43.1%)	124 (79.0%)	
Median Time to First TEAE, months (95% CI)	1.18 (0.85, 3.02)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.893 (2.615, 5.796)	
p-value		<0.0001	
PD-L1 Status			0.4145
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	41 (62.1%)	12 (21.1%)	
Patients (%) Without Events (Censored)	25 (37.9%)	45 (78.9%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.20)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.605 (2.411, 8.796)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	56 (51.4%)	22 (20.2%)	
Patients (%) Without Events (Censored)	53 (48.6%)	87 (79.8%)	
Median Time to First TEAE, months (95% CI)	1.64 (0.95, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.344 (2.038, 5.485)	
p-value		<0.0001	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
BRCA 1/2 status			0.4181
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	40 (61.5%)	17 (27.0%)	
Patients (%) Without Events (Censored)	25 (38.5%)	46 (73.0%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.72, 3.02)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.216 (1.820, 5.685)	
p-value		<0.0001	
Mutant			
Total Patients	12	10	
Patients (%) With Events	5 (41.7%)	3 (30.0%)	
Patients (%) Without Events (Censored)	7 (58.3%)	7 (70.0%)	
Median Time to First TEAE, months (95% CI)	NR (0.59, NR)	NR (0.43, NR)	
Hazard Ratio (95% CI)		1.533 (0.364, 6.457)	
p-value		0.5578	
Menopausal status			0.1718
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	24 (64.9%)	8 (16.7%)	
Patients (%) Without Events (Censored)	13 (35.1%)	40 (83.3%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.56, 5.32)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.833 (2.608, 13.046)	
p-value		<0.0001	
Post-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	138	117	
Patients (%) With Events	73 (52.9%)	26 (22.2%)	
Patients (%) Without Events (Censored)	65 (47.1%)	91 (77.8%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.95, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.278 (2.092, 5.137)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.25. Table 1.1.13: Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Blood and lymphatic system disorders		
Total Patients	175	166
Patients (%) With Events	85 (48.6%)	110 (66.3%)
Patients (%) Without Events (Censored)	90 (51.4%)	56 (33.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	11.17 (3.58, 23.66)	2.53 (1.84, 3.48)

	SG (N=175)	TPC (N=166)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.653 (0.490, 0.872)
p-value		0.0030
Anaemia		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	36 (21.7%)
Patients (%) Without Events (Censored)	169 (96.6%)	130 (78.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.131 (0.055, 0.312)
p-value		<0.0001
Febrile neutropenia		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	3 (1.8%)
Patients (%) Without Events (Censored)	167 (95.4%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.570 (0.682, 9.687)
p-value		0.1478
Leukopenia		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	32 (19.3%)

	SG (N=175)	TPC (N=166)
Patients (%) Without Events (Censored)	163 (93.1%)	134 (80.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (28.25, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.296 (0.151, 0.579)
p-value		0.0002
Lymphopenia		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	6 (3.6%)
Patients (%) Without Events (Censored)	167 (95.4%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.053 (0.362, 3.066)
p-value		0.9251
Neutropenia		
Total Patients	175	166
Patients (%) With Events	74 (42.3%)	92 (55.4%)
Patients (%) Without Events (Censored)	101 (57.7%)	74 (44.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	22.34 (7.20, NR)	3.48 (2.37, 8.48)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.685 (0.502, 0.935)
p-value		0.0150

	SG (N=175)	TPC (N=166)
Thrombocytopenia		
Total Patients	175	166
Patients (%) With Events	2 (1.1%)	35 (21.1%)
Patients (%) Without Events (Censored)	173 (98.9%)	131 (78.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (17.31, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.039 (0.009, 0.164)
p-value		<0.0001
Gastrointestinal disorders		
Total Patients	175	166
Patients (%) With Events	33 (18.9%)	7 (4.2%)
Patients (%) Without Events (Censored)	142 (81.1%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (26.97, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.379 (1.934, 9.916)
p-value		0.0001
Diarrhoea		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	3 (1.8%)
Patients (%) Without Events (Censored)	157 (89.7%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (26.97, NR)

	SG (N=175)	TPC (N=166)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		5.581 (1.642, 18.972)
p-value		0.0019
General disorders and administration site conditions		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	11 (6.6%)
Patients (%) Without Events (Censored)	163 (93.1%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.813 (0.353, 1.874)
p-value		0.6272
Fatigue		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	8 (4.8%)
Patients (%) Without Events (Censored)	167 (95.4%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.716 (0.263, 1.946)
p-value		0.5112
Infections and infestations		
Total Patients	175	166
Patients (%) With Events	20 (11.4%)	16 (9.6%)

	SG (N=175)	TPC (N=166)
Patients (%) Without Events (Censored)	155 (88.6%)	150 (90.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (28.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.061 (0.548, 2.056)
p-value		0.8605
Injury, poisoning and procedural complications		
Total Patients	175	166
Patients (%) With Events	2 (1.1%)	8 (4.8%)
Patients (%) Without Events (Censored)	173 (98.9%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.188 (0.039, 0.903)
p-value		0.0205
Investigations		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	20 (12.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	146 (88.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.411 (0.191, 0.885)
p-value		0.0191

	SG (N=175)	TPC (N=166)
Alanine aminotransferase increased		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	15 (9.0%)
Patients (%) Without Events (Censored)	167 (95.4%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.429 (0.180, 1.024)
p-value		0.0501
Metabolism and nutrition disorders		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	7 (4.2%)
Patients (%) Without Events (Censored)	163 (93.1%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.350 (0.526, 3.464)
p-value		0.5319
Respiratory, thoracic and mediastinal disorders		
Total Patients	175	166
Patients (%) With Events	13 (7.4%)	10 (6.0%)
Patients (%) Without Events (Censored)	162 (92.6%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)

	SG (N=175)	TPC (N=166)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.158 (0.507, 2.648)
p-value		0.7269
Pulmonary embolism		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	5 (3.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.942 (0.273, 3.253)
p-value		0.9243

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.26. Table 1.1.14.1: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.4186

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
De novo			
Total Patients	55	48	
Patients (%) With Events	25 (45.5%)	25 (52.1%)	
Patients (%) Without Events (Censored)	30 (54.5%)	23 (47.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (1.77, NR)	4.60 (2.27, NR)	
Hazard Ratio (95% CI)		0.923 (0.529, 1.610)	
p-value		0.7654	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	22 (64.7%)	27 (81.8%)	
Patients (%) Without Events (Censored)	12 (35.3%)	6 (18.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.97 (0.56, 23.66)	1.18 (0.92, 2.37)	
Hazard Ratio (95% CI)		0.762 (0.428, 1.358)	
p-value		0.3343	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	38 (44.2%)	58 (68.2%)	
Patients (%) Without Events (Censored)	48 (55.8%)	27 (31.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.83, NR)	2.53 (1.71, 3.45)	
Hazard Ratio (95% CI)		0.523 (0.345, 0.793)	
p-value		0.0017	
Geographic region			0.8958
US/Canada/Western Europe			
Total Patients	55	50	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	22 (40.0%)	27 (54.0%)	
Patients (%) Without Events (Censored)	33 (60.0%)	23 (46.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.14, NR)	3.22 (1.87, NR)	
Hazard Ratio (95% CI)		0.678 (0.385, 1.195)	
p-value		0.1679	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	63 (52.5%)	83 (71.6%)	
Patients (%) Without Events (Censored)	57 (47.5%)	33 (28.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (1.77, 23.66)	2.30 (1.61, 3.09)	
Hazard Ratio (95% CI)		0.647 (0.463, 0.905)	
p-value		0.0090	
Age group			0.3632
< 65			
Total Patients	132	128	
Patients (%) With Events	62 (47.0%)	85 (66.4%)	
Patients (%) Without Events (Censored)	70 (53.0%)	43 (33.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.14, NR)	2.50 (1.84, 3.22)	
Hazard Ratio (95% CI)		0.614 (0.440, 0.856)	
p-value		0.0032	
>= 65			
Total Patients	43	38	
Patients (%) With Events	23 (53.5%)	25 (65.8%)	
Patients (%) Without Events (Censored)	20 (46.5%)	13 (34.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	5.09 (0.66, NR)	3.45 (1.05, 8.97)	
Hazard Ratio (95% CI)		0.799 (0.449, 1.421)	
p-value		0.4290	
Race			0.0234
White			
Total Patients	114	101	
Patients (%) With Events	45 (39.5%)	65 (64.4%)	
Patients (%) Without Events (Censored)	69 (60.5%)	36 (35.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (11.17, NR)	2.37 (1.61, 3.22)	
Hazard Ratio (95% CI)		0.522 (0.356, 0.767)	
p-value		0.0007	
Asian			
Total Patients	38	38	
Patients (%) With Events	27 (71.1%)	24 (63.2%)	
Patients (%) Without Events (Censored)	11 (28.9%)	14 (36.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.56, 6.28)	3.45 (1.71, 9.53)	
Hazard Ratio (95% CI)		1.236 (0.706, 2.164)	
p-value		0.4928	
Other			
Total Patients	18	24	
Patients (%) With Events	12 (66.7%)	20 (83.3%)	
Patients (%) Without Events (Censored)	6 (33.3%)	4 (16.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.03 (0.30, 23.66)	2.30 (0.89, 4.40)	
Hazard Ratio (95% CI)		0.677 (0.316, 1.451)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.3014	
Baseline ECOG status			0.4530
0			
Total Patients	115	104	
Patients (%) With Events	61 (53.0%)	74 (71.2%)	
Patients (%) Without Events (Censored)	54 (47.0%)	30 (28.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	4.34 (1.58, NR)	2.50 (1.64, 3.48)	
Hazard Ratio (95% CI)		0.724 (0.514, 1.019)	
p-value		0.0565	
1			
Total Patients	60	62	
Patients (%) With Events	24 (40.0%)	36 (58.1%)	
Patients (%) Without Events (Censored)	36 (60.0%)	26 (41.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.24, 23.66)	3.02 (1.61, 5.09)	
Hazard Ratio (95% CI)		0.504 (0.292, 0.873)	
p-value		0.0117	
The physician's choice of chemotherapy selected prior to randomization			<0.0001
Taxane			
Total Patients	51	44	
Patients (%) With Events	24 (47.1%)	7 (15.9%)	
Patients (%) Without Events (Censored)	27 (52.9%)	37 (84.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (2.04, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.369 (1.445, 7.858)	
p-value		0.0029	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	61 (49.2%)	103 (84.4%)	
Patients (%) Without Events (Censored)	63 (50.8%)	19 (15.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (2.56, NR)	1.64 (1.05, 2.30)	
Hazard Ratio (95% CI)		0.449 (0.324, 0.622)	
p-value		<0.0001	
History of liver metastasis			0.8195
Yes			
Total Patients	47	37	
Patients (%) With Events	25 (53.2%)	24 (64.9%)	
Patients (%) Without Events (Censored)	22 (46.8%)	13 (35.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.92 (0.92, NR)	1.64 (0.95, 3.12)	
Hazard Ratio (95% CI)		0.755 (0.429, 1.330)	
p-value		0.3239	
No			
Total Patients	128	129	
Patients (%) With Events	60 (46.9%)	86 (66.7%)	
Patients (%) Without Events (Censored)	68 (53.1%)	43 (33.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.14, NR)	3.02 (2.10, 4.60)	
Hazard Ratio (95% CI)		0.616 (0.440, 0.863)	
p-value		0.0037	
History of brain metastasis			0.8556
Yes			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	8	9	
Patients (%) With Events	3 (37.5%)	5 (55.6%)	
Patients (%) Without Events (Censored)	5 (62.5%)	4 (44.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.43, NR)	2.10 (0.66, NR)	
Hazard Ratio (95% CI)		0.648 (0.154, 2.730)	
p-value		0.5518	
No			
Total Patients	167	157	
Patients (%) With Events	82 (49.1%)	105 (66.9%)	
Patients (%) Without Events (Censored)	85 (50.9%)	52 (33.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (3.48, 23.66)	2.99 (1.84, 4.27)	
Hazard Ratio (95% CI)		0.657 (0.490, 0.881)	
p-value		0.0040	
PD-L1 Status			0.6615
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	30 (45.5%)	39 (68.4%)	
Patients (%) Without Events (Censored)	36 (54.5%)	18 (31.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.58, NR)	2.37 (1.41, 4.63)	
Hazard Ratio (95% CI)		0.652 (0.404, 1.054)	
p-value		0.0742	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	55 (50.5%)	71 (65.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	54 (49.5%)	38 (34.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (2.56, 22.34)	3.02 (1.84, 4.40)	
Hazard Ratio (95% CI)		0.653 (0.455, 0.938)	
p-value		0.0176	
BRCA 1/2 status			0.3514
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	33 (50.8%)	38 (60.3%)	
Patients (%) Without Events (Censored)	32 (49.2%)	25 (39.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (1.58, NR)	2.10 (1.18, 7.79)	
Hazard Ratio (95% CI)		0.719 (0.447, 1.157)	
p-value		0.1622	
Mutant			
Total Patients	12	10	
Patients (%) With Events	7 (58.3%)	7 (70.0%)	
Patients (%) Without Events (Censored)	5 (41.7%)	3 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.26, NR)	4.63 (0.95, NR)	
Hazard Ratio (95% CI)		1.204 (0.417, 3.481)	
p-value		0.7369	
Menopausal status			0.8127
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	17 (45.9%)	31 (64.6%)	
Patients (%) Without Events (Censored)	20 (54.1%)	17 (35.4%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.89, NR)	3.02 (1.84, 4.93)	
Hazard Ratio (95% CI)		0.711 (0.393, 1.287)	
p-value		0.2483	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	68 (49.3%)	79 (67.5%)	
Patients (%) Without Events (Censored)	70 (50.7%)	38 (32.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (2.56, 23.66)	2.50 (1.61, 3.88)	
Hazard Ratio (95% CI)		0.628 (0.451, 0.874)	
p-value		0.0046	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.27. Table 1.1.14.2: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — SOC: Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Menopausal status			0.0069
Pre-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	37	48	
Patients (%) With Events	0 (0.0%)	9 (18.8%)	
Patients (%) Without Events (Censored)	37 (100.0%)	39 (81.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0058	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	10 (7.2%)	11 (9.4%)	
Patients (%) Without Events (Censored)	128 (92.8%)	106 (90.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.674 (0.284, 1.599)	
p-value		0.3681	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.28. Table 1.1.14.3: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Leukopenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.6272
Taxane			
Total Patients	51	44	
Patients (%) With Events	1 (2.0%)	1 (2.3%)	
Patients (%) Without Events (Censored)	50 (98.0%)	43 (97.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.852 (0.053, 13.614)	
p-value		0.9094	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	11 (8.9%)	31 (25.4%)	
Patients (%) Without Events (Censored)	113 (91.1%)	91 (74.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (13.63, NR)	
Hazard Ratio (95% CI)		0.305 (0.153, 0.611)	
p-value		0.0004	
History of brain metastasis			0.2771
Yes			
Total Patients	8	9	
Patients (%) With Events	0 (0.0%)	2 (22.2%)	
Patients (%) Without Events (Censored)	8 (100.0%)	7 (77.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		NC	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.1161	
No			
Total Patients	167	157	
Patients (%) With Events	12 (7.2%)	30 (19.1%)	
Patients (%) Without Events (Censored)	155 (92.8%)	127 (80.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (28.25, NR)	
Hazard Ratio (95% CI)		0.314 (0.160, 0.619)	
p-value		0.0004	
Menopausal status			0.2366
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	1 (2.7%)	10 (20.8%)	
Patients (%) Without Events (Censored)	36 (97.3%)	38 (79.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (15.08, NR)	NR (13.63, NR)	
Hazard Ratio (95% CI)		0.083 (0.010, 0.665)	
p-value		0.0036	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	11 (8.0%)	22 (18.8%)	
Patients (%) Without Events (Censored)	127 (92.0%)	95 (81.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (28.25, NR)	
Hazard Ratio (95% CI)		0.369 (0.178, 0.765)	
p-value		0.0053	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.29. Table 1.1.14.4: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.3983
De novo			
Total Patients	55	48	
Patients (%) With Events	21 (38.2%)	19 (39.6%)	
Patients (%) Without Events (Censored)	34 (61.8%)	29 (60.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (2.20, NR)	NR (3.48, NR)	
Hazard Ratio (95% CI)		1.040 (0.559, 1.937)	
p-value		0.9081	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	20 (58.8%)	23 (69.7%)	
Patients (%) Without Events (Censored)	14 (41.2%)	10 (30.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.69, NR)	1.18 (0.92, 4.40)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.776 (0.420, 1.435)	
p-value		0.3989	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	33 (38.4%)	50 (58.8%)	
Patients (%) Without Events (Censored)	53 (61.6%)	35 (41.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (6.28, NR)	3.22 (2.10, 9.40)	
Hazard Ratio (95% CI)		0.541 (0.346, 0.845)	
p-value		0.0058	
Geographic region			0.9751
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	19 (34.5%)	22 (44.0%)	
Patients (%) Without Events (Censored)	36 (65.5%)	28 (56.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (21.39, NR)	5.82 (3.12, NR)	
Hazard Ratio (95% CI)		0.700 (0.377, 1.299)	
p-value		0.2474	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	55 (45.8%)	70 (60.3%)	
Patients (%) Without Events (Censored)	65 (54.2%)	46 (39.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.34, NR)	3.02 (1.87, 5.78)	
Hazard Ratio (95% CI)		0.683 (0.476, 0.981)	
p-value		0.0349	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Age group			0.5040
< 65			
Total Patients	132	128	
Patients (%) With Events	55 (41.7%)	71 (55.5%)	
Patients (%) Without Events (Censored)	77 (58.3%)	57 (44.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	23.66 (7.20, NR)	3.22 (2.30, 9.40)	
Hazard Ratio (95% CI)		0.657 (0.460, 0.939)	
p-value		0.0188	
>= 65			
Total Patients	43	38	
Patients (%) With Events	19 (44.2%)	21 (55.3%)	
Patients (%) Without Events (Censored)	24 (55.8%)	17 (44.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (1.61, NR)	4.27 (1.71, 9.69)	
Hazard Ratio (95% CI)		0.798 (0.425, 1.497)	
p-value		0.4670	
Race			0.0128
White			
Total Patients	114	101	
Patients (%) With Events	37 (32.5%)	55 (54.5%)	
Patients (%) Without Events (Censored)	77 (67.5%)	46 (45.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (21.39, NR)	3.22 (2.10, 9.69)	
Hazard Ratio (95% CI)		0.507 (0.333, 0.773)	
p-value		0.0012	
Asian			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	38	38	
Patients (%) With Events	25 (65.8%)	20 (52.6%)	
Patients (%) Without Events (Censored)	13 (34.2%)	18 (47.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.48 (0.69, 11.24)	5.78 (1.87, NR)	
Hazard Ratio (95% CI)		1.386 (0.761, 2.524)	
p-value		0.3026	
Other			
Total Patients	18	24	
Patients (%) With Events	11 (61.1%)	17 (70.8%)	
Patients (%) Without Events (Censored)	7 (38.9%)	7 (29.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.38 (0.49, NR)	2.50 (0.92, 4.93)	
Hazard Ratio (95% CI)		0.812 (0.368, 1.791)	
p-value		0.5998	
Baseline ECOG status			0.9067
0			
Total Patients	115	104	
Patients (%) With Events	52 (45.2%)	63 (60.6%)	
Patients (%) Without Events (Censored)	63 (54.8%)	41 (39.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (4.14, NR)	3.45 (2.27, 5.82)	
Hazard Ratio (95% CI)		0.715 (0.494, 1.034)	
p-value		0.0678	
1			
Total Patients	60	62	
Patients (%) With Events	22 (36.7%)	29 (46.8%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	38 (63.3%)	33 (53.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.24, 23.66)	8.48 (1.87, NR)	
Hazard Ratio (95% CI)		0.603 (0.336, 1.083)	
p-value		0.0848	
The physician's choice of chemotherapy selected prior to randomization			<0.0001
Taxane			
Total Patients	51	44	
Patients (%) With Events	20 (39.2%)	3 (6.8%)	
Patients (%) Without Events (Censored)	31 (60.8%)	41 (93.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (3.48, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.331 (1.872, 21.410)	
p-value		0.0007	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	54 (43.5%)	89 (73.0%)	
Patients (%) Without Events (Censored)	70 (56.5%)	33 (27.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (5.09, NR)	2.10 (1.41, 3.02)	
Hazard Ratio (95% CI)		0.480 (0.340, 0.678)	
p-value		<0.0001	
History of liver metastasis			0.5923
Yes			
Total Patients	47	37	
Patients (%) With Events	21 (44.7%)	18 (48.6%)	
Patients (%) Without Events (Censored)	26 (55.3%)	19 (51.4%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.58, NR)	2.99 (1.41, NR)	
Hazard Ratio (95% CI)		0.874 (0.464, 1.647)	
p-value		0.6758	
No			
Total Patients	128	129	
Patients (%) With Events	53 (41.4%)	74 (57.4%)	
Patients (%) Without Events (Censored)	75 (58.6%)	55 (42.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (11.17, NR)	4.40 (2.37, 9.40)	
Hazard Ratio (95% CI)		0.637 (0.445, 0.912)	
p-value		0.0116	
History of brain metastasis			0.3872
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	5 (55.6%)	
Patients (%) Without Events (Censored)	6 (75.0%)	4 (44.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.72, NR)	2.50 (0.66, NR)	
Hazard Ratio (95% CI)		0.366 (0.071, 1.896)	
p-value		0.2120	
No			
Total Patients	167	157	
Patients (%) With Events	72 (43.1%)	87 (55.4%)	
Patients (%) Without Events (Censored)	95 (56.9%)	70 (44.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (6.28, NR)	4.27 (2.37, 9.40)	
Hazard Ratio (95% CI)		0.706 (0.515, 0.970)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0283	
PD-L1 Status			0.4900
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	25 (37.9%)	33 (57.9%)	
Patients (%) Without Events (Censored)	41 (62.1%)	24 (42.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (3.48, NR)	3.45 (1.71, 9.69)	
Hazard Ratio (95% CI)		0.646 (0.382, 1.091)	
p-value		0.0968	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	49 (45.0%)	59 (54.1%)	
Patients (%) Without Events (Censored)	60 (55.0%)	50 (45.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.86, 23.66)	4.40 (2.30, 9.53)	
Hazard Ratio (95% CI)		0.710 (0.481, 1.046)	
p-value		0.0749	
BRCA 1/2 status			0.3895
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	29 (44.6%)	33 (52.4%)	
Patients (%) Without Events (Censored)	36 (55.4%)	30 (47.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (2.92, NR)	3.48 (1.41, NR)	
Hazard Ratio (95% CI)		0.749 (0.451, 1.242)	
p-value		0.2521	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Mutant			
Total Patients	12	10	
Patients (%) With Events	7 (58.3%)	7 (70.0%)	
Patients (%) Without Events (Censored)	5 (41.7%)	3 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.26, NR)	4.63 (0.95, NR)	
Hazard Ratio (95% CI)		1.204 (0.417, 3.481)	
p-value		0.7369	
Menopausal status			0.4315
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	16 (43.2%)	25 (52.1%)	
Patients (%) Without Events (Censored)	21 (56.8%)	23 (47.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.89, NR)	4.40 (2.27, NR)	
Hazard Ratio (95% CI)		0.899 (0.479, 1.685)	
p-value		0.7246	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	58 (42.0%)	67 (57.3%)	
Patients (%) Without Events (Censored)	80 (58.0%)	50 (42.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (7.20, NR)	3.45 (1.87, 8.48)	
Hazard Ratio (95% CI)		0.625 (0.437, 0.894)	
p-value		0.0084	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.30. Table 1.1.15: Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Blood and lymphatic system disorders		
Total Patients	175	166
Patients (%) With Events	13 (7.4%)	20 (12.0%)
Patients (%) Without Events (Censored)	162 (92.6%)	146 (88.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	31.47 (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.578 (0.286, 1.167)
p-value		0.1206
Neutropenia		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	8 (4.8%)
Patients (%) Without Events (Censored)	170 (97.1%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)

	SG (N=175)	TPC (N=166)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.576 (0.188, 1.762)
p-value		0.3271
Thrombocytopenia		
Total Patients	175	166
Patients (%) With Events	0 (0.0%)	10 (6.0%)
Patients (%) Without Events (Censored)	175 (100.0%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0009
Gastrointestinal disorders		
Total Patients	175	166
Patients (%) With Events	16 (9.1%)	2 (1.2%)
Patients (%) Without Events (Censored)	159 (90.9%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		7.405 (1.700, 32.246)
p-value		0.0017
Infections and infestations		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	17 (10.2%)

	SG (N=175)	TPC (N=166)
Patients (%) Without Events (Censored)	154 (88.0%)	149 (89.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (28.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.062 (0.558, 2.020)
p-value		0.8556
Respiratory, thoracic and mediastinal disorders		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	7 (4.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.006 (0.363, 2.786)
p-value		0.9907

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

6.31. Table 1.1.16: Subgroup Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

No Eligible Subgroups

6.32. Table 1.1.17: Incidence of TEAE leading to Study Drug Discontinuation by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Number (%) of Participants with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	9 (5.1%)	29 (17.5%)
Blood and lymphatic system disorders	1 (0.6%)	14 (8.4%)
Thrombocytopenia	0	9 (5.4%)
Neutropenia	0	3 (1.8%)
Anaemia	0	2 (1.2%)
Febrile neutropenia	1 (0.6%)	0
Cardiac disorders	0	1 (0.6%)
Cardiac failure congestive	0	1 (0.6%)
Gastrointestinal disorders	2 (1.1%)	0
Diarrhoea	1 (0.6%)	0
Neutropenic colitis	1 (0.6%)	0
General disorders and administration site conditions	0	2 (1.2%)
Fatigue	0	2 (1.2%)
Hepatobiliary disorders	0	1 (0.6%)
Hypertransaminasaemia	0	1 (0.6%)
Immune system disorders	0	2 (1.2%)
Hypersensitivity	0	2 (1.2%)
Infections and infestations	1 (0.6%)	1 (0.6%)
Nail bed infection	0	1 (0.6%)
Urosepsis	1 (0.6%)	0

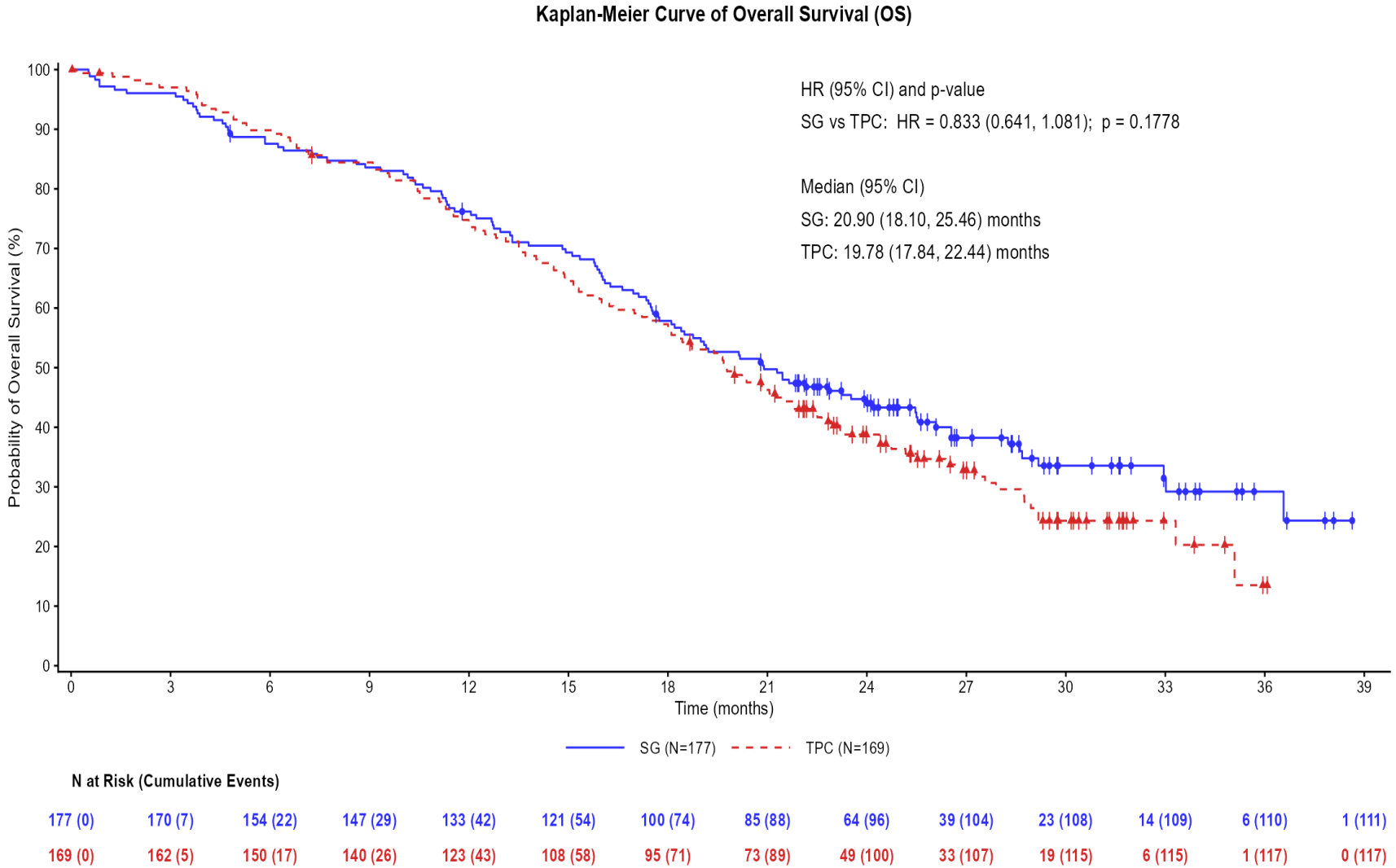
	SG (N=175)	TPC (N=166)
Injury, poisoning and procedural complications	1 (0.6%)	3 (1.8%)
Infusion related reaction	1 (0.6%)	3 (1.8%)
Musculoskeletal and connective tissue disorders	0	1 (0.6%)
Musculoskeletal pain	0	1 (0.6%)
Nervous system disorders	0	1 (0.6%)
Neuropathy peripheral	0	1 (0.6%)
Psychiatric disorders	1 (0.6%)	1 (0.6%)
Panic attack	0	1 (0.6%)
Restlessness	1 (0.6%)	0
Respiratory, thoracic and mediastinal disorders	3 (1.7%)	1 (0.6%)
Interstitial lung disease	2 (1.1%)	0
Pneumonitis	1 (0.6%)	0
Pulmonary embolism	0	1 (0.6%)
Skin and subcutaneous tissue disorders	0	2 (1.2%)
Eczema	0	1 (0.6%)
Skin oedema	0	1 (0.6%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Adverse events were coded according to MedDRA Version 27.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.
Data Cut Date: 22 APR 2026.

7. KM FIGURES — Efficacy

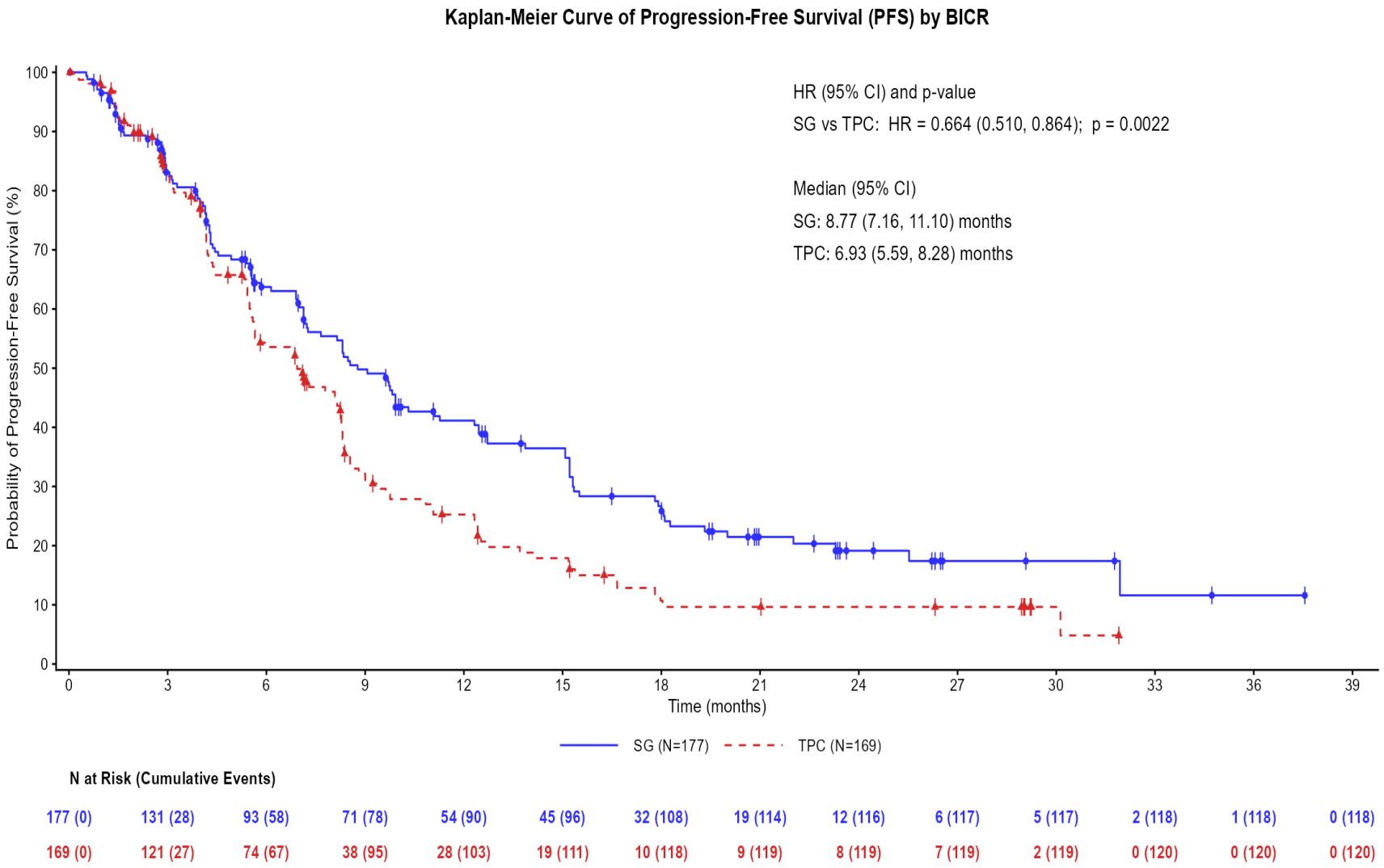
7.1. mITT — Excluding patients preselected to receive nab-paclitaxel

7.2. Figure 1.1.1: Kaplan-Meier Curve of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel



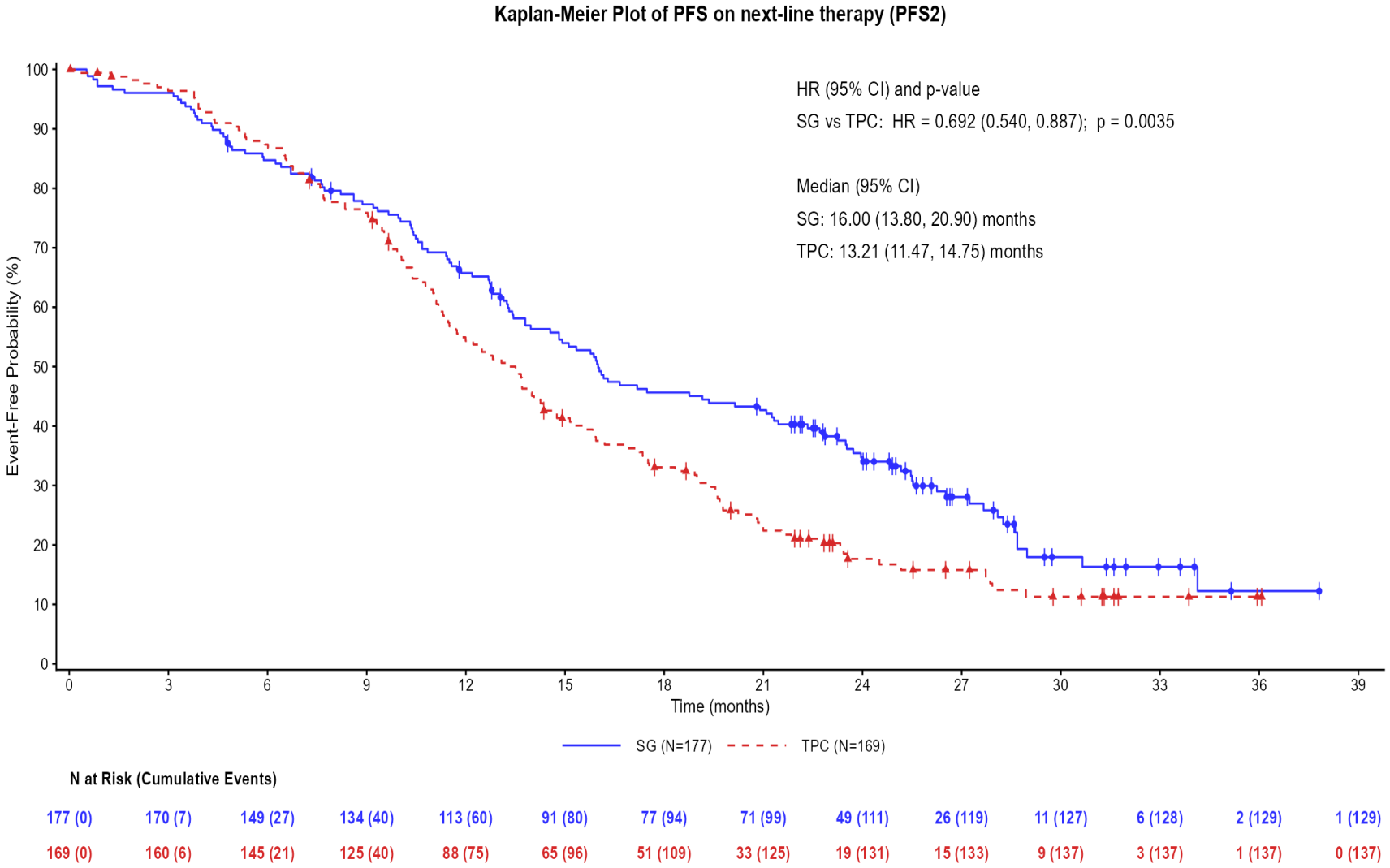
Two-sided p-value from the log-rank test stratified by the randomization stratification factors (STRAT1, STRAT2) from IWRS; hazard ratio from a Cox model adjusted for the same factors as covariates. SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.3. Figure 1.1.2: Kaplan-Meier Curve of Progression-Free Survival (PFS) by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel



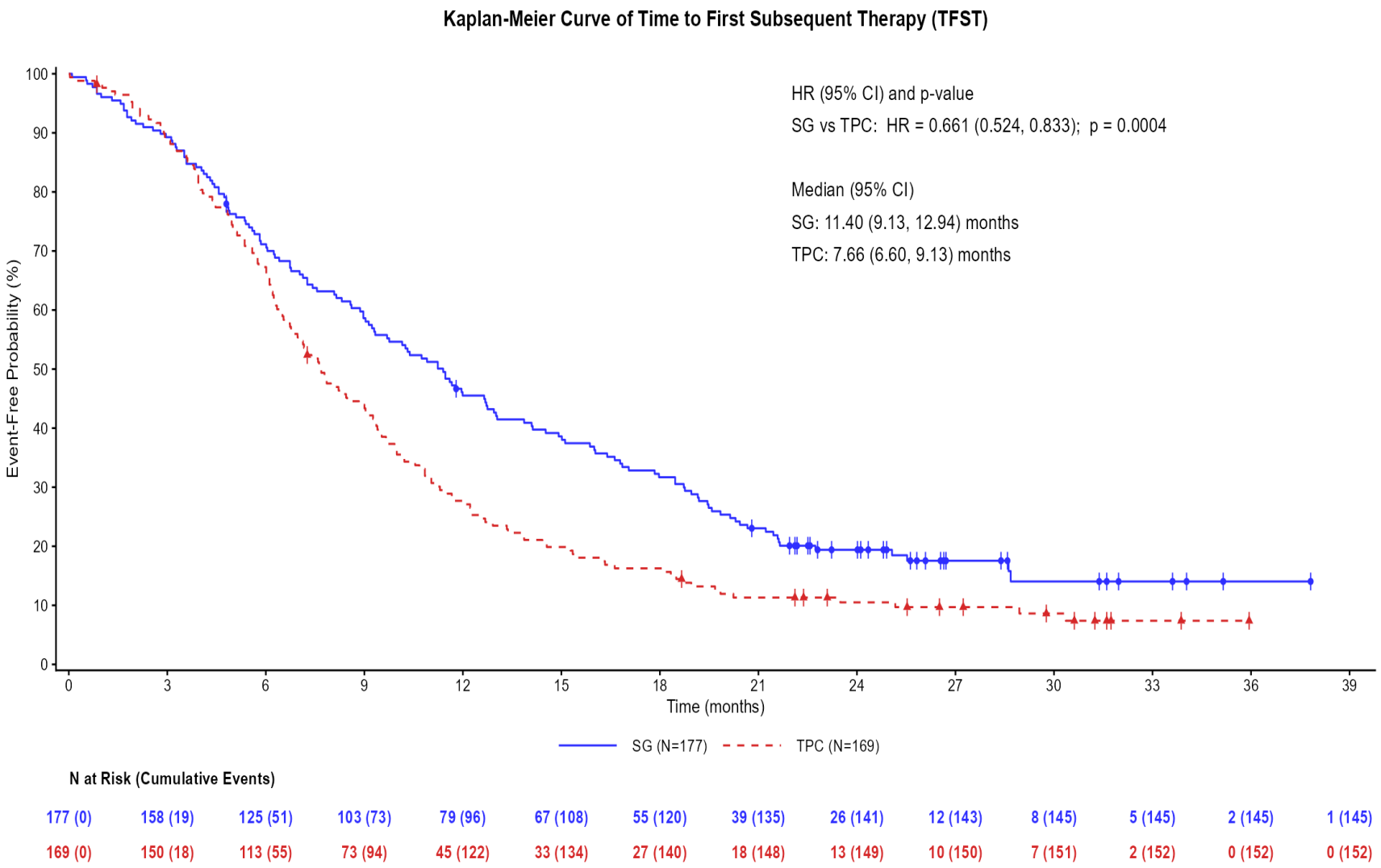
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.4. Figure 1.1.3: Kaplan-Meier Plot of PFS on next-line therapy (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel



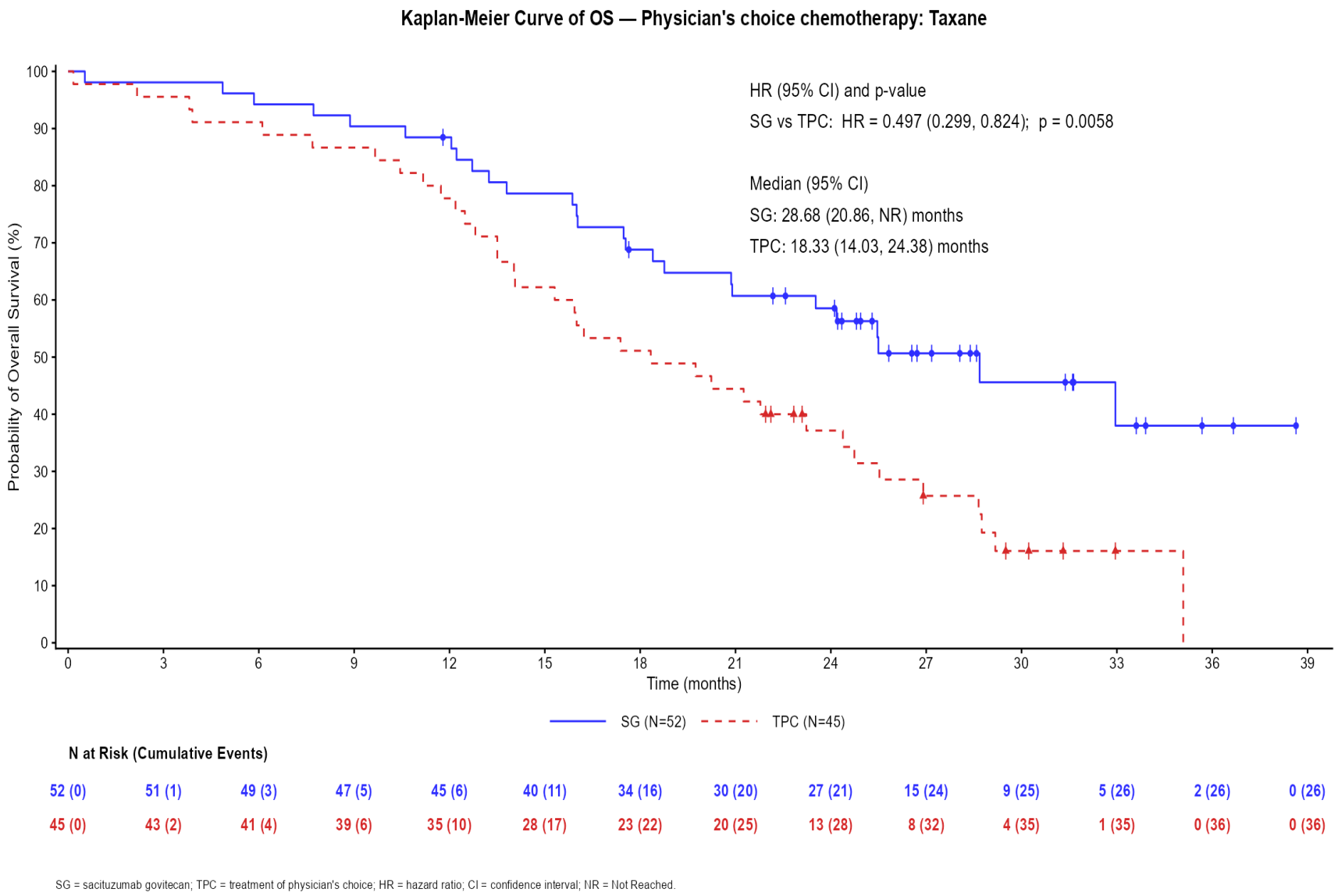
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.5. Figure 1.1.4: Kaplan-Meier Curve of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel



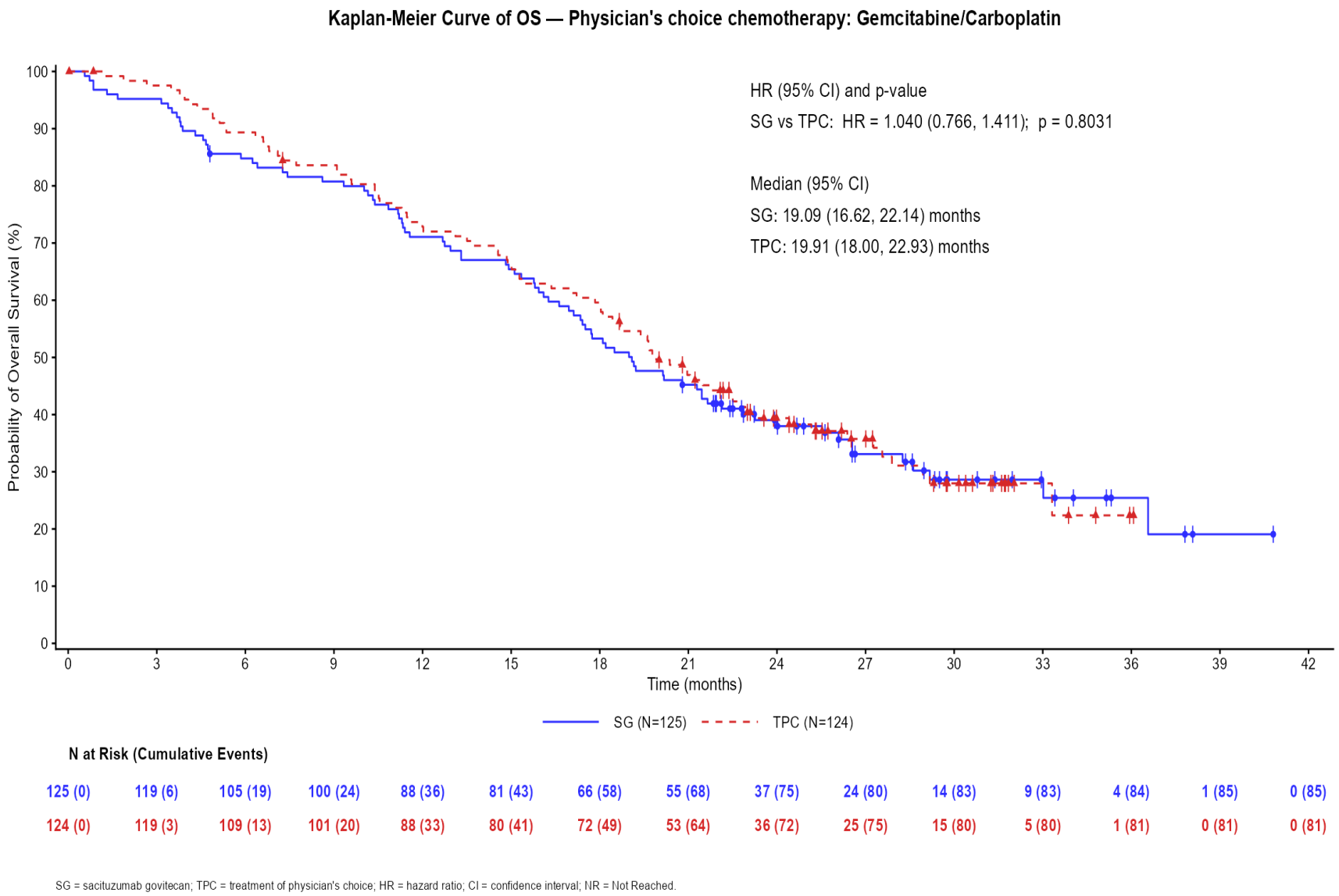
Two-sided p-value from the log-rank test stratified by the randomization stratification factors (STRAT1, STRAT2) from IWRS; hazard ratio from a Cox model adjusted for the same factors as covariates. SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.6. Figure 1.1.6: Kaplan-Meier Curve of OS — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



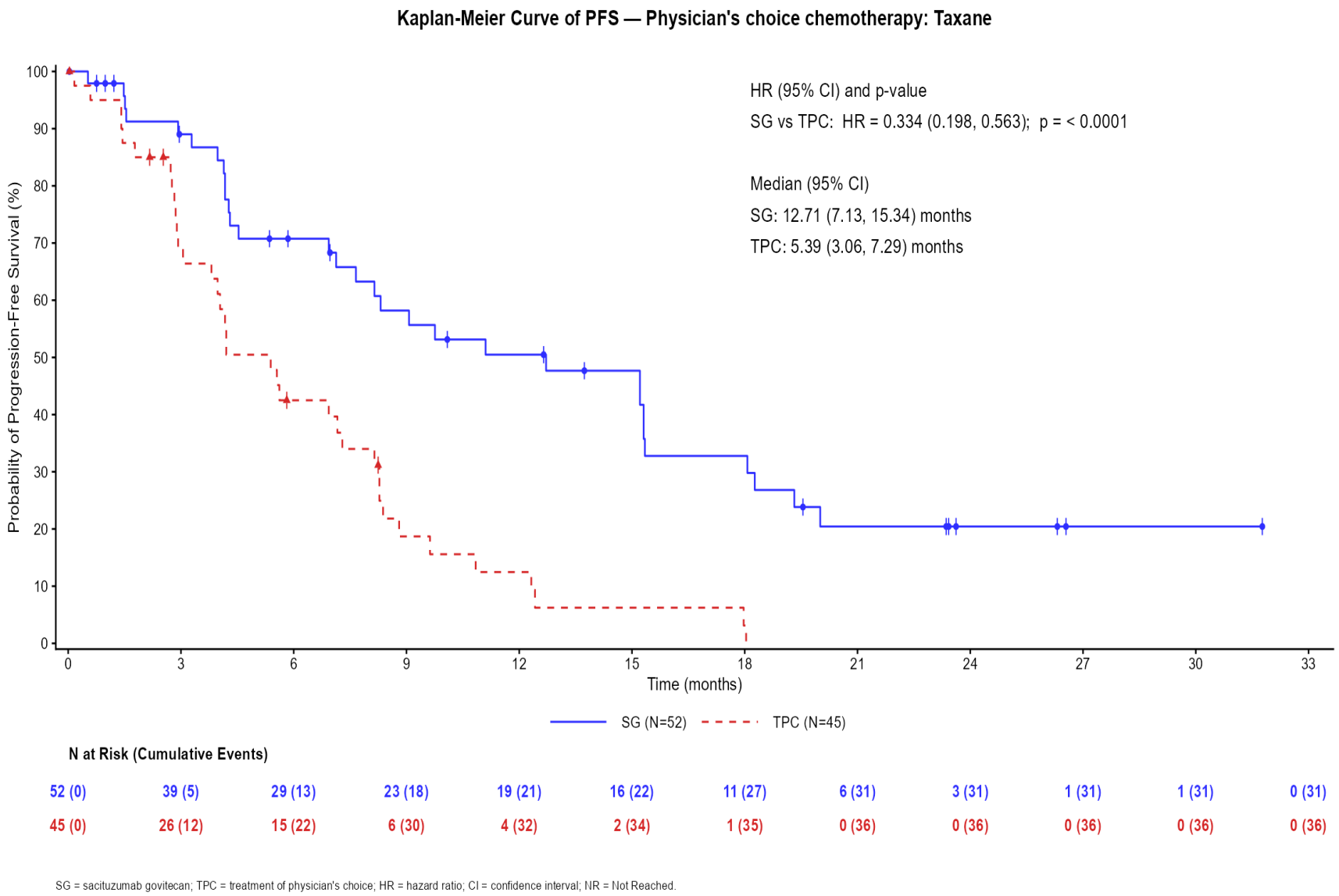
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.7. Figure 1.1.7: Kaplan-Meier Curve of OS — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



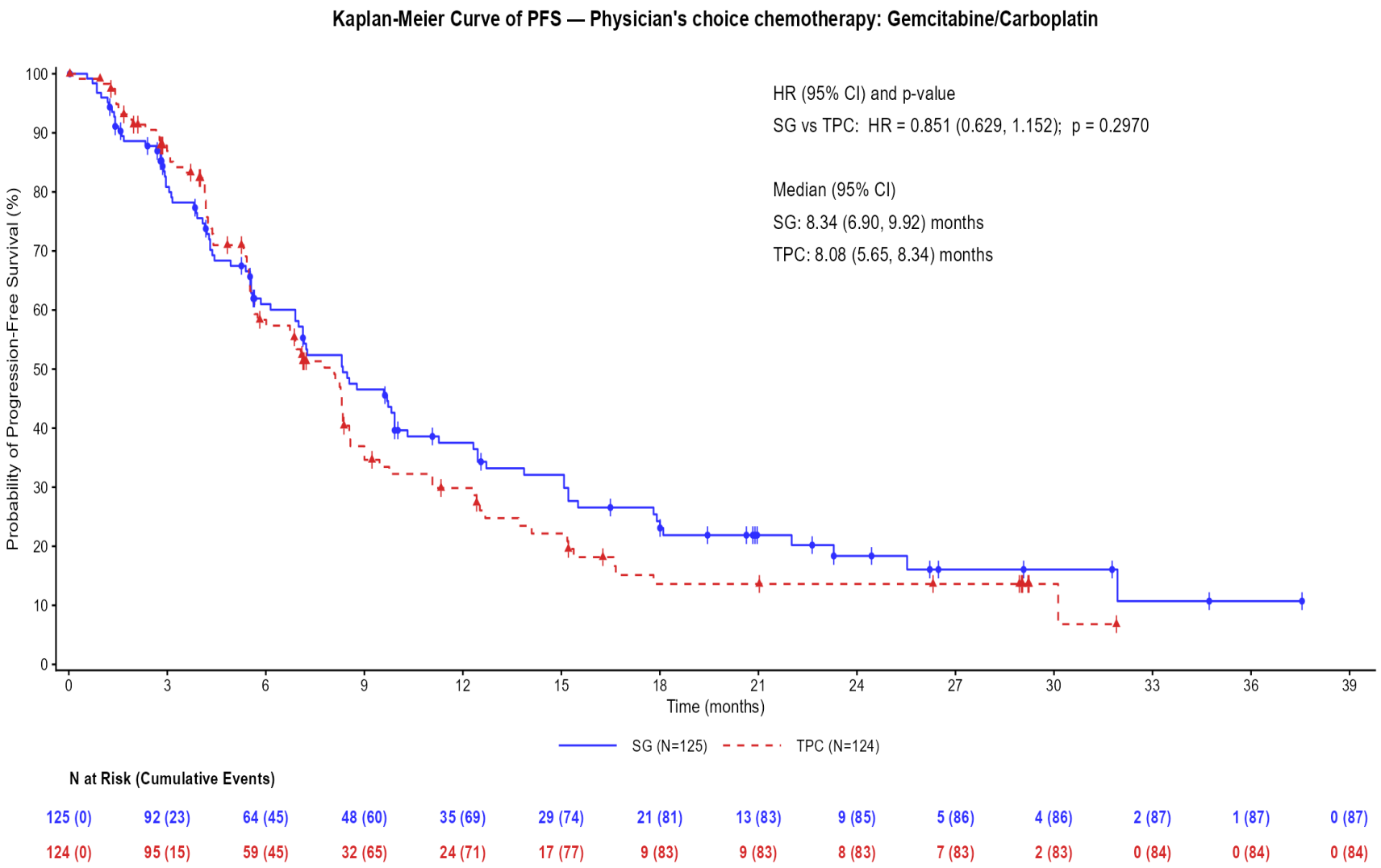
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.8. Figure 1.1.8: Kaplan-Meier Curve of PFS — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



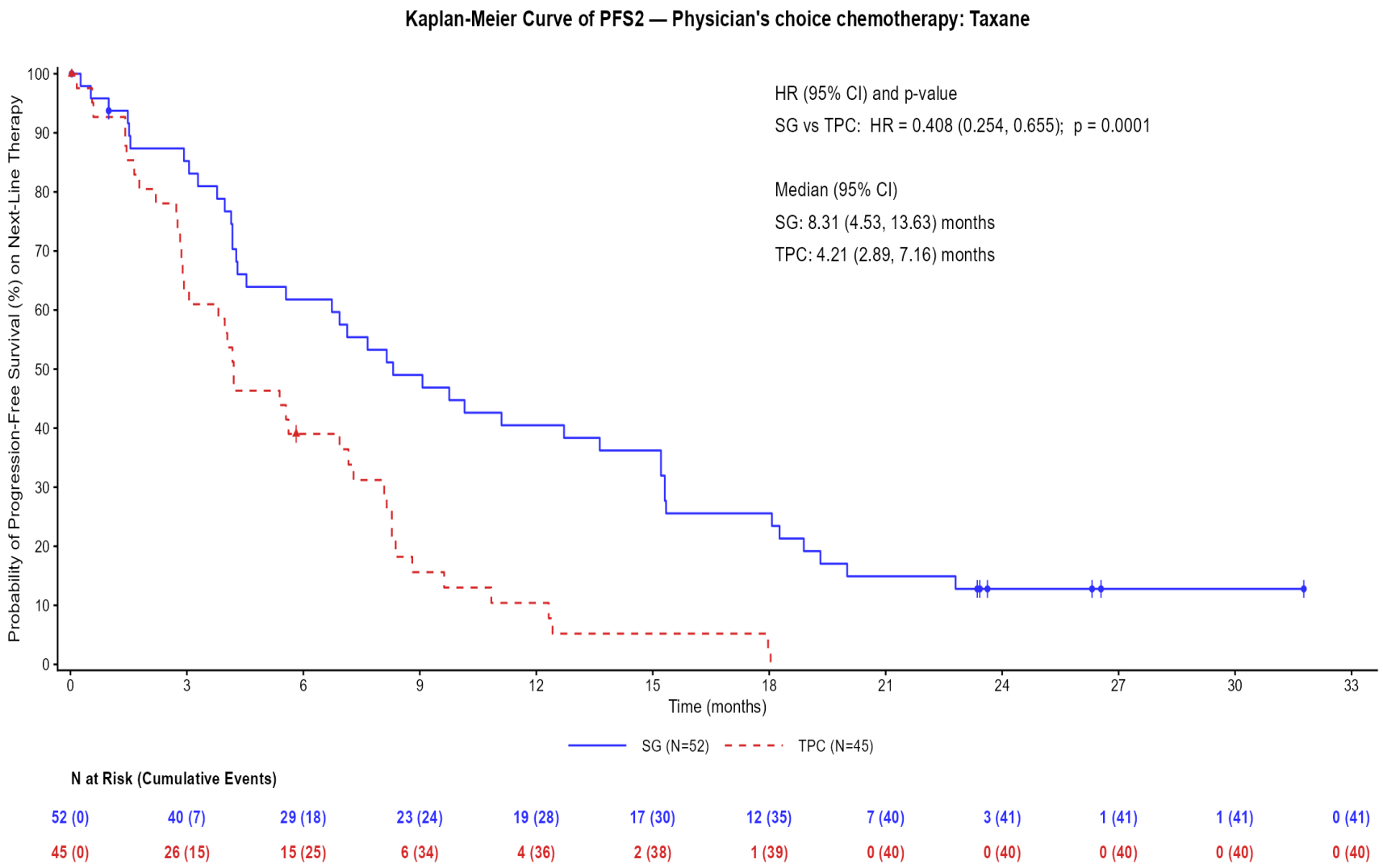
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.9. Figure 1.1.9: Kaplan-Meier Curve of PFS — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



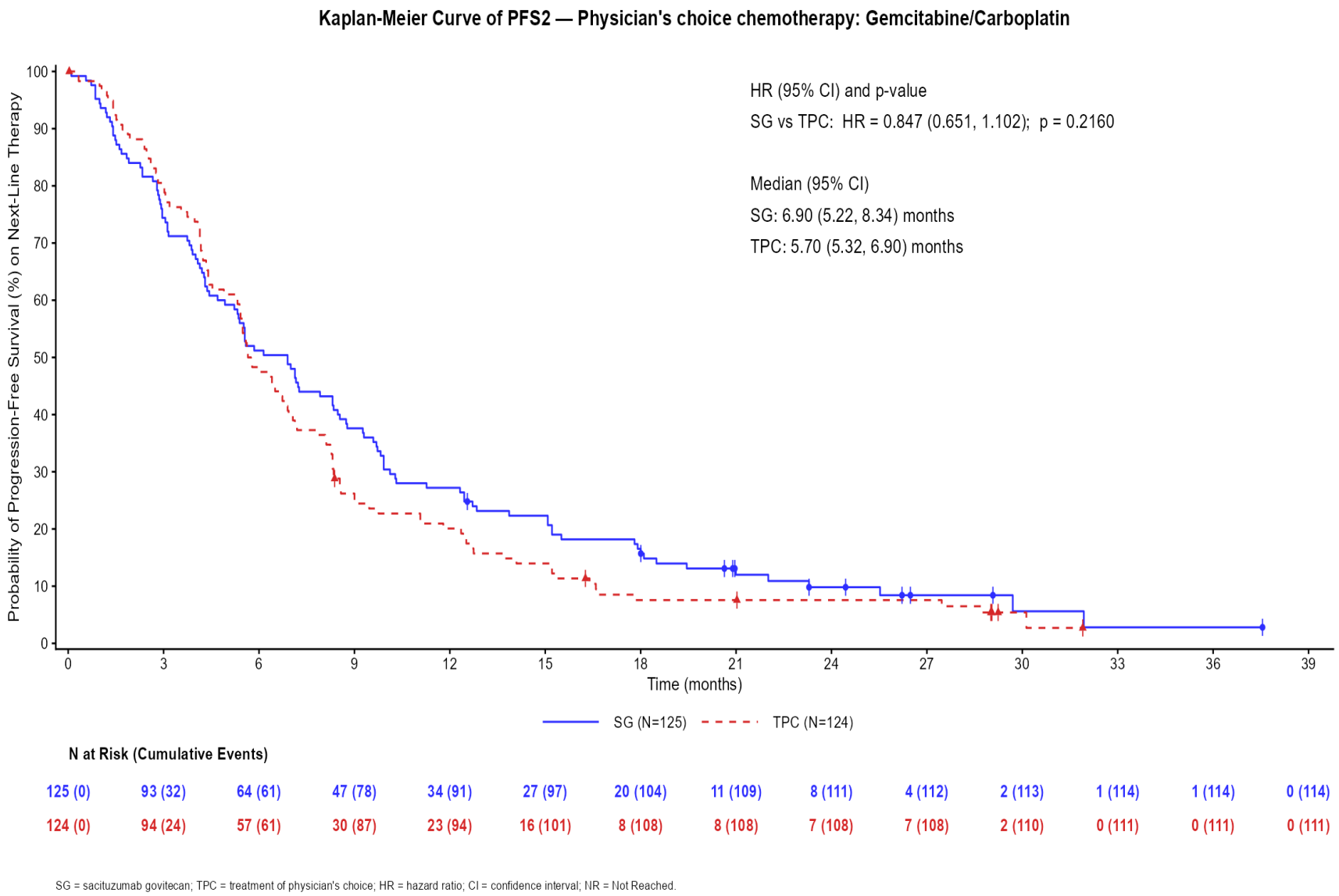
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.10. Figure 1.1.10: Kaplan-Meier Curve of PFS2 — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



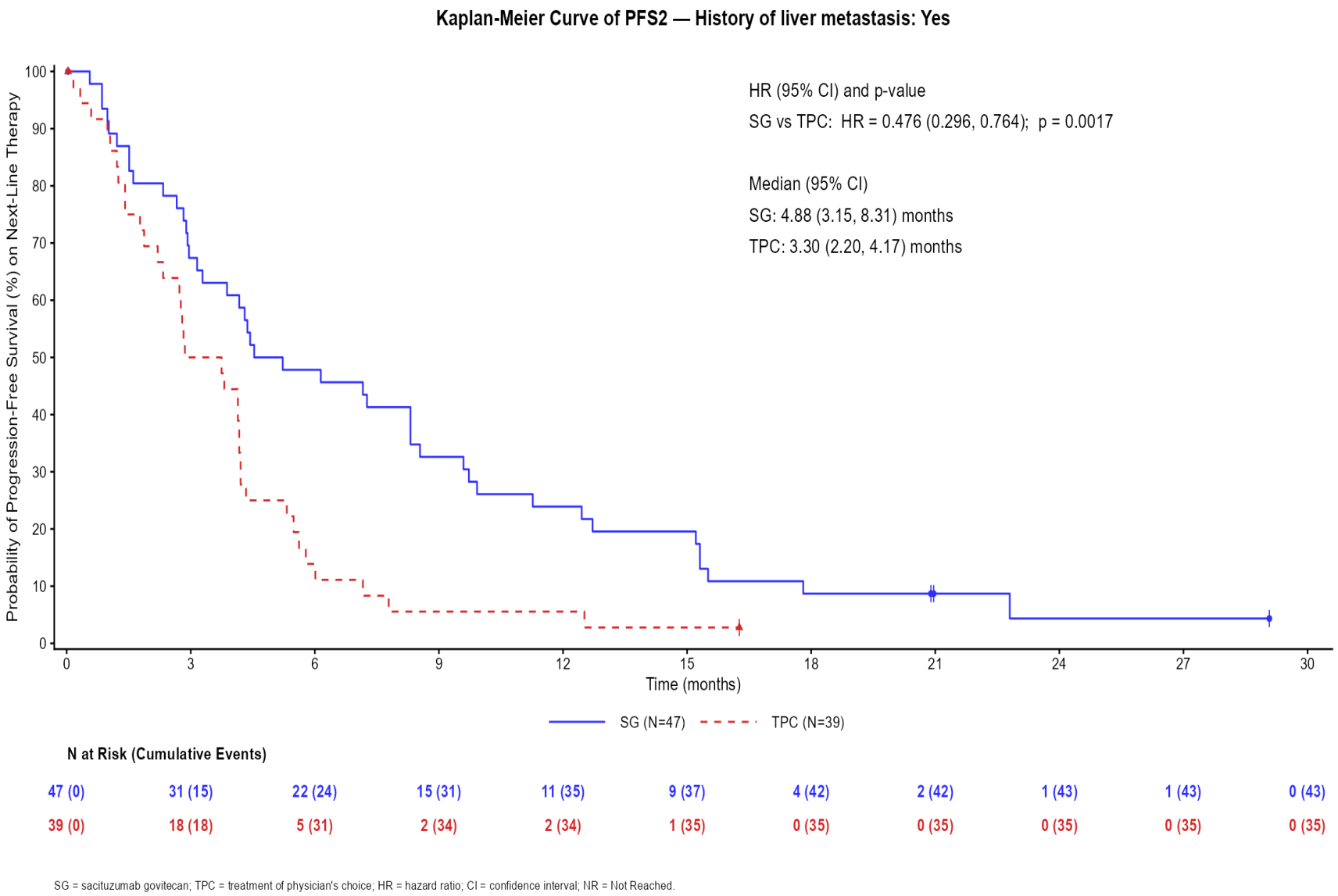
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.11. Figure 1.1.11: Kaplan-Meier Curve of PFS2 — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



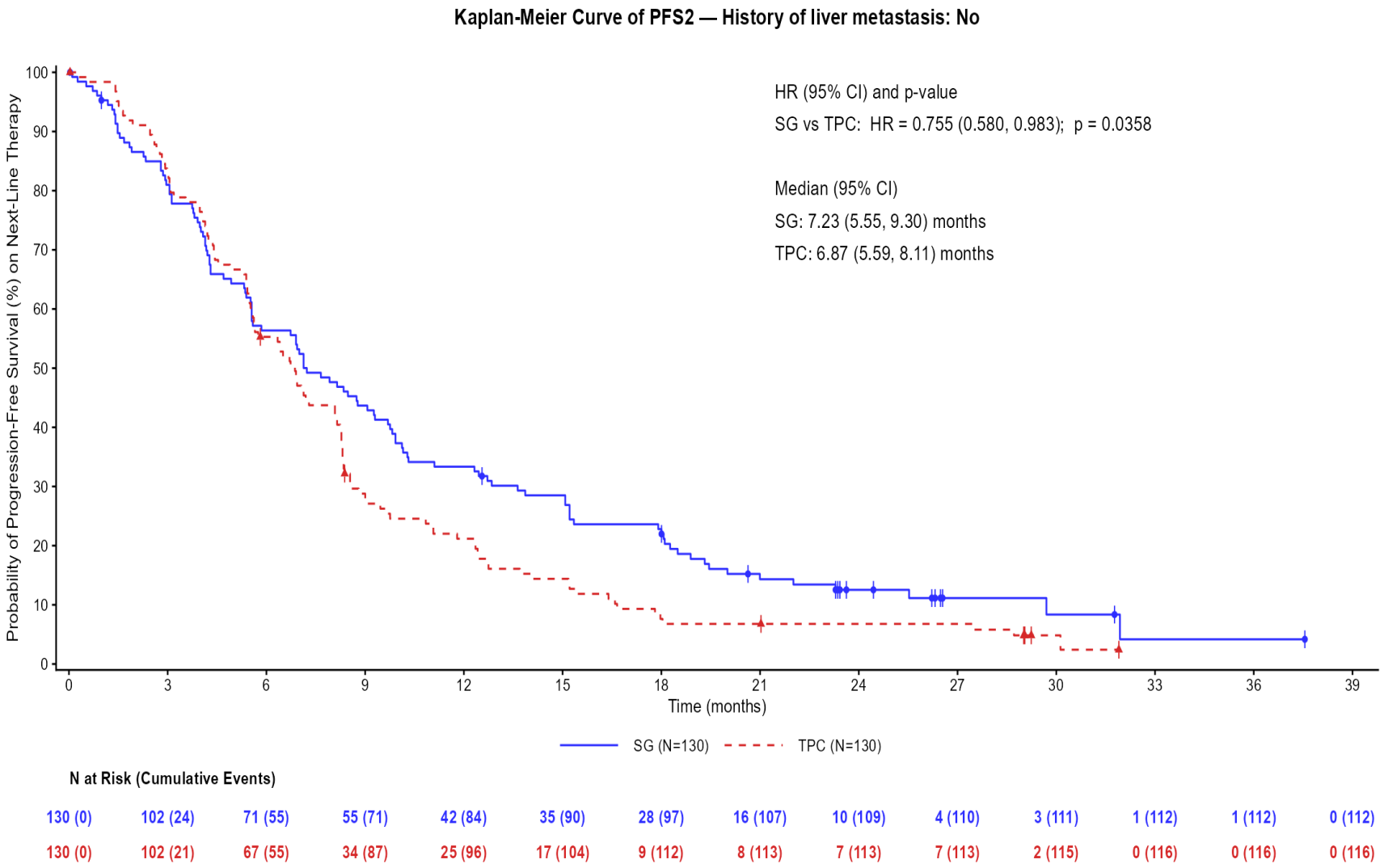
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.12. Figure 1.1.12: Kaplan-Meier Curve of PFS2 — History of liver metastasis: Yes — mITT — Excluding patients preselected to receive nab-paclitaxel



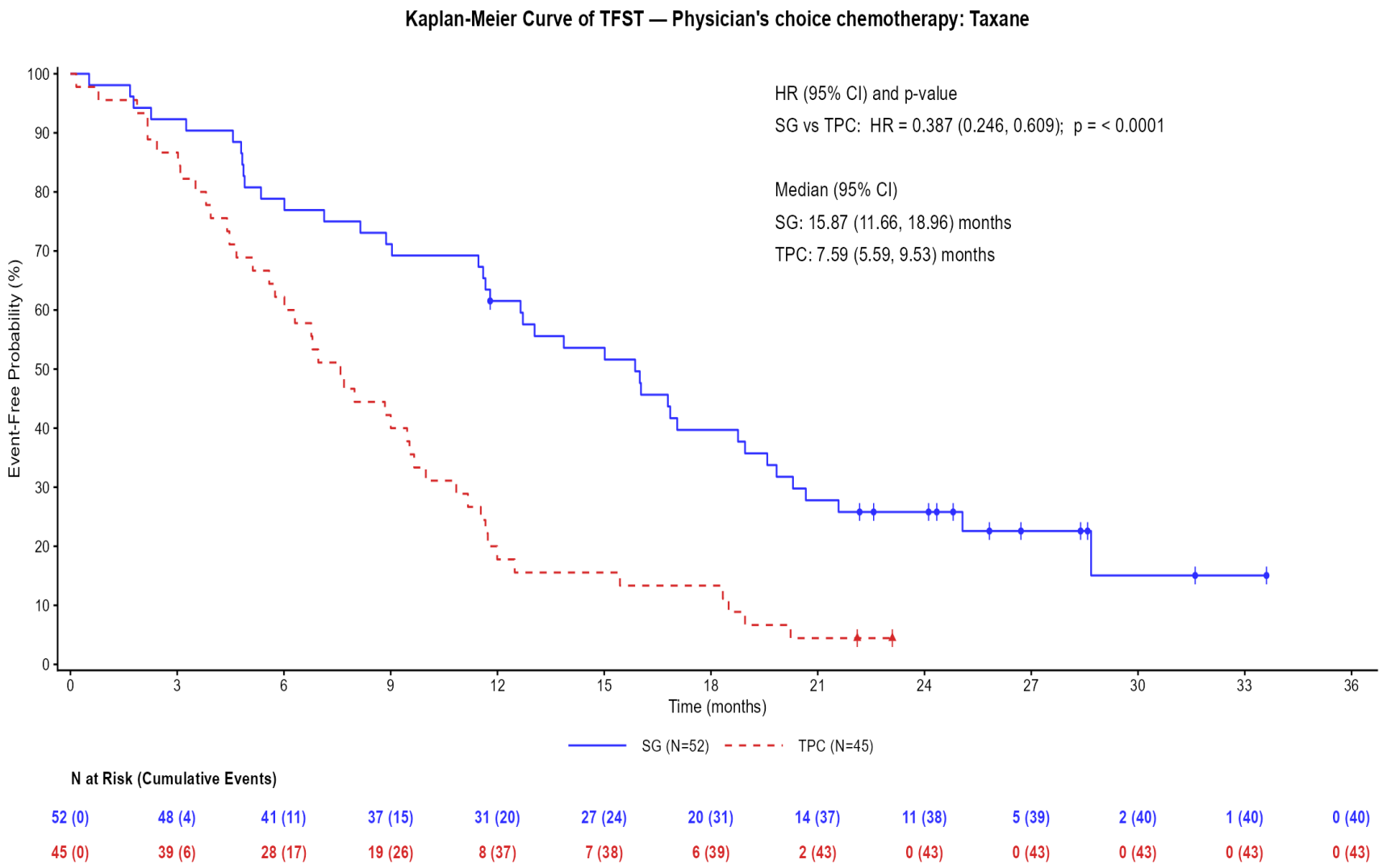
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.13. Figure 1.1.13: Kaplan-Meier Curve of PFS2 — History of liver metastasis: No — mITT — Excluding patients preselected to receive nab-paclitaxel



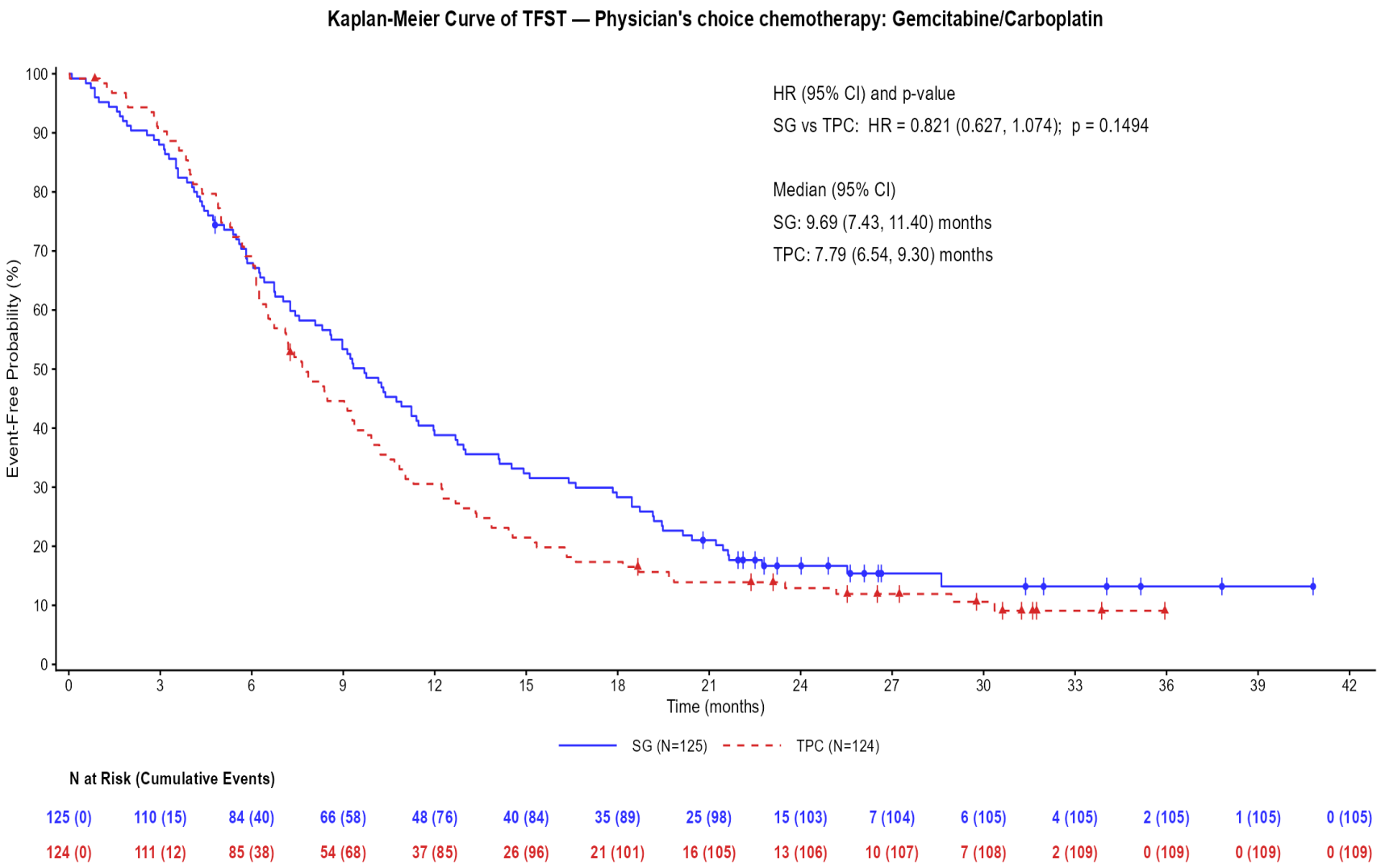
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.14. Figure 1.1.14: Kaplan-Meier Curve of TFST — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

7.15. Figure 1.1.15: Kaplan-Meier Curve of TFST — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel

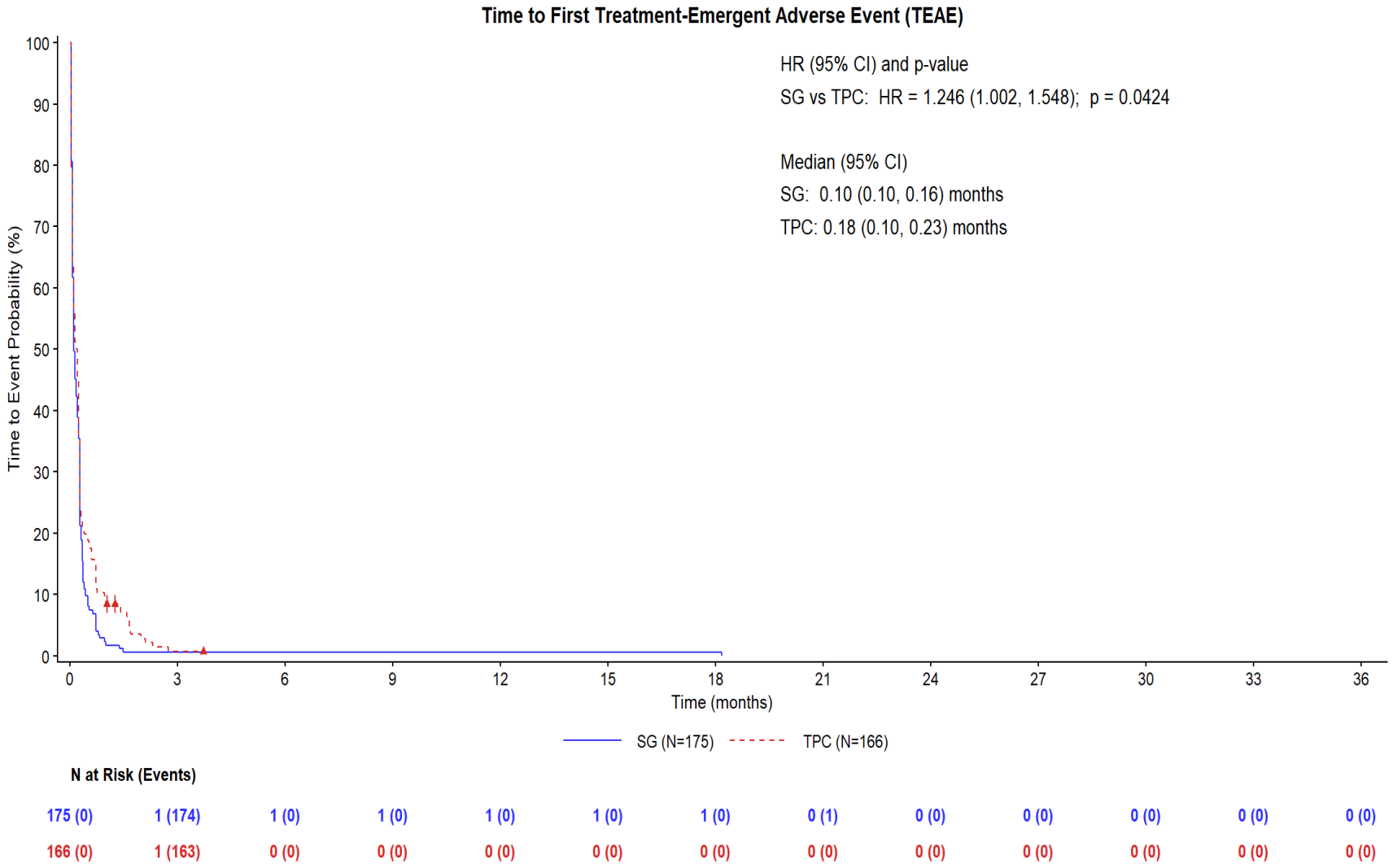


SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached.

8. KM FIGURES — Safety

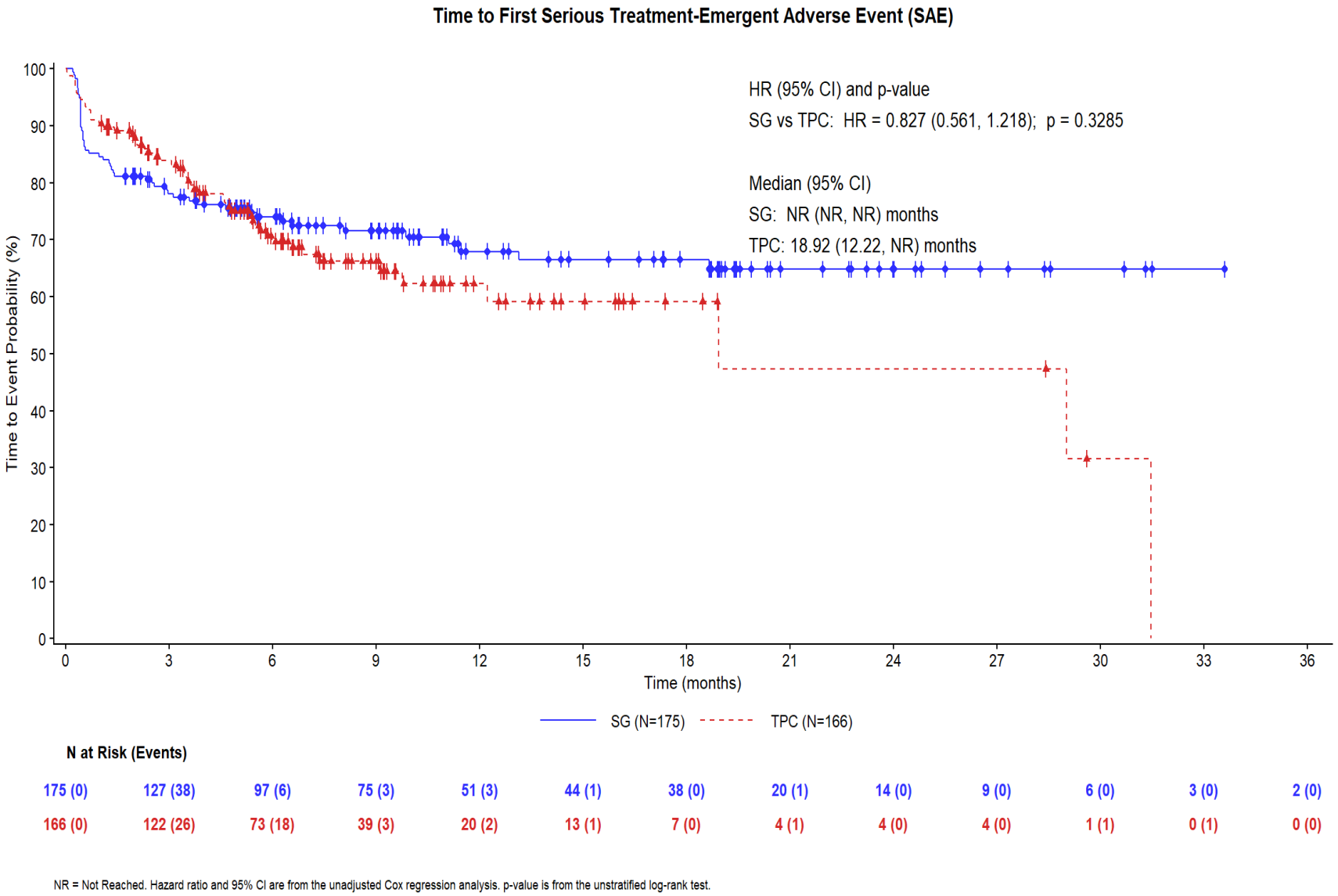
8.1. mSAF — Excluding patients preselected to receive nab-paclitaxel

8.2. Figure 1.1.1: Kaplan Meier Plot of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel



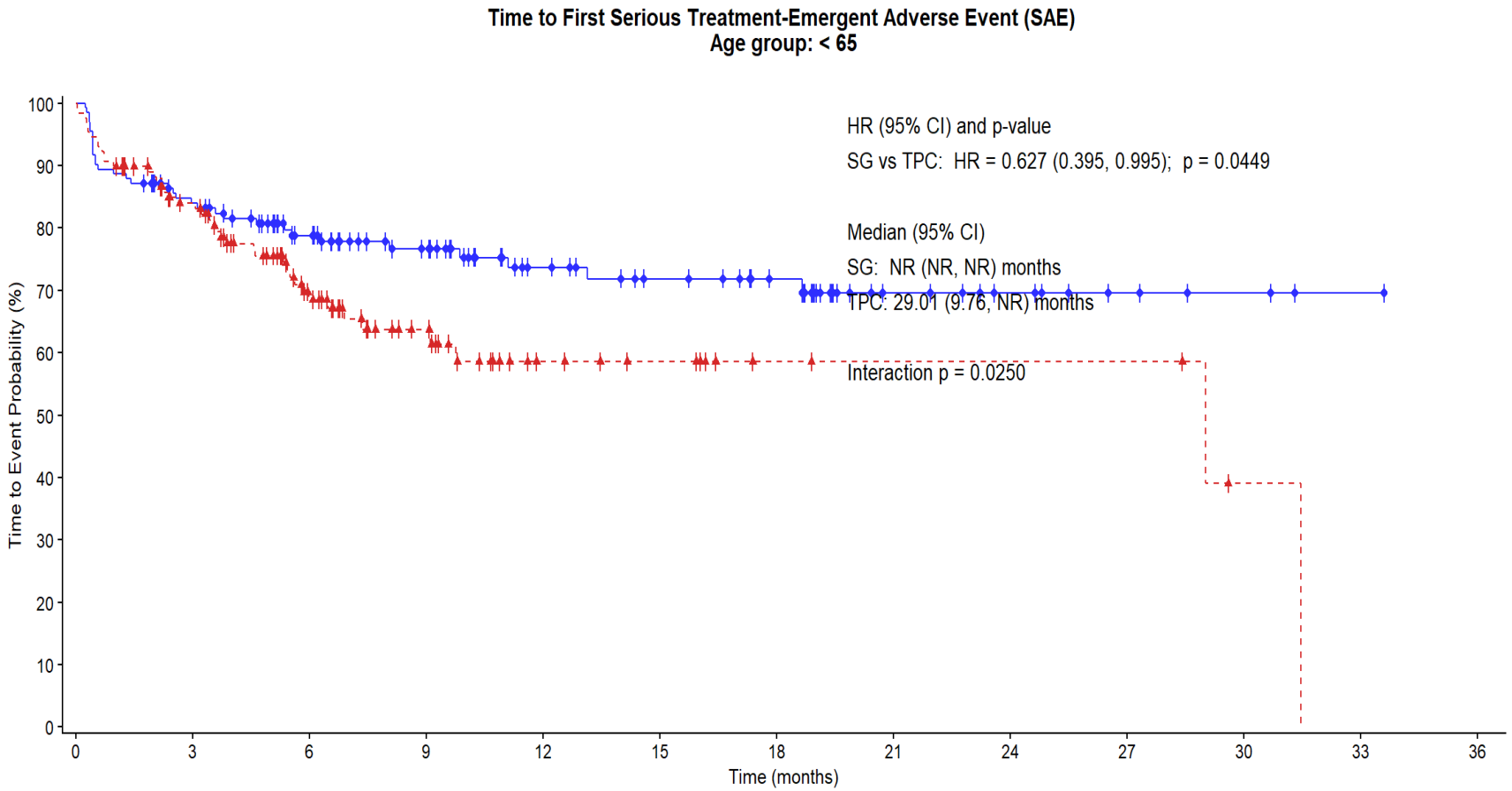
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.3. Figure 1.1.2: Kaplan Meier Plot of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel



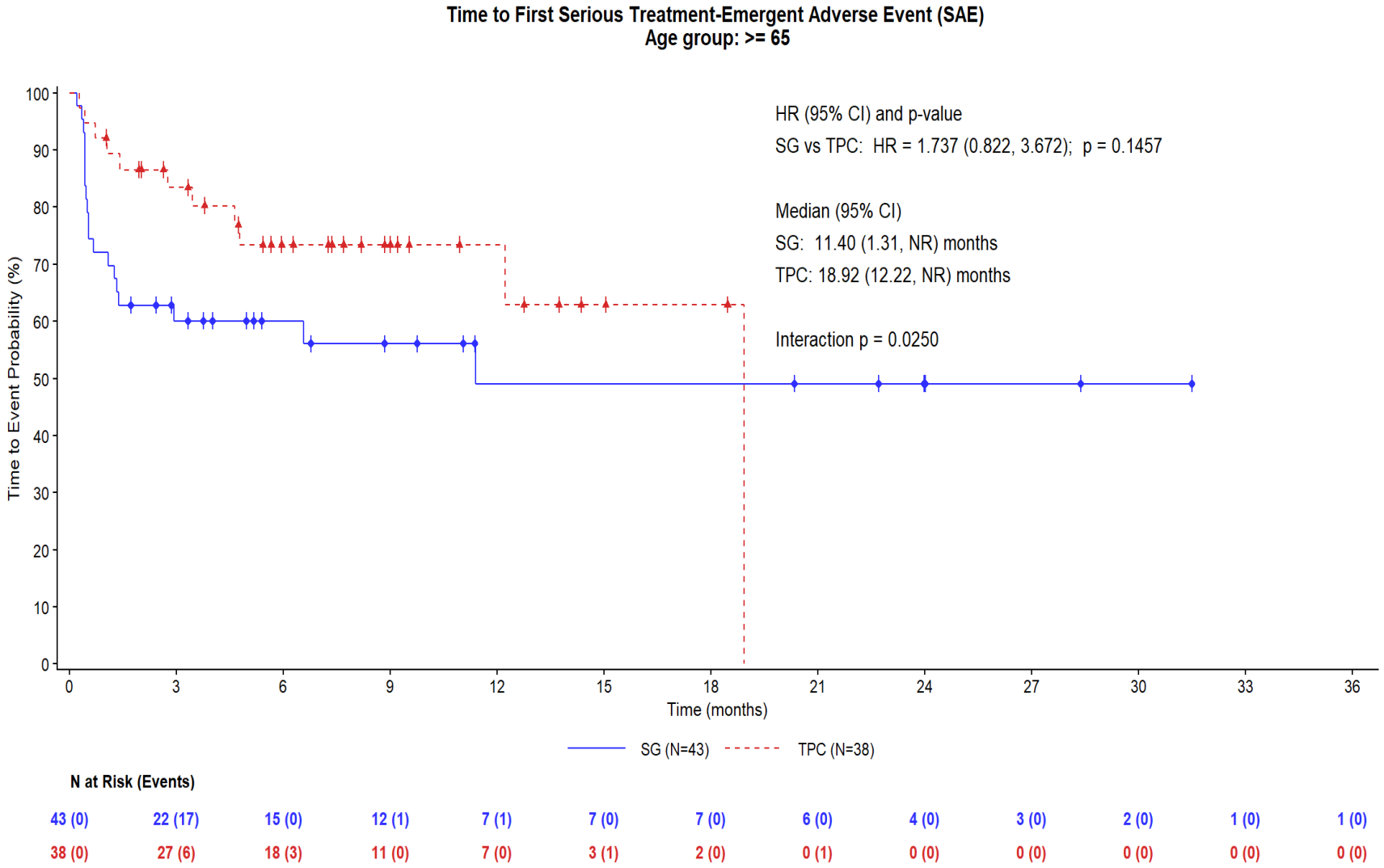
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.4. Figure 1.1.3: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



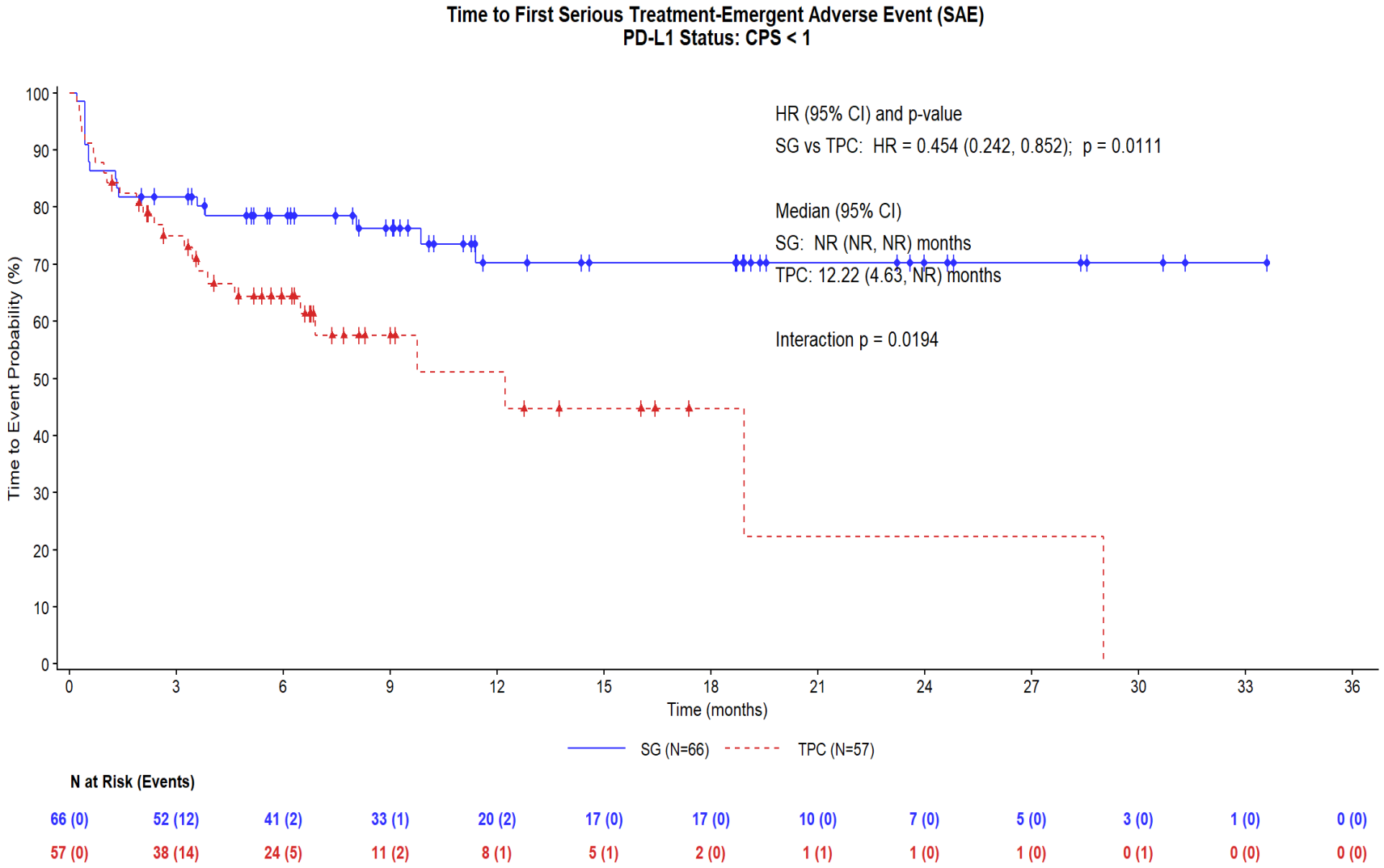
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.5. Figure 1.1.4: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



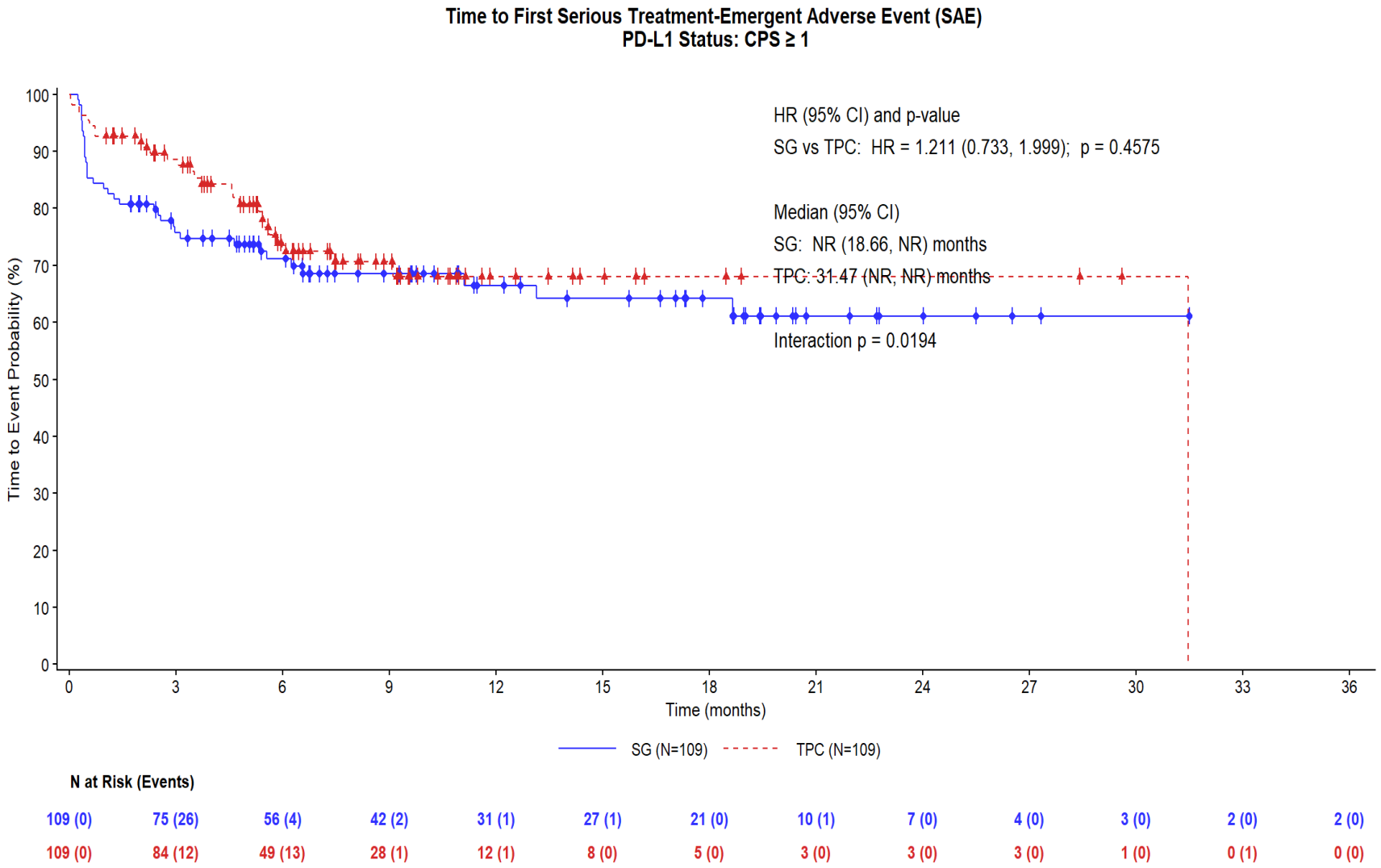
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.6. Figure 1.1.5: Kaplan Meier Plot of Time to First Serious TEAE (SAE) PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



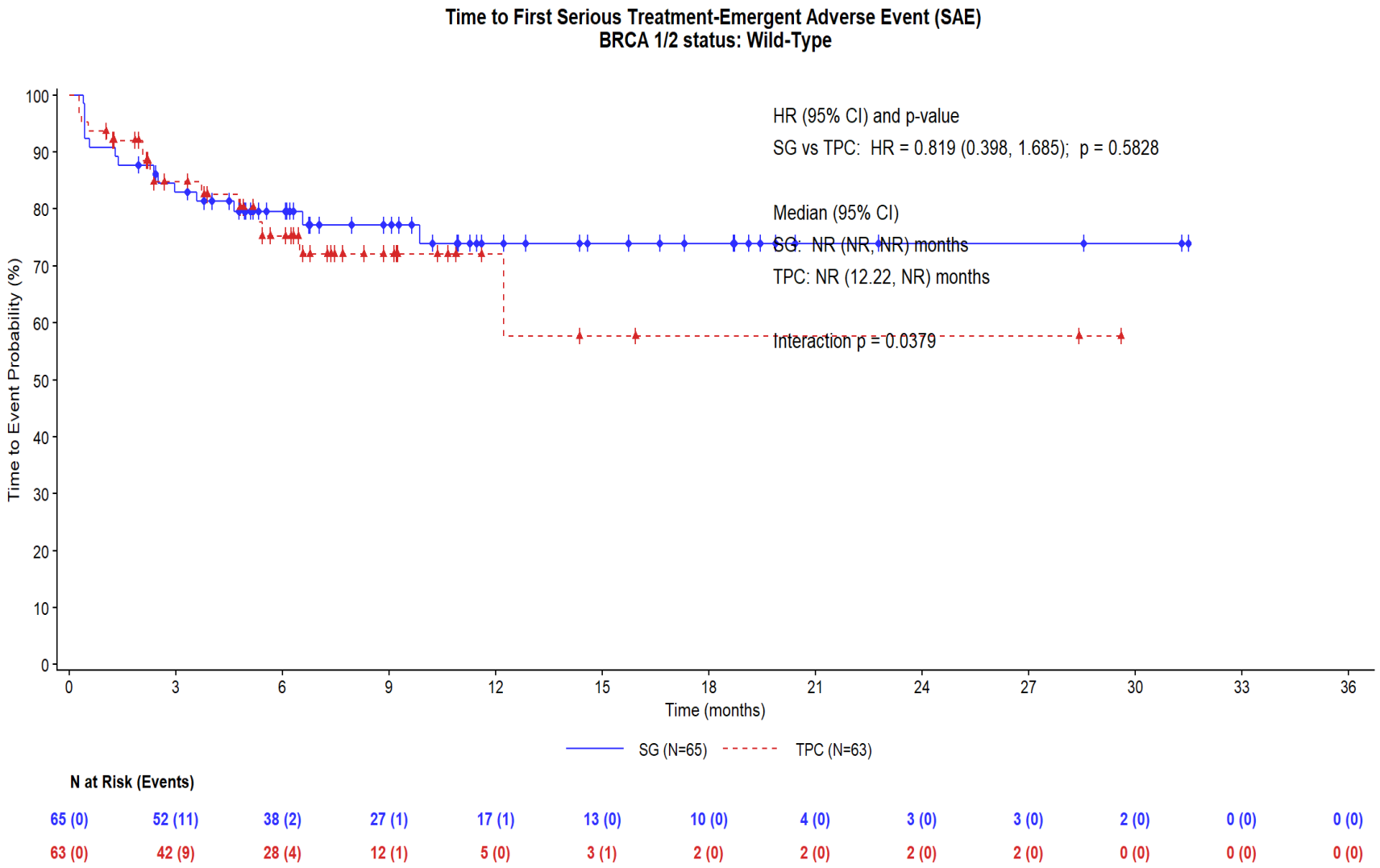
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.7. Figure 1.1.6: Kaplan Meier Plot of Time to First Serious TEAE (SAE) PD L1 Status CPS 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



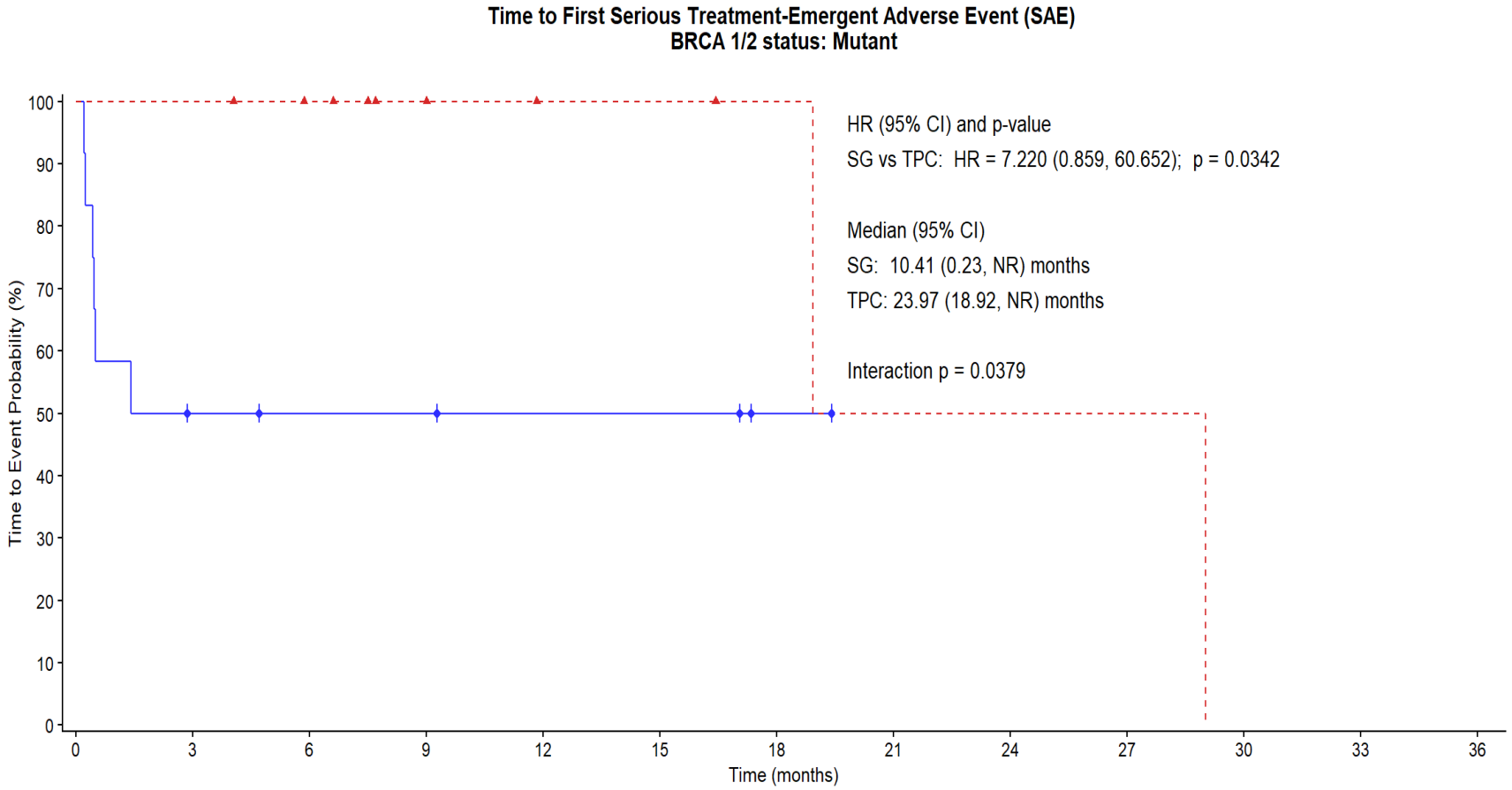
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.8. Figure 1.1.7: Kaplan Meier Plot of Time to First Serious TEAE (SAE) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel



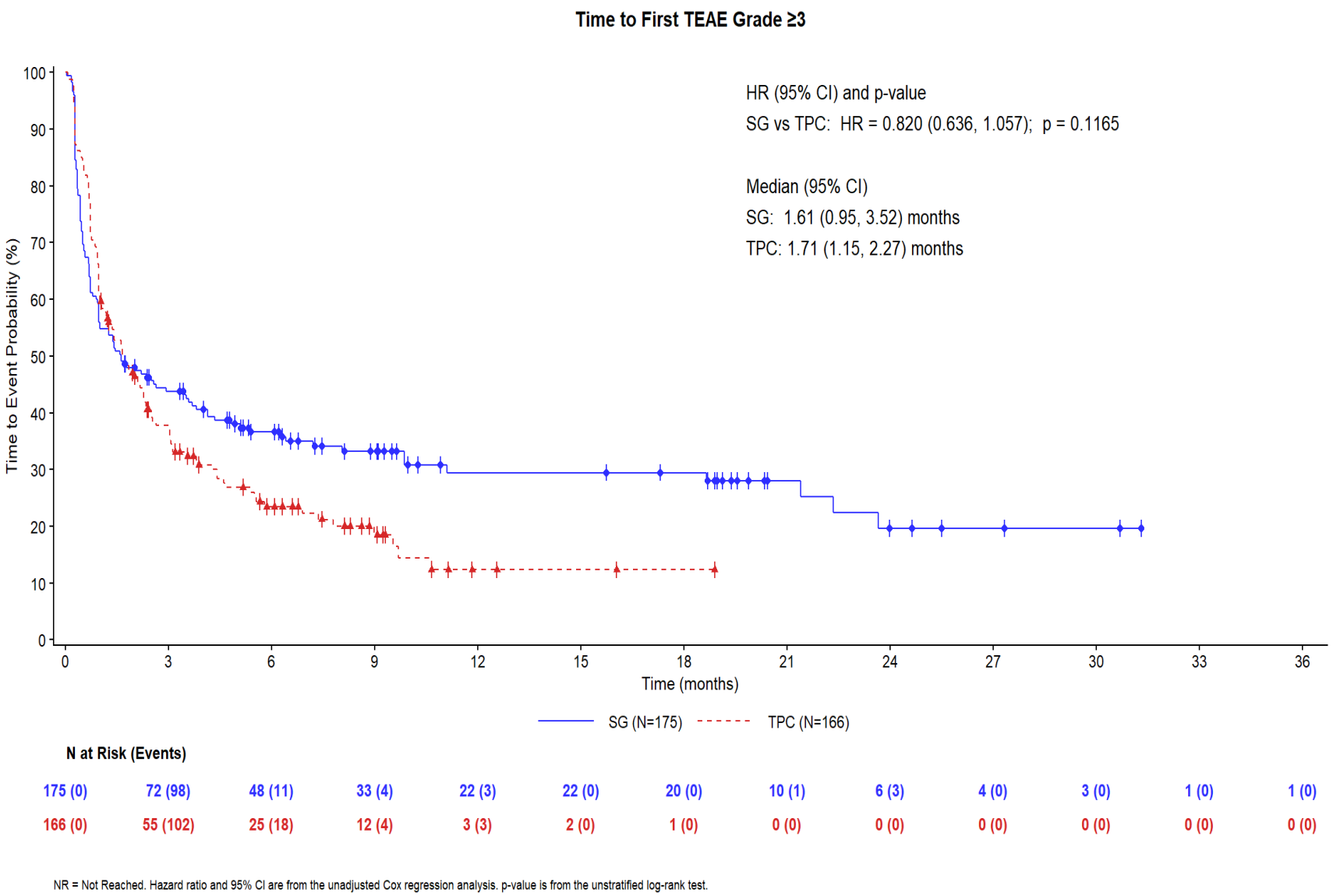
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.9. Figure 1.1.8: Kaplan Meier Plot of Time to First Serious TEAE (SAE) BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel



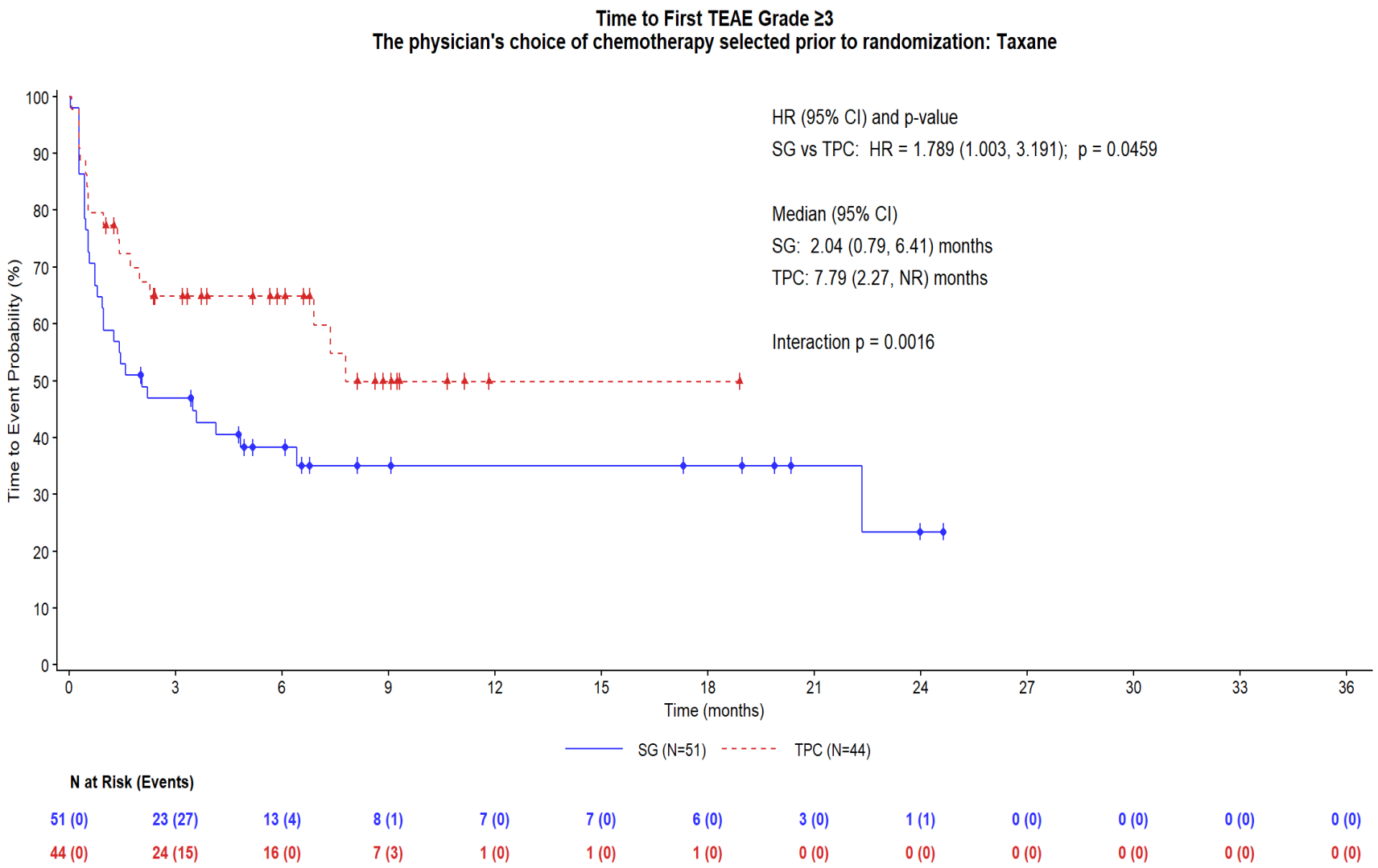
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.10. Figure 1.1.9: Kaplan Meier Plot of Time to First TEAE Grade 3 or higher — mSAF — Excluding patients preselected to receive nab-paclitaxel



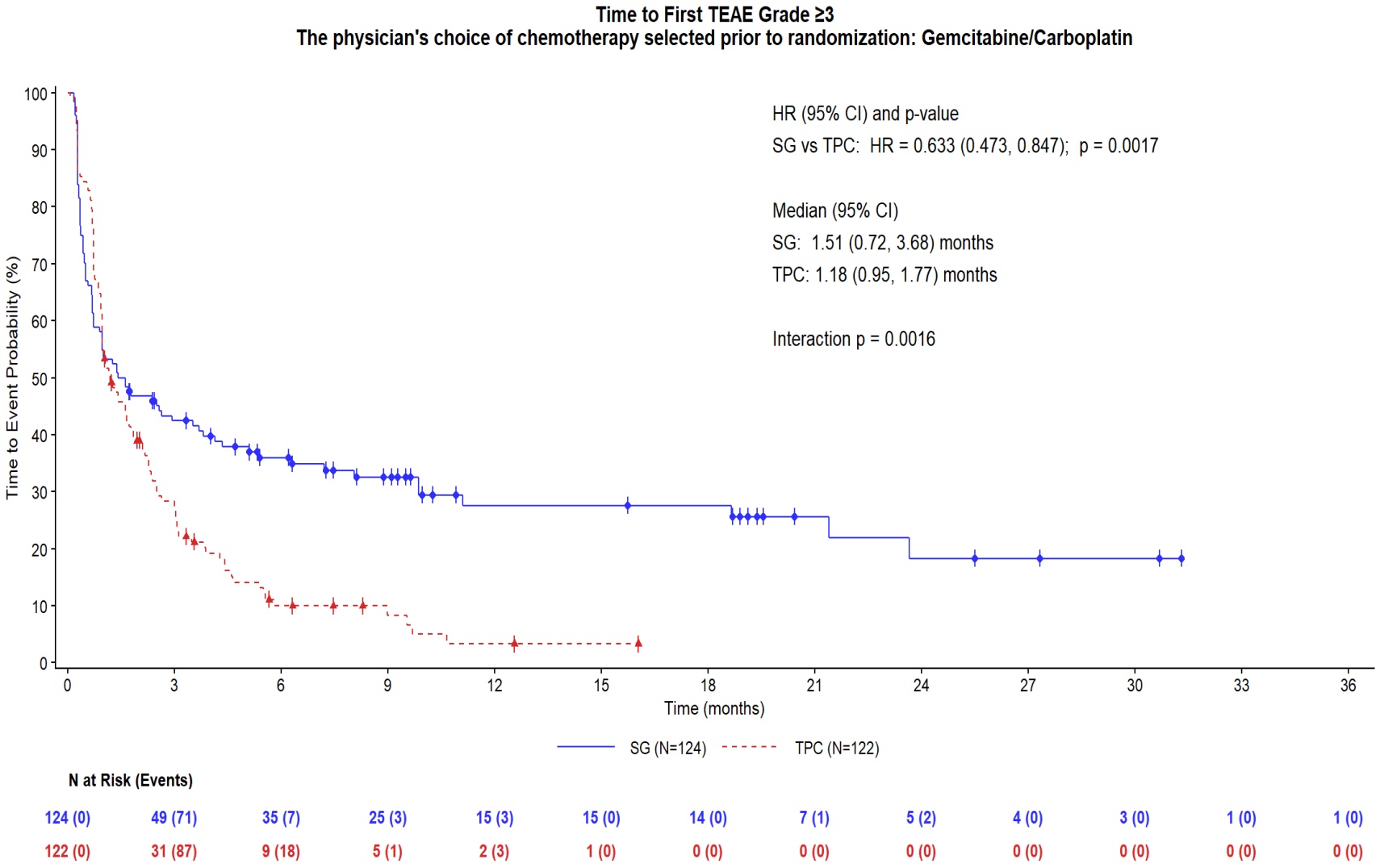
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.11. Figure 1.1.10: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



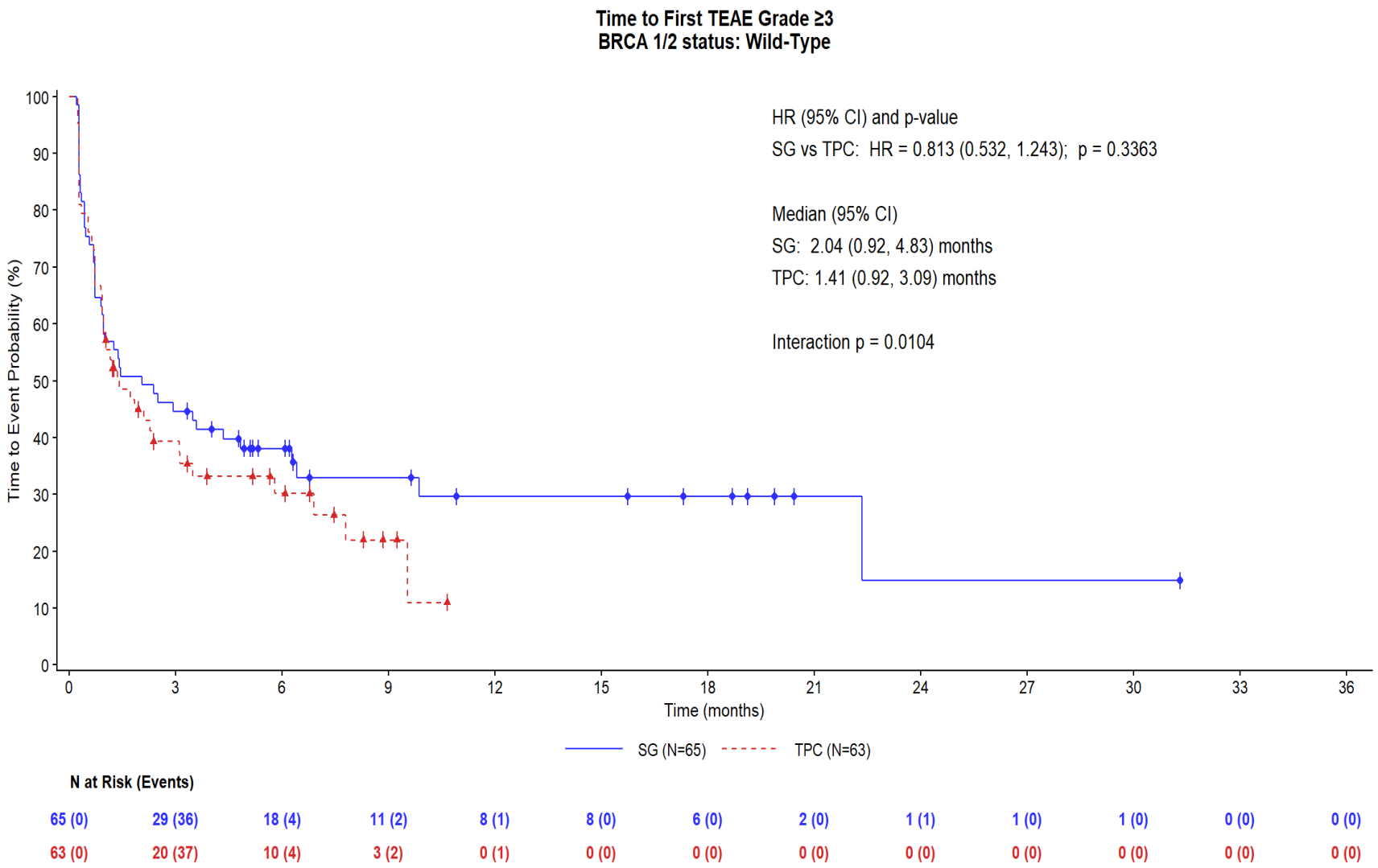
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.12. Figure 1.1.11: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



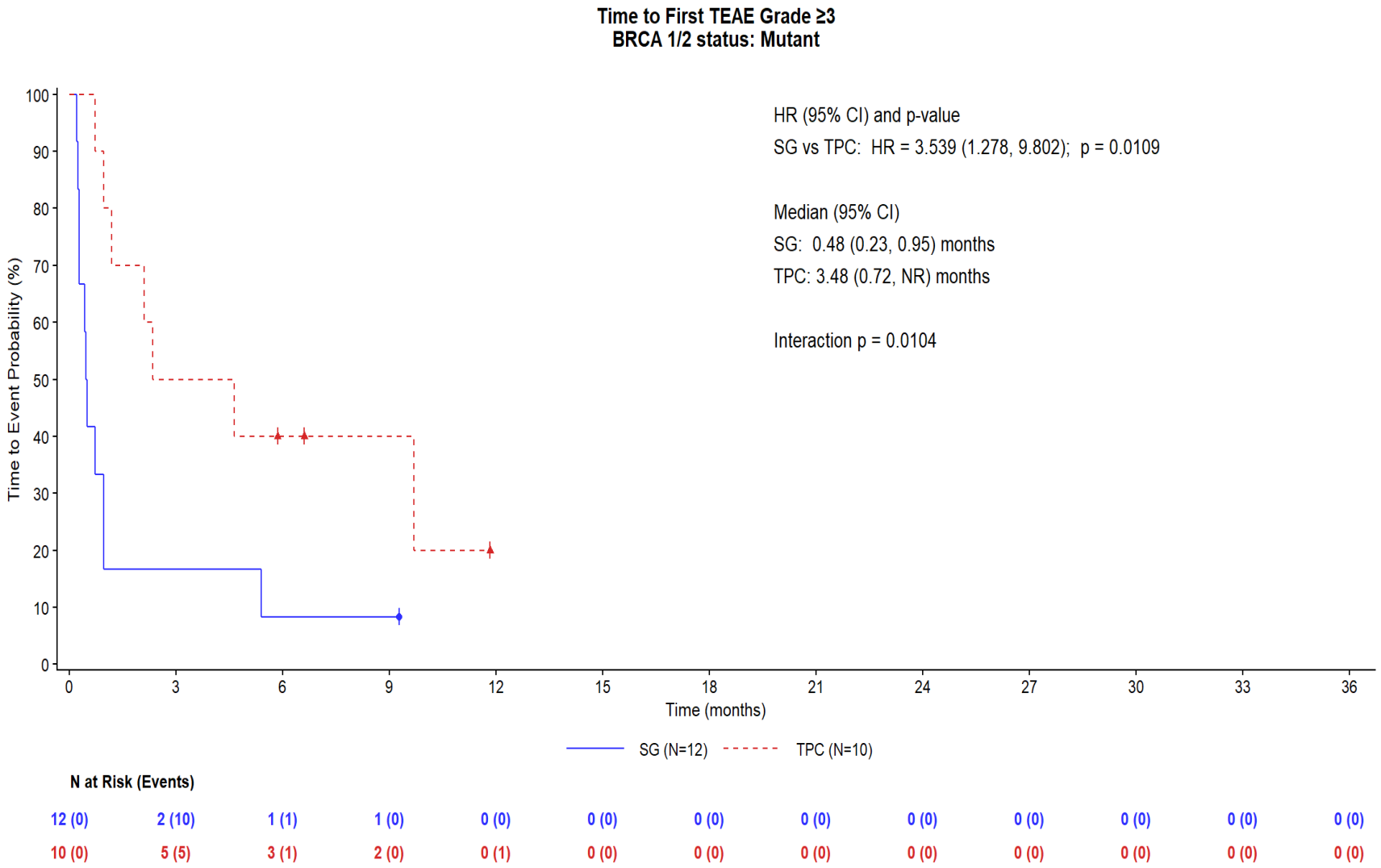
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.13. Figure 1.1.12: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel



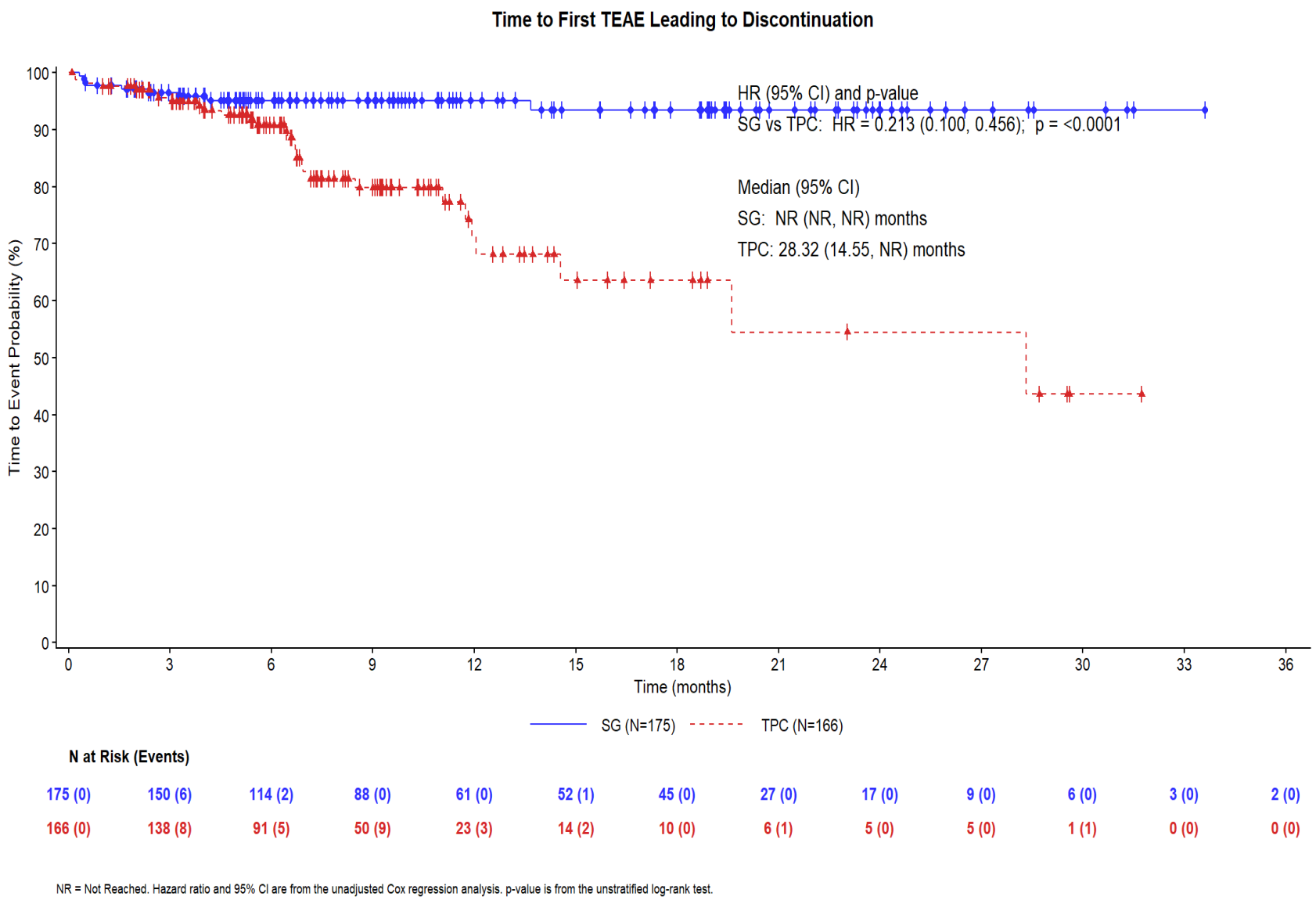
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.14. Figure 1.1.13: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel



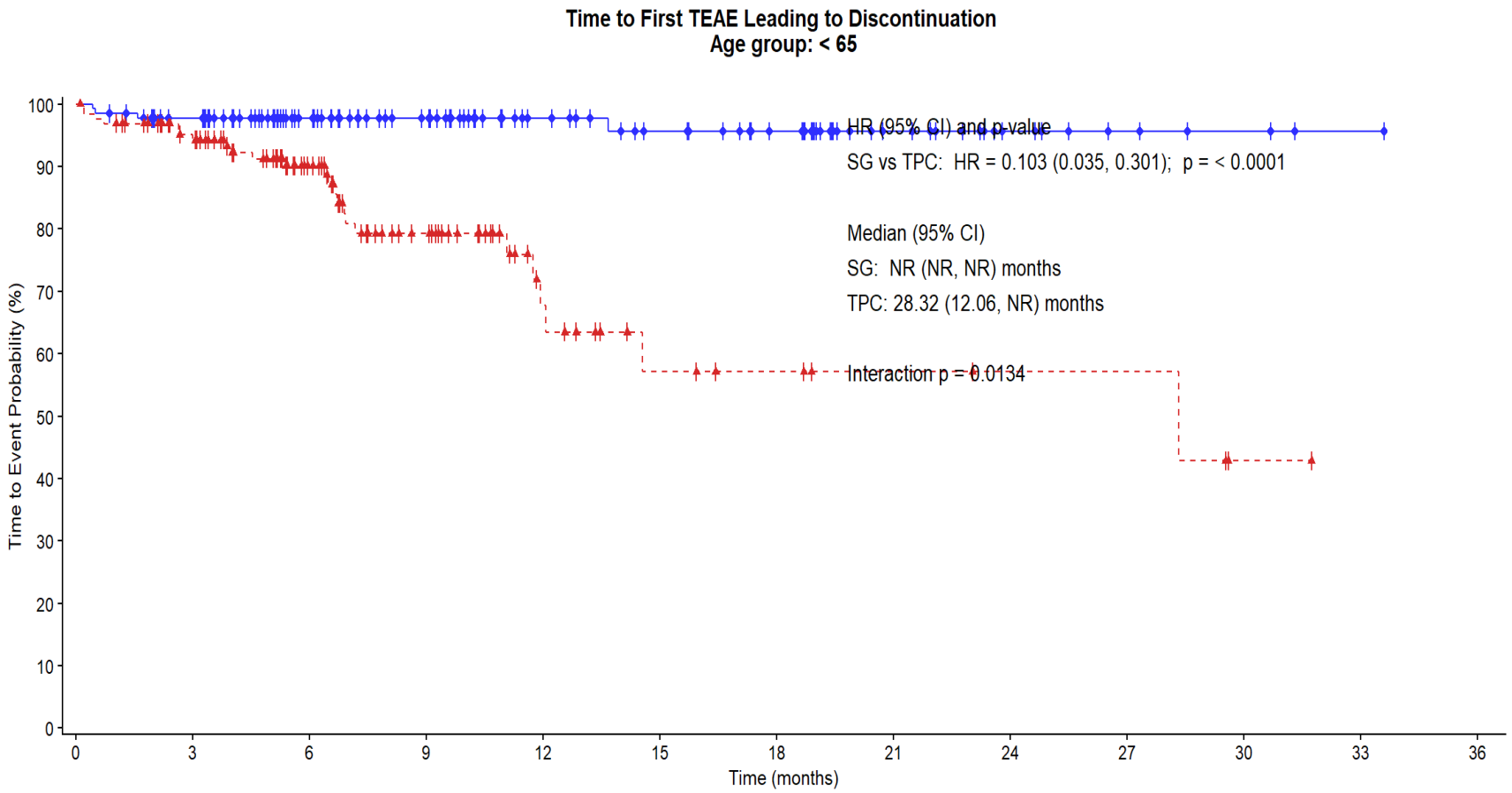
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.15. Figure 1.1.14: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel



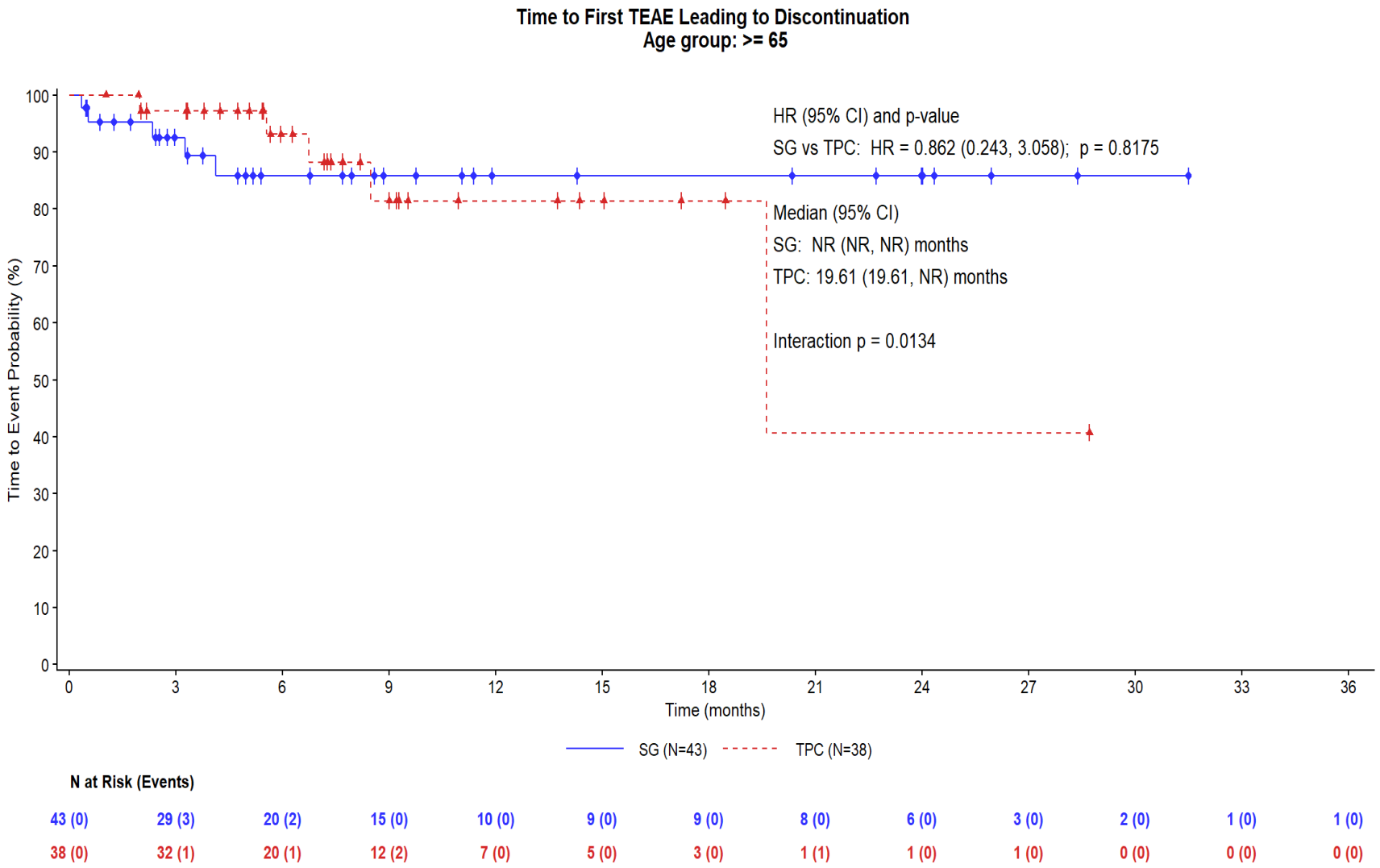
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.16. Figure 1.1.15: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



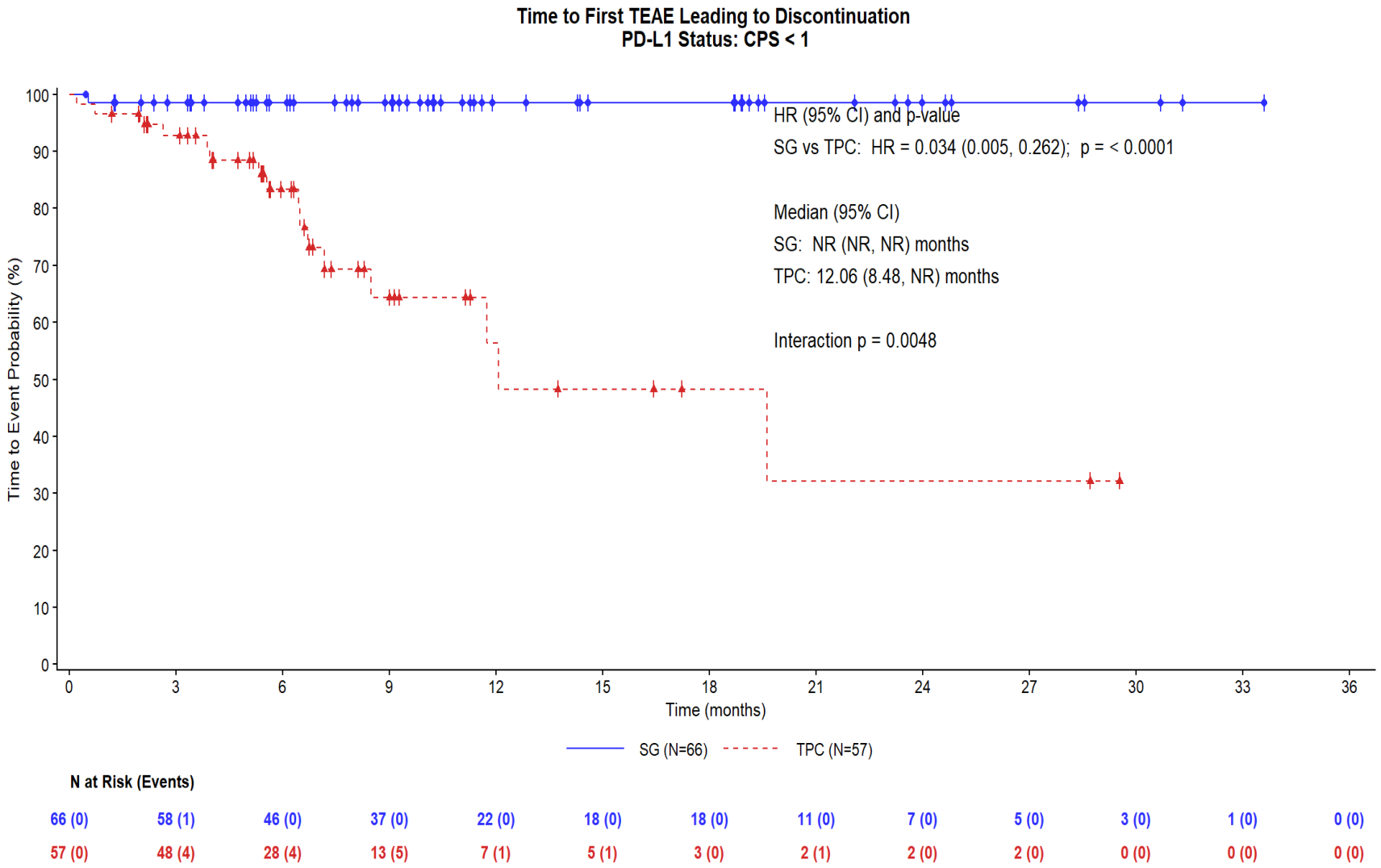
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.17. Figure 1.1.16: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



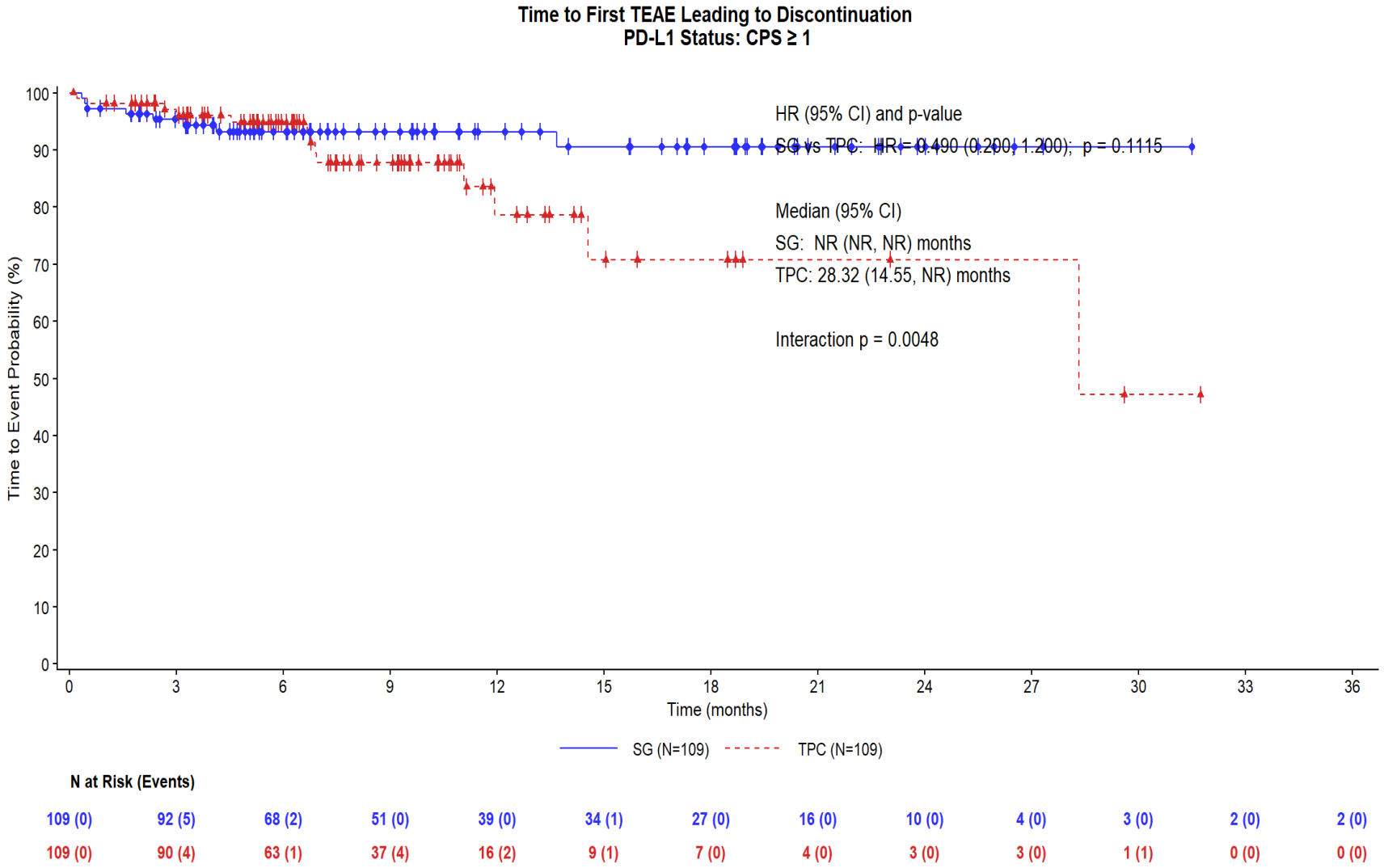
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.18. Figure 1.1.17: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



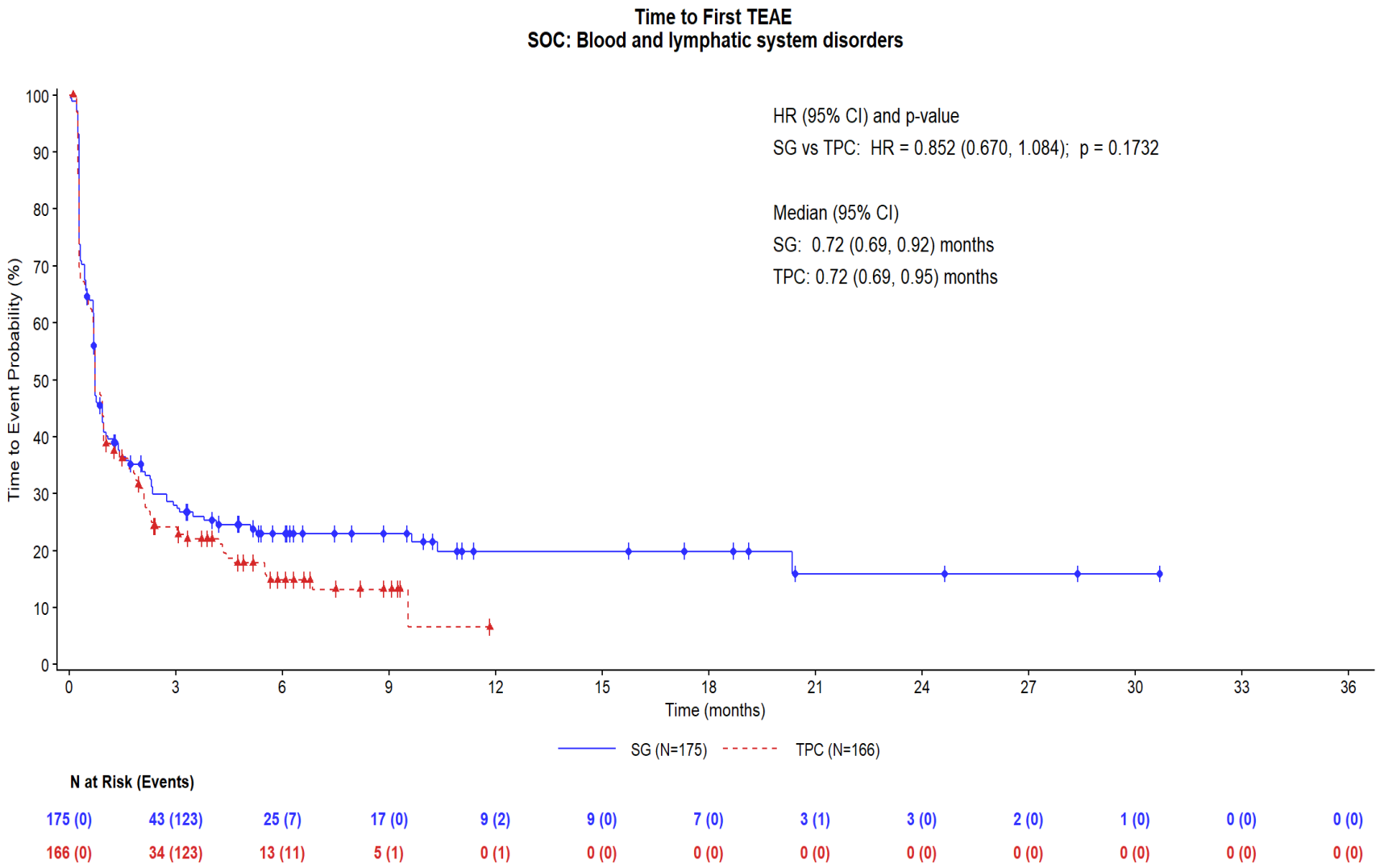
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.19. Figure 1.1.18: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



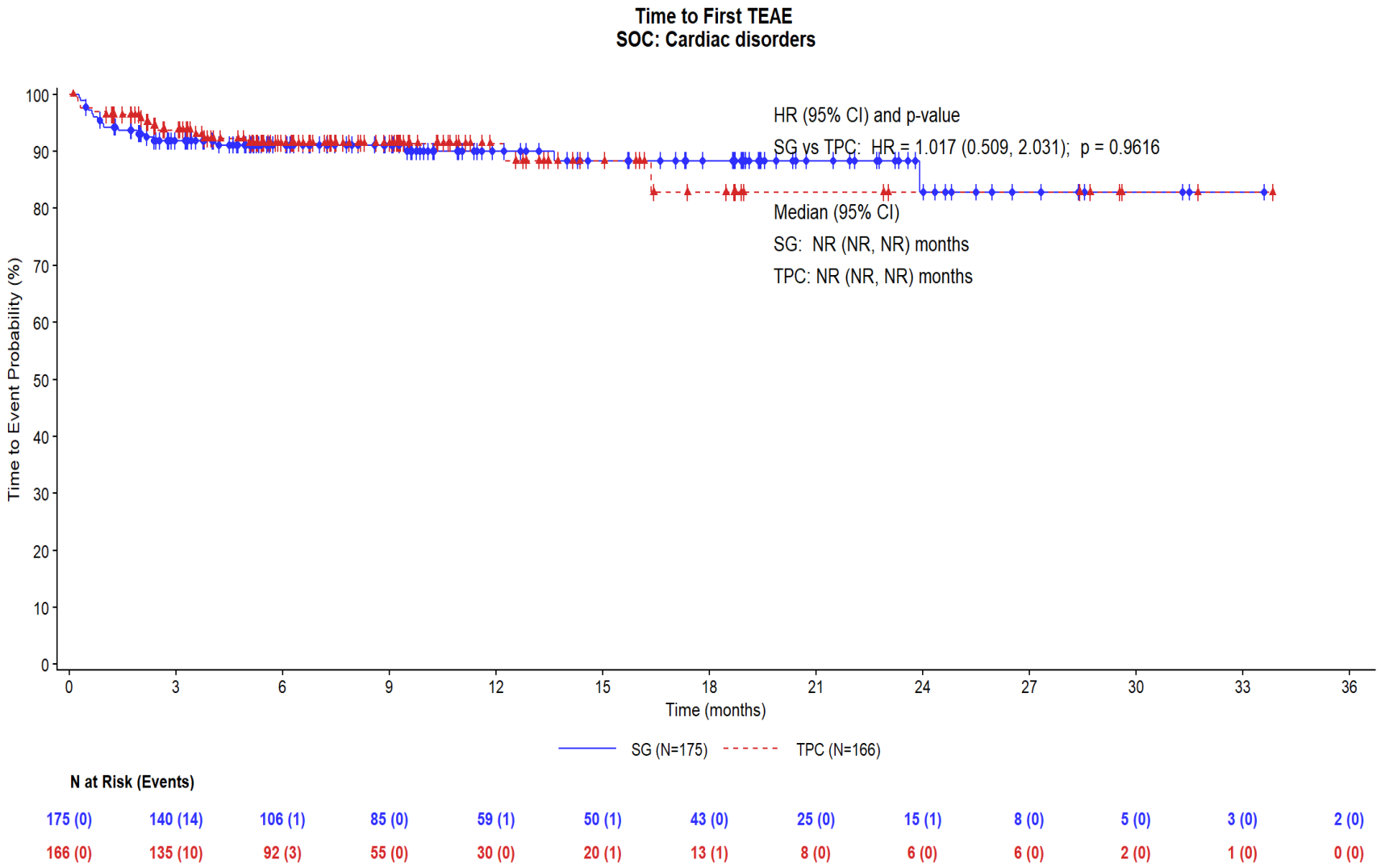
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.20. Figure 1.1.19: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



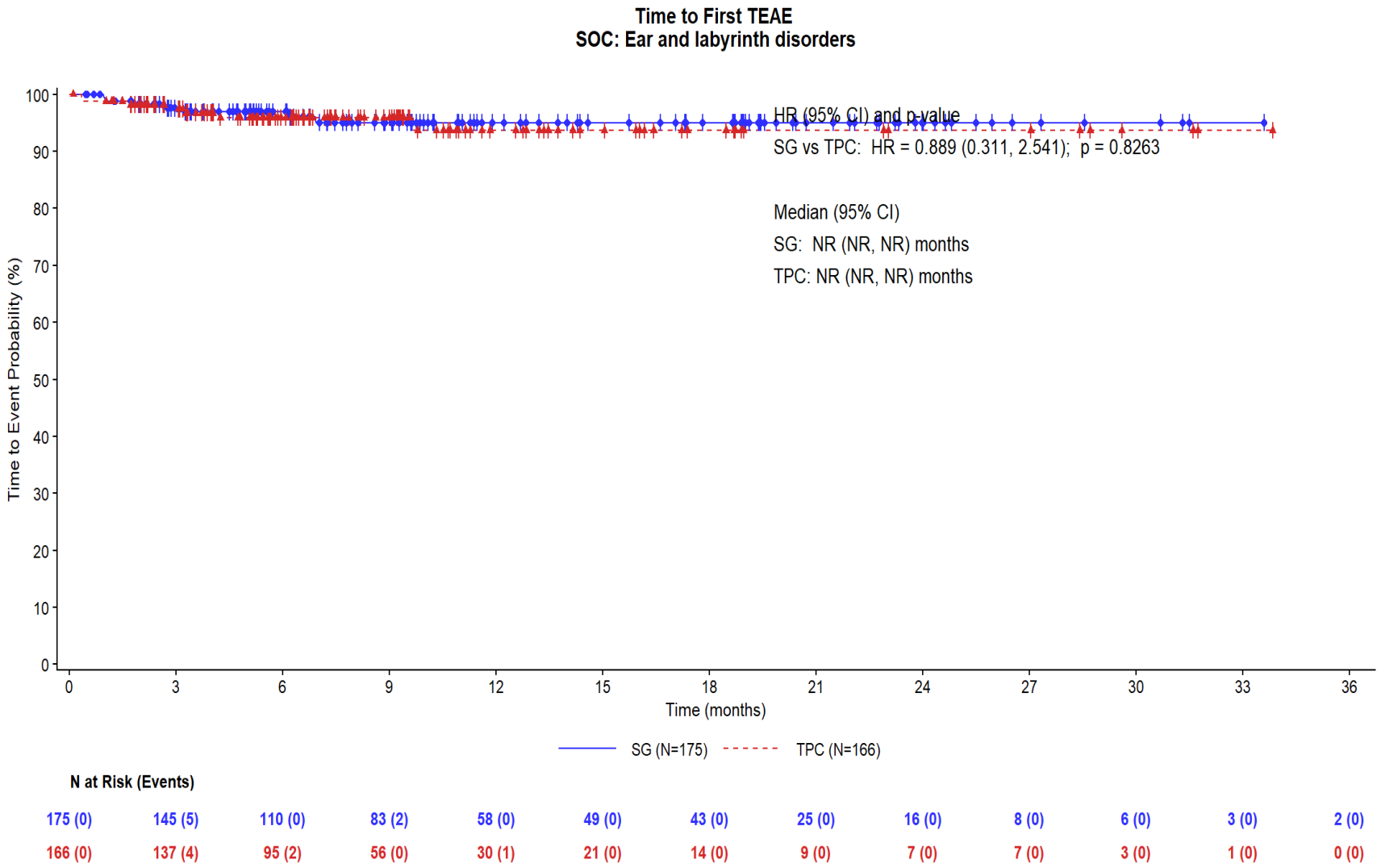
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.21. Figure 1.1.20: Kaplan Meier Plot of Time to First TEAE by SOC Cardiac disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



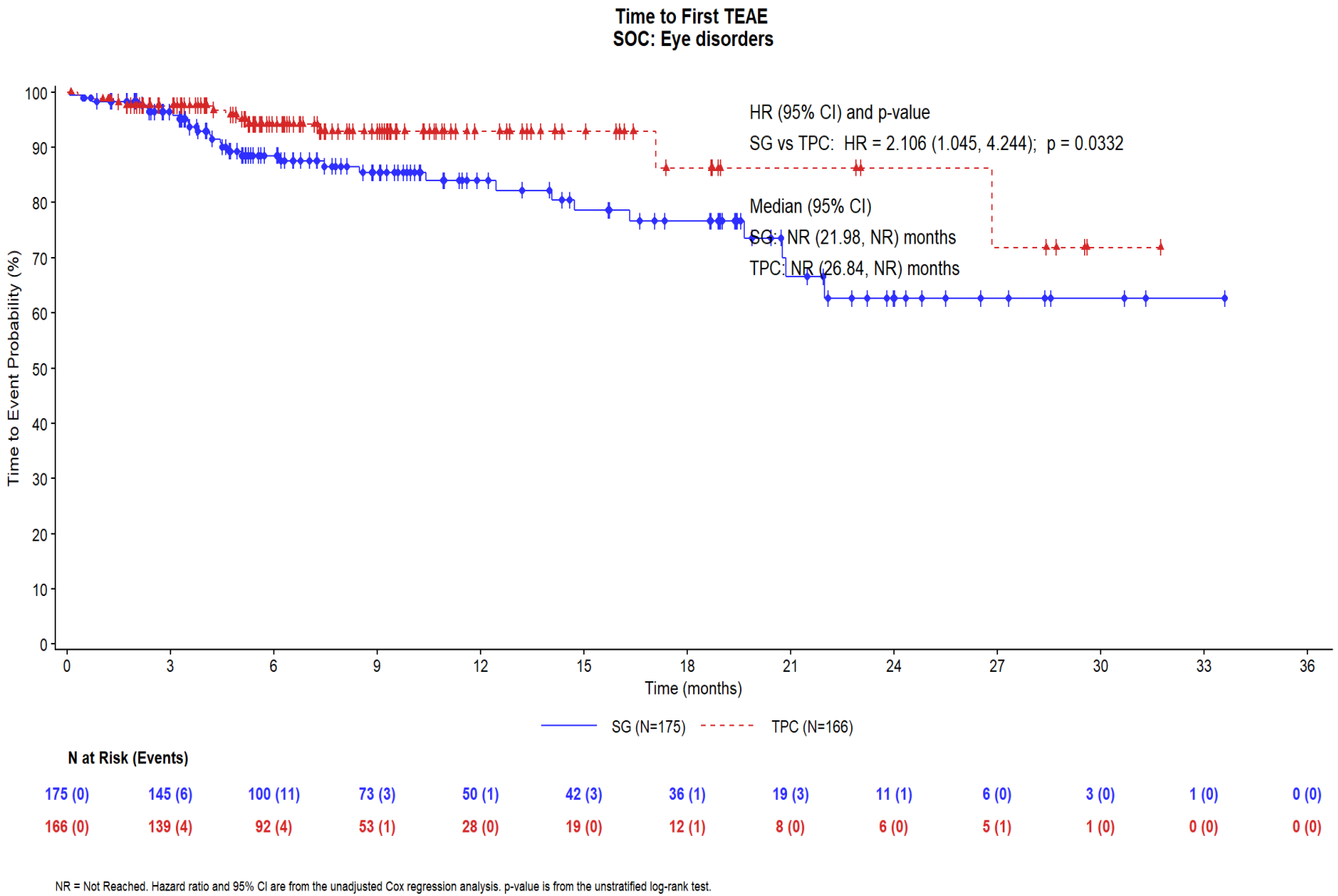
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.22. Figure 1.1.21: Kaplan Meier Plot of Time to First TEAE by SOC Ear and labyrinth disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



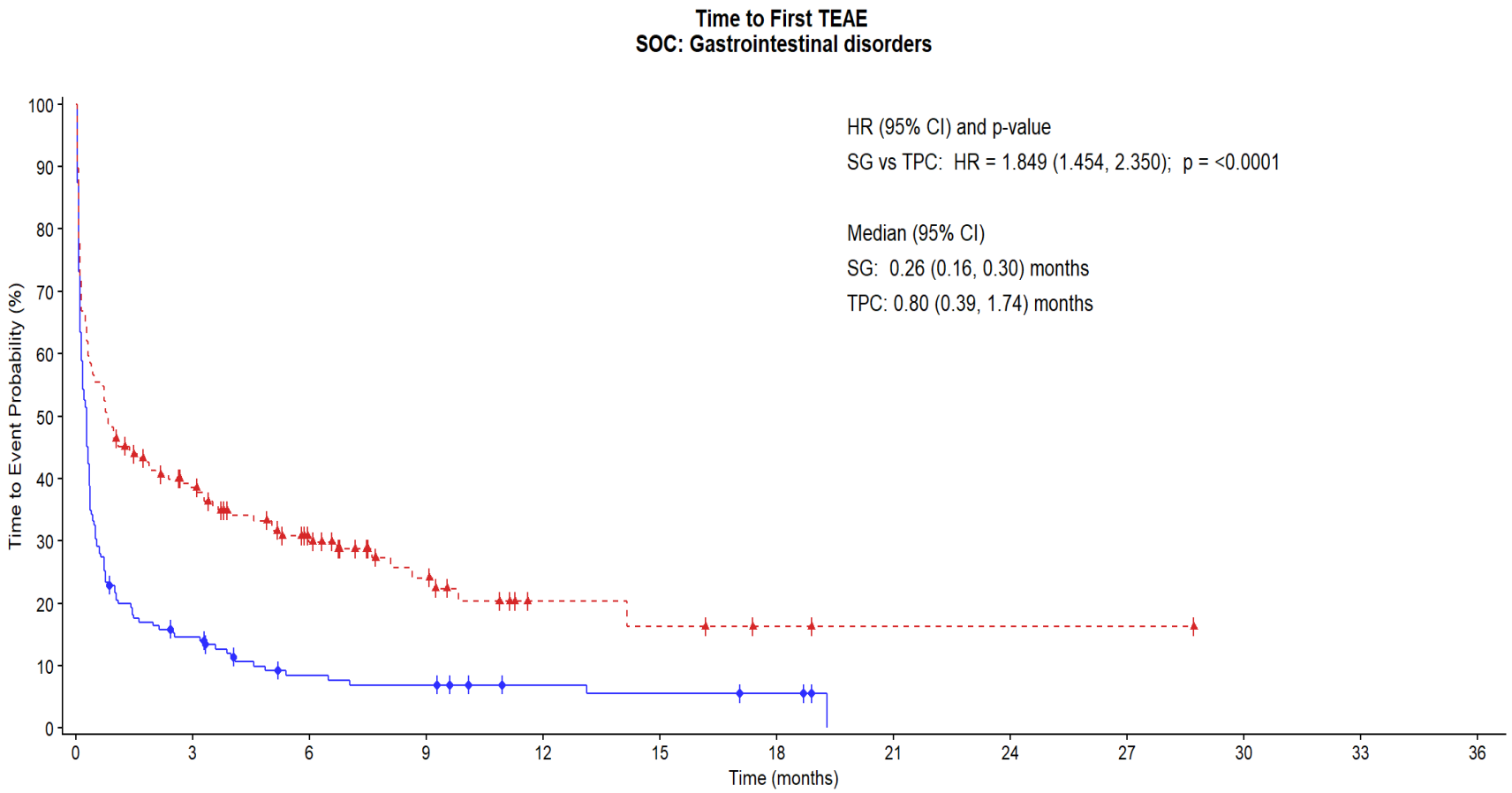
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.23. Figure 1.1.22: Kaplan Meier Plot of Time to First TEAE by SOC Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



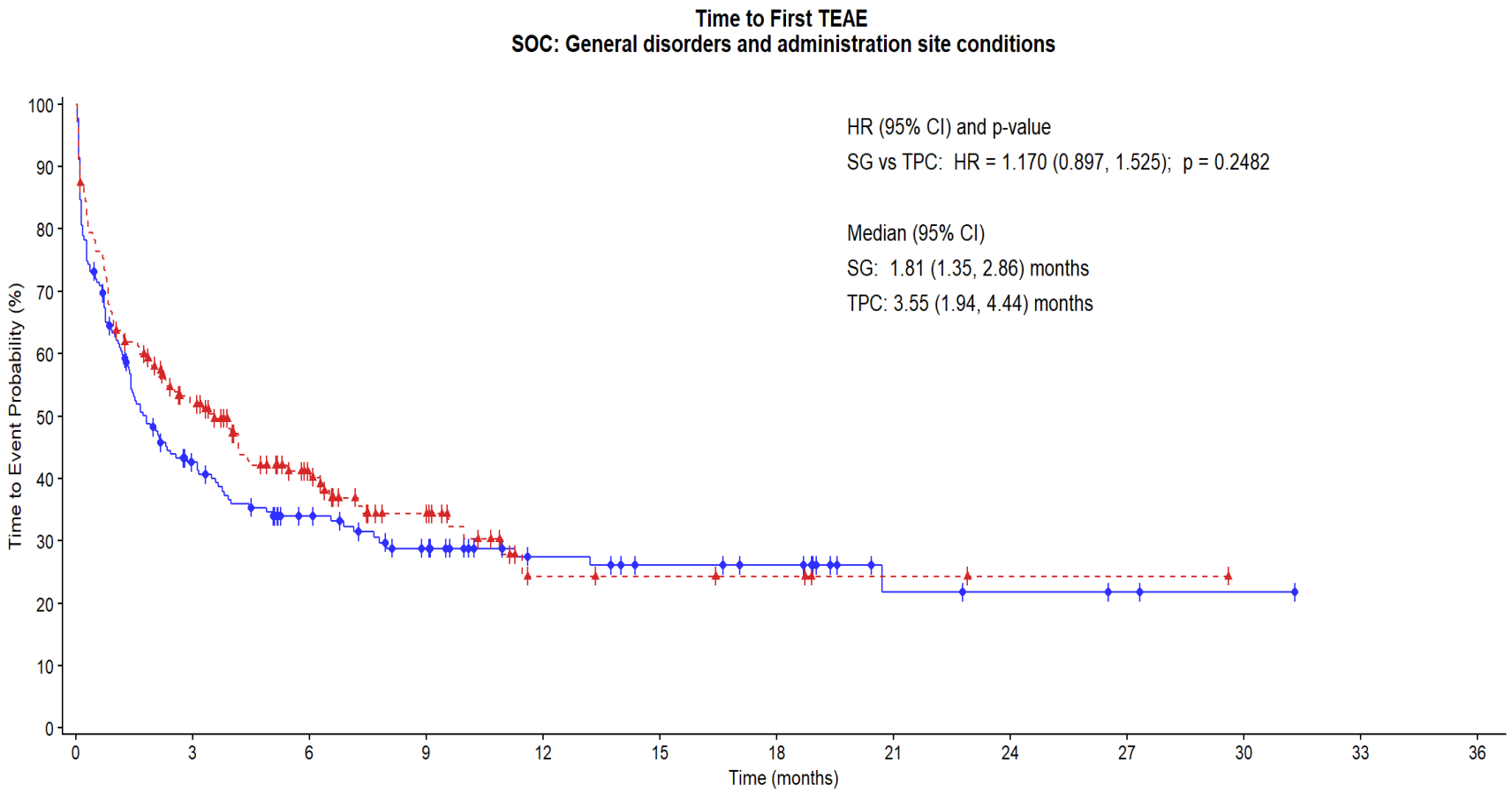
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.24. Figure 1.1.23: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



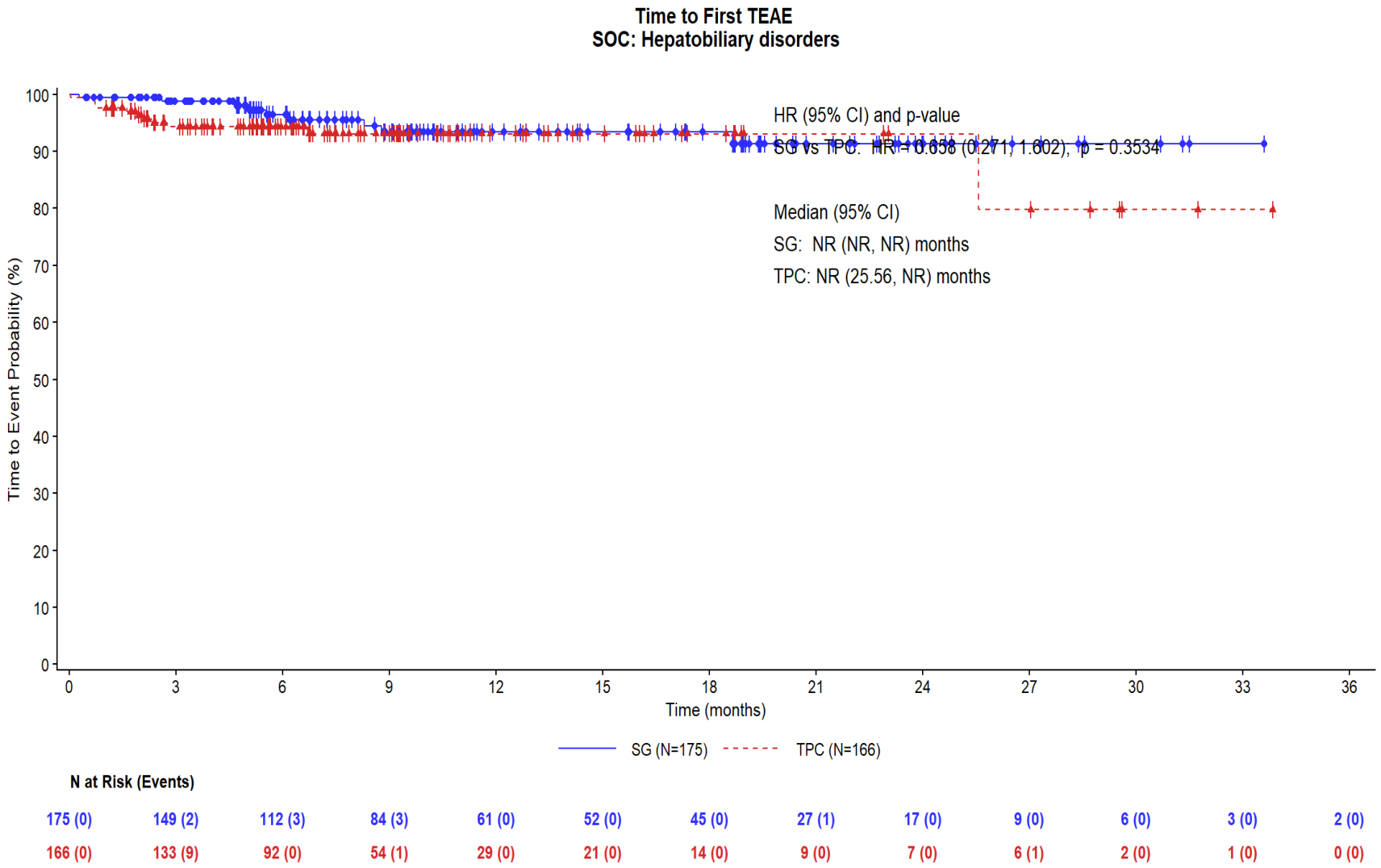
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.25. Figure 1.1.24: Kaplan Meier Plot of Time to First TEAE by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel



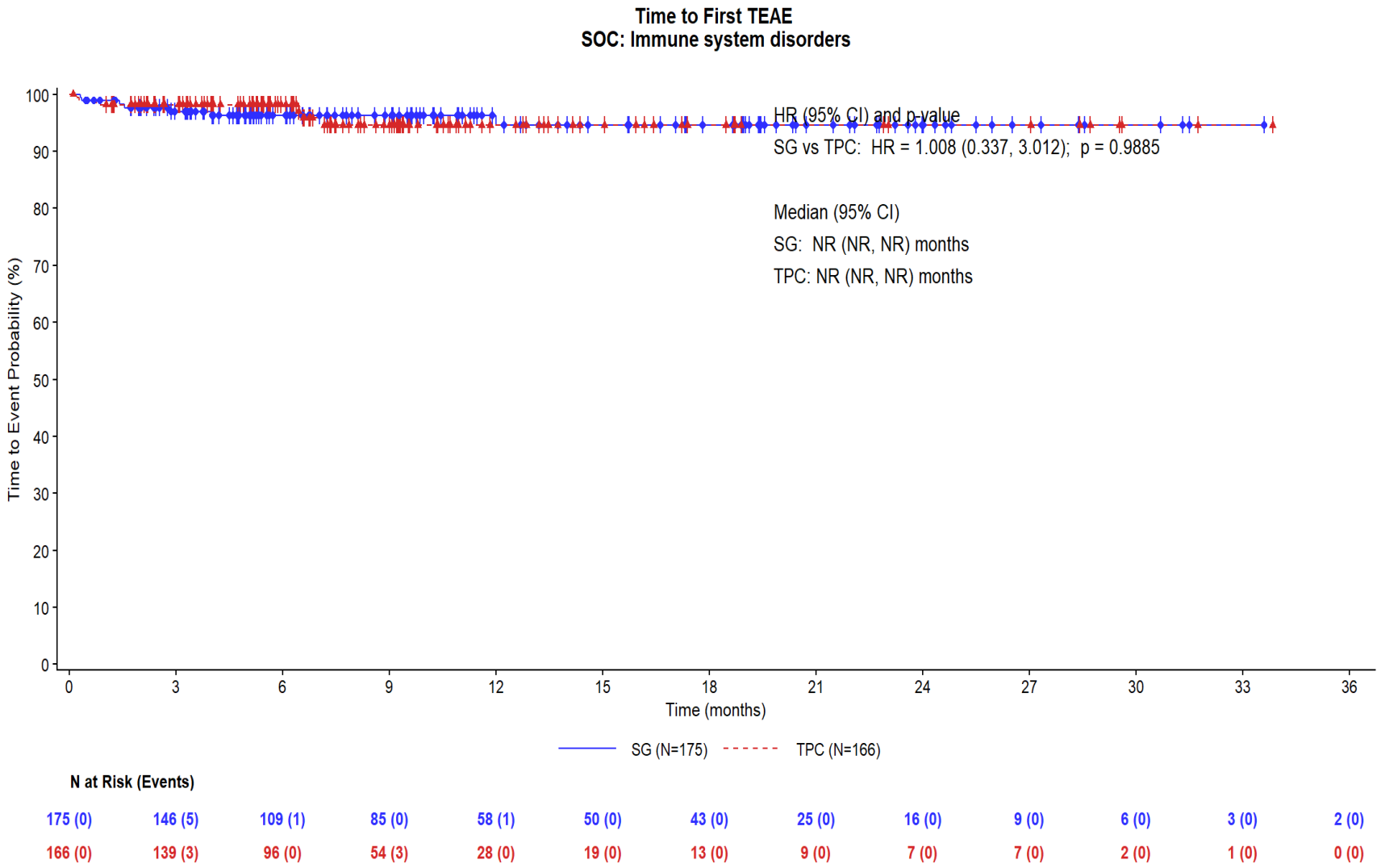
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.26. Figure 1.1.25: Kaplan Meier Plot of Time to First TEAE by SOC Hepatobiliary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



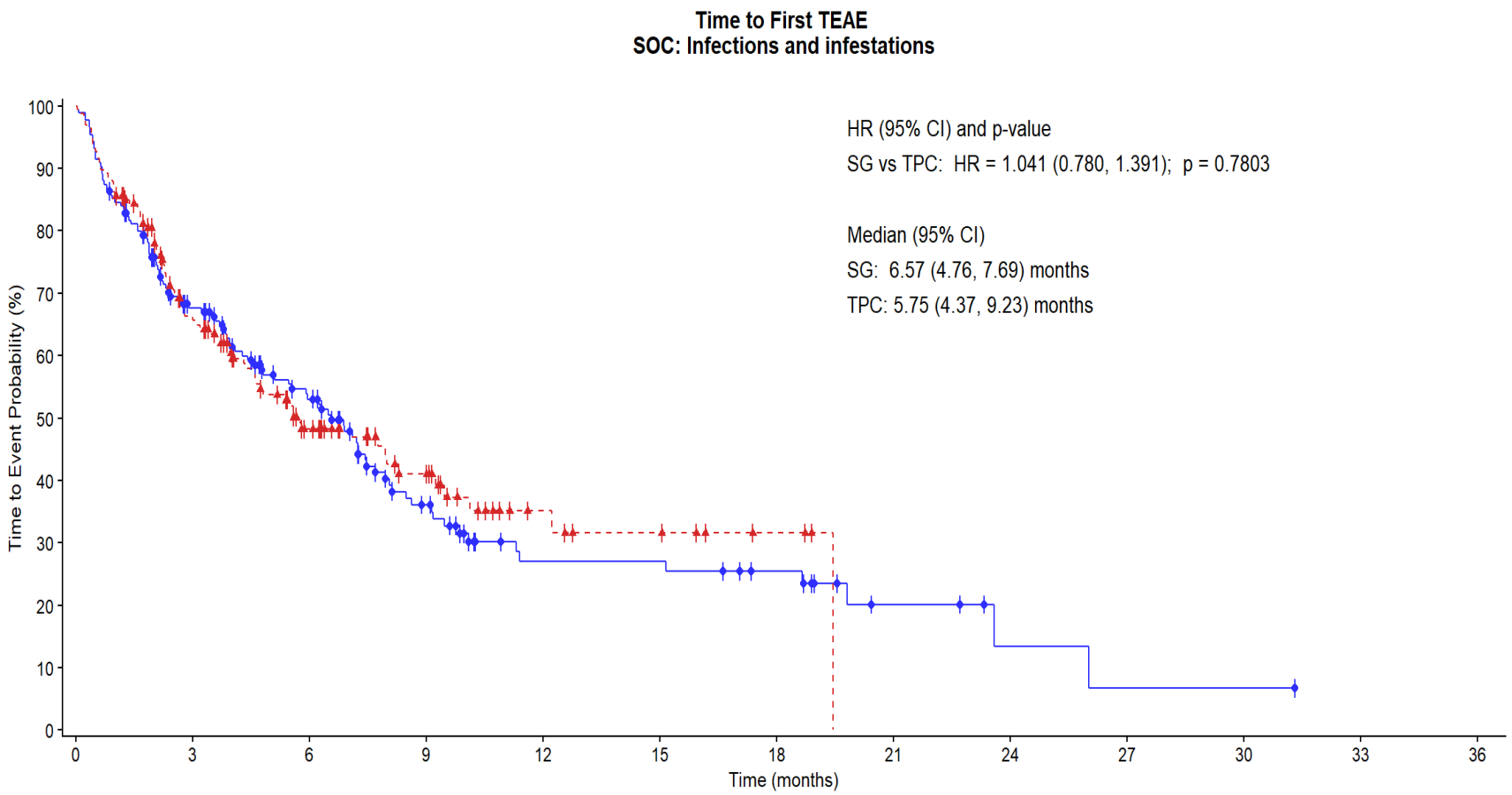
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.27. Figure 1.1.26: Kaplan Meier Plot of Time to First TEAE by SOC Immune system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



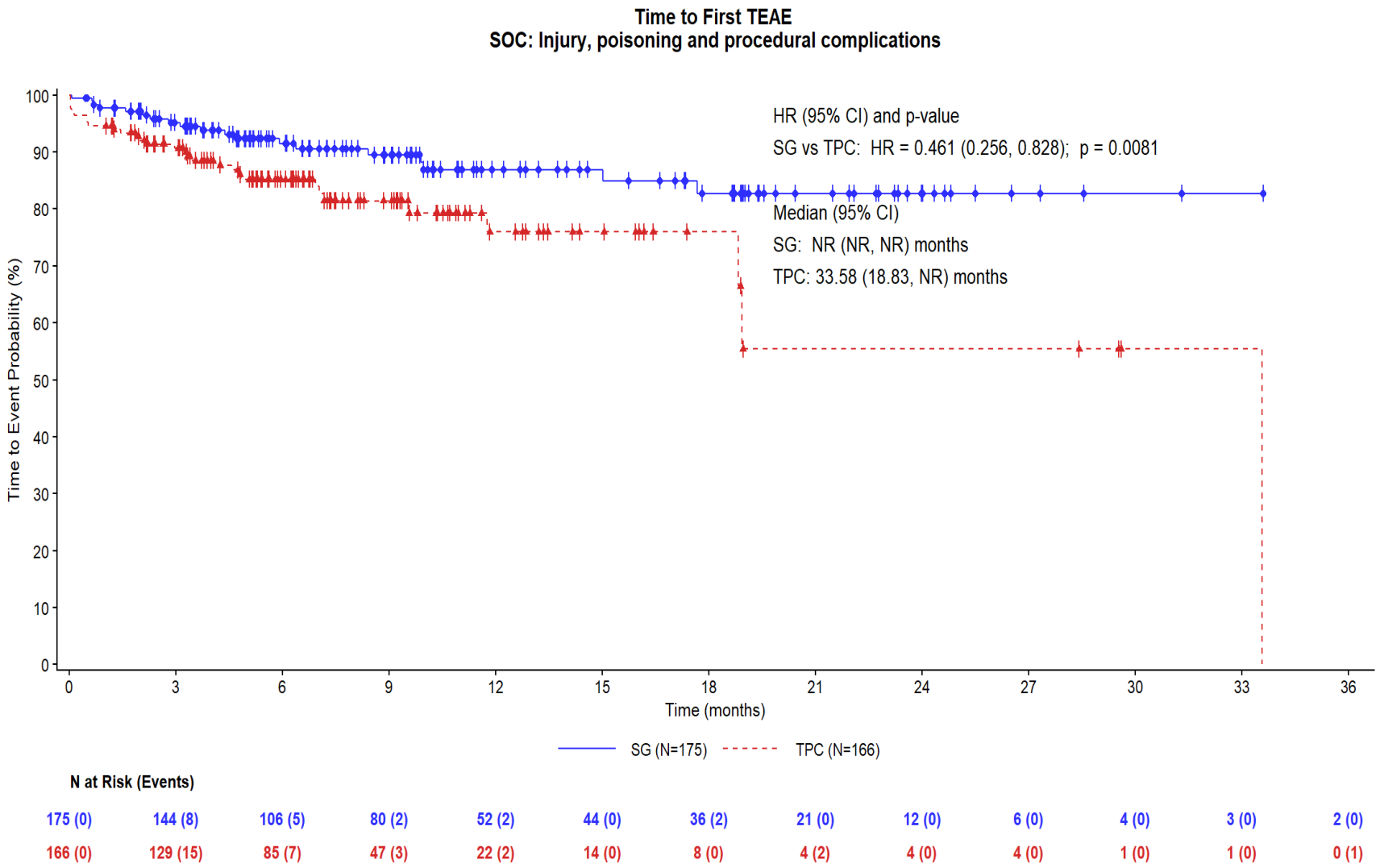
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.28. Figure 1.1.27: Kaplan Meier Plot of Time to First TEAE by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel



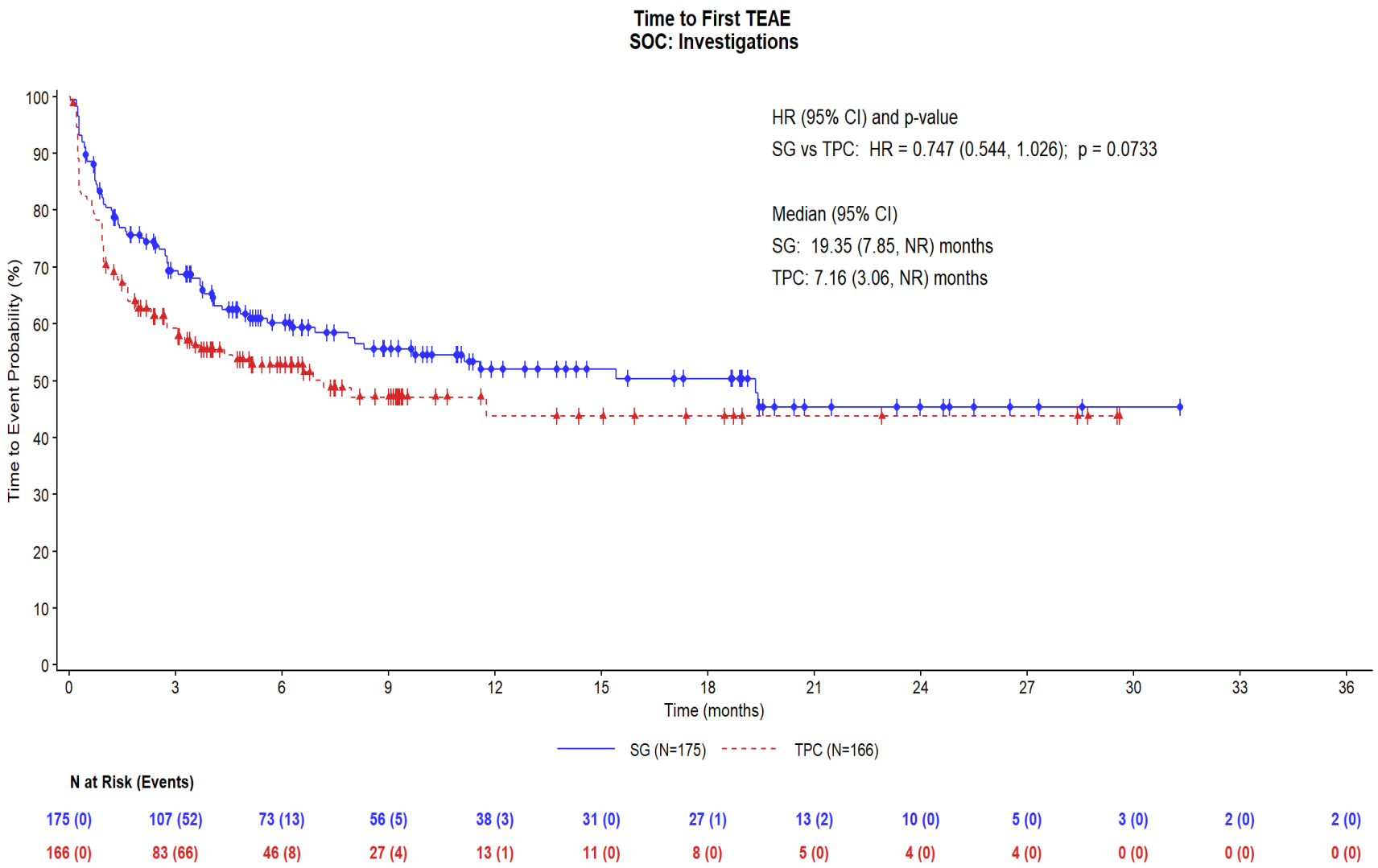
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.29. Figure 1.1.28: Kaplan Meier Plot of Time to First TEAE by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel



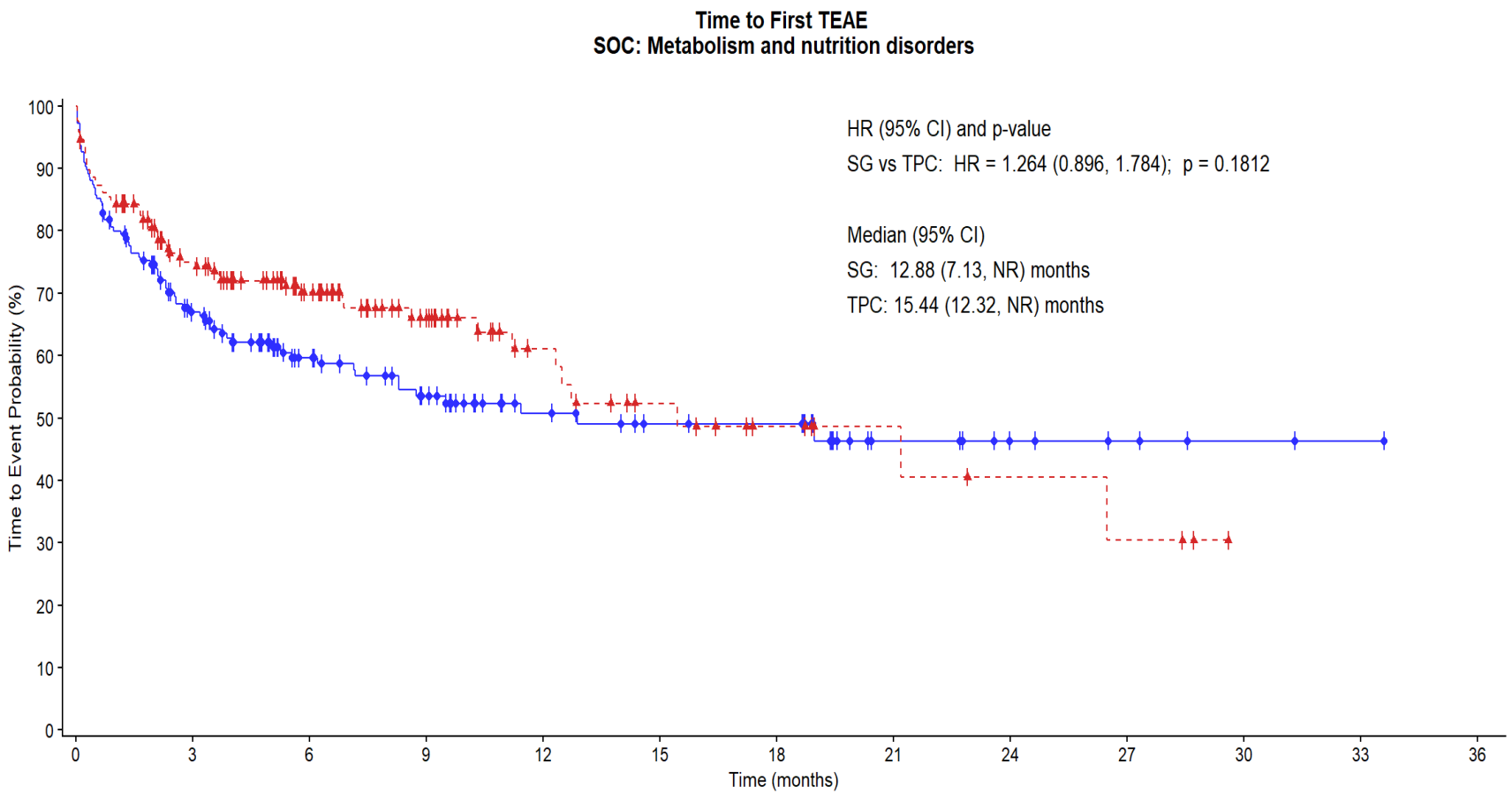
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.30. Figure 1.1.29: Kaplan Meier Plot of Time to First TEAE by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel



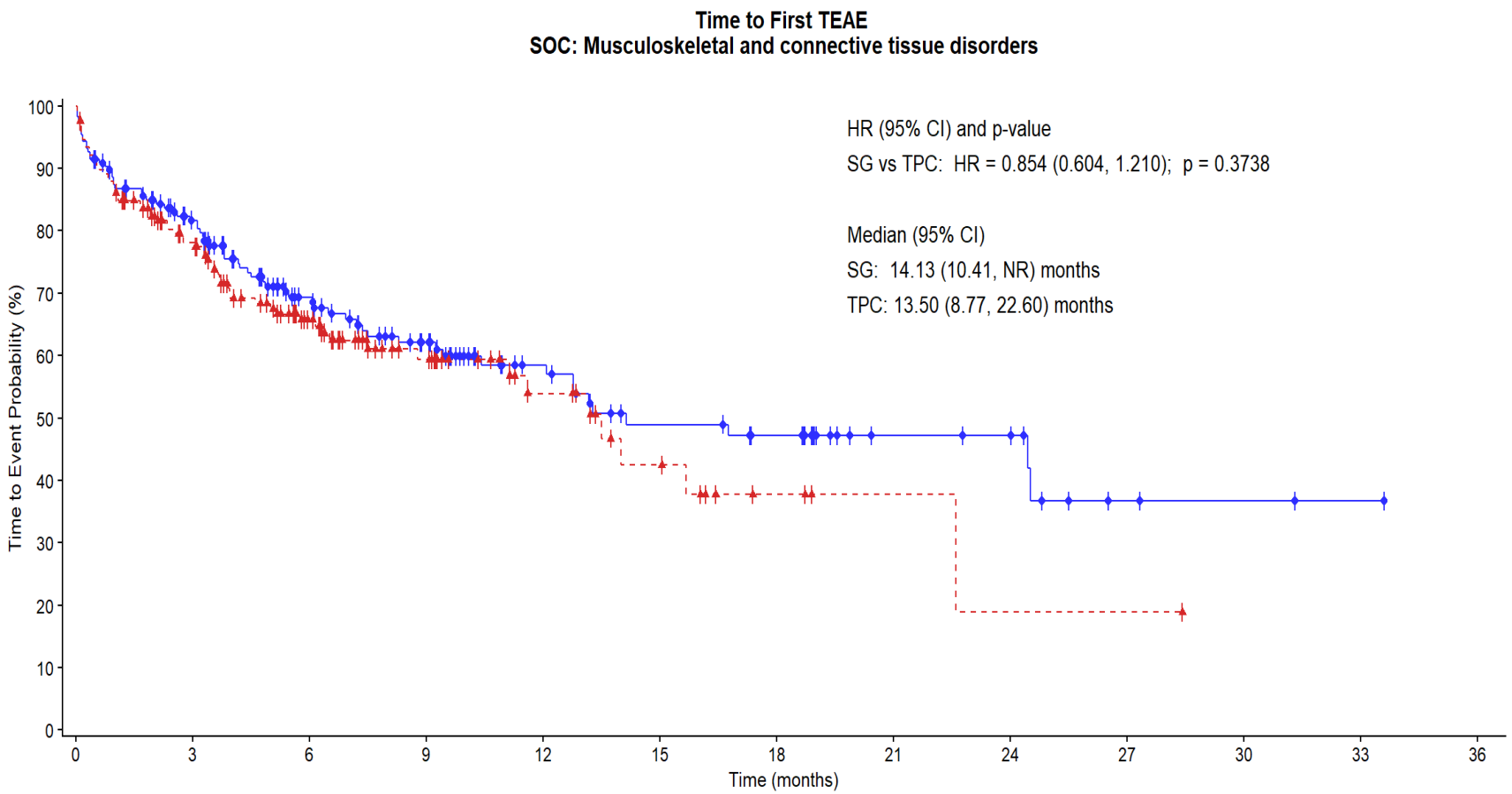
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.31. Figure 1.1.30: Kaplan Meier Plot of Time to First TEAE by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



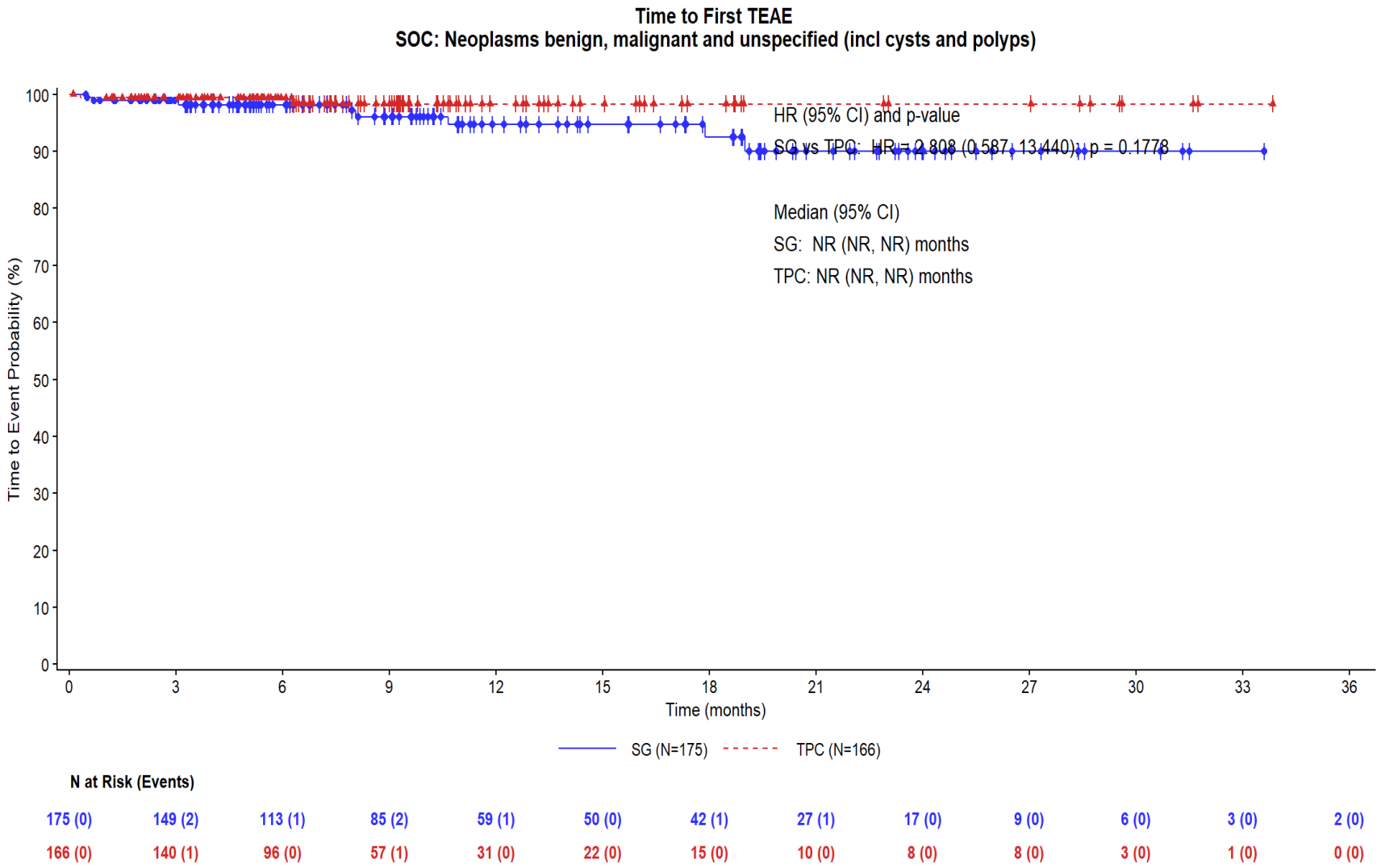
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.32. Figure 1.1.31: Kaplan Meier Plot of Time to First TEAE by SOC Musculoskeletal and connective tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



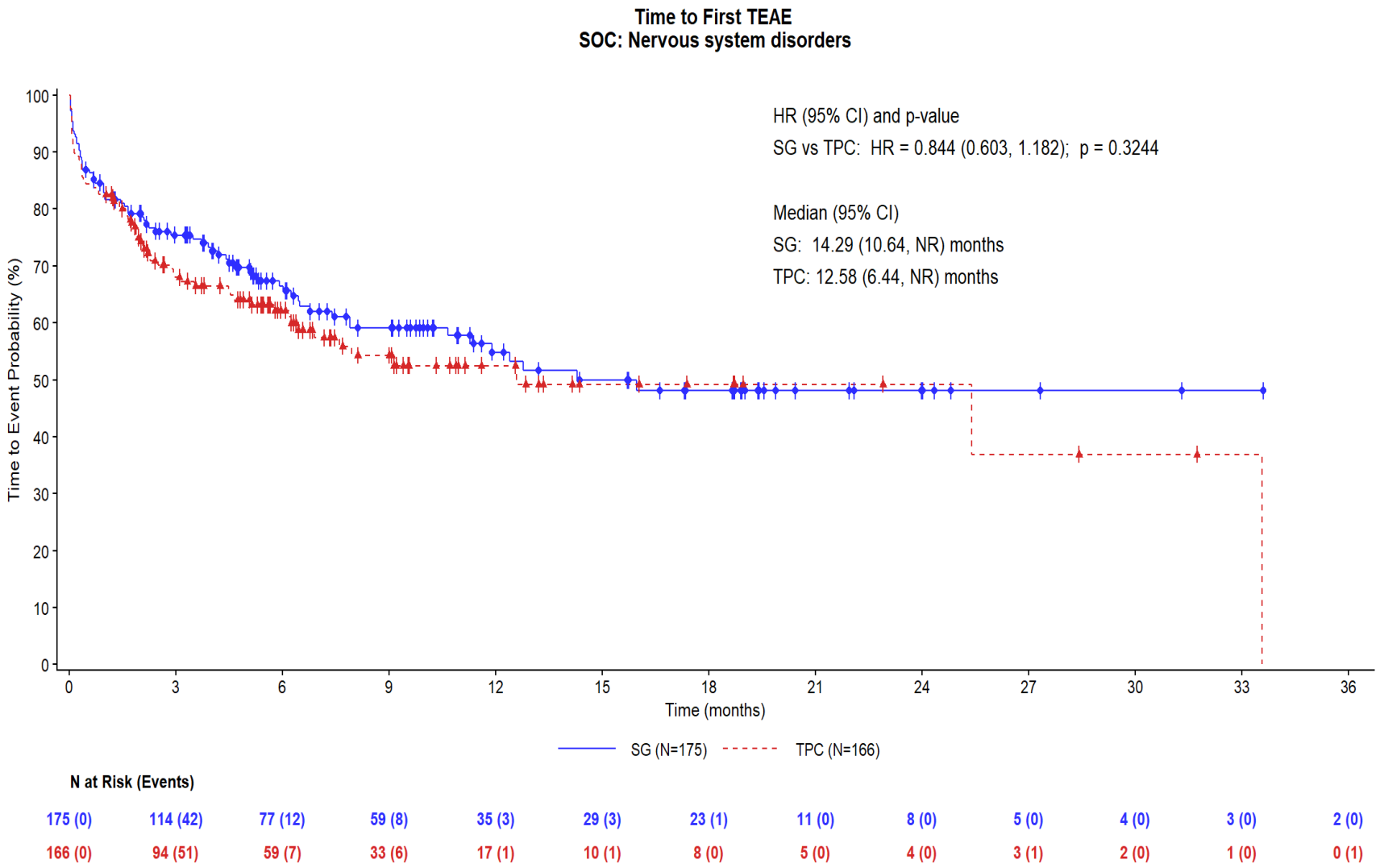
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.33. Figure 1.1.32: Kaplan Meier Plot of Time to First TEAE by SOC Neoplasms benign malignant and unspecified incl cysts and polyps — mSAF — Excluding patients preselected to receive nab-paclitaxel



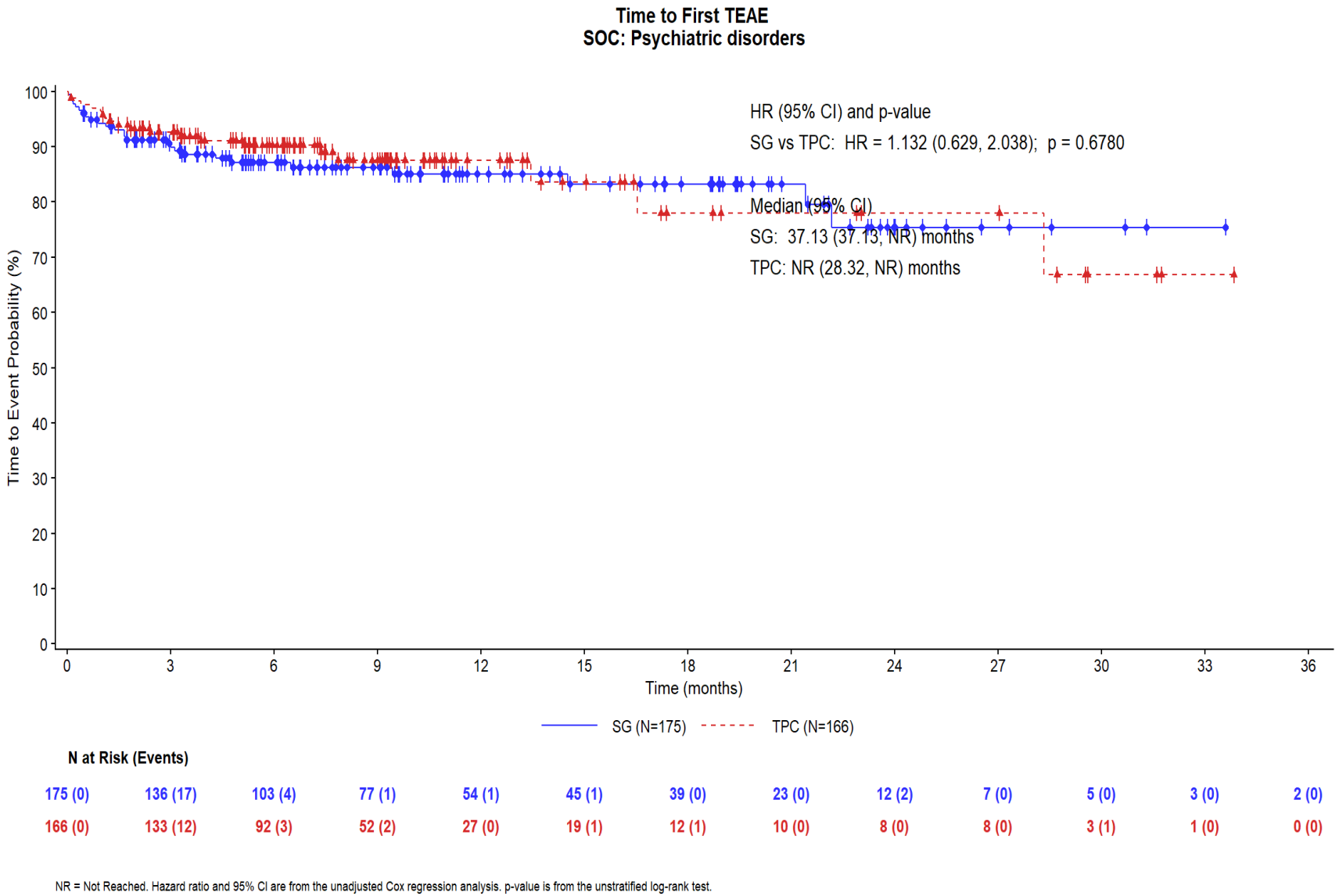
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.34. Figure 1.1.33: Kaplan Meier Plot of Time to First TEAE by SOC Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



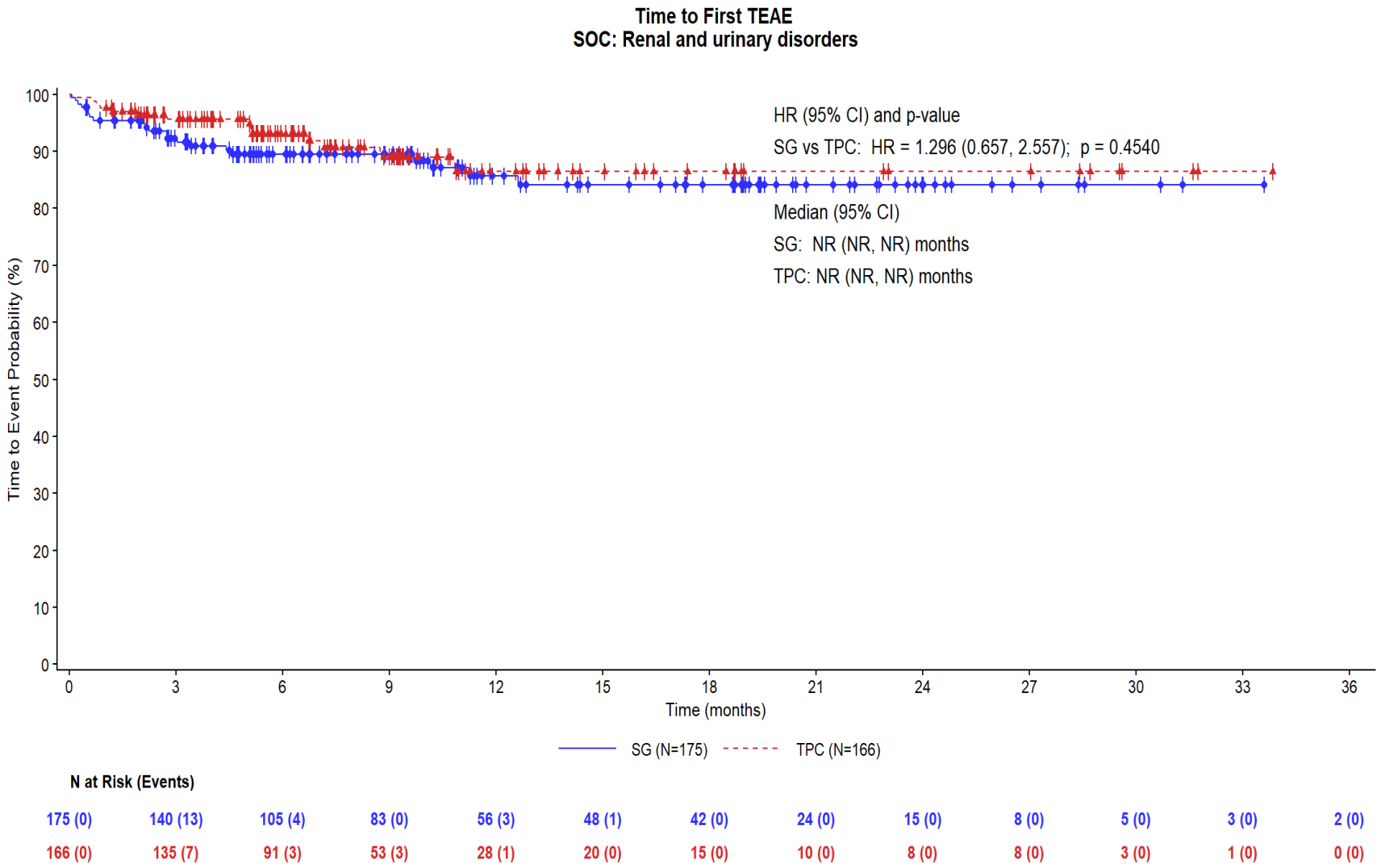
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.35. Figure 1.1.34: Kaplan Meier Plot of Time to First TEAE by SOC Psychiatric disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



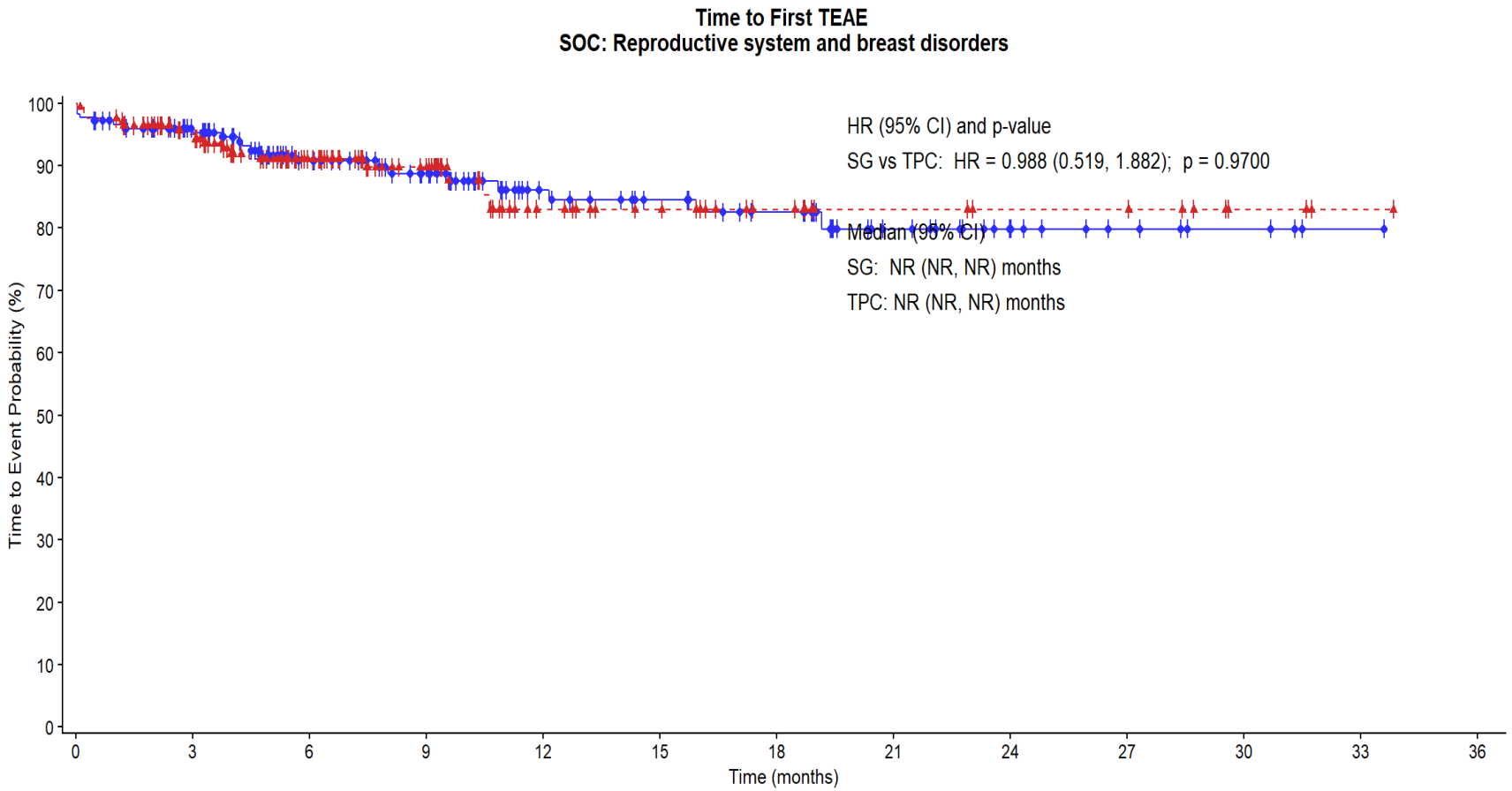
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.36. Figure 1.1.35: Kaplan Meier Plot of Time to First TEAE by SOC Renal and urinary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



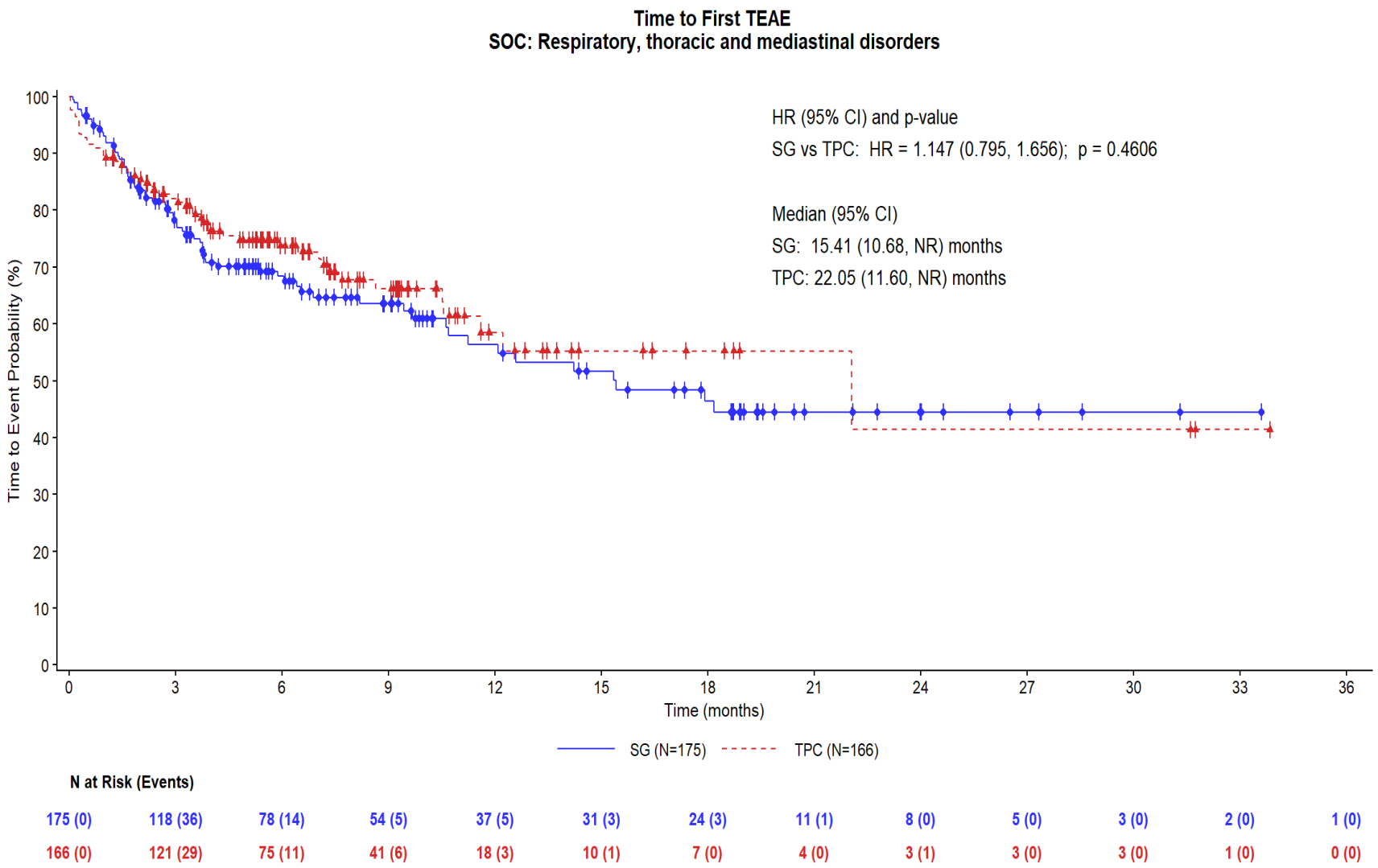
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.37. Figure 1.1.36: Kaplan Meier Plot of Time to First TEAE by SOC Reproductive system and breast disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



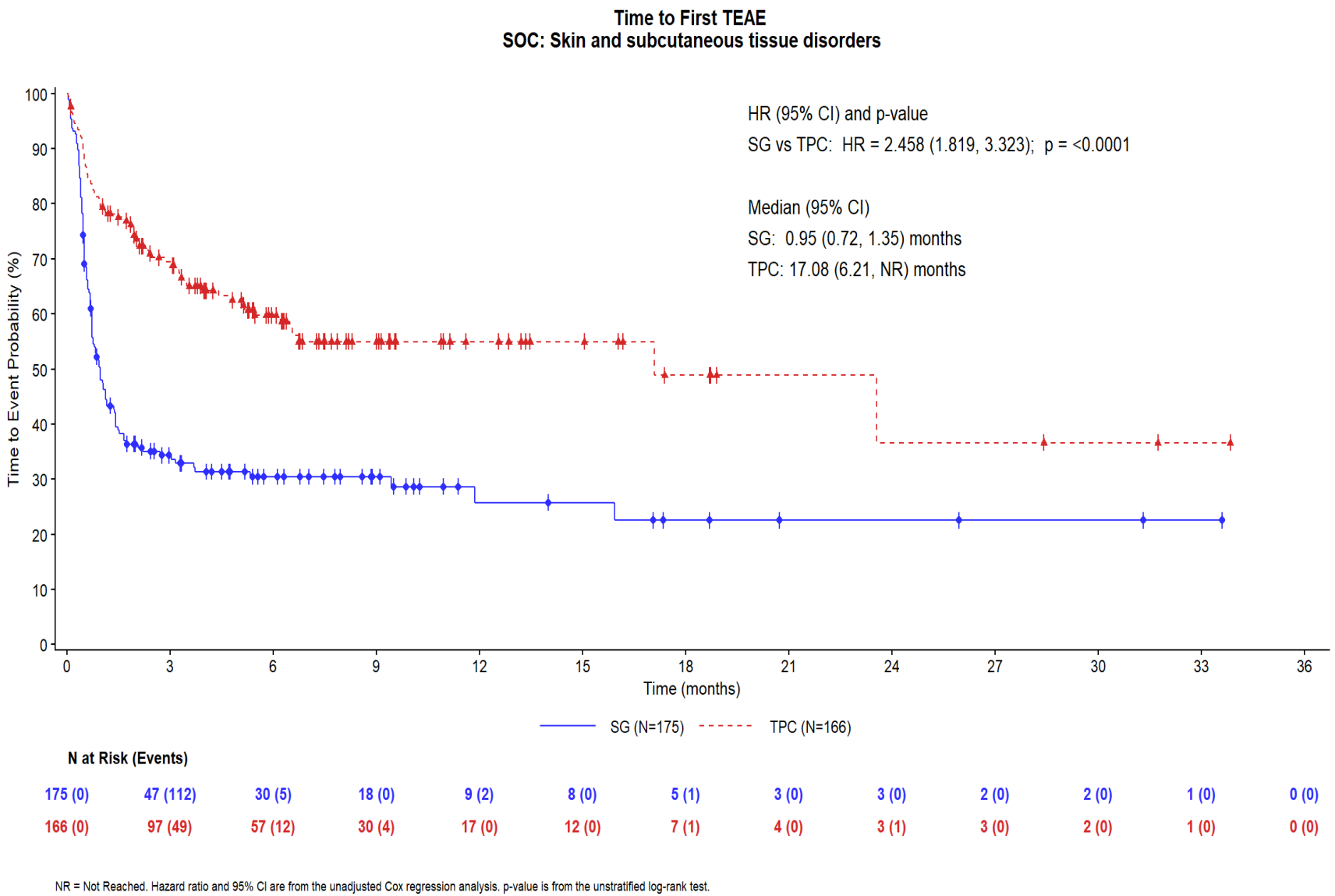
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.38. Figure 1.1.37: Kaplan Meier Plot of Time to First TEAE by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



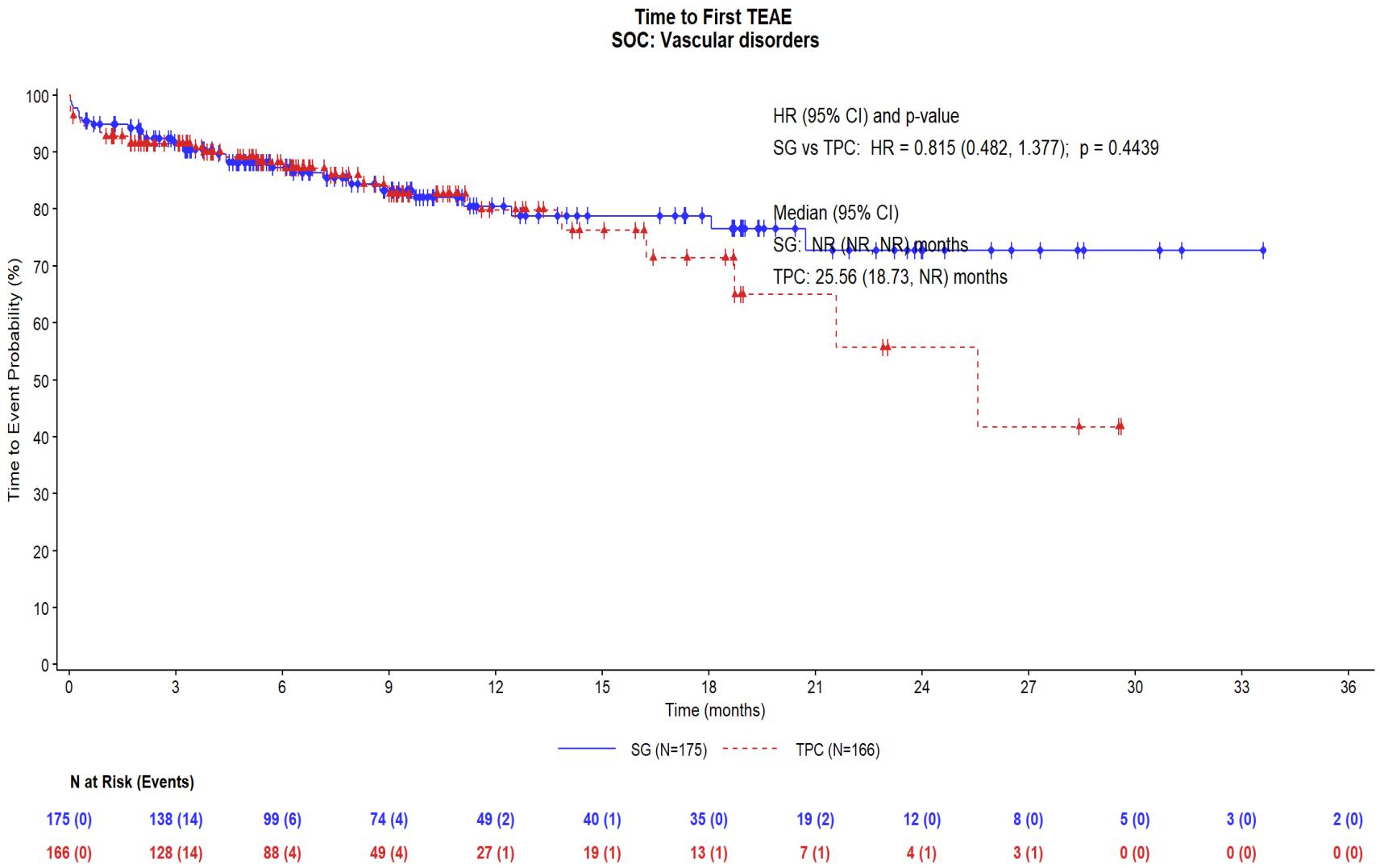
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.39. Figure 1.1.38: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



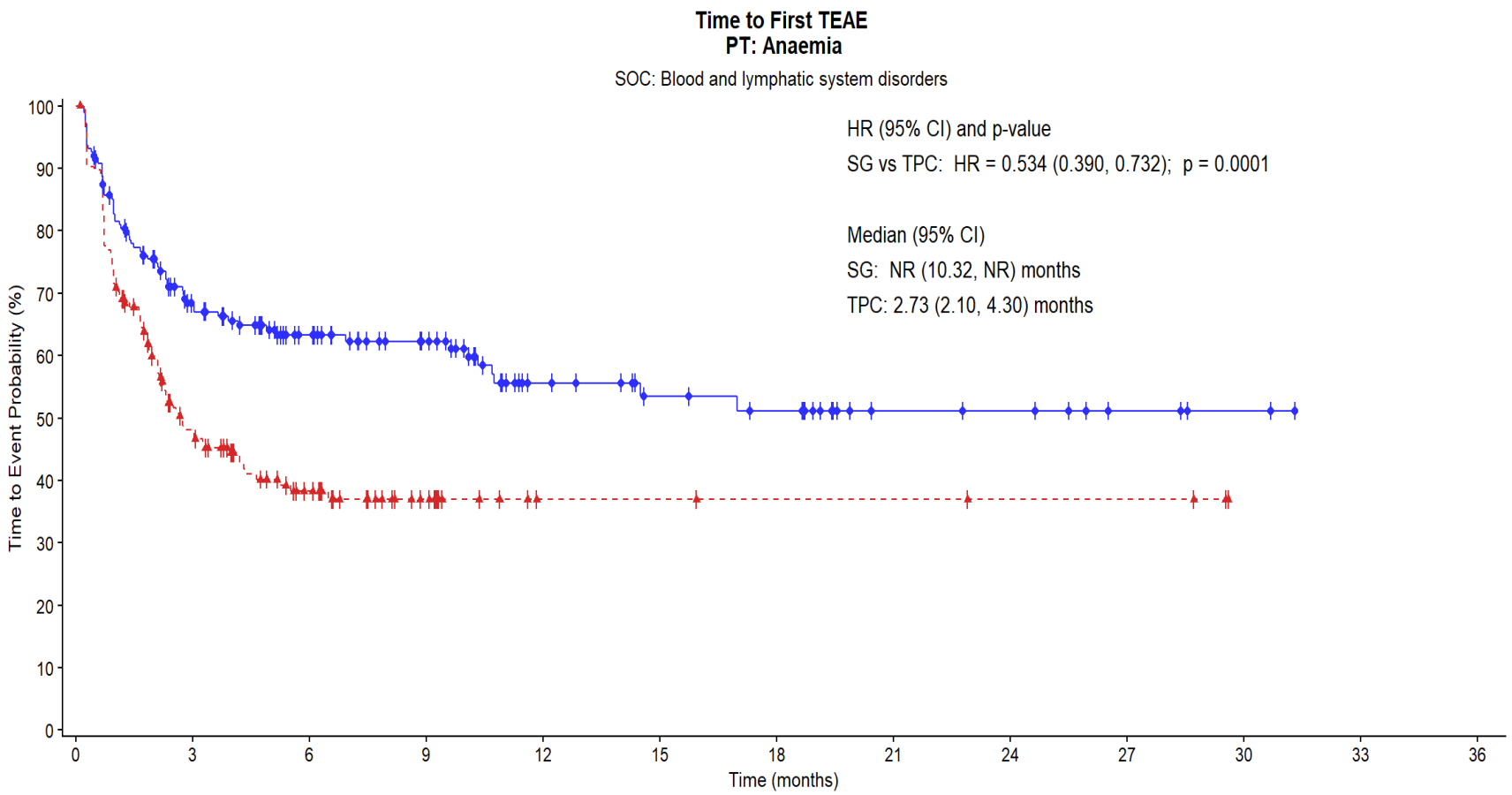
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.40. Figure 1.1.39: Kaplan Meier Plot of Time to First TEAE by SOC Vascular disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



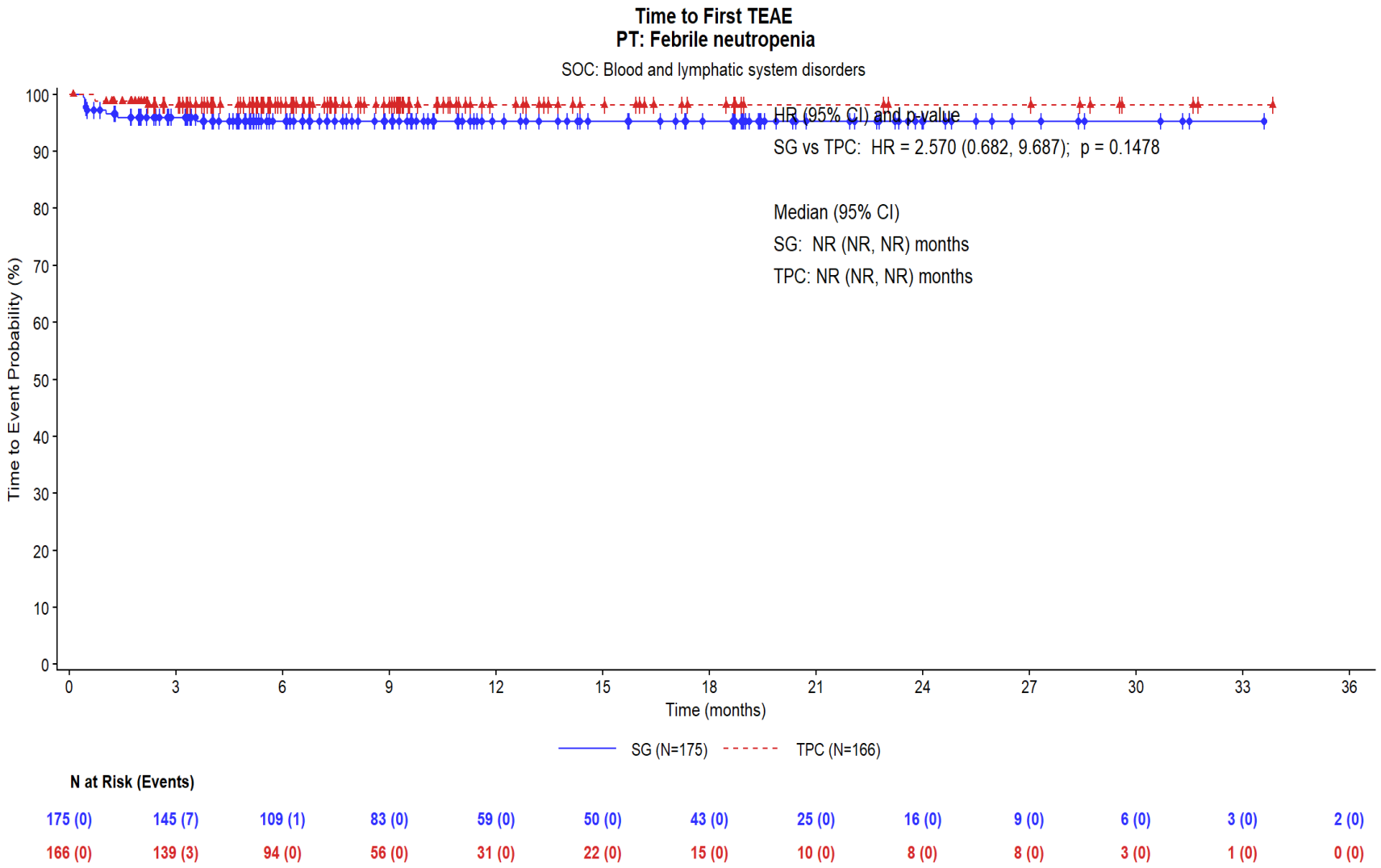
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.41. Figure 1.1.40: Kaplan Meier Plot of Time to First TEAE by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



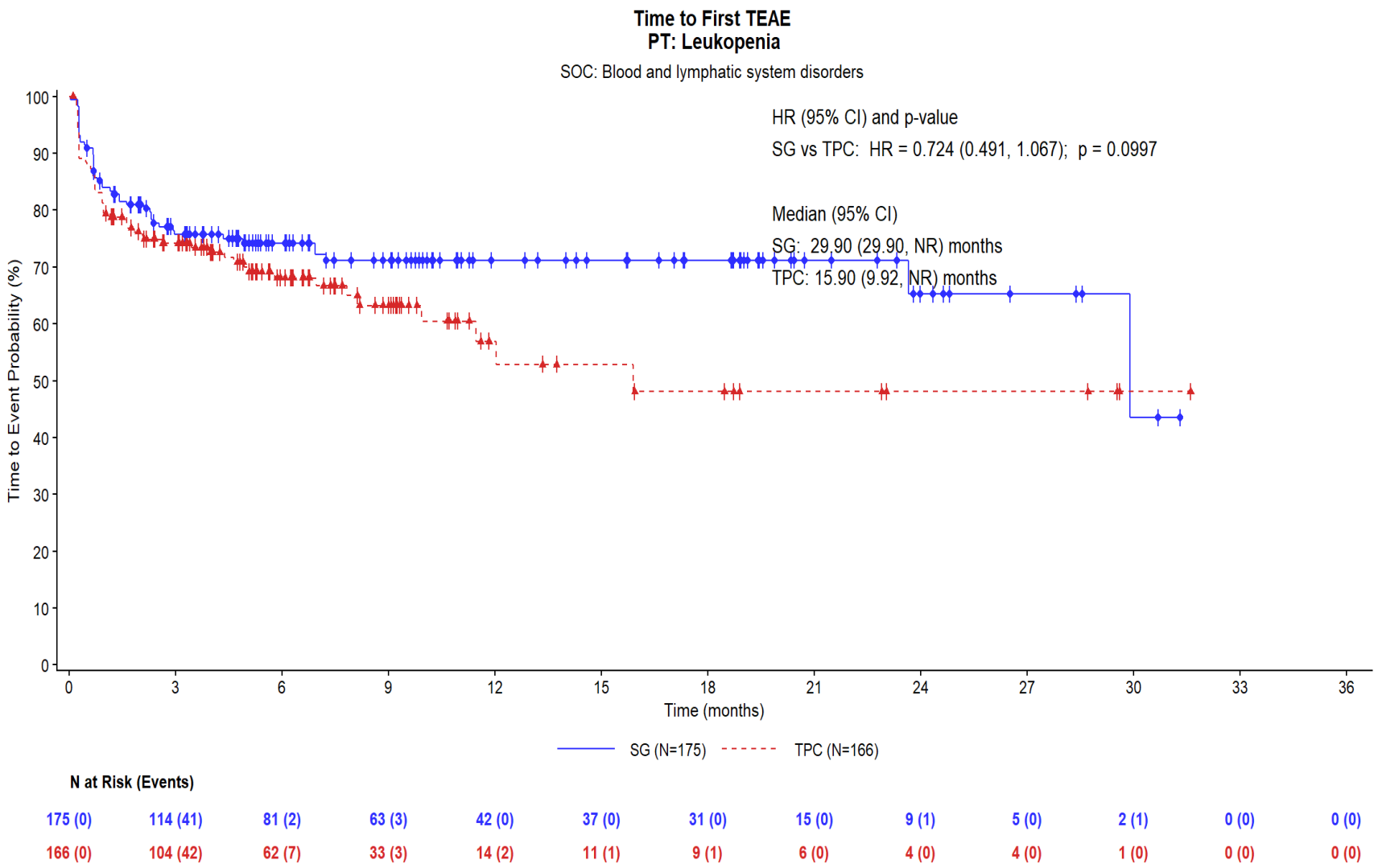
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.42. Figure 1.1.41: Kaplan Meier Plot of Time to First TEAE by PT Febrile neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



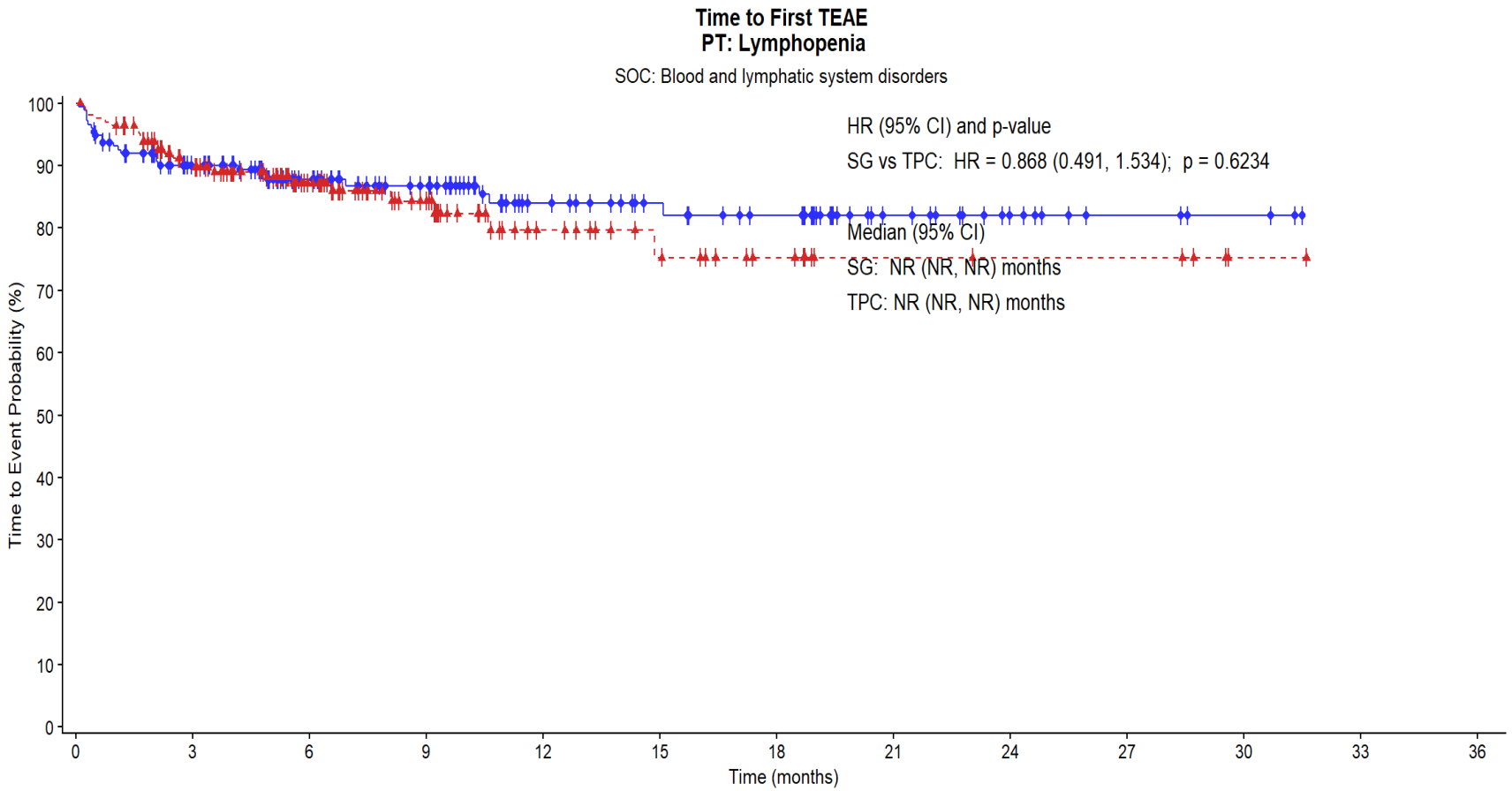
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.43. Figure 1.1.42: Kaplan Meier Plot of Time to First TEAE by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



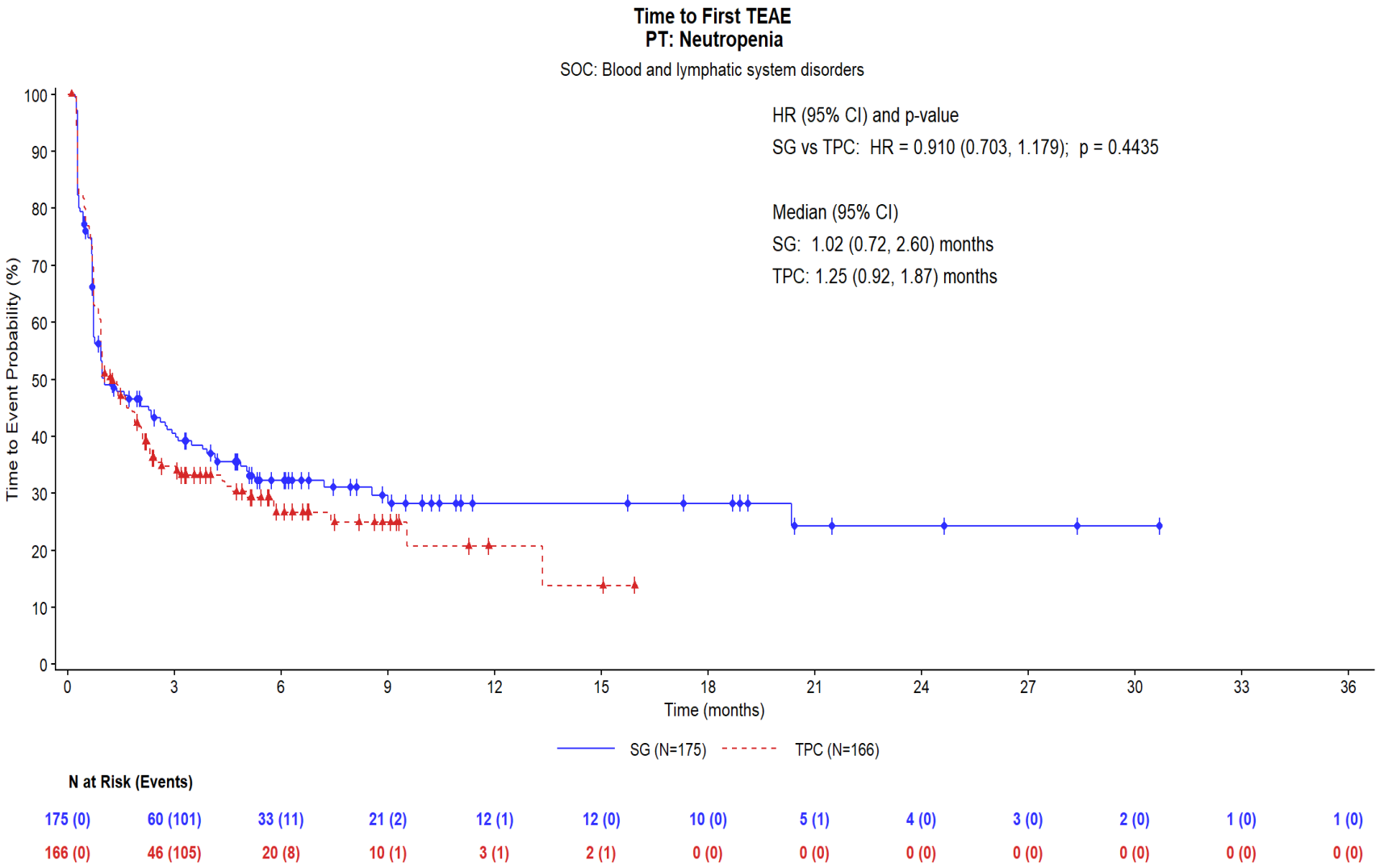
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.44. Figure 1.1.43: Kaplan Meier Plot of Time to First TEAE by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



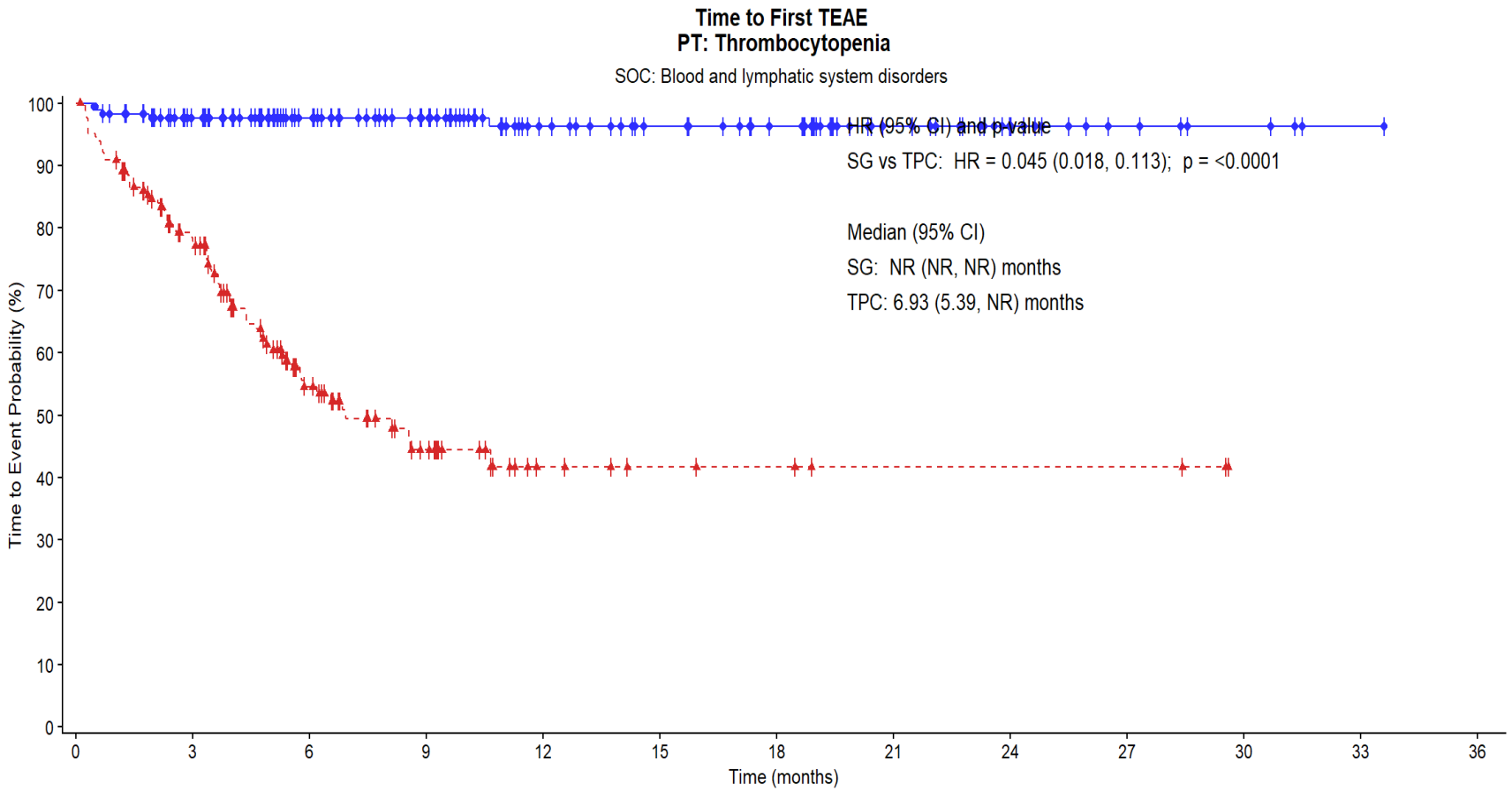
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.45. Figure 1.1.44: Kaplan Meier Plot of Time to First TEAE by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



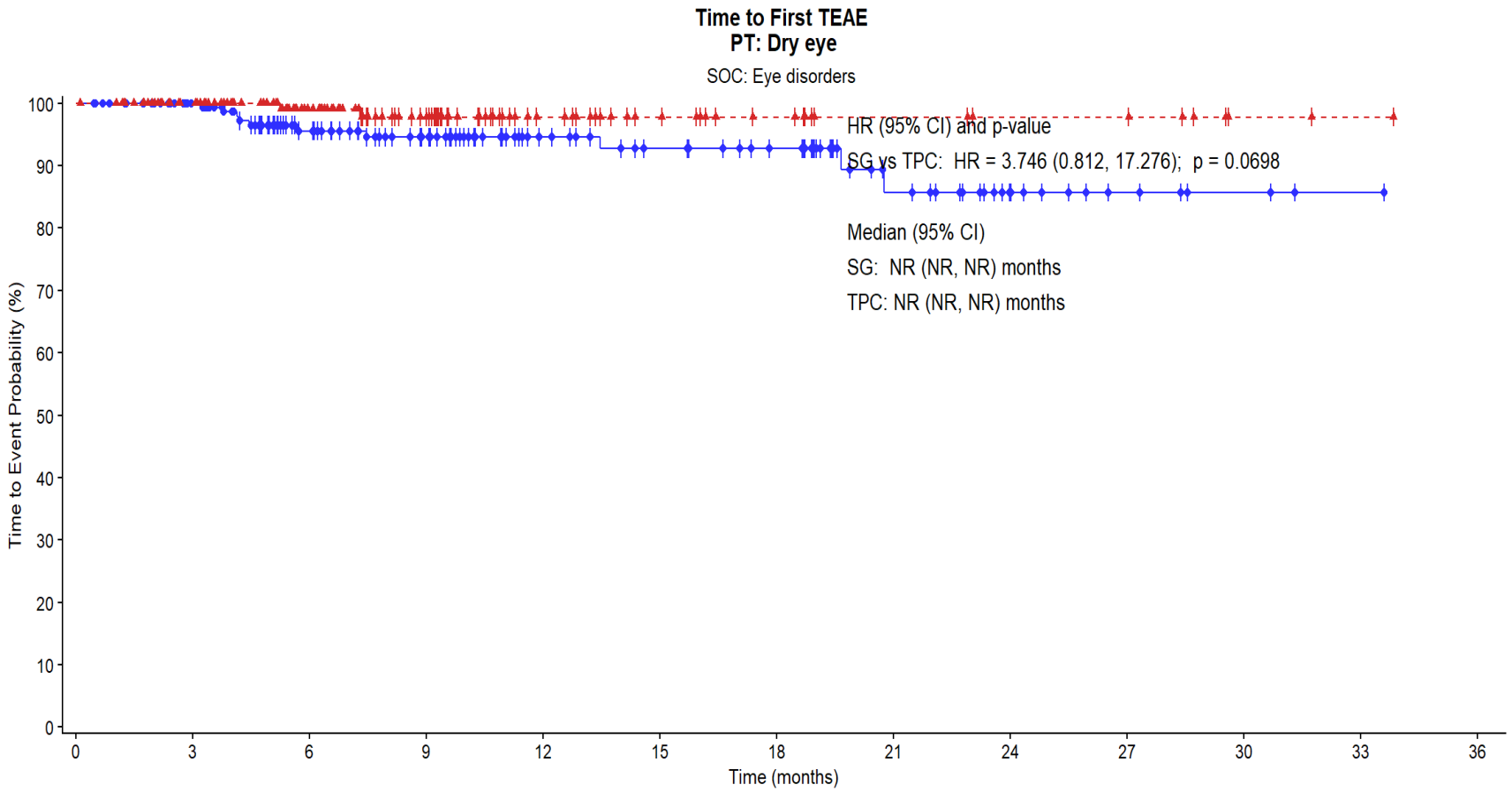
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.46. Figure 1.1.45: Kaplan Meier Plot of Time to First TEAE by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



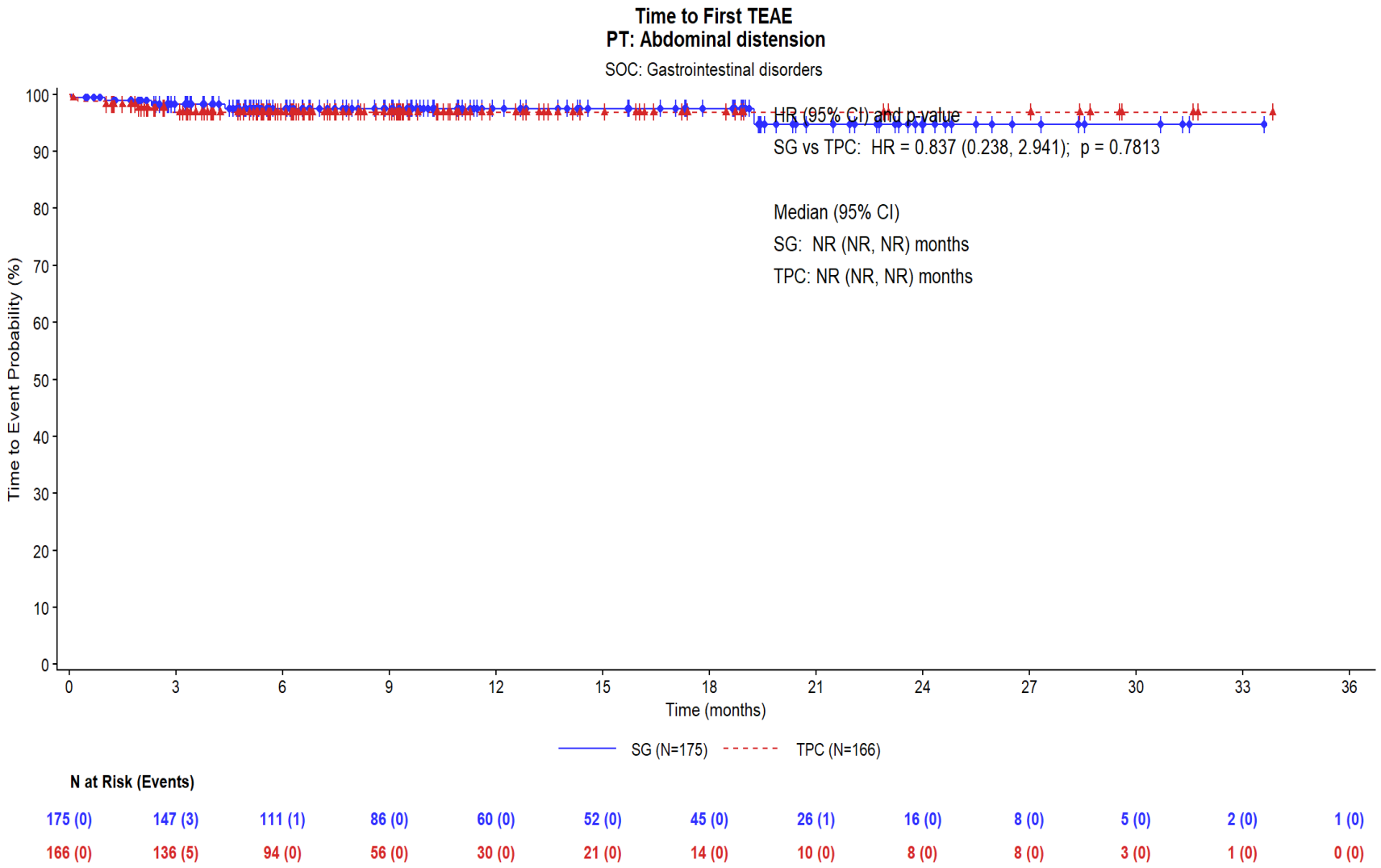
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.47. Figure 1.1.46: Kaplan Meier Plot of Time to First TEAE by PT Dry eye — mSAF — Excluding patients preselected to receive nab-paclitaxel



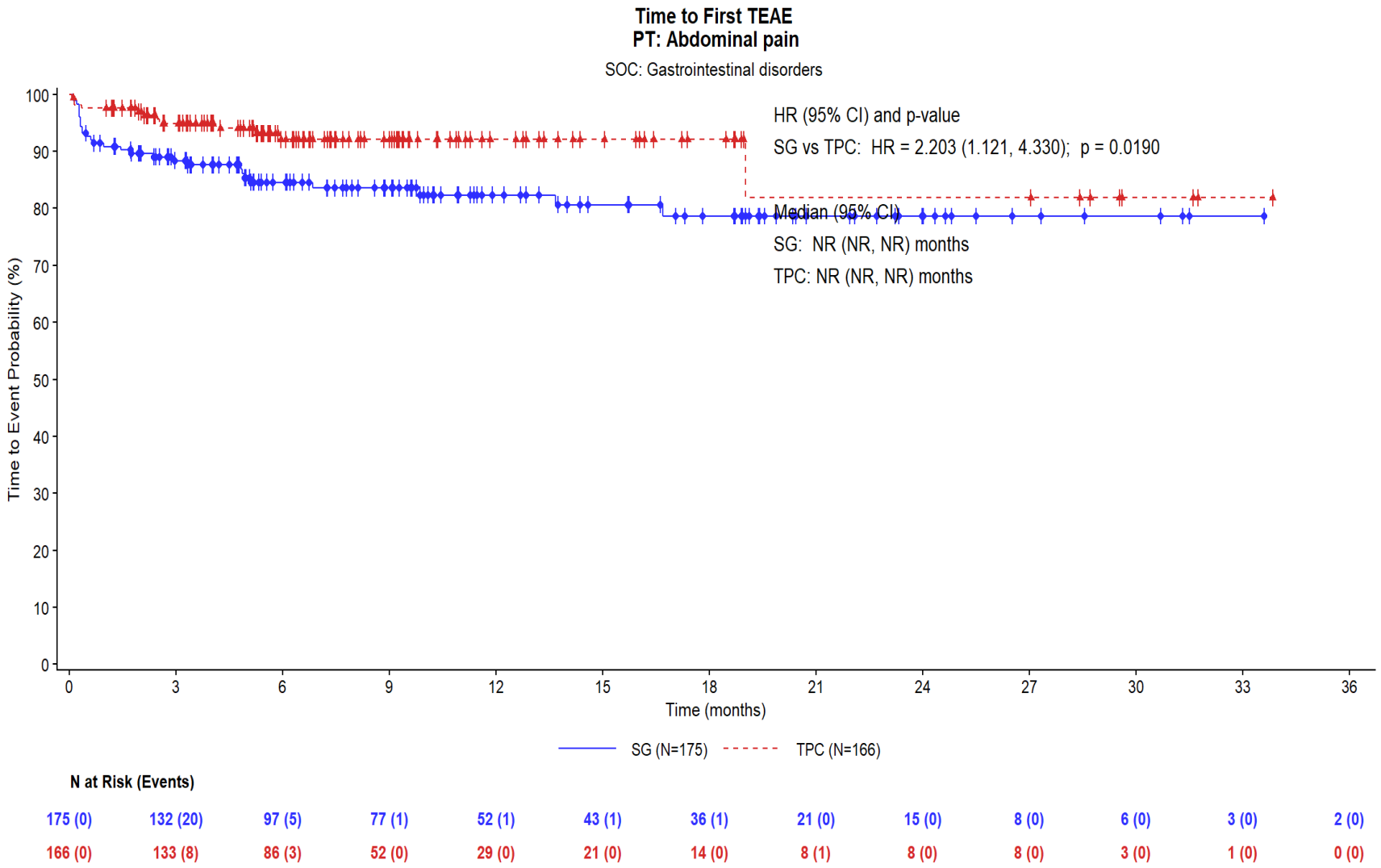
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.48. Figure 1.1.47: Kaplan Meier Plot of Time to First TEAE by PT Abdominal distension — mSAF — Excluding patients preselected to receive nab-paclitaxel



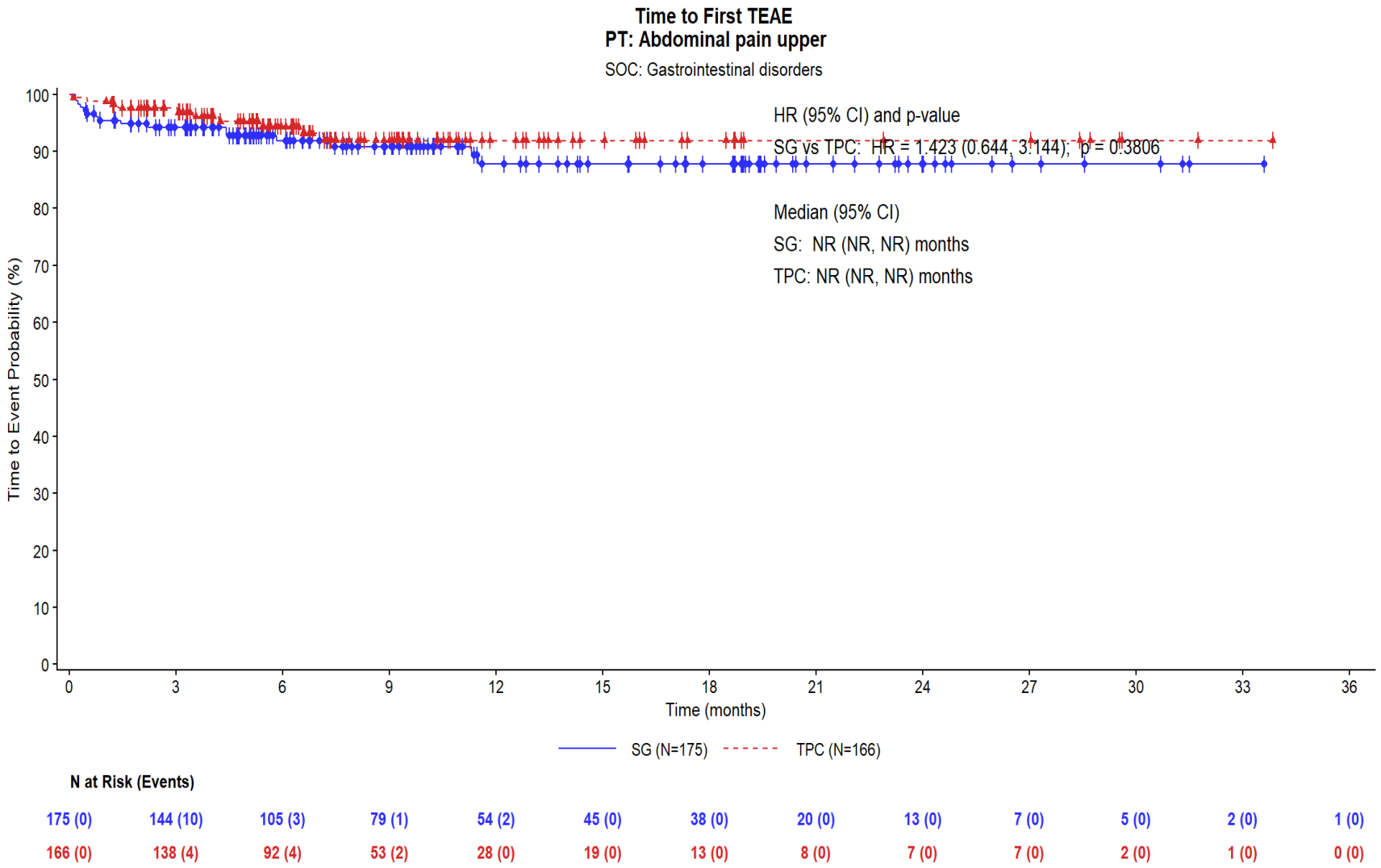
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.49. Figure 1.1.48: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



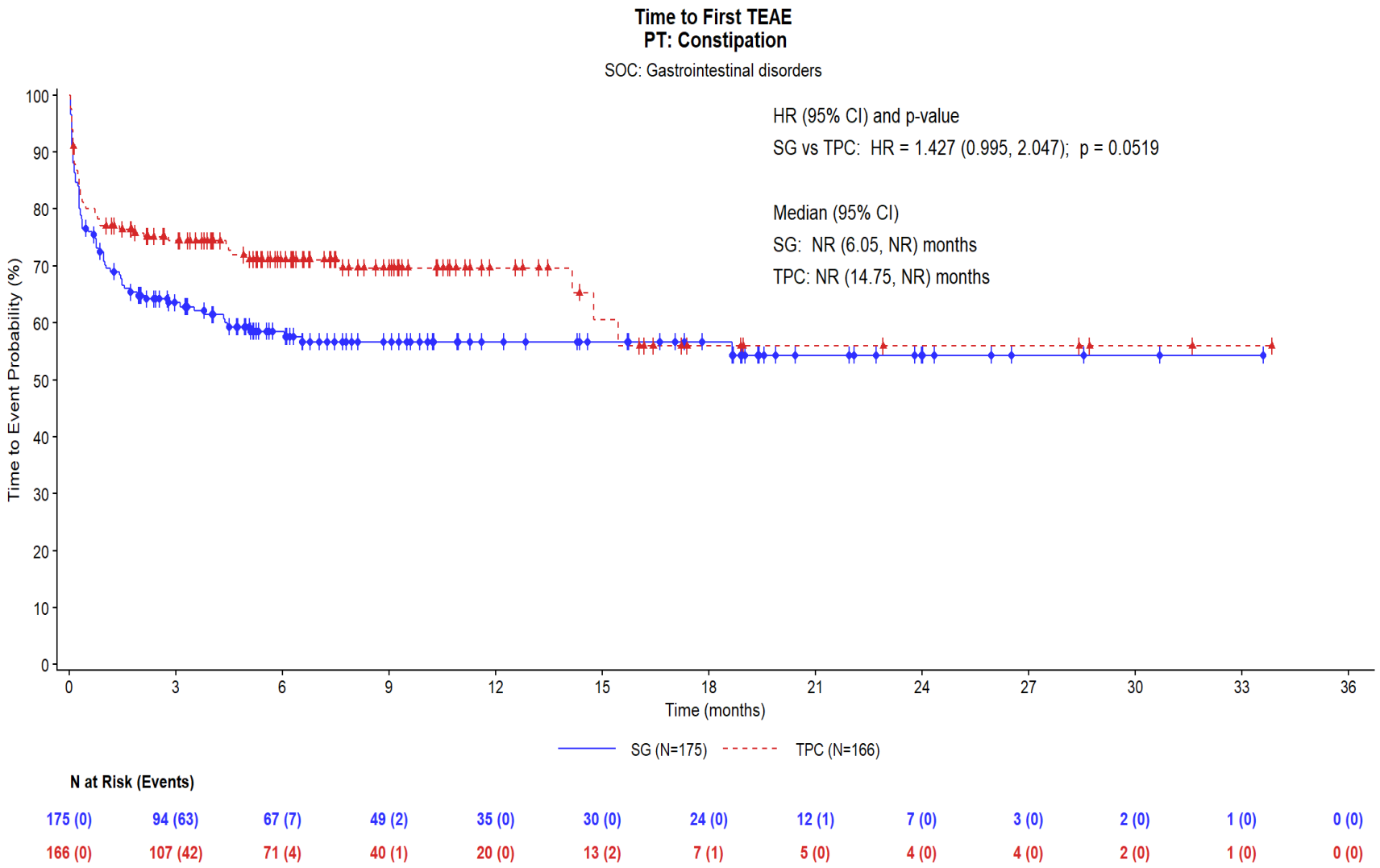
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.50. Figure 1.1.49: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain upper — mSAF — Excluding patients preselected to receive nab-paclitaxel



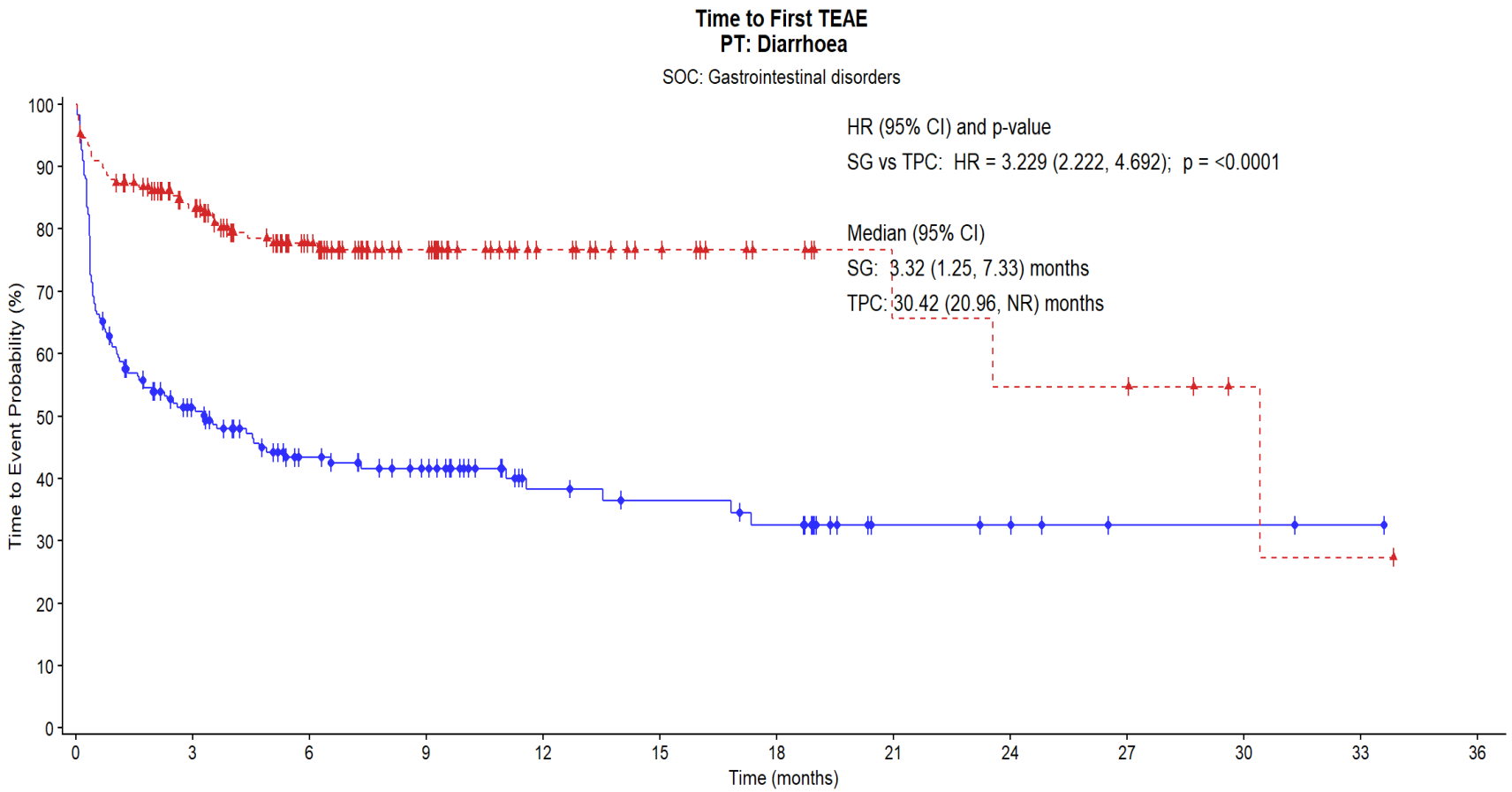
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.51. Figure 1.1.50: Kaplan Meier Plot of Time to First TEAE by PT Constipation — mSAF — Excluding patients preselected to receive nab-paclitaxel



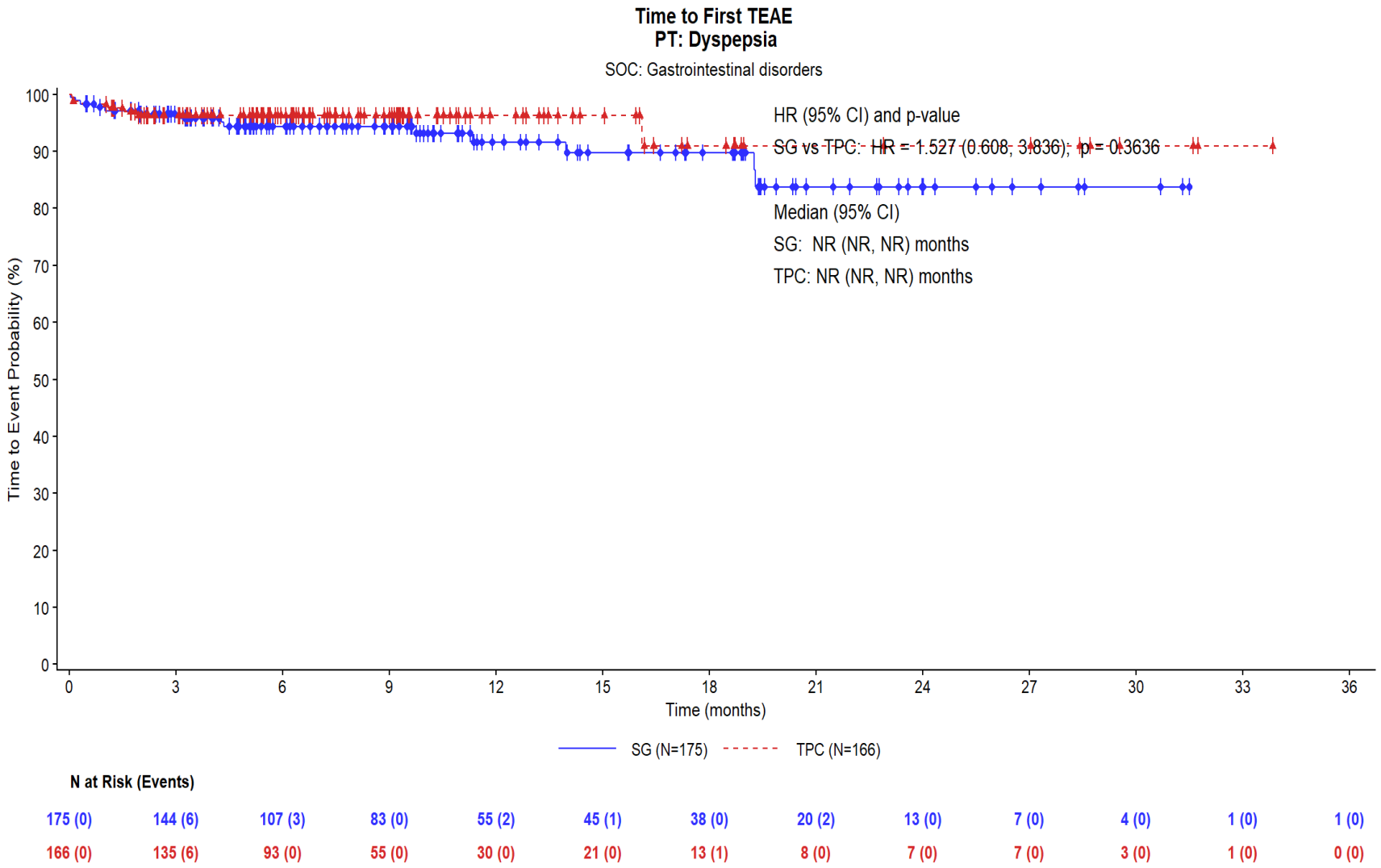
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.52. Figure 1.1.51: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



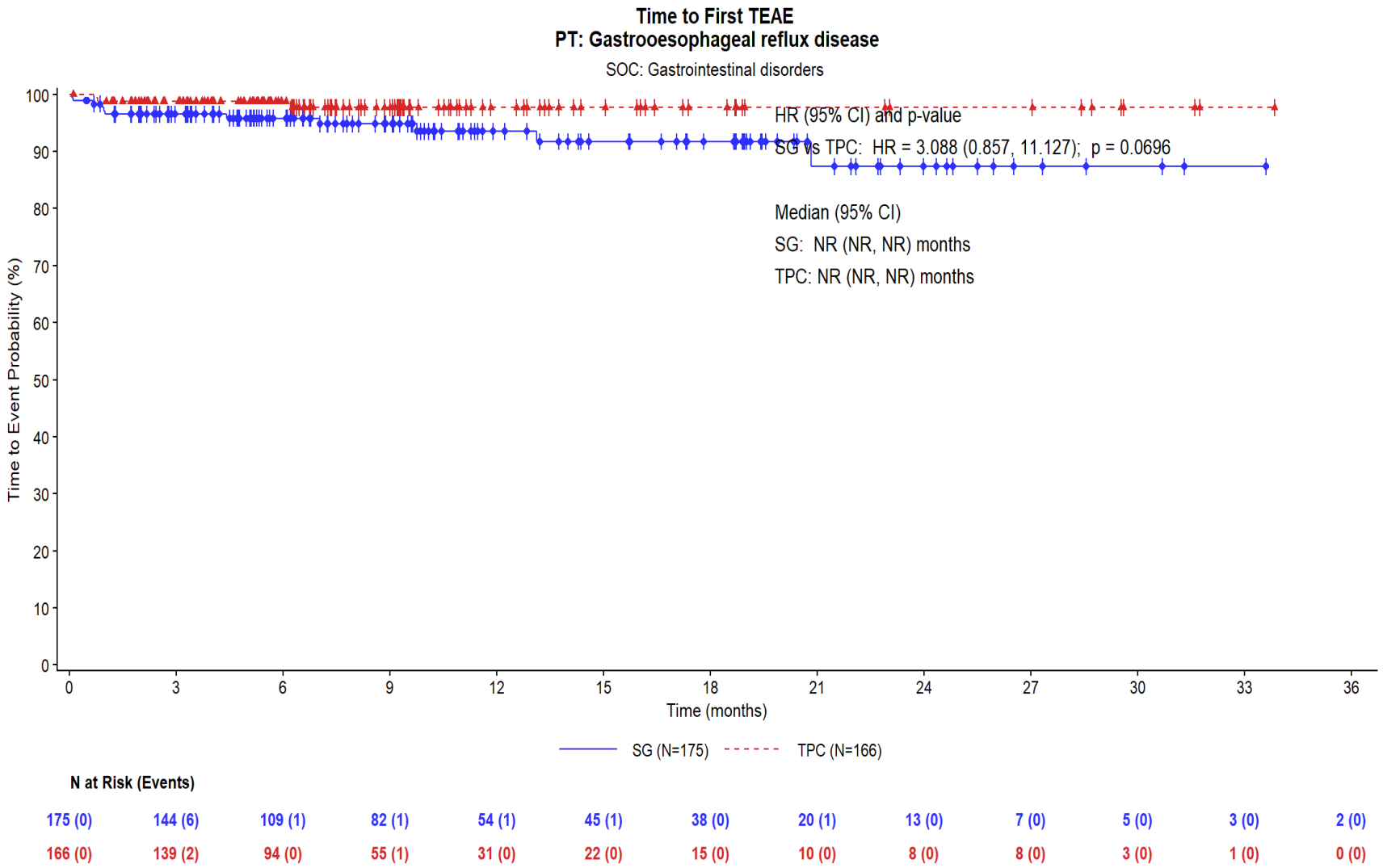
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.53. Figure 1.1.52: Kaplan Meier Plot of Time to First TEAE by PT Dyspepsia — mSAF — Excluding patients preselected to receive nab-paclitaxel



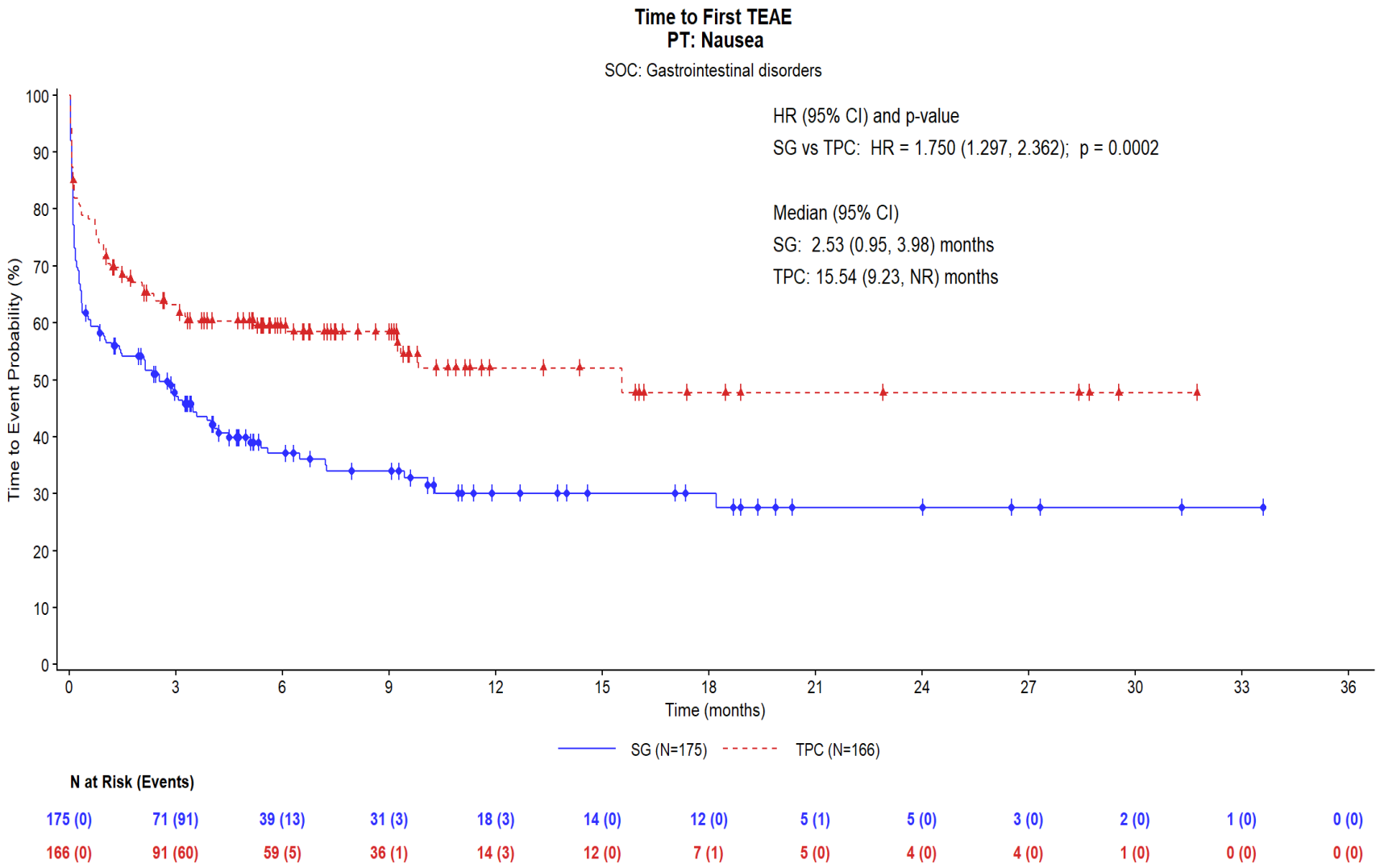
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.54. Figure 1.1.53: Kaplan Meier Plot of Time to First TEAE by PT Gastrooesophageal reflux disease — mSAF — Excluding patients preselected to receive nab-paclitaxel



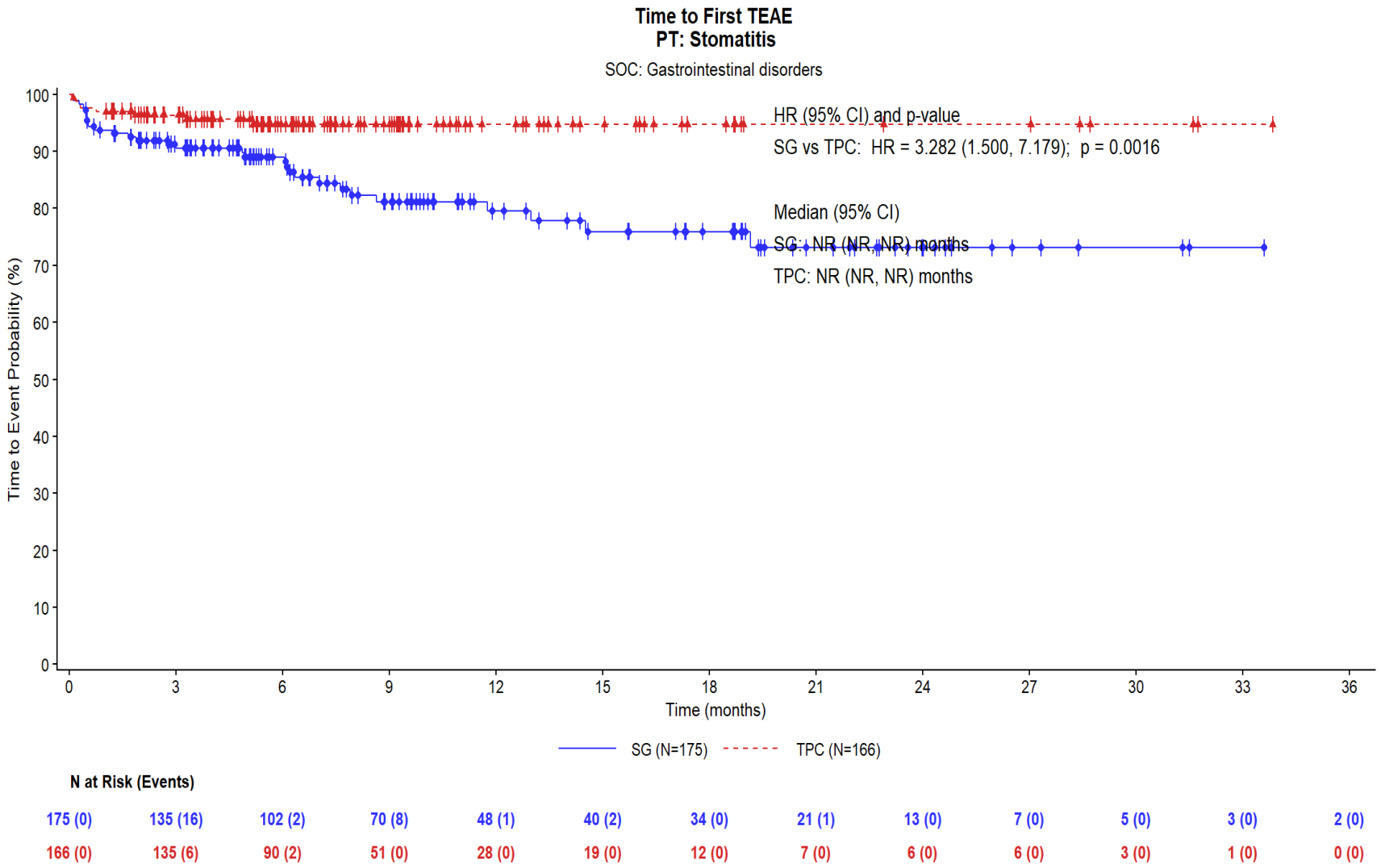
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.55. Figure 1.1.54: Kaplan Meier Plot of Time to First TEAE by PT Nausea — mSAF — Excluding patients preselected to receive nab-paclitaxel



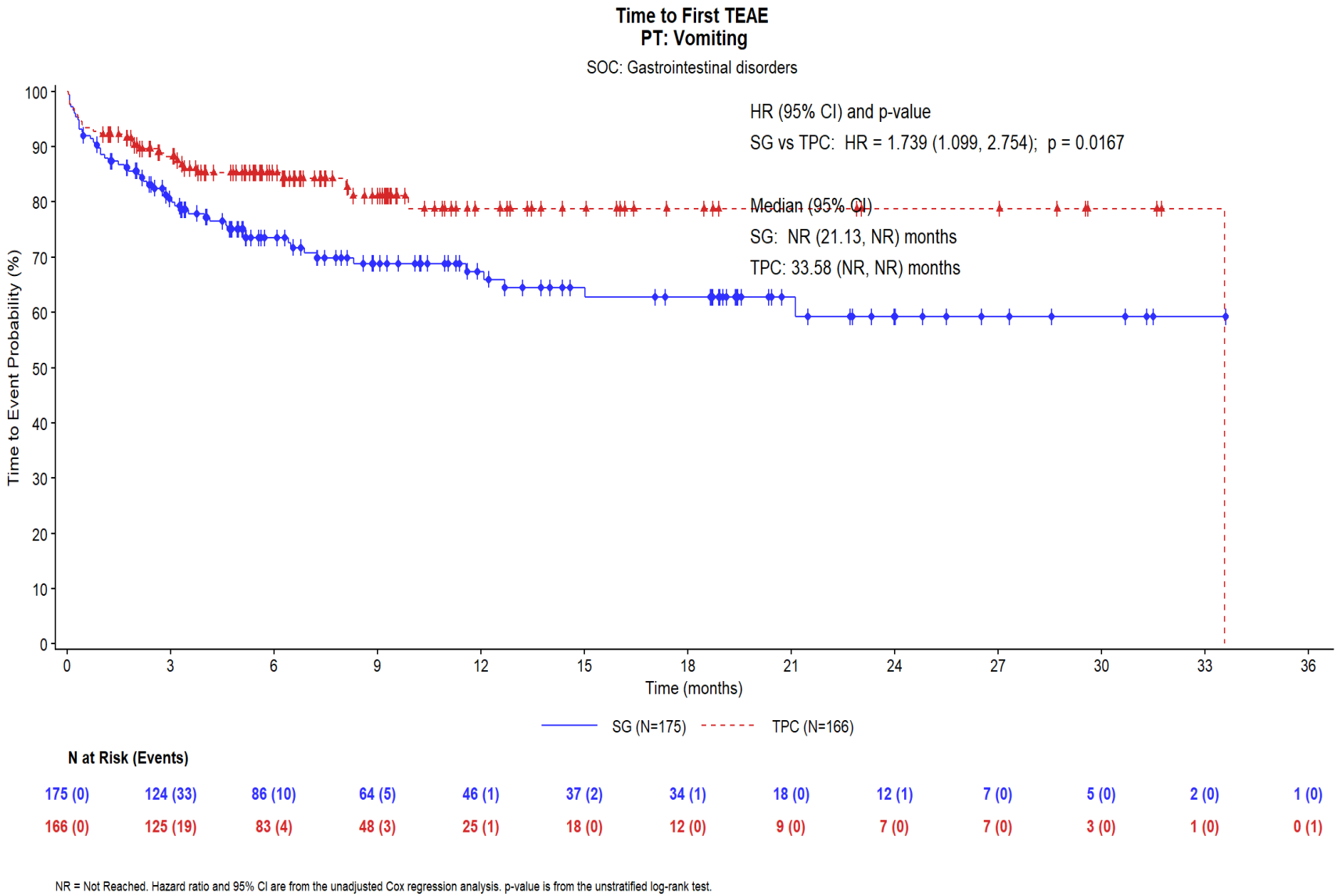
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.56. Figure 1.1.55: Kaplan Meier Plot of Time to First TEAE by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel



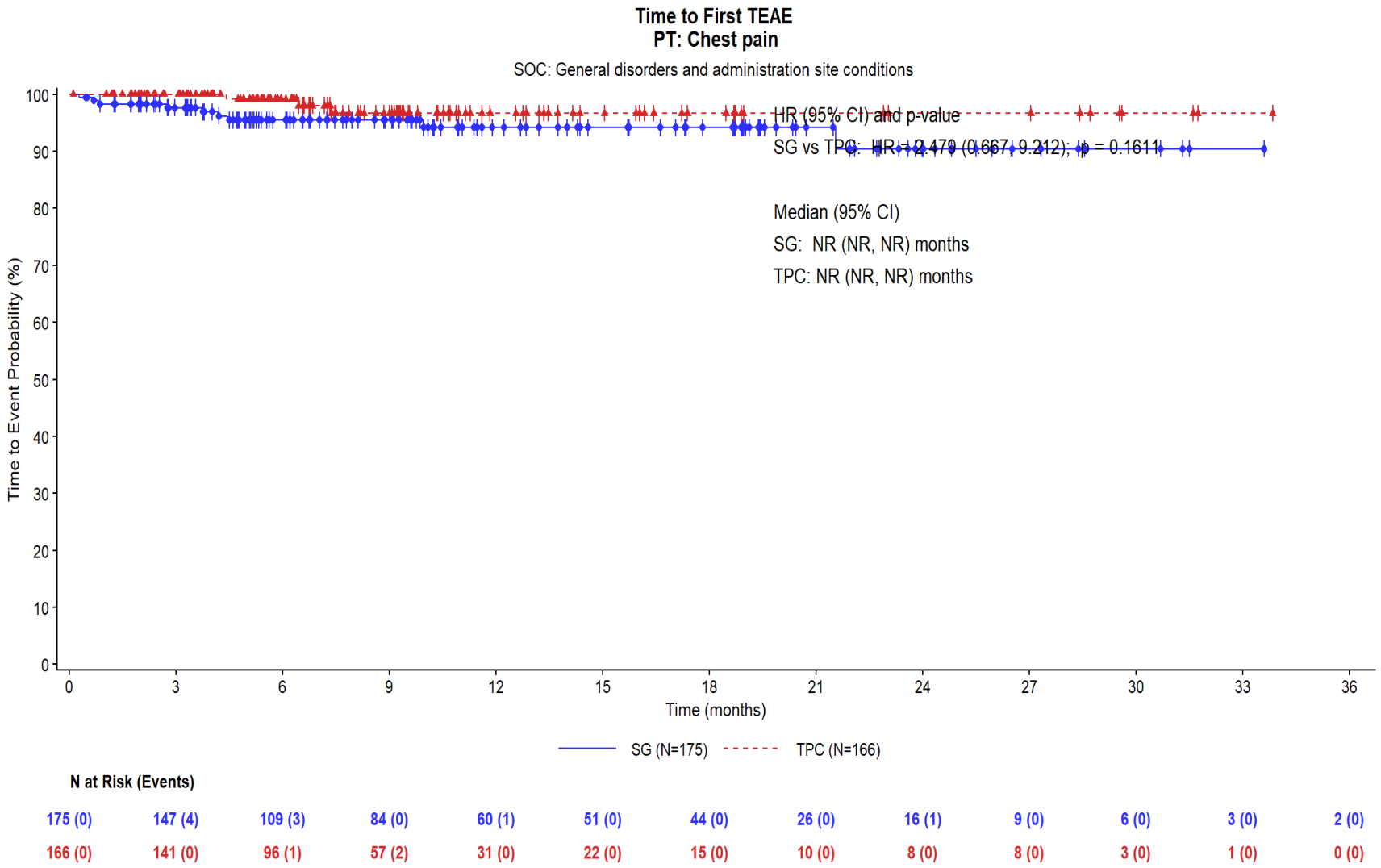
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.57. Figure 1.1.56: Kaplan Meier Plot of Time to First TEAE by PT Vomiting — mSAF — Excluding patients preselected to receive nab-paclitaxel



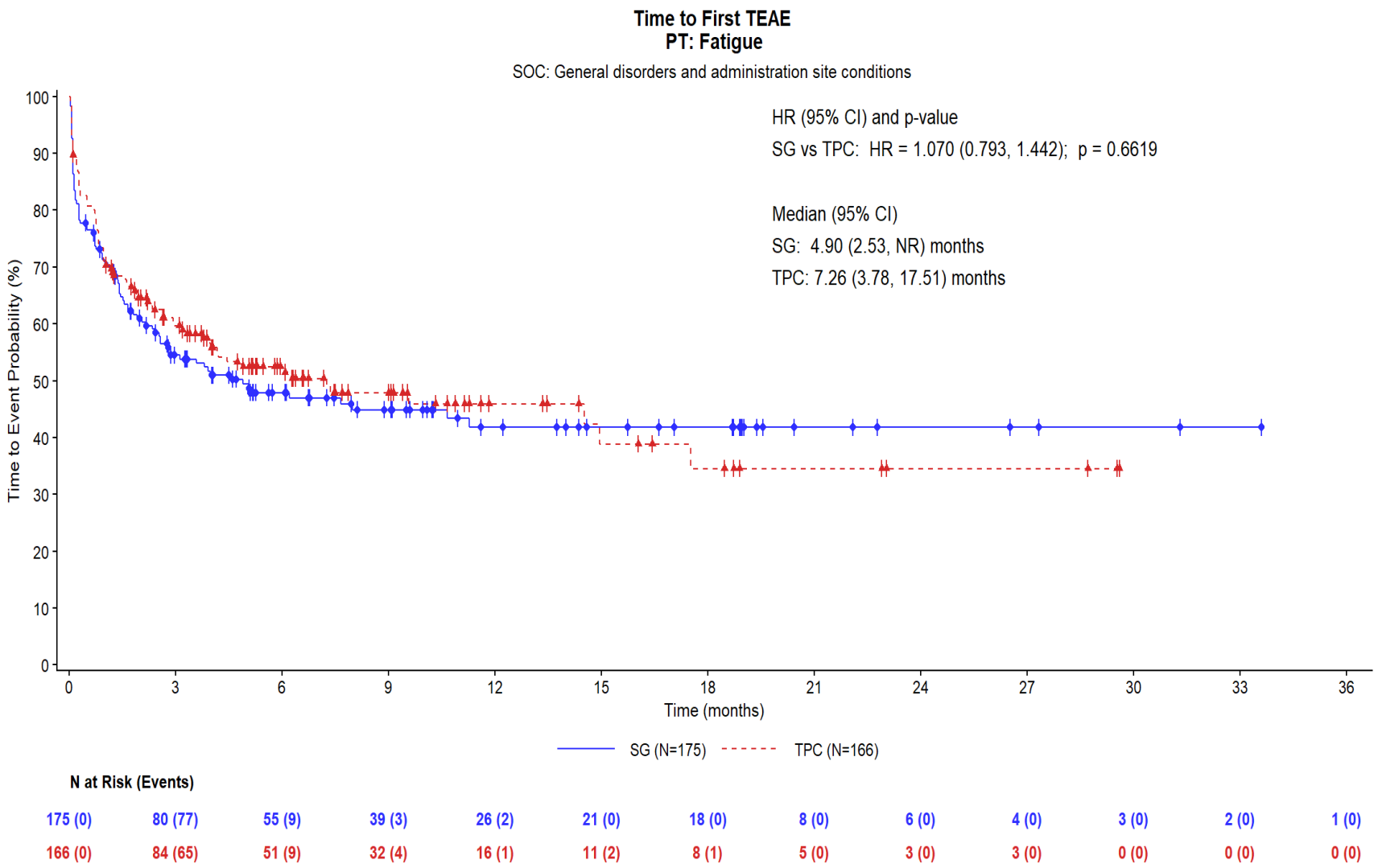
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.58. Figure 1.1.57: Kaplan Meier Plot of Time to First TEAE by PT Chest pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



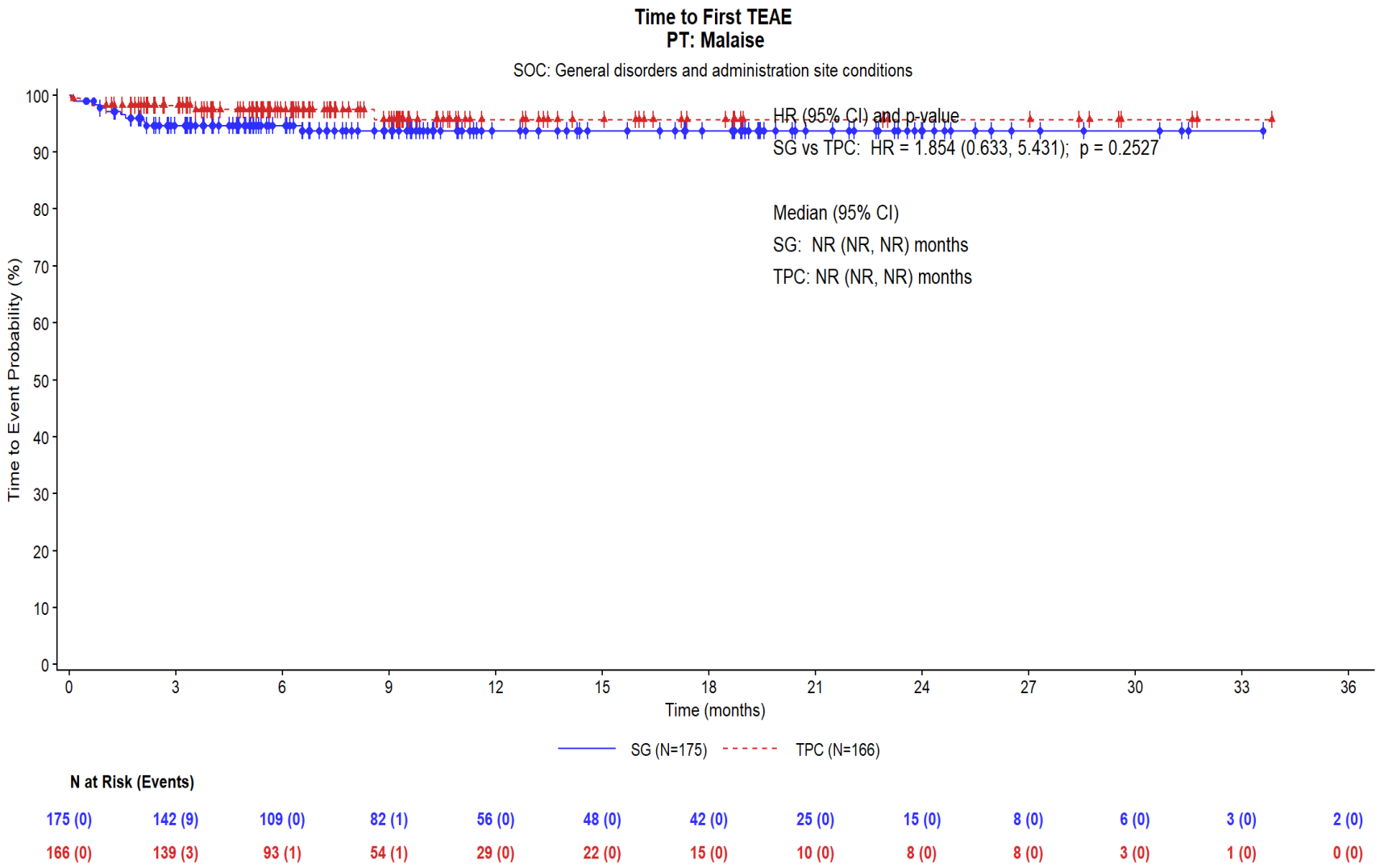
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.59. Figure 1.1.58: Kaplan Meier Plot of Time to First TEAE by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel



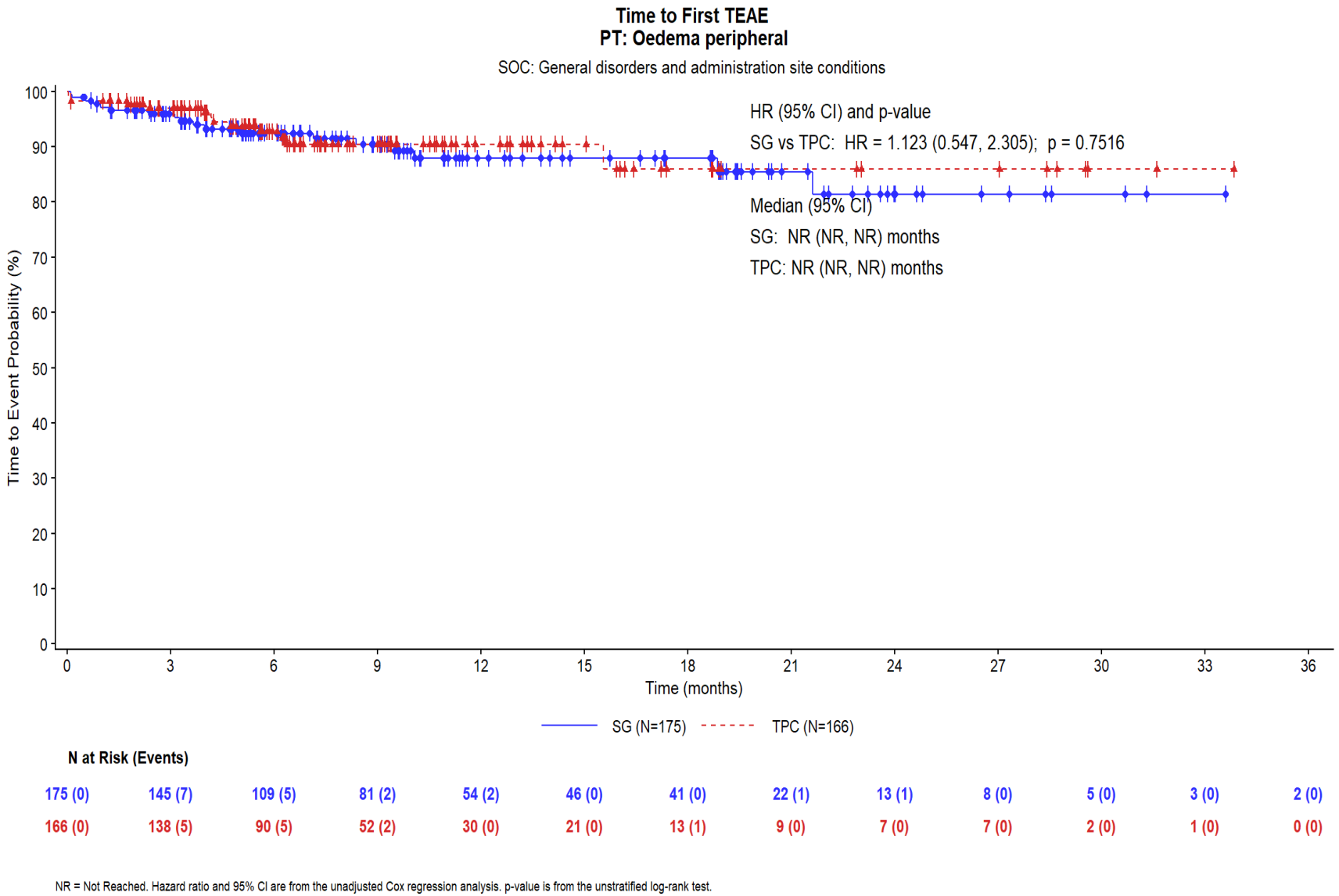
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.60. Figure 1.1.59: Kaplan Meier Plot of Time to First TEAE by PT Malaise — mSAF — Excluding patients preselected to receive nab-paclitaxel



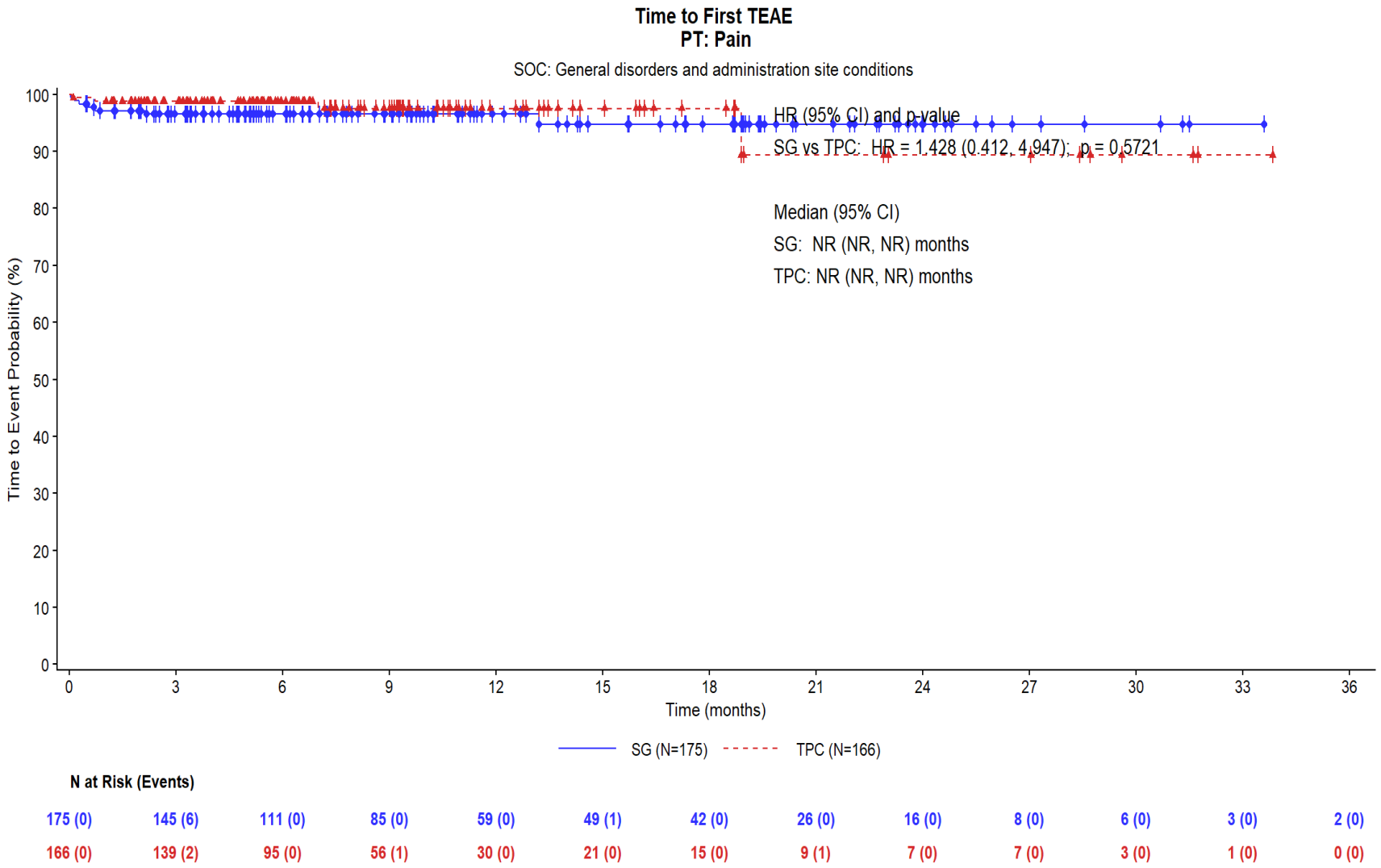
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.61. Figure 1.1.60: Kaplan Meier Plot of Time to First TEAE by PT Oedema peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel



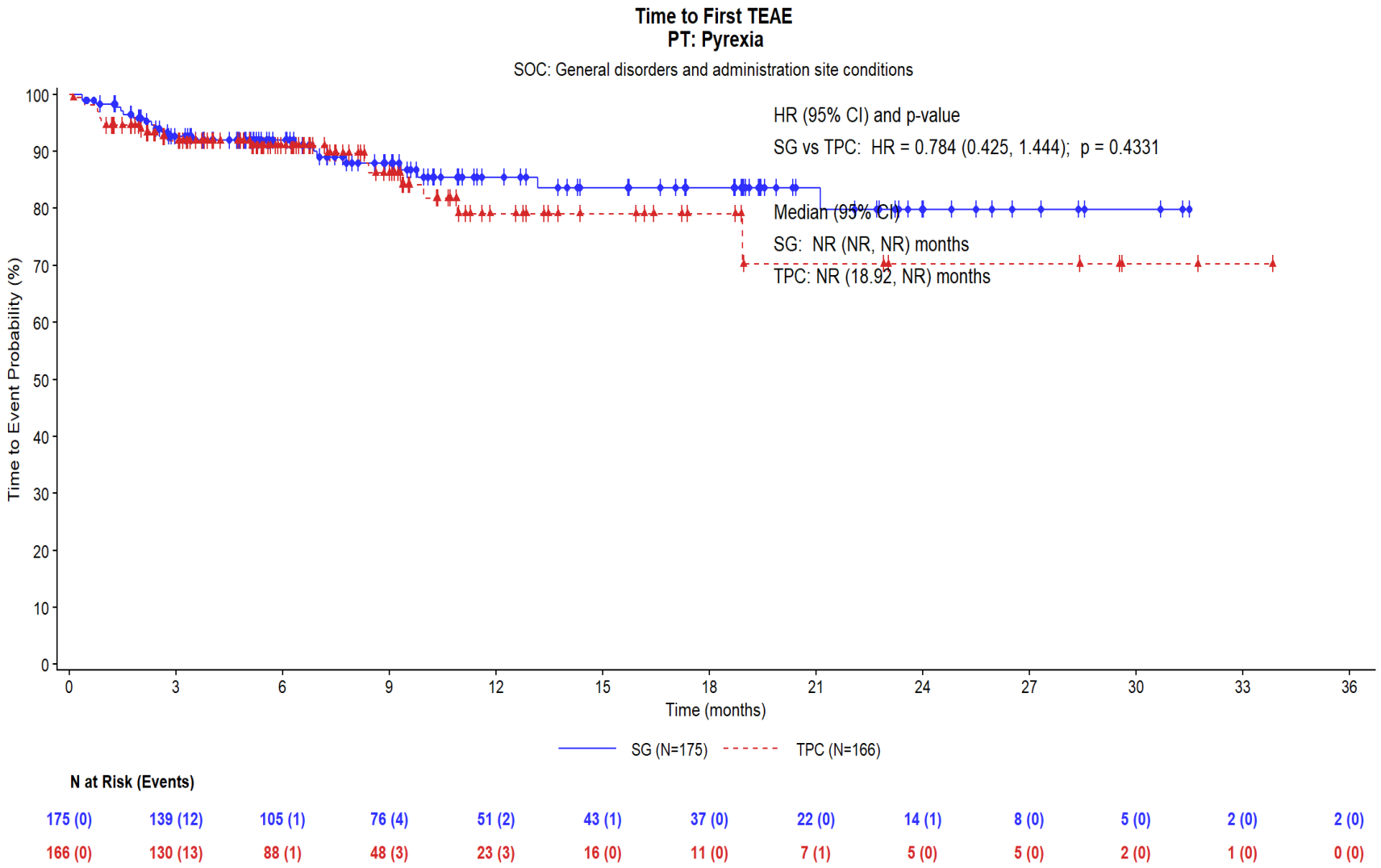
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.62. Figure 1.1.61: Kaplan Meier Plot of Time to First TEAE by PT Pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



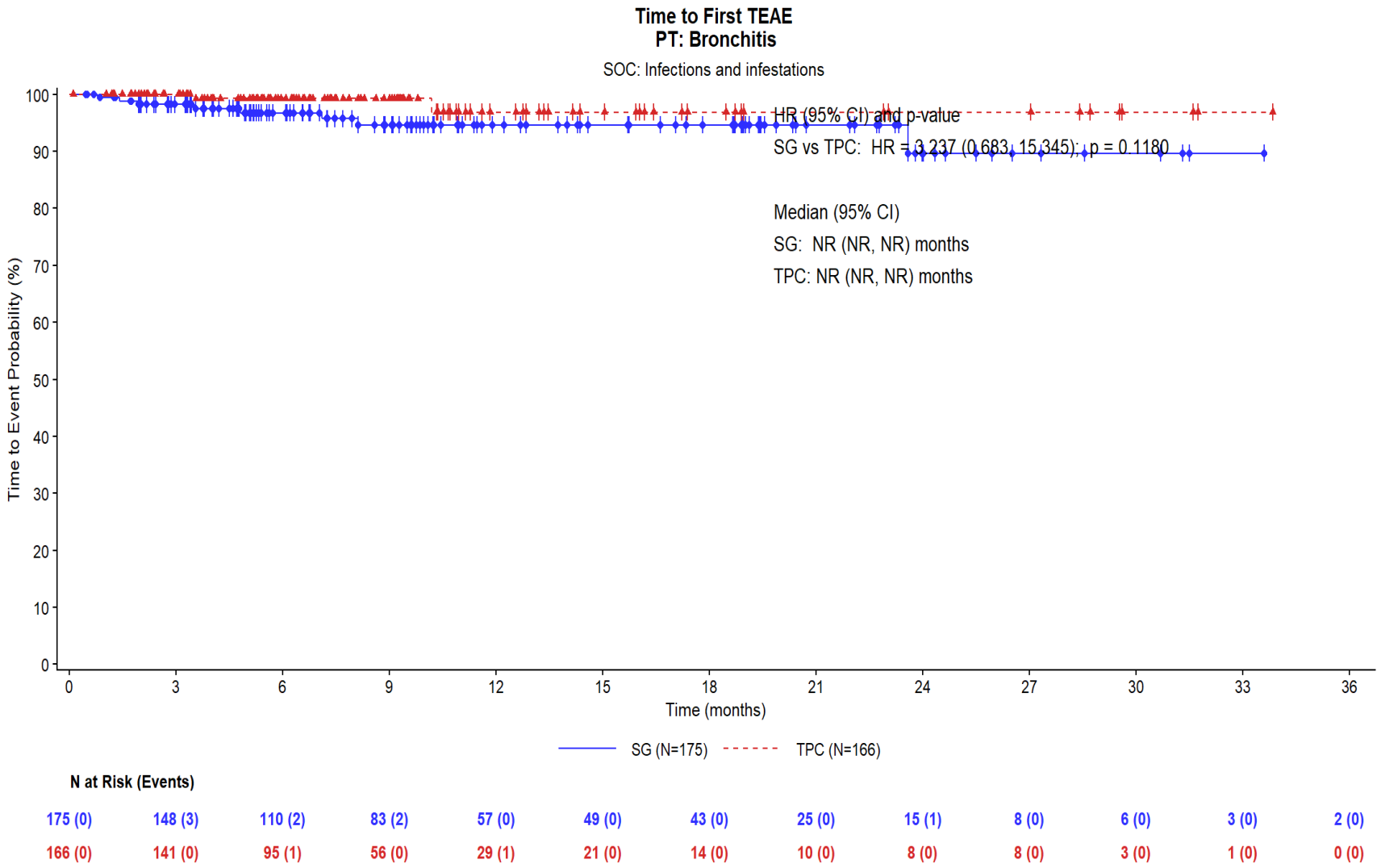
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.63. Figure 1.1.62: Kaplan Meier Plot of Time to First TEAE by PT Pyrexia — mSAF — Excluding patients preselected to receive nab-paclitaxel



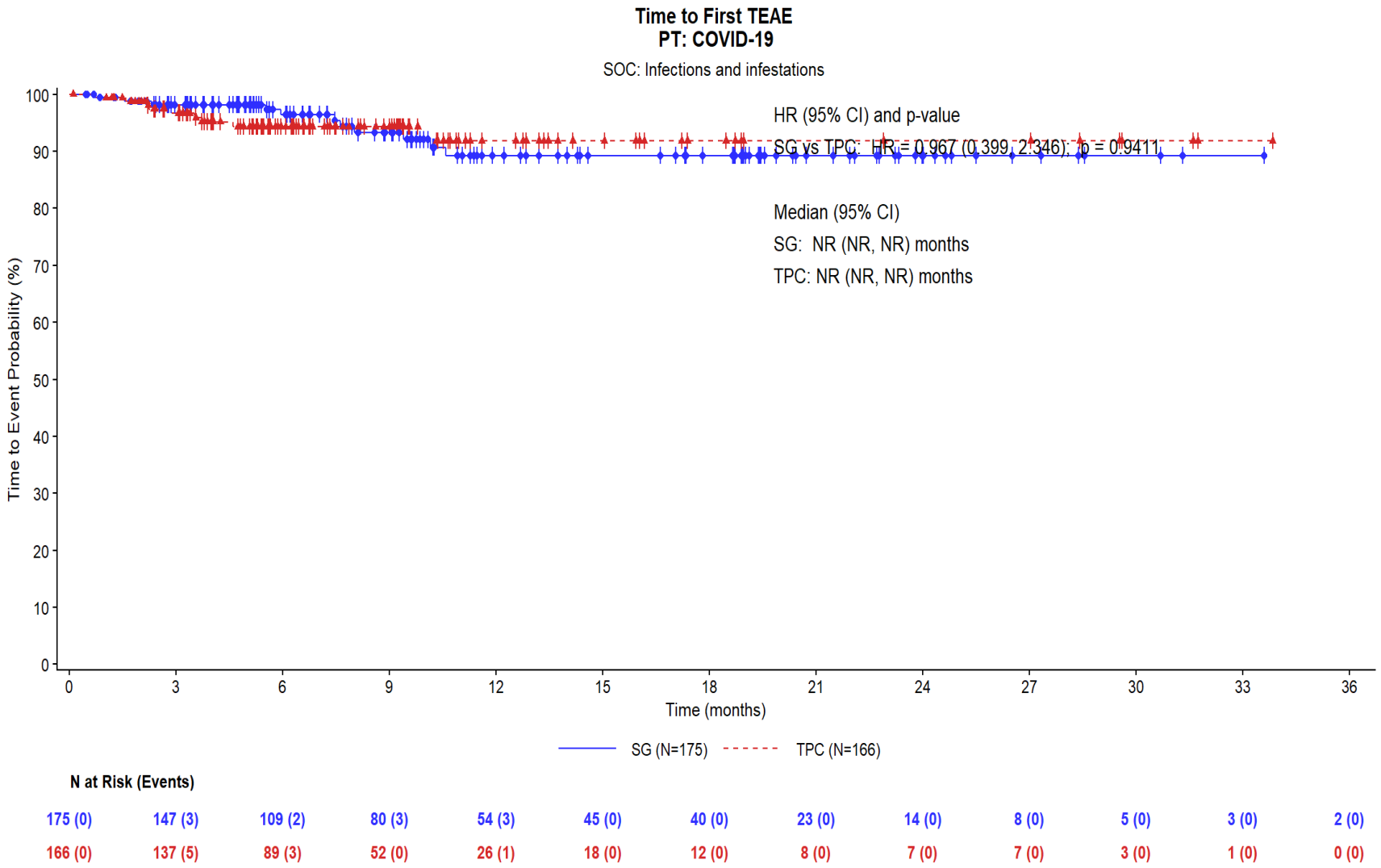
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.64. Figure 1.1.63: Kaplan Meier Plot of Time to First TEAE by PT Bronchitis — mSAF — Excluding patients preselected to receive nab-paclitaxel



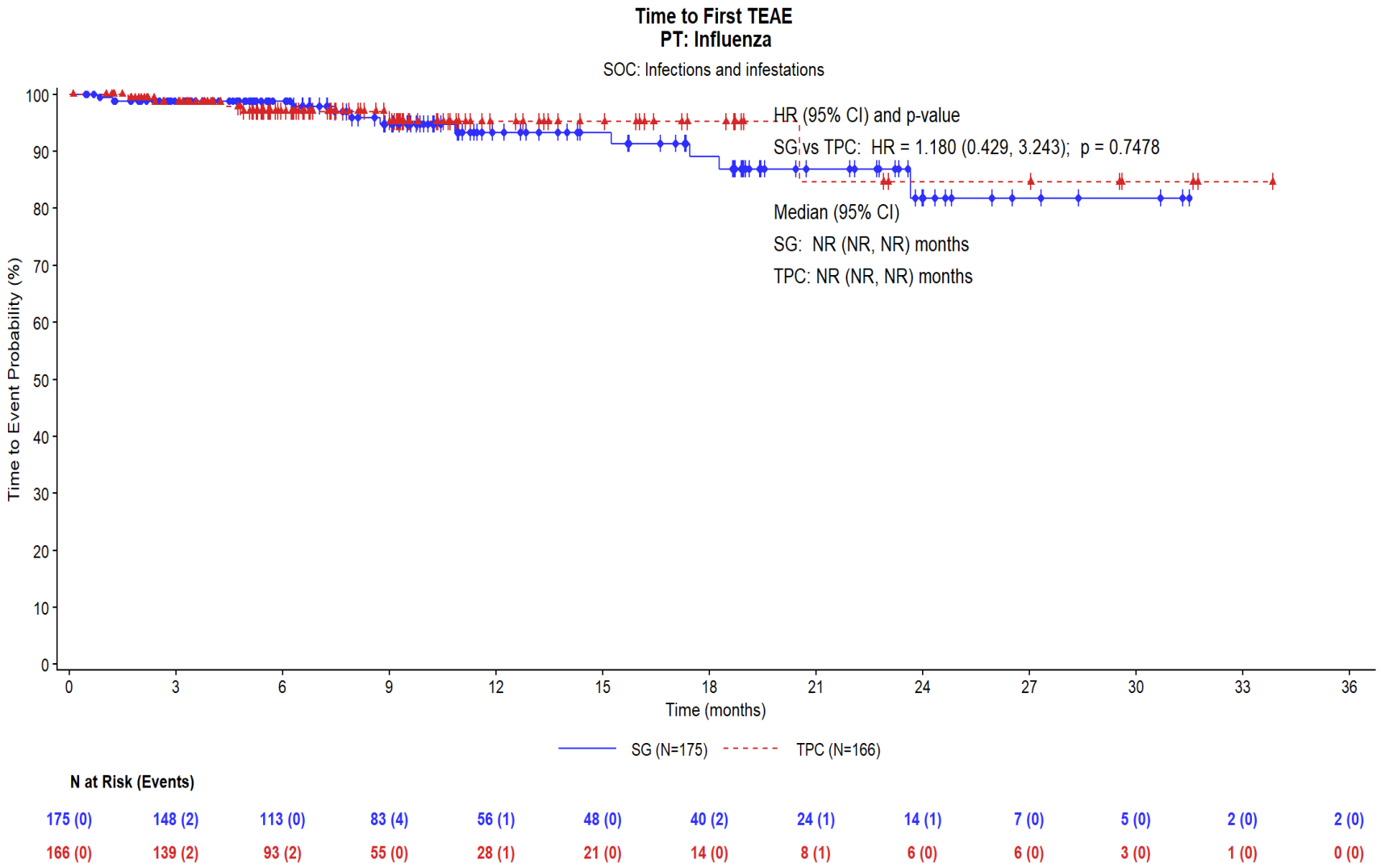
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.65. Figure 1.1.64: Kaplan Meier Plot of Time to First TEAE by PT COVID 19 — mSAF — Excluding patients preselected to receive nab-paclitaxel



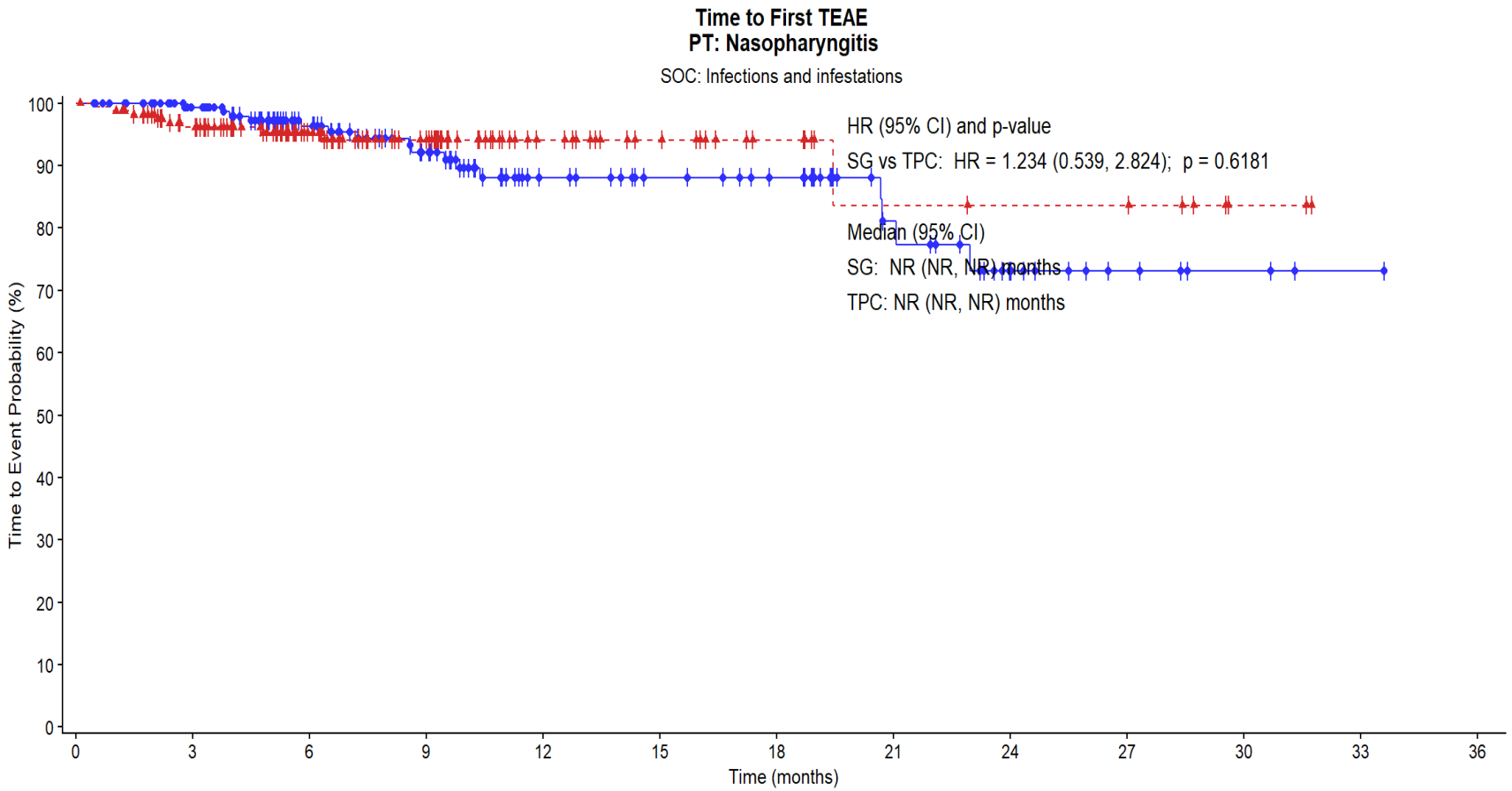
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.66. Figure 1.1.65: Kaplan Meier Plot of Time to First TEAE by PT Influenza — mSAF — Excluding patients preselected to receive nab-paclitaxel



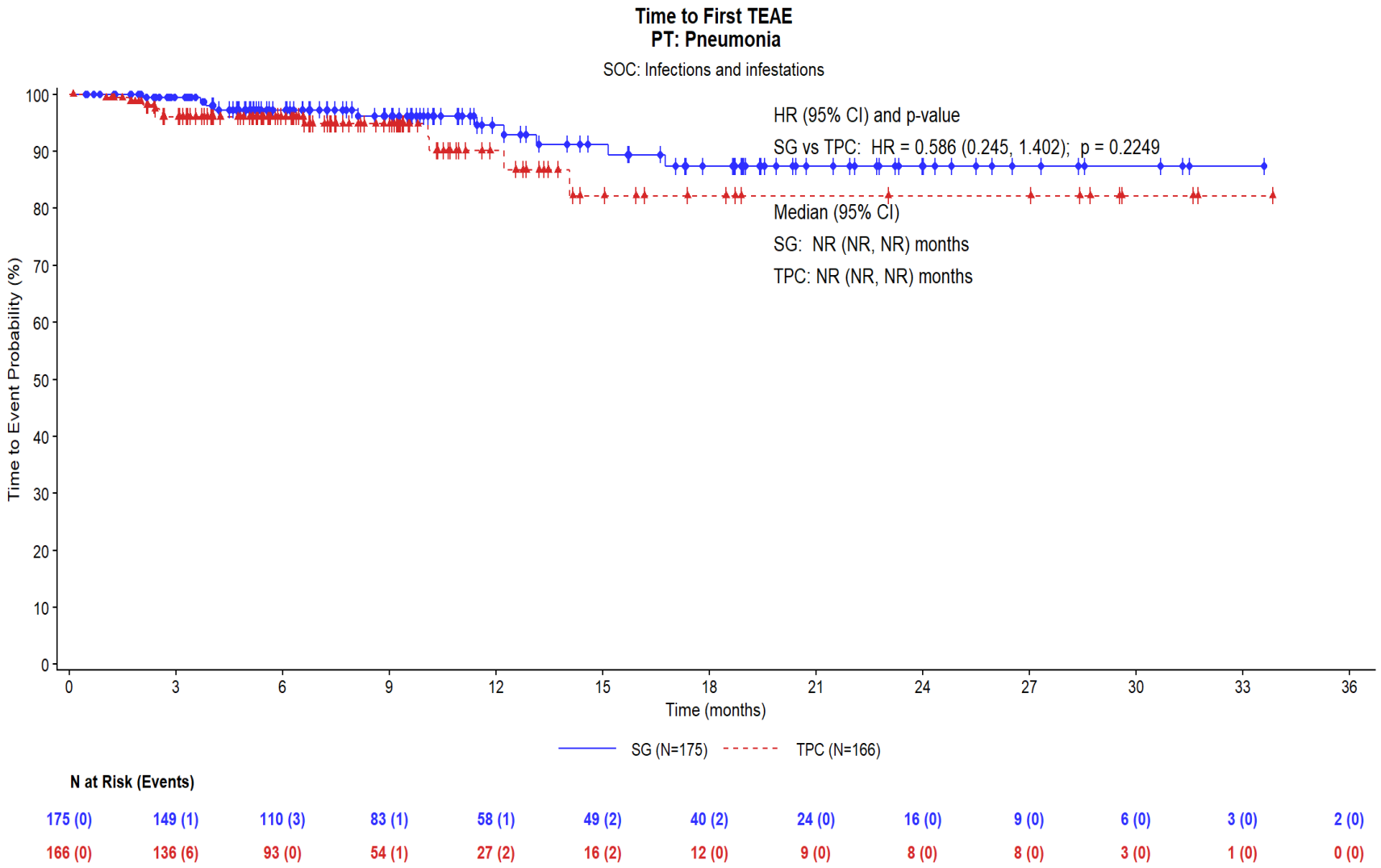
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.67. Figure 1.1.66: Kaplan Meier Plot of Time to First TEAE by PT Nasopharyngitis — mSAF — Excluding patients preselected to receive nab-paclitaxel



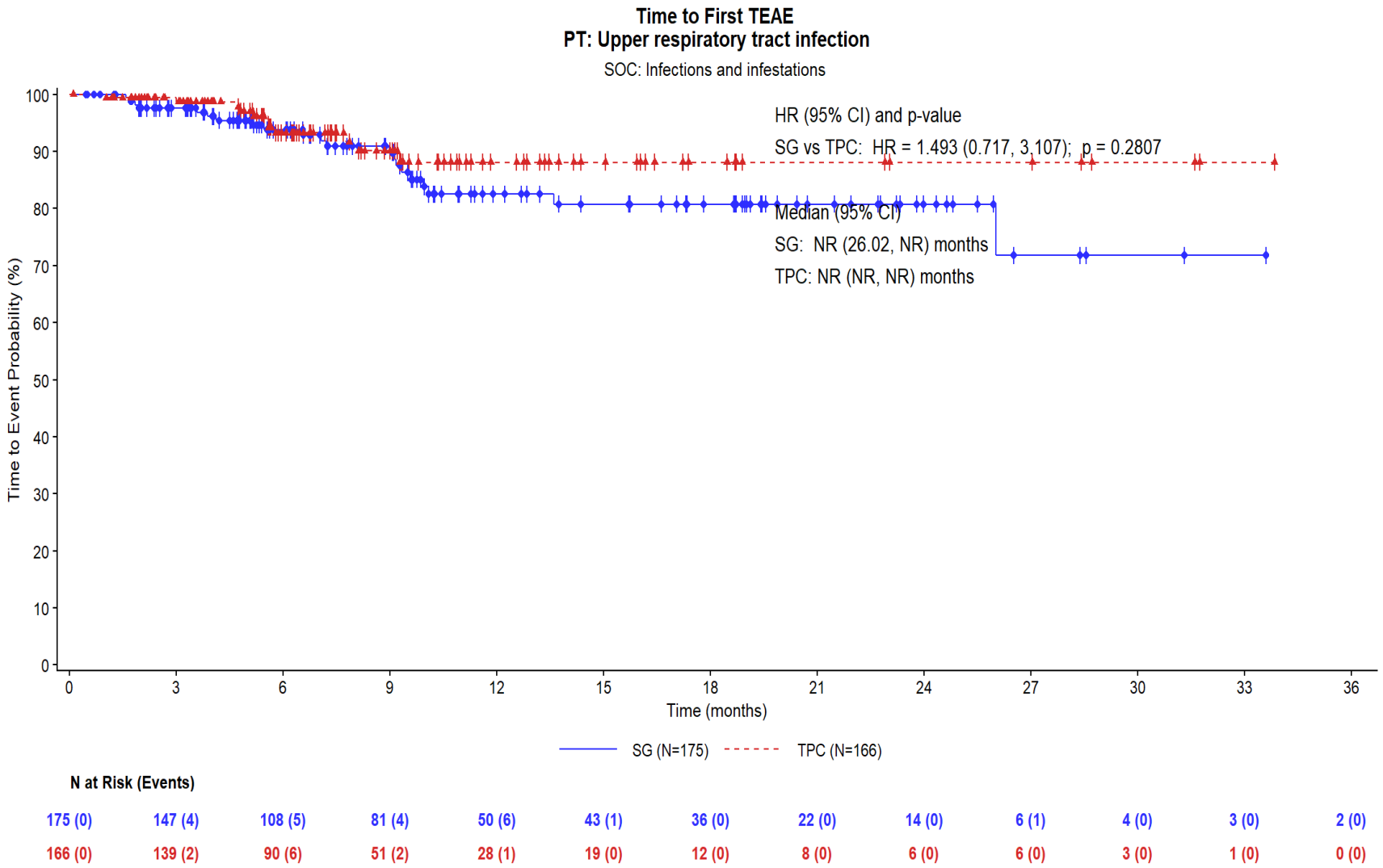
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.68. Figure 1.1.67: Kaplan Meier Plot of Time to First TEAE by PT Pneumonia — mSAF — Excluding patients preselected to receive nab-paclitaxel



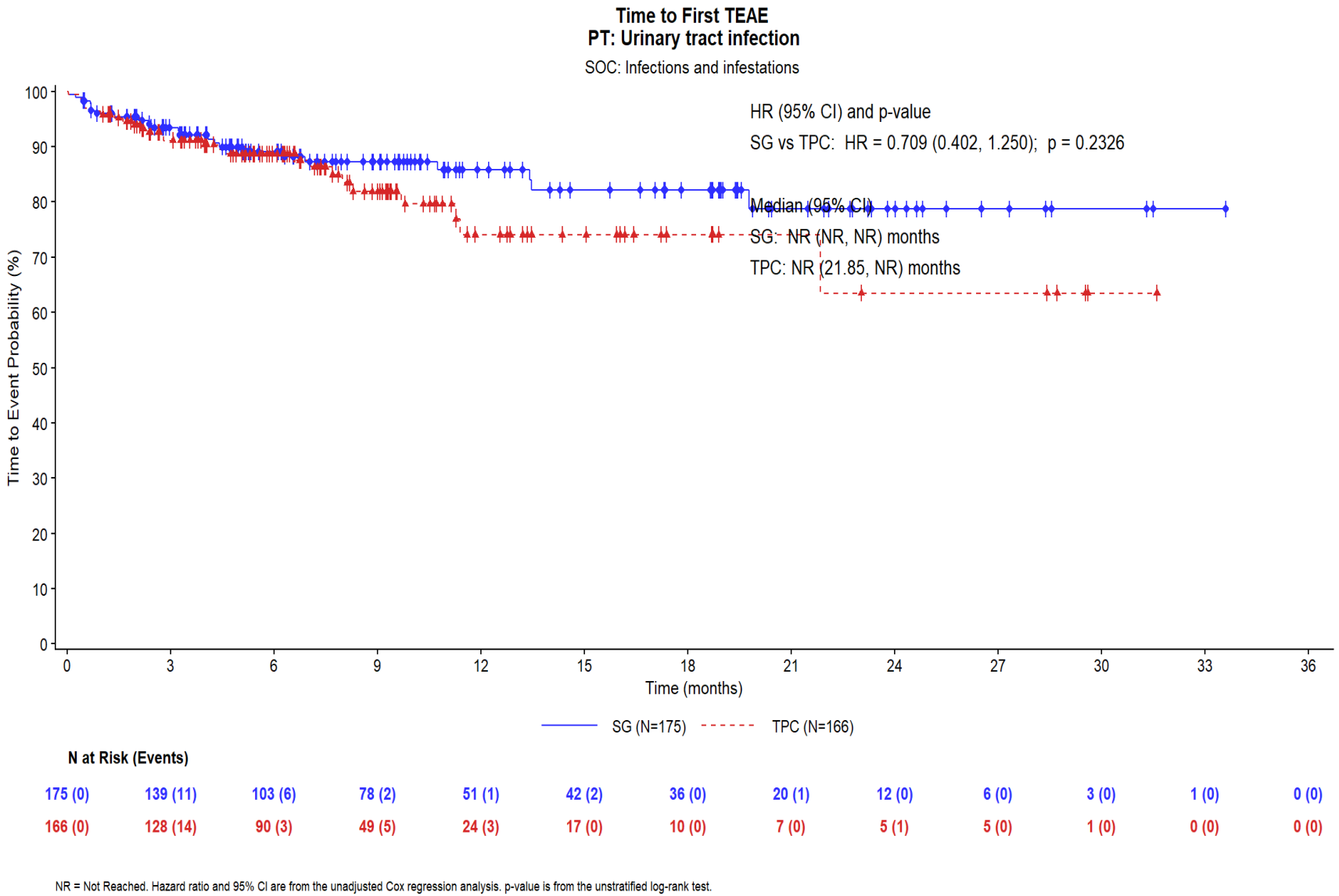
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.69. Figure 1.1.68: Kaplan Meier Plot of Time to First TEAE by PT Upper respiratory tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel



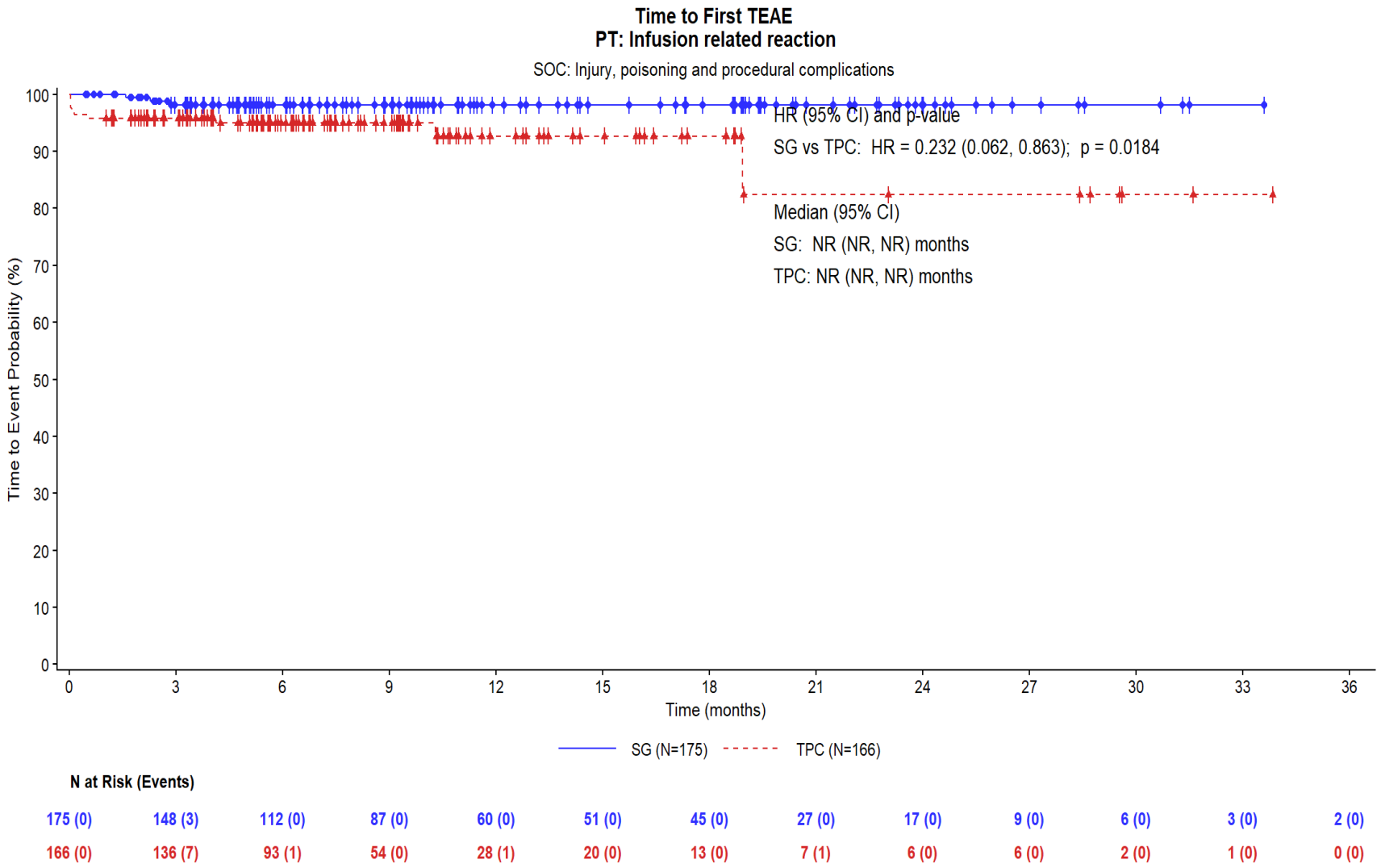
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.70. Figure 1.1.69: Kaplan Meier Plot of Time to First TEAE by PT Urinary tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel



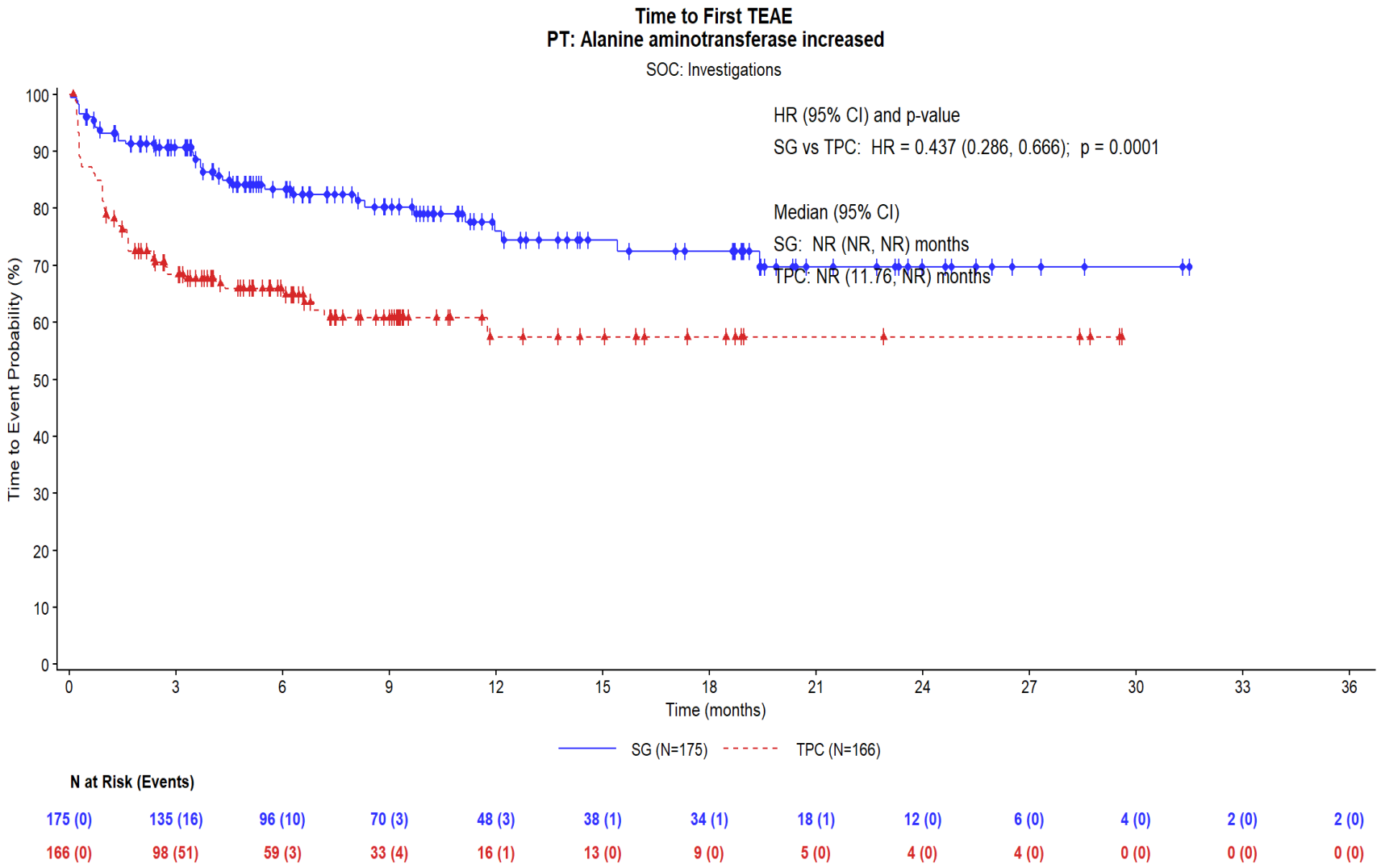
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.71. Figure 1.1.70: Kaplan Meier Plot of Time to First TEAE by PT Infusion related reaction — mSAF — Excluding patients preselected to receive nab-paclitaxel



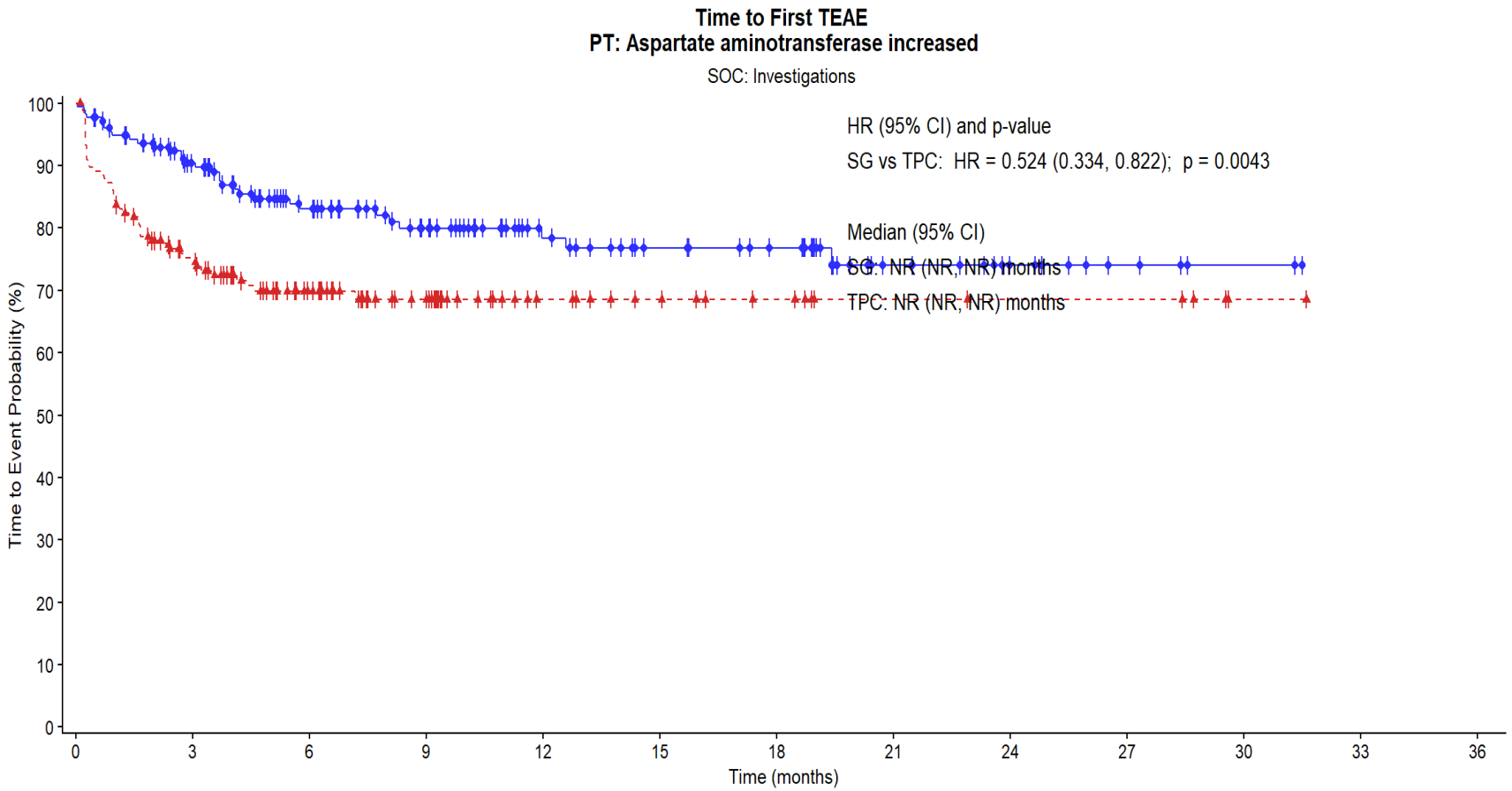
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.72. Figure 1.1.71: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



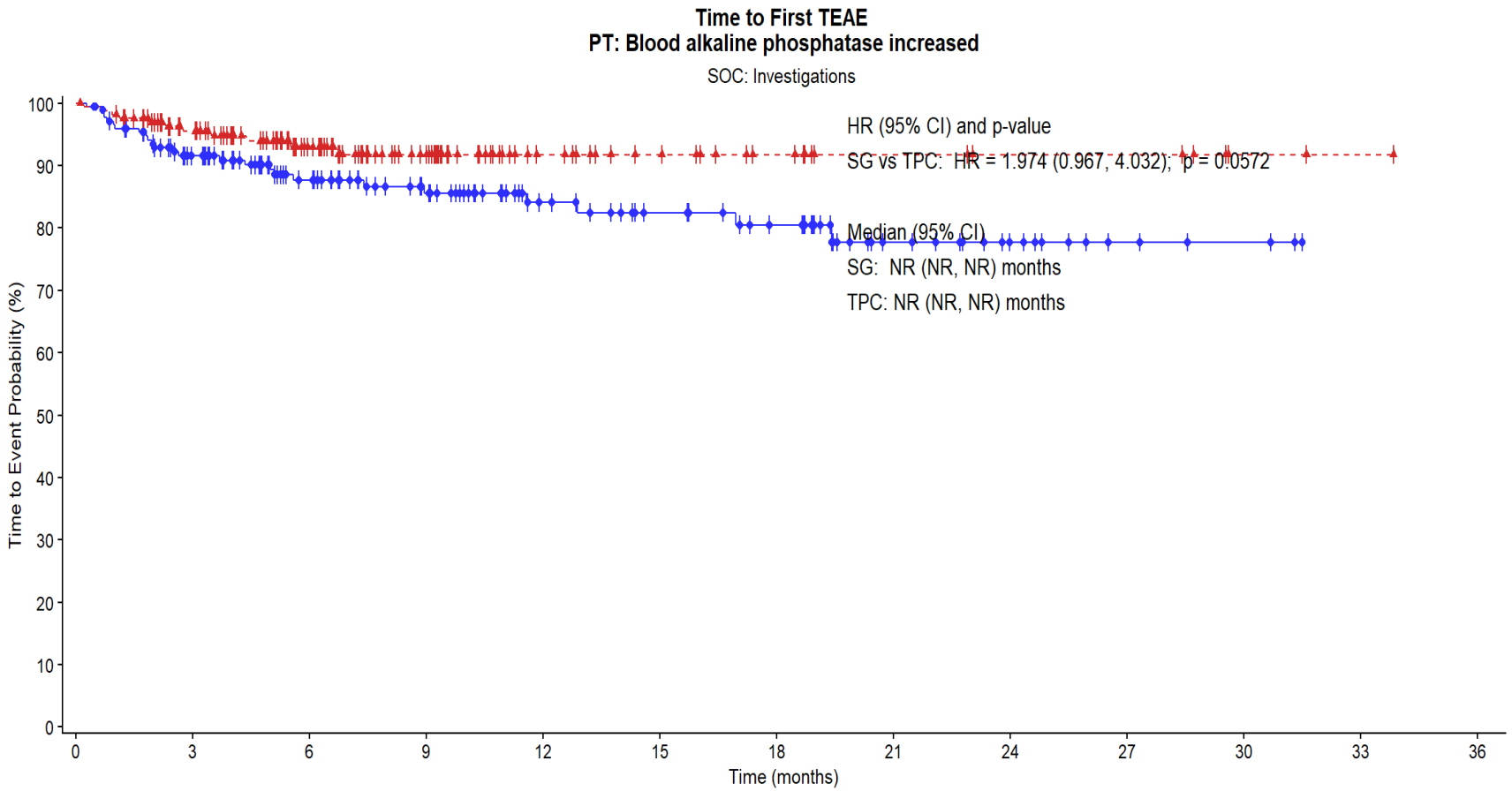
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.73. Figure 1.1.72: Kaplan Meier Plot of Time to First TEAE by PT Aspartate aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



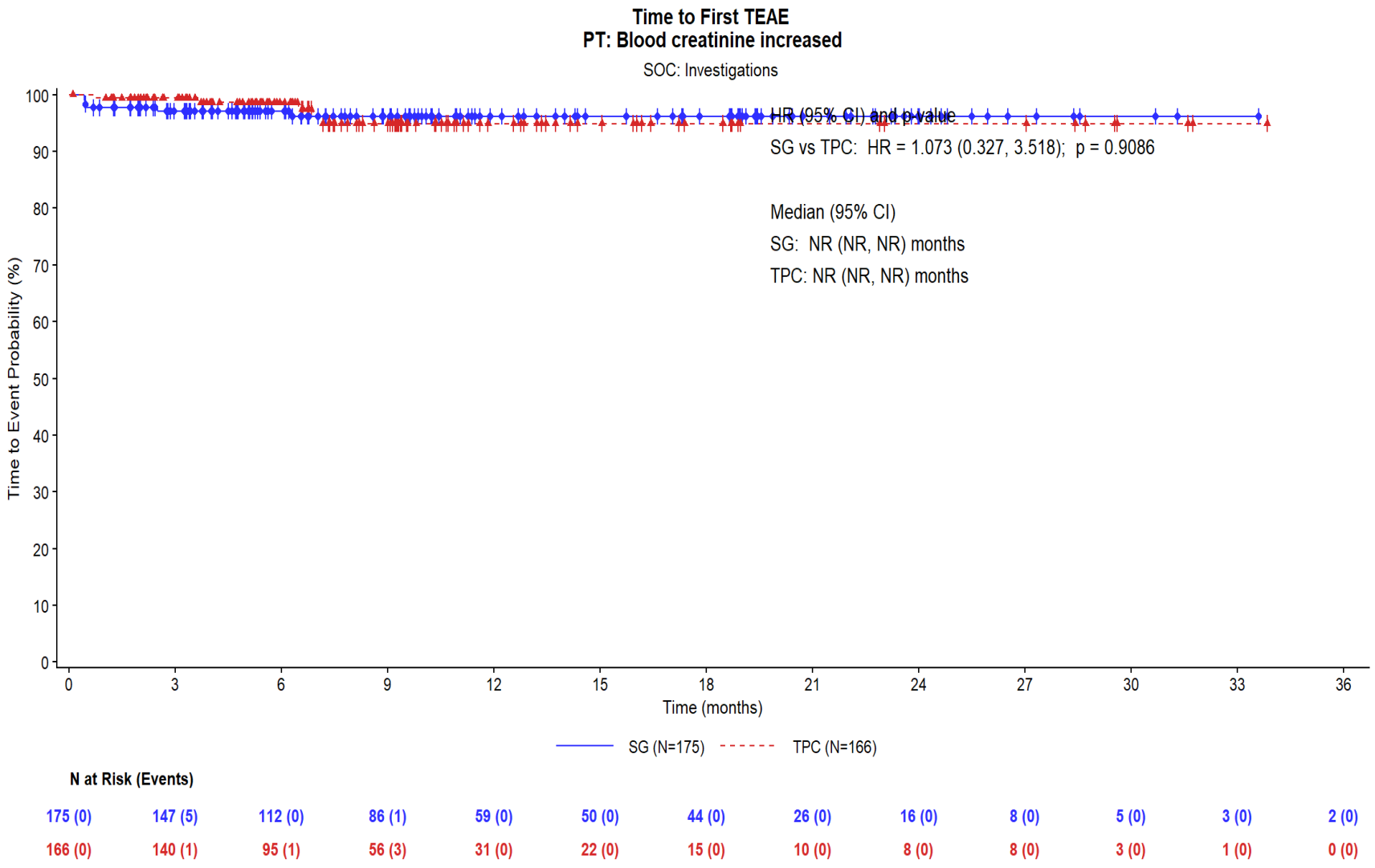
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.74. Figure 1.1.73: Kaplan Meier Plot of Time to First TEAE by PT Blood alkaline phosphatase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



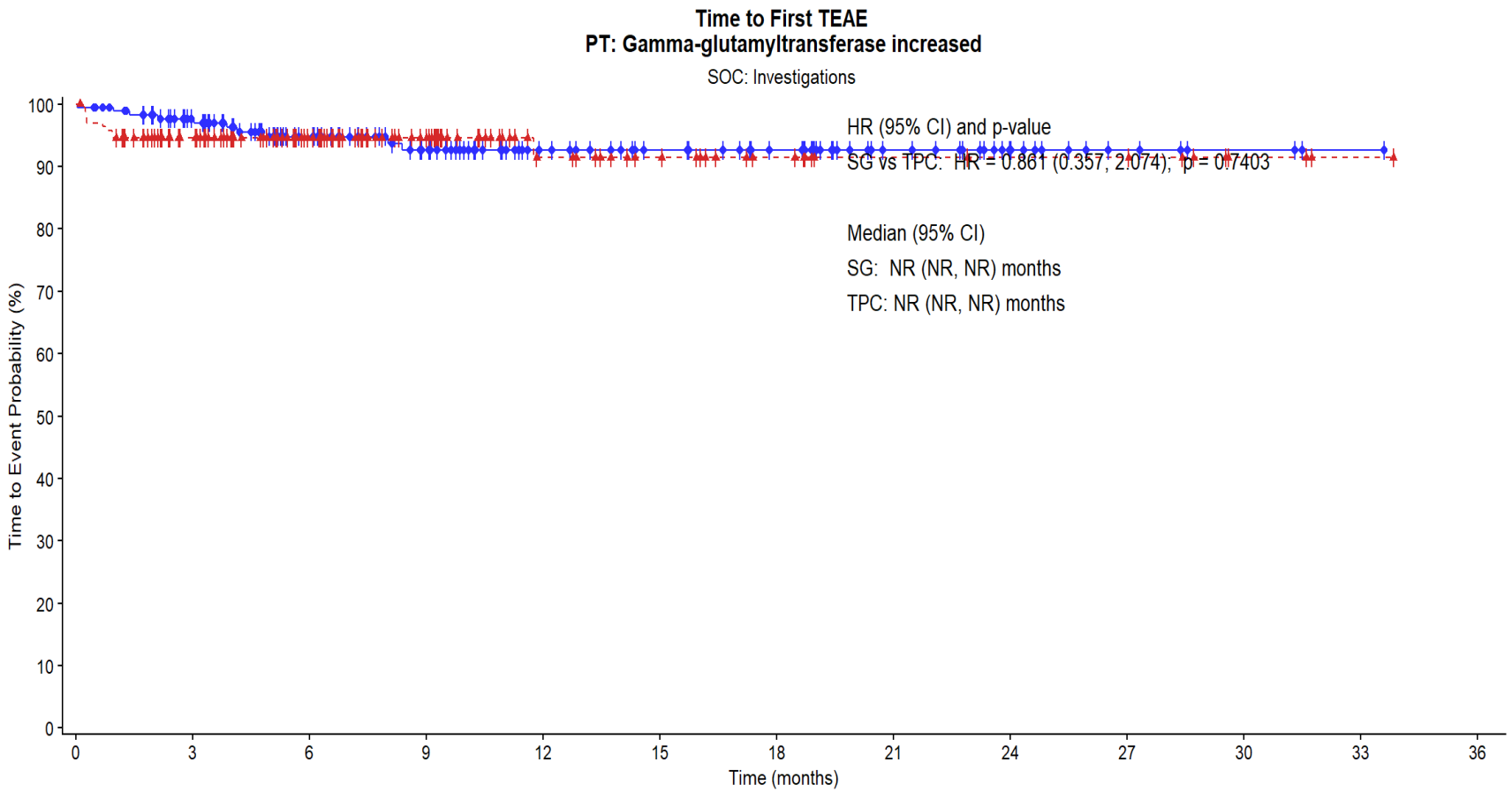
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.75. Figure 1.1.74: Kaplan Meier Plot of Time to First TEAE by PT Blood creatinine increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



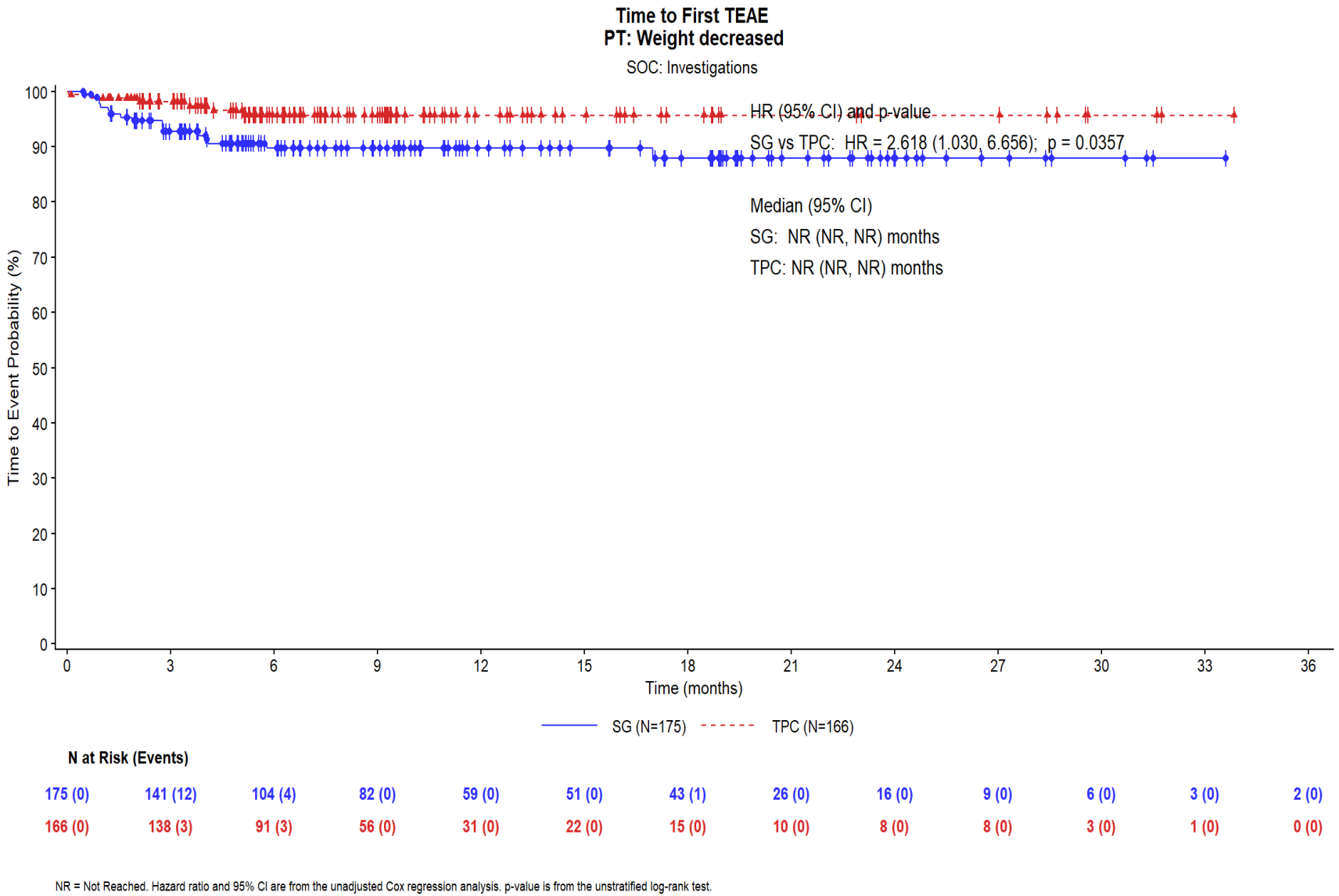
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.76. Figure 1.1.75: Kaplan Meier Plot of Time to First TEAE by PT Gamma glutamyltransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



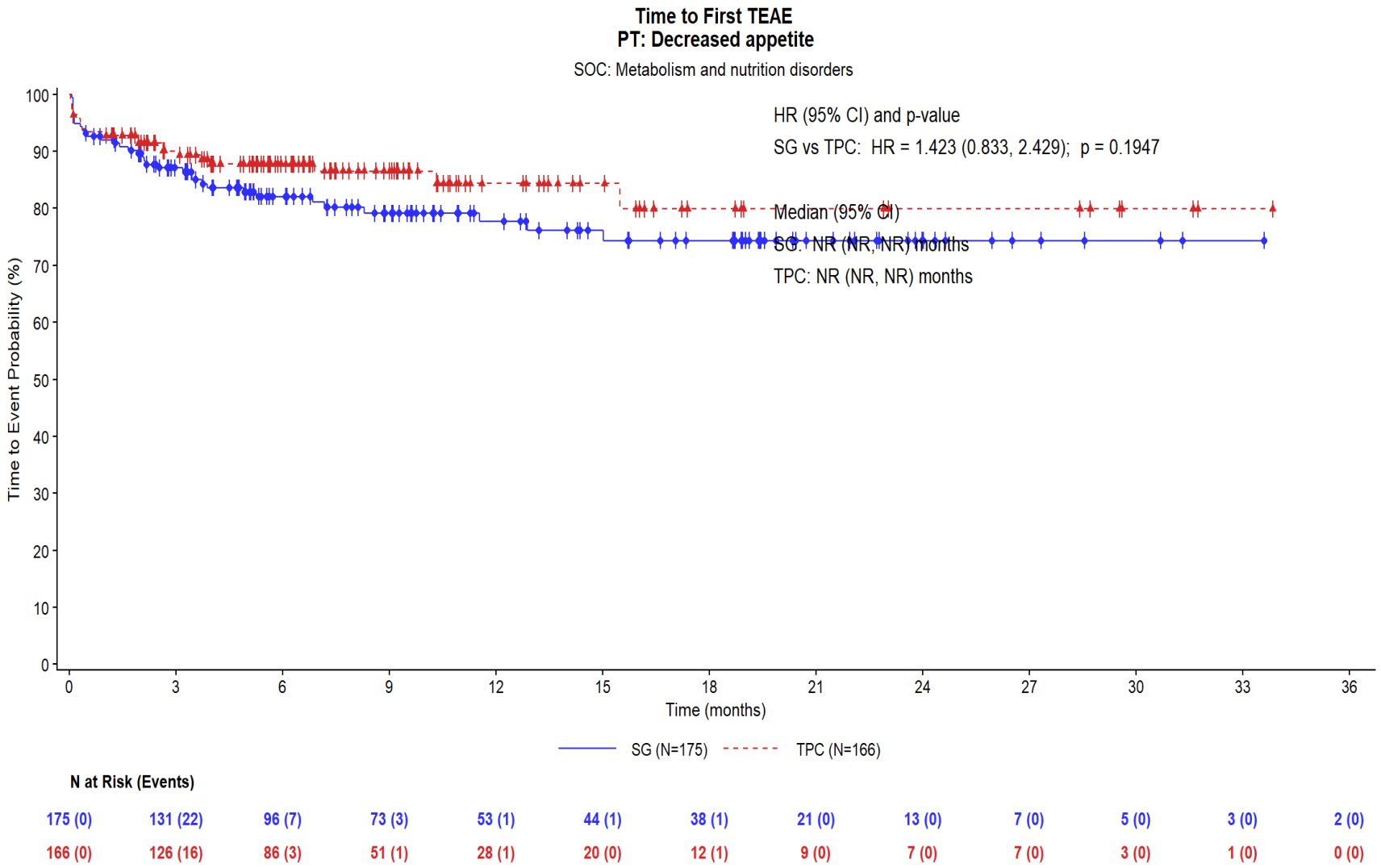
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.77. Figure 1.1.76: Kaplan Meier Plot of Time to First TEAE by PT Weight decreased — mSAF — Excluding patients preselected to receive nab-paclitaxel



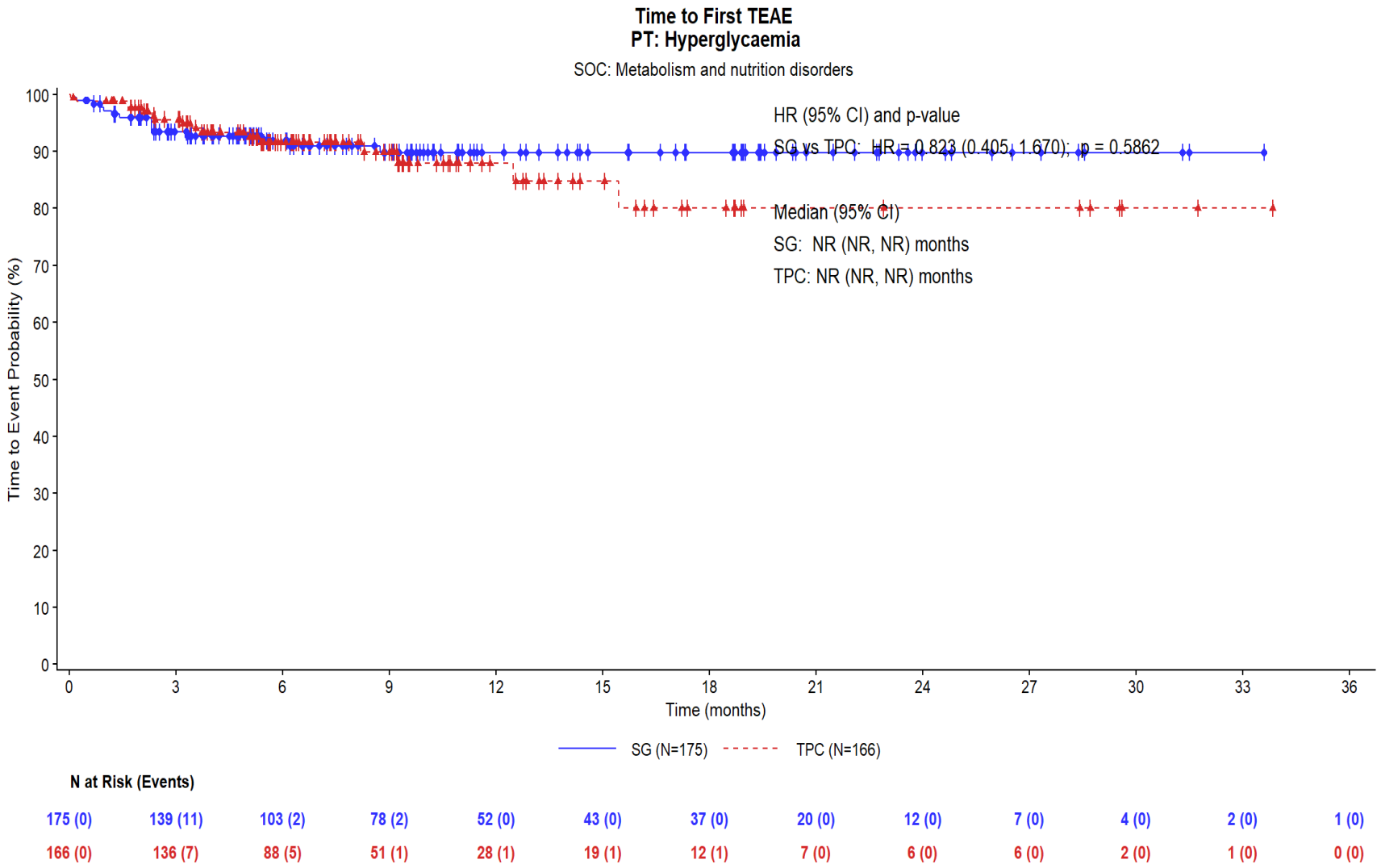
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.78. Figure 1.1.77: Kaplan Meier Plot of Time to First TEAE by PT Decreased appetite — mSAF — Excluding patients preselected to receive nab-paclitaxel



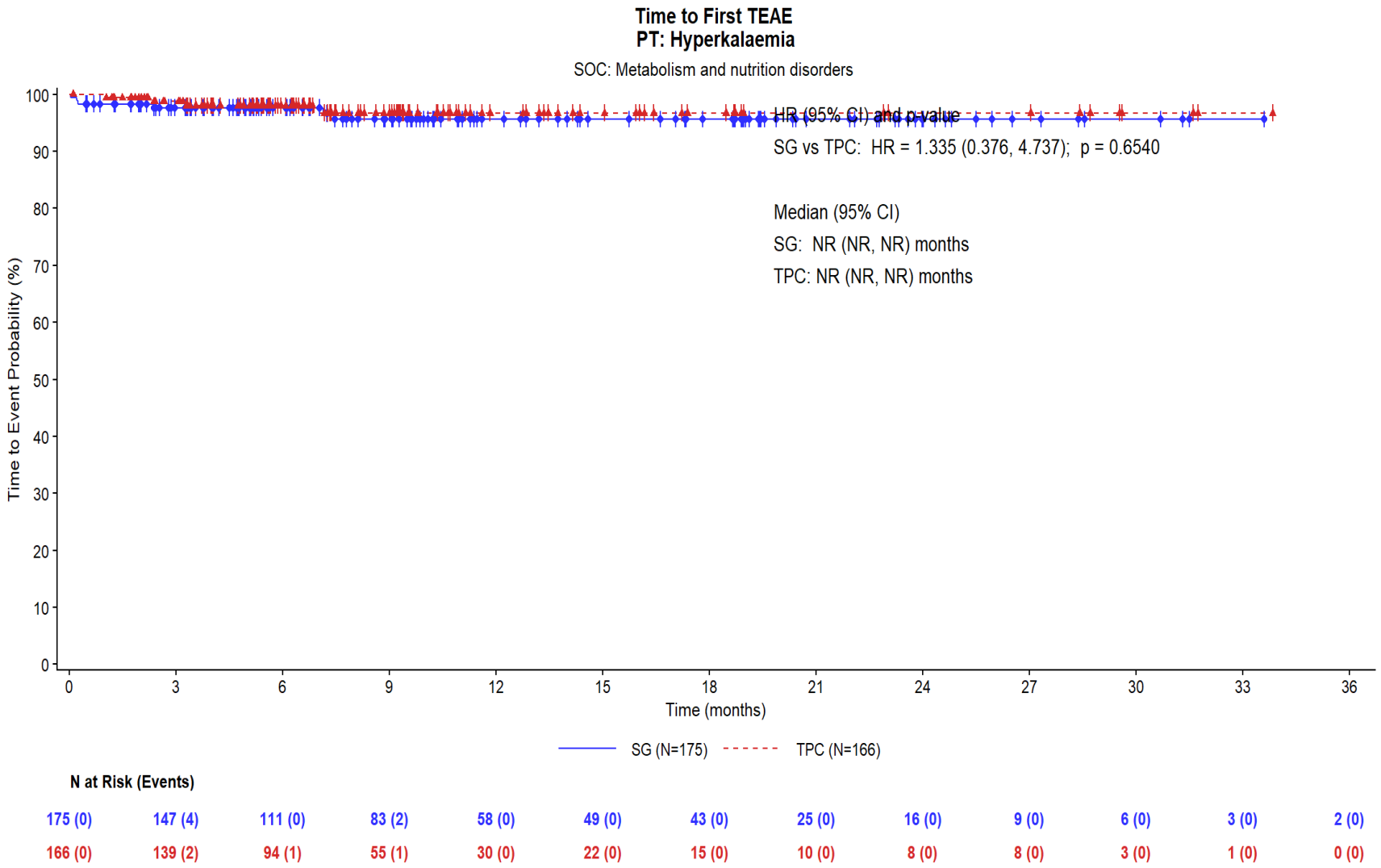
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.79. Figure 1.1.78: Kaplan Meier Plot of Time to First TEAE by PT Hyperglycaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



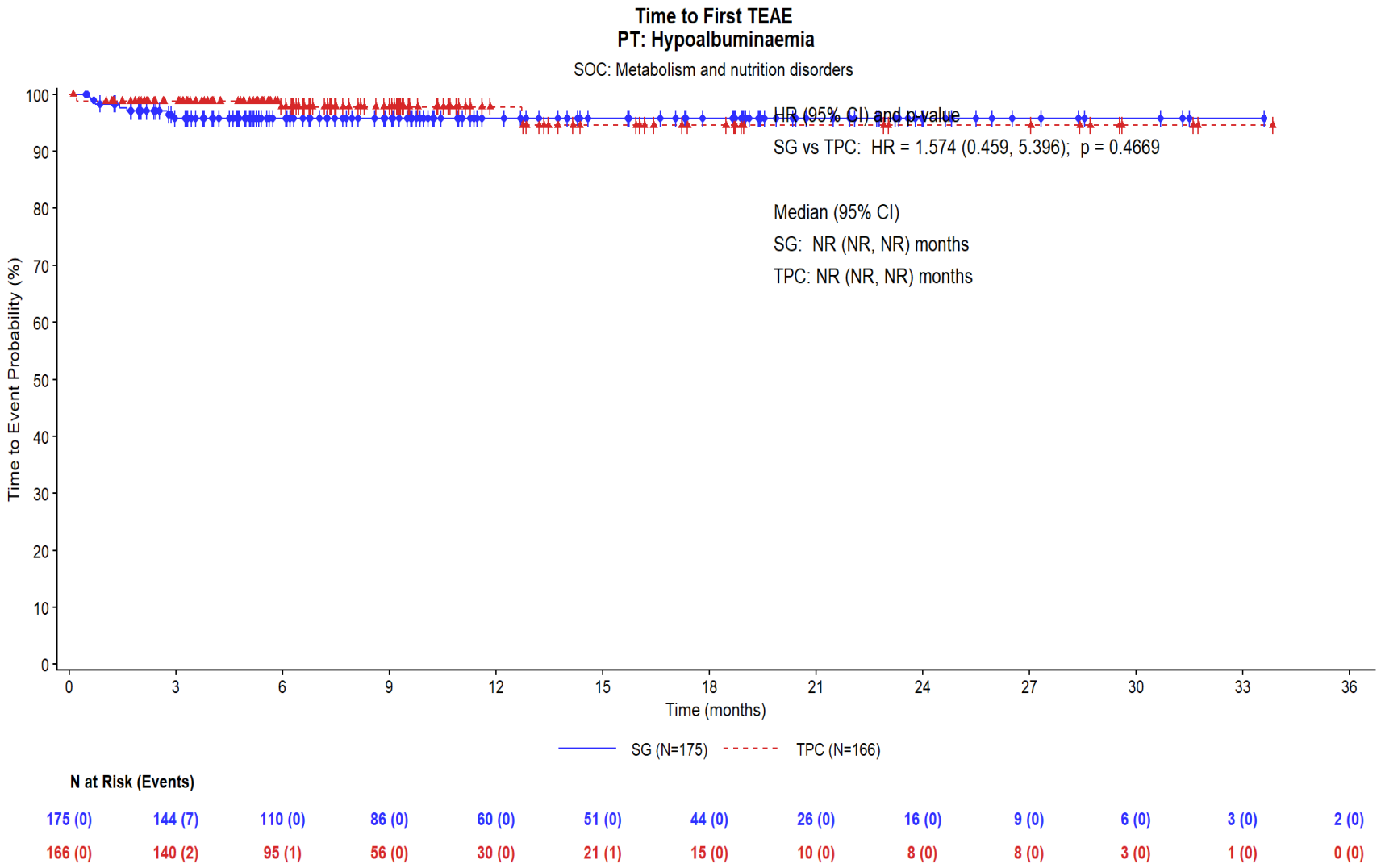
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.80. Figure 1.1.79: Kaplan Meier Plot of Time to First TEAE by PT Hyperkalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



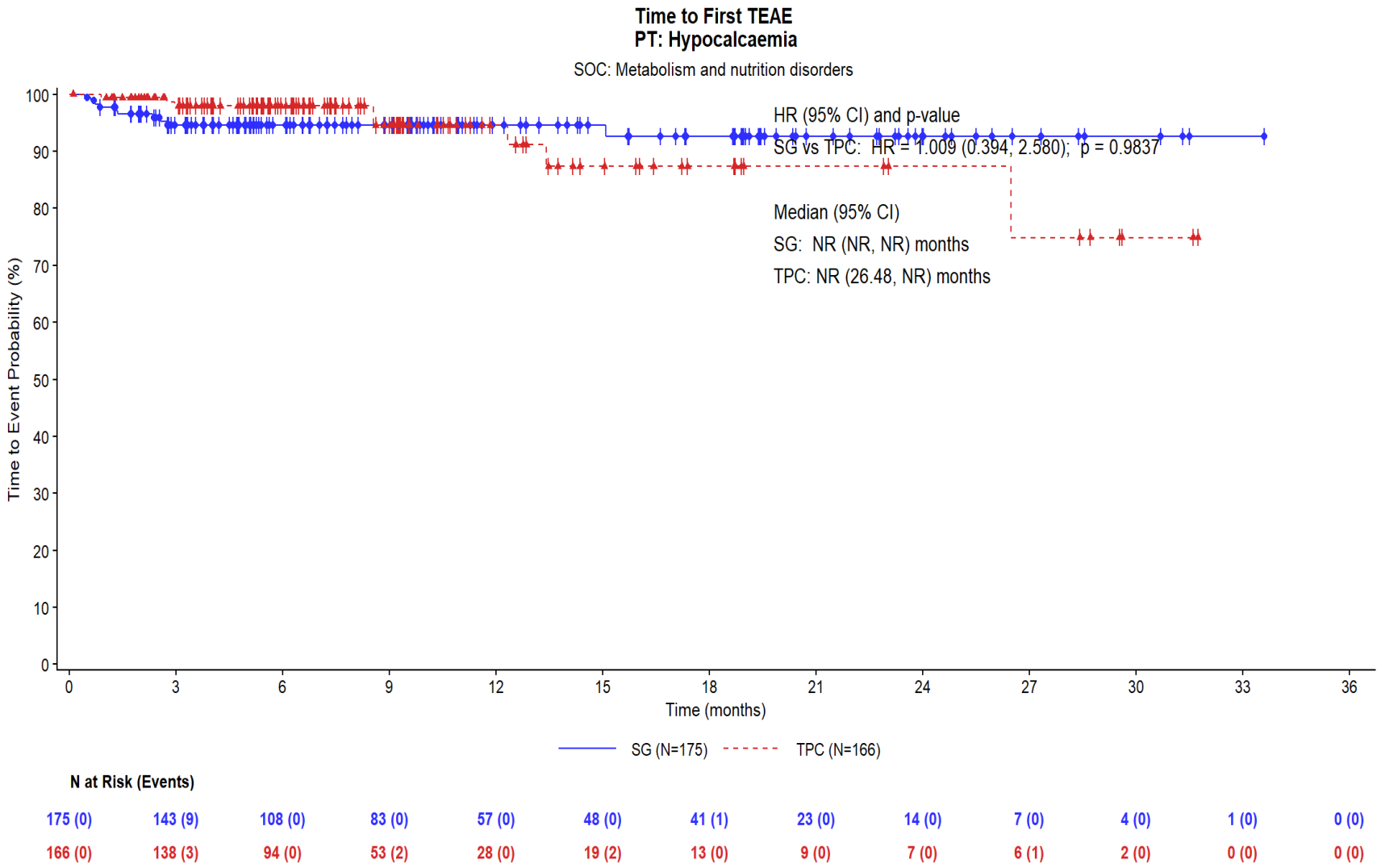
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.81. Figure 1.1.80: Kaplan Meier Plot of Time to First TEAE by PT Hypoalbuminaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



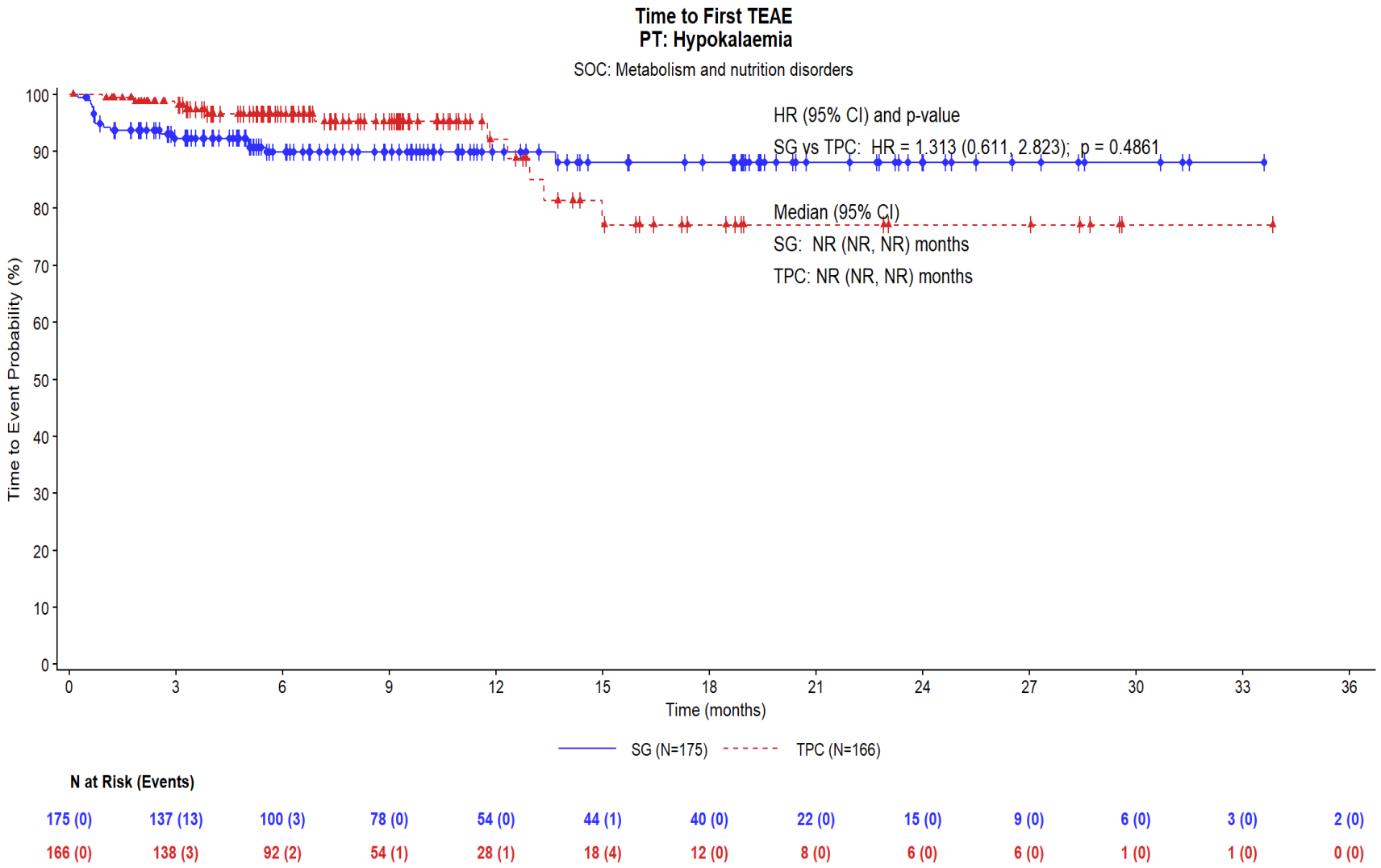
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.82. Figure 1.1.81: Kaplan Meier Plot of Time to First TEAE by PT Hypocalcaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



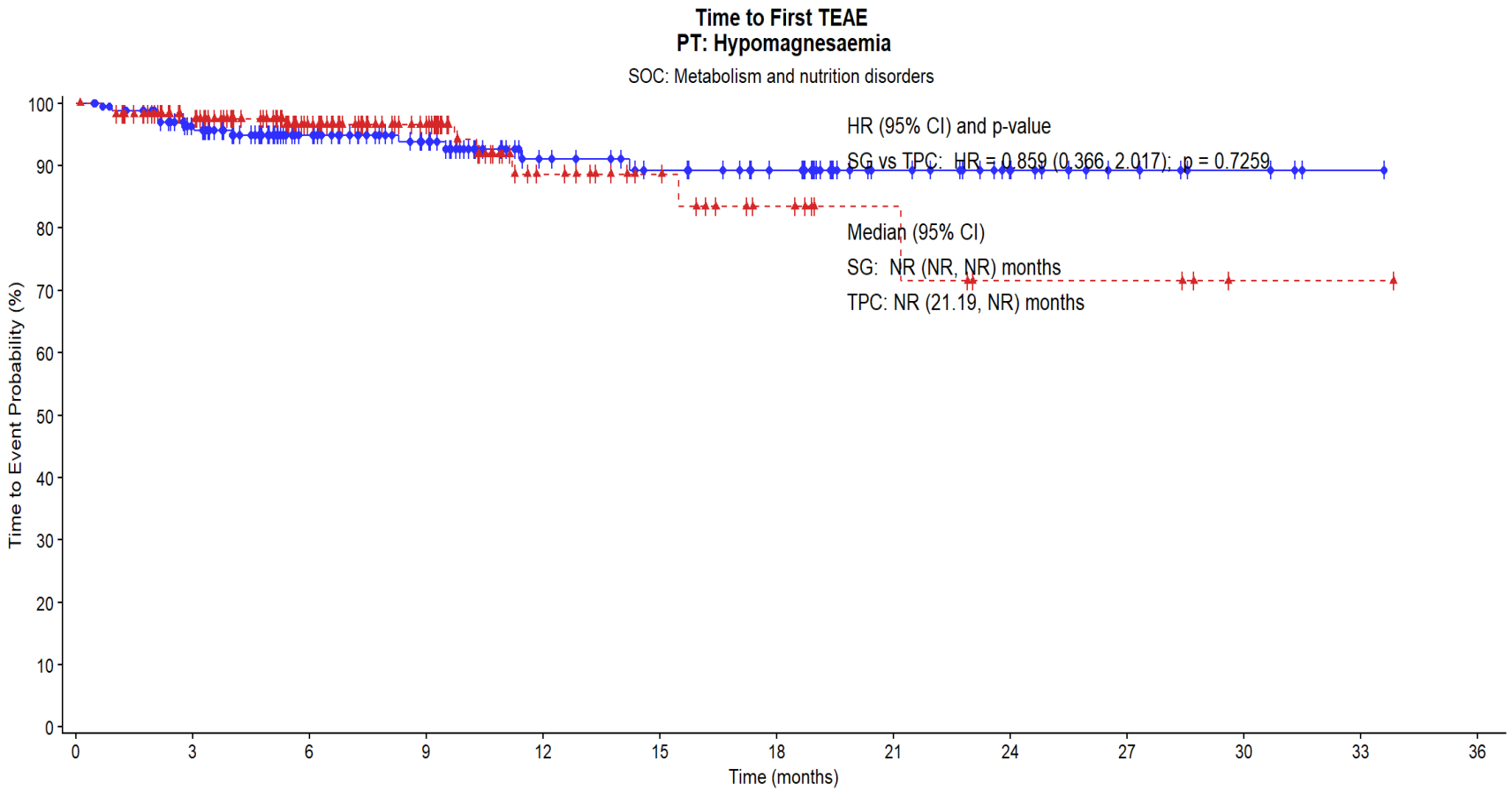
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.83. Figure 1.1.82: Kaplan Meier Plot of Time to First TEAE by PT Hypokalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



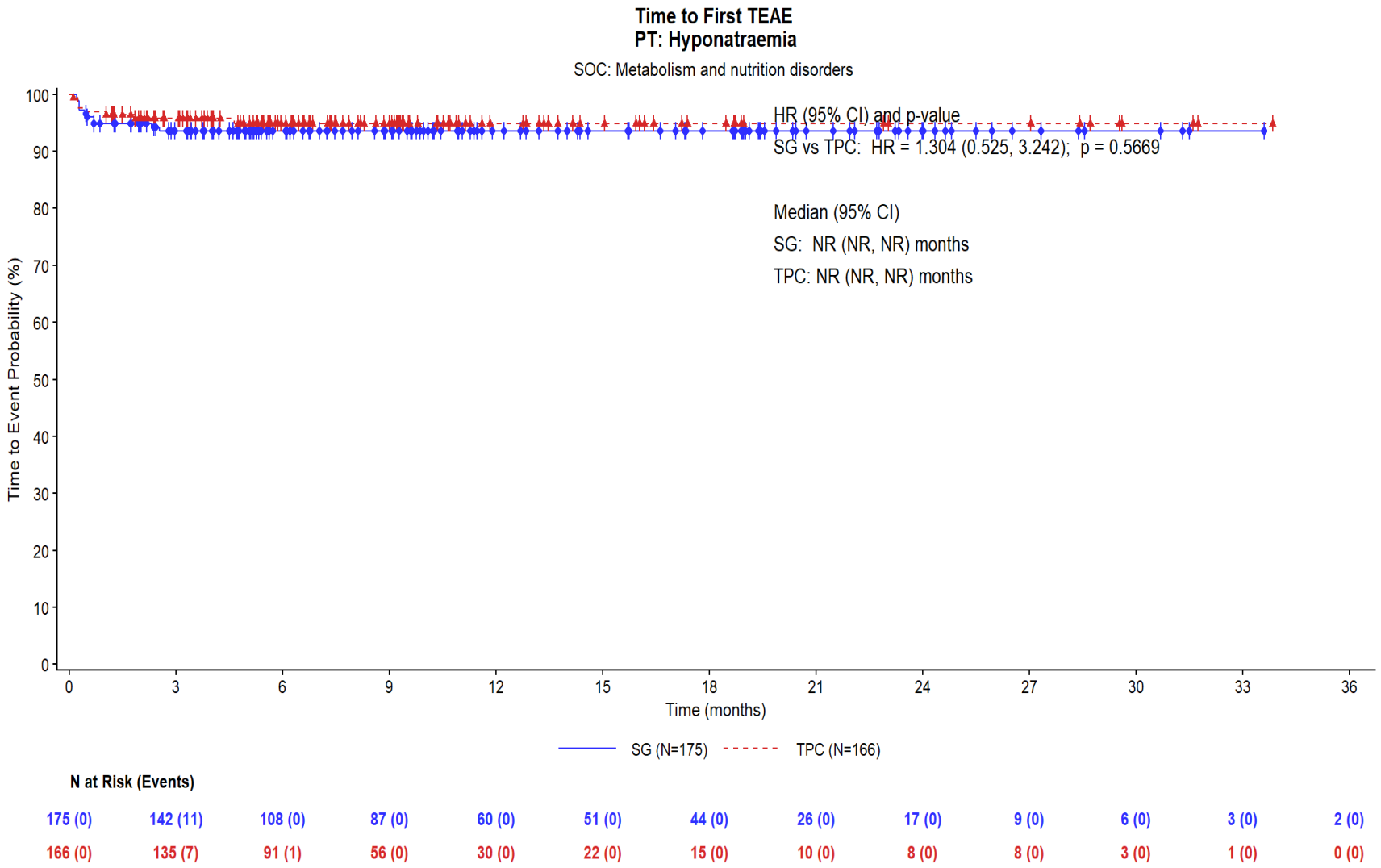
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.84. Figure 1.1.83: Kaplan Meier Plot of Time to First TEAE by PT Hypomagnesaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



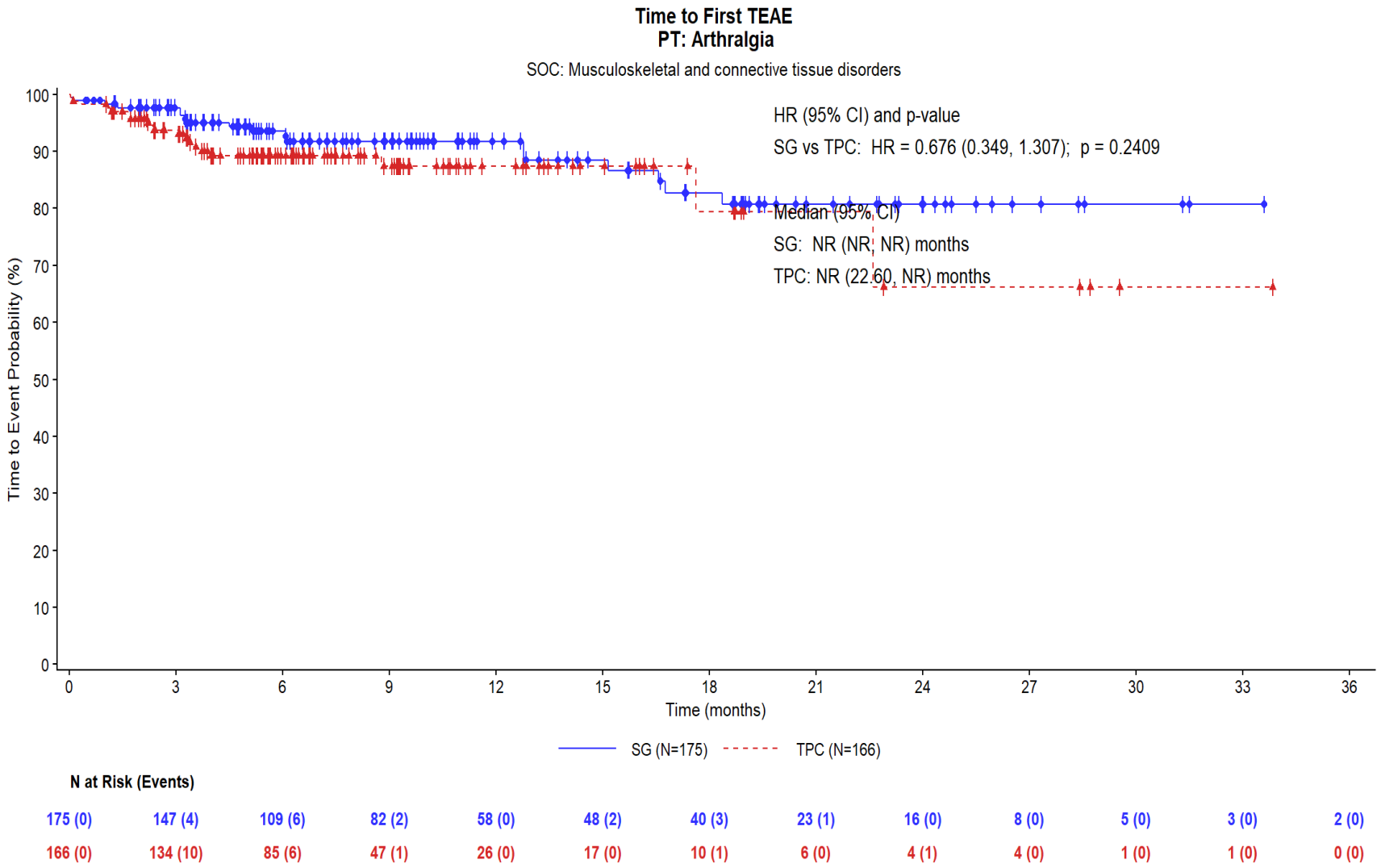
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.85. Figure 1.1.84: Kaplan Meier Plot of Time to First TEAE by PT Hyponatraemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



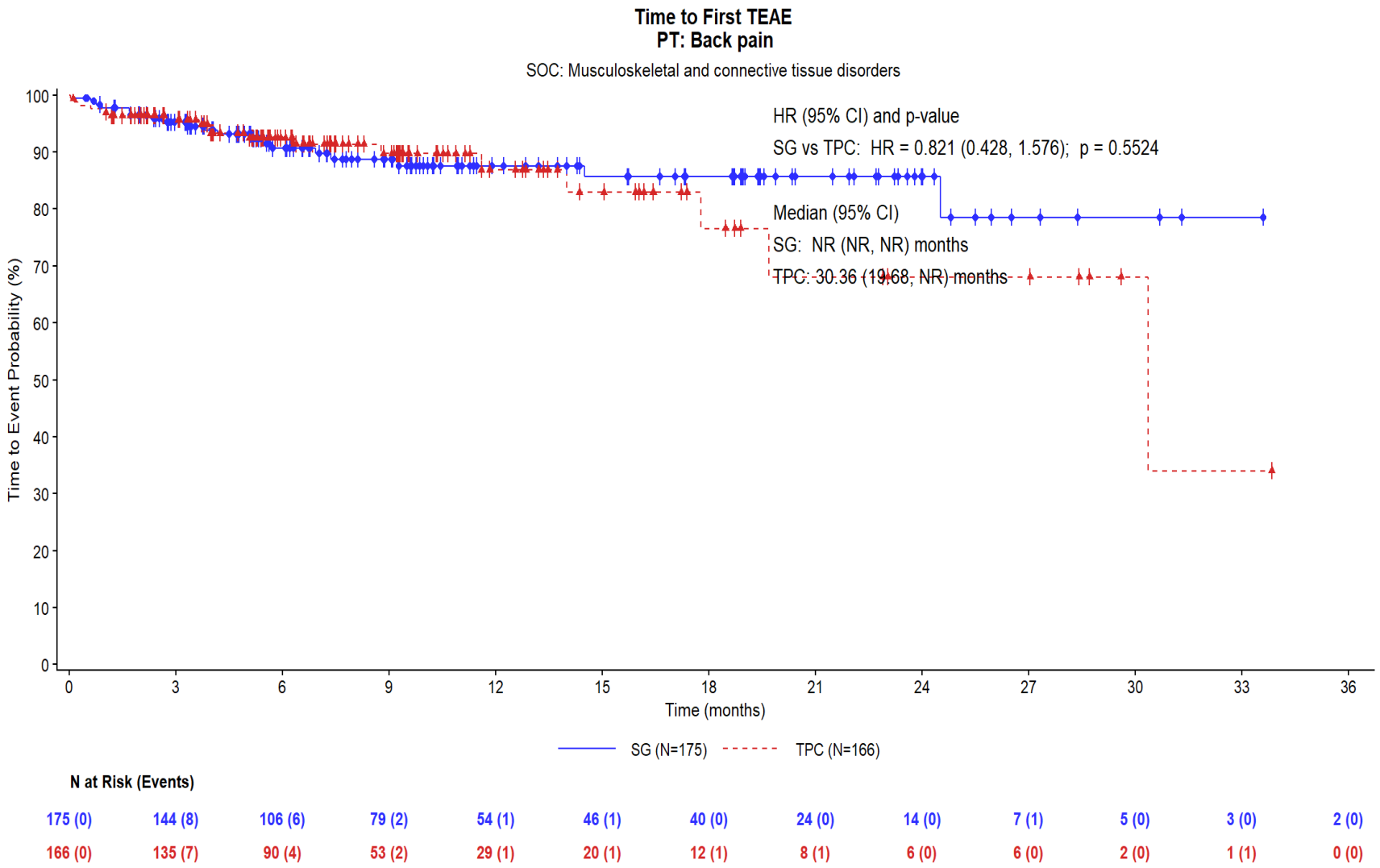
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.86. Figure 1.1.85: Kaplan Meier Plot of Time to First TEAE by PT Arthralgia — mSAF — Excluding patients preselected to receive nab-paclitaxel



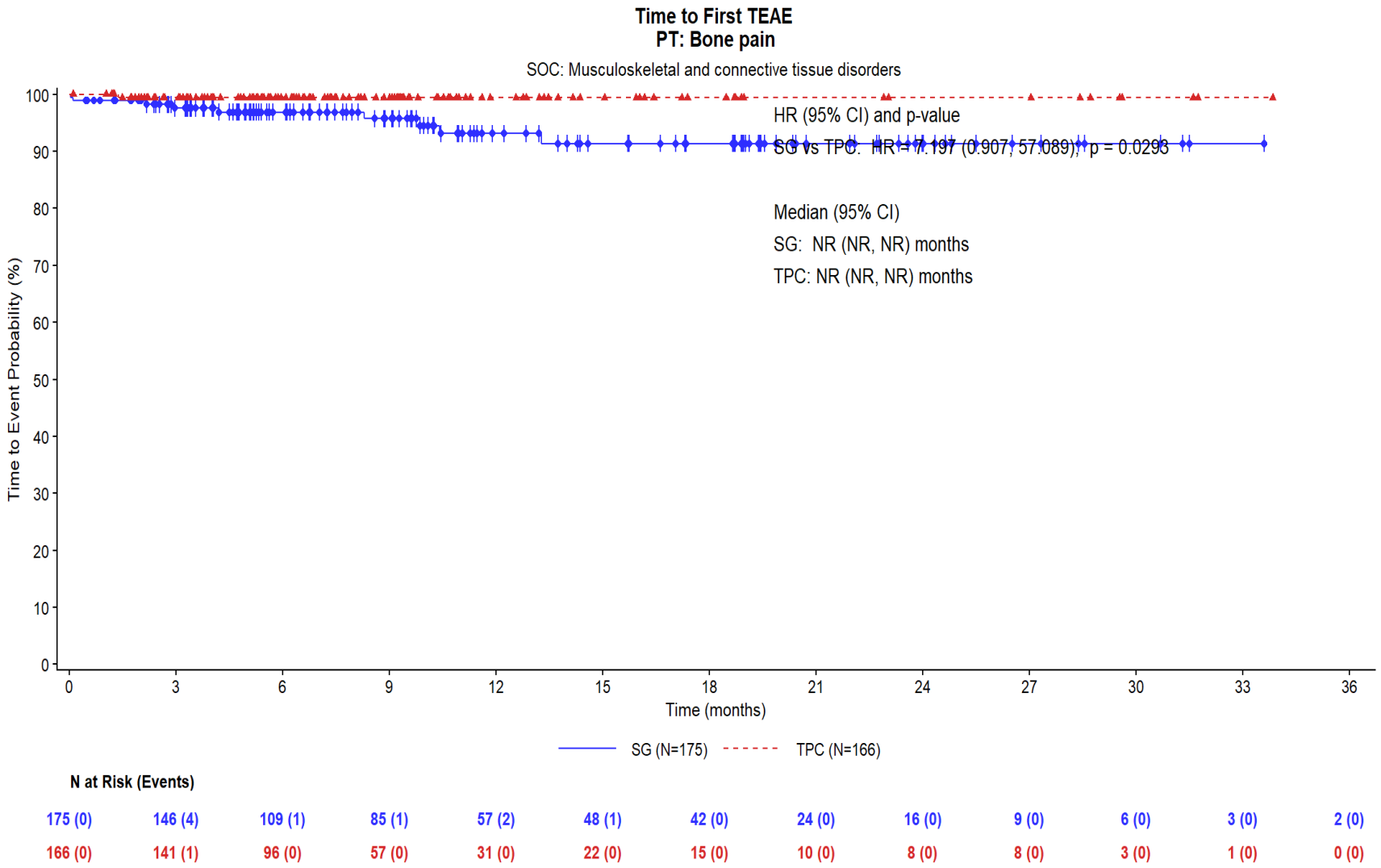
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.87. Figure 1.1.86: Kaplan Meier Plot of Time to First TEAE by PT Back pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



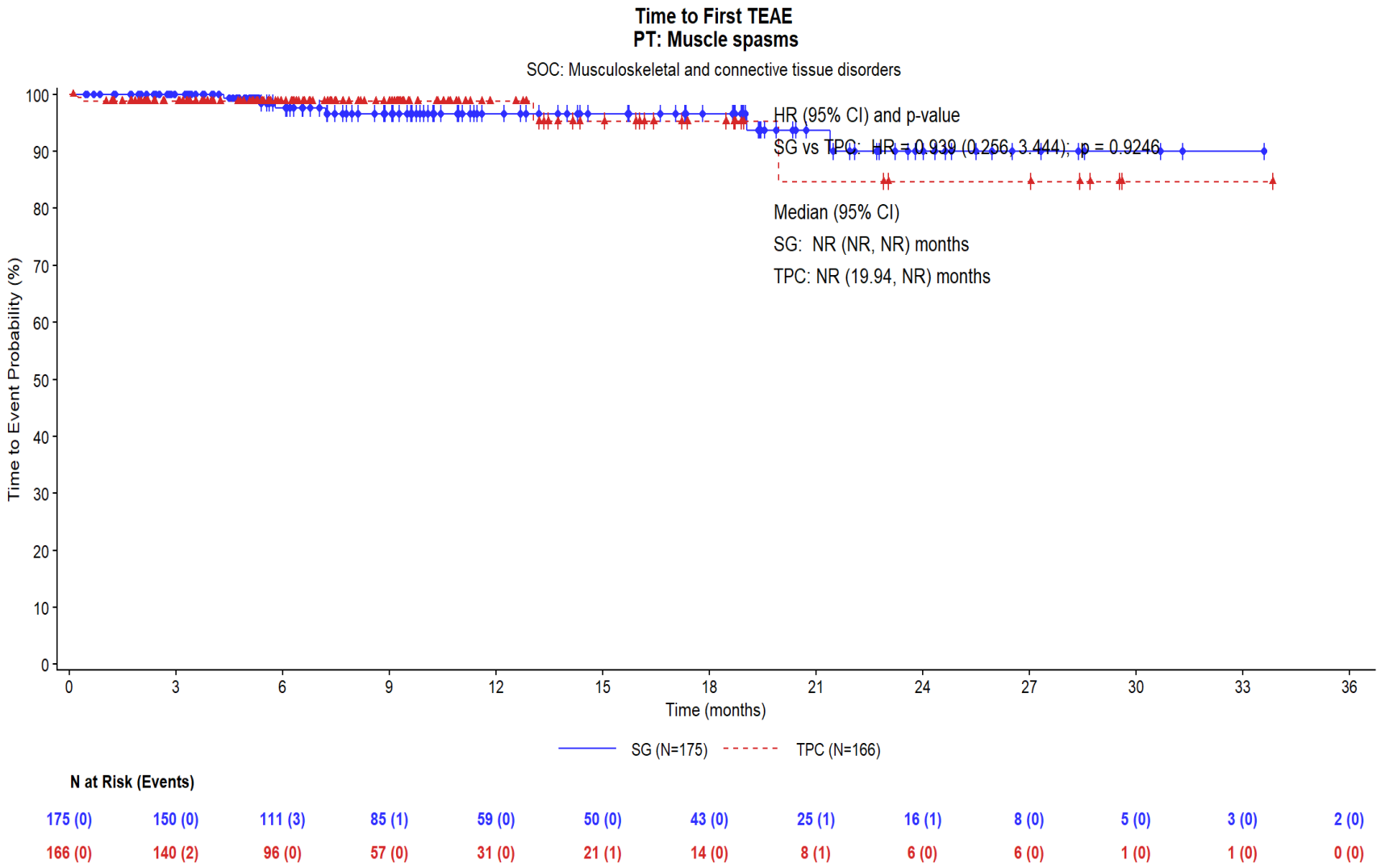
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.88. Figure 1.1.87: Kaplan Meier Plot of Time to First TEAE by PT Bone pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



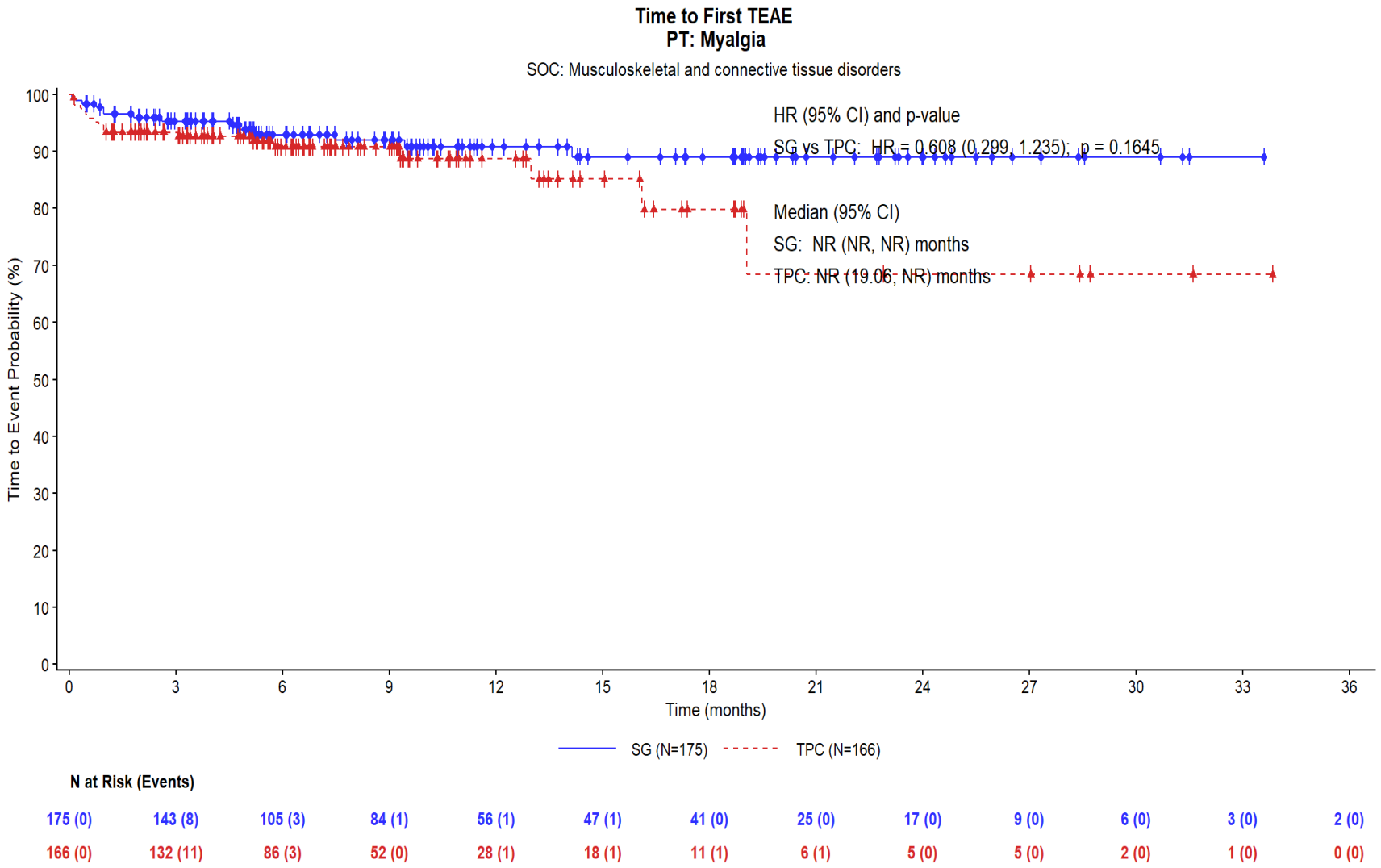
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.89. Figure 1.1.88: Kaplan Meier Plot of Time to First TEAE by PT Muscle spasms — mSAF — Excluding patients preselected to receive nab-paclitaxel



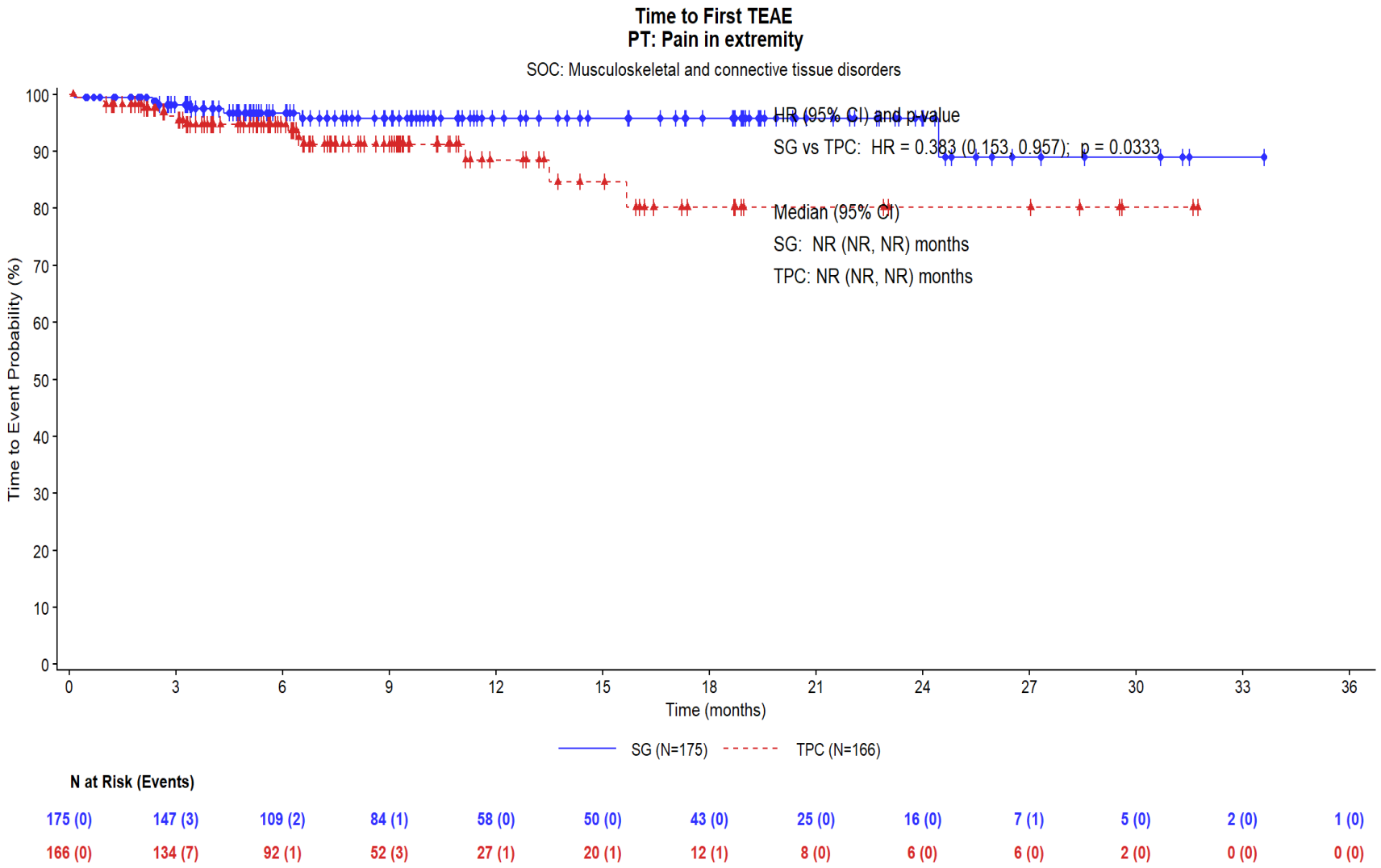
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.90. Figure 1.1.89: Kaplan Meier Plot of Time to First TEAE by PT Myalgia — mSAF — Excluding patients preselected to receive nab-paclitaxel



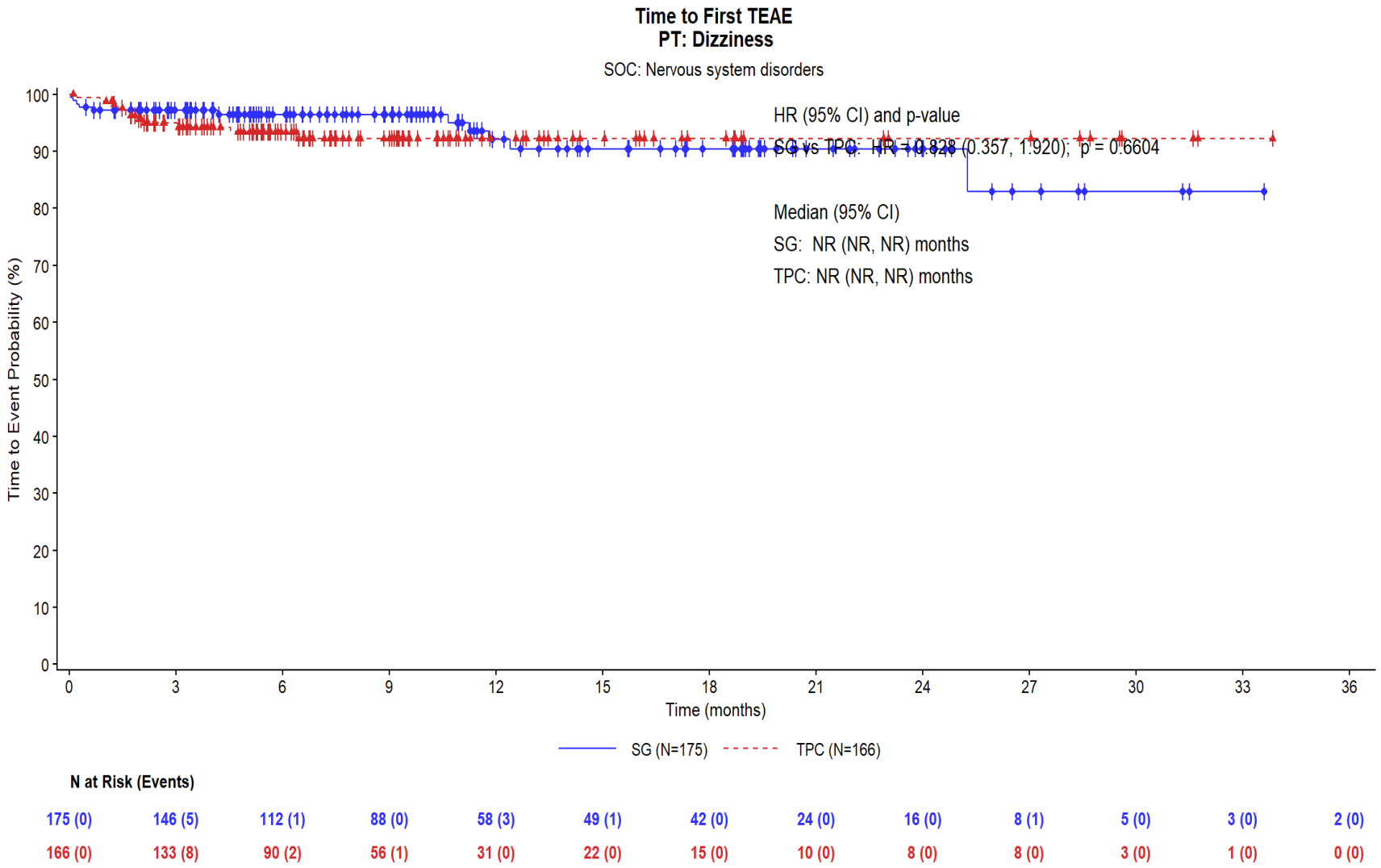
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.91. Figure 1.1.90: Kaplan Meier Plot of Time to First TEAE by PT Pain in extremity — mSAF — Excluding patients preselected to receive nab-paclitaxel



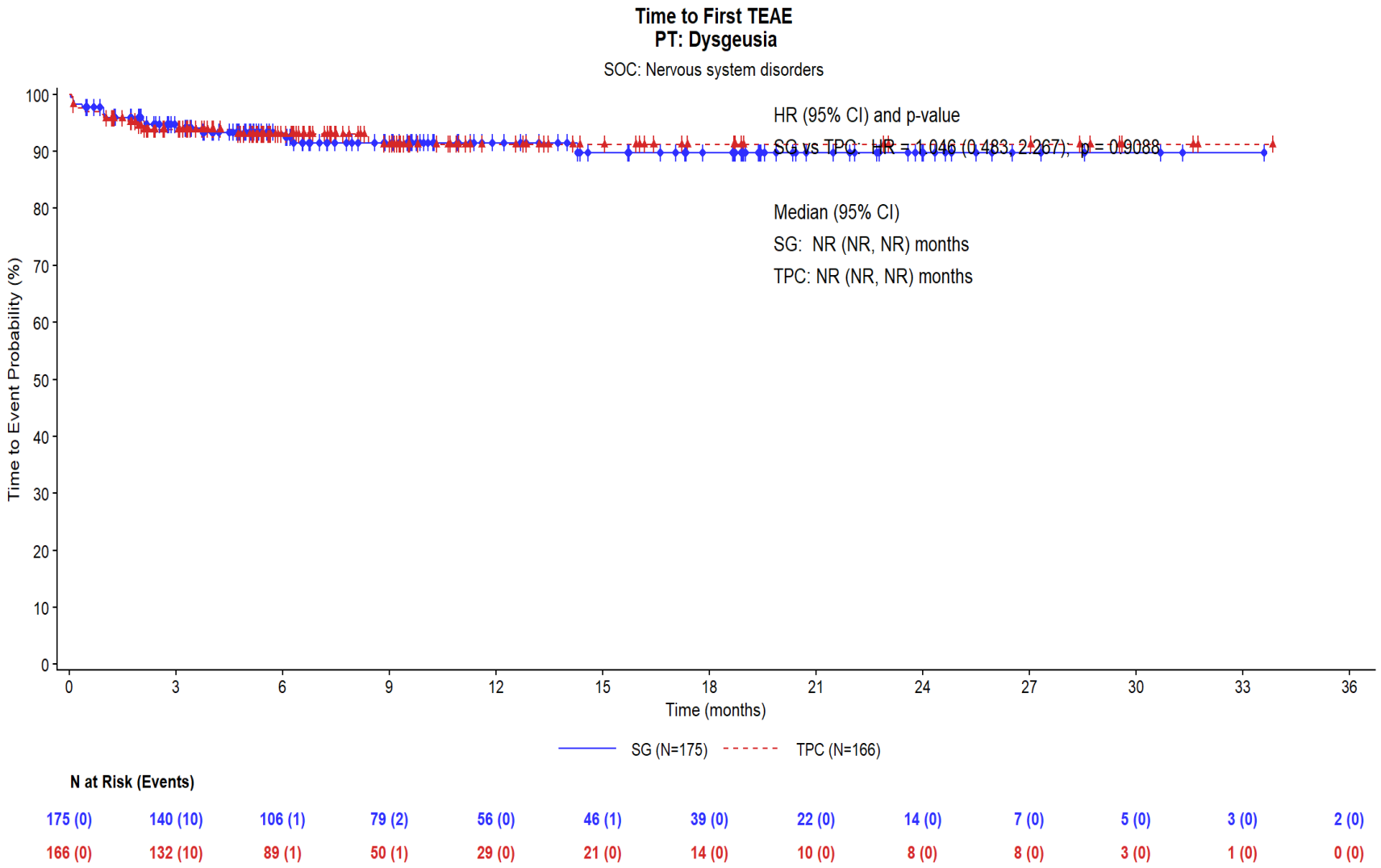
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.92. Figure 1.1.91: Kaplan Meier Plot of Time to First TEAE by PT Dizziness — mSAF — Excluding patients preselected to receive nab-paclitaxel



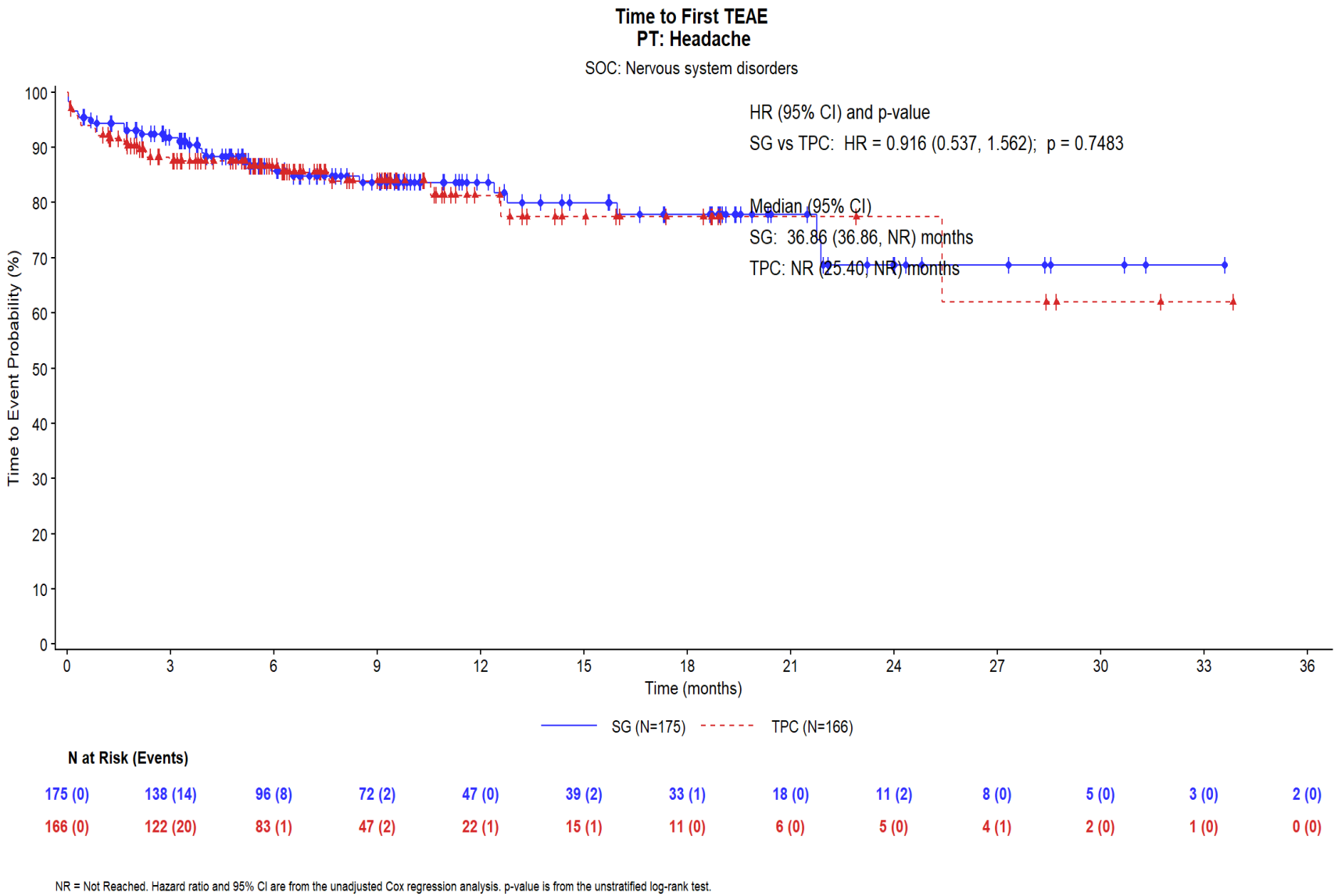
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.93. Figure 1.1.92: Kaplan Meier Plot of Time to First TEAE by PT Dysgeusia — mSAF — Excluding patients preselected to receive nab-paclitaxel



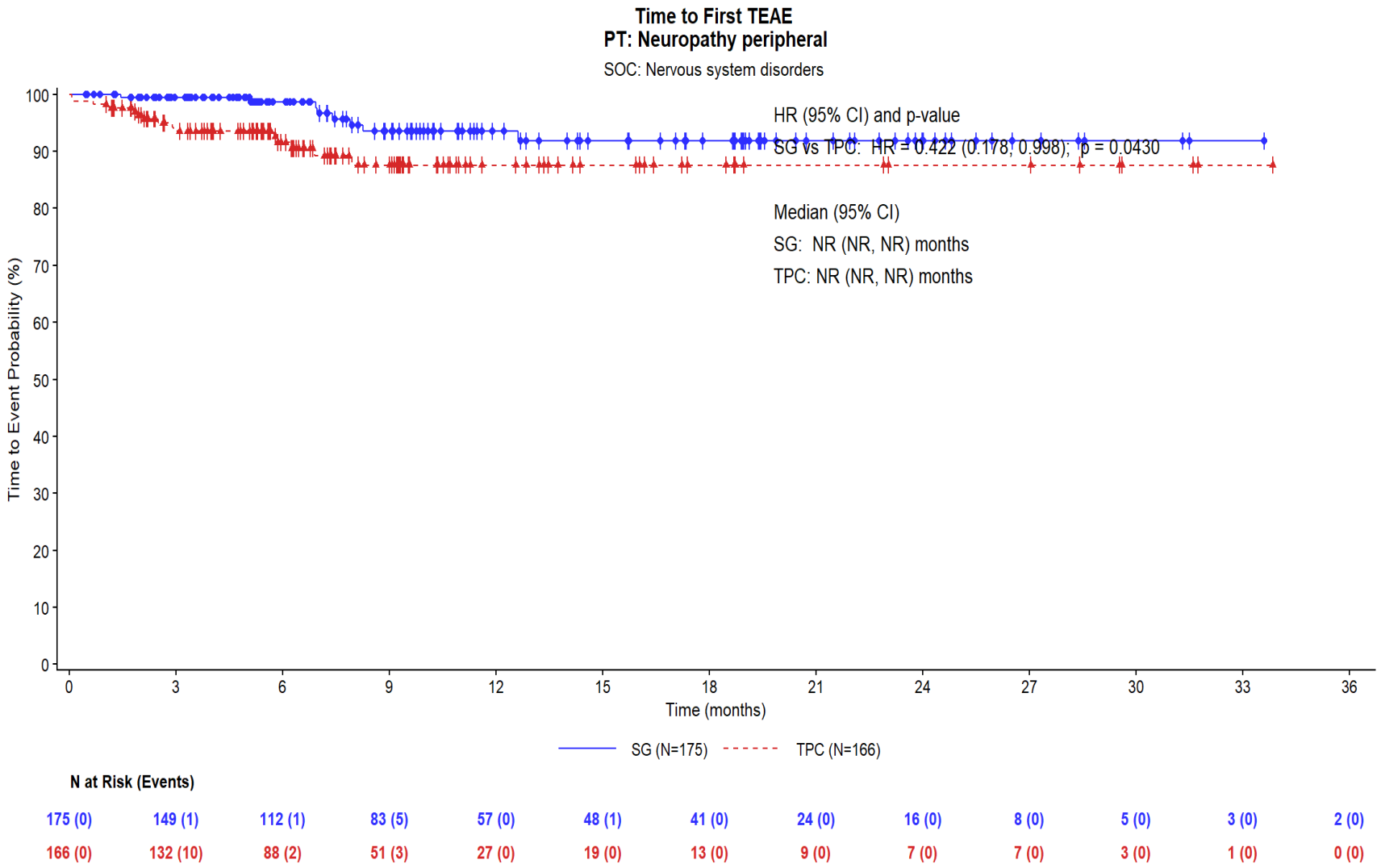
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.94. Figure 1.1.93: Kaplan Meier Plot of Time to First TEAE by PT Headache — mSAF — Excluding patients preselected to receive nab-paclitaxel



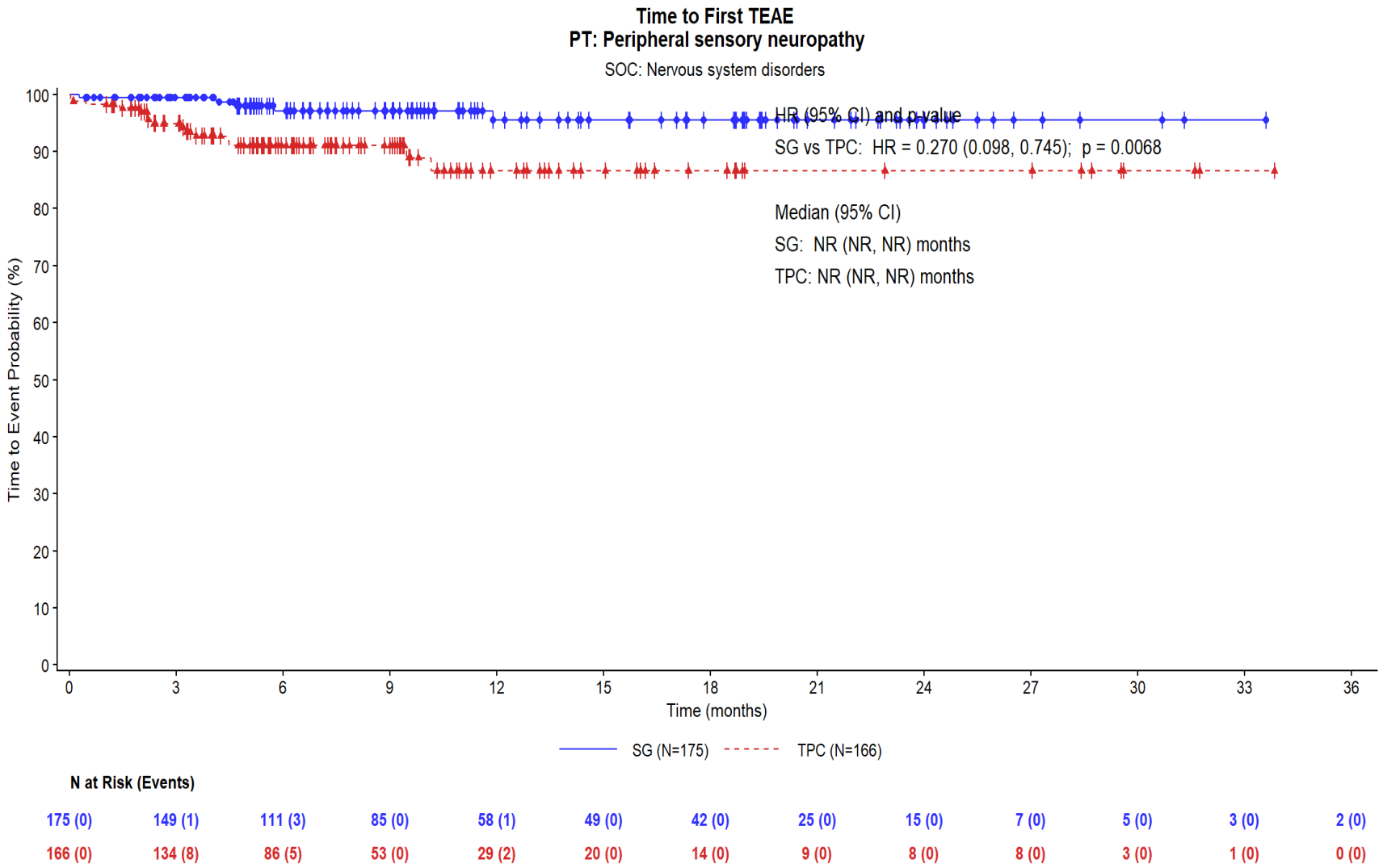
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.95. Figure 1.1.94: Kaplan Meier Plot of Time to First TEAE by PT Neuropathy peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel



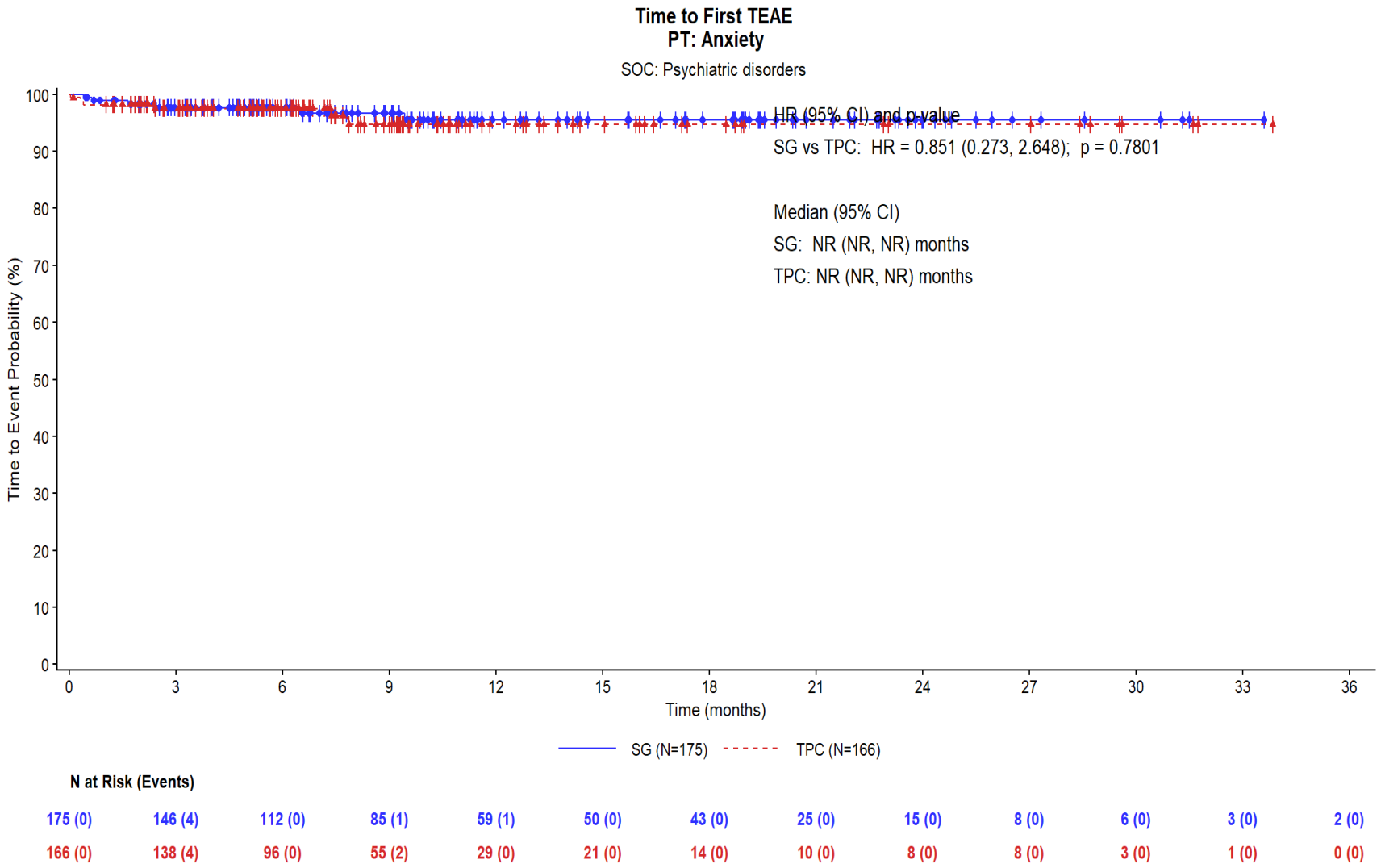
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.96. Figure 1.1.95: Kaplan Meier Plot of Time to First TEAE by PT Peripheral sensory neuropathy — mSAF — Excluding patients preselected to receive nab-paclitaxel



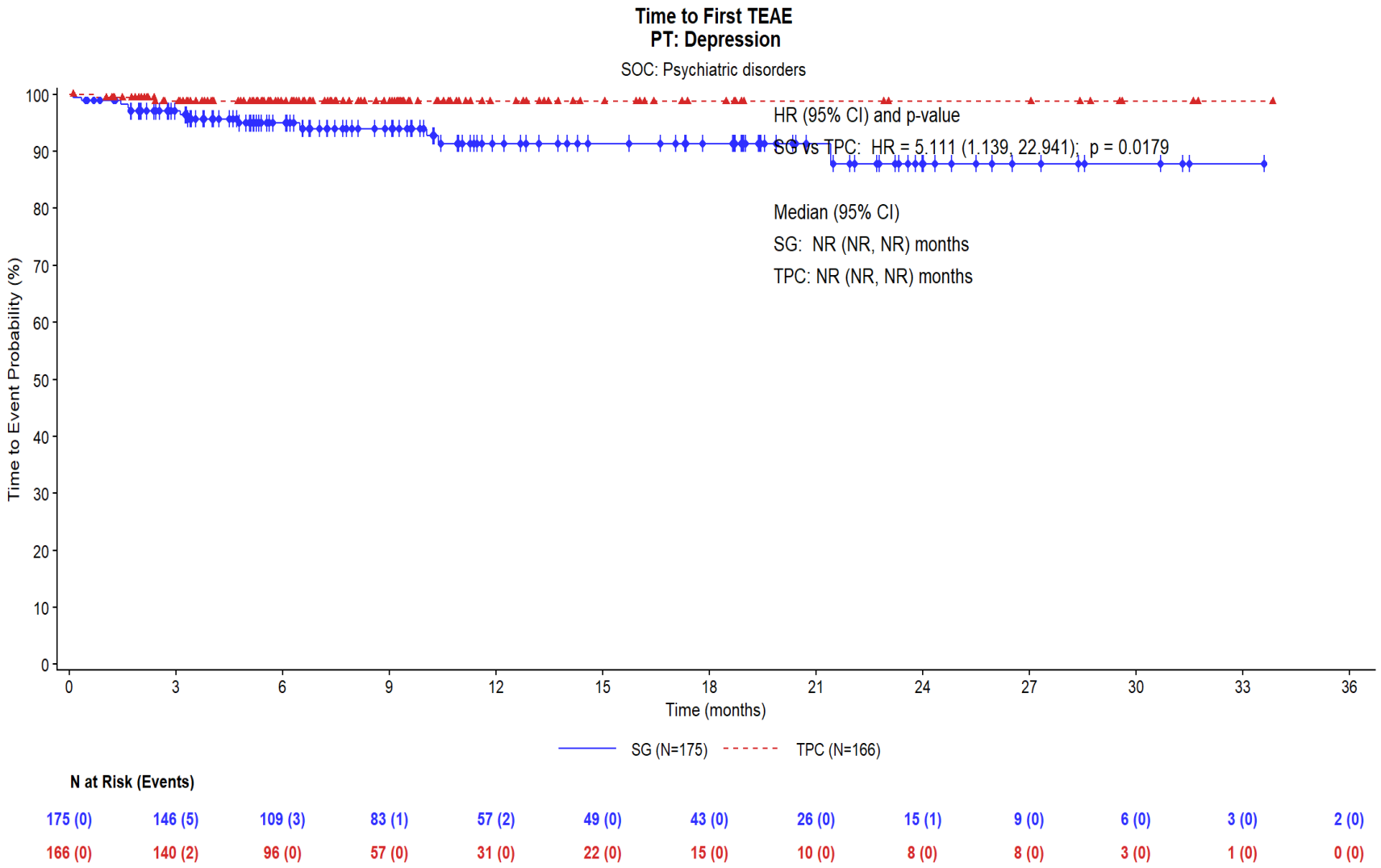
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.97. Figure 1.1.96: Kaplan Meier Plot of Time to First TEAE by PT Anxiety — mSAF — Excluding patients preselected to receive nab-paclitaxel



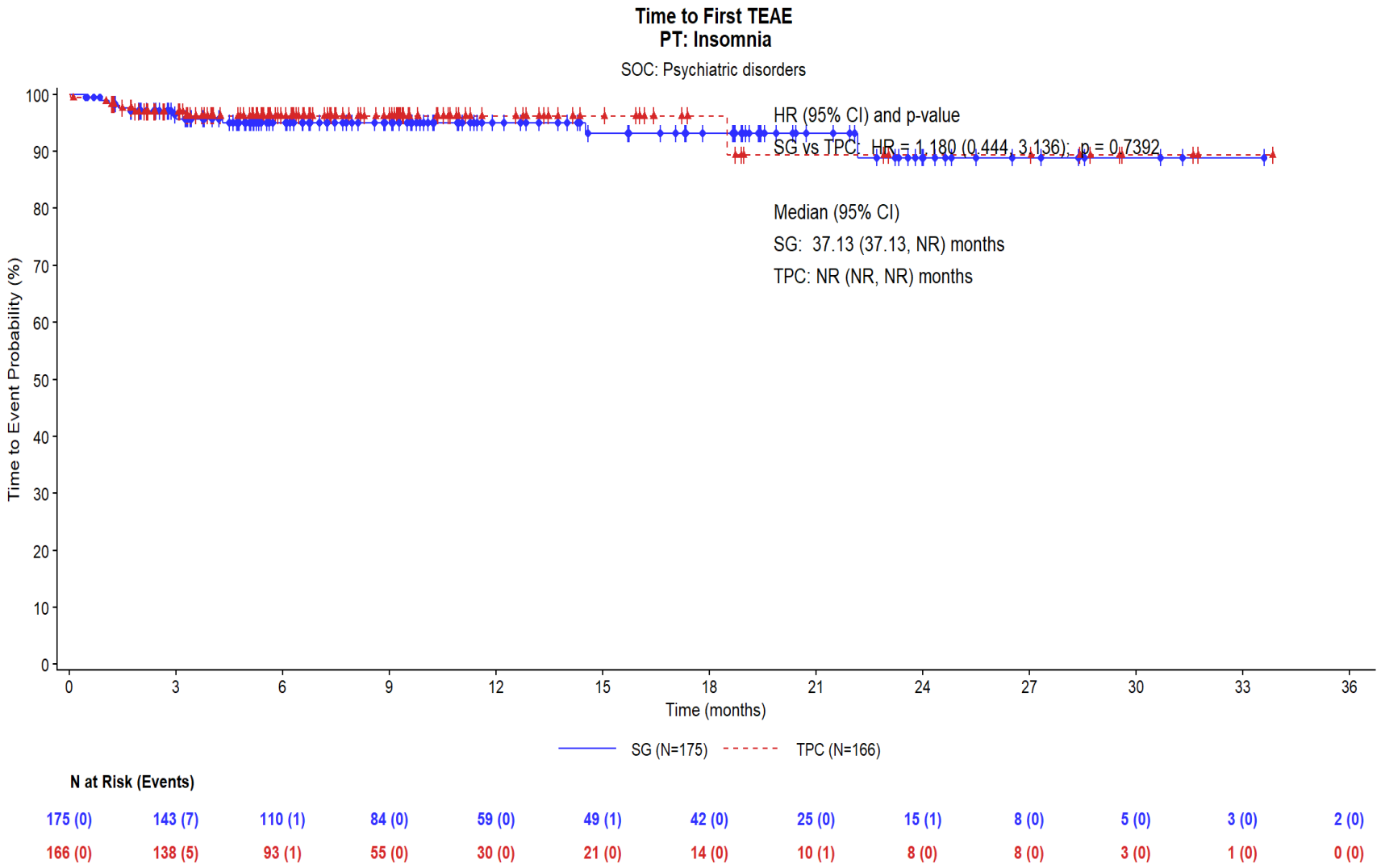
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.98. Figure 1.1.97: Kaplan Meier Plot of Time to First TEAE by PT Depression — mSAF — Excluding patients preselected to receive nab-paclitaxel



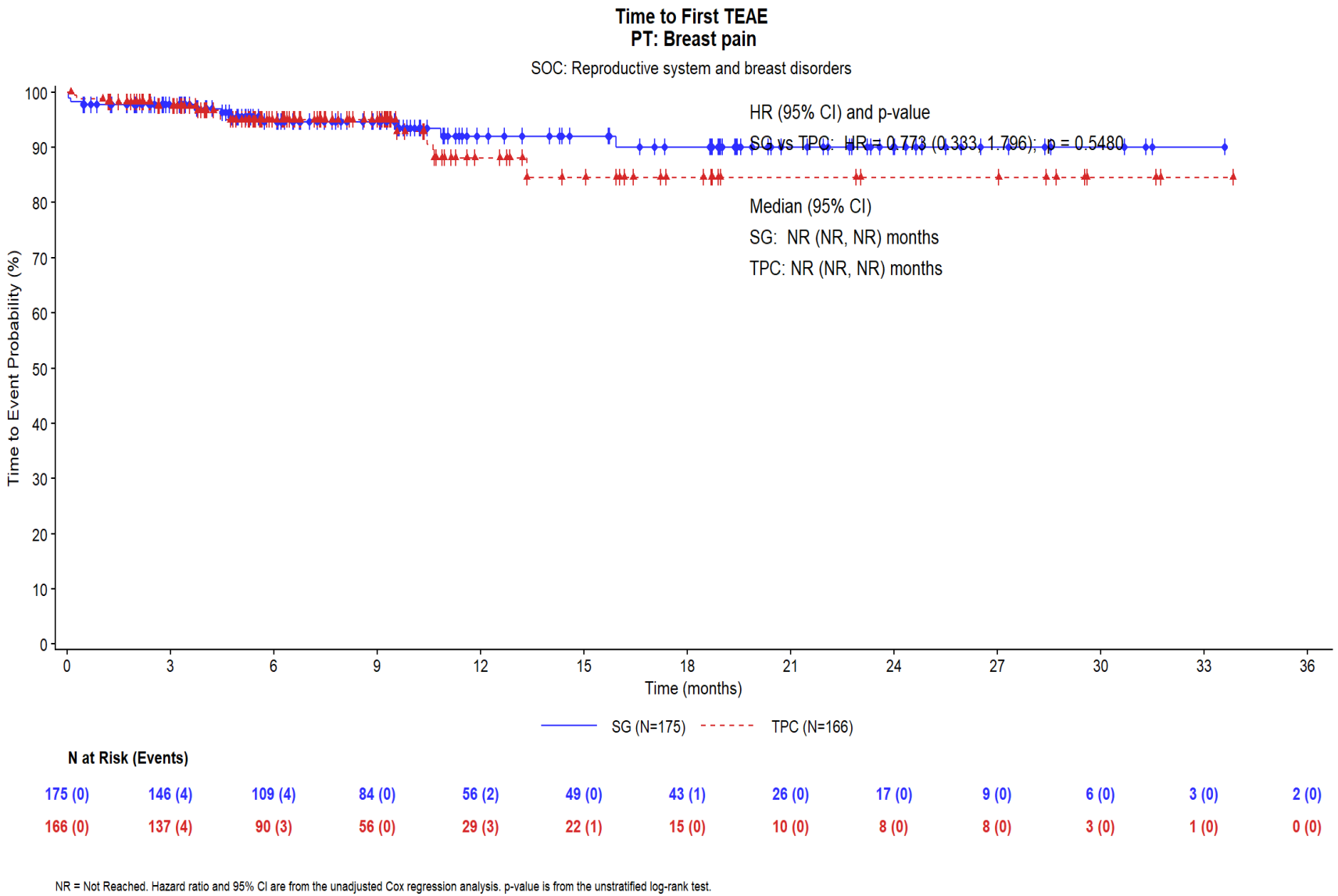
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.99. Figure 1.1.98: Kaplan Meier Plot of Time to First TEAE by PT Insomnia — mSAF — Excluding patients preselected to receive nab-paclitaxel



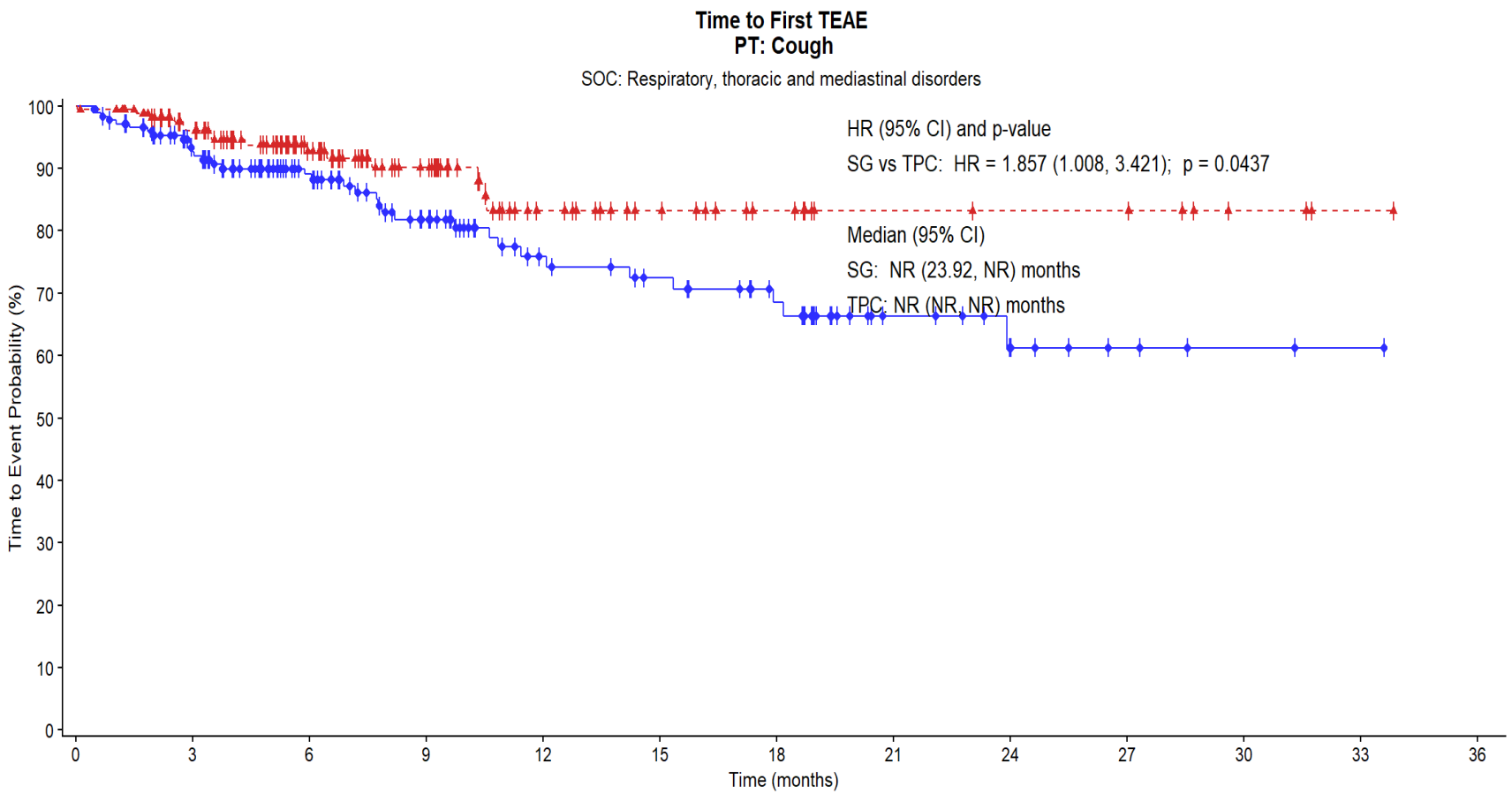
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.100. Figure 1.1.99: Kaplan Meier Plot of Time to First TEAE by PT Breast pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



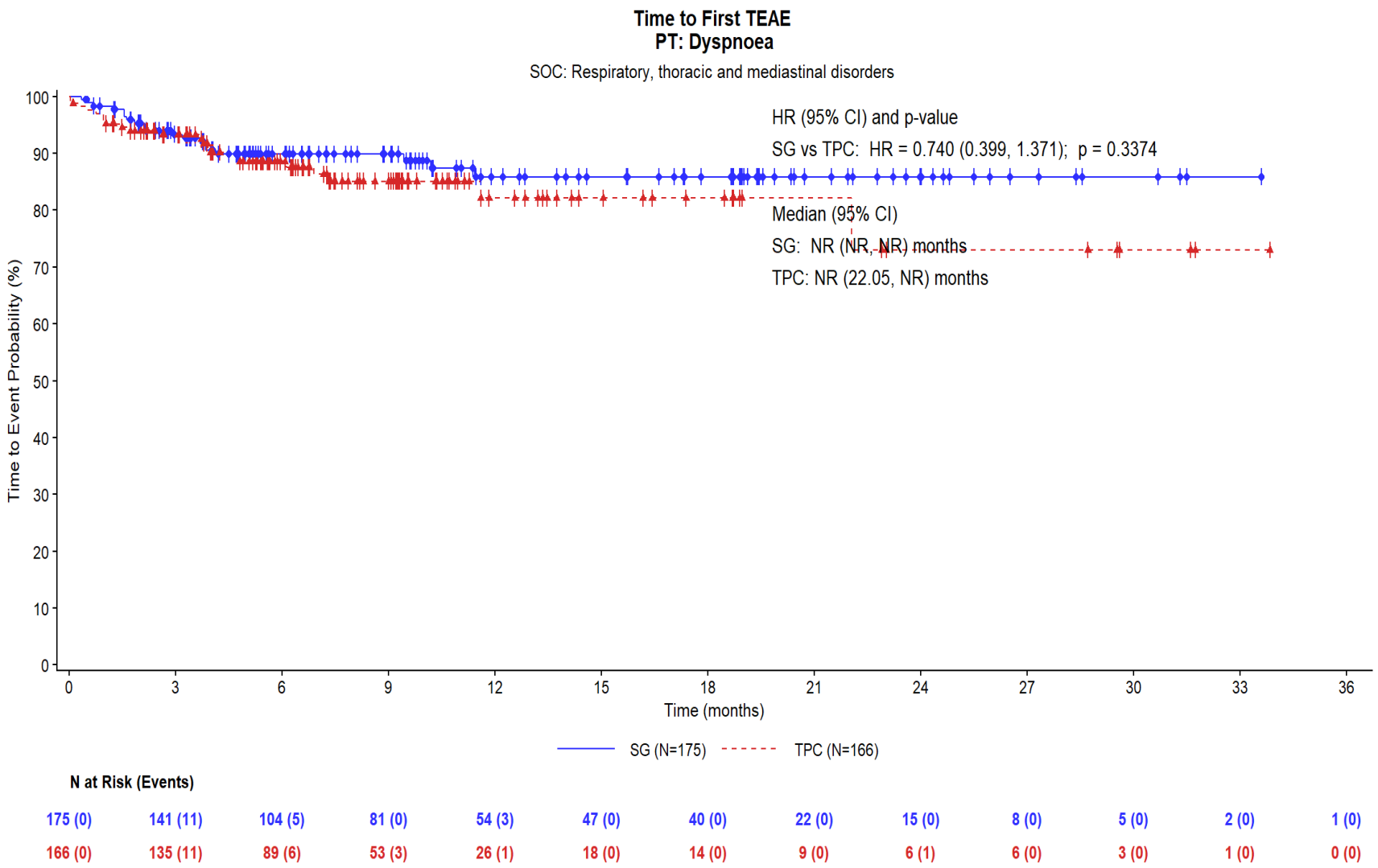
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.101. Figure 1.1.100: Kaplan Meier Plot of Time to First TEAE by PT Cough — mSAF — Excluding patients preselected to receive nab-paclitaxel



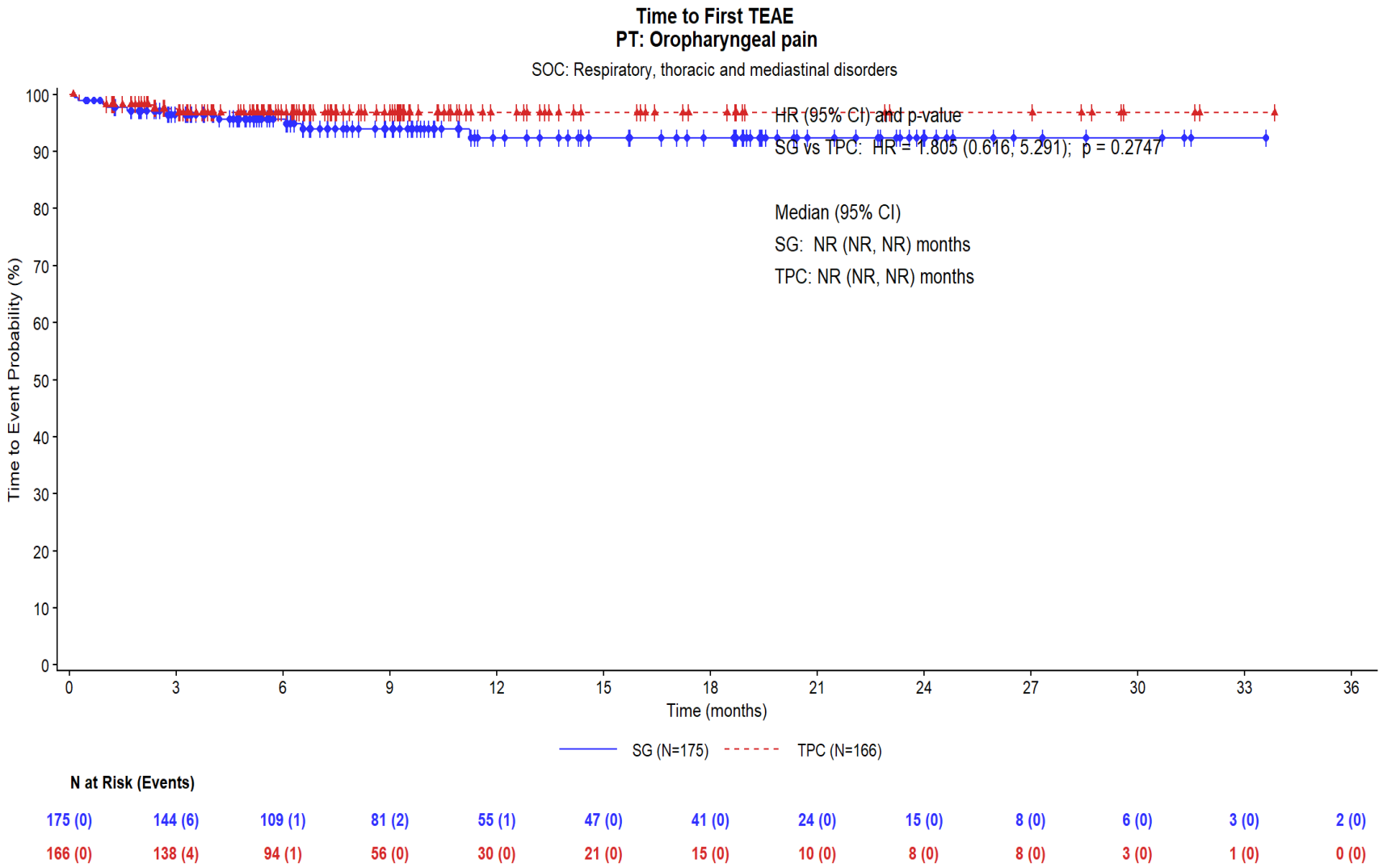
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.102. Figure 1.1.101: Kaplan Meier Plot of Time to First TEAE by PT Dyspnoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



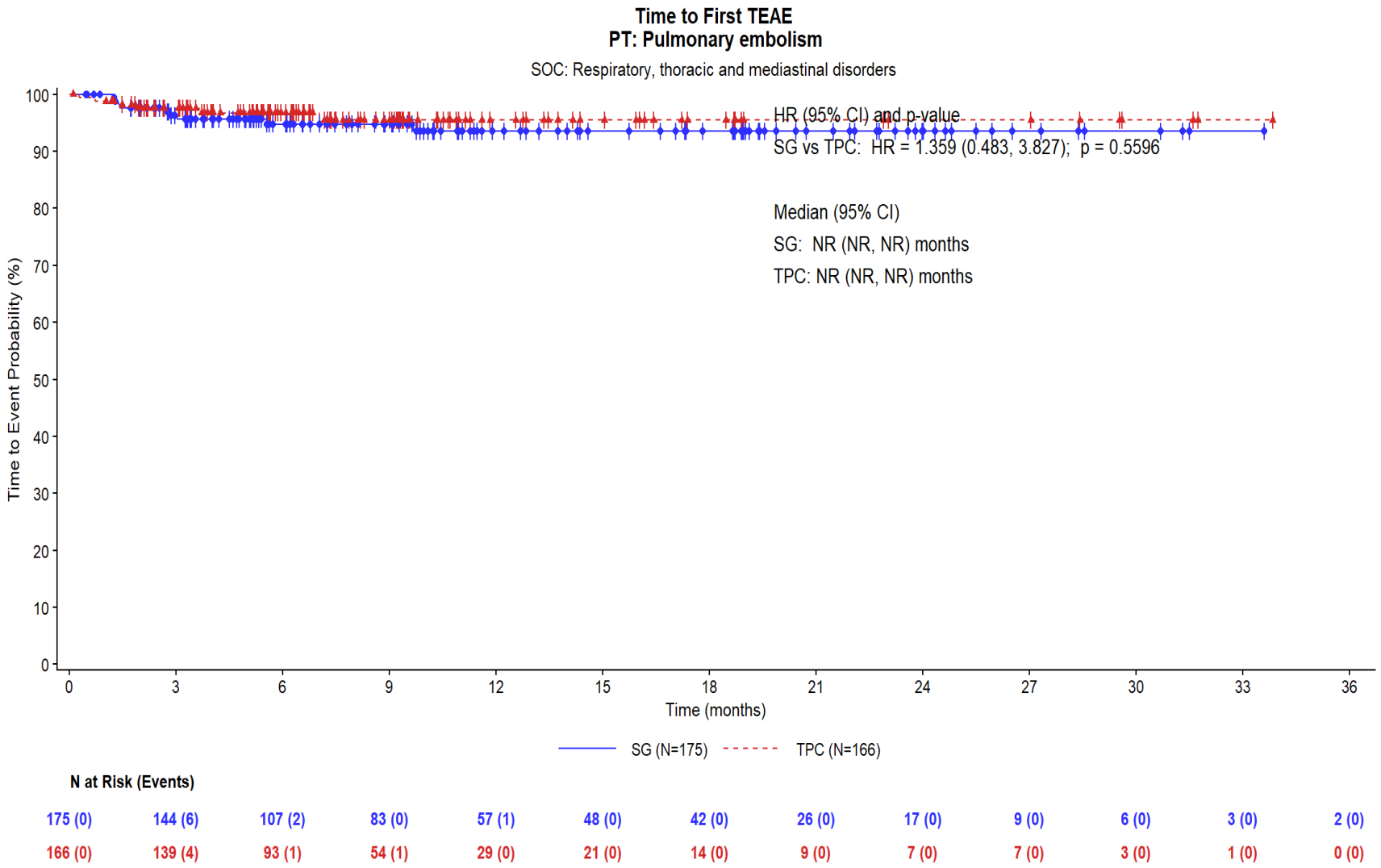
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.103. Figure 1.1.102: Kaplan Meier Plot of Time to First TEAE by PT Oropharyngeal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



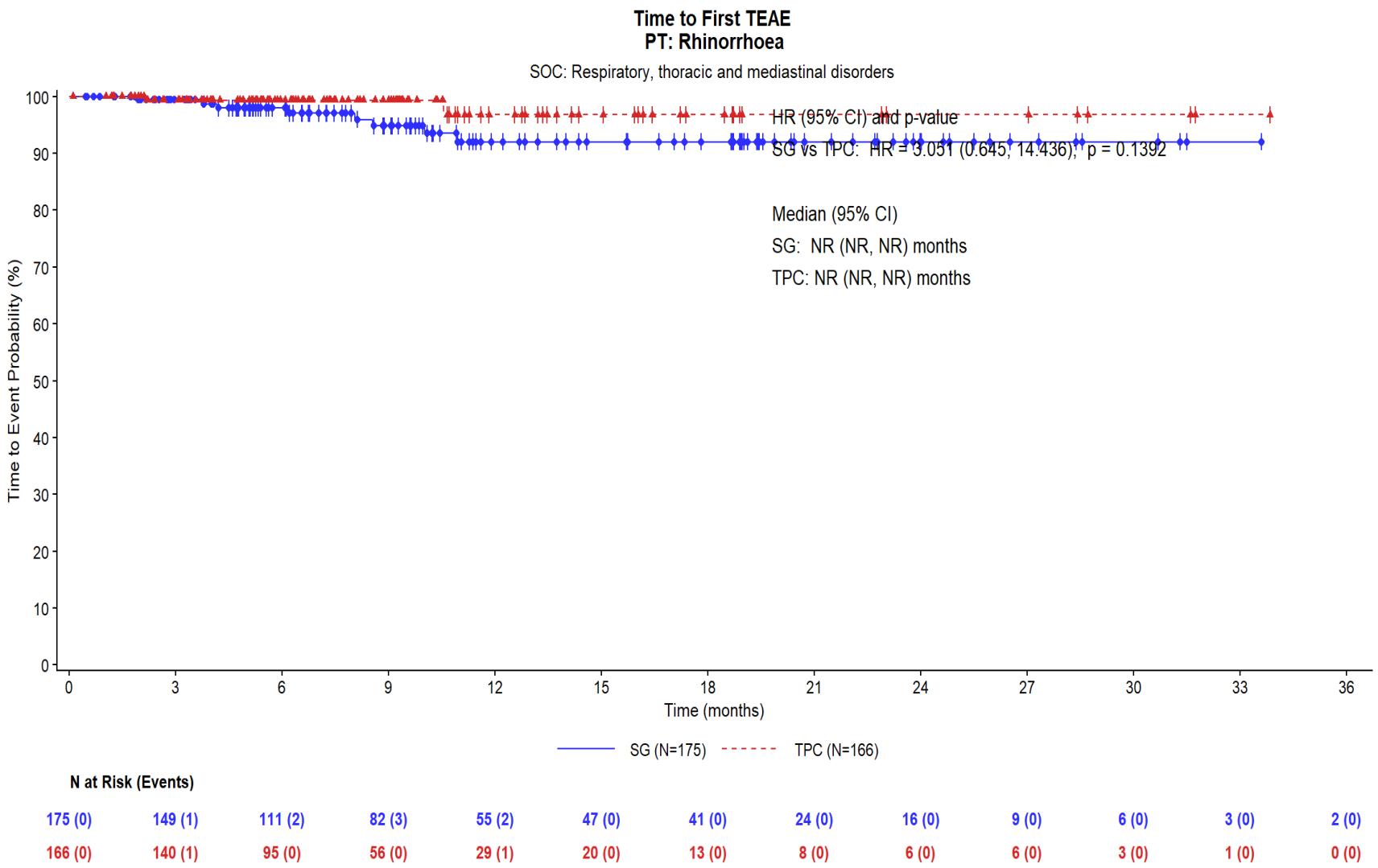
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.104. Figure 1.1.103: Kaplan Meier Plot of Time to First TEAE by PT Pulmonary embolism — mSAF — Excluding patients preselected to receive nab-paclitaxel



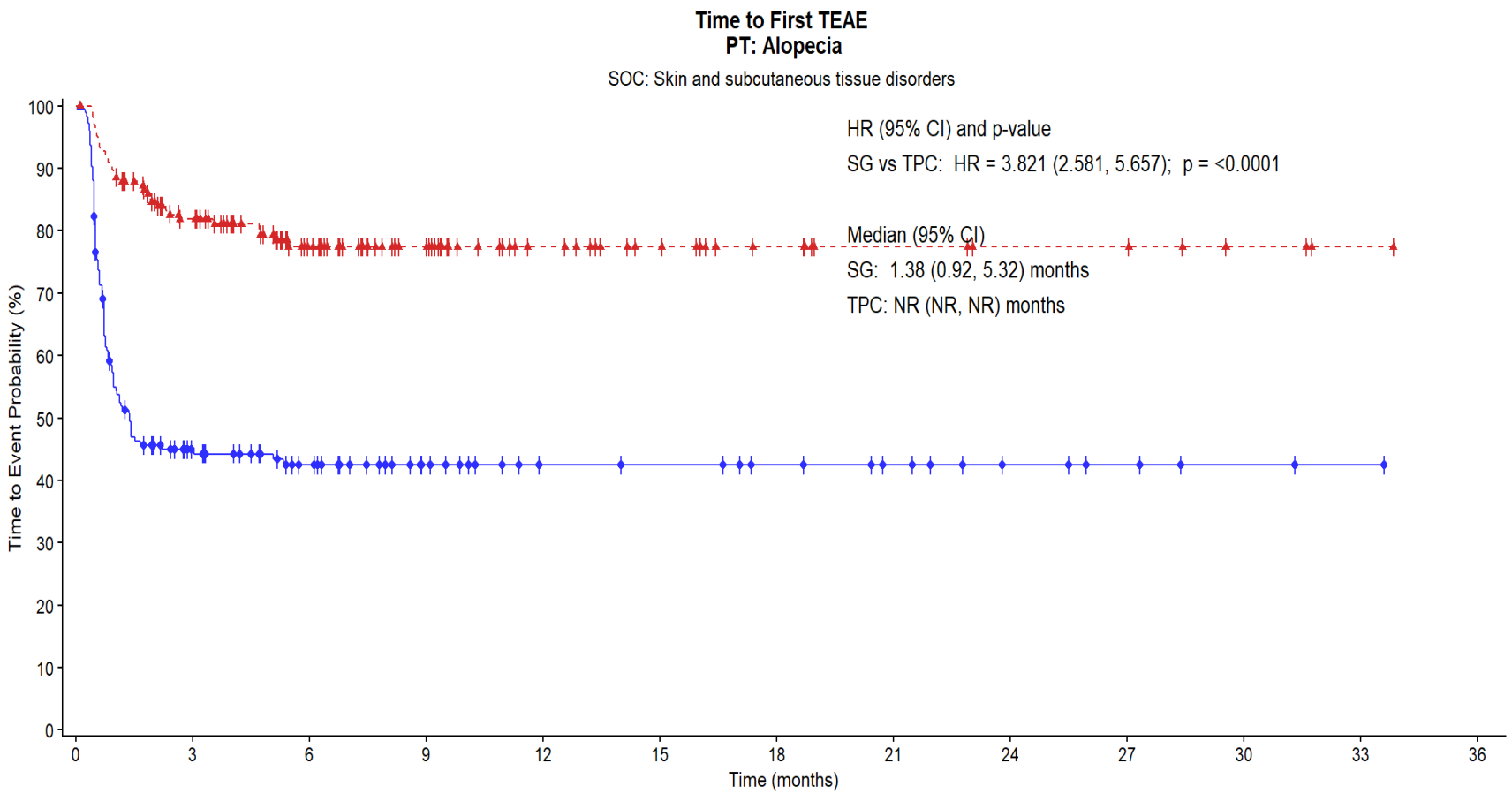
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.105. Figure 1.1.104: Kaplan Meier Plot of Time to First TEAE by PT Rhinorrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



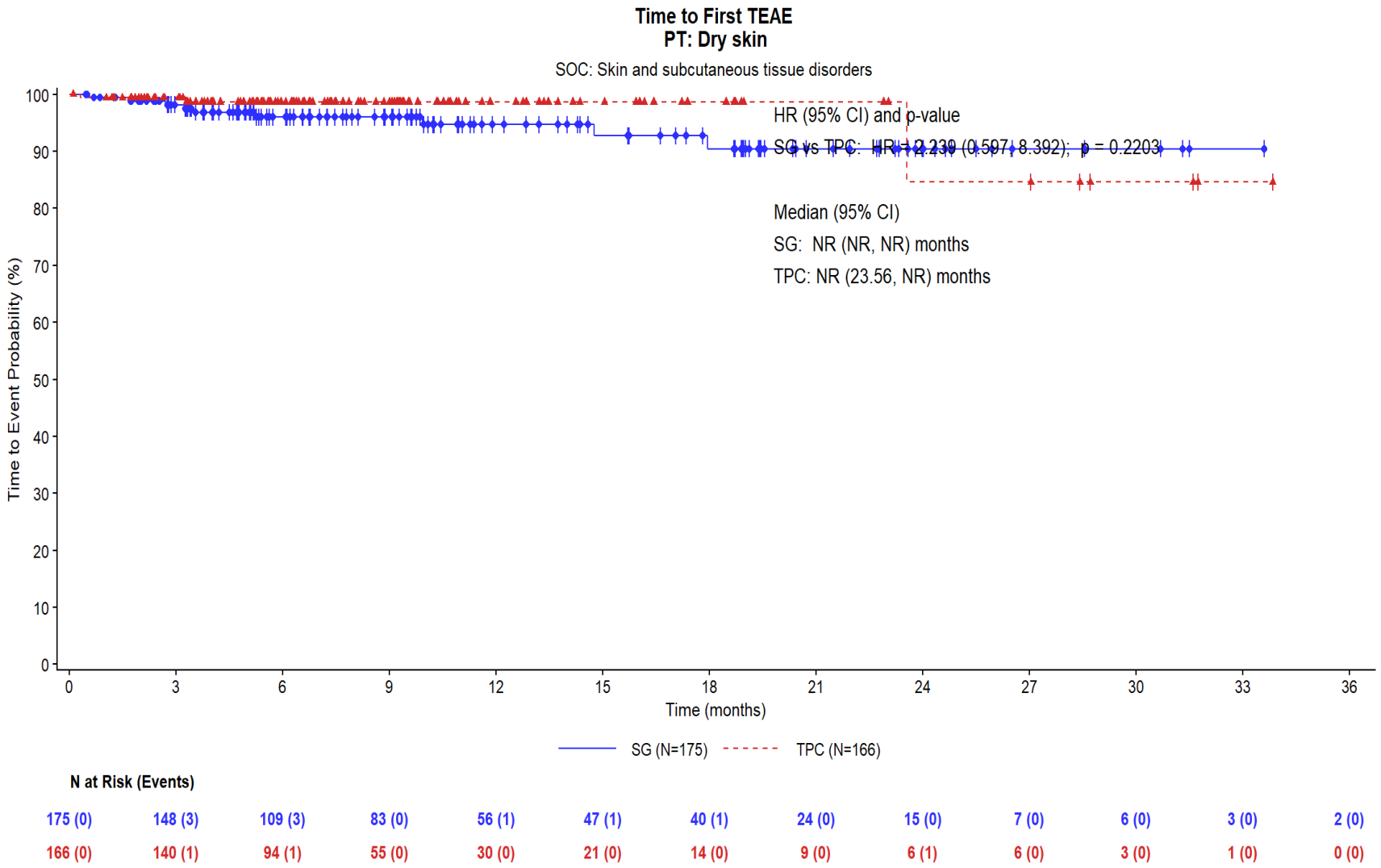
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.106. Figure 1.1.105: Kaplan Meier Plot of Time to First TEAE by PT Alopecia — mSAF — Excluding patients preselected to receive nab-paclitaxel



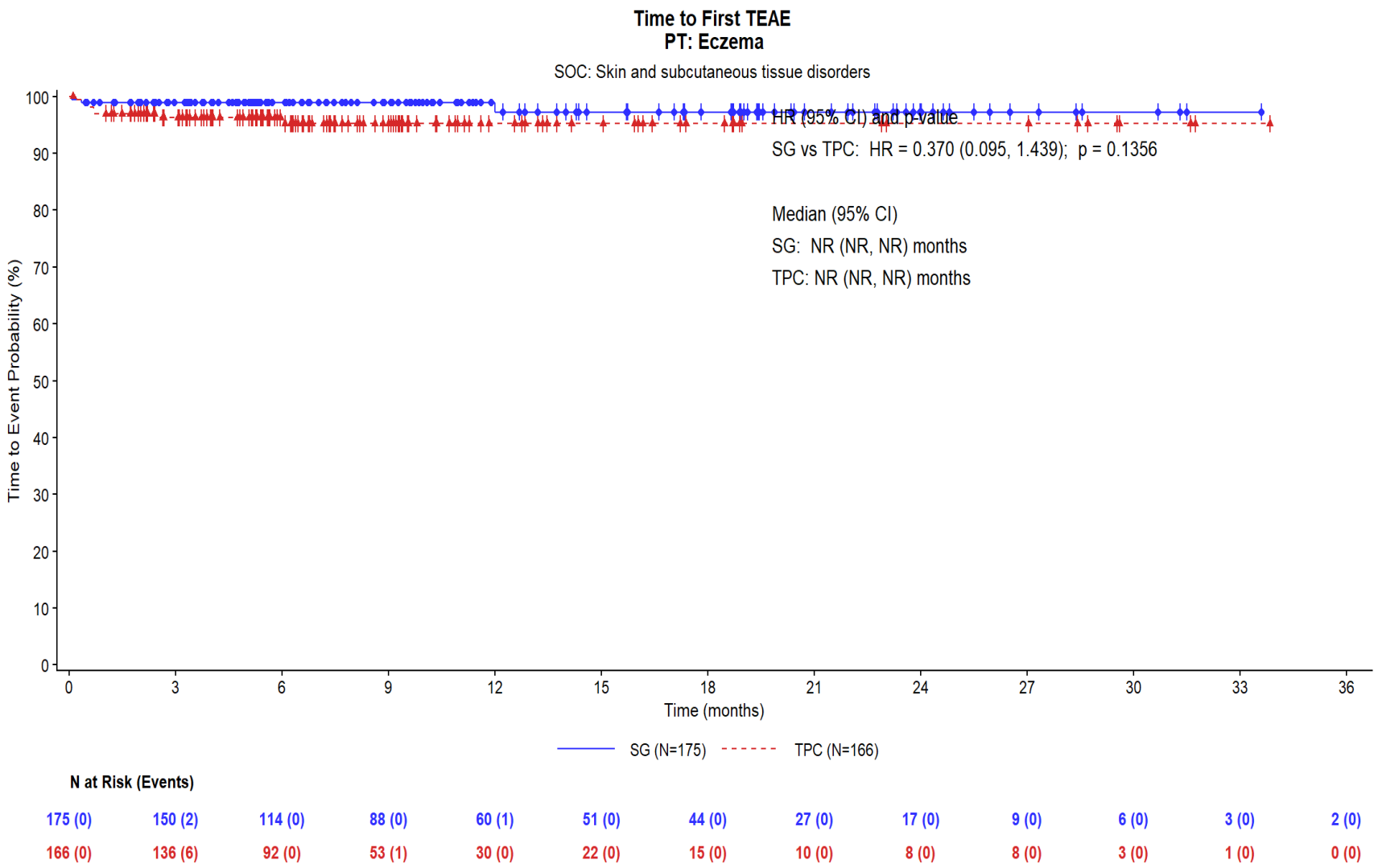
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.107. Figure 1.1.106: Kaplan Meier Plot of Time to First TEAE by PT Dry skin — mSAF — Excluding patients preselected to receive nab-paclitaxel



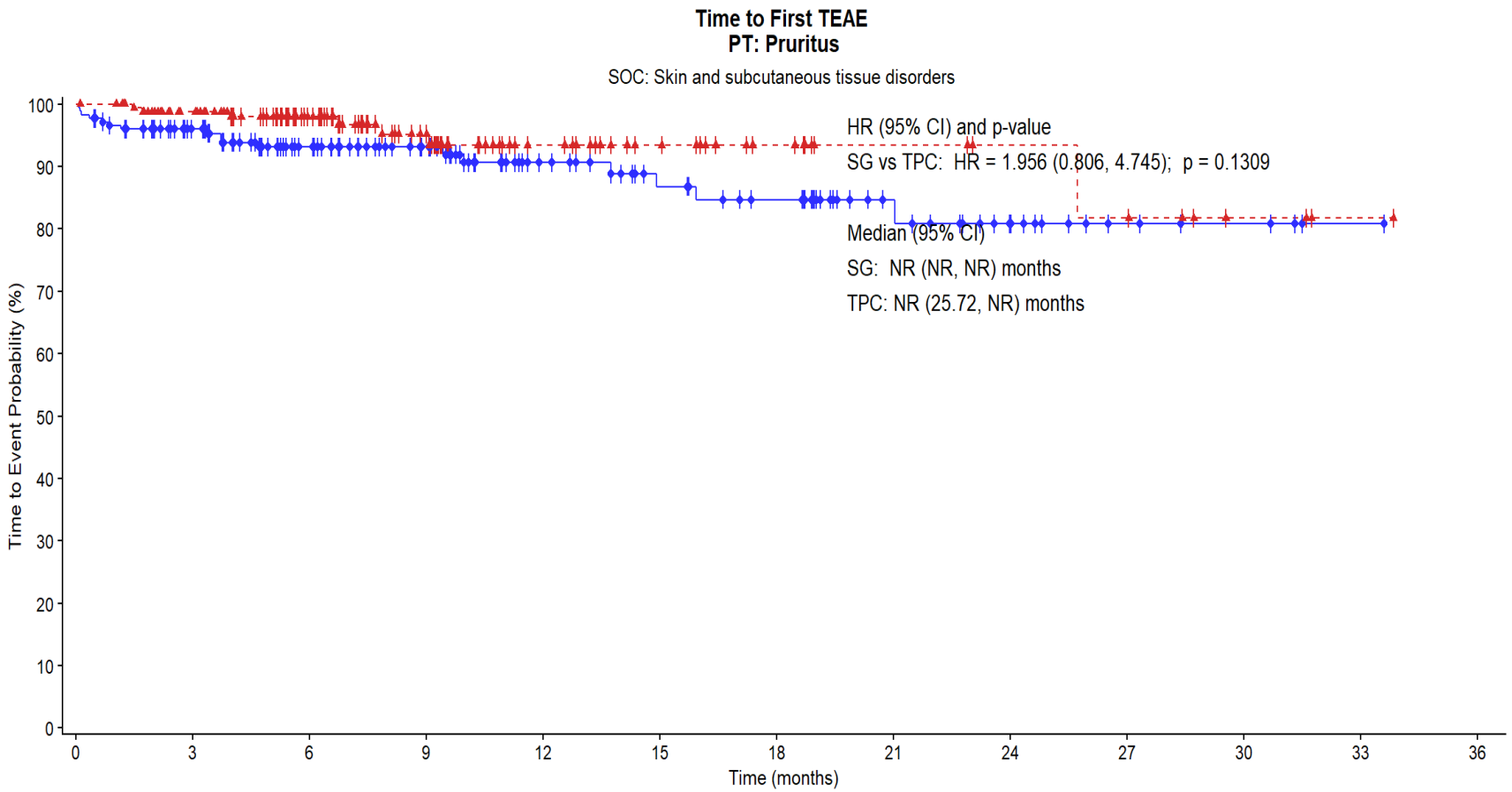
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.108. Figure 1.1.107: Kaplan Meier Plot of Time to First TEAE by PT Eczema — mSAF — Excluding patients preselected to receive nab-paclitaxel



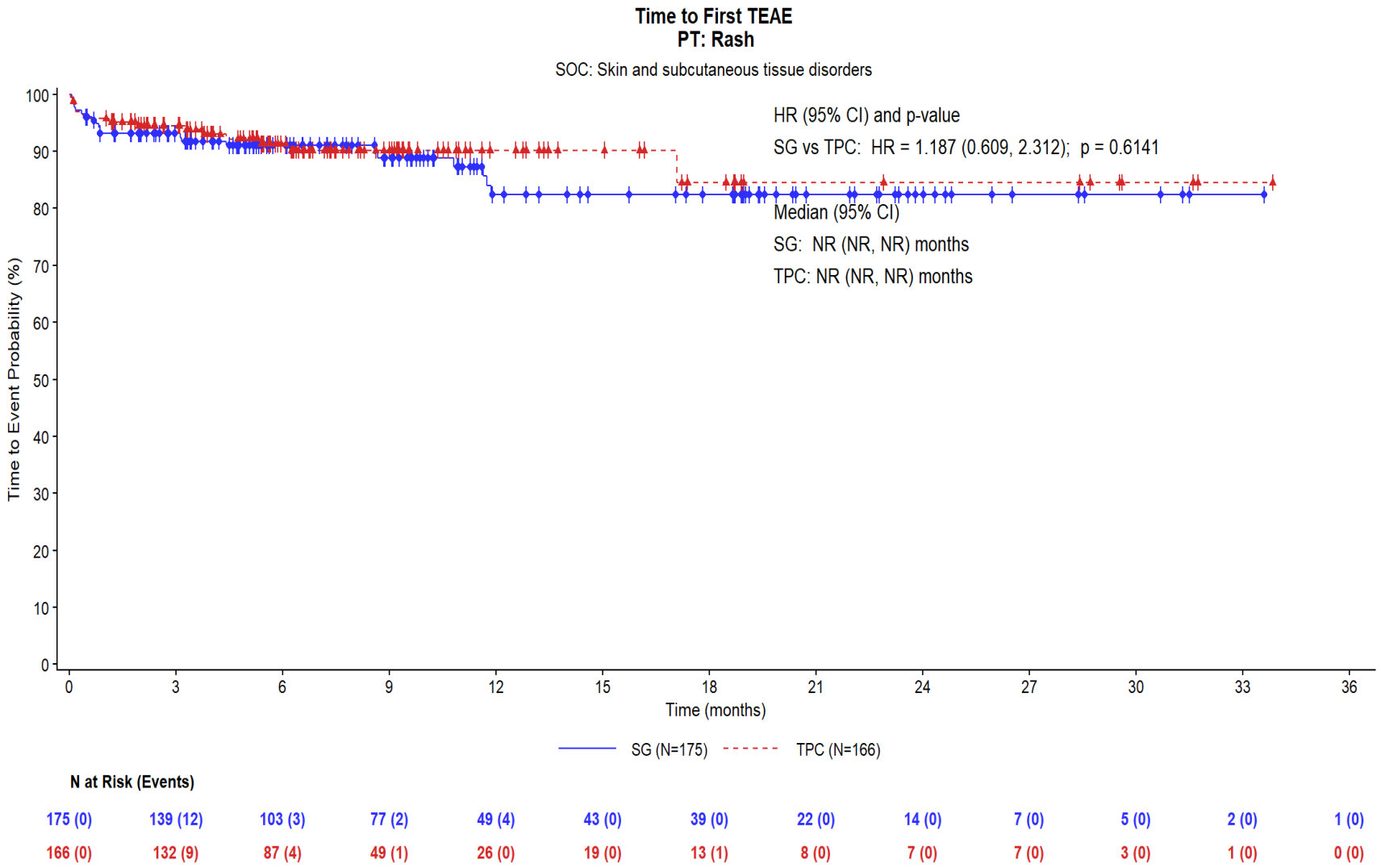
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.109. Figure 1.1.108: Kaplan Meier Plot of Time to First TEAE by PT Pruritus — mSAF — Excluding patients preselected to receive nab-paclitaxel



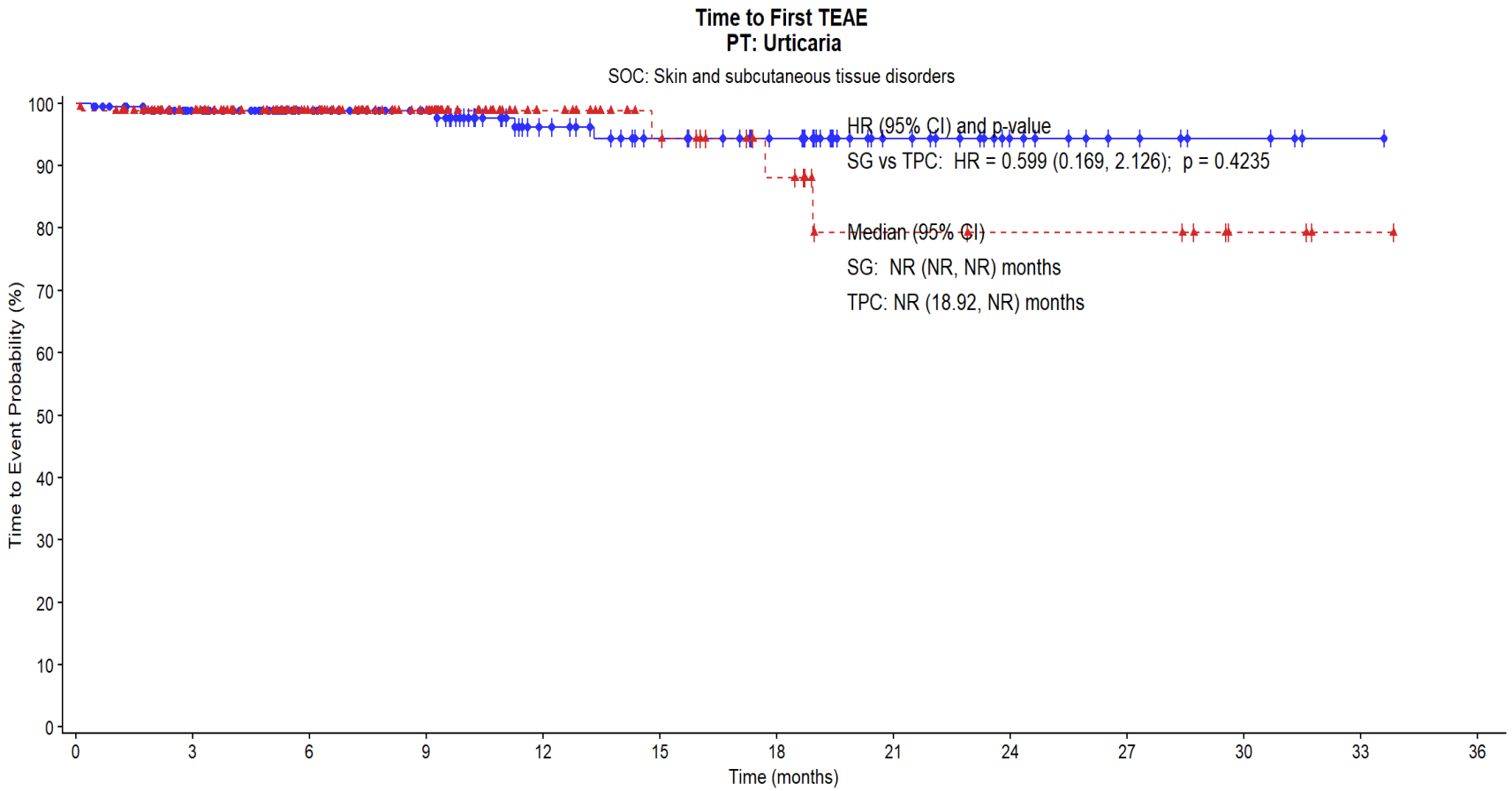
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.110. Figure 1.1.109: Kaplan Meier Plot of Time to First TEAE by PT Rash — mSAF — Excluding patients preselected to receive nab-paclitaxel



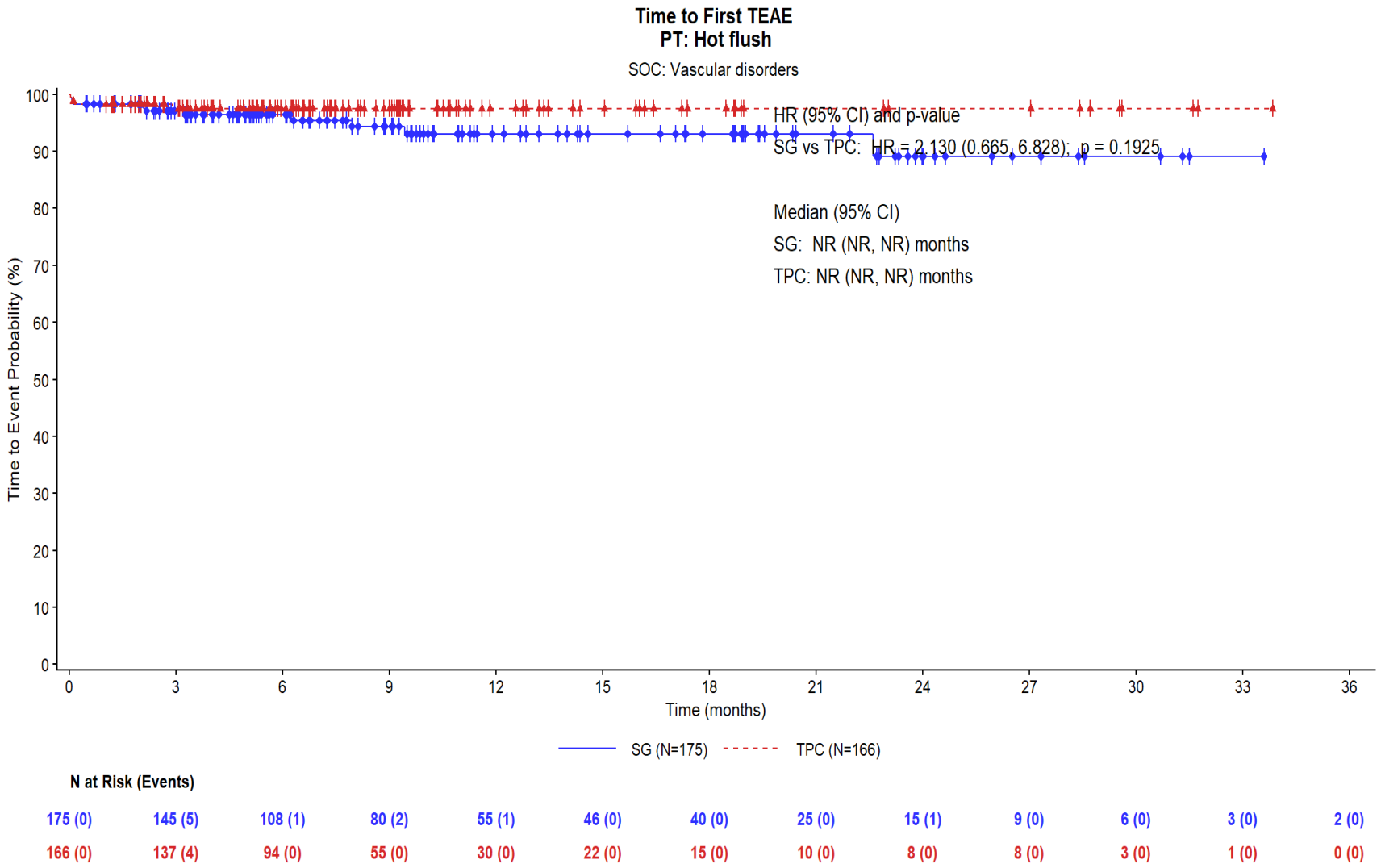
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.111. Figure 1.1.110: Kaplan Meier Plot of Time to First TEAE by PT Urticaria — mSAF — Excluding patients preselected to receive nab-paclitaxel



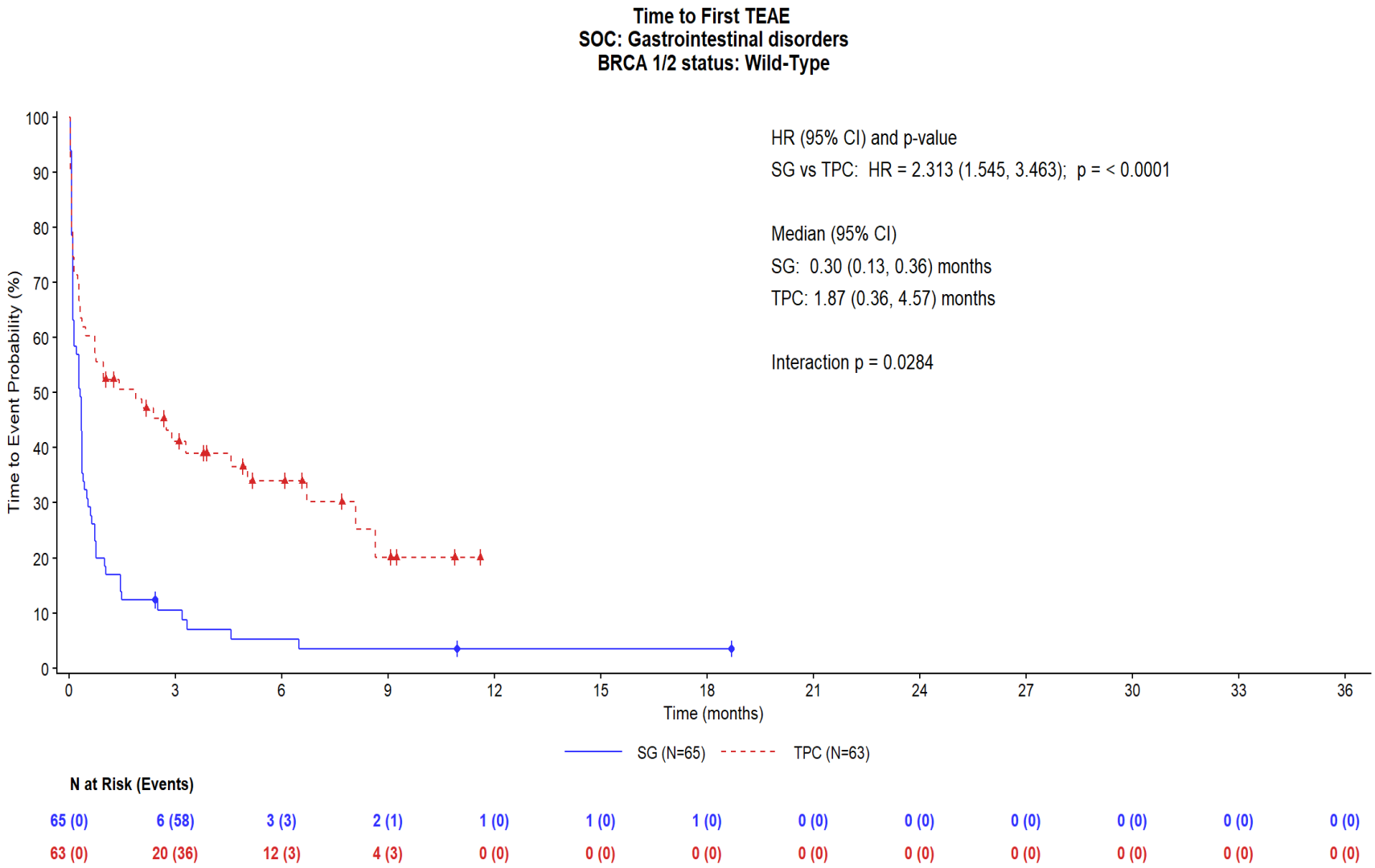
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8.112. Figure 1.1.111: Kaplan Meier Plot of Time to First TEAE by PT Hot flush — mSAF — Excluding patients preselected to receive nab-paclitaxel



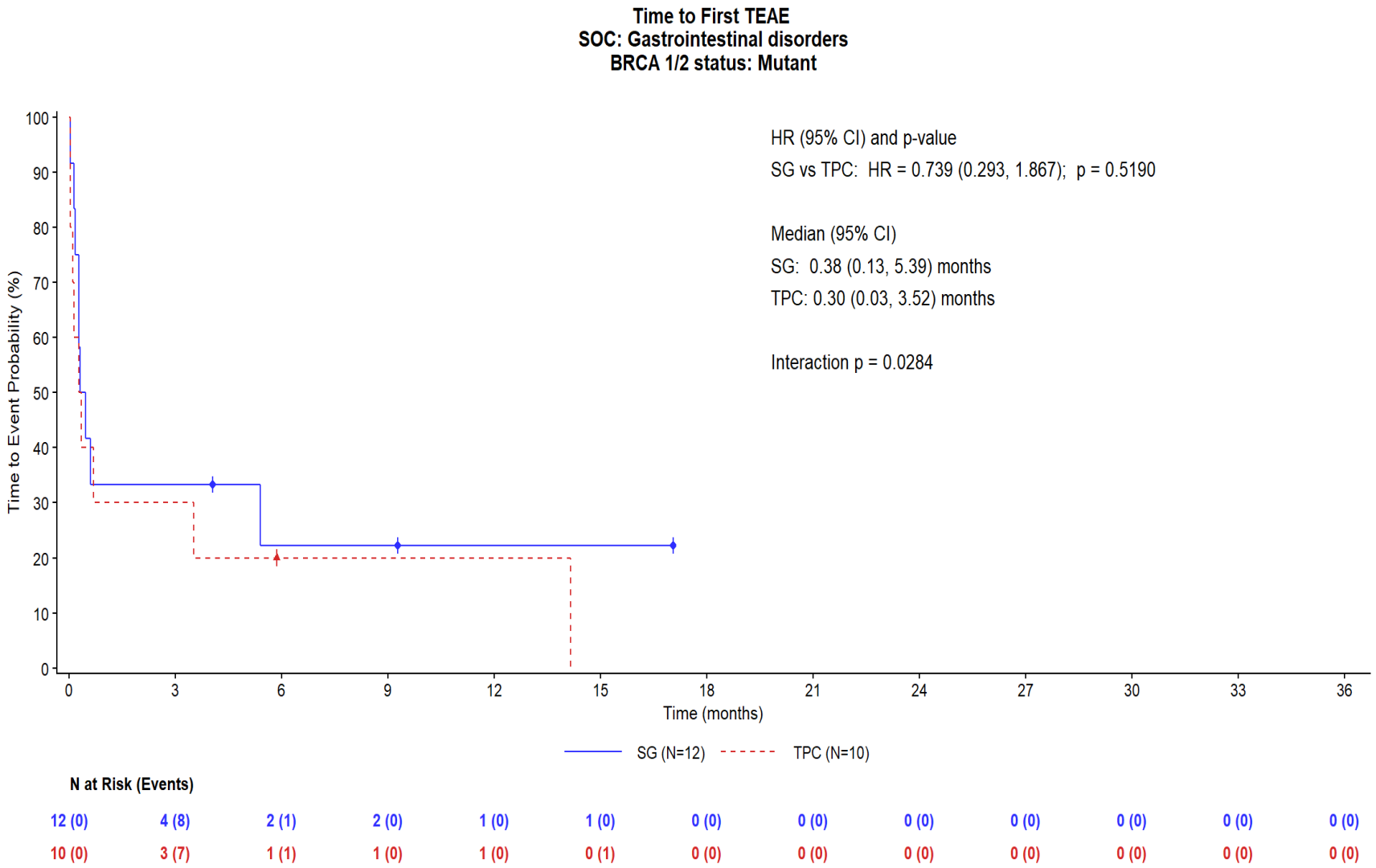
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.113. Figure 1.1.112: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel



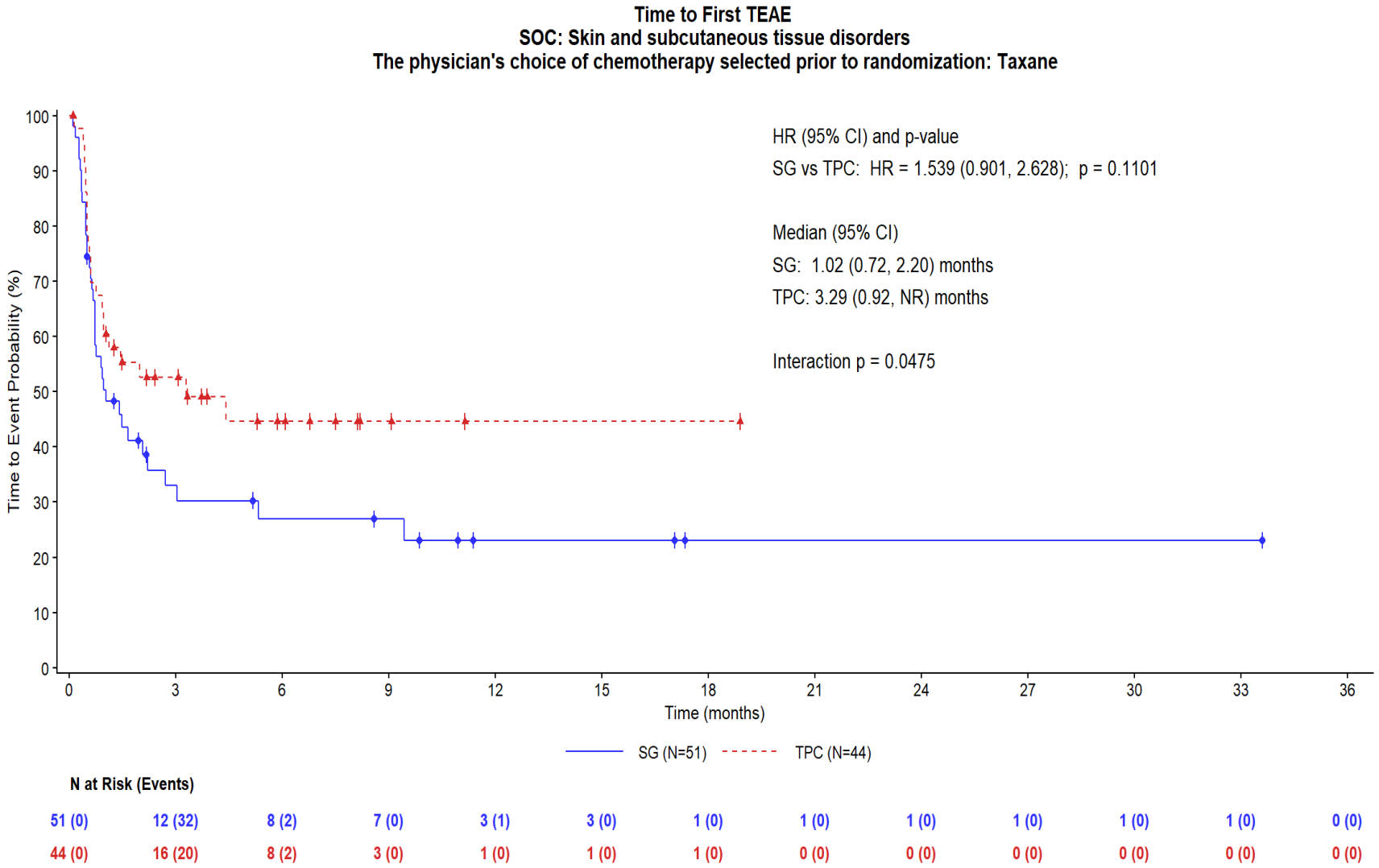
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.114. Figure 1.1.113: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel



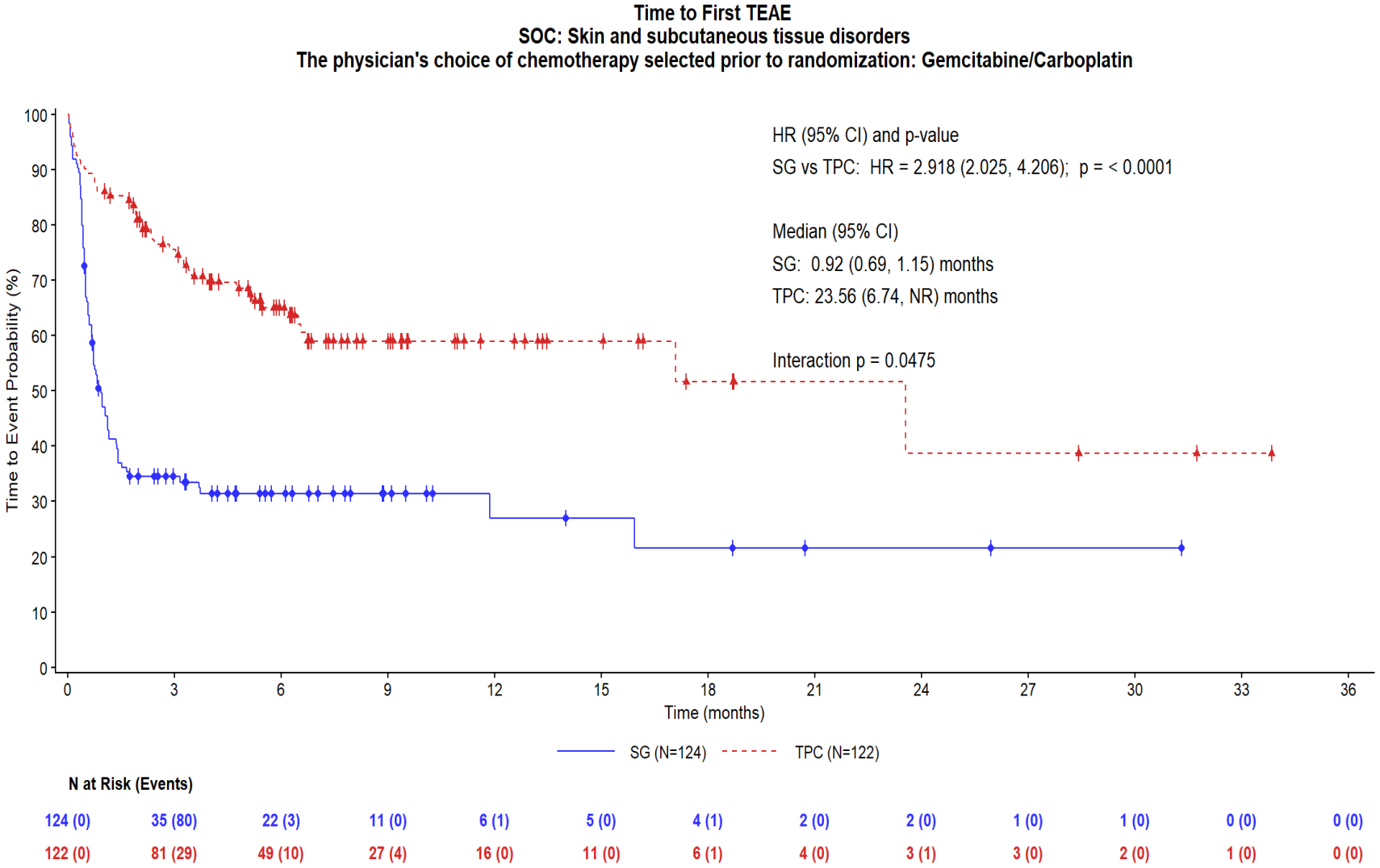
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.115. Figure 1.1.114: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



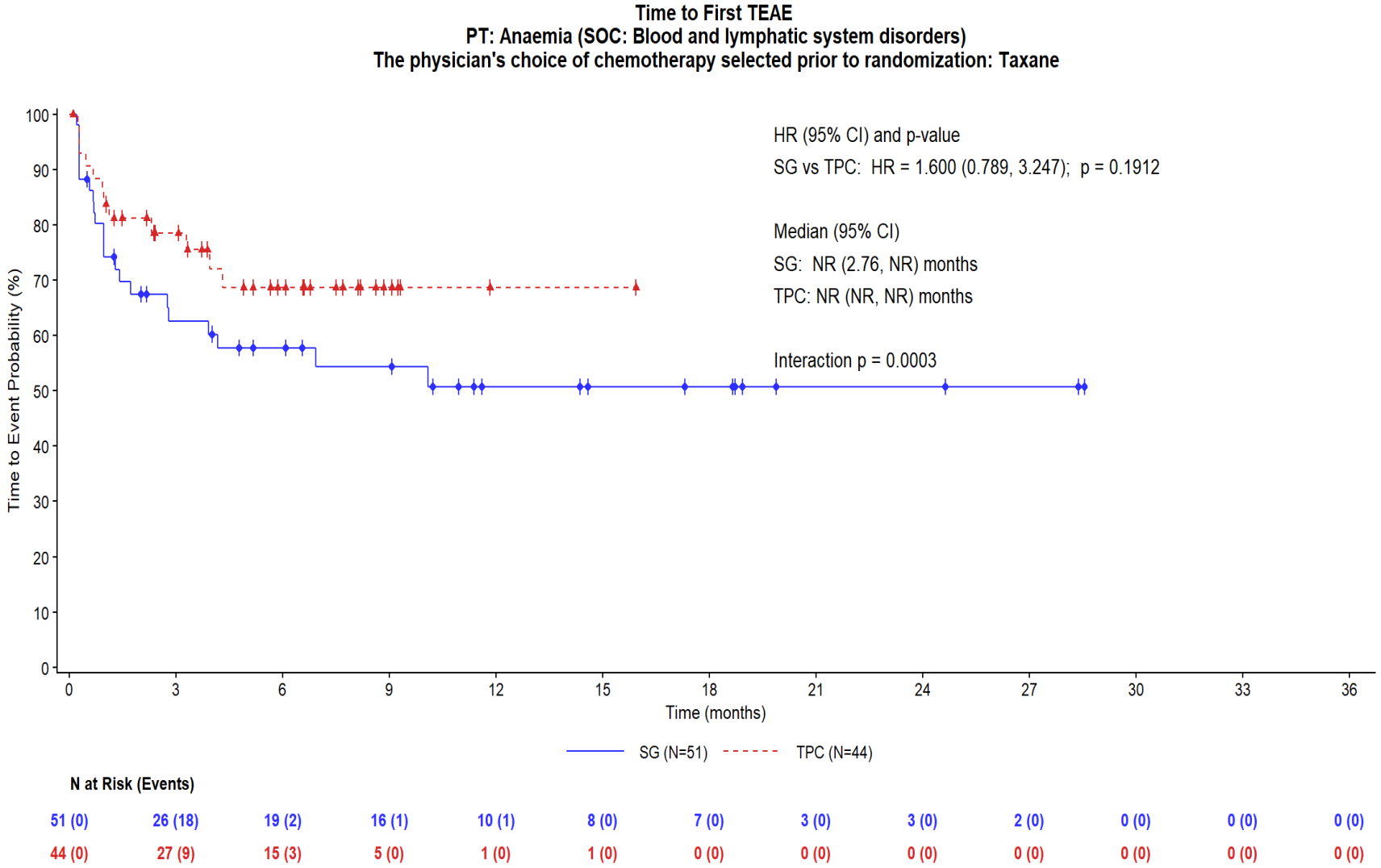
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.116. Figure 1.1.115: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



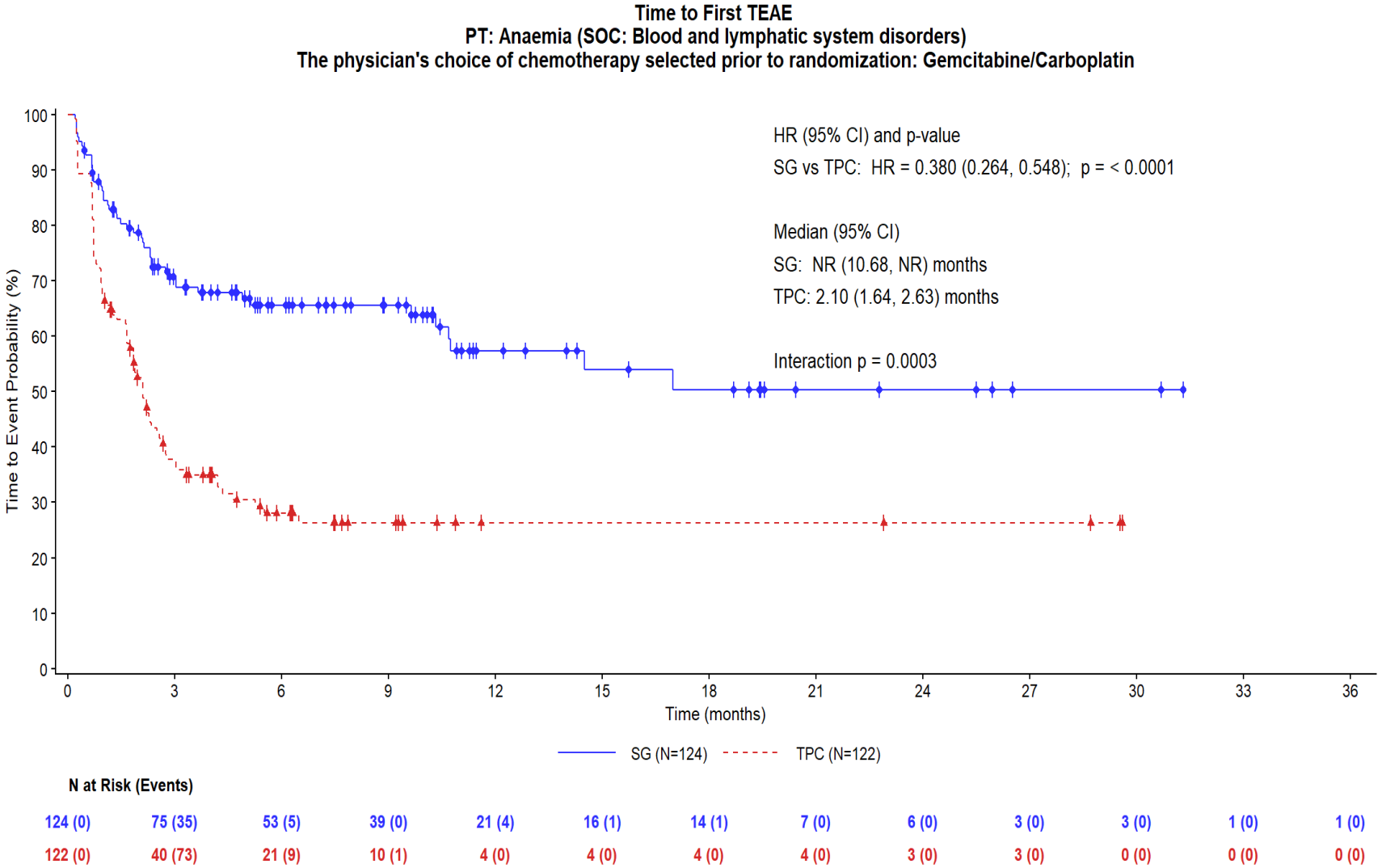
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.117. Figure 1.1.116: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



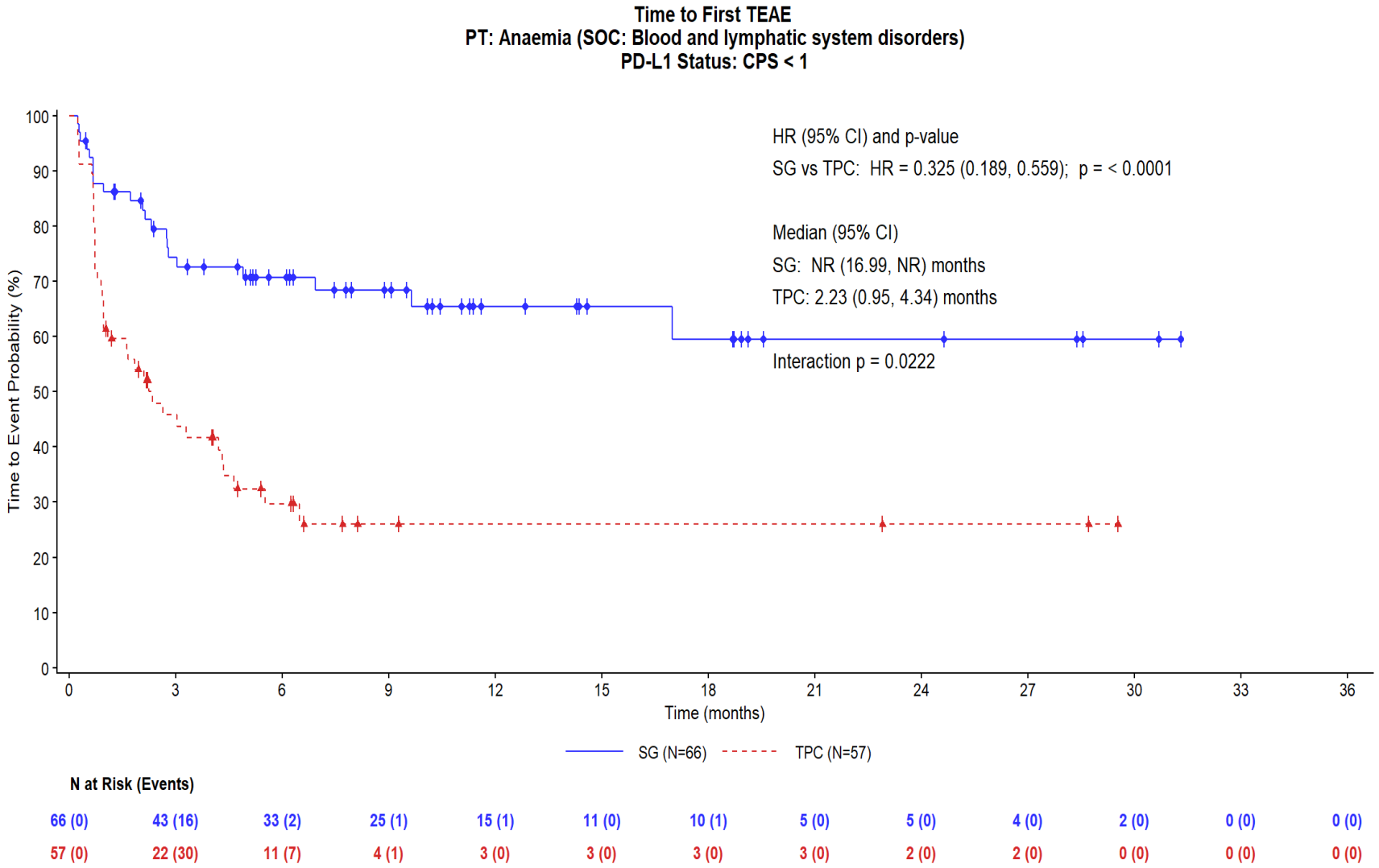
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.118. Figure 1.1.117: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



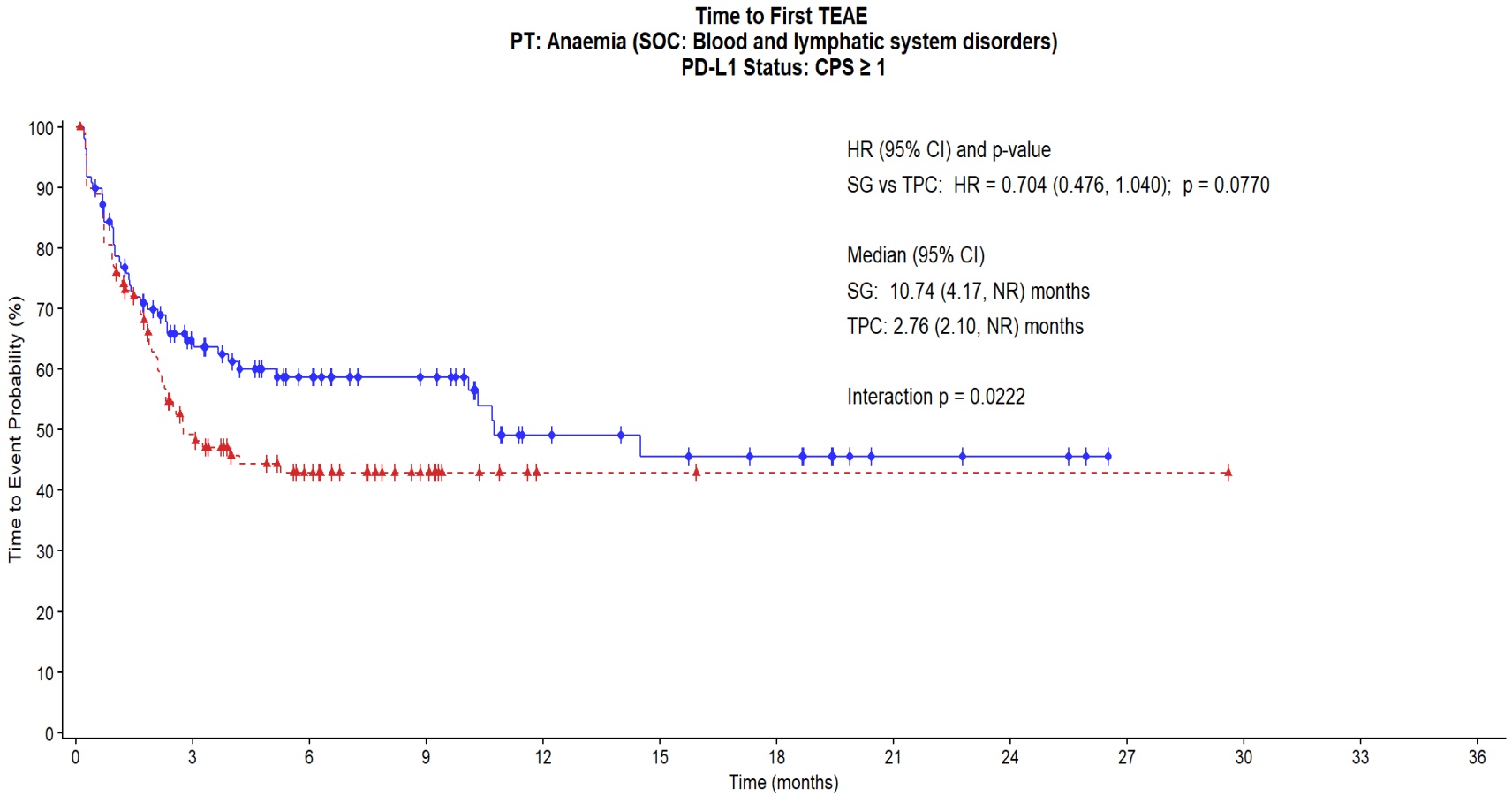
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.119. Figure 1.1.118: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



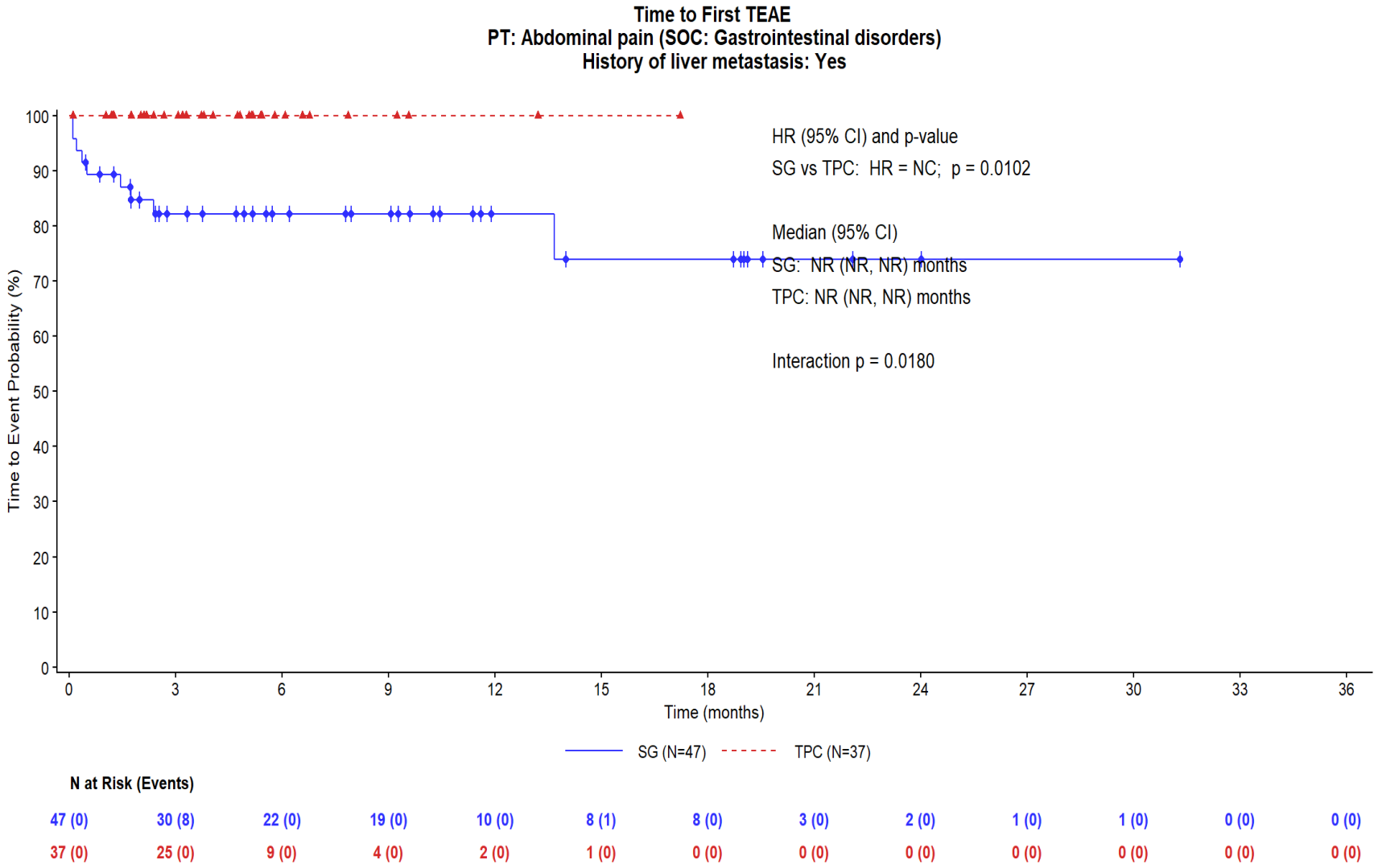
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.120. Figure 1.1.119: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) PD L1 Status CPS 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



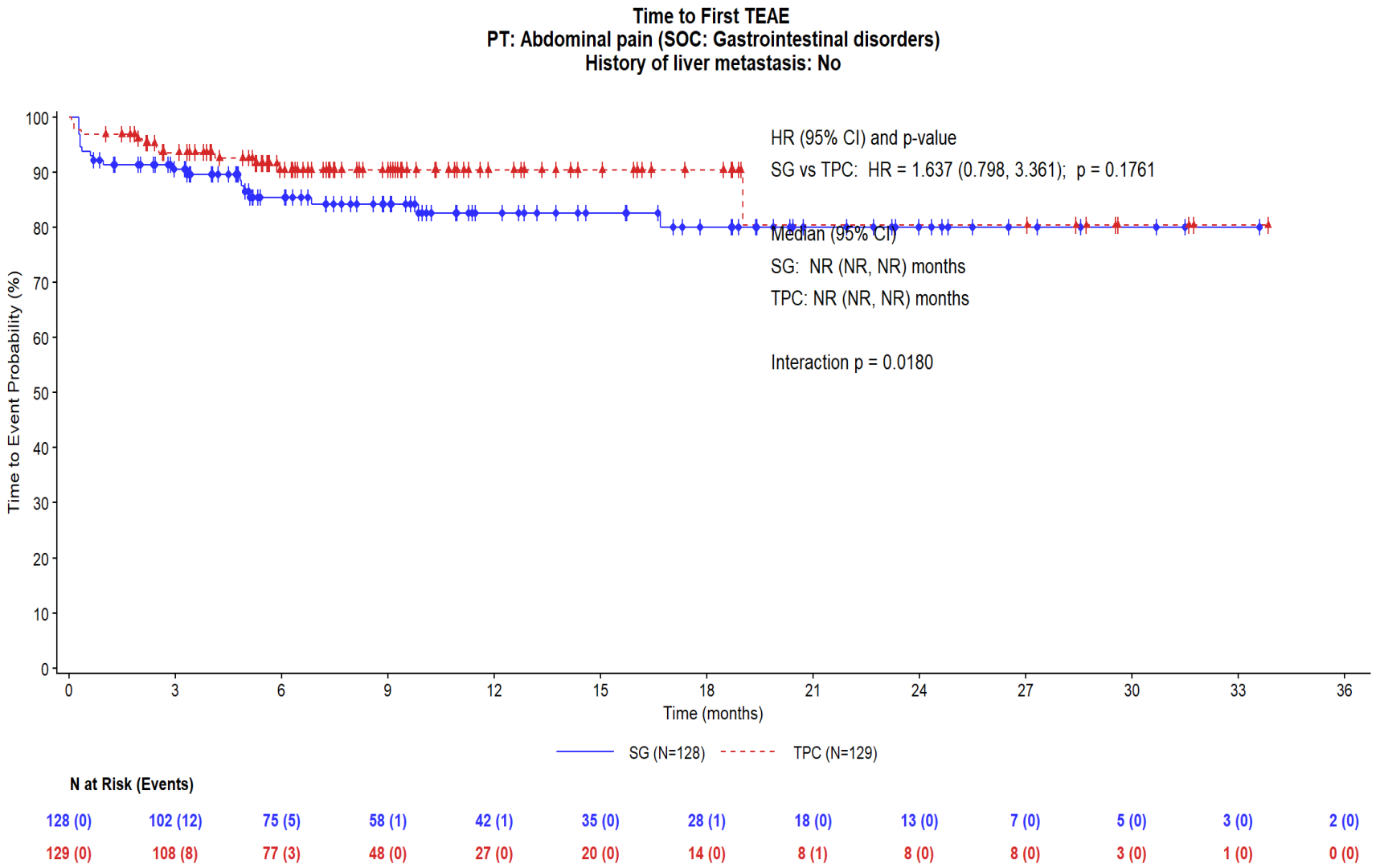
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.121. Figure 1.1.120: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain (SOC Gastrointestinal disorders) History of liver metastasis Yes — mSAF — Excluding patients preselected to receive nab-paclitaxel



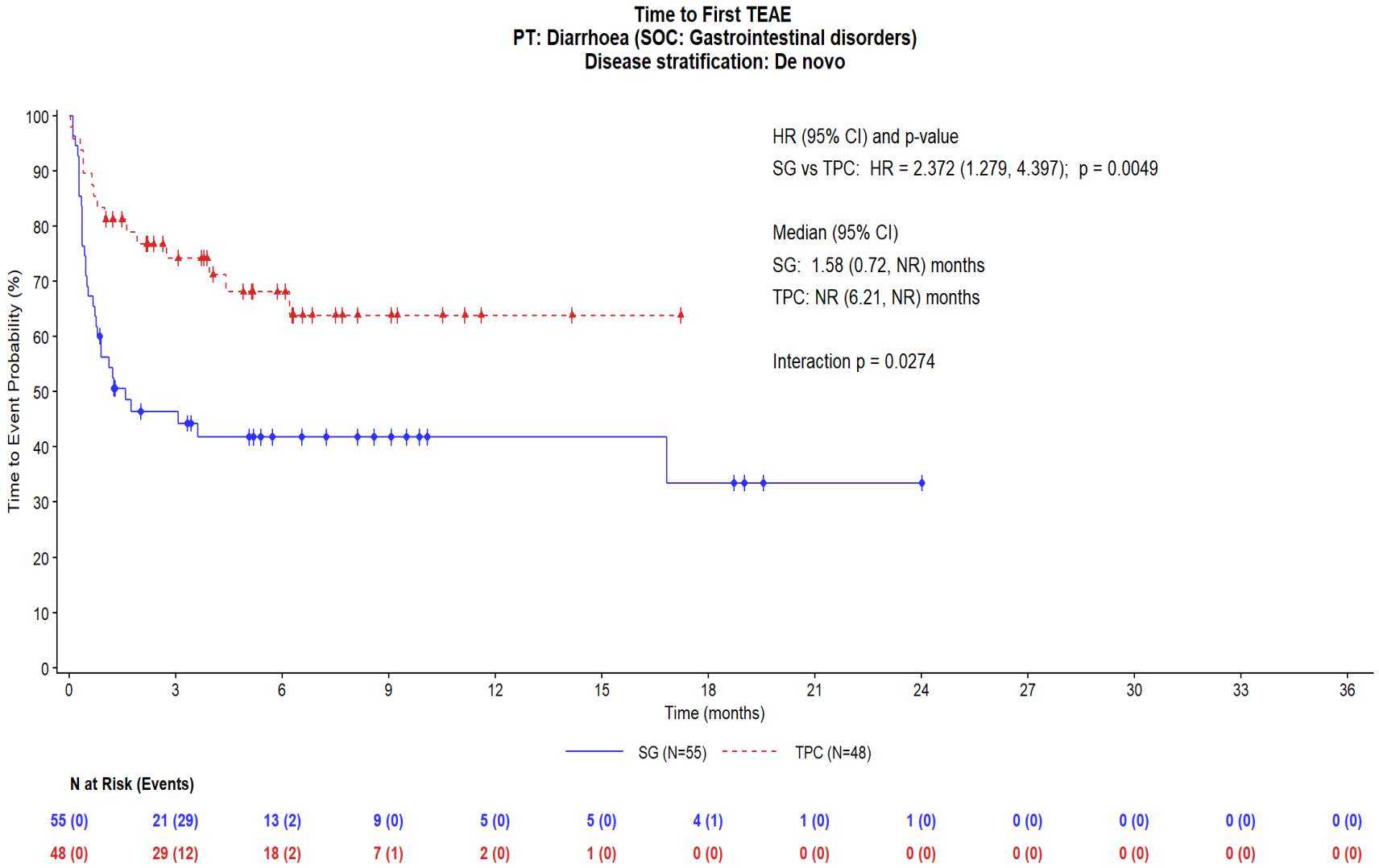
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.122. Figure 1.1.121: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain (SOC Gastrointestinal disorders) History of liver metastasis No — mSAF — Excluding patients preselected to receive nab-paclitaxel



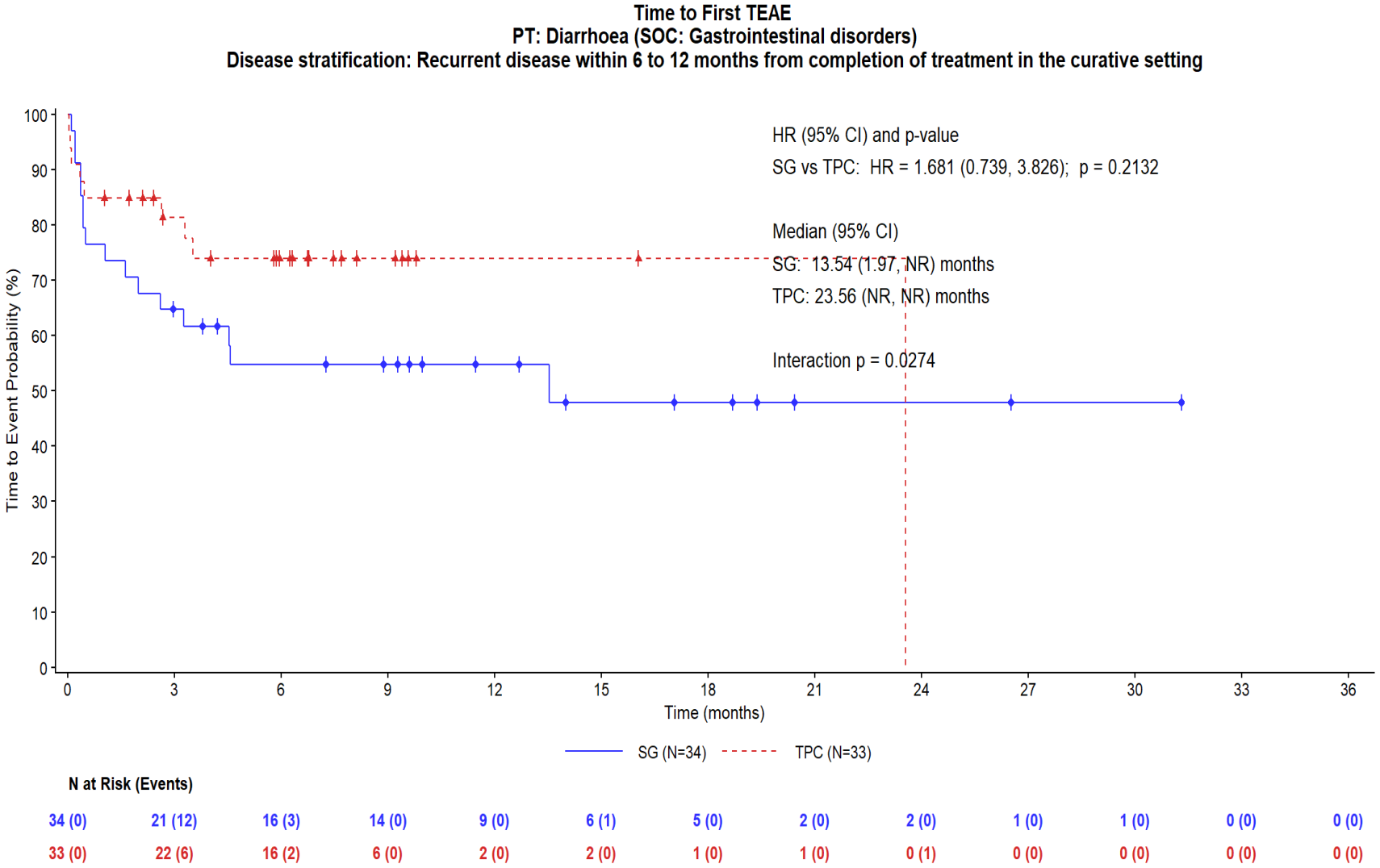
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.123. Figure 1.1.122: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification De novo — mSAF — Excluding patients preselected to receive nab-paclitaxel



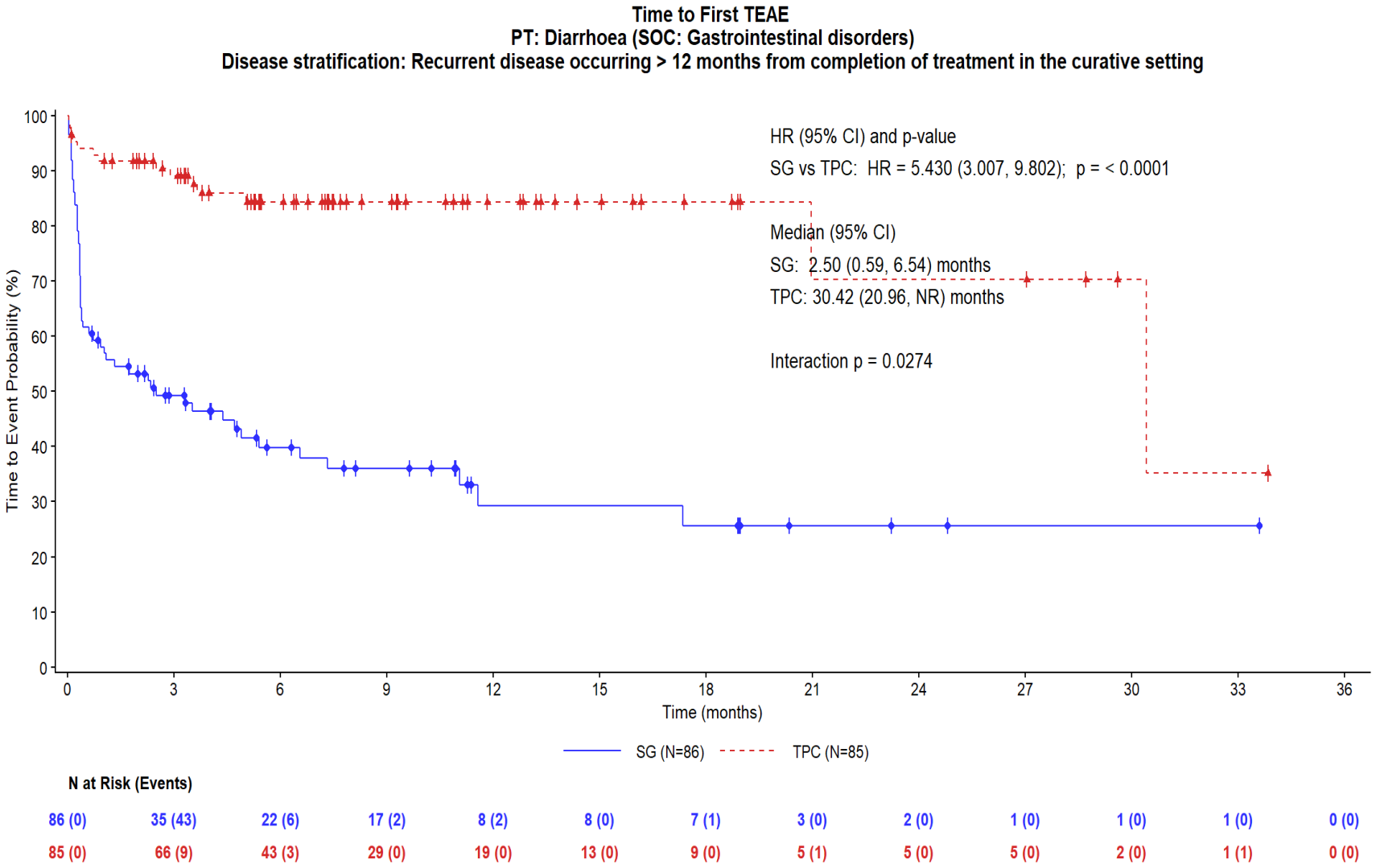
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.124. Figure 1.1.123: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease within 6 to 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel



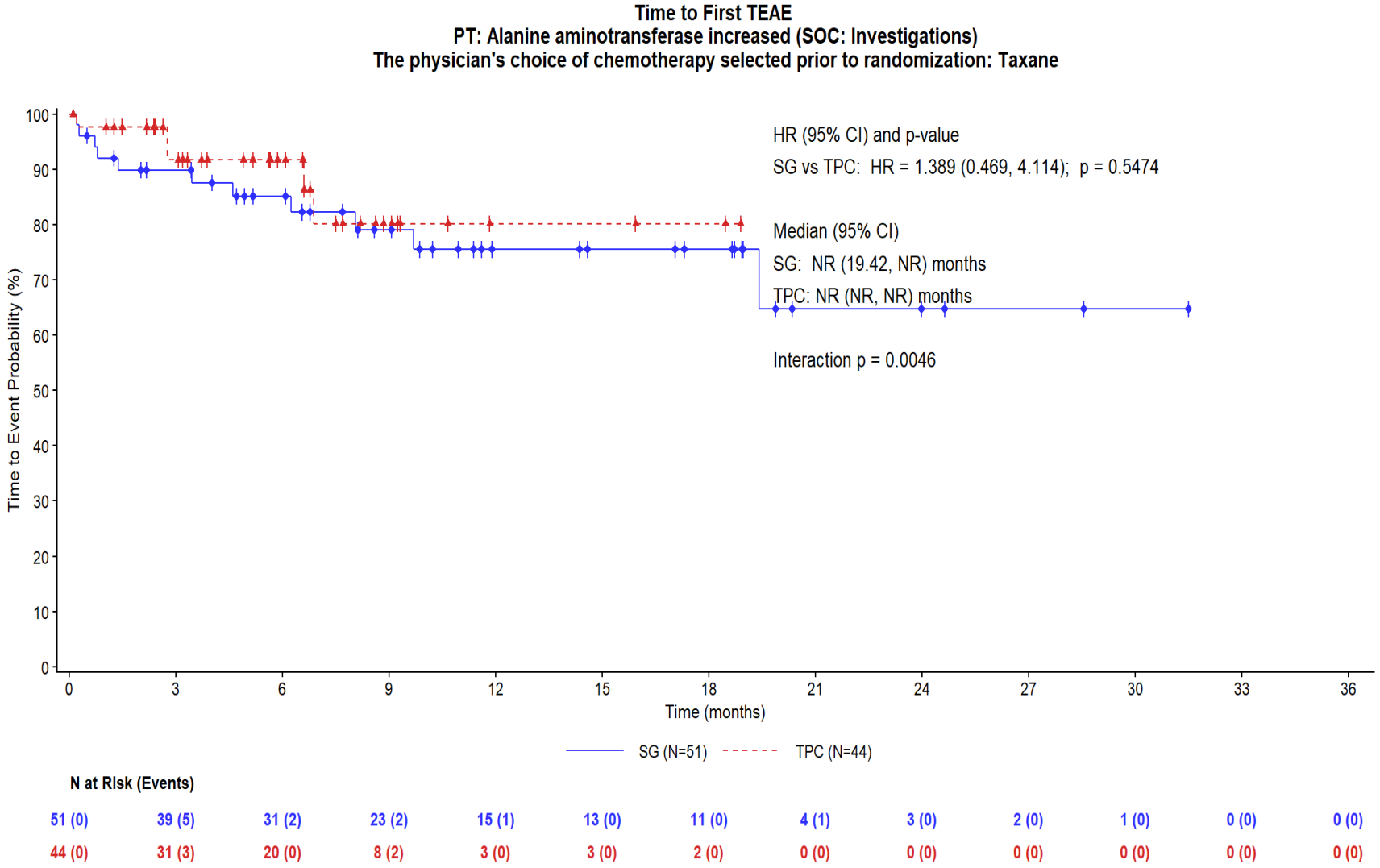
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.125. Figure 1.1.124: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease occurring greater than 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel



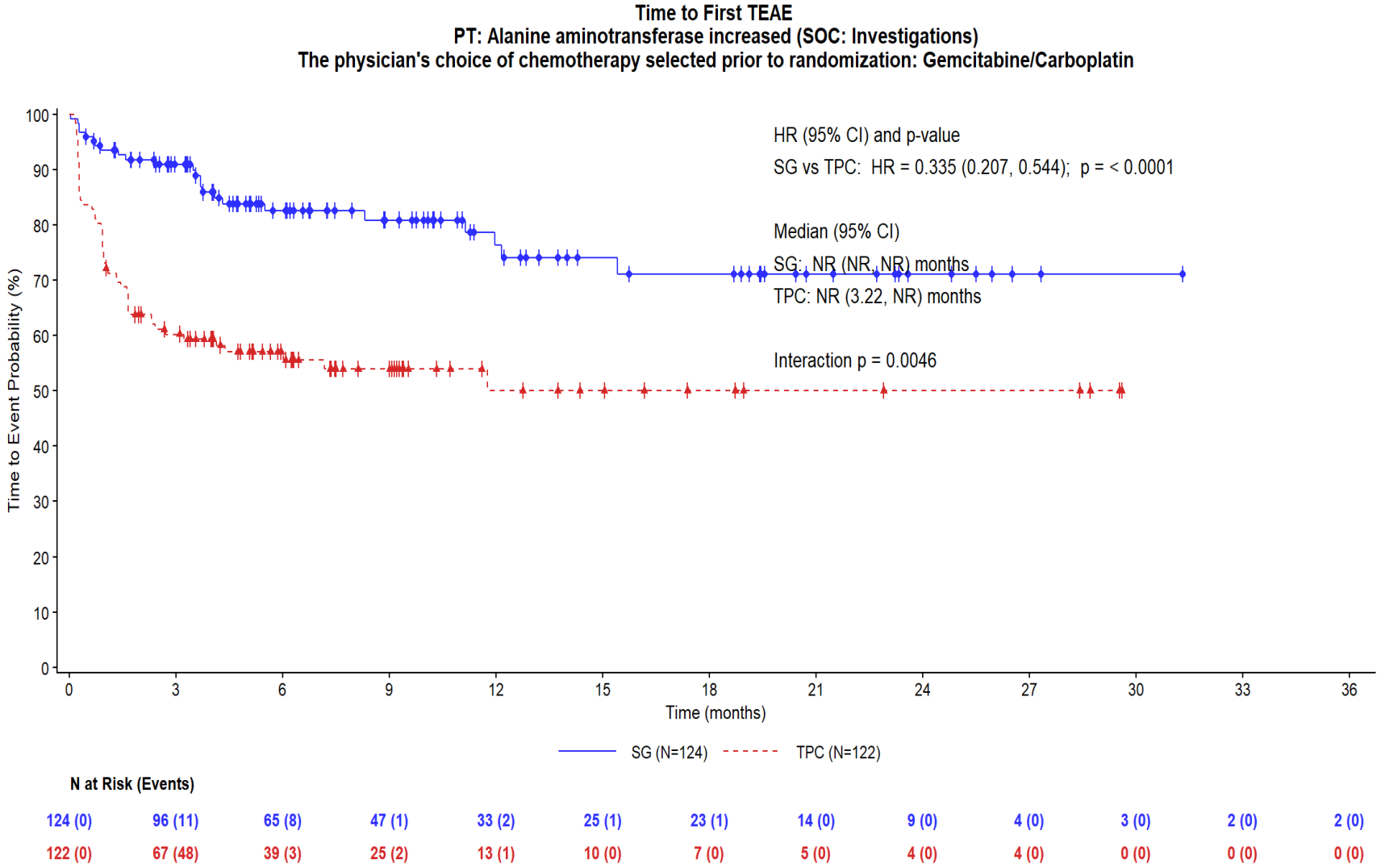
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.126. Figure 1.1.125: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased (SOC Investigations) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



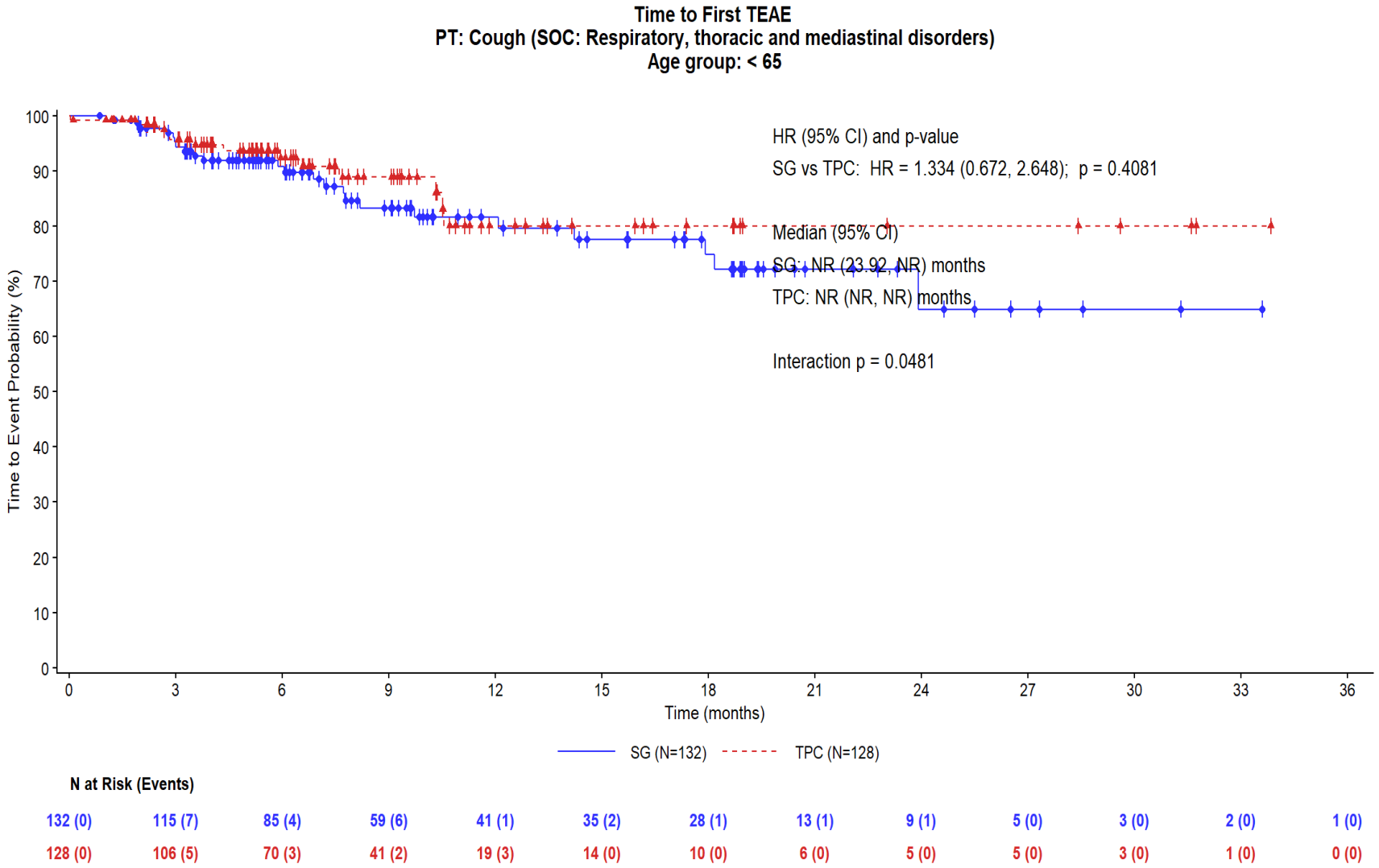
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.127. Figure 1.1.126: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased (SOC Investigations) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



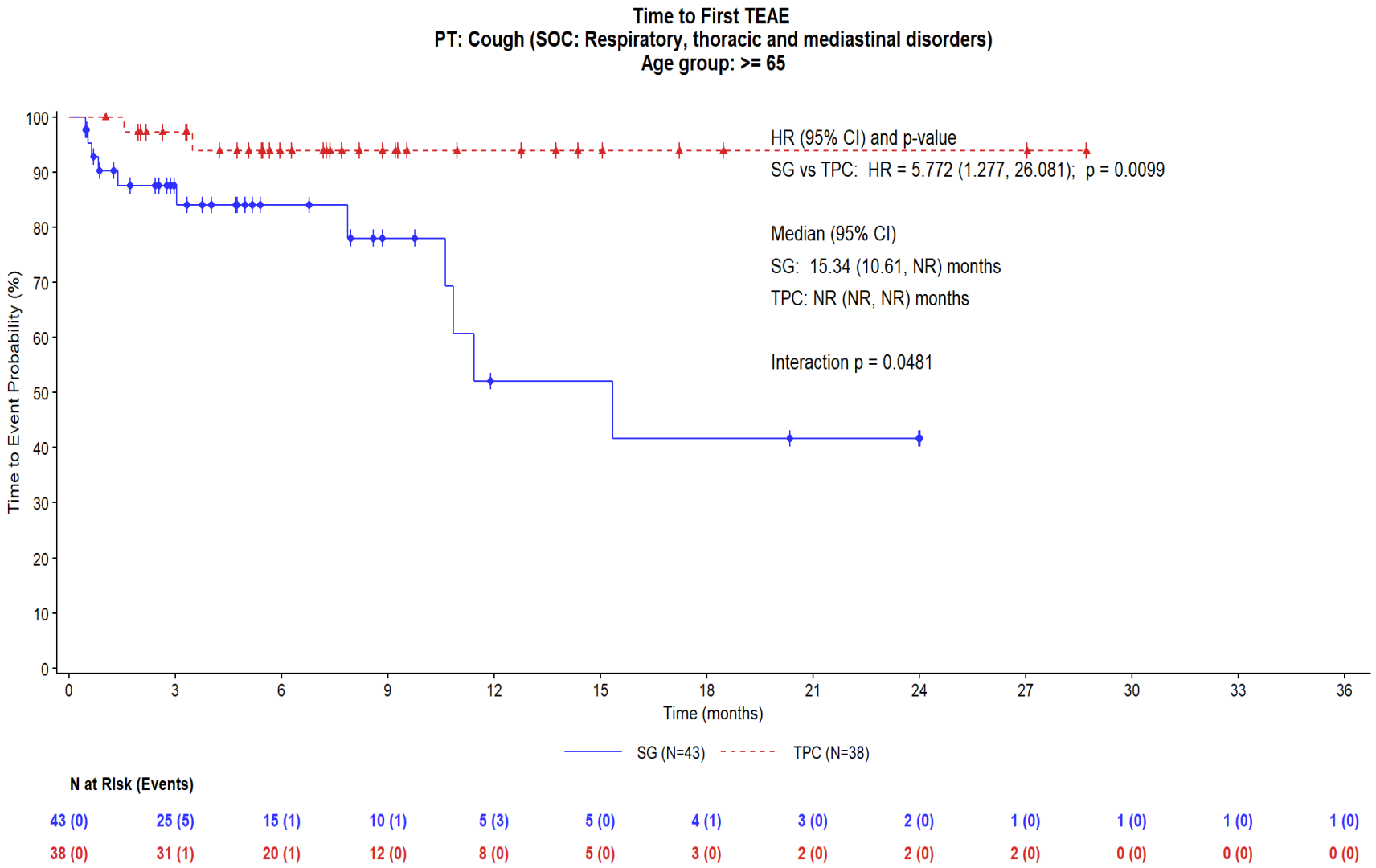
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.128. Figure 1.1.127: Kaplan Meier Plot of Time to First TEAE by PT Cough (SOC Respiratory thoracic and mediastinal disorders) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



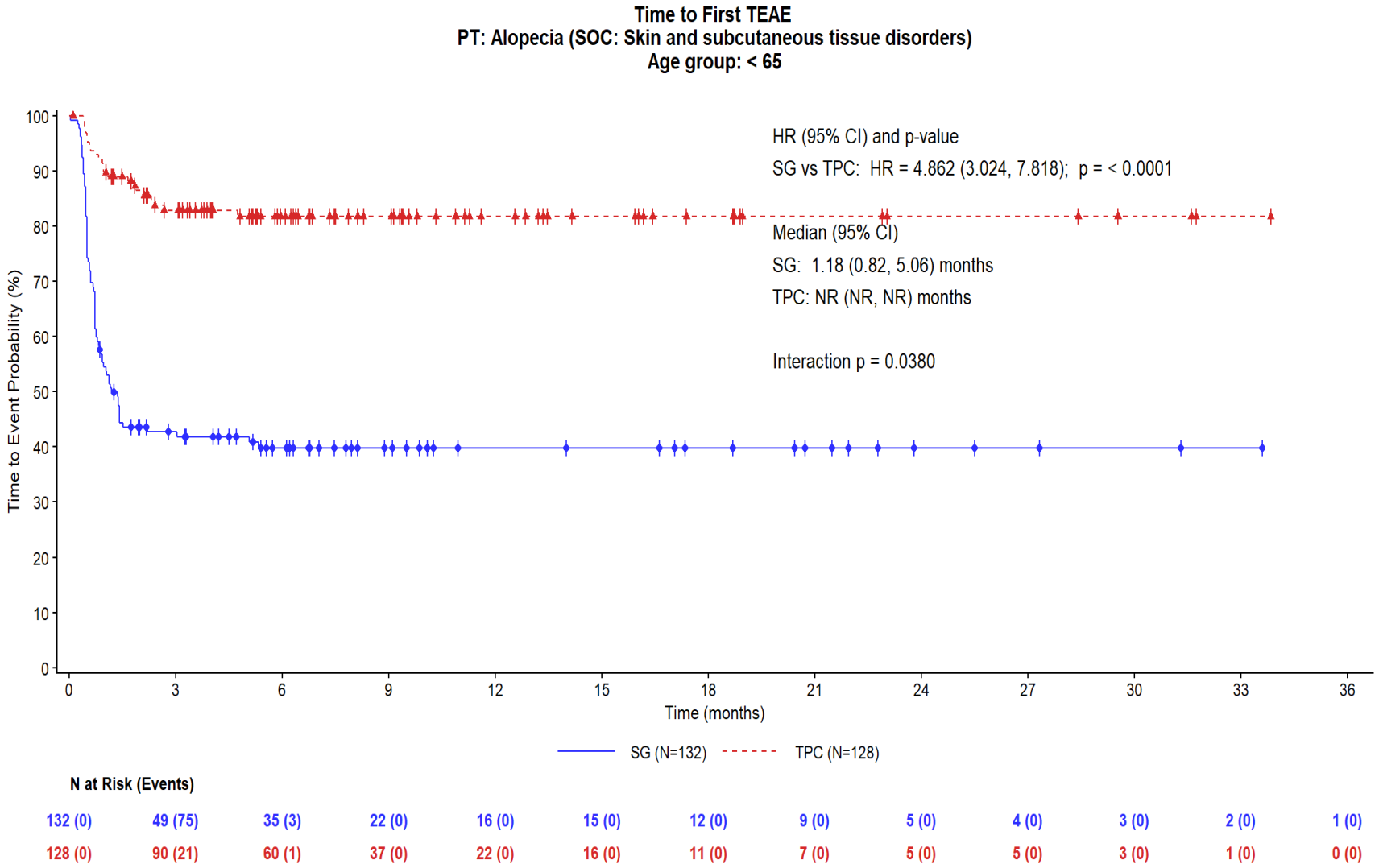
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.129. Figure 1.1.128: Kaplan Meier Plot of Time to First TEAE by PT Cough (SOC Respiratory thoracic and mediastinal disorders) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



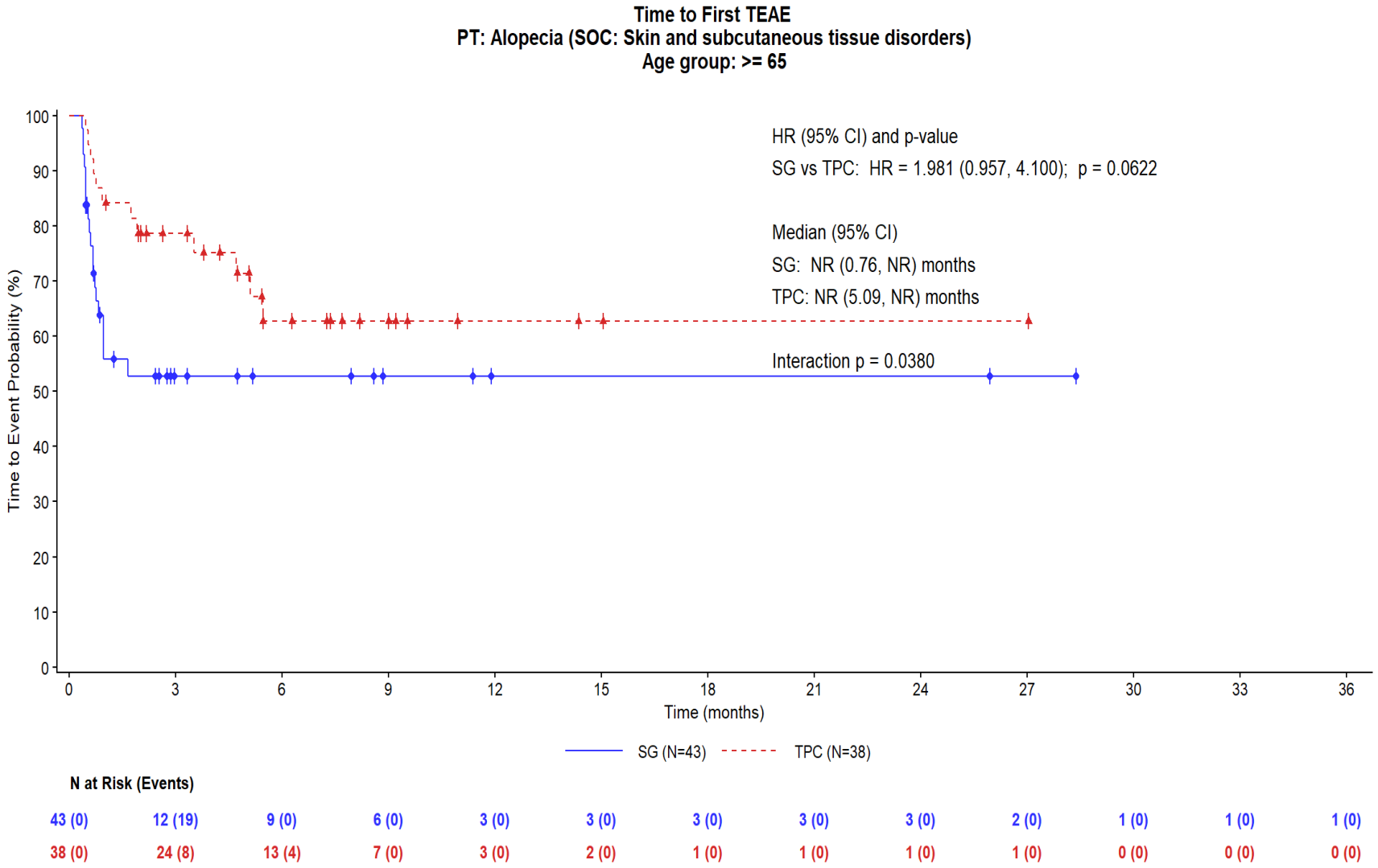
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.130. Figure 1.1.129: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



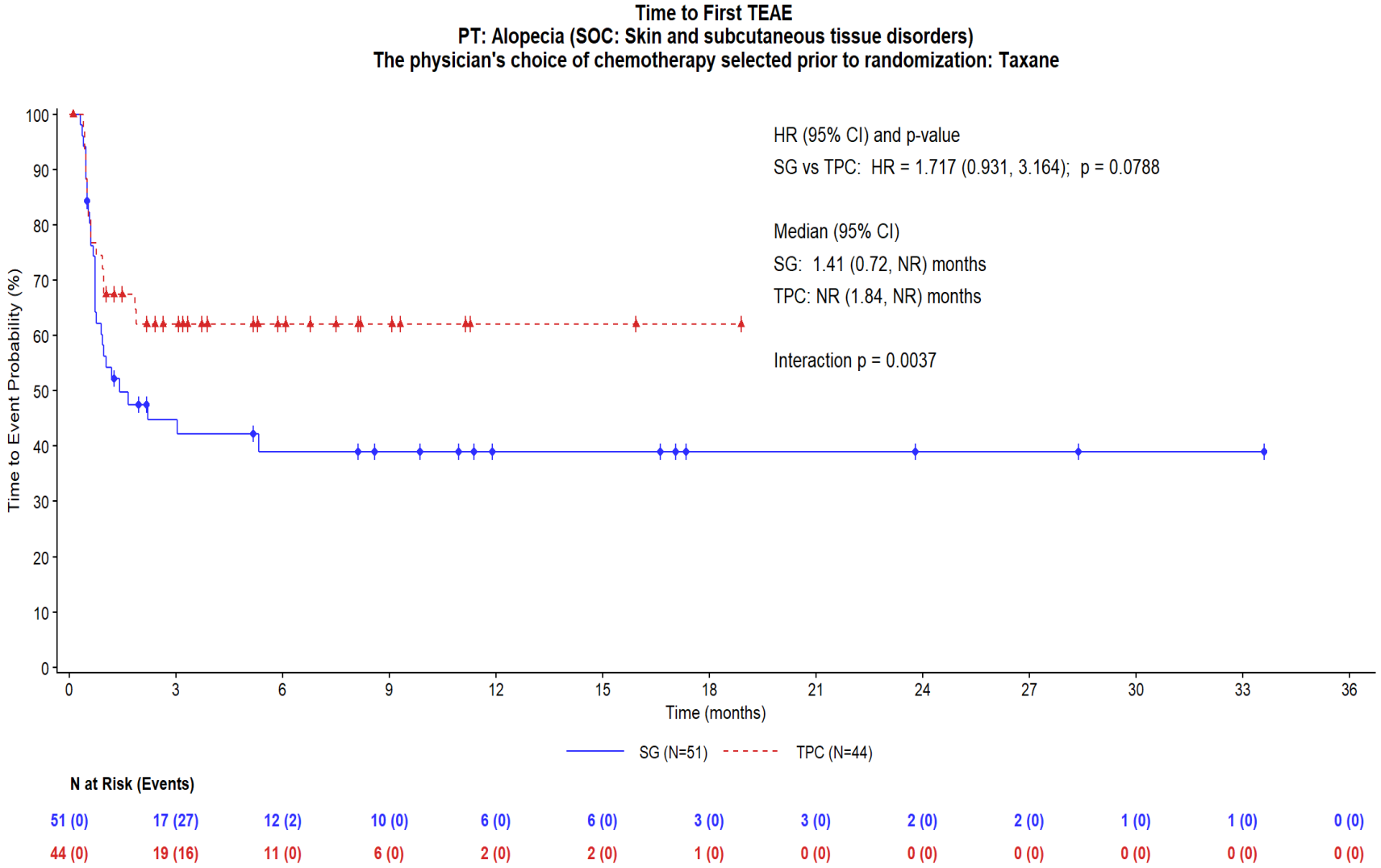
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.131. Figure 1.1.130: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



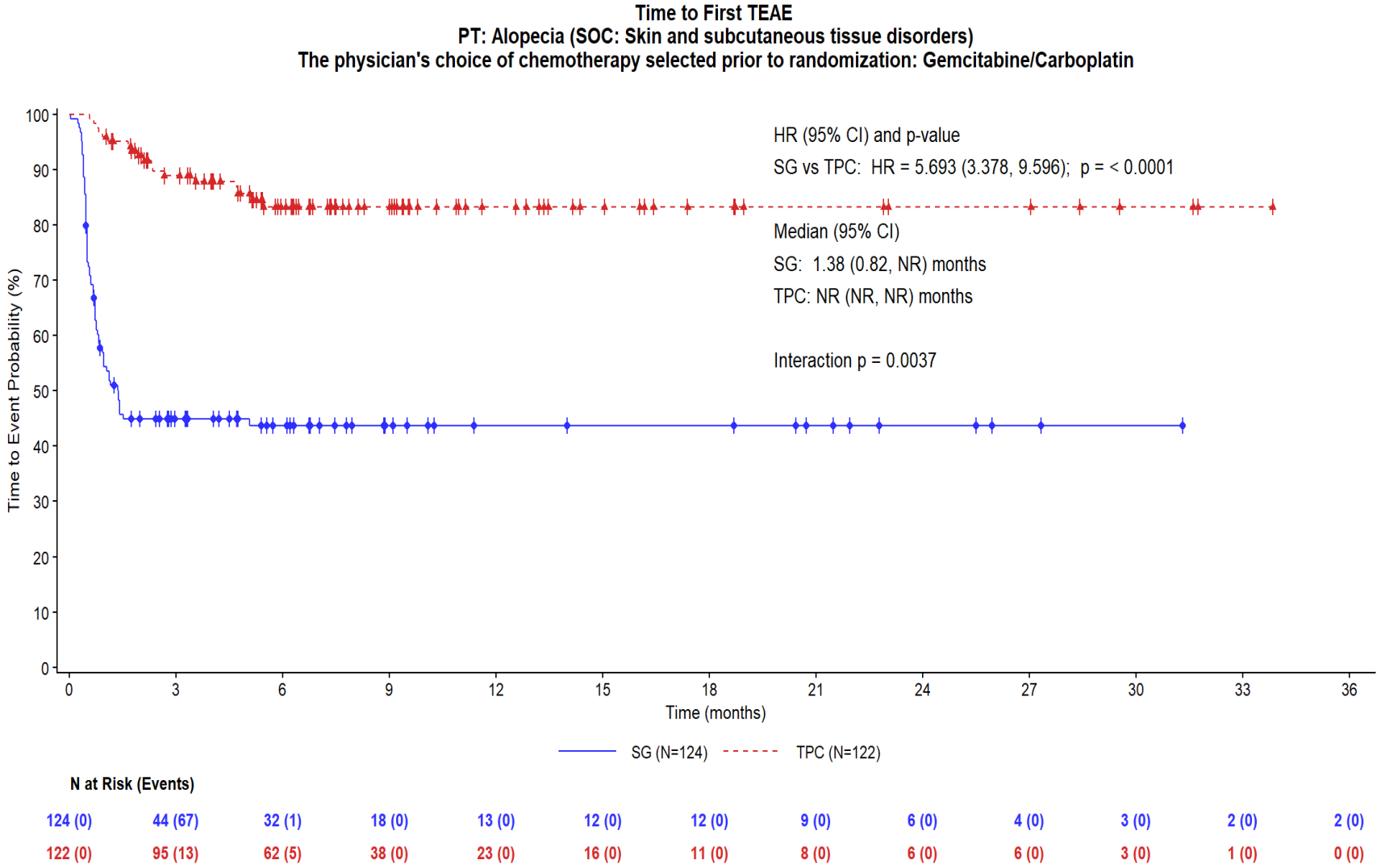
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.132. Figure 1.1.131: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



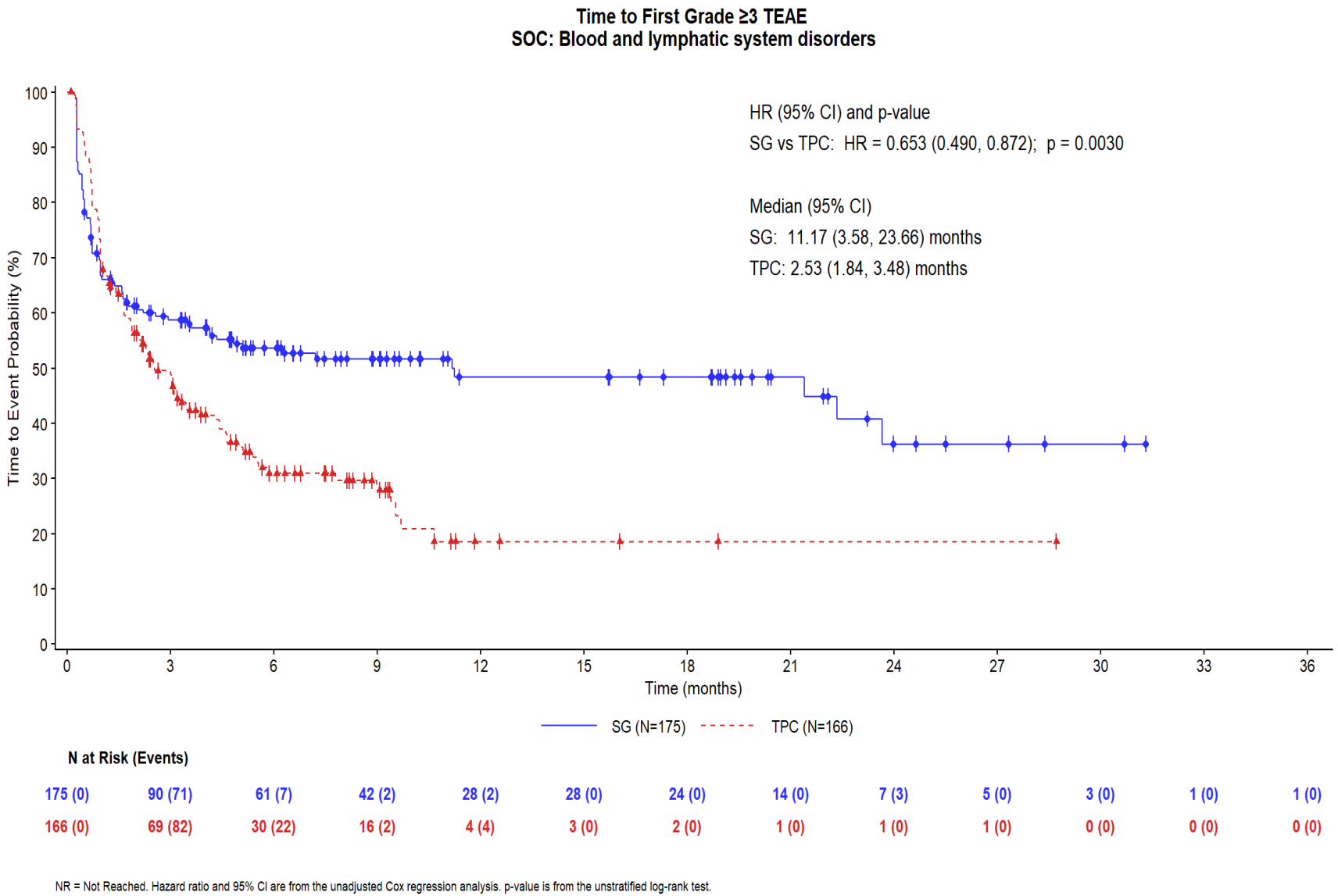
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8.133. Figure 1.1.132: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



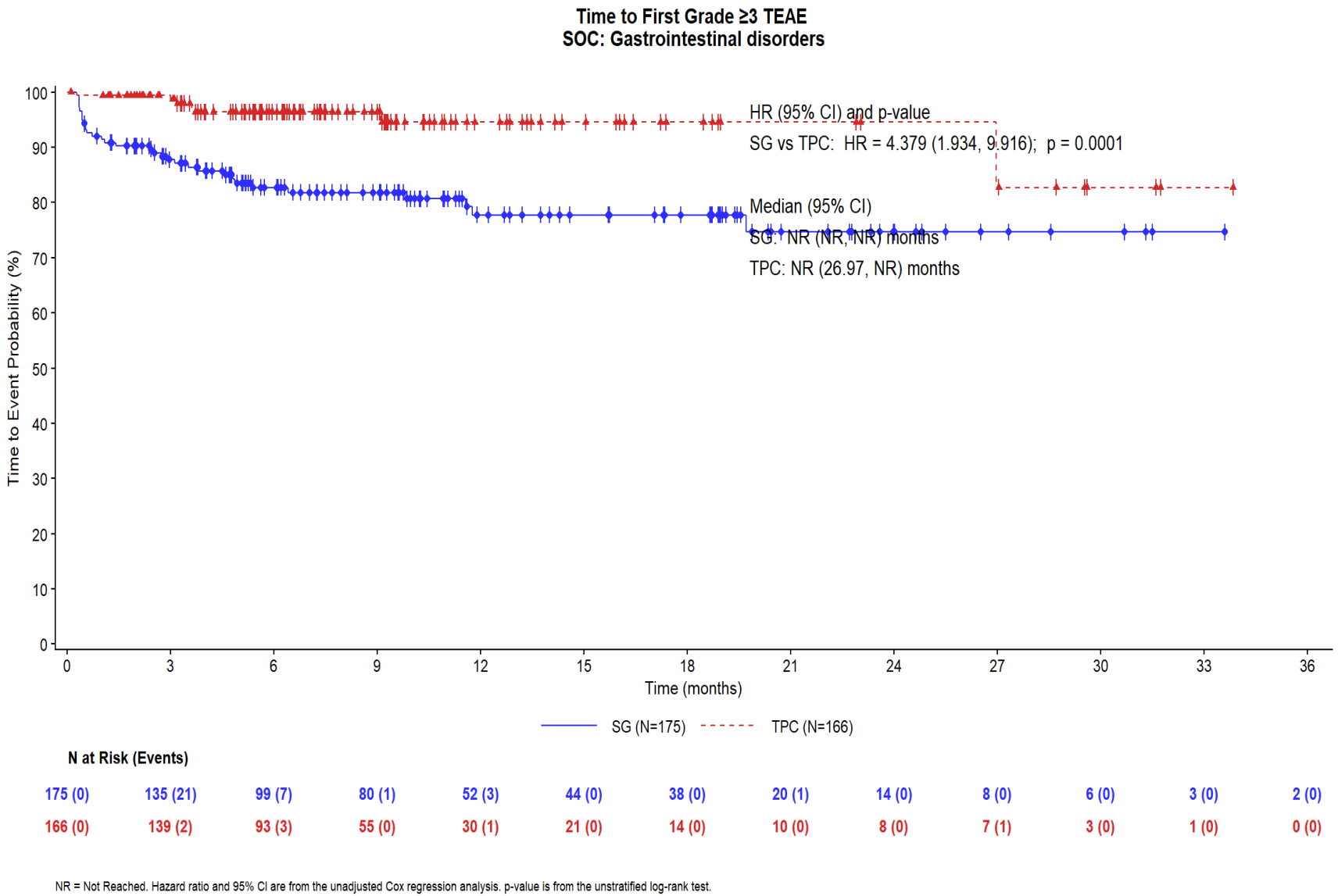
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.134. Figure 1.1.133: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



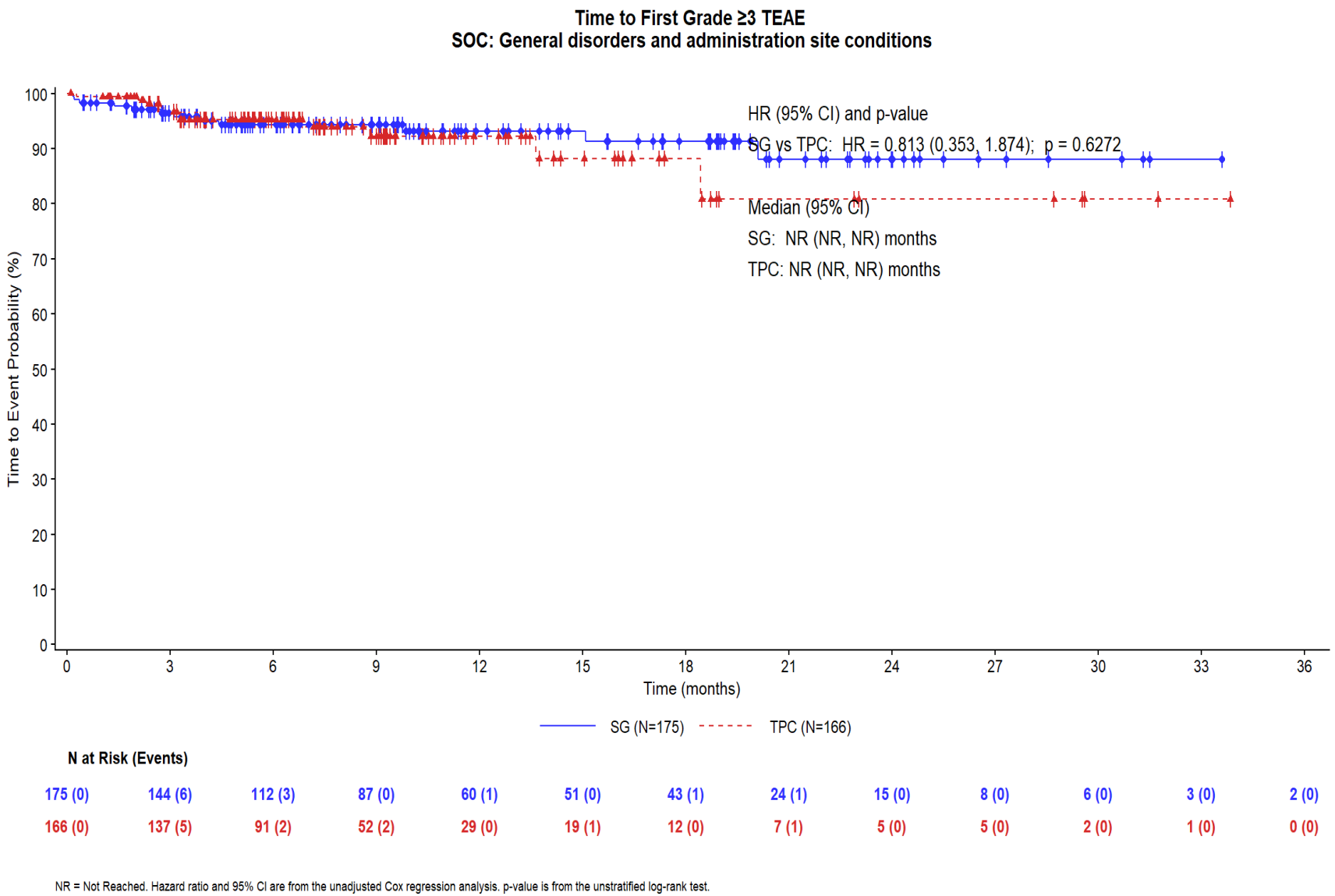
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.135. Figure 1.1.134: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



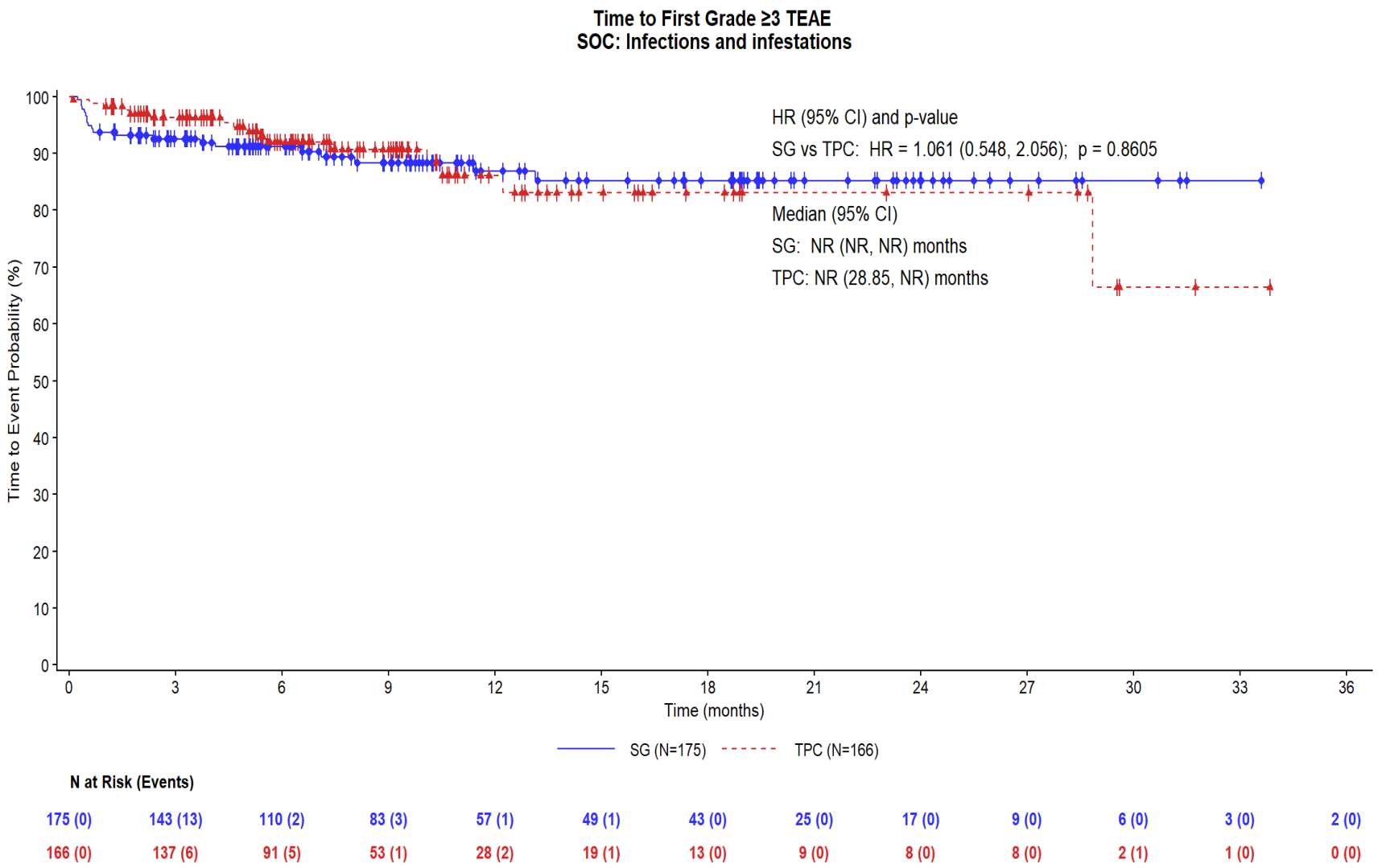
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.136. Figure 1.1.135: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel



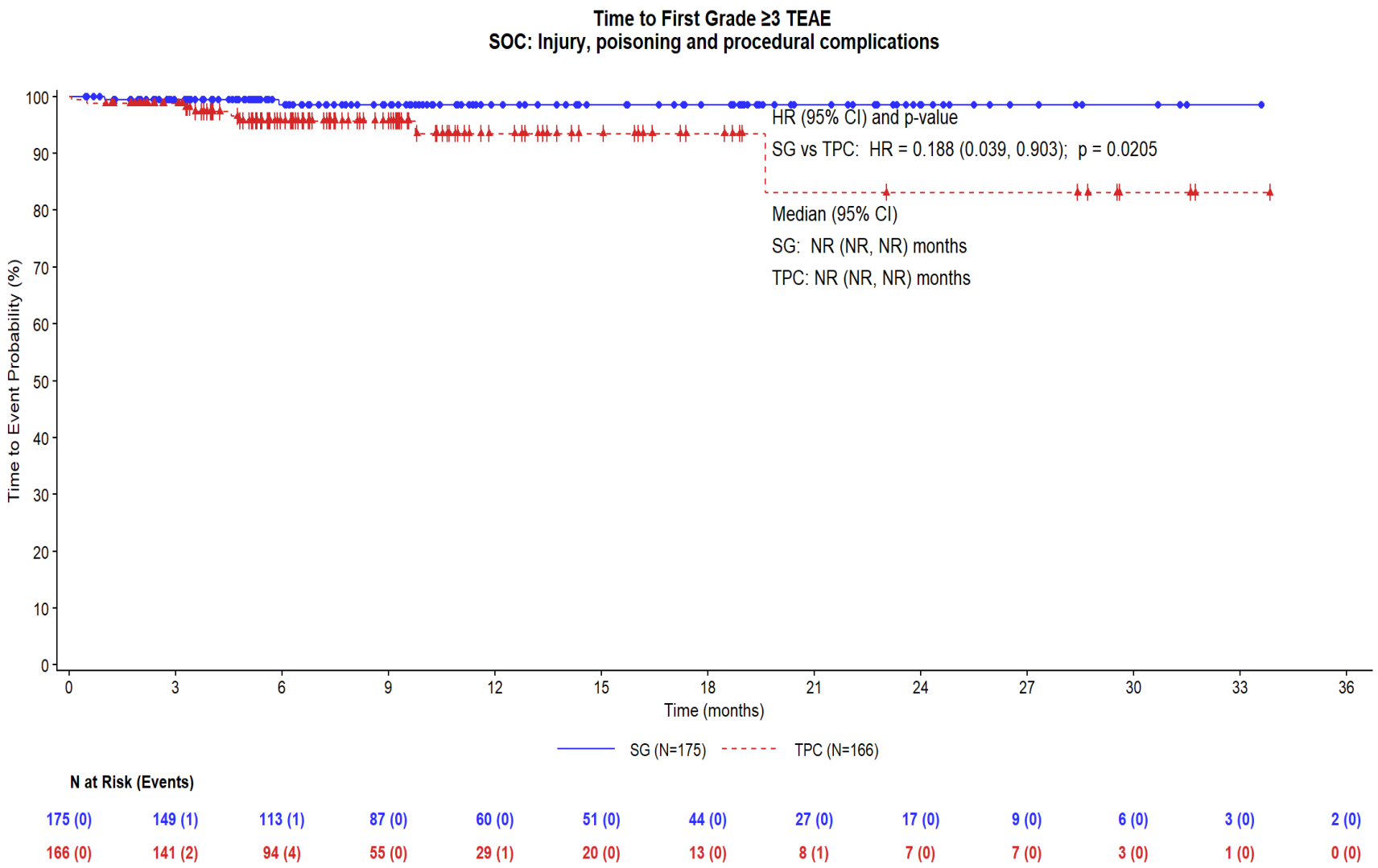
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.137. Figure 1.1.136: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel



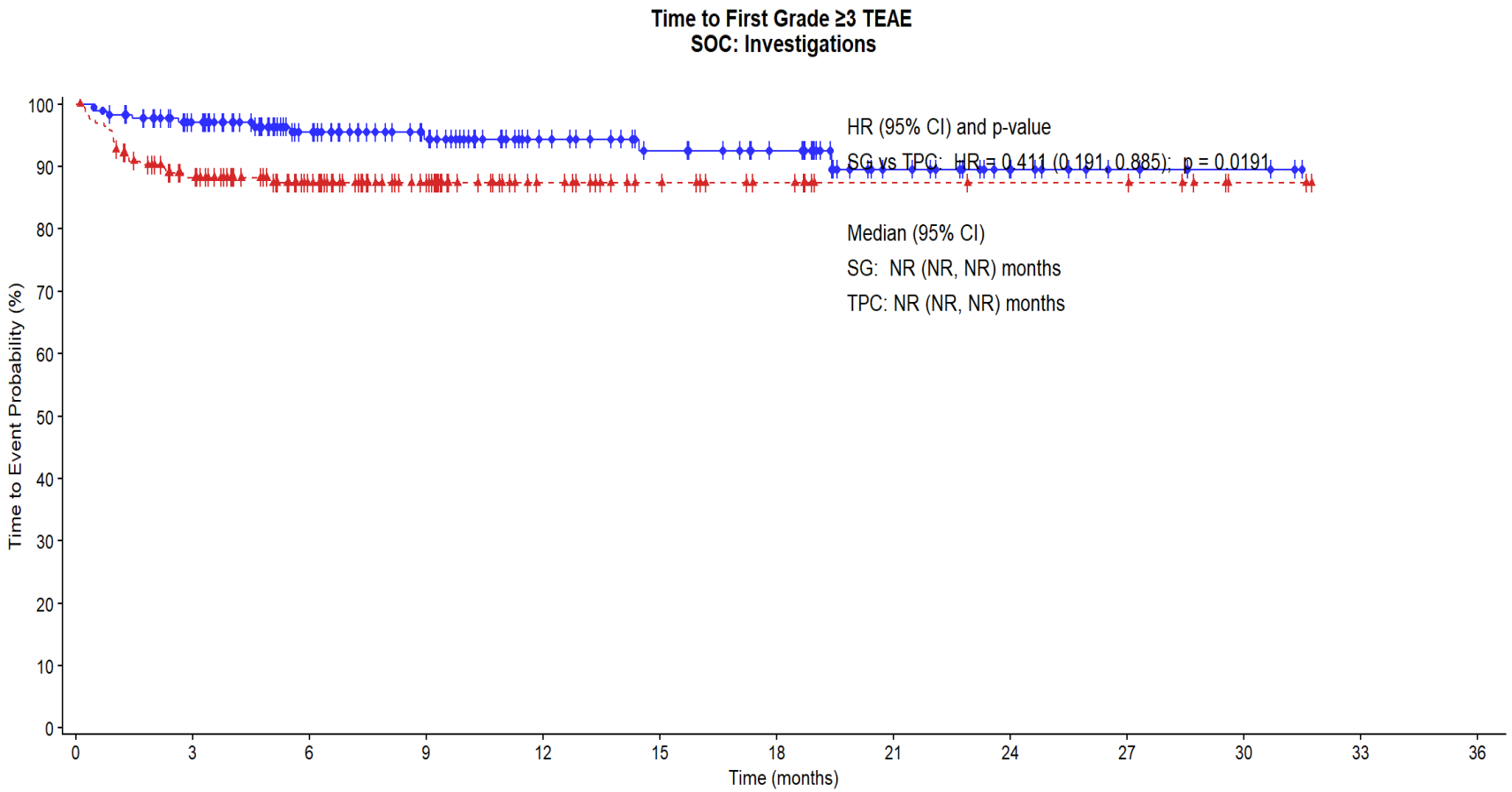
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.138. Figure 1.1.137: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel



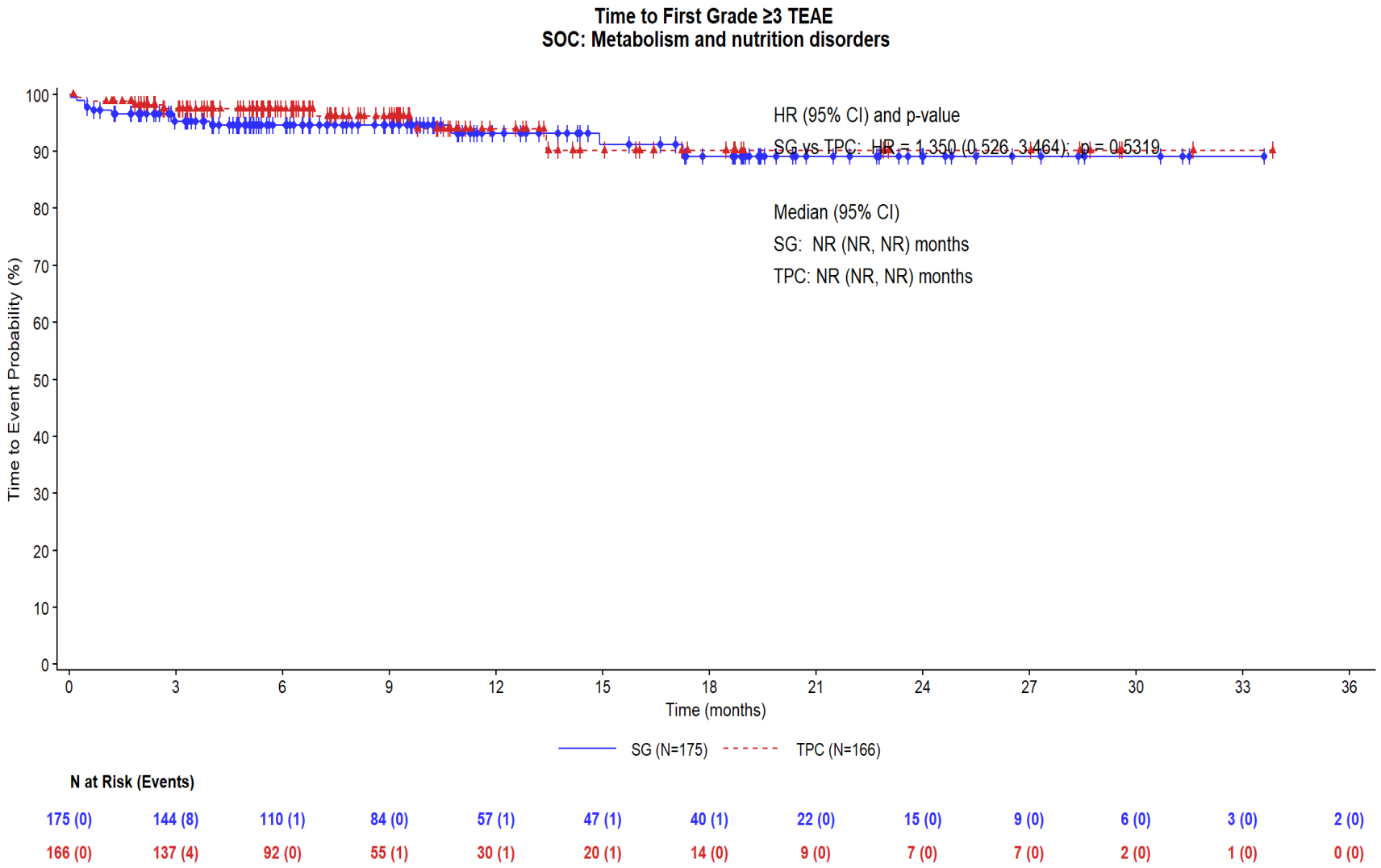
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.139. Figure 1.1.138: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel



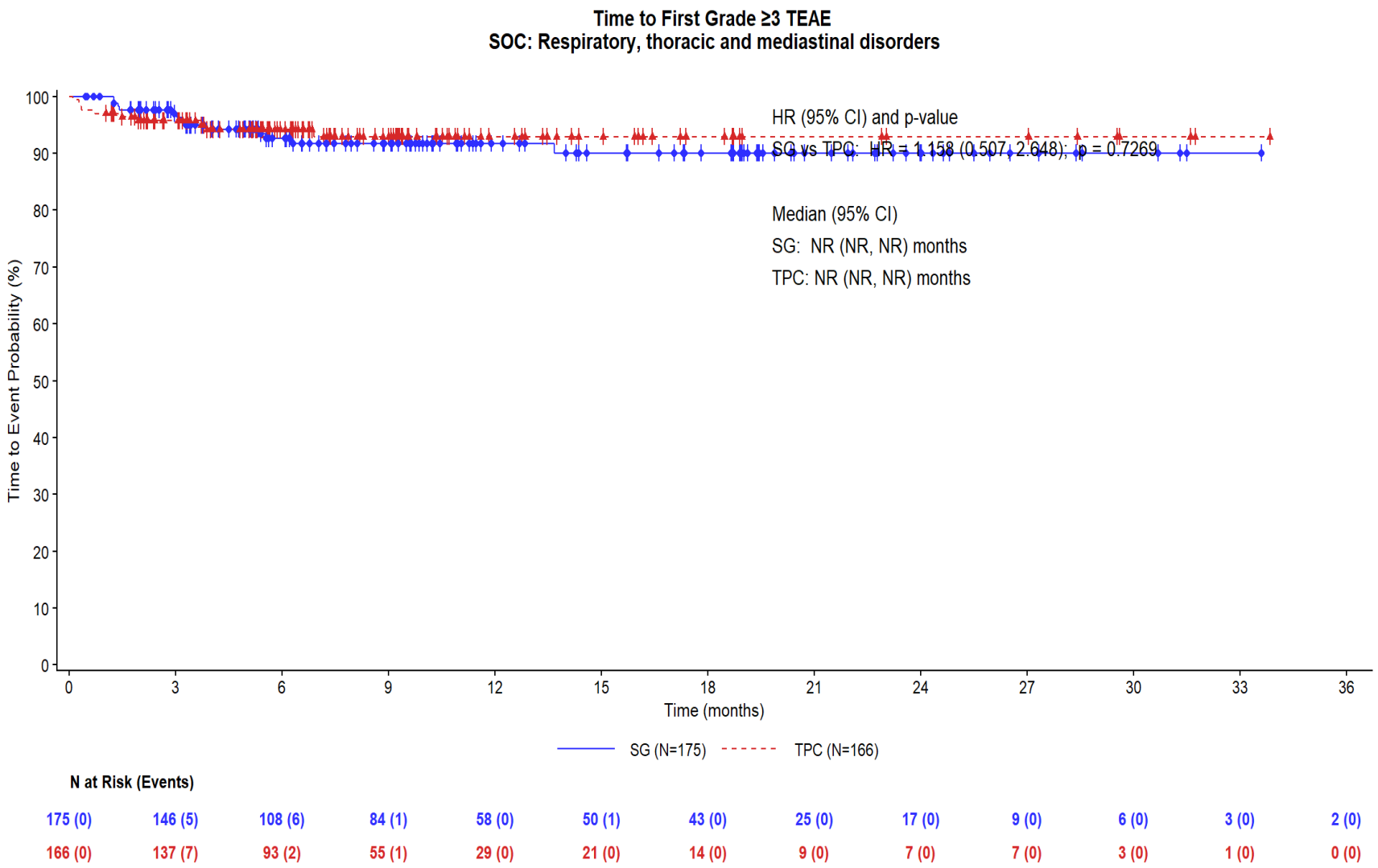
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.140. Figure 1.1.139: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



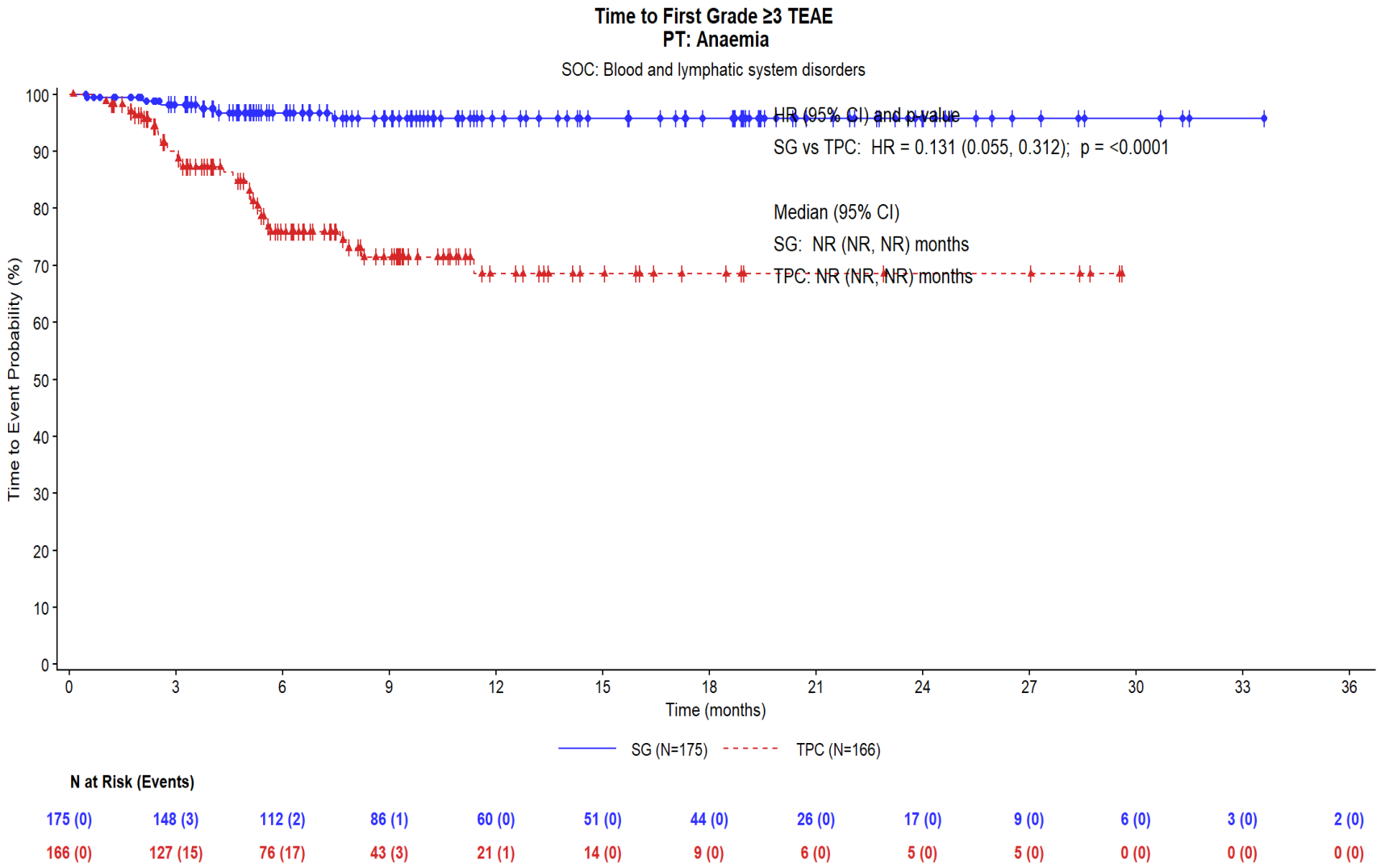
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.141. Figure 1.1.140: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



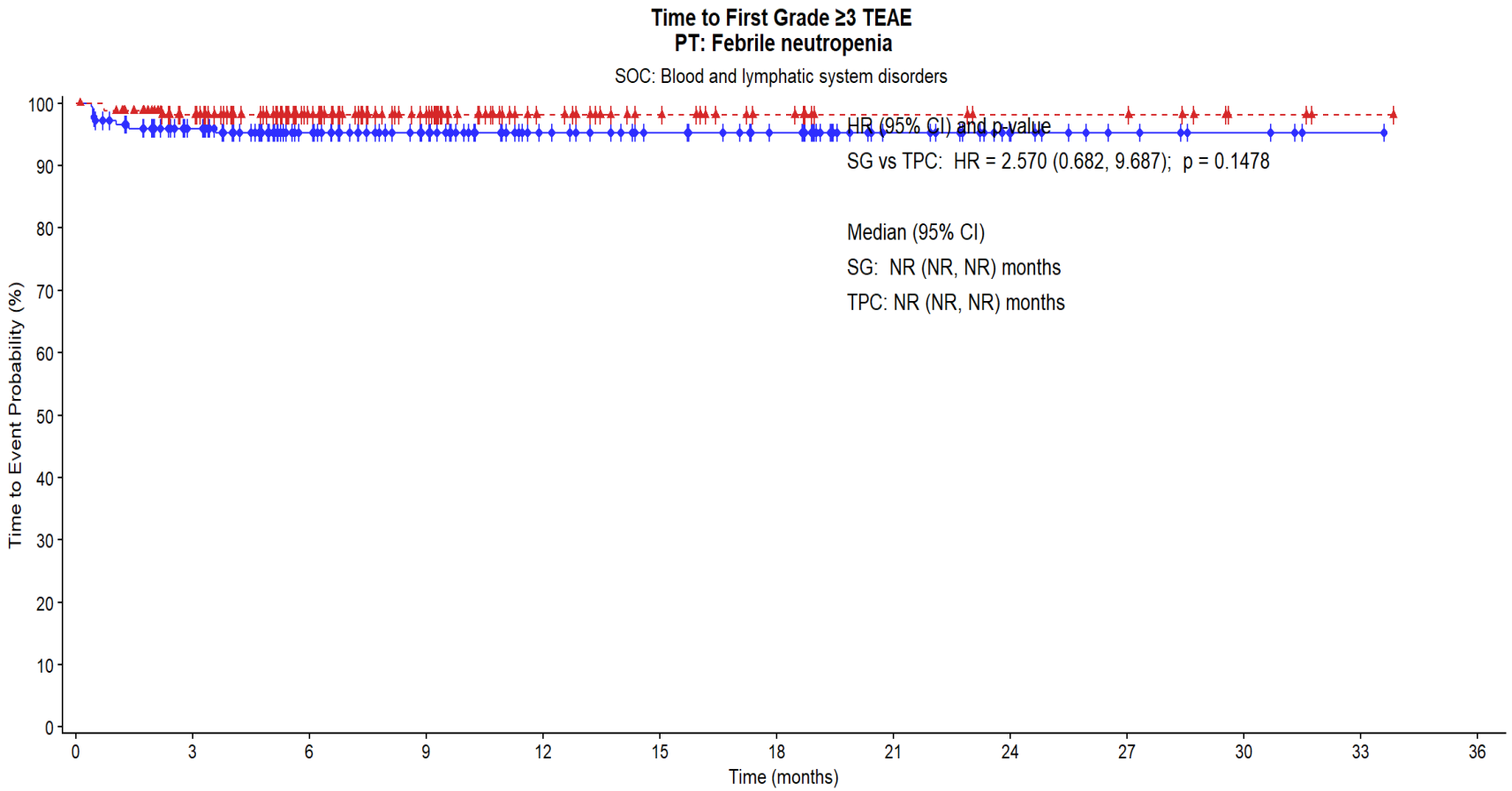
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.142. Figure 1.1.141: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



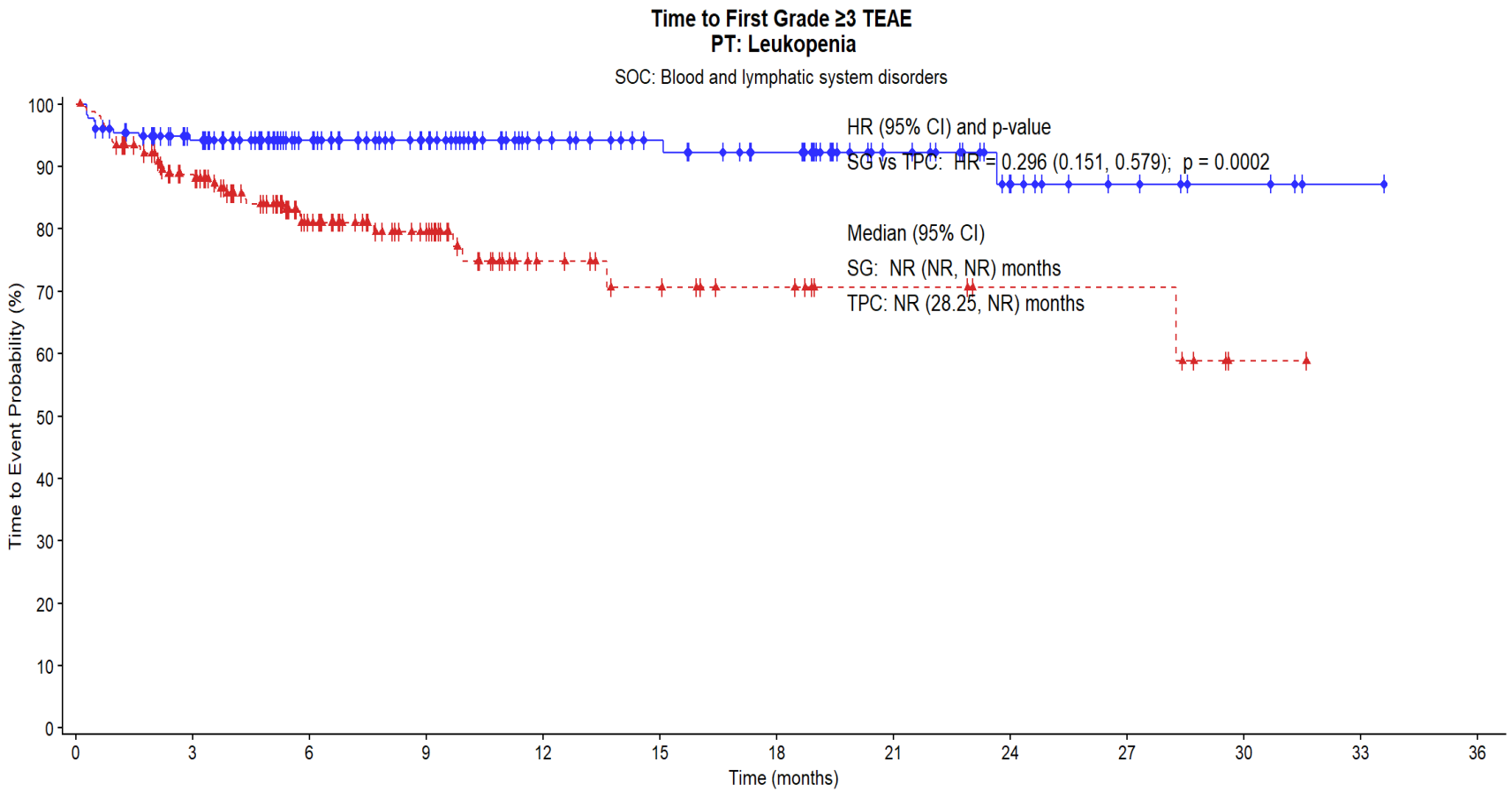
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.143. Figure 1.1.142: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Febrile neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



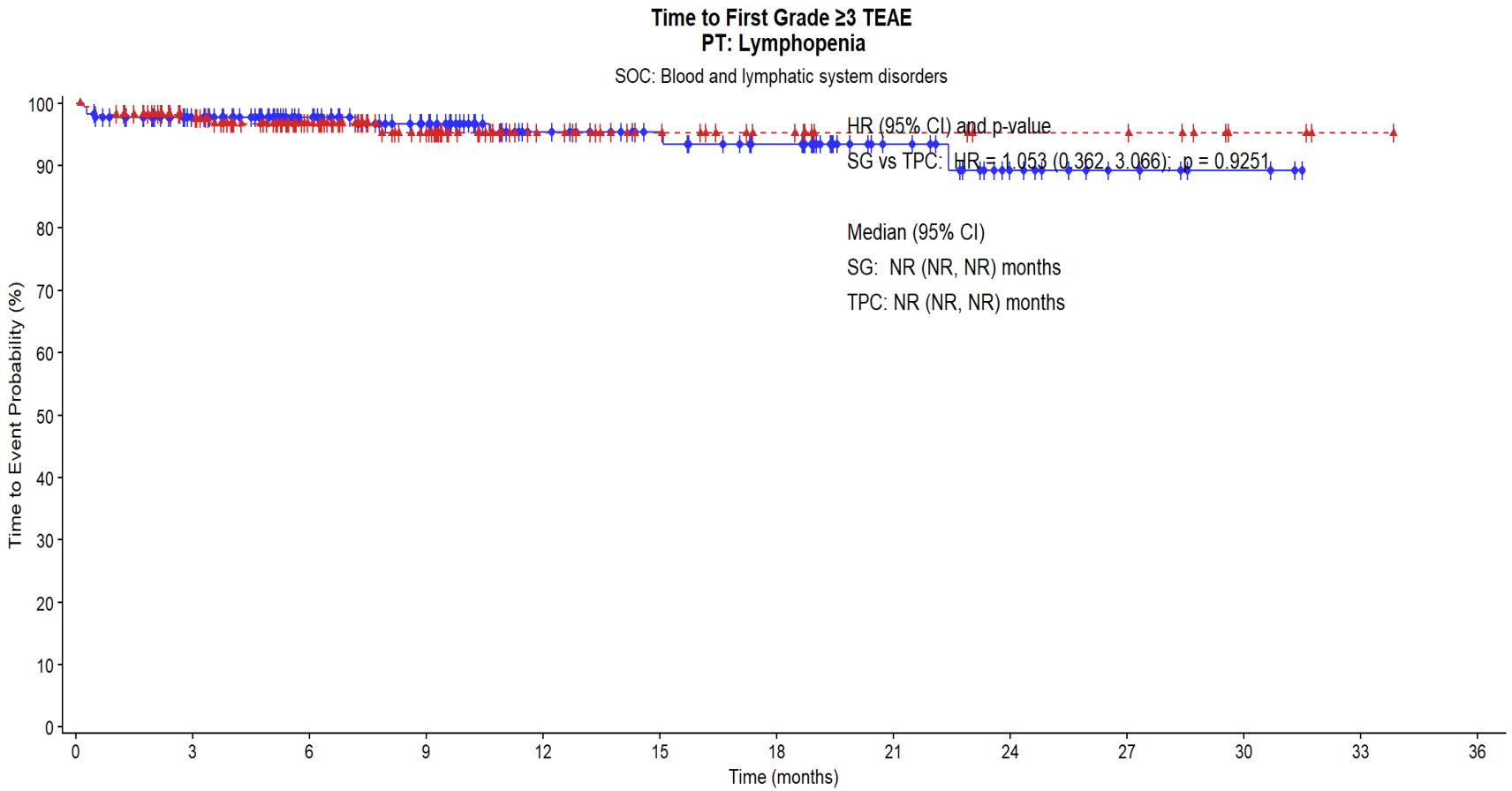
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.144. Figure 1.1.143: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



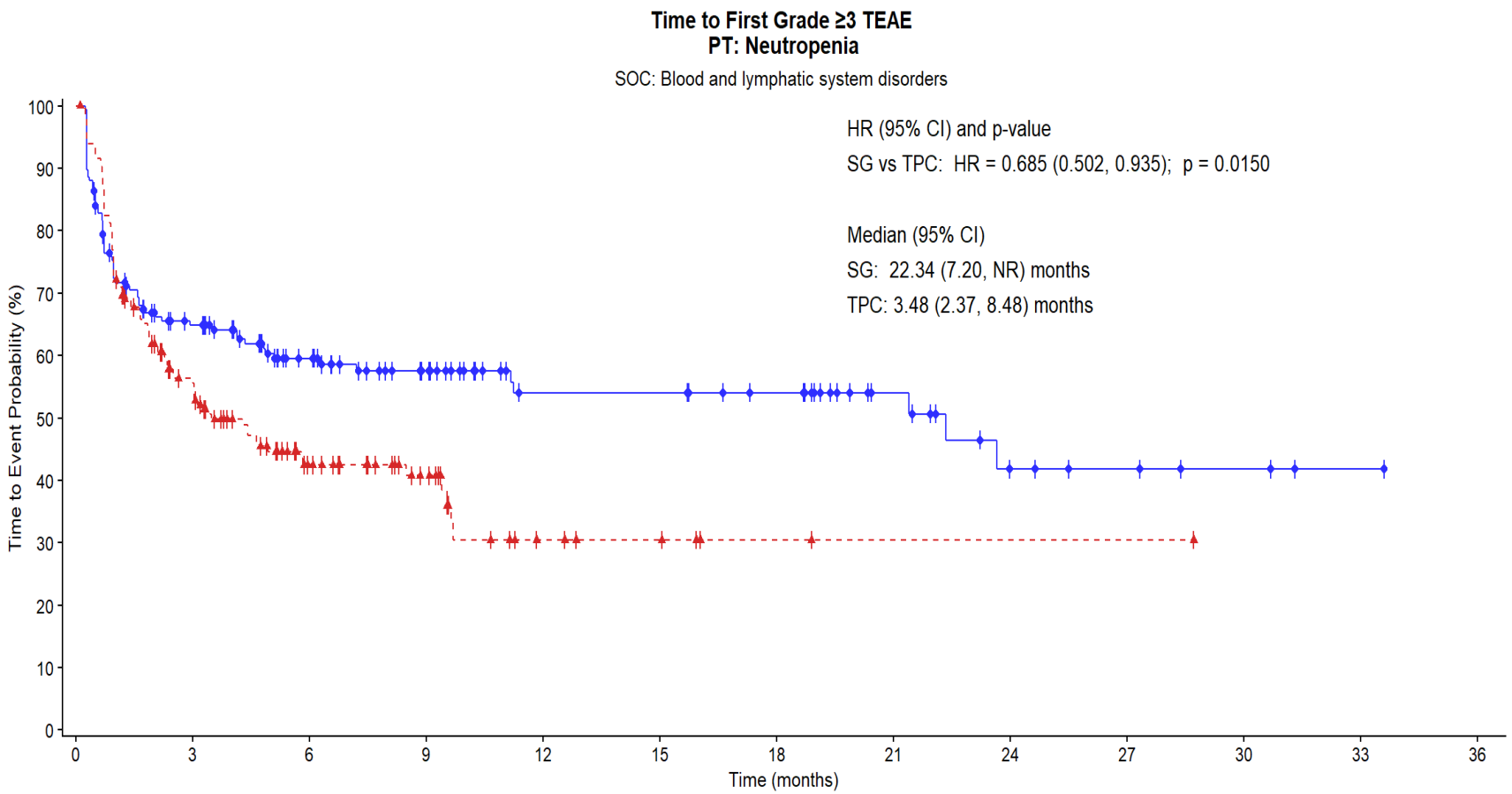
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8.145. Figure 1.1.144: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



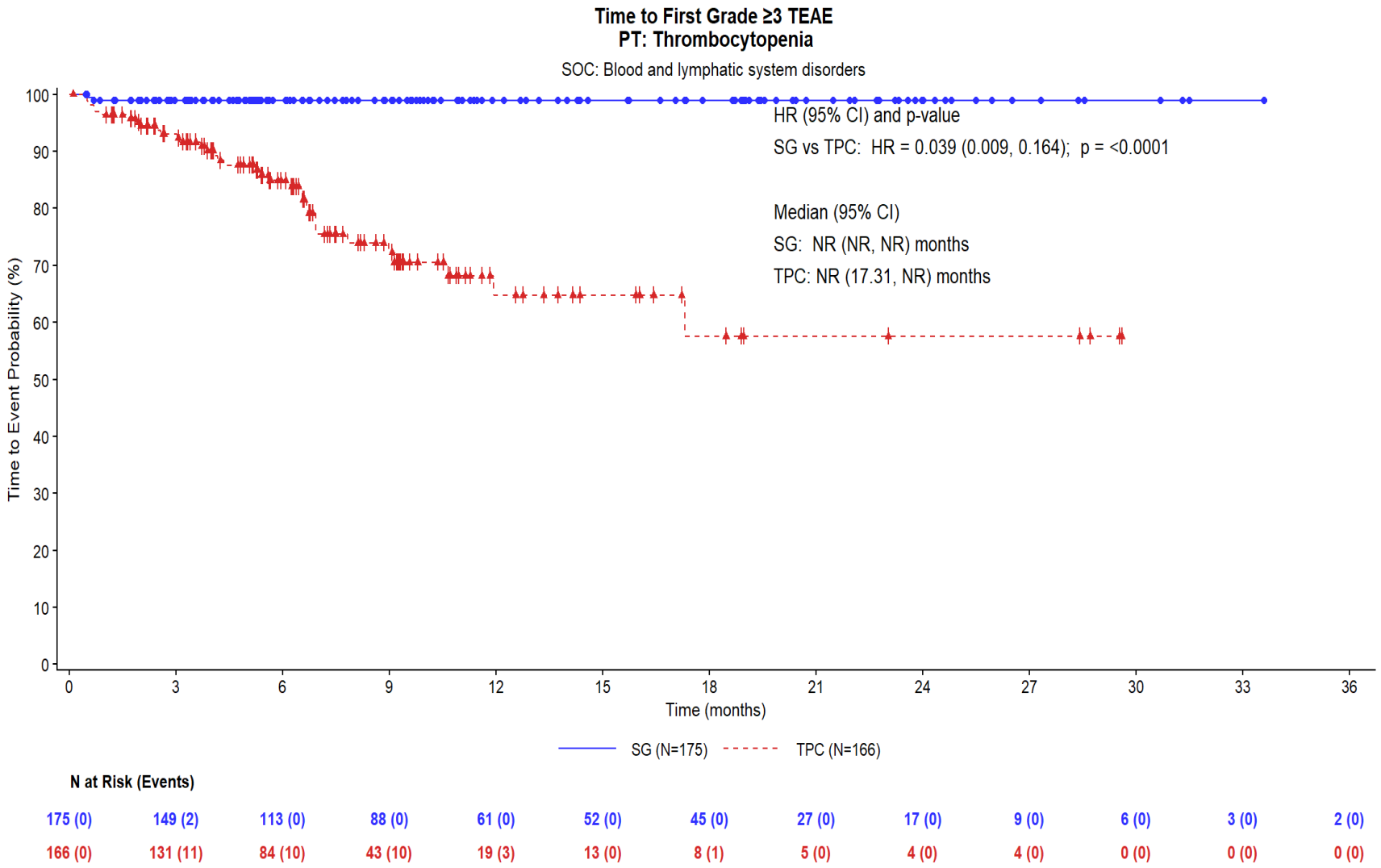
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.146. Figure 1.1.145: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



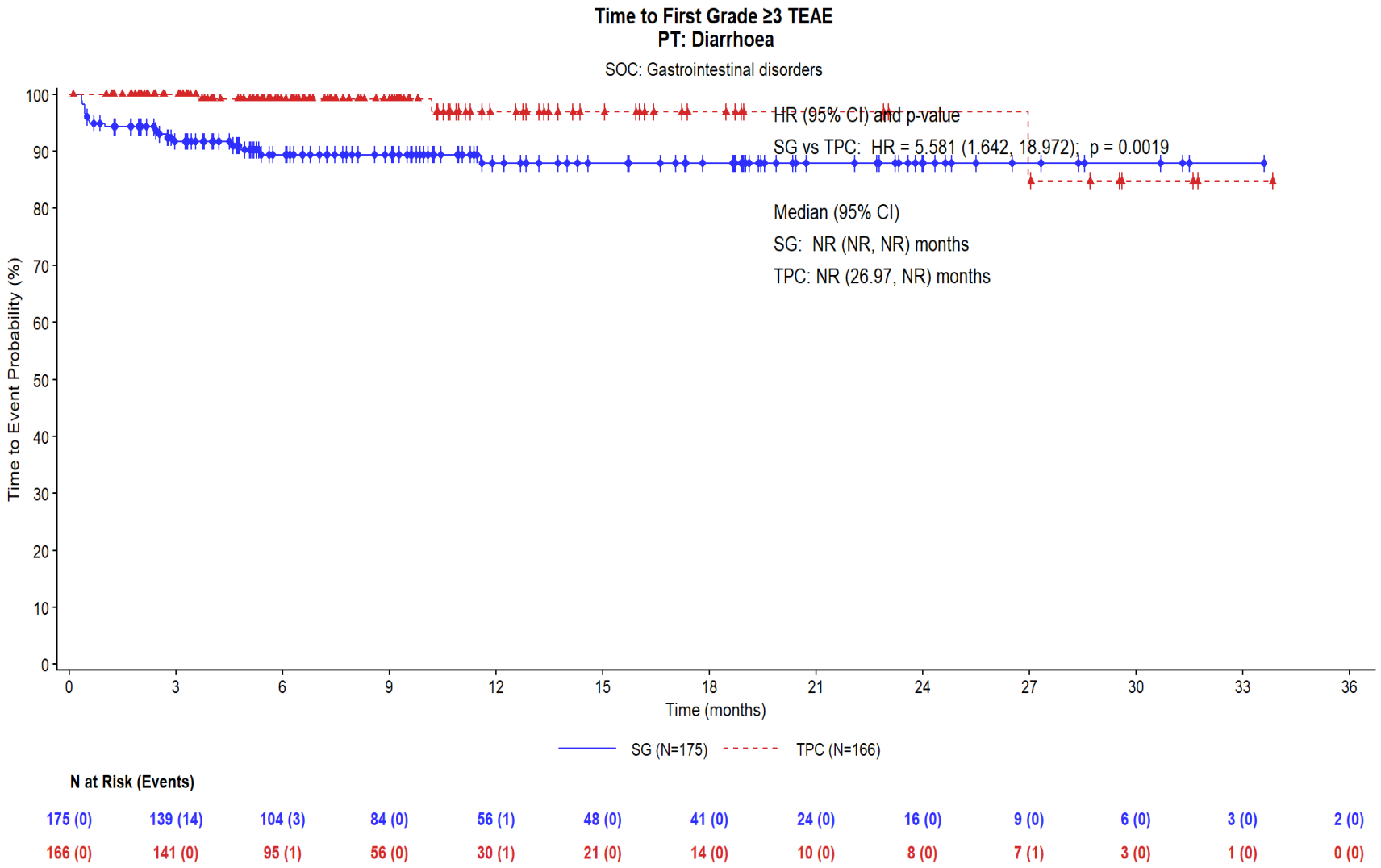
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8.147. Figure 1.1.146: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



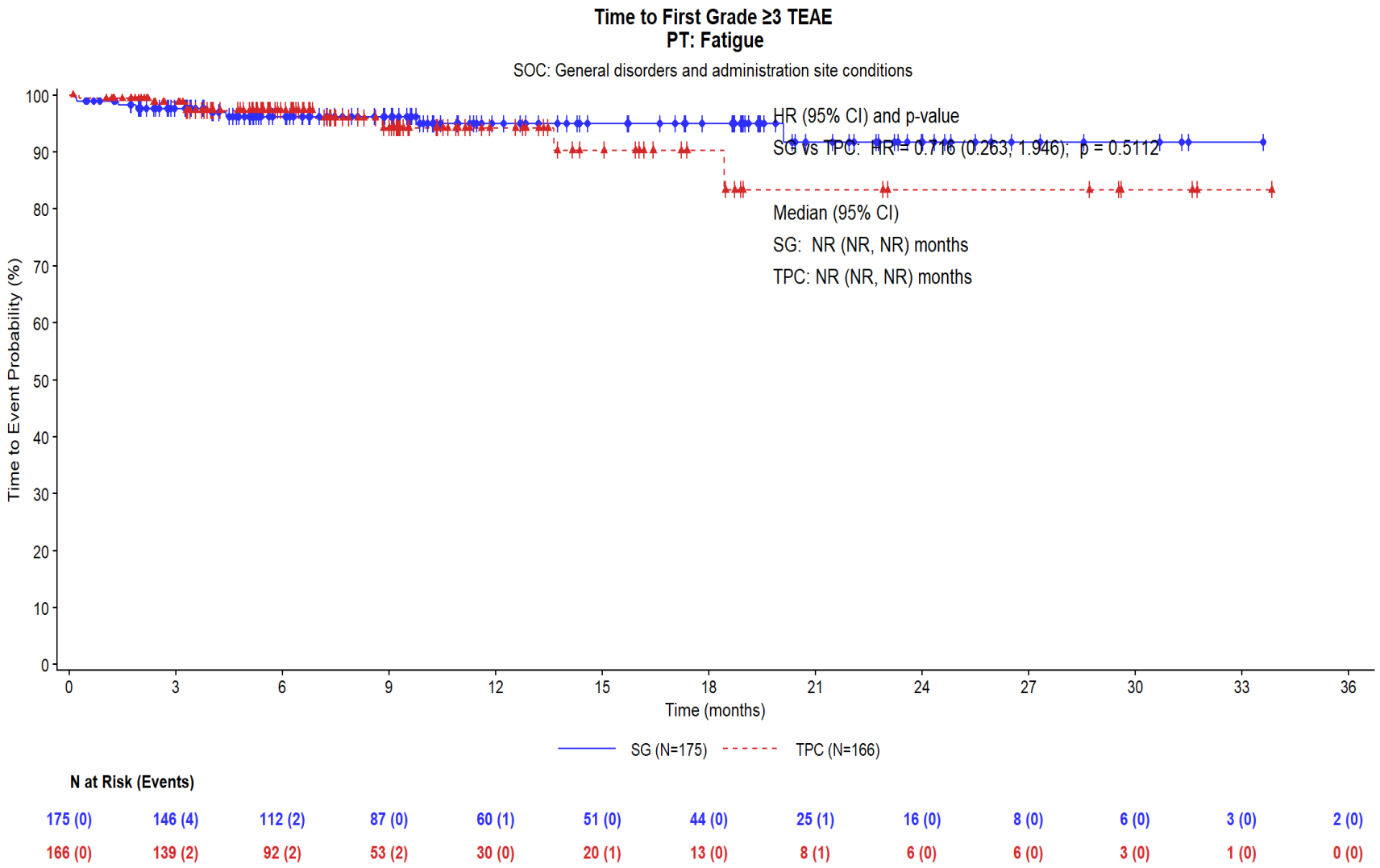
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8.148. Figure 1.1.147: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



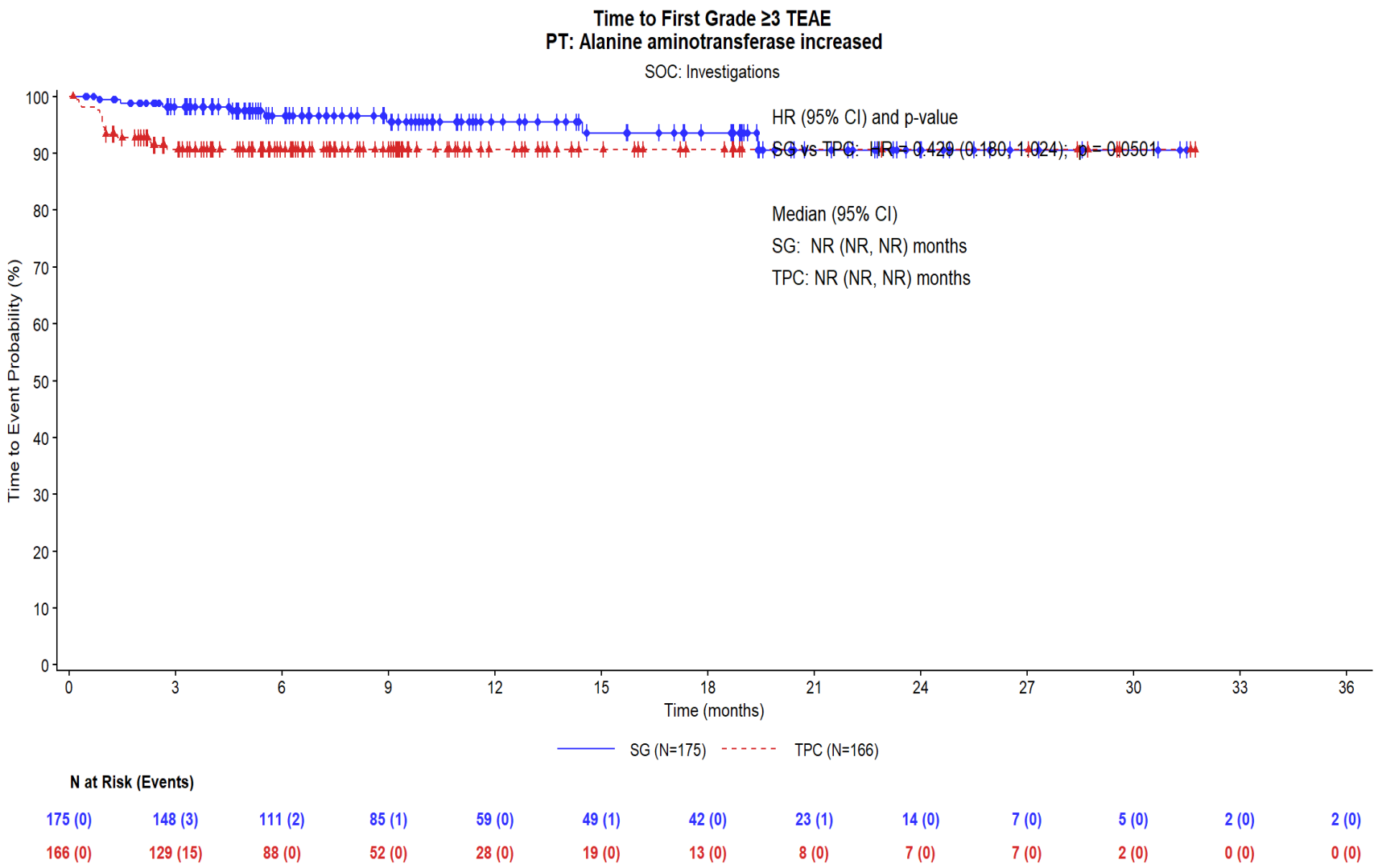
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8.149. Figure 1.1.148: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel



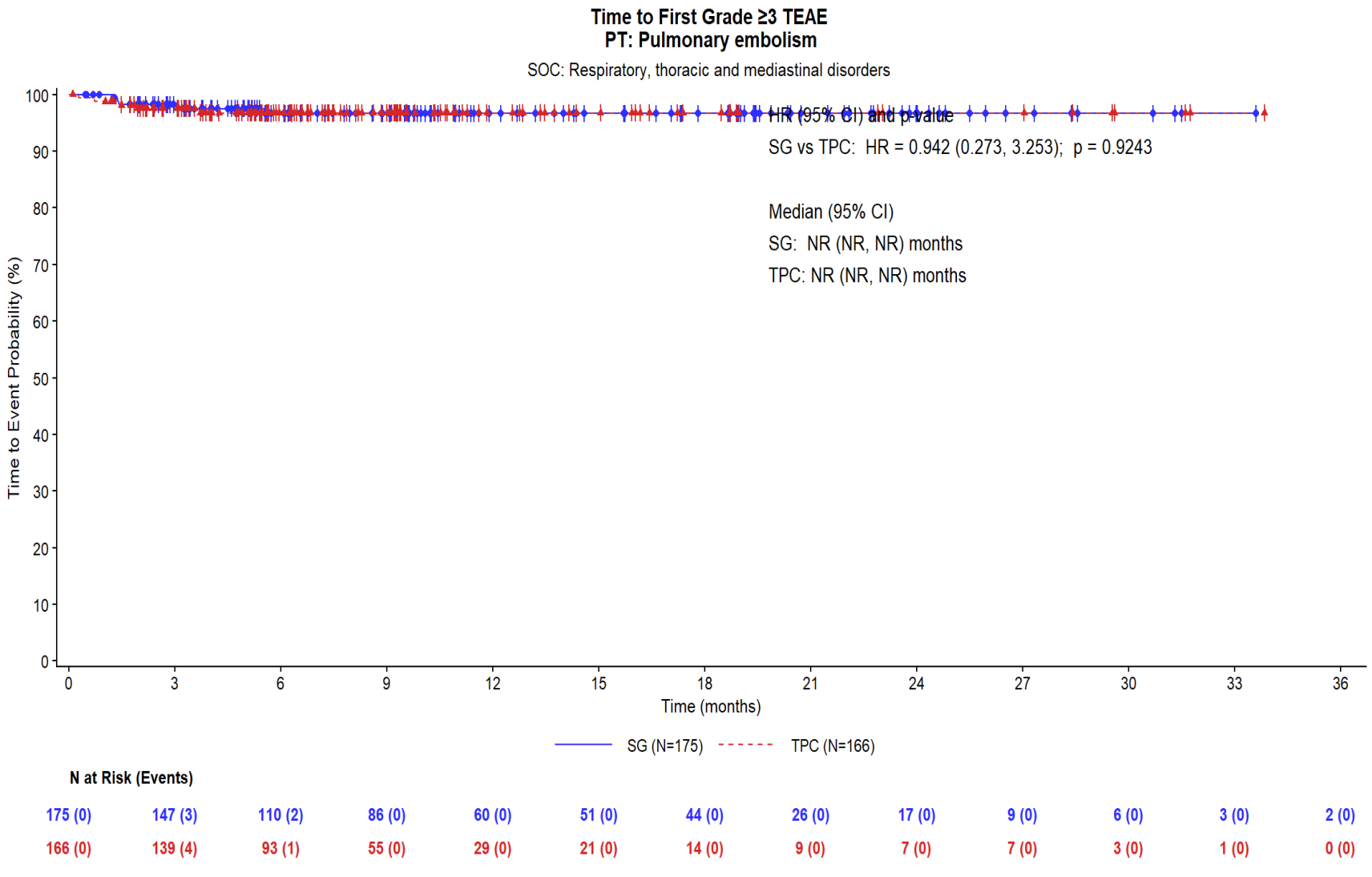
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.150. Figure 1.1.149: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



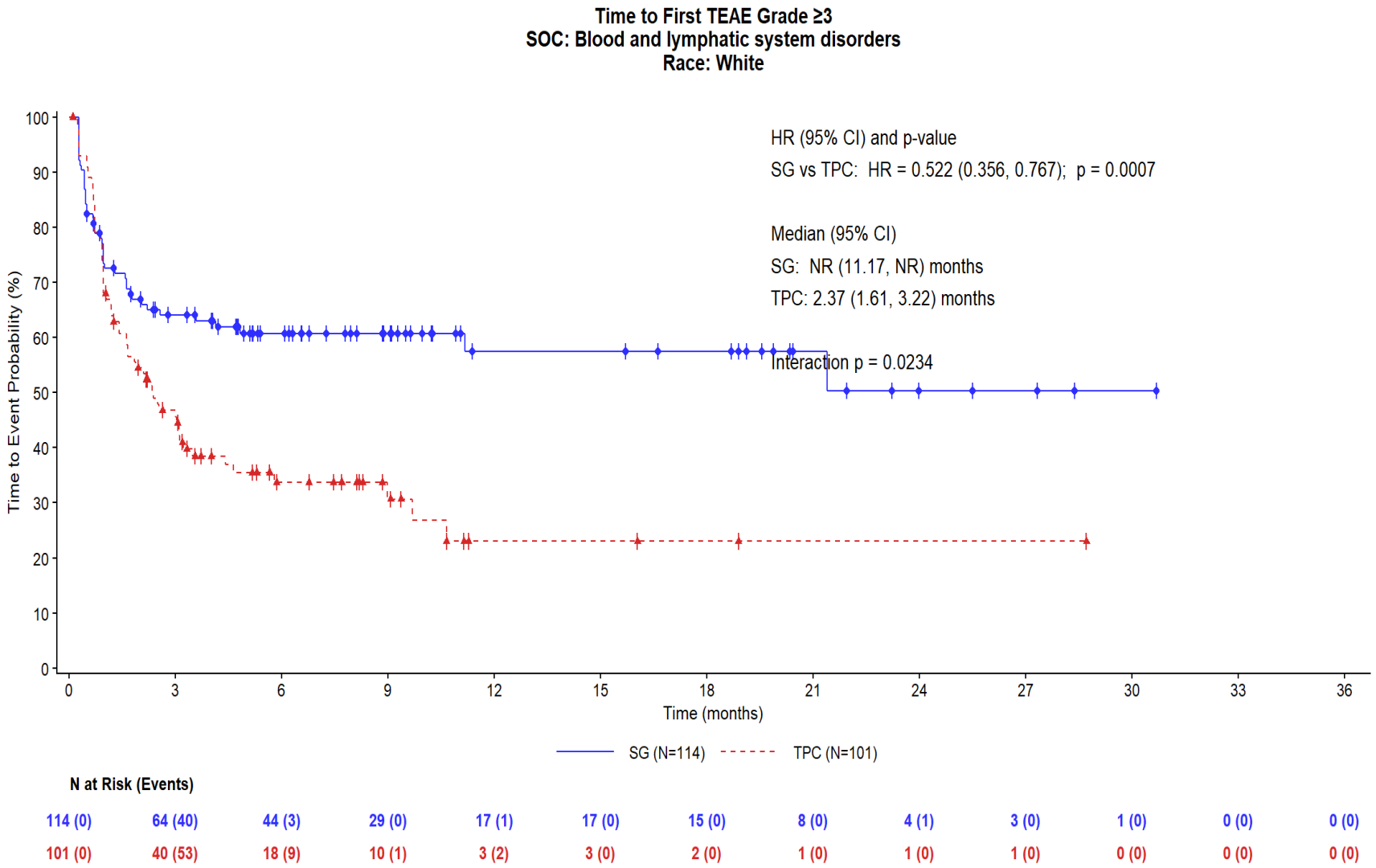
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.151. Figure 1.1.150: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Pulmonary embolism — mSAF — Excluding patients preselected to receive nab-paclitaxel



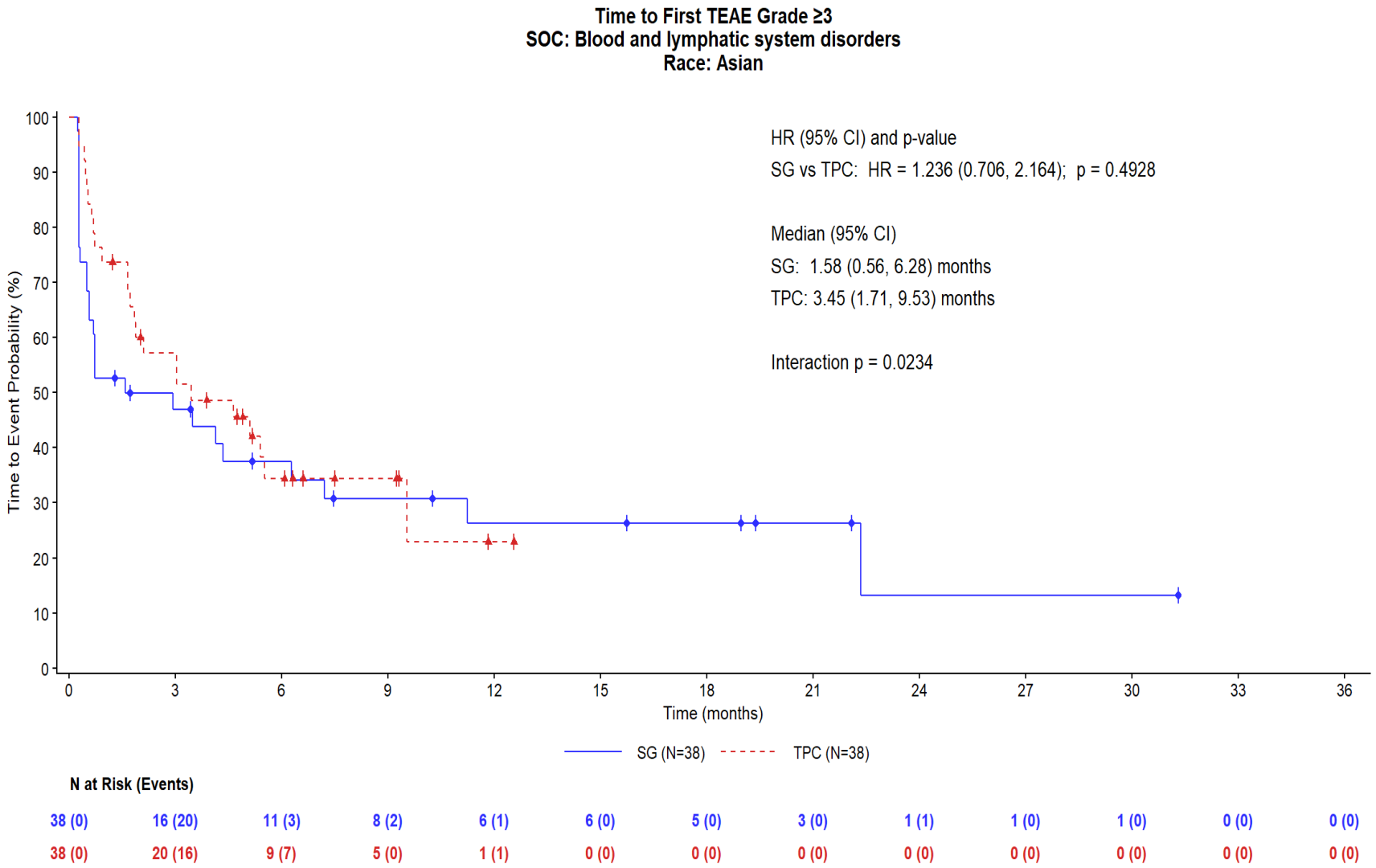
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.152. Figure 1.1.151: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel



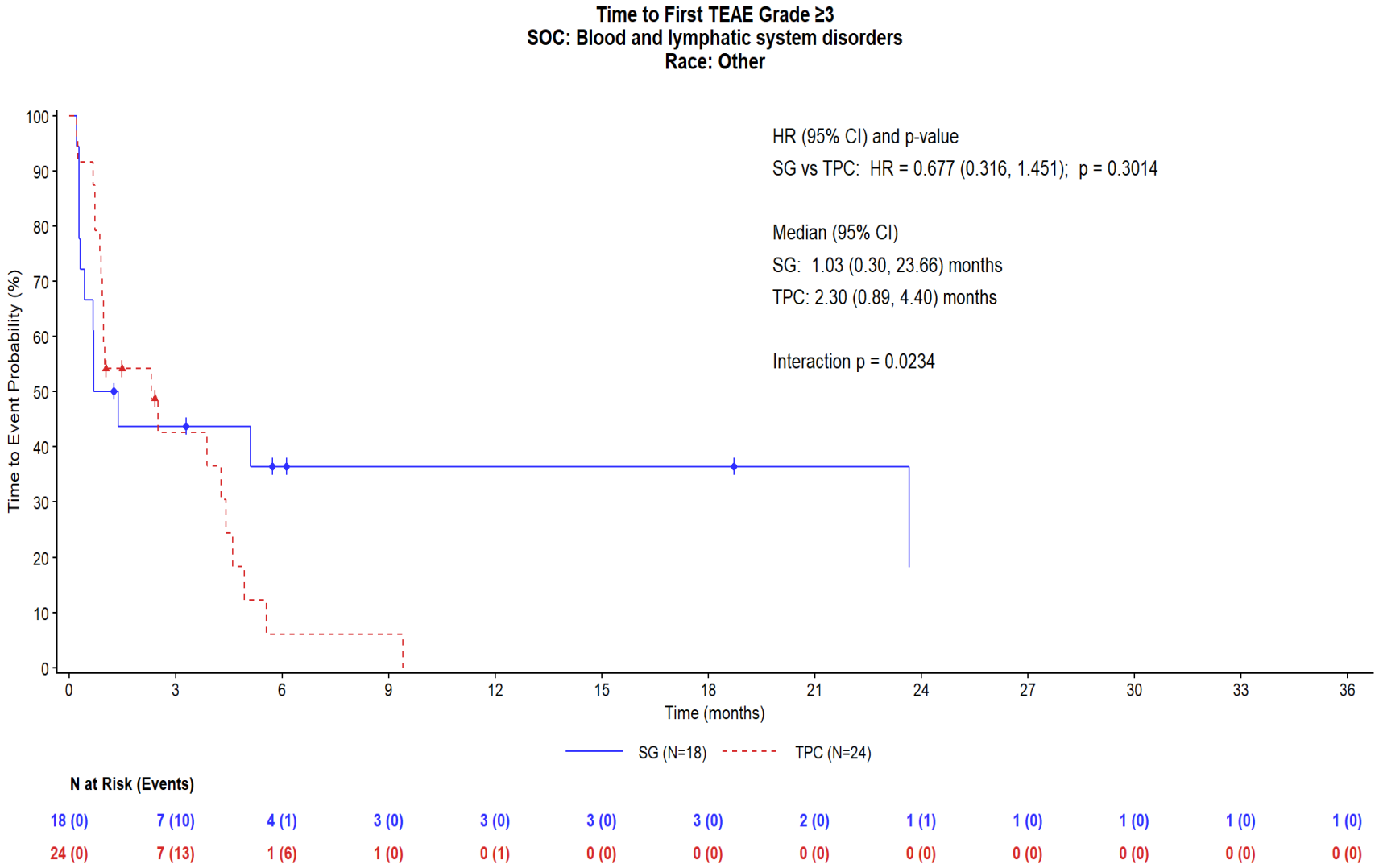
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.153. Figure 1.1.152: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Race Asian — mSAF — Excluding patients preselected to receive nab-paclitaxel



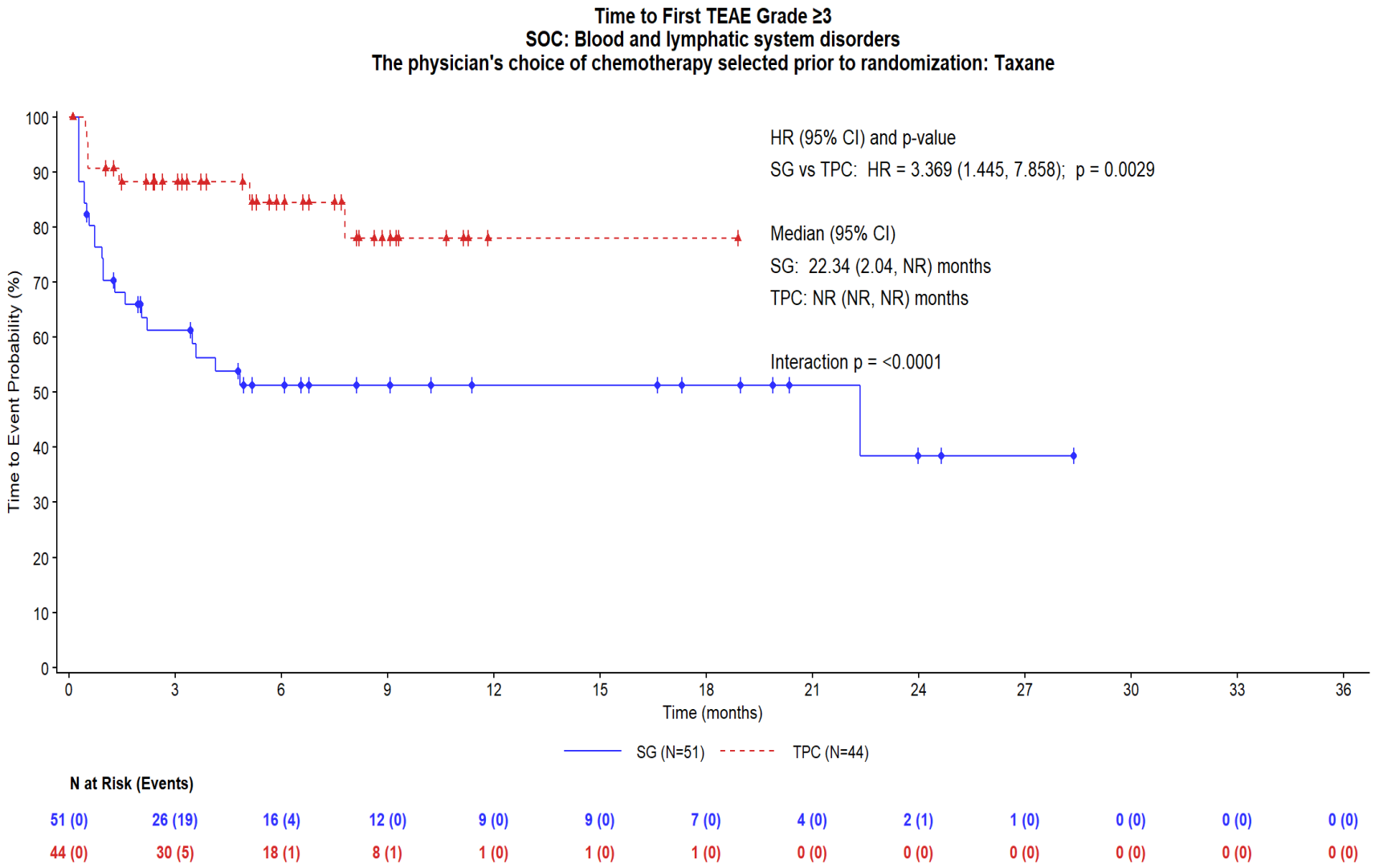
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.154. Figure 1.1.153: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel



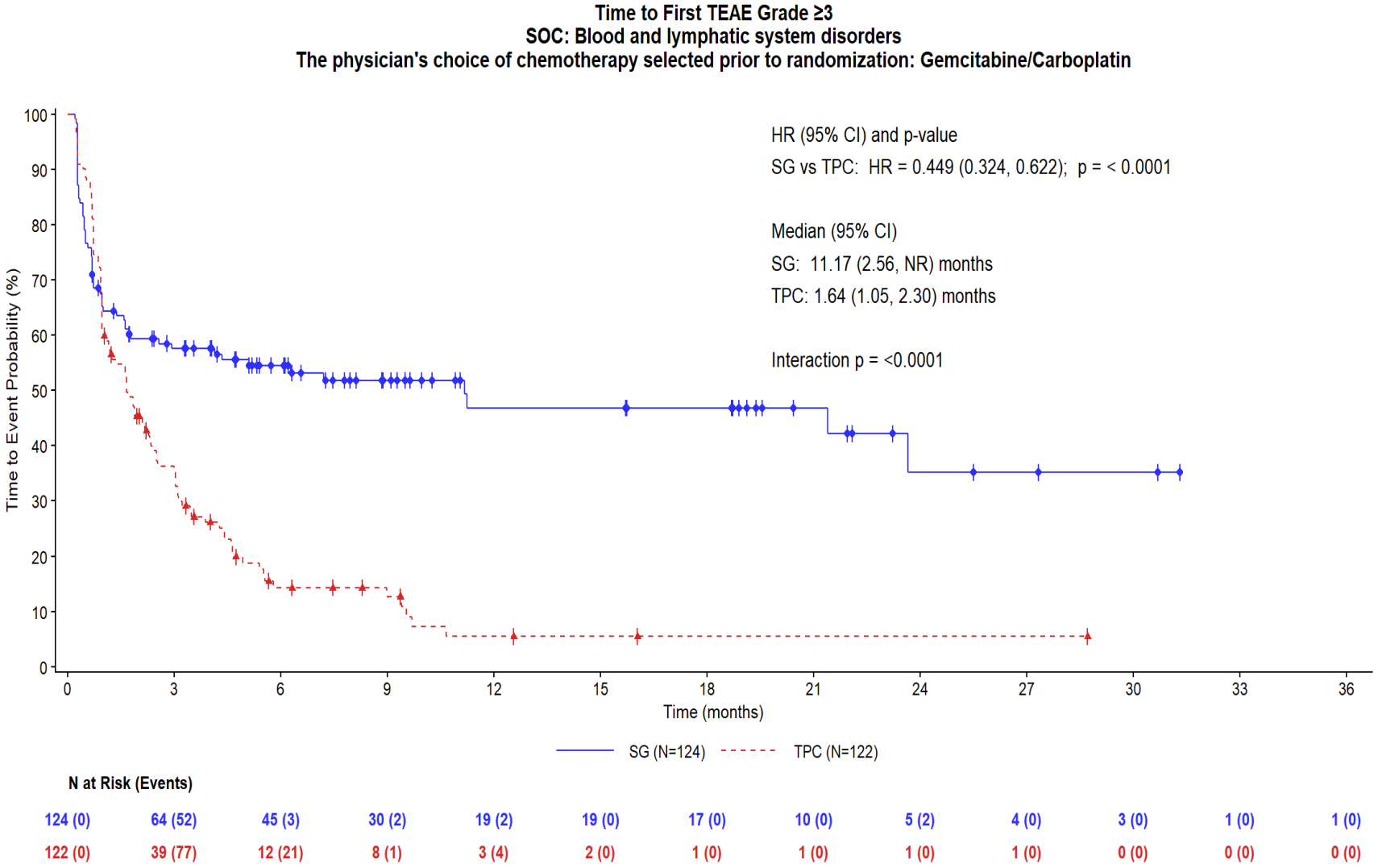
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.155. Figure 1.1.154: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Physician s chemotherapy choice Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



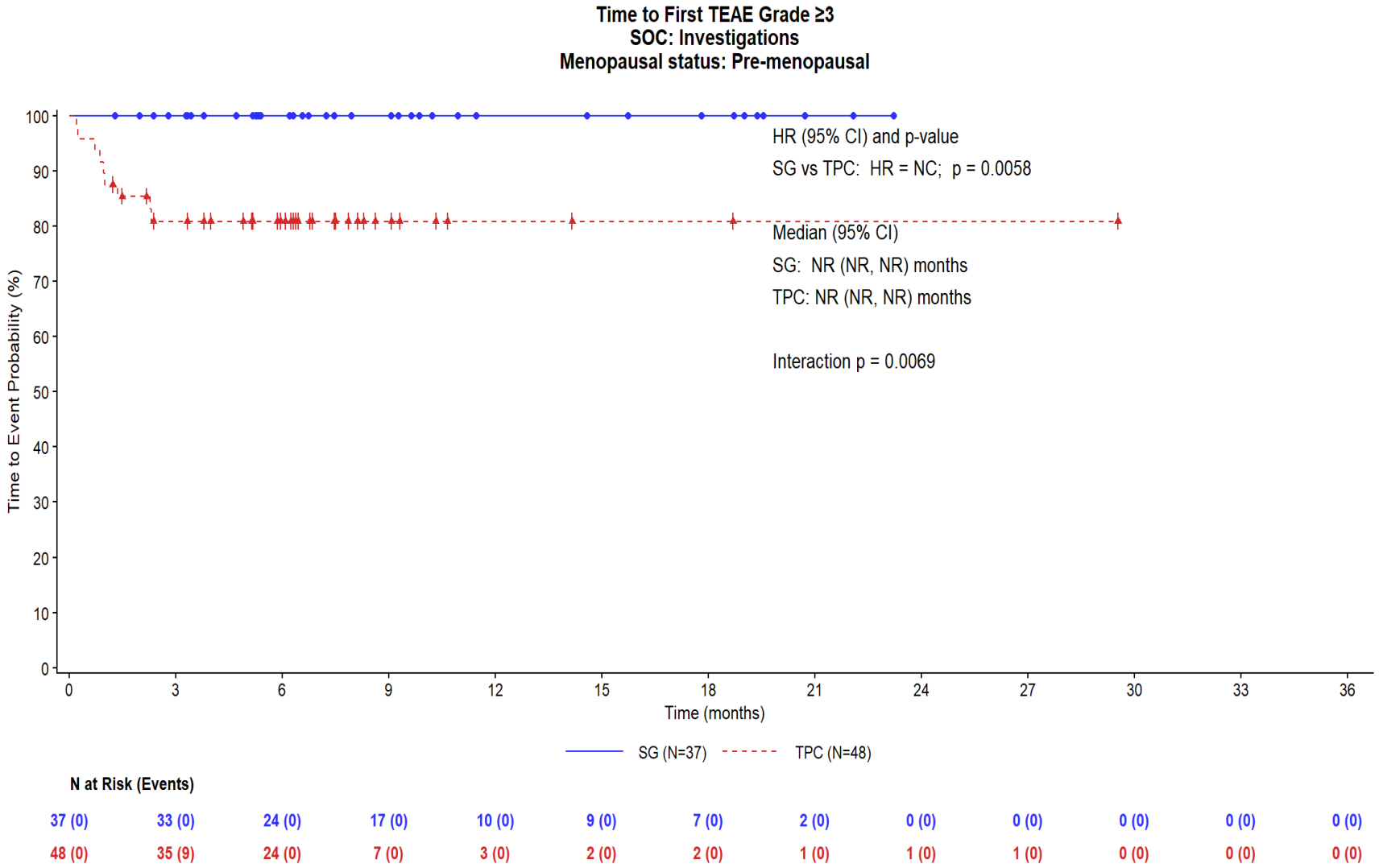
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.156. Figure 1.1.155: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Physician s chemotherapy choice Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



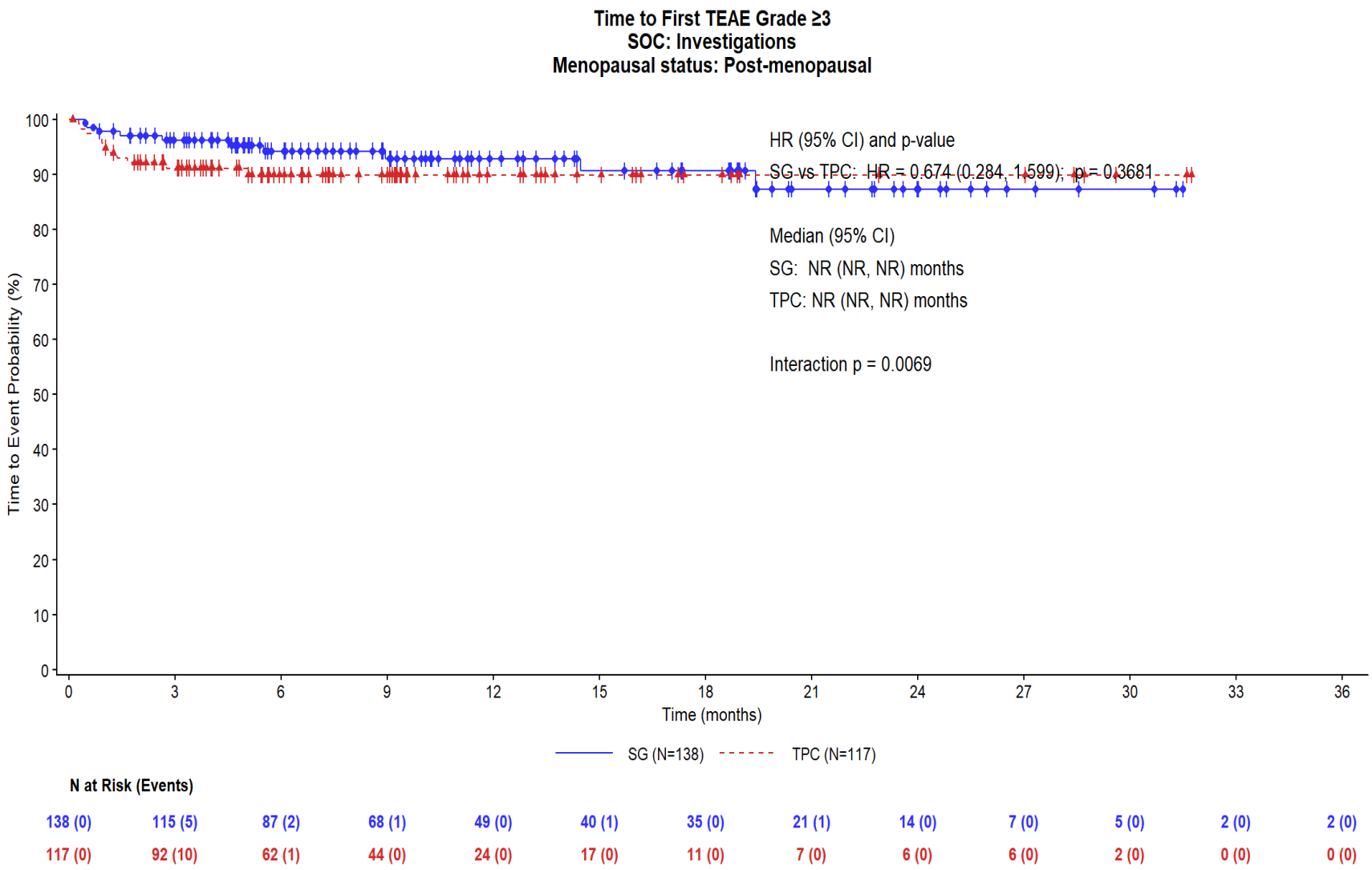
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8.157. Figure 1.1.156: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Investigations Menopausal status Pre menopausal — mSAF — Excluding patients preselected to receive nab-paclitaxel



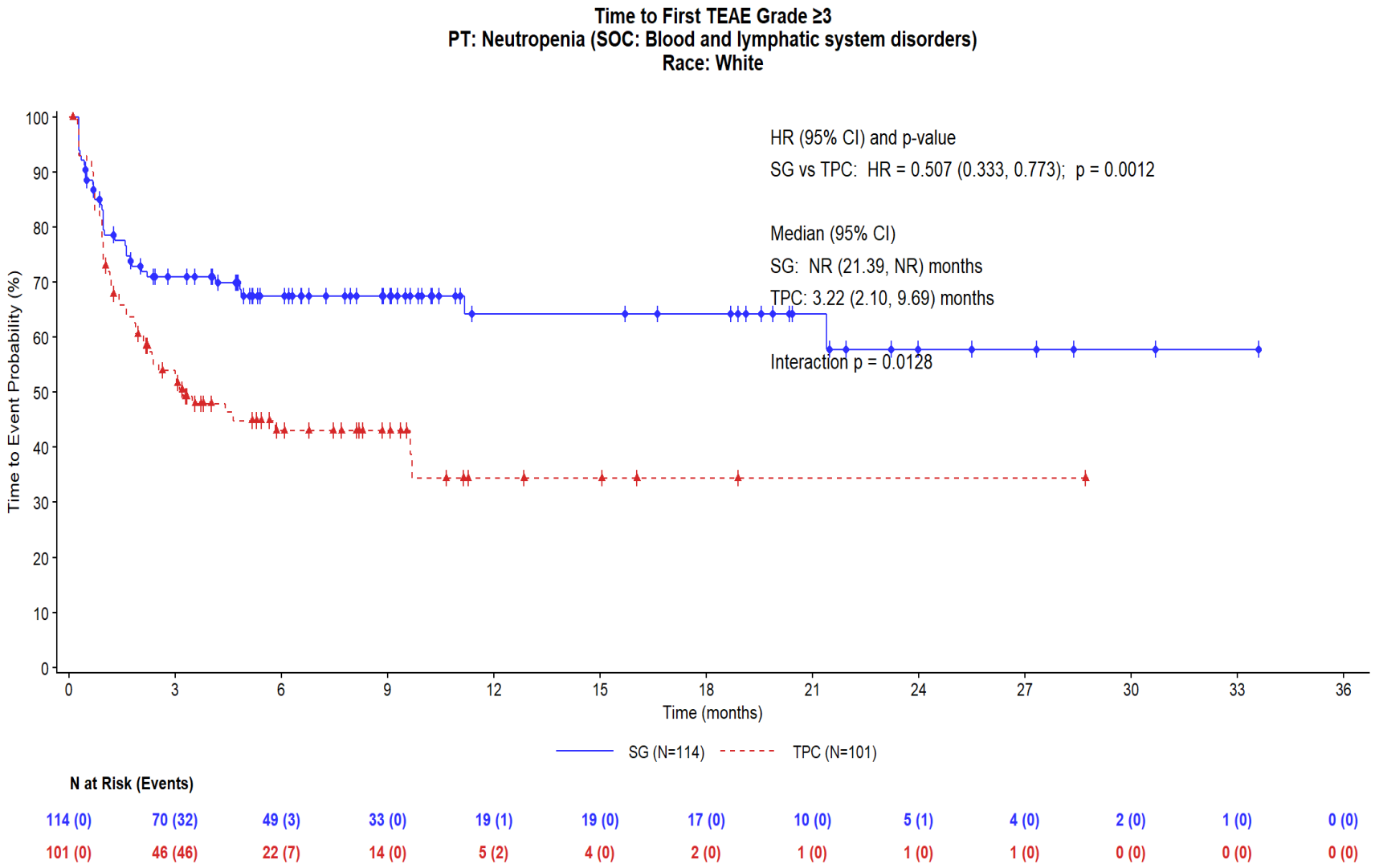
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.158. Figure 1.1.157: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Investigations Menopausal status Post menopausal — mSAF — Excluding patients preselected to receive nab-paclitaxel



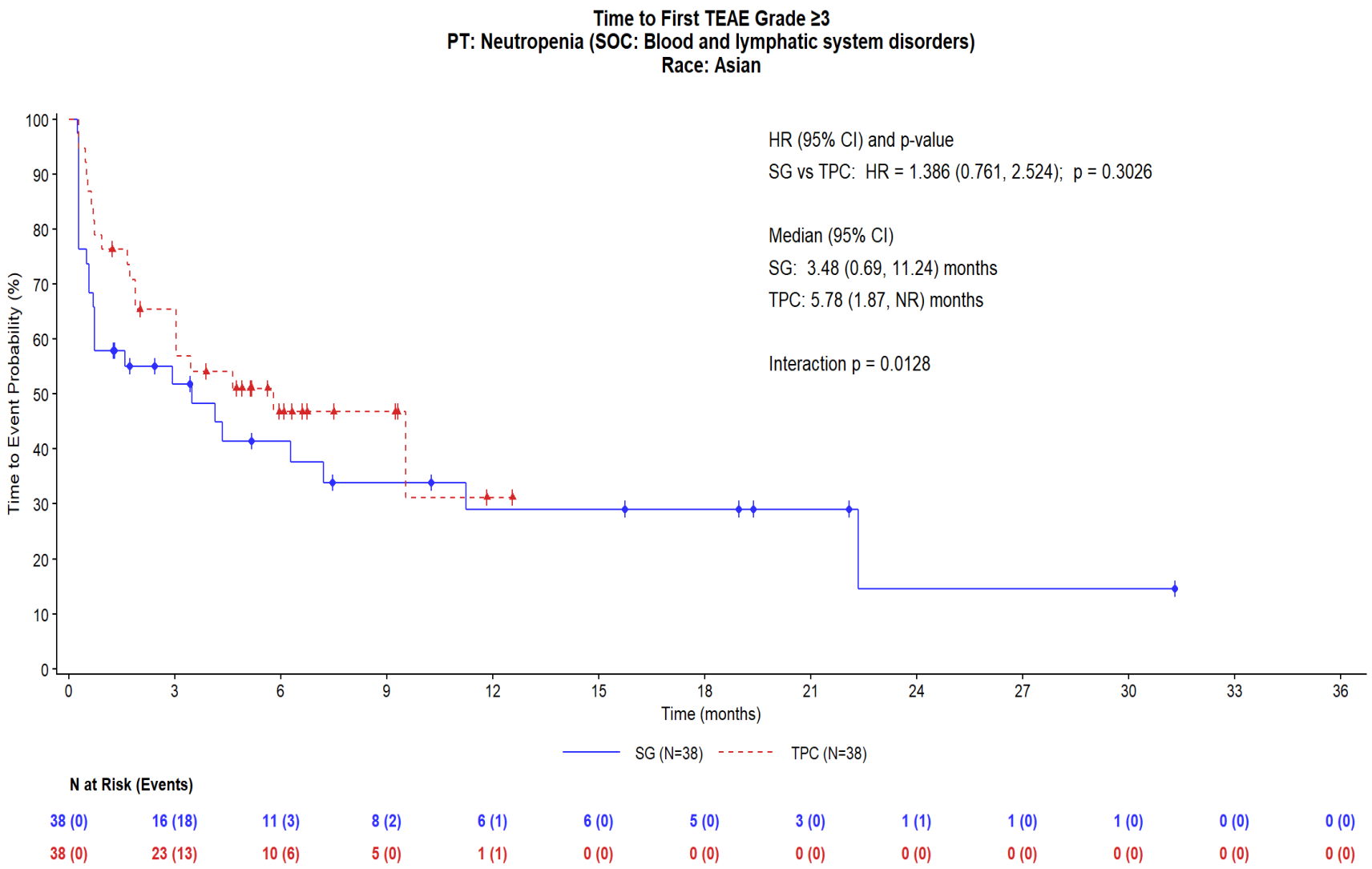
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8.159. Figure 1.1.158: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel



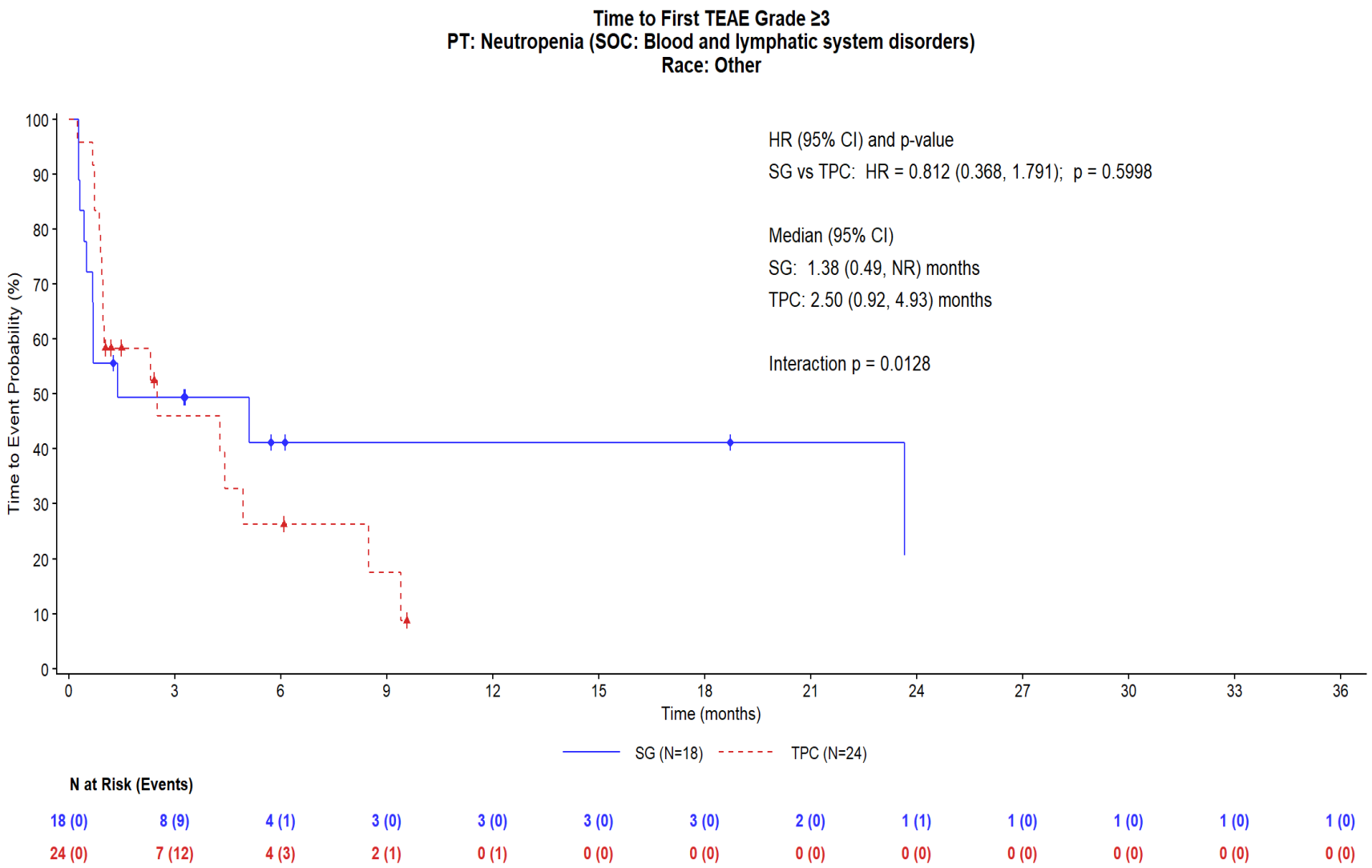
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.160. Figure 1.1.159: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Race Asian — mSAF — Excluding patients preselected to receive nab-paclitaxel



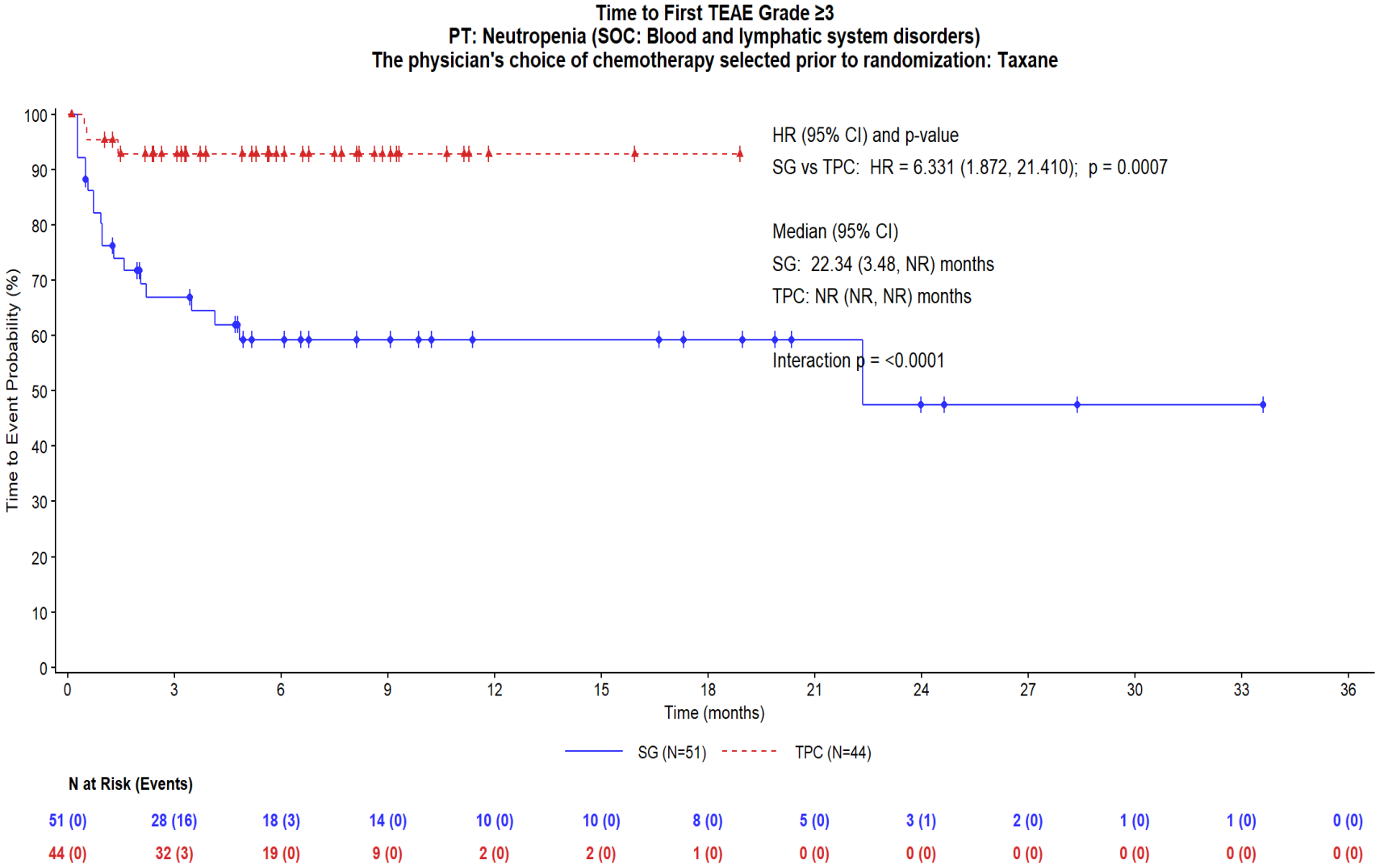
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.161. Figure 1.1.160: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel



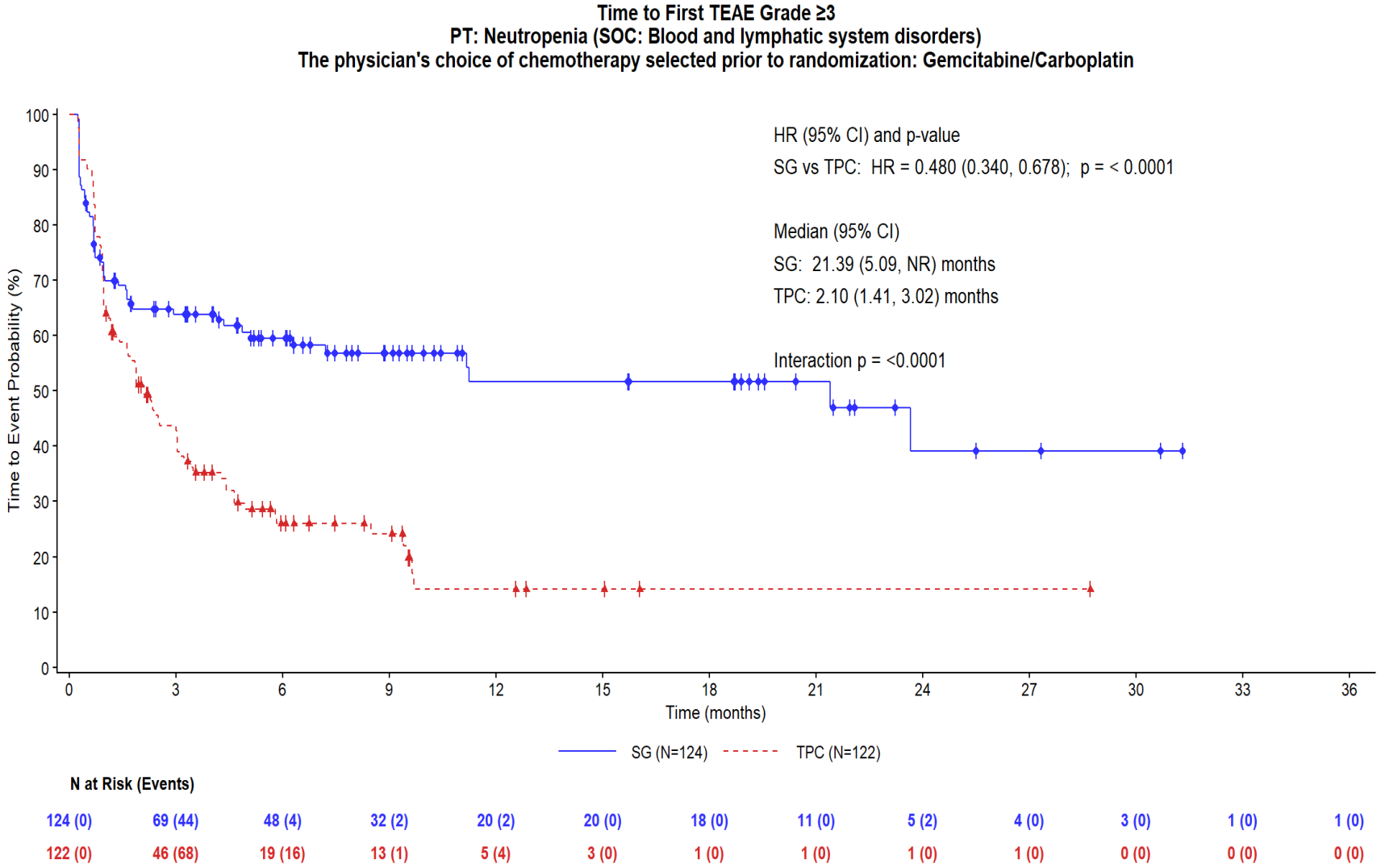
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.162. Figure 1.1.161: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Physician s chemotherapy choice Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



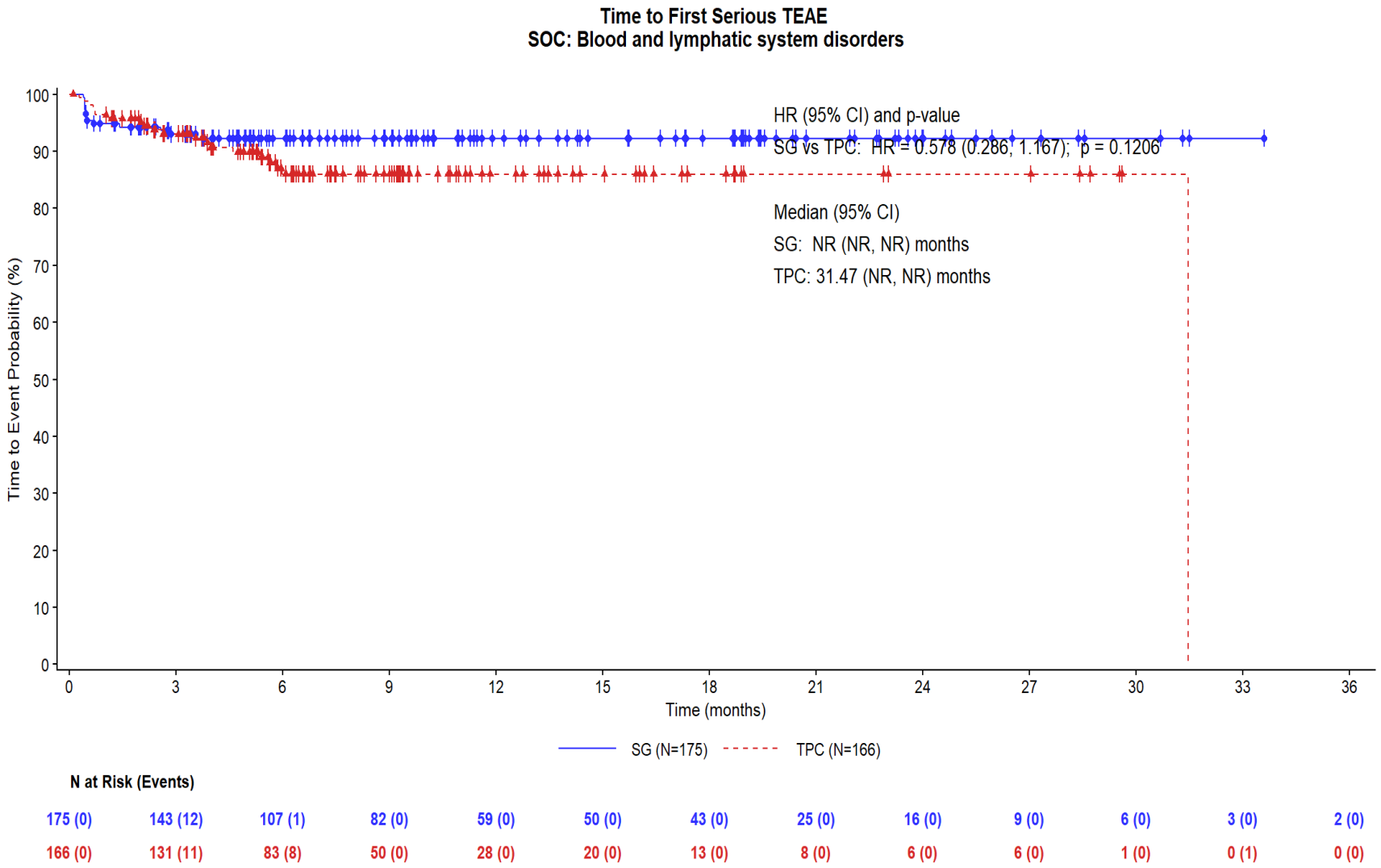
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8.163. Figure 1.1.162: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Physician s chemotherapy choice Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



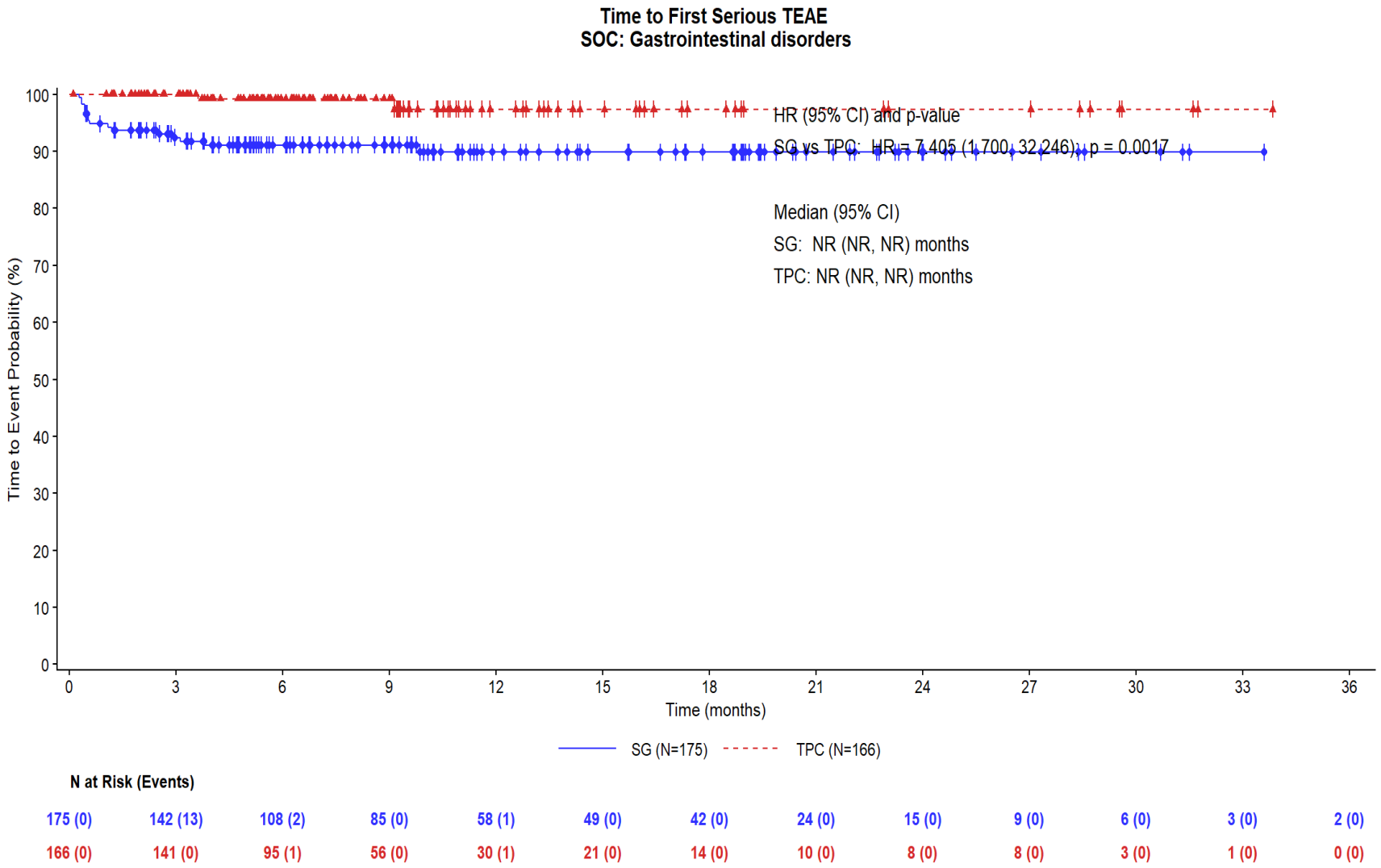
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.164. Figure 1.1.163: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



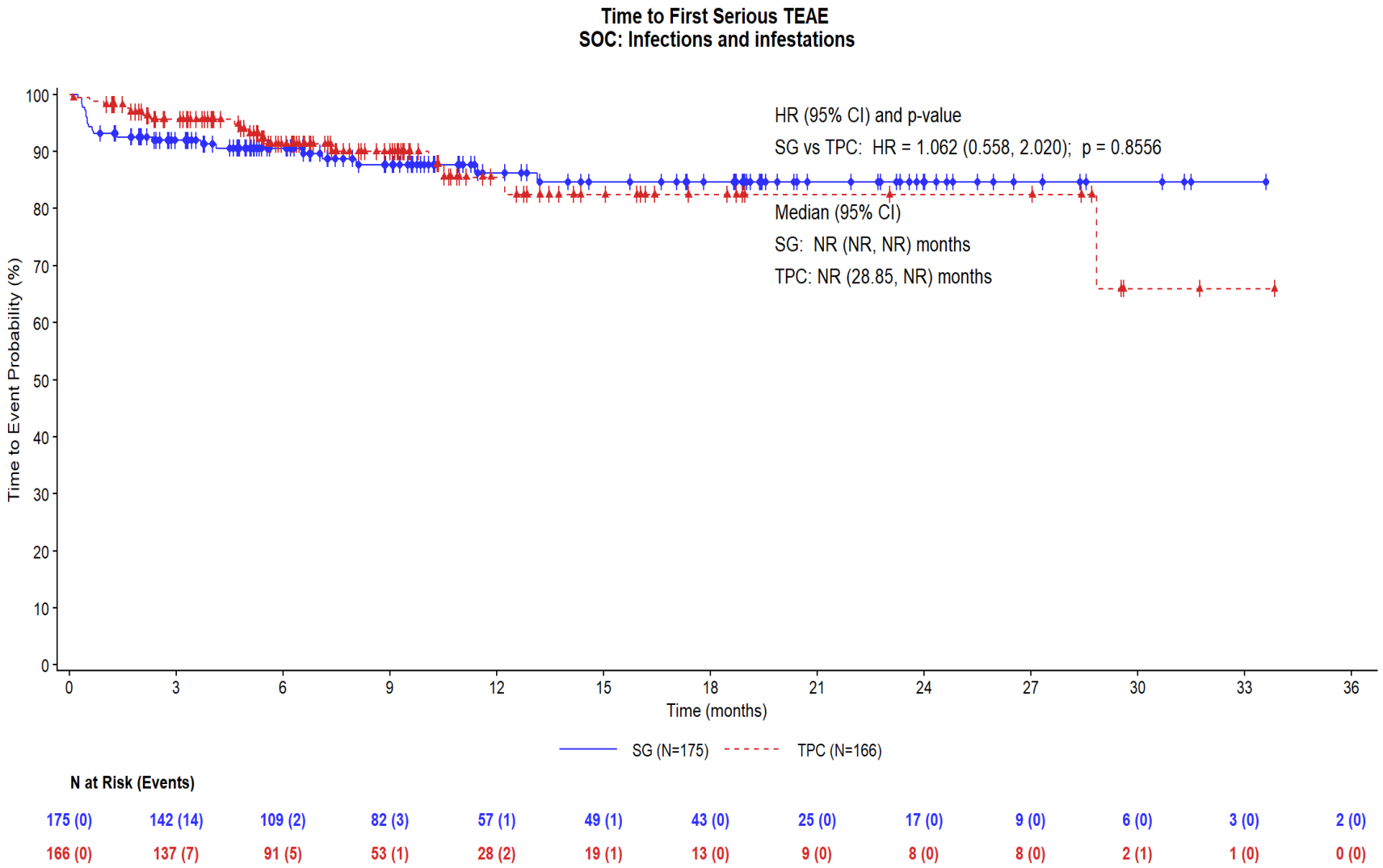
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8.165. Figure 1.1.164: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



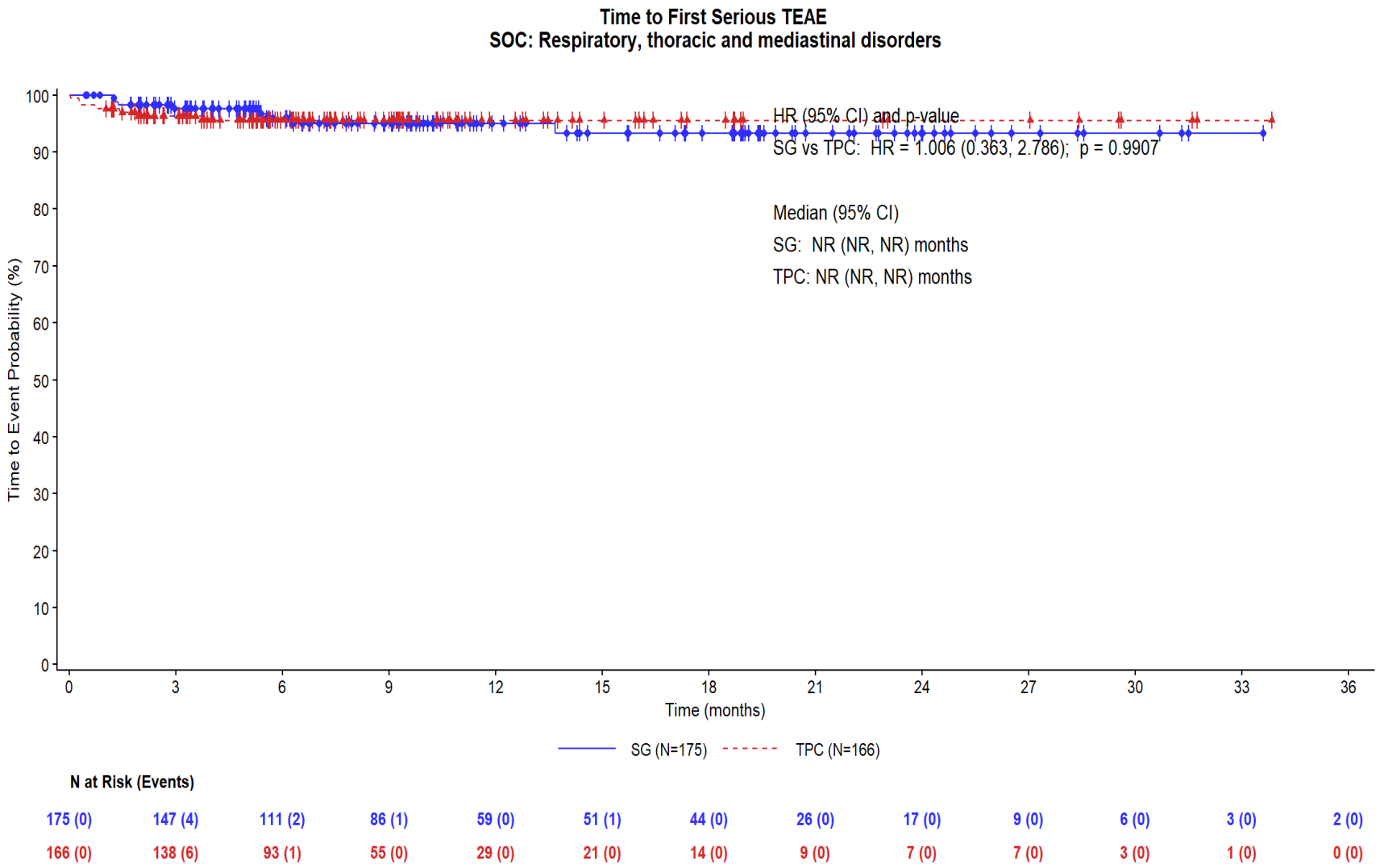
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.166. Figure 1.1.165: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel



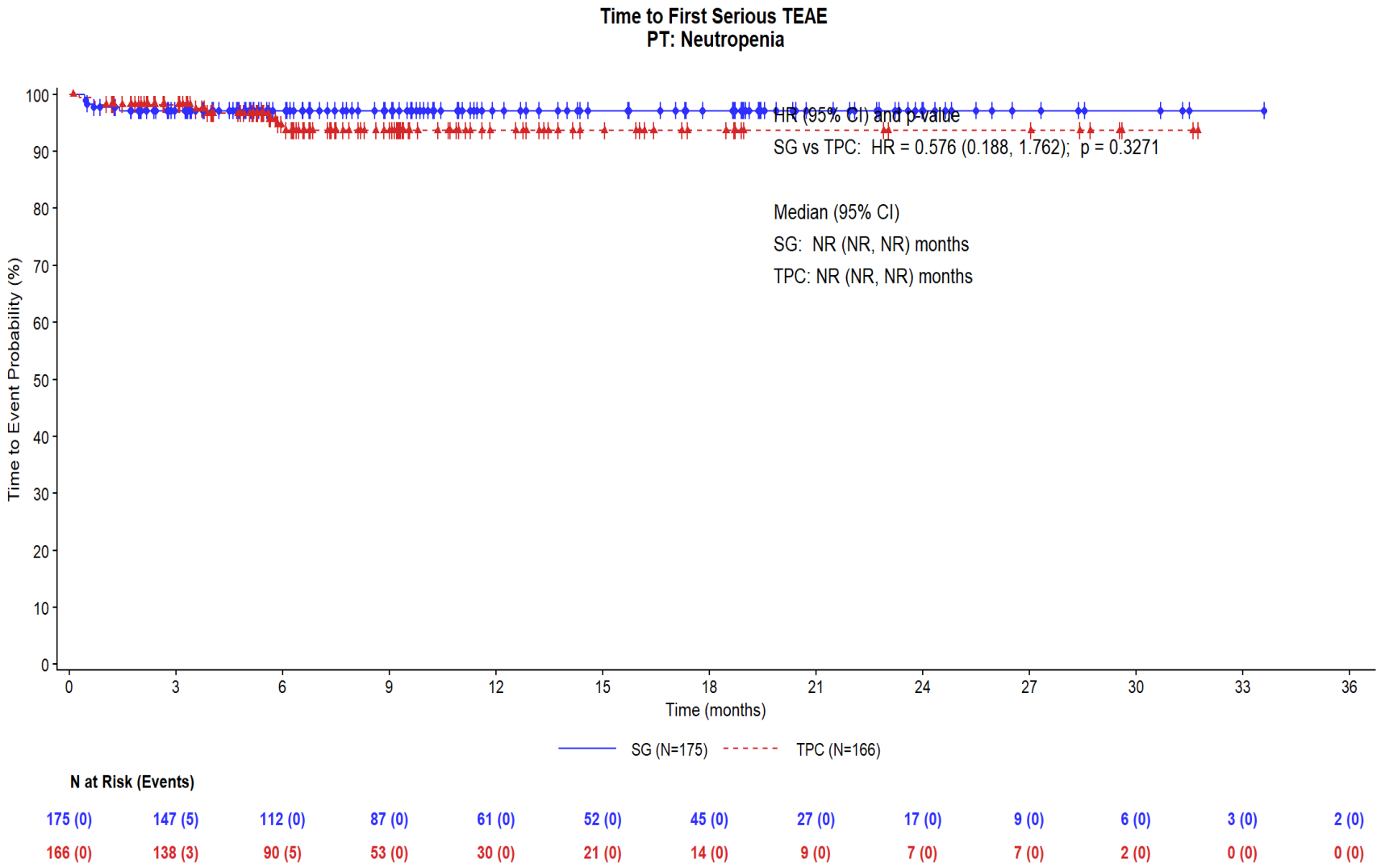
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.167. Figure 1.1.166: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



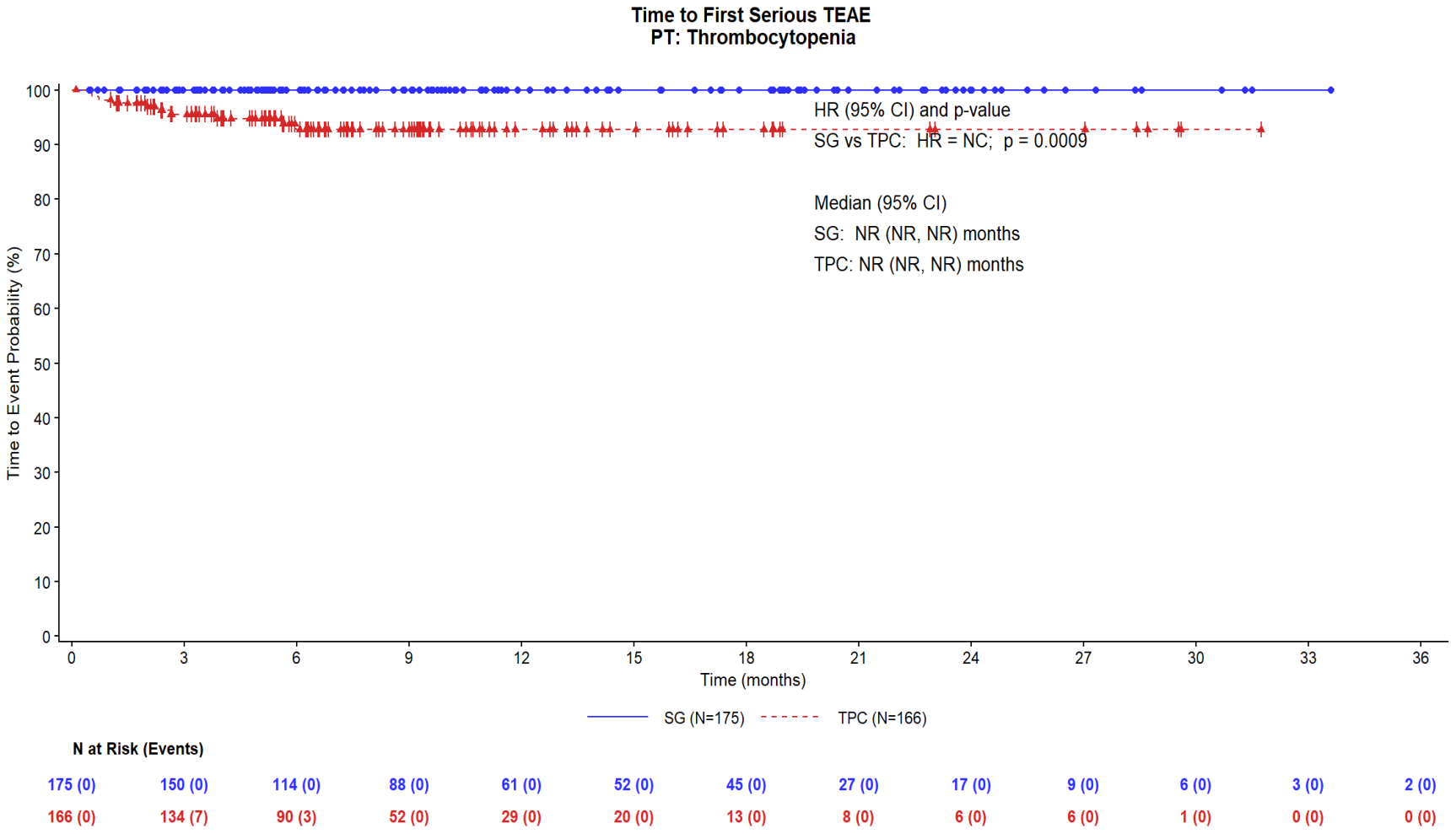
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.168. Figure 1.1.167: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.169. Figure 1.1.168: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

Table. Recurrence of diarrhoea TEAE — mSAF1: Excluding patients preselected to nab-paclitaxel

	SG (N=175)			TPC (N=166)		
Incidence of diarrhoea TEAE	**1 event**	**2 events**	**>2 events**	**1 event**	**2 events**	**>2 events**
Grade 1	46 (26.3%)	16 (9.1%)	18 (10.3%)	28 (16.9%)	2 (1.2%)	4 (2.4%)
Grade 2	36 (20.6%)	10 (5.7%)	5 (2.9%)	11 (6.6%)	2 (1.2%)	1 (0.6%)
Grade ≥3	17 (9.7%)	1 (0.6%)	0	3 (1.8%)	0	0
Grade 3	18 (10.3%)	0	0	3 (1.8%)	0	0
Grade 4	1 (0.6%)	0	0	0	0	0
Grade 5	0	0	0	0	0	0

n = number of events per patient;

GS-US-592-6238-20788-92106 (SG): 2 diarrhoea episodes at Grade≥3 (1×Grade 3 + 1×Grade 4)

Data cut off:- 22 APR 2026

Descriptive Analysis of G-CSF Use Prior to First Febrile Neutropenia AE

	Febrile Neutropenia CTCAE Grade ≥3[1]			Febrile Neutropenia Serious Adverse Event (SAE)[2]		
Parameter	**SG (N=175)**	**TPC (N=166)**	**Overall (N=341)**	**SG (N=175)**	**TPC (N=166)**	**Overall (N=341)**
Total Patients in Safety Analysis Set	**175**	**166**	**341**	**175**	**166**	**341**
Patients with Febrile Neutropenia, n (%)	**8 (4.6%)**	**3 (1.8%)**	**11 (3.2%)**	**6 (3.4%)**	**2 (1.2%)**	**8 (2.3%)**
G-CSF Prophylaxis Prior to AE						
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	8 (100.0%)	3 (100.0%)	11 (100.0%)	6 (100.0%)	2 (100.0%)	8 (100.0%)
Patients Without Febrile Neutropenia, n (%)	**167 (95.4%)**	**163 (98.2%)**	**330 (96.8%)**	**169 (96.6%)**	**164 (98.8%)**	**333 (97.7%)**

n (%) = number of subjects and percentage of the relevant denominator.
Denominator for Total Patients, Patients with Febrile Neutropenia, and Patients without Febrile Neutropenia rows = total number of patients in each treatment arm (or overall) in the Safety Analysis Set.
Denominator for G-CSF Prophylaxis Yes/No rows = number of patients who experienced a febrile neutropenia event in the respective treatment arm or overall.
[a] Observation period is the time from first dose until the earliest of: the data cut-off (DCO) date; the date of study treatment discontinuation plus 30 days; or death; whichever occurs first and stops the collection of endpoint data. The same observation period applies to any adverse event and any serious adverse event, so the adverse-event and serious-adverse-event windows coincide. Only febrile neutropenia events with an onset date within this period are counted.
Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 28.1.

[1] Febrile neutropenia with CTCAE Grade ≥3: includes only febrile neutropenia events with a toxicity grade of 3 or higher and an onset date within the adverse-event observation period defined in footnote [a]. [2] Febrile neutropenia classified as a Serious Adverse Event (SAE): includes only febrile neutropenia events that met at least one seriousness criterion and had an onset date within the serious-adverse-event observation period defined in footnote [a].

1. Statistical Analysis for German Submission of ASCENT-03

2. Study : ASCENT-03

Population: Triple-Negative Breast Cancer (mTNBC)

Sub-Population:
- mITT — Excluding patients preselected to receive nab-paclitaxel

Data Cut Date: 27 October 2025
Report Date: 1 May 2026

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4. Disposition - mITT — Excluding patients preselected to receive nab-paclitaxel

4.1. Table 1.1.1: Participant Disposition — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Screened			346
mITT (Excluding patients preselected to receive nab-paclitaxel)	177	169	346
Randomized but not Treated	2	3	5
Safety Analysis Set	175	166	341
Study Treatment Completion Status (Randomized Phase)			
Continuing Study Treatment	29 (16.4%)	9 (5.3%)	38 (11.0%)
Discontinued Study Treatment	148 (83.6%)	160 (94.7%)	308 (89.0%)
Adverse Event	9 (5.1%)	16 (9.5%)	25 (7.2%)
Pregnancy	0	0	0
Investigator's Discretion	8 (4.5%)	6 (3.6%)	14 (4.0%)
Non-Compliance with Study Drug	0	0	0
Subject Decision	8 (4.5%)	13 (7.7%)	21 (6.1%)
Study Terminated by Sponsor	0	0	0
Progressive Disease	118 (66.7%)	124 (73.4%)	242 (69.9%)
Lost to Follow-Up	0	0	0
Death	5 (2.8%)	1 (0.6%)	6 (1.7%)
Received Study Treatment in Crossover Phase		74 (43.8%)	
Study Completion Status			
Continuing Study	82 (46.3%)	66 (39.1%)	148 (42.8%)
Discontinued Study	95 (53.7%)	103 (60.9%)	198 (57.2%)
Death	88 (49.7%)	92 (54.4%)	180 (52.0%)
Withdrew Consent	7 (4.0%)	11 (6.5%)	18 (5.2%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Lost to Follow-Up	0	0	0
Study Terminated by Sponsor	0	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Screened Population: Participants who have signed an informed consent and participated in the screening procedures at site to assess eligibility.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug.
Denominator of percentages is the number of participants in each treatment group.
Randomized Phase excludes crossover phase when participants in TPC arm started to receive SG.
Data Cut Date: 27 October 2025.

Source: mITT1/Table1.Disposition of participants.R

4.2. Table 1.1.2: Demographic and Baseline Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Age (years)			
N	177	169	346
Mean (Sd)	56.3 (12.1)	53.7 (12.1)	55.1 (12.2)
Median	55.0	52.0	54.0
Q1, Q3	48.0, 64.0	45.0, 63.0	46.0, 63.8
Min, Max	28.0, 84.0	28.0, 86.0	28.0, 86.0
Age Group			
< 65	133 (75.1%)	131 (77.5%)	264 (76.3%)
>= 65	44 (24.9%)	38 (22.5%)	82 (23.7%)
Sex at Birth			
F	177 (100.0%)	168 (99.4%)	345 (99.7%)
M	0	1 (0.6%)	1 (0.3%)
Race			
AMERICAN INDIAN OR ALASKA NATIVE	6 (3.4%)	11 (6.5%)	17 (4.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
ASIAN	38 (21.5%)	38 (22.5%)	76 (22.0%)
BLACK OR AFRICAN AMERICAN	5 (2.8%)	5 (3.0%)	10 (2.9%)
NOT REPORTED	5 (2.8%)	3 (1.8%)	8 (2.3%)
OTHER	8 (4.5%)	8 (4.7%)	16 (4.6%)
WHITE	115 (65.0%)	104 (61.5%)	219 (63.3%)
Ethnicity			
HISPANIC OR LATINO	46 (26.0%)	50 (29.6%)	96 (27.7%)
NOT HISPANIC OR LATINO	128 (72.3%)	117 (69.2%)	245 (70.8%)
NOT REPORTED	3 (1.7%)	2 (1.2%)	5 (1.4%)
Region			
Rest of the World	121 (68.4%)	117 (69.2%)	238 (68.8%)
US/Canada/Western Europe	56 (31.6%)	52 (30.8%)	108 (31.2%)
Country			
Argentina	10 (5.6%)	12 (7.1%)	22 (6.4%)
Australia	4 (2.3%)	0	4 (1.2%)
Belgium	2 (1.1%)	3 (1.8%)	5 (1.4%)
Brazil	18 (10.2%)	15 (8.9%)	33 (9.5%)
Canada	5 (2.8%)	1 (0.6%)	6 (1.7%)
Chile	4 (2.3%)	5 (3.0%)	9 (2.6%)
China	2 (1.1%)	5 (3.0%)	7 (2.0%)
Czech Republic	3 (1.7%)	2 (1.2%)	5 (1.4%)
France	10 (5.6%)	6 (3.6%)	16 (4.6%)
Germany	7 (4.0%)	3 (1.8%)	10 (2.9%)
Hong Kong	1 (0.6%)	1 (0.6%)	2 (0.6%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hungary	3 (1.7%)	4 (2.4%)	7 (2.0%)
Israel	9 (5.1%)	5 (3.0%)	14 (4.0%)
Italy	10 (5.6%)	12 (7.1%)	22 (6.4%)
Japan	20 (11.3%)	15 (8.9%)	35 (10.1%)
Korea, Republic of	12 (6.8%)	9 (5.3%)	21 (6.1%)
Malaysia	3 (1.7%)	4 (2.4%)	7 (2.0%)
Mexico	12 (6.8%)	16 (9.5%)	28 (8.1%)
Netherlands	4 (2.3%)	2 (1.2%)	6 (1.7%)
Poland	1 (0.6%)	0	1 (0.3%)
South Africa	4 (2.3%)	5 (3.0%)	9 (2.6%)
Spain	7 (4.0%)	10 (5.9%)	17 (4.9%)
Turkey	15 (8.5%)	14 (8.3%)	29 (8.4%)
United States	11 (6.2%)	11 (6.5%)	22 (6.4%)
Austria	0	2 (1.2%)	2 (0.6%)
Romania	0	1 (0.6%)	1 (0.3%)
Slovakia	0	2 (1.2%)	2 (0.6%)
Taiwan	0	2 (1.2%)	2 (0.6%)
United Kingdom	0	2 (1.2%)	2 (0.6%)
Weight (kg)			
N	177	169	346
Mean (Sd)	70.4 (15.9)	67.7 (13.8)	69.1 (15.0)
Median	68.8	66.8	68.0
Q1, Q3	59.0, 80.0	56.0, 77.0	58.0, 79.3
Min, Max	38.1, 131.4	42.0, 113.0	38.1, 131.4

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Height (cm)			
N	177	169	346
Mean (Sd)	160.9 (7.5)	160.7 (7.0)	160.8 (7.3)
Median	161.0	160.0	160.9
Q1, Q3	156.2, 166.0	155.0, 166.0	156.0, 166.0
Min, Max	140.0, 180.0	145.0, 183.0	140.0, 183.0
BMI (kg/m2)			
N	177	169	346
Mean (Sd)	27.2 (5.9)	26.2 (5.2)	26.7 (5.6)
Median	26.2	25.4	26.0
Q1, Q3	22.9, 30.9	22.3, 29.3	22.7, 30.1
Min, Max	14.1, 54.8	16.8, 44.1	14.1, 54.8

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Age (in years) was collected on the date of first study drug administration (Day 1) if dosed, or randomization if not dosed.
Not Permitted = local regulators did not allow collection of race or ethnicity information or participant refused to provide information.
*Body Mass Index (BMI) (kg/m^2) = [Weight (kg) / Height (cm)^2]*10,000*
Data Cut Date: 27 October 2025.

Source: mITT1/Table2.Demographic and Baseline Characteristics.R

4.3. Table 1.1.3: Other Baseline Disease Characteristics — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Baseline ECOG Score			
0	116 (65.5%)	106 (62.7%)	222 (64.2%)
1	61 (34.5%)	63 (37.3%)	124 (35.8%)
UGT1A1 Genotype			
*1/*1	76 (42.9%)	78 (46.2%)	154 (44.5%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
*1/*28	68 (38.4%)	55 (32.5%)	123 (35.5%)
*1/*6	10 (5.6%)	7 (4.1%)	17 (4.9%)
*28/*28	14 (7.9%)	18 (10.7%)	32 (9.2%)
*28/*37	2 (1.1%)	0 (0.0%)	2 (0.6%)
*6/*28	1 (0.6%)	2 (1.2%)	3 (0.9%)
*6/*6	1 (0.6%)	1 (0.6%)	2 (0.6%)
Missing/Not Done	5 (2.8%)	6 (3.6%)	11 (3.2%)
*1/*37	0 (0.0%)	1 (0.6%)	1 (0.3%)
*27/*28	0 (0.0%)	1 (0.6%)	1 (0.3%)
Menopausal Status (Females Only)			
Post-menopausal	140 (79.1%)	119 (70.8%)	259 (75.1%)
Pre-menopausal	37 (20.9%)	49 (29.2%)	86 (24.9%)
BRCA1 Mutation Status (Local testing)			
Mutant	11 (6.2%)	8 (4.7%)	19 (5.5%)
Unknown	99 (55.9%)	95 (56.2%)	194 (56.1%)
Wild Type	67 (37.9%)	66 (39.1%)	133 (38.4%)
BRCA2 Mutation Status (Local testing)			
Mutant	3 (1.7%)	3 (1.8%)	6 (1.7%)
Unknown	99 (55.9%)	99 (58.6%)	198 (57.2%)
Wild Type	75 (42.4%)	67 (39.6%)	142 (41.0%)
BRCA1/2 Mutation Status (Local testing)			
Mutant	12 (6.8%)	10 (5.9%)	22 (6.4%)
Unknown	99 (55.9%)	94 (55.6%)	193 (55.8%)
Wild Type	66 (37.3%)	65 (38.5%)	131 (37.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
BRCA1 Genotype (BRCA Central Testing)			
Mutant	15 (8.5%)	15 (8.9%)	30 (8.7%)
Unknown	37 (20.9%)	50 (29.6%)	87 (25.1%)
Wild Type	125 (70.6%)	104 (61.5%)	229 (66.2%)
BRCA2 Genotype (BRCA Central Testing)			
Mutant	13 (7.3%)	9 (5.3%)	22 (6.4%)
Unknown	37 (20.9%)	50 (29.6%)	87 (25.1%)
Wild Type	127 (71.8%)	110 (65.1%)	237 (68.5%)
BRCA1/BRCA2 Mutation Category (BRCA Central Testing)			
Mutant	24 (13.6%)	22 (13.0%)	46 (13.3%)
Unknown	37 (20.9%)	50 (29.6%)	87 (25.1%)
Wild Type	116 (65.5%)	97 (57.4%)	213 (61.6%)
BRCA1/2 Mutation Category (Central or local testing)			
Mutant	30 (16.9%)	25 (14.8%)	55 (15.9%)
Wild-type	125 (70.6%)	110 (65.1%)	235 (67.9%)
Unknown	22 (12.4%)	34 (20.1%)	56 (16.2%)
BRCA1 Genotype (Central or local testing)			
Mutant	21 (11.9%)	18 (10.7%)	39 (11.3%)
Wild-type	134 (75.7%)	117 (69.2%)	251 (72.5%)
Unknown	22 (12.4%)	34 (20.1%)	56 (16.2%)
BRCA2 Genotype (Central or local testing)			
Mutant	15 (8.5%)	10 (5.9%)	25 (7.2%)
Wild-type	140 (79.1%)	124 (73.4%)	264 (76.3%)
Unknown	22 (12.4%)	35 (20.7%)	57 (16.5%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
PD-L1 CPS			
1 to <10	108 (61.0%)	110 (65.1%)	218 (63.0%)
<1	67 (37.9%)	59 (34.9%)	126 (36.4%)
>=10	1 (0.6%)	0 (0.0%)	1 (0.3%)
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Estrogen Receptor Status			
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Positive (>= 1%)	1 (0.6%)	0 (0.0%)	1 (0.3%)
Negative (< 1%)	175 (98.9%)	169 (100.0%)	344 (99.4%)
Progesterone Receptor Status			
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Negative (< 1%)	176 (99.4%)	169 (100.0%)	345 (99.7%)
HER2 Status			
Missing	1 (0.6%)	0 (0.0%)	1 (0.3%)
Negative	176 (99.4%)	169 (100.0%)	345 (99.7%)
Disease Stratification			
De novo	55 (31.1%)	49 (29.0%)	104 (30.1%)
Recurrent disease occurring > 12 months	88 (49.7%)	86 (50.9%)	174 (50.3%)
Recurrent disease within 6 to 12 months	34 (19.2%)	34 (20.1%)	68 (19.7%)
Pre-selected TPC Prior to Randomization			
Gemcitabine/Carboplatin	125 (70.6%)	124 (73.4%)	249 (72.0%)
Taxane	52 (29.4%)	45 (26.6%)	97 (28.0%)
Breast Cancer Stage at Initial Diagnosis			
STAGE 1	27 (15.3%)	20 (11.8%)	47 (13.6%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
STAGE 2	60 (33.9%)	61 (36.1%)	121 (35.0%)
STAGE 3	40 (22.6%)	42 (24.9%)	82 (23.7%)
STAGE 4	50 (28.2%)	46 (27.2%)	96 (27.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subtype of Cancer at Initial Diagnosis			
HR+/HER2+	3 (1.7%)	3 (1.8%)	6 (1.7%)
HR+/HER2-	22 (12.4%)	23 (13.6%)	45 (13.0%)
HR-/HER2+	3 (1.7%)	0 (0.0%)	3 (0.9%)
HR-/HER2- (TNBC)	148 (83.6%)	141 (83.4%)	289 (83.5%)
Missing	1 (0.6%)	2 (1.2%)	3 (0.9%)
Disease Status at Screening			
Locally advanced and Inoperable	4 (2.3%)	5 (3.0%)	9 (2.6%)
Metastatic	173 (97.7%)	164 (97.0%)	337 (97.4%)
Site of Metastasis at Screening			
Bone	63 (35.6%)	51 (30.2%)	114 (32.9%)
Brain	8 (4.5%)	9 (5.3%)	17 (4.9%)
Liver	47 (26.6%)	39 (23.1%)	86 (24.9%)
Lung	106 (59.9%)	103 (60.9%)	209 (60.4%)
Lymph Node	116 (65.5%)	107 (63.3%)	223 (64.5%)
Other	55 (31.1%)	59 (34.9%)	114 (32.9%)
Time from Locally Advanced and Inoperable or Metastatic Disease to Randomization (months) [a]			
N	176	169	345
Mean (StD)	2.2 (1.60)	2.5 (2.10)	2.3 (1.87)
Median	1.8	1.8	1.8

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Q1, Q3	1.3, 2.5	1.3, 2.9	1.3, 2.7
Min, Max	0.5, 14.3	0.1, 13.2	0.1, 14.3

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages for other baseline characteristics is the number of participants in each treatment group.
[a] Mutant denotes participant is either BRCA1 or BRCA2 mutant, or both mutant. Wild type denotes participant is both BRCA1 and BRCA2 wild type. Unknown denotes participant is BRCA1 unknown and BRCA2 wild type or unknown, or participant is BRCA1 wild type or unknown and BRCA2 unknown.
PD-L1 CPS (combined positive score) and TNBC status were collected centrally.
Data Cut Date: 27 October 2025.

Source: mITT1/Table3.Other Baseline Disease Characteristics.R

4.4. Table 1.1.4: Medical History by System Organ Class and Preferred Term — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Number (%) of Participants with Any Medical History	160 (90.4%)	151 (89.3%)	311 (89.9%)
Blood and lymphatic system disorders	12 (6.8%)	17 (10.1%)	29 (8.4%)
Anaemia	10 (5.6%)	14 (8.3%)	24 (6.9%)
Lymphopenia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Coagulopathy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Increased tendency to bruise	1 (0.6%)	0 (0.0%)	1 (6.9%)
Leukopenia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lymphadenopathy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Neutropenia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Thrombocytopenia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Thrombocytosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac disorders	12 (6.8%)	15 (8.9%)	27 (8.4%)
Atrial fibrillation	2 (1.1%)	2 (1.2%)	4 (6.9%)
Sinus tachycardia	2 (1.1%)	2 (1.2%)	4 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Tachycardia	3 (1.7%)	1 (0.6%)	4 (6.9%)
Arrhythmia	2 (1.1%)	1 (0.6%)	3 (6.9%)
Ventricular extrasystoles	0 (0.0%)	3 (1.8%)	3 (6.9%)
Cardiomyopathy	1 (0.6%)	1 (0.6%)	2 (6.9%)
Angina pectoris	0 (0.0%)	1 (0.6%)	1 (6.9%)
Arrhythmia supraventricular	1 (0.6%)	0 (0.0%)	1 (6.9%)
Arteriosclerosis coronary artery	0 (0.0%)	1 (0.6%)	1 (6.9%)
Bradycardia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac failure chronic	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac failure congestive	1 (0.6%)	0 (0.0%)	1 (6.9%)
Carditis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Myocardial infarction	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pericardial effusion	0 (0.0%)	1 (0.6%)	1 (6.9%)
Sinus bradycardia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Supraventricular extrasystoles	0 (0.0%)	1 (0.6%)	1 (6.9%)
Congenital, familial and genetic disorders	3 (1.7%)	8 (4.7%)	11 (8.4%)
Congenital neuropathy	2 (1.1%)	0 (0.0%)	2 (6.9%)
Adenomatous polyposis coli	0 (0.0%)	1 (0.6%)	1 (6.9%)
Coarctation of the aorta	0 (0.0%)	1 (0.6%)	1 (6.9%)
Congenital musculoskeletal disorder of limbs	0 (0.0%)	1 (0.6%)	1 (6.9%)
Developmental hip dysplasia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Factor V Leiden mutation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Kidney duplex	0 (0.0%)	1 (0.6%)	1 (6.9%)
Renal fusion anomaly	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Thalassaemia sickle cell	0 (0.0%)	1 (0.6%)	1 (6.9%)
Venous angioma of brain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Ear and labyrinth disorders	8 (4.5%)	3 (1.8%)	11 (8.4%)
Vertigo	2 (1.1%)	2 (1.2%)	4 (6.9%)
Deafness	2 (1.1%)	0 (0.0%)	2 (6.9%)
Hypoacusis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Cholesteatoma	1 (0.6%)	0 (0.0%)	1 (6.9%)
Meniere's disease	0 (0.0%)	1 (0.6%)	1 (6.9%)
Sudden hearing loss	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vertigo positional	1 (0.6%)	0 (0.0%)	1 (6.9%)
Endocrine disorders	25 (14.1%)	25 (14.8%)	50 (8.4%)
Hypothyroidism	16 (9.0%)	18 (10.7%)	34 (6.9%)
Hyperthyroidism	2 (1.1%)	5 (3.0%)	7 (6.9%)
Autoimmune thyroiditis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Hyperparathyroidism	1 (0.6%)	1 (0.6%)	2 (6.9%)
Thyroid disorder	2 (1.1%)	0 (0.0%)	2 (6.9%)
Thyroid mass	2 (1.1%)	0 (0.0%)	2 (6.9%)
Autoimmune hypothyroidism	1 (0.6%)	0 (0.0%)	1 (6.9%)
Goitre	0 (0.0%)	1 (0.6%)	1 (6.9%)
Eye disorders	16 (9.0%)	10 (5.9%)	26 (8.4%)
Cataract	3 (1.7%)	3 (1.8%)	6 (6.9%)
Dry eye	2 (1.1%)	4 (2.4%)	6 (6.9%)
Myopia	2 (1.1%)	3 (1.8%)	5 (6.9%)
Glaucoma	1 (0.6%)	2 (1.2%)	3 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Presbyopia	2 (1.1%)	1 (0.6%)	3 (6.9%)
Astigmatism	0 (0.0%)	2 (1.2%)	2 (6.9%)
Conjunctivitis allergic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Eye pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Fuchs' syndrome	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hypermetropia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Macular degeneration	1 (0.6%)	0 (0.0%)	1 (6.9%)
Macular oedema	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pterygium	1 (0.6%)	0 (0.0%)	1 (6.9%)
Retinal haemorrhage	1 (0.6%)	0 (0.0%)	1 (6.9%)
Retinal vein occlusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Strabismus	0 (0.0%)	1 (0.6%)	1 (6.9%)
Vision blurred	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gastrointestinal disorders	42 (23.7%)	43 (25.4%)	85 (8.4%)
Constipation	9 (5.1%)	14 (8.3%)	23 (6.9%)
Gastrooesophageal reflux disease	10 (5.6%)	7 (4.1%)	17 (6.9%)
Nausea	2 (1.1%)	8 (4.7%)	10 (6.9%)
Abdominal pain upper	3 (1.7%)	3 (1.8%)	6 (6.9%)
Hiatus hernia	3 (1.7%)	2 (1.2%)	5 (6.9%)
Diarrhoea	2 (1.1%)	2 (1.2%)	4 (6.9%)
Irritable bowel syndrome	2 (1.1%)	2 (1.2%)	4 (6.9%)
Colitis ulcerative	1 (0.6%)	2 (1.2%)	3 (6.9%)
Dyspepsia	2 (1.1%)	1 (0.6%)	3 (6.9%)
Gastric ulcer	2 (1.1%)	1 (0.6%)	3 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Gastritis	1 (0.6%)	2 (1.2%)	3 (6.9%)
Tooth loss	2 (1.1%)	1 (0.6%)	3 (6.9%)
Abdominal pain	1 (0.6%)	1 (0.6%)	2 (6.9%)
Coeliac disease	1 (0.6%)	1 (0.6%)	2 (6.9%)
Crohn's disease	0 (0.0%)	2 (1.2%)	2 (6.9%)
Dysphagia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Haemorrhoids	1 (0.6%)	1 (0.6%)	2 (6.9%)
Large intestine polyp	2 (1.1%)	0 (0.0%)	2 (6.9%)
Umbilical hernia	0 (0.0%)	2 (1.2%)	2 (6.9%)
Abdominal discomfort	0 (0.0%)	1 (0.6%)	1 (6.9%)
Abdominal distension	1 (0.6%)	0 (0.0%)	1 (6.9%)
Anal incontinence	1 (0.6%)	0 (0.0%)	1 (6.9%)
Anal sphincter atony	1 (0.6%)	0 (0.0%)	1 (6.9%)
Ascites	1 (0.6%)	0 (0.0%)	1 (6.9%)
Chronic gastritis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Diverticulum	0 (0.0%)	1 (0.6%)	1 (6.9%)
Diverticulum intestinal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Food poisoning	0 (0.0%)	1 (0.6%)	1 (6.9%)
Gastrointestinal disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gastrointestinal pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Haemorrhoidal haemorrhage	1 (0.6%)	0 (0.0%)	1 (6.9%)
Inguinal hernia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lumbar hernia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Mucosal prolapse syndrome	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Obstructive pancreatitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Oral pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pancreatitis chronic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Periodontal disease	1 (0.6%)	0 (0.0%)	1 (6.9%)
Stomatitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tongue pigmentation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vomiting	1 (0.6%)	0 (0.0%)	1 (6.9%)
General disorders and administration site conditions	21 (11.9%)	20 (11.8%)	41 (8.4%)
Fatigue	7 (4.0%)	6 (3.6%)	13 (6.9%)
Pain	3 (1.7%)	4 (2.4%)	7 (6.9%)
Asthenia	2 (1.1%)	4 (2.4%)	6 (6.9%)
Chest pain	2 (1.1%)	4 (2.4%)	6 (6.9%)
Oedema peripheral	4 (2.3%)	1 (0.6%)	5 (6.9%)
Peripheral swelling	1 (0.6%)	1 (0.6%)	2 (6.9%)
Pyrexia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Axillary pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Drug intolerance	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gait disturbance	0 (0.0%)	1 (0.6%)	1 (6.9%)
Non-cardiac chest pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Oedema	0 (0.0%)	1 (0.6%)	1 (6.9%)
Supraclavicular fossa pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hepatobiliary disorders	15 (8.5%)	8 (4.7%)	23 (8.4%)
Cholelithiasis	5 (2.8%)	5 (3.0%)	10 (6.9%)
Hepatic function abnormal	3 (1.7%)	1 (0.6%)	4 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hepatic steatosis	2 (1.1%)	1 (0.6%)	3 (6.9%)
Cholecystitis chronic	2 (1.1%)	0 (0.0%)	2 (6.9%)
Hyperbilirubinaemia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Autoimmune hepatitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Biliary fistula	1 (0.6%)	0 (0.0%)	1 (6.9%)
Cholangitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cholecystitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hypertransaminasaemia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Jaundice cholestatic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Liver disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Metabolic dysfunction-associated steatohepatitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Immune system disorders	17 (9.6%)	21 (12.4%)	38 (8.4%)
Drug hypersensitivity	5 (2.8%)	12 (7.1%)	17 (6.9%)
Seasonal allergy	8 (4.5%)	7 (4.1%)	15 (6.9%)
Contrast media allergy	2 (1.1%)	1 (0.6%)	3 (6.9%)
Hypersensitivity	1 (0.6%)	1 (0.6%)	2 (6.9%)
Allergy to arthropod sting	1 (0.6%)	0 (0.0%)	1 (6.9%)
Food allergy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Immunodeficiency	0 (0.0%)	1 (0.6%)	1 (6.9%)
Iodine allergy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Rubber sensitivity	0 (0.0%)	1 (0.6%)	1 (6.9%)
Infections and infestations	24 (13.6%)	20 (11.8%)	44 (8.4%)
COVID-19	5 (2.8%)	1 (0.6%)	6 (6.9%)
Appendicitis	5 (2.8%)	0 (0.0%)	5 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Urinary tract infection	1 (0.6%)	4 (2.4%)	5 (6.9%)
Herpes zoster	3 (1.7%)	1 (0.6%)	4 (6.9%)
Pneumonia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Empyema	1 (0.6%)	1 (0.6%)	2 (6.9%)
Labyrinthitis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Rhinitis	0 (0.0%)	2 (1.2%)	2 (6.9%)
American trypanosomiasis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Anal abscess	0 (0.0%)	1 (0.6%)	1 (6.9%)
Breast abscess	0 (0.0%)	1 (0.6%)	1 (6.9%)
Conjunctivitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Dengue fever	0 (0.0%)	1 (0.6%)	1 (6.9%)
Erysipelas	1 (0.6%)	0 (0.0%)	1 (6.9%)
Furuncle	0 (0.0%)	1 (0.6%)	1 (6.9%)
Genital herpes	0 (0.0%)	1 (0.6%)	1 (6.9%)
Gingivitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
HIV infection	0 (0.0%)	1 (0.6%)	1 (6.9%)
Helicobacter infection	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hepatitis B	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hepatitis viral	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lung abscess	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nosocomial infection	1 (0.6%)	0 (0.0%)	1 (6.9%)
Periodontitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Peritonitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pyelonephritis acute	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Rash pustular	0 (0.0%)	1 (0.6%)	1 (6.9%)
Skin candida	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tonsillitis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tuberculosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Upper respiratory tract infection	0 (0.0%)	1 (0.6%)	1 (6.9%)
Viral pericarditis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Injury, poisoning and procedural complications	10 (5.6%)	1 (0.6%)	11 (8.4%)
Pelvic fracture	2 (1.1%)	0 (0.0%)	2 (6.9%)
Ankle fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Compression fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Contusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Femur fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Foot fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Humerus fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint dislocation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Neck injury	1 (0.6%)	0 (0.0%)	1 (6.9%)
Postoperative ileus	1 (0.6%)	0 (0.0%)	1 (6.9%)
Procedural pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Radiation skin injury	1 (0.6%)	0 (0.0%)	1 (6.9%)
Upper limb fracture	1 (0.6%)	0 (0.0%)	1 (6.9%)
Wound complication	1 (0.6%)	0 (0.0%)	1 (6.9%)
Investigations	26 (14.7%)	22 (13.0%)	48 (8.4%)
Aspartate aminotransferase increased	10 (5.6%)	5 (3.0%)	15 (6.9%)
Blood alkaline phosphatase increased	8 (4.5%)	2 (1.2%)	10 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Blood cholesterol increased	3 (1.7%)	5 (3.0%)	8 (6.9%)
Alanine aminotransferase increased	4 (2.3%)	1 (0.6%)	5 (6.9%)
Blood lactate dehydrogenase increased	2 (1.1%)	3 (1.8%)	5 (6.9%)
Hepatic enzyme increased	2 (1.1%)	1 (0.6%)	3 (6.9%)
Arthroscopy	1 (0.6%)	1 (0.6%)	2 (6.9%)
Blood bilirubin increased	1 (0.6%)	1 (0.6%)	2 (6.9%)
Blood glucose increased	1 (0.6%)	1 (0.6%)	2 (6.9%)
Blood triglycerides increased	0 (0.0%)	2 (1.2%)	2 (6.9%)
Blood uric acid increased	0 (0.0%)	2 (1.2%)	2 (6.9%)
Gamma-glutamyltransferase increased	1 (0.6%)	1 (0.6%)	2 (6.9%)
Alpha 1 foetoprotein abnormal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Bile acids increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Biopsy breast	1 (0.6%)	0 (0.0%)	1 (6.9%)
Biopsy liver	1 (0.6%)	0 (0.0%)	1 (6.9%)
Biopsy lung	0 (0.0%)	1 (0.6%)	1 (6.9%)
Biopsy skin	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood albumin decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Blood chloride increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood glucose abnormal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Blood potassium increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood pressure increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood sodium increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Blood urea increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cardiac murmur functional	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Ejection fraction decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Electrocardiogram QT shortened	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hepatitis B core antibody positive	1 (0.6%)	0 (0.0%)	1 (6.9%)
Liver function test abnormal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Low density lipoprotein increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lymph node palpable	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lymphocyte count decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Platelet count decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
Transaminases increased	0 (0.0%)	1 (0.6%)	1 (6.9%)
Weight decreased	1 (0.6%)	0 (0.0%)	1 (6.9%)
White blood cells urine positive	0 (0.0%)	1 (0.6%)	1 (6.9%)
Metabolism and nutrition disorders	54 (30.5%)	41 (24.3%)	95 (8.4%)
Diabetes mellitus	16 (9.0%)	7 (4.1%)	23 (6.9%)
Dyslipidaemia	13 (7.3%)	7 (4.1%)	20 (6.9%)
Hypercholesterolaemia	13 (7.3%)	4 (2.4%)	17 (6.9%)
Type 2 diabetes mellitus	5 (2.8%)	6 (3.6%)	11 (6.9%)
Hyperlipidaemia	3 (1.7%)	4 (2.4%)	7 (6.9%)
Hyperglycaemia	3 (1.7%)	3 (1.8%)	6 (6.9%)
Hypoalbuminaemia	2 (1.1%)	3 (1.8%)	5 (6.9%)
Vitamin D deficiency	2 (1.1%)	3 (1.8%)	5 (6.9%)
Decreased appetite	1 (0.6%)	3 (1.8%)	4 (6.9%)
Hypertriglyceridaemia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Hyponatraemia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Obesity	2 (1.1%)	2 (1.2%)	4 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Glucose tolerance impaired	2 (1.1%)	1 (0.6%)	3 (6.9%)
Hypercalcaemia	1 (0.6%)	2 (1.2%)	3 (6.9%)
Hypomagnesaemia	1 (0.6%)	2 (1.2%)	3 (6.9%)
Hyperuricaemia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Insulin resistance	2 (1.1%)	0 (0.0%)	2 (6.9%)
Lactose intolerance	2 (1.1%)	0 (0.0%)	2 (6.9%)
Food intolerance	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gout	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hypocalcaemia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hypoglycaemia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Malnutrition	0 (0.0%)	1 (0.6%)	1 (6.9%)
Sarcopenic obesity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tetany	0 (0.0%)	1 (0.6%)	1 (6.9%)
Vitamin B12 deficiency	1 (0.6%)	0 (0.0%)	1 (6.9%)
Musculoskeletal and connective tissue disorders	54 (30.5%)	43 (25.4%)	97 (8.4%)
Back pain	13 (7.3%)	12 (7.1%)	25 (6.9%)
Arthralgia	13 (7.3%)	10 (5.9%)	23 (6.9%)
Osteoarthritis	4 (2.3%)	9 (5.3%)	13 (6.9%)
Osteoporosis	7 (4.0%)	4 (2.4%)	11 (6.9%)
Pain in extremity	6 (3.4%)	3 (1.8%)	9 (6.9%)
Bone pain	4 (2.3%)	3 (1.8%)	7 (6.9%)
Intervertebral disc protrusion	5 (2.8%)	1 (0.6%)	6 (6.9%)
Arthritis	2 (1.1%)	3 (1.8%)	5 (6.9%)
Musculoskeletal chest pain	0 (0.0%)	5 (3.0%)	5 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Osteopenia	2 (1.1%)	2 (1.2%)	4 (6.9%)
Fibromyalgia	3 (1.7%)	0 (0.0%)	3 (6.9%)
Groin pain	1 (0.6%)	1 (0.6%)	2 (6.9%)
Muscle spasms	1 (0.6%)	1 (0.6%)	2 (6.9%)
Muscular weakness	1 (0.6%)	1 (0.6%)	2 (6.9%)
Myalgia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Neck pain	1 (0.6%)	1 (0.6%)	2 (6.9%)
Rheumatoid arthritis	1 (0.6%)	1 (0.6%)	2 (6.9%)
Axillary mass	1 (0.6%)	0 (0.0%)	1 (6.9%)
Foot deformity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Intervertebral disc compression	1 (0.6%)	0 (0.0%)	1 (6.9%)
Intervertebral disc degeneration	0 (0.0%)	1 (0.6%)	1 (6.9%)
Jaw cyst	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint contracture	0 (0.0%)	1 (0.6%)	1 (6.9%)
Musculoskeletal pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Rheumatic disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sacral pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Scoliosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Spinal osteoarthritis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Trigger finger	0 (0.0%)	1 (0.6%)	1 (6.9%)
Vertebral foraminal stenosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (13.6%)	35 (20.7%)	59 (8.4%)
Cancer pain	12 (6.8%)	11 (6.5%)	23 (6.9%)
Uterine leiomyoma	2 (1.1%)	7 (4.1%)	9 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Tumour pain	4 (2.3%)	4 (2.4%)	8 (6.9%)
Breast cancer	2 (1.1%)	4 (2.4%)	6 (6.9%)
Basal cell carcinoma	3 (1.7%)	1 (0.6%)	4 (6.9%)
Tumour ulceration	2 (1.1%)	0 (0.0%)	2 (6.9%)
Cervix carcinoma	0 (0.0%)	1 (0.6%)	1 (6.9%)
Colorectal adenoma	0 (0.0%)	1 (0.6%)	1 (6.9%)
Dysplastic naevus	0 (0.0%)	1 (0.6%)	1 (6.9%)
Follicular lymphoma	0 (0.0%)	1 (0.6%)	1 (6.9%)
Haemangioma of liver	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hormone receptor positive breast cancer	0 (0.0%)	1 (0.6%)	1 (6.9%)
Infected neoplasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Intraductal papillary mucinous neoplasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lymphangiosis carcinomatosa	0 (0.0%)	1 (0.6%)	1 (6.9%)
Mediastinum neoplasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Metastases to bone	0 (0.0%)	1 (0.6%)	1 (6.9%)
Ovarian cancer	1 (0.6%)	0 (0.0%)	1 (6.9%)
Ovarian cancer recurrent	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pituitary tumour benign	0 (0.0%)	1 (0.6%)	1 (6.9%)
Prolactin-producing pituitary tumour	1 (0.6%)	0 (0.0%)	1 (6.9%)
Squamous cell carcinoma of skin	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tumour exudation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Tumour inflammation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Tumour thrombosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Nervous system disorders	28 (15.8%)	34 (20.1%)	62 (8.4%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Headache	6 (3.4%)	6 (3.6%)	12 (6.9%)
Peripheral sensory neuropathy	5 (2.8%)	5 (3.0%)	10 (6.9%)
Migraine	5 (2.8%)	4 (2.4%)	9 (6.9%)
Neuropathy peripheral	6 (3.4%)	3 (1.8%)	9 (6.9%)
Epilepsy	1 (0.6%)	2 (1.2%)	3 (6.9%)
Polyneuropathy	1 (0.6%)	2 (1.2%)	3 (6.9%)
Cerebrovascular accident	2 (1.1%)	0 (0.0%)	2 (6.9%)
Cervicobrachial syndrome	1 (0.6%)	1 (0.6%)	2 (6.9%)
Paraesthesia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Presyncope	2 (1.1%)	0 (0.0%)	2 (6.9%)
Sciatica	0 (0.0%)	2 (1.2%)	2 (6.9%)
Amnesia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Brain fog	0 (0.0%)	1 (0.6%)	1 (6.9%)
Carotid arteriosclerosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Cerebral small vessel ischaemic disease	0 (0.0%)	1 (0.6%)	1 (6.9%)
Complex regional pain syndrome	0 (0.0%)	1 (0.6%)	1 (6.9%)
Essential tremor	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hydromyelia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hypoaesthesia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Intercostal neuralgia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nervous system disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Neurotoxicity	0 (0.0%)	1 (0.6%)	1 (6.9%)
Peripheral motor neuropathy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Petit mal epilepsy	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Restless legs syndrome	0 (0.0%)	1 (0.6%)	1 (6.9%)
Spinal cord compression	0 (0.0%)	1 (0.6%)	1 (6.9%)
Syncope	1 (0.6%)	0 (0.0%)	1 (6.9%)
Taste disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Trigeminal neuralgia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Trigeminal neuropathy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Psychiatric disorders	37 (20.9%)	34 (20.1%)	71 (8.4%)
Insomnia	17 (9.6%)	13 (7.7%)	30 (6.9%)
Anxiety	13 (7.3%)	14 (8.3%)	27 (6.9%)
Depression	13 (7.3%)	12 (7.1%)	25 (6.9%)
Bipolar disorder	1 (0.6%)	1 (0.6%)	2 (6.9%)
Burnout syndrome	0 (0.0%)	2 (1.2%)	2 (6.9%)
Schizophrenia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Affective disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Anxiety disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Attention deficit hyperactivity disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Claustrophobia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Generalised anxiety disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Irritability	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nightmare	1 (0.6%)	0 (0.0%)	1 (6.9%)
Post-traumatic stress disorder	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sleep disorder due to general medical condition, insomnia type	0 (0.0%)	1 (0.6%)	1 (6.9%)
Suicidal ideation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Renal and urinary disorders	10 (5.6%)	4 (2.4%)	14 (8.4%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Urinary incontinence	3 (1.7%)	0 (0.0%)	3 (6.9%)
Chronic kidney disease	2 (1.1%)	0 (0.0%)	2 (6.9%)
Nephrolithiasis	2 (1.1%)	0 (0.0%)	2 (6.9%)
Stress urinary incontinence	1 (0.6%)	1 (0.6%)	2 (6.9%)
Calculus bladder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Haematuria	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hydronephrosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
IgA nephropathy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pollakiuria	1 (0.6%)	0 (0.0%)	1 (6.9%)
Proteinuria	1 (0.6%)	0 (0.0%)	1 (6.9%)
Renal colic	0 (0.0%)	1 (0.6%)	1 (6.9%)
Urge incontinence	1 (0.6%)	0 (0.0%)	1 (6.9%)
Reproductive system and breast disorders	17 (9.6%)	17 (10.1%)	34 (8.4%)
Breast pain	11 (6.2%)	8 (4.7%)	19 (6.9%)
Menopausal symptoms	2 (1.1%)	1 (0.6%)	3 (6.9%)
Ovarian cyst	2 (1.1%)	1 (0.6%)	3 (6.9%)
Amenorrhoea	1 (0.6%)	0 (0.0%)	1 (6.9%)
Breast discomfort	1 (0.6%)	0 (0.0%)	1 (6.9%)
Breast mass	0 (0.0%)	1 (0.6%)	1 (6.9%)
Breast ulceration	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cervical dysplasia	0 (0.0%)	1 (0.6%)	1 (6.9%)
Endometriosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Menstrual disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)
Premenstrual dysphoric disorder	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Rectocele	1 (0.6%)	0 (0.0%)	1 (6.9%)
Uterovaginal prolapse	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vaginal prolapse	0 (0.0%)	1 (0.6%)	1 (6.9%)
Respiratory, thoracic and mediastinal disorders	41 (23.2%)	40 (23.7%)	81 (8.4%)
Cough	19 (10.7%)	20 (11.8%)	39 (6.9%)
Dyspnoea	7 (4.0%)	8 (4.7%)	15 (6.9%)
Rhinitis allergic	8 (4.5%)	6 (3.6%)	14 (6.9%)
Asthma	7 (4.0%)	5 (3.0%)	12 (6.9%)
Pleural effusion	1 (0.6%)	5 (3.0%)	6 (6.9%)
Dysphonia	1 (0.6%)	1 (0.6%)	2 (6.9%)
Productive cough	2 (1.1%)	0 (0.0%)	2 (6.9%)
Sleep apnoea syndrome	1 (0.6%)	1 (0.6%)	2 (6.9%)
Bronchial hyperreactivity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Bronchospasm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Chronic obstructive pulmonary disease	1 (0.6%)	0 (0.0%)	1 (6.9%)
Dyspnoea exertional	0 (0.0%)	1 (0.6%)	1 (6.9%)
Hyperventilation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Nasal septum deviation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Oropharyngeal pain	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pleuritic pain	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pulmonary arterial hypertension	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pulmonary artery thrombosis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pulmonary embolism	0 (0.0%)	1 (0.6%)	1 (6.9%)
Pulmonary hypertension	0 (0.0%)	1 (0.6%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Pulmonary mass	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pulmonary toxicity	1 (0.6%)	0 (0.0%)	1 (6.9%)
Pulmonary venous thrombosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sinus congestion	0 (0.0%)	1 (0.6%)	1 (6.9%)
Tracheal mass	1 (0.6%)	0 (0.0%)	1 (6.9%)
Skin and subcutaneous tissue disorders	18 (10.2%)	8 (4.7%)	26 (8.4%)
Dermatitis atopic	2 (1.1%)	1 (0.6%)	3 (6.9%)
Dry skin	1 (0.6%)	2 (1.2%)	3 (6.9%)
Dermatitis contact	2 (1.1%)	0 (0.0%)	2 (6.9%)
Eczema	1 (0.6%)	1 (0.6%)	2 (6.9%)
Pruritus	2 (1.1%)	0 (0.0%)	2 (6.9%)
Actinic keratosis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Alopecia	1 (0.6%)	0 (0.0%)	1 (6.9%)
Dermatitis	0 (0.0%)	1 (0.6%)	1 (6.9%)
Dermatitis acneiform	0 (0.0%)	1 (0.6%)	1 (6.9%)
Dermatitis allergic	1 (0.6%)	0 (0.0%)	1 (6.9%)
Erythema	1 (0.6%)	0 (0.0%)	1 (6.9%)
Henoch-Schonlein purpura	0 (0.0%)	1 (0.6%)	1 (6.9%)
Nail bed bleeding	1 (0.6%)	0 (0.0%)	1 (6.9%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.0%)	1 (0.6%)	1 (6.9%)
Psoriasis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Rash	0 (0.0%)	1 (0.6%)	1 (6.9%)
Rash erythematous	1 (0.6%)	0 (0.0%)	1 (6.9%)
Skin mass	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Skin ulcer	1 (0.6%)	0 (0.0%)	1 (6.9%)
Xeroderma	1 (0.6%)	0 (0.0%)	1 (6.9%)
Social circumstances	5 (2.8%)	4 (2.4%)	9 (8.4%)
Edentulous	2 (1.1%)	0 (0.0%)	2 (6.9%)
Menopause	1 (0.6%)	1 (0.6%)	2 (6.9%)
Postmenopause	0 (0.0%)	2 (1.2%)	2 (6.9%)
Ex-tobacco user	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint prosthesis user	1 (0.6%)	0 (0.0%)	1 (6.9%)
Orthodontic appliance user	0 (0.0%)	1 (0.6%)	1 (6.9%)
Surgical and medical procedures	46 (26.0%)	33 (19.5%)	79 (8.4%)
Hysterectomy	14 (7.9%)	7 (4.1%)	21 (6.9%)
Cholecystectomy	11 (6.2%)	5 (3.0%)	16 (6.9%)
Caesarean section	5 (2.8%)	3 (1.8%)	8 (6.9%)
Female sterilisation	3 (1.7%)	4 (2.4%)	7 (6.9%)
Salpingo-oophorectomy bilateral	2 (1.1%)	3 (1.8%)	5 (6.9%)
Appendicectomy	4 (2.3%)	0 (0.0%)	4 (6.9%)
Tonsillectomy	1 (0.6%)	3 (1.8%)	4 (6.9%)
Breast conserving surgery	2 (1.1%)	1 (0.6%)	3 (6.9%)
Hysterosalpingo-oophorectomy	3 (1.7%)	0 (0.0%)	3 (6.9%)
Mastectomy	3 (1.7%)	0 (0.0%)	3 (6.9%)
Cardiac pacemaker insertion	2 (1.1%)	0 (0.0%)	2 (6.9%)
Central venous catheterisation	2 (1.1%)	0 (0.0%)	2 (6.9%)
Corneal transplant	2 (1.1%)	0 (0.0%)	2 (6.9%)
Fracture treatment	1 (0.6%)	1 (0.6%)	2 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hip arthroplasty	0 (0.0%)	2 (1.2%)	2 (6.9%)
Knee arthroplasty	2 (1.1%)	0 (0.0%)	2 (6.9%)
Oophorectomy	2 (1.1%)	0 (0.0%)	2 (6.9%)
Ovarian cystectomy	0 (0.0%)	2 (1.2%)	2 (6.9%)
Thyroidectomy	1 (0.6%)	1 (0.6%)	2 (6.9%)
Aortic valve replacement	1 (0.6%)	0 (0.0%)	1 (6.9%)
Axillary lymphadenectomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Breast reconstruction	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cartilage operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Cataract operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Constipation prophylaxis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Corneal operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Eye excision	0 (0.0%)	1 (0.6%)	1 (6.9%)
Eye prosthesis insertion	0 (0.0%)	1 (0.6%)	1 (6.9%)
Gastric ulcer surgery	1 (0.6%)	0 (0.0%)	1 (6.9%)
Gastrointestinal disorder prophylaxis	1 (0.6%)	0 (0.0%)	1 (6.9%)
Hernia repair	1 (0.6%)	0 (0.0%)	1 (6.9%)
Implantable cardiac monitor insertion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Joint arthroplasty	0 (0.0%)	1 (0.6%)	1 (6.9%)
Knee operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Lung operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Lymphadenectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Mammoplasty	0 (0.0%)	1 (0.6%)	1 (6.9%)
Metabolic surgery	1 (0.6%)	0 (0.0%)	1 (6.9%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Myomectomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Myopia correction	1 (0.6%)	0 (0.0%)	1 (6.9%)
Nasal septal operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Oophorectomy bilateral	1 (0.6%)	0 (0.0%)	1 (6.9%)
Ovarian operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Peptic ulcer repair	1 (0.6%)	0 (0.0%)	1 (6.9%)
Radical mastectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Red blood cell transfusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Retinal operation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Salpingo-oophorectomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Salpingo-oophorectomy unilateral	0 (0.0%)	1 (0.6%)	1 (6.9%)
Skin graft	1 (0.6%)	0 (0.0%)	1 (6.9%)
Spinal operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Sterilisation	0 (0.0%)	1 (0.6%)	1 (6.9%)
Surgery	1 (0.6%)	0 (0.0%)	1 (6.9%)
Synovectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Thrombectomy	0 (0.0%)	1 (0.6%)	1 (6.9%)
Thyroid nodule removal	0 (0.0%)	1 (0.6%)	1 (6.9%)
Tracheostomy	1 (0.6%)	0 (0.0%)	1 (6.9%)
Transfusion	1 (0.6%)	0 (0.0%)	1 (6.9%)
Varicose vein operation	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vascular access placement	1 (0.6%)	0 (0.0%)	1 (6.9%)
Wisdom teeth removal	1 (0.6%)	0 (0.0%)	1 (6.9%)
Vascular disorders	69 (39.0%)	53 (31.4%)	122 (8.4%)

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Hypertension	59 (33.3%)	49 (29.0%)	108 (6.9%)
Lymphoedema	4 (2.3%)	4 (2.4%)	8 (6.9%)
Deep vein thrombosis	4 (2.3%)	2 (1.2%)	6 (6.9%)
Varicose vein	3 (1.7%)	2 (1.2%)	5 (6.9%)
Peripheral venous disease	3 (1.7%)	0 (0.0%)	3 (6.9%)
Hot flush	1 (0.6%)	1 (0.6%)	2 (6.9%)
Aneurysm	0 (0.0%)	1 (0.6%)	1 (6.9%)
Orthostatic hypotension	1 (0.6%)	0 (0.0%)	1 (6.9%)
Raynaud's phenomenon	1 (0.6%)	0 (0.0%)	1 (6.9%)
White coat hypertension	0 (0.0%)	1 (0.6%)	1 (6.9%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Medical history was coded according to MedDRA Version 27.1.
Participants may report >=1 medical history per system organ class or preferred term. At each level of summarization, a participant was counted once if the participant reported 1 or more medical history.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
Data Cut Date: 27 October 2025.

Source: mITT1/Table4.Summary of Medical History.R

4.5. Table 1.1.5: Summary of Prior Systemic Therapy — mITT — Excluding patients preselected to receive nab-paclitaxel

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
Patients with Prior Systemic Therapy	117 (66.1%)	118 (69.8%)	235 (67.9%)
Number of Prior Regimens			
1	62 (35.0%)	65 (38.5%)	127 (36.7%)
2	37 (20.9%)	38 (22.5%)	75 (21.7%)
3	17 (9.6%)	11 (6.5%)	28 (8.1%)
4	1 (0.6%)	4 (2.4%)	5 (1.4%)
Regimen Setting			

Characteristic	SG (N=177)	TPC (N=169)	Total (N=346)
ADJUVANT	85 (48.0%)	73 (43.2%)	158 (45.7%)
NEO-ADJUVANT	32 (18.1%)	44 (26.0%)	76 (22.0%)
METASTATIC	0 (0.0%)	1 (0.6%)	1 (0.3%)
Best Response to Prior Therapy			
Complete Remission	18 (10.2%)	19 (11.2%)	37 (10.7%)
Partial Remission	14 (7.9%)	14 (8.3%)	28 (8.1%)
Stable Disease	7 (4.0%)	10 (5.9%)	17 (4.9%)
Progressive Disease	7 (4.0%)	13 (7.7%)	20 (5.8%)
Unevaluable	6 (3.4%)	5 (3.0%)	11 (3.2%)
Not Available	40 (22.6%)	29 (17.2%)	69 (19.9%)
Unknown	25 (14.1%)	28 (16.6%)	53 (15.3%)
Progression After Prior Therapy			
Yes	97 (54.8%)	94 (55.6%)	191 (55.2%)
No	20 (11.3%)	24 (14.2%)	44 (12.7%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
Data Cut Date: 27 October 2025.

Source: mITT1/Table5.Summary of Prior Systemic Therapy.R

4.6. Table 1.1.6: Prior Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Participants with Any Prior Anti-Cancer Therapy, n (%)	117 (66.1%)	118 (69.8%)	235 (67.9%)
Prior Neoadjuvant or Adjuvant Anti-cancer Therapy [a]			
Yes	117 (66.1%)	117 (69.2%)	234 (67.6%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Taxanes	101 (57.1%)	102 (60.4%)	203 (58.7%)
Anthracyclines	93 (52.5%)	97 (57.4%)	190 (54.9%)
Platinum	23 (13.0%)	21 (12.4%)	44 (12.7%)
Anti-PD-1/PD-L1 agents	9 (5.1%)	5 (3.0%)	14 (4.0%)
Capecitabine	33 (18.6%)	31 (18.3%)	64 (18.5%)
PARP inhibitors	1 (0.6%)	0	1 (0.3%)
Other	107 (60.5%)	103 (60.9%)	210 (60.7%)
No	0	1 (0.6%)	1 (0.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Denominator of percentages is the number of participants in each treatment group.
[a] Participants can receive multiple categories of prior neoadjuvant or adjuvant anti-cancer therapy. Participants who received any prior neoadjuvant or adjuvant anti-cancer therapy will be summarized as "Yes". Participants who received prior anti-cancer therapy but did not receive any prior neoadjuvant/adjuvant anti-cancer therapy will be summarized as "No".
Data Cut Date: 27 October 2025.

Source: mITT1/Table6.Prior Anti-Cancer Therapy.R

4.7. Table 1.1.7: Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Participants with Any Subsequent Anti Cancer Therapy, n (%)	103 (58.2%)	121 (71.6%)	224 (64.7%)
Taxanes	42 (23.7%)	20 (11.8%)	62 (17.9%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.6%)	1 (0.3%)
DOCETAXEL	4 (2.3%)	3 (1.8%)	7 (2.0%)
PACLITAXEL	34 (19.2%)	14 (8.3%)	48 (13.9%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	6 (3.4%)	2 (1.2%)	8 (2.3%)
Anthracyclines	19 (10.7%)	16 (9.5%)	35 (10.1%)
DOXORUBICIN	6 (3.4%)	7 (4.1%)	13 (3.8%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
DOXORUBICIN HYDROCHLORIDE	1 (0.6%)	4 (2.4%)	5 (1.4%)
EPIRUBICIN	5 (2.8%)	3 (1.8%)	8 (2.3%)
EPIRUBICIN HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
LIPOSOMAL DOXORUBICIN	2 (1.1%)	1 (0.6%)	3 (0.9%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	5 (2.8%)	1 (0.6%)	6 (1.7%)
Platinum	45 (25.4%)	23 (13.6%)	68 (19.7%)
CARBOPLATIN	39 (22.0%)	19 (11.2%)	58 (16.8%)
CISPLATIN	6 (3.4%)	4 (2.4%)	10 (2.9%)
Anti-PD-1/PD-L1 agents	8 (4.5%)	9 (5.3%)	17 (4.9%)
ATEZOLIZUMAB	1 (0.6%)	2 (1.2%)	3 (0.9%)
PEMBROLIZUMAB	7 (4.0%)	5 (3.0%)	12 (3.5%)
SINTILIMAB	0	1 (0.6%)	1 (0.3%)
TISLELIZUMAB	0	1 (0.6%)	1 (0.3%)
PARP inhibitors	4 (2.3%)	3 (1.8%)	7 (2.0%)
OLAPARIB	4 (2.3%)	2 (1.2%)	6 (1.7%)
TALAZOPARIB	0	1 (0.6%)	1 (0.3%)
ADC	21 (11.9%)	105 (62.1%)	126 (36.4%)
SACITUZUMAB GOVITECAN	1 (0.6%)	104 (61.5%)	105 (30.3%)
TRASTUZUMAB DERUXTECAN	18 (10.2%)	19 (11.2%)	37 (10.7%)
TRASTUZUMAB DERUXTECAN NXKI	2 (1.1%)	0	2 (0.6%)
Other	74 (41.8%)	65 (38.5%)	139 (40.2%)
ABBV 400	1 (0.6%)	0	1 (0.3%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.6%)	0	1 (0.3%)
BEVACIZUMAB	6 (3.4%)	3 (1.8%)	9 (2.6%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
CAPECITABINE	27 (15.3%)	30 (17.8%)	57 (16.5%)
CATEQUENTINIB HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
CHLORINE DIOXIDE	0	1 (0.6%)	1 (0.3%)
CYCLOPHOSPHAMIDE	10 (5.6%)	10 (5.9%)	20 (5.8%)
ERIBULIN	22 (12.4%)	14 (8.3%)	36 (10.4%)
ERIBULIN MESILATE	7 (4.0%)	10 (5.9%)	17 (4.9%)
ETOPOSIDE	0	1 (0.6%)	1 (0.3%)
FLUOROURACIL	3 (1.7%)	2 (1.2%)	5 (1.4%)
GEMCITABINE	22 (12.4%)	12 (7.1%)	34 (9.8%)
GEMCITABINE HYDROCHLORIDE	8 (4.5%)	5 (3.0%)	13 (3.8%)
GEN 1047	0	1 (0.6%)	1 (0.3%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	3 (1.7%)	0	3 (0.9%)
IMC 002	0	1 (0.6%)	1 (0.3%)
INVESTIGATIONAL DRUG	1 (0.6%)	1 (0.6%)	2 (0.6%)
IXABEPILONE	0	1 (0.6%)	1 (0.3%)
LAROTRECTINIB	0	1 (0.6%)	1 (0.3%)
METHOTREXATE	2 (1.1%)	3 (1.8%)	5 (1.4%)
NADUNOLIMAB	1 (0.6%)	0	1 (0.3%)
NATURAL KILLER CELLS	1 (0.6%)	0	1 (0.3%)
NIVOLUMAB	0	3 (1.8%)	3 (0.9%)
ONDANSETRON	1 (0.6%)	0	1 (0.3%)
PERTUZUMAB	1 (0.6%)	0	1 (0.3%)
RADIOTHERAPY	1 (0.6%)	0	1 (0.3%)
REPOTRECTINIB	0	1 (0.6%)	1 (0.3%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
RUCAPARIB	0	1 (0.6%)	1 (0.3%)
TRASTUZUMAB	1 (0.6%)	0	1 (0.3%)
TUCATINIB	1 (0.6%)	0	1 (0.3%)
TUMOR-INFILTRATING LYMPHOCYTES	0	1 (0.6%)	1 (0.3%)
VINORELBINE	6 (3.4%)	4 (2.4%)	10 (2.9%)
VINORELBINE TARTRATE	4 (2.3%)	4 (2.4%)	8 (2.3%)
XMT 1660	1 (0.6%)	0	1 (0.3%)
ZEN 3694	0	1 (0.6%)	1 (0.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name.
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 27 October 2025.

Source: mITT1/Table10.Subsequent Anti cancer by preferred drug name.R

4.8. Table 1.1.8: First Subsequent Anti-Cancer Therapy by Category and Preferred Drug Name — mITT — Excluding patients preselected to receive nab-paclitaxel

Category	SG (N=177)	TPC (N=169)	Total (N=346)
Participants with First Subsequent Anti-Cancer Therapy, n (%)	103 (58.2%)	120 (71.0%)	223 (64.5%)
Taxanes	36 (20.3%)	5 (3.0%)	41 (11.8%)
ALBUMIN HUMAN;PACLITAXEL	0	1 (0.6%)	1 (0.3%)
DOCETAXEL	2 (1.1%)	1 (0.6%)	3 (0.9%)
PACLITAXEL	29 (16.4%)	2 (1.2%)	31 (9.0%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	5 (2.8%)	1 (0.6%)	6 (1.7%)
Anthracyclines	7 (4.0%)	2 (1.2%)	9 (2.6%)
DOXORUBICIN	1 (0.6%)	0	1 (0.3%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
EPIRUBICIN	2 (1.1%)	2 (1.2%)	4 (1.2%)
EPIRUBICIN HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
LIPOSOMAL DOXORUBICIN	1 (0.6%)	0	1 (0.3%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	2 (1.1%)	0	2 (0.6%)
Platinum	35 (19.8%)	2 (1.2%)	37 (10.7%)
CARBOPLATIN	29 (16.4%)	2 (1.2%)	31 (9.0%)
CISPLATIN	6 (3.4%)	0	6 (1.7%)
Anti-PD-1/PD-L1 agents	5 (2.8%)	2 (1.2%)	7 (2.0%)
ATEZOLIZUMAB	1 (0.6%)	1 (0.6%)	2 (0.6%)
PEMBROLIZUMAB	4 (2.3%)	0	4 (1.2%)
SINTILIMAB	0	1 (0.6%)	1 (0.3%)
PARP inhibitors	3 (1.7%)	2 (1.2%)	5 (1.4%)
OLAPARIB	3 (1.7%)	1 (0.6%)	4 (1.2%)
TALAZOPARIB	0	1 (0.6%)	1 (0.3%)
ADC	10 (5.6%)	97 (57.4%)	107 (30.9%)
SACITUZUMAB GOVITECAN	0	95 (56.2%)	95 (27.5%)
TRASTUZUMAB DERUXTECAN	8 (4.5%)	2 (1.2%)	10 (2.9%)
TRASTUZUMAB DERUXTECAN NXKI	2 (1.1%)	0	2 (0.6%)
Other	60 (33.9%)	16 (9.5%)	76 (22.0%)
ABBV 400	1 (0.6%)	0	1 (0.3%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.6%)	0	1 (0.3%)
BEVACIZUMAB	5 (2.8%)	0	5 (1.4%)
CAPECITABINE	15 (8.5%)	11 (6.5%)	26 (7.5%)
CYCLOPHOSPHAMIDE	4 (2.3%)	1 (0.6%)	5 (1.4%)

Category	SG (N=177)	TPC (N=169)	Total (N=346)
ERIBULIN	14 (7.9%)	1 (0.6%)	15 (4.3%)
ERIBULIN MESILATE	2 (1.1%)	0	2 (0.6%)
GEMCITABINE	18 (10.2%)	1 (0.6%)	19 (5.5%)
GEMCITABINE HYDROCHLORIDE	3 (1.7%)	1 (0.6%)	4 (1.2%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	1 (0.6%)	0	1 (0.3%)
INVESTIGATIONAL DRUG	1 (0.6%)	0	1 (0.3%)
LAROTRECTINIB	0	1 (0.6%)	1 (0.3%)
NADUNOLIMAB	1 (0.6%)	0	1 (0.3%)
NATURAL KILLER CELLS	1 (0.6%)	0	1 (0.3%)
PERTUZUMAB	1 (0.6%)	0	1 (0.3%)
TRASTUZUMAB	1 (0.6%)	0	1 (0.3%)
TUCATINIB	1 (0.6%)	0	1 (0.3%)
VINORELBINE	2 (1.1%)	0	2 (0.6%)
VINORELBINE TARTRATE	1 (0.6%)	0	1 (0.3%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
The denominator of percentages is the number of participants in each treatment group.
Medications are mapped using WHODRUG dictionary version BMAR24.
Participants are counted only once for each category and preferred drug name. Participants may be counted in more than one drug category if they received multiple drugs as part of their first subsequent anti-cancer therapy. The total number of participants with any subsequent anti-cancer therapy differs by 1 from the first subsequent therapy count because one patient in the TPC arm has a missing first subsequent therapy record but has two entries recorded for the fourth subsequent therapy. This patient is therefore counted in "Participants with any subsequent anti-cancer therapy" but not in "First subsequent anti-cancer therapy"
The preferred drug name "Sacituzumab Govitecan" includes both commercial use and crossover to SG on study.
Data Cut Date: 27 October 2025.

Source: mITT1/Table11.First Subsequent Anti-cancer therapy by Preferred drug name.R

5. Efficacy - mITT — Excluding patients preselected to receive nab-paclitaxel

5.1. Table 1.1.1: Observation Period (Months) for Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	SG (N=177)	TPC (N=169)	Total (N=346)
Observation Period (months)			
N	177	169	346
Mean (SD)	17 (7.8)	16.5 (7.4)	16.8 (7.6)
Median	17.5	17.3	17.4
Q1, Q3	12.1, 22.2	11.3, 21.5	11.5, 22
Min, Max	0.5, 35	0, 34.2	0, 35

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
Observation period is defined as time from randomisation to death date or the last date known alive.
Data Cut Date: 27 OCT 2025.

5.2. Table 1.1.2: Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events (Death)	91 (51.4%)	96 (56.8%)
Number (%) of Participants Censored	86 (48.6%)	73 (43.2%)
Ongoing [a]	82 (46.3%)	66 (39.1%)
Discontinued Study	4 (2.3%)	7 (4.1%)
Kaplan-Meier Estimate of OS (Months) (95% CI) [b]		
Q1	12.68 (10.32, 15.34)	11.73 (9.66, 14.03)
Median	21.45 (17.71, 26.55)	19.68 (17.38, 22.51)

Parameter	SG (N=177)	TPC (N=169)
Q3	NR (NR, NR)	28.75 (26.38, NR)
Absolute Difference in Median OS, SG vs TPC (Months)	1.77	
Kaplan-Meier Estimate of OS Rate (95% CI) [b]		
At 12 Months	0.762 (0.692, 0.818)	0.741 (0.667, 0.801)
At 18 Months	0.569 (0.491, 0.640)	0.566 (0.486, 0.638)
At 24 Months	0.439 (0.354, 0.521)	0.391 (0.307, 0.474)
At 30 Months	0.366 (0.261, 0.471)	0.232 (0.113, 0.377)
At 36 Months	NR (NR, NR)	NR (NR, NR)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.4119	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.886 (0.663, 1.183)	
Duration of OS Follow-up (Months) [e]		
N	177	169
Mean (StD)	17.04 (7.768)	16.49 (7.416)
Median	17.51	17.28
Q1, Q3	12.06, 22.24	11.30, 21.52
Min, Max	0.53, 34.99	0.03, 34.23
>=12 Months	133 (75.1%)	122 (72.2%)
>=18 Months	83 (46.9%)	81 (47.9%)
>=24 Months	29 (16.4%)	29 (17.2%)
>=30 Months	7 (4.0%)	3 (1.8%)
>=36 Months	0	0

SG = sacituzumab govitecan, TPC = treatment of physician's choice; NR = Not Reached; IWRS = Interactive Web Response System.
[a] Ongoing participants are those who have not discontinued participation in the study by the data cutoff date.
[b] OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Based on Kaplan-Meier estimates with 95% CI using the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test, adjusted for randomization stratification factors (IWRS).
[d] Hazard ratio and 95% CIs are calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).

Parameter	SG (N=177)	TPC (N=169)

[e] Duration of OS follow-up (months) = (date of death or censoring - date of randomization + 1) / 30.4375.
Data Cut Date: 27 OCT 2025.

5.3. Table 1.1.3: Subgroup Analysis of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

label	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.4473
Number (%) of Participants with Events (Death)	26 (47.3%)	32 (65.3%)	
Number (%) of Participants Censored	29 (52.7%)	17 (34.7%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (16.62, NR)	18.00 (13.11, 24.38)	
Log-Rank Test p-value (unstratified)	0.1571		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.689 (0.410, 1.158)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Death)	20 (58.8%)	22 (64.7%)	
Number (%) of Participants Censored	14 (41.2%)	12 (35.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.54 (15.93, NR)	16.99 (13.70, 22.44)	
Log-Rank Test p-value (unstratified)	0.4826		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.805 (0.439, 1.476)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Death)	45 (51.1%)	42 (48.8%)	
Number (%) of Participants Censored	43 (48.9%)	44 (51.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

label	SG (N=177)	TPC (N=169)	Interaction
Median	21.45 (17.41, NR)	21.26 (18.04, NR)	
Log-Rank Test p-value (unstratified)	0.8133		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.052 (0.690, 1.602)		
Geographic region			
US/Canada/Western Europe	56	52	0.1284
Number (%) of Participants with Events (Death)	26 (46.4%)	33 (63.5%)	
Number (%) of Participants Censored	30 (53.6%)	19 (36.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	26.55 (17.51, NR)	18.04 (13.50, 21.75)	
Log-Rank Test p-value (unstratified)	0.0691		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.623 (0.373, 1.043)		
Rest of the world	121	117	
Number (%) of Participants with Events (Death)	65 (53.7%)	63 (53.8%)	
Number (%) of Participants Censored	56 (46.3%)	54 (46.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.14 (17.41, 25.53)	20.24 (17.22, 24.38)	
Log-Rank Test p-value (unstratified)	0.9573		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.010 (0.713, 1.429)		
Age group			
< 65	133	131	0.7042
Number (%) of Participants with Events (Death)	68 (51.1%)	71 (54.2%)	
Number (%) of Participants Censored	65 (48.9%)	60 (45.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.74, 26.55)	19.75 (17.22, 27.27)	

label	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.4851		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.888 (0.636, 1.239)		
>= 65	44	38	
Number (%) of Participants with Events (Death)	23 (52.3%)	25 (65.8%)	
Number (%) of Participants Censored	21 (47.7%)	13 (34.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.78 (11.40, NR)	18.69 (14.55, 22.93)	
Log-Rank Test p-value (unstratified)	0.4553		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.806 (0.456, 1.422)		
Race			
White	115	104	0.2564
Number (%) of Participants with Events (Death)	63 (54.8%)	64 (61.5%)	
Number (%) of Participants Censored	52 (45.2%)	40 (38.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.86 (16.95, 23.52)	18.69 (15.41, 21.26)	
Log-Rank Test p-value (unstratified)	0.3664		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.601, 1.206)		
Asian	38	38	
Number (%) of Participants with Events (Death)	15 (39.5%)	13 (34.2%)	
Number (%) of Participants Censored	23 (60.5%)	25 (65.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (17.71, NR)	27.27 (22.93, NR)	
Log-Rank Test p-value (unstratified)	0.5773		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.234 (0.586, 2.601)		

label	SG (N=177)	TPC (N=169)	Interaction
Other	19	24	
Number (%) of Participants with Events (Death)	10 (52.6%)	17 (70.8%)	
Number (%) of Participants Censored	9 (47.4%)	7 (29.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	26.55 (13.31, NR)	14.85 (10.51, 19.61)	
Log-Rank Test p-value (unstratified)	0.1078		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.514 (0.225, 1.173)		
Baseline ECOG status			
0	116	106	0.8300
Number (%) of Participants with Events (Death)	52 (44.8%)	52 (49.1%)	
Number (%) of Participants Censored	64 (55.2%)	54 (50.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	25.53 (18.99, NR)	22.44 (19.38, 28.75)	
Log-Rank Test p-value (unstratified)	0.5494		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.889 (0.605, 1.306)		
1	61	63	
Number (%) of Participants with Events (Death)	39 (63.9%)	44 (69.8%)	
Number (%) of Participants Censored	22 (36.1%)	19 (30.2%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	16.95 (12.68, 21.45)	15.15 (10.55, 18.73)	
Log-Rank Test p-value (unstratified)	0.5338		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.872 (0.566, 1.343)		
Physician's choice of chemotherapy			
Taxane	52	45	0.0346

label	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Death)	19 (36.5%)	27 (60.0%)	
Number (%) of Participants Censored	33 (63.5%)	18 (40.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	NR (20.86, NR)	19.75 (14.03, 28.75)	
Log-Rank Test p-value (unstratified)	0.0248		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.516 (0.286, 0.929)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Death)	72 (57.6%)	69 (55.6%)	
Number (%) of Participants Censored	53 (42.4%)	55 (44.4%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.50 (16.62, 22.14)	19.68 (17.84, 22.93)	
Log-Rank Test p-value (unstratified)	0.7508		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.055 (0.758, 1.469)		
History of liver metastasis			
Yes	47	39	0.6007
Number (%) of Participants with Events (Death)	32 (68.1%)	29 (74.4%)	
Number (%) of Participants Censored	15 (31.9%)	10 (25.6%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	15.80 (11.20, 19.15)	12.48 (7.69, 16.99)	
Log-Rank Test p-value (unstratified)	0.2878		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.761 (0.460, 1.260)		
No	130	130	
Number (%) of Participants with Events (Death)	59 (45.4%)	67 (51.5%)	
Number (%) of Participants Censored	71 (54.6%)	63 (48.5%)	

label	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	22.87 (20.14, NR)	21.75 (18.73, 26.38)	
Log-Rank Test p-value (unstratified)	0.4055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.862 (0.607, 1.224)		
History of brain metastasis			
Yes	8	9	0.9366
Number (%) of Participants with Events (Death)	6 (75.0%)	6 (66.7%)	
Number (%) of Participants Censored	2 (25.0%)	3 (33.3%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	17.48 (0.85, NR)	13.50 (0.16, NR)	
Log-Rank Test p-value (unstratified)	0.5485		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.680 (0.191, 2.417)		
No	169	160	
Number (%) of Participants with Events (Death)	85 (50.3%)	90 (56.2%)	
Number (%) of Participants Censored	84 (49.7%)	70 (43.8%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.71, 29.17)	19.75 (17.38, 22.93)	
Log-Rank Test p-value (unstratified)	0.3352		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.864 (0.642, 1.163)		
PD-L1 Status			
CPS < 1	67	59	0.4966
Number (%) of Participants with Events (Death)	32 (47.8%)	35 (59.3%)	
Number (%) of Participants Censored	35 (52.2%)	24 (40.7%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			

label	SG (N=177)	TPC (N=169)	Interaction
Median	25.53 (15.34, NR)	19.91 (13.50, 25.17)	
Log-Rank Test p-value (unstratified)	0.2400		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.751 (0.465, 1.213)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Death)	59 (54.1%)	61 (55.5%)	
Number (%) of Participants Censored	50 (45.9%)	49 (44.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.86 (17.54, 26.55)	19.68 (16.99, 24.38)	
Log-Rank Test p-value (unstratified)	0.6751		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.926 (0.647, 1.326)		
BRCA 1/2 status			
Wild-Type	66	65	0.1625
Number (%) of Participants with Events (Death)	35 (53.0%)	38 (58.5%)	
Number (%) of Participants Censored	31 (47.0%)	27 (41.5%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	20.14 (16.26, NR)	18.43 (13.70, 25.17)	
Log-Rank Test p-value (unstratified)	0.3184		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.791 (0.499, 1.255)		
Mutant	12	10	
Number (%) of Participants with Events (Death)	6 (50.0%)	3 (30.0%)	
Number (%) of Participants Censored	6 (50.0%)	7 (70.0%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	26.55 (3.15, NR)	28.75 (7.72, NR)	
Log-Rank Test p-value (unstratified)	0.2844		

label	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.108 (0.522, 8.516)		
Menopausal status			
Pre-menopausal	37	49	0.1718
Number (%) of Participants with Events (Death)	23 (62.2%)	28 (57.1%)	
Number (%) of Participants Censored	14 (37.8%)	21 (42.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	18.99 (12.75, 23.52)	19.75 (15.01, 27.27)	
Log-Rank Test p-value (unstratified)	0.4307		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.247 (0.717, 2.168)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Death)	68 (48.6%)	68 (57.1%)	
Number (%) of Participants Censored	72 (51.4%)	51 (42.9%)	
Kaplan-Meier Estimate of OS (Months) (95% CI)			
Median	21.45 (17.71, NR)	18.73 (16.23, 22.93)	
Log-Rank Test p-value (unstratified)	0.1524		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.783 (0.559, 1.096)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
OS (months) = (date of death or censoring − date of randomisation + 1) / 30.4375. Median OS from Kaplan-Meier estimate. 95% CI based on log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
Log-rank test is unstratified.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Participants with unknown BRCA 1/2 status were excluded from that subgroup.
Disease stratification and geographic region are collected from IWRS.
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.4. Table 1.1.6: Follow-up Duration (Months) for PFS and Tumor Response by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	SG (N=177)	TPC (N=169)	Total (N=346)
Follow-up duration (months) for Progression-Free Survival by Blinded Independent Central Review (BICR) [a]			
N	177	169	346
Mean (SD)	8.9 (7)	6.8 (5.7)	7.9 (6.5)
Median	7	5.5	5.7
Q1, Q3	3, 15.1	2.8, 8.4	2.9, 11.1
Min, Max	0, 31.9	0, 26.4	0, 31.9
Tumor Response by Blinded Independent Central Review (BICR), n (%)			
CR	17 (9.6%)	11 (6.5%)	28 (8.1%)
PR	85 (48.0%)	76 (45.0%)	161 (46.5%)
SD	48 (27.1%)	52 (30.8%)	100 (28.9%)
PD	15 (8.5%)	17 (10.1%)	32 (9.2%)
NE	1 (0.6%)	2 (1.2%)	3 (0.9%)
NON-CR/NON-PD	1 (0.6%)	1 (0.6%)	2 (0.6%)
Missing/NE	10 (5.6%)	10 (5.9%)	20 (5.8%)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; BICR = blinded independent central review; IWRS = Interactive Web Response System; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE = not evaluable; NON-CR/NON-PD = non-complete response/non-progressive disease (applicable to non-measurable disease).
[a] Observation period for PFS is defined as time from randomisation to the event or censoring date of progression-free survival.
Tumour response assessed by BICR per RECIST v1.1; confirmed responses only.
Data Cut Date: 27 OCT 2025.

5.5. Table 1.1.7: Analysis of PFS by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events	113 (63.8%)	117 (69.2%)
Disease Progression (PD)	100 (56.5%)	112 (66.3%)

Parameter	SG (N=177)	TPC (N=169)
Death	13 (7.3%)	5 (3.0%)
Number (%) of Participants Censored	64 (36.2%)	52 (30.8%)
PD after Starting New Anti-Cancer Therapy	1 (0.6%)	1 (0.6%)
PD right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	1 (0.6%)	2 (1.2%)
Death after Starting New Anti-Cancer Therapy	17 (9.6%)	12 (7.1%)
Death right after >=2 Consecutive Missing and/or Not Evaluable Tumor Assessments	2 (1.1%)	5 (3.0%)
No PD and No Death without New Anti-Cancer Therapy	30 (16.9%)	15 (8.9%)
No PD and No Death with New Anti-Cancer Therapy	11 (6.2%)	12 (7.1%)
No Baseline or Postbaseline Evaluable Assessment [a]	2 (1.1%)	5 (3.0%)
Kaplan-Meier Estimate of PFS (Months) (95% CI) [b]		
Q1	4.17 (3.15, 5.39)	4.14 (3.06, 4.34)
Median	9.07 (7.16, 11.27)	6.93 (5.59, 8.28)
Q3	18.10 (15.21, 25.53)	12.32 (8.80, 15.18)
Absolute Difference in Median PFS, SG vs TPC (Months)	2.14	
Kaplan-Meier Estimate of PFS Rate (95% CI) [c]		
At 3 Months	0.832 (0.766, 0.881)	0.824 (0.754, 0.876)
At 6 Months	0.639 (0.560, 0.709)	0.543 (0.458, 0.620)
At 9 Months	0.501 (0.419, 0.577)	0.322 (0.244, 0.402)
At 12 Months	0.415 (0.336, 0.493)	0.253 (0.181, 0.331)
At 18 Months	0.277 (0.203, 0.356)	0.111 (0.059, 0.180)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [d]	0.0016	
Stratified Hazard Ratio of SG vs TPC (95% CI) [e]	0.651 (0.498, 0.851)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
[a] Censoring due to no baseline or no postbaseline evaluable assessment does not include death events before the second scheduled postbaseline visit.
[b] PFS (months) = (date of event or censoring − date of randomisation + 1) / 30.4375. The 95% CI is based on the log-log transformation.

Parameter	SG (N=177)	TPC (N=169)

[c] PFS rate is the proportion of participants alive without progressive disease (PD). The 95% CI is based on the log-log transformation.
[d] The two-sided p-value is from stratified log-rank test.
[e] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, stratified for randomization stratification factors (IWRS).
Data Cut Date: 27 OCT 2025.

5.6. Table 1.1.8: Analysis of PFS by BICR – Subgroup — mITT — Excluding patients preselected to receive nab-paclitaxel

label	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.5388
Number (%) of Participants with Events	37 (67.3%)	39 (79.6%)	
Disease Progression (PD)	32 (58.2%)	38 (77.6%)	
Death	5 (9.1%)	1 (2.0%)	
Number (%) of Participants Censored	18 (32.7%)	10 (20.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.31 (5.52, 15.21)	5.42 (4.14, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.552 (0.346, 0.881)		
p-value (Log-Rank Test, Unstratified)	0.0115		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events	26 (76.5%)	24 (70.6%)	
Disease Progression (PD)	25 (73.5%)	24 (70.6%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	8 (23.5%)	10 (29.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (5.39, 9.92)	6.74 (5.52, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.660 (0.373, 1.169)		
p-value (Log-Rank Test, Unstratified)	0.1495		

label	SG (N=177)	TPC (N=169)	Interaction
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events	50 (56.8%)	54 (62.8%)	
Disease Progression (PD)	43 (48.9%)	50 (58.1%)	
Death	7 (8.0%)	4 (4.7%)	
Number (%) of Participants Censored	38 (43.2%)	32 (37.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.76 (7.13, 15.31)	8.31 (5.59, 11.07)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.754 (0.512, 1.109)		
p-value (Log-Rank Test, Unstratified)	0.1504		
Geographic region			
US/Canada/Western Europe	56	52	0.5738
Number (%) of Participants with Events	34 (60.7%)	31 (59.6%)	
Disease Progression (PD)	32 (57.1%)	31 (59.6%)	
Death	2 (3.6%)	0	
Number (%) of Participants Censored	22 (39.3%)	21 (40.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (7.26, 15.21)	6.87 (5.39, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.604 (0.368, 0.991)		
p-value (Log-Rank Test, Unstratified)	0.0428		
Rest of the world	121	117	
Number (%) of Participants with Events	79 (65.3%)	86 (73.5%)	
Disease Progression (PD)	68 (56.2%)	81 (69.2%)	
Death	11 (9.1%)	5 (4.3%)	
Number (%) of Participants Censored	42 (34.7%)	31 (26.5%)	

label	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.77 (6.93, 12.45)	7.13 (5.49, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.722 (0.531, 0.983)		
p-value (Log-Rank Test, Unstratified)	0.0376		
Age group			
< 65	133	131	0.1935
Number (%) of Participants with Events	87 (65.4%)	95 (72.5%)	
Disease Progression (PD)	80 (60.2%)	92 (70.2%)	
Death	7 (5.3%)	3 (2.3%)	
Number (%) of Participants Censored	46 (34.6%)	36 (27.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.77 (7.13, 11.10)	6.93 (5.49, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.626 (0.467, 0.840)		
p-value (Log-Rank Test, Unstratified)	0.0016		
>= 65	44	38	
Number (%) of Participants with Events	26 (59.1%)	22 (57.9%)	
Disease Progression (PD)	20 (45.5%)	20 (52.6%)	
Death	6 (13.6%)	2 (5.3%)	
Number (%) of Participants Censored	18 (40.9%)	16 (42.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.76 (4.30, 15.21)	8.38 (5.42, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.954 (0.537, 1.694)		
p-value (Log-Rank Test, Unstratified)	0.8708		
Race			

label	SG (N=177)	TPC (N=169)	Interaction
White	115	104	0.5460
Number (%) of Participants with Events	75 (65.2%)	66 (63.5%)	
Disease Progression (PD)	68 (59.1%)	62 (59.6%)	
Death	7 (6.1%)	4 (3.8%)	
Number (%) of Participants Censored	40 (34.8%)	38 (36.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (6.93, 10.32)	6.93 (5.42, 8.31)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.760 (0.544, 1.061)		
p-value (Log-Rank Test, Unstratified)	0.1052		
Asian	38	38	
Number (%) of Participants with Events	23 (60.5%)	31 (81.6%)	
Disease Progression (PD)	19 (50.0%)	31 (81.6%)	
Death	4 (10.5%)	0	
Number (%) of Participants Censored	15 (39.5%)	7 (18.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (7.13, 18.07)	7.06 (4.21, 8.57)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.521 (0.300, 0.906)		
p-value (Log-Rank Test, Unstratified)	0.0189		
Other	19	24	
Number (%) of Participants with Events	12 (63.2%)	17 (70.8%)	
Disease Progression (PD)	11 (57.9%)	16 (66.7%)	
Death	1 (5.3%)	1 (4.2%)	
Number (%) of Participants Censored	7 (36.8%)	7 (29.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=177)	TPC (N=169)	Interaction
Median	8.15 (5.52, 18.00)	7.13 (4.40, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.741 (0.350, 1.567)		
p-value (Log-Rank Test, Unstratified)	0.4357		
Baseline ECOG status			
0	116	106	0.4691
Number (%) of Participants with Events	68 (58.6%)	73 (68.9%)	
Disease Progression (PD)	62 (53.4%)	71 (67.0%)	
Death	6 (5.2%)	2 (1.9%)	
Number (%) of Participants Censored	48 (41.4%)	33 (31.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.45 (9.59, 15.21)	8.15 (6.87, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.618 (0.443, 0.863)		
p-value (Log-Rank Test, Unstratified)	0.0043		
1	61	63	
Number (%) of Participants with Events	45 (73.8%)	44 (69.8%)	
Disease Progression (PD)	38 (62.3%)	41 (65.1%)	
Death	7 (11.5%)	3 (4.8%)	
Number (%) of Participants Censored	16 (26.2%)	19 (30.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.55 (4.21, 7.13)	5.39 (4.14, 6.90)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.835 (0.548, 1.272)		
p-value (Log-Rank Test, Unstratified)	0.3996		
Physician's choice of chemotherapy			
Taxane	52	45	0.0023

label	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events	29 (55.8%)	35 (77.8%)	
Disease Progression (PD)	27 (51.9%)	33 (73.3%)	
Death	2 (3.8%)	2 (4.4%)	
Number (%) of Participants Censored	23 (44.2%)	10 (22.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	12.71 (7.66, 15.34)	5.39 (3.06, 7.29)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.330 (0.195, 0.560)		
p-value (Log-Rank Test, Unstratified)	<0.0001		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events	84 (67.2%)	82 (66.1%)	
Disease Progression (PD)	73 (58.4%)	79 (63.7%)	
Death	11 (8.8%)	3 (2.4%)	
Number (%) of Participants Censored	41 (32.8%)	42 (33.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.34 (6.90, 9.92)	8.08 (5.65, 8.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.867 (0.639, 1.177)		
p-value (Log-Rank Test, Unstratified)	0.3601		
History of liver metastasis			
Yes	47	39	0.2654
Number (%) of Participants with Events	38 (80.9%)	28 (71.8%)	
Disease Progression (PD)	34 (72.3%)	24 (61.5%)	
Death	4 (8.5%)	4 (10.3%)	
Number (%) of Participants Censored	9 (19.1%)	11 (28.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=177)	TPC (N=169)	Interaction
Median	7.16 (3.88, 9.59)	4.17 (2.76, 4.34)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.524 (0.314, 0.875)		
p-value (Log-Rank Test, Unstratified)	0.0119		
No	130	130	
Number (%) of Participants with Events	75 (57.7%)	89 (68.5%)	
Disease Progression (PD)	66 (50.8%)	88 (67.7%)	
Death	9 (6.9%)	1 (0.8%)	
Number (%) of Participants Censored	55 (42.3%)	41 (31.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.92 (7.66, 15.21)	8.28 (6.93, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.672 (0.493, 0.917)		
p-value (Log-Rank Test, Unstratified)	0.0117		
History of brain metastasis			
Yes	8	9	0.4227
Number (%) of Participants with Events	7 (87.5%)	6 (66.7%)	
Disease Progression (PD)	6 (75.0%)	5 (55.6%)	
Death	1 (12.5%)	1 (11.1%)	
Number (%) of Participants Censored	1 (12.5%)	3 (33.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (0.85, 8.54)	8.08 (0.16, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.904 (0.289, 2.830)		
p-value (Log-Rank Test, Unstratified)	0.8623		
No	169	160	
Number (%) of Participants with Events	106 (62.7%)	111 (69.4%)	

label	SG (N=177)	TPC (N=169)	Interaction
Disease Progression (PD)	94 (55.6%)	107 (66.9%)	
Death	12 (7.1%)	4 (2.5%)	
Number (%) of Participants Censored	63 (37.3%)	49 (30.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.72 (7.26, 12.71)	6.93 (5.55, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.677 (0.517, 0.886)		
p-value (Log-Rank Test, Unstratified)	0.0042		
PD-L1 Status			
CPS < 1	67	59	0.2926
Number (%) of Participants with Events	45 (67.2%)	35 (59.3%)	
Disease Progression (PD)	39 (58.2%)	34 (57.6%)	
Death	6 (9.0%)	1 (1.7%)	
Number (%) of Participants Censored	22 (32.8%)	24 (40.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.48 (6.93, 12.45)	7.06 (4.34, 12.35)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.841 (0.538, 1.315)		
p-value (Log-Rank Test, Unstratified)	0.4484		
CPS ≥ 1	109	110	
Number (%) of Participants with Events	68 (62.4%)	82 (74.5%)	
Disease Progression (PD)	61 (56.0%)	78 (70.9%)	
Death	7 (6.4%)	4 (3.6%)	
Number (%) of Participants Censored	41 (37.6%)	28 (25.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (6.90, 15.08)	6.90 (5.55, 8.28)	

label	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.617 (0.445, 0.855)		
p-value (Log-Rank Test, Unstratified)	0.0033		
BRCA 1/2 status			
Wild-Type	66	65	0.0740
Number (%) of Participants with Events	43 (65.2%)	46 (70.8%)	
Disease Progression (PD)	39 (59.1%)	45 (69.2%)	
Death	4 (6.1%)	1 (1.5%)	
Number (%) of Participants Censored	23 (34.8%)	19 (29.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.66 (4.53, 12.45)	5.52 (4.07, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.608 (0.398, 0.927)		
p-value (Log-Rank Test, Unstratified)	0.0196		
Mutant	12	10	
Number (%) of Participants with Events	9 (75.0%)	6 (60.0%)	
Disease Progression (PD)	7 (58.3%)	6 (60.0%)	
Death	2 (16.7%)	0	
Number (%) of Participants Censored	3 (25.0%)	4 (40.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.26 (1.51, NR)	10.84 (2.89, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.745 (0.612, 4.975)		
p-value (Log-Rank Test, Unstratified)	0.2920		
Menopausal status			
Pre-menopausal	37	49	0.9966
Number (%) of Participants with Events	24 (64.9%)	37 (75.5%)	

label	SG (N=177)	TPC (N=169)	Interaction
Disease Progression (PD)	22 (59.5%)	36 (73.5%)	
Death	2 (5.4%)	1 (2.0%)	
Number (%) of Participants Censored	13 (35.1%)	12 (24.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.93 (5.52, 15.08)	5.62 (4.21, 7.79)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.701 (0.418, 1.175)		
p-value (Log-Rank Test, Unstratified)	0.1758		
Post-menopausal	140	119	
Number (%) of Participants with Events	89 (63.6%)	79 (66.4%)	
Disease Progression (PD)	78 (55.7%)	75 (63.0%)	
Death	11 (7.9%)	4 (3.4%)	
Number (%) of Participants Censored	51 (36.4%)	40 (33.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.69 (7.26, 12.71)	8.11 (5.62, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.693 (0.509, 0.942)		
p-value (Log-Rank Test, Unstratified)	0.0181		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Intent-to-treat (ITT) Analysis Set includes all participants who were randomised in the study.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS (months) = (date of events or censoring − date of randomisation + 1) / 30.4375. 95% CI based on log-log transformation. Median PFS from Kaplan-Meier estimate.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
[a] Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.7. Table 1.1.9: Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events	111 (62.7%)	124 (73.4%)
Disease Progression (PD)	56 (31.6%)	87 (51.5%)
Death	55 (31.1%)	37 (21.9%)
Number (%) of Participants Censored	66 (37.3%)	45 (26.6%)
Alive Without PFS2 Event and Without Second Next-Line Therapy	22 (12.4%)	16 (9.5%)
Alive Without PFS2 Event and With Second Next-Line Therapy	4 (2.3%)	6 (3.6%)
Discontinued Study	0	0
No Baseline or Postbaseline Evaluable Assessment	0	0
Kaplan-Meier Estimate of PFS2 (Months) (95% CI) [a]		
Q1	9.95 (7.43, 11.40)	9.10 (7.16, 10.05)
Median	15.97 (13.80, 20.14)	13.21 (11.33, 14.75)
Q3	28.98 (24.84, NR)	20.24 (18.92, 25.17)
Absolute Difference in Median PFS2, SG vs TPC (Months)	2.76	
Kaplan-Meier Estimate of PFS2 Rate (95% CI) [b]		
At 3 Months	0.960 (0.919, 0.981)	0.964 (0.922, 0.984)
At 6 Months	0.847 (0.785, 0.893)	0.874 (0.813, 0.916)
At 9 Months	0.773 (0.704, 0.828)	0.759 (0.686, 0.817)
At 12 Months	0.657 (0.582, 0.723)	0.542 (0.462, 0.615)
At 18 Months	0.449 (0.373, 0.522)	0.326 (0.254, 0.401)
Treatment Comparison		
Stratified Log-rank p-value of SG vs TPC [c]	0.0050	
Stratified Hazard Ratio of SG vs TPC (95% CI) [d]	0.688 (0.530, 0.894)	

Parameter	SG (N=177)	TPC (N=169)

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first. Next line therapy is defined as the first new systemic anti-cancer therapy (including crossover treatment) initiated after discontinuation of study treatment regardless of end of treatment reason.
[a] Quantile of PFS2 is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (IWRS).
Data Cut Date: 27 OCT 2025.

5.8. Table 1.1.10: Subgroup Analysis of Second Progression-Free Survival (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel

label	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.3714
Number (%) of Participants with Events	46 (83.6%)	45 (91.8%)	
Disease Progression (PD)	41 (74.5%)	44 (89.8%)	
Death	5 (9.1%)	1 (2.0%)	
Number (%) of Participants Censored	9 (16.4%)	4 (8.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.59 (4.27, 10.32)	5.39 (3.98, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.608 (0.398, 0.931)		
p-value (Log-Rank Test, Unstratified)	0.0205		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events	28 (82.4%)	29 (85.3%)	
Disease Progression (PD)	27 (79.4%)	29 (85.3%)	
Death	1 (2.9%)	0	
Number (%) of Participants Censored	6 (17.6%)	5 (14.7%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			

label	SG (N=177)	TPC (N=169)	Interaction
Median	8.31 (4.37, 9.92)	5.63 (4.90, 7.20)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.541 (0.314, 0.932)		
p-value (Log-Rank Test, Unstratified)	0.0247		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events	72 (81.8%)	74 (86.0%)	
Disease Progression (PD)	65 (73.9%)	70 (81.4%)	
Death	7 (8.0%)	4 (4.7%)	
Number (%) of Participants Censored	16 (18.2%)	12 (14.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (4.53, 9.30)	6.34 (4.34, 8.28)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.832 (0.601, 1.153)		
p-value (Log-Rank Test, Unstratified)	0.2696		
Geographic region			
US/Canada/Western Europe	56	52	0.4981
Number (%) of Participants with Events	48 (85.7%)	45 (86.5%)	
Disease Progression (PD)	46 (82.1%)	45 (86.5%)	
Death	2 (3.6%)	0	
Number (%) of Participants Censored	8 (14.3%)	7 (13.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.92 (5.22, 9.30)	5.49 (2.99, 6.41)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.629 (0.415, 0.954)		
p-value (Log-Rank Test, Unstratified)	0.0273		
Rest of the world	121	117	
Number (%) of Participants with Events	98 (81.0%)	103 (88.0%)	

label	SG (N=177)	TPC (N=169)	Interaction
Disease Progression (PD)	87 (71.9%)	98 (83.8%)	
Death	11 (9.1%)	5 (4.3%)	
Number (%) of Participants Censored	23 (19.0%)	14 (12.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.00 (4.93, 9.07)	5.63 (4.53, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.745 (0.563, 0.985)		
p-value (Log-Rank Test, Unstratified)	0.0377		
Age group			
< 65	133	131	0.2005
Number (%) of Participants with Events	110 (82.7%)	116 (88.5%)	
Disease Progression (PD)	103 (77.4%)	113 (86.3%)	
Death	7 (5.3%)	3 (2.3%)	
Number (%) of Participants Censored	23 (17.3%)	15 (11.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.15 (5.55, 8.77)	5.50 (4.21, 6.74)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.653 (0.501, 0.849)		
p-value (Log-Rank Test, Unstratified)	0.0014		
>= 65	44	38	
Number (%) of Participants with Events	36 (81.8%)	32 (84.2%)	
Disease Progression (PD)	30 (68.2%)	30 (78.9%)	
Death	6 (13.6%)	2 (5.3%)	
Number (%) of Participants Censored	8 (18.2%)	6 (15.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.74 (2.89, 9.76)	6.41 (4.53, 8.38)	

label	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.952 (0.586, 1.547)		
p-value (Log-Rank Test, Unstratified)	0.8444		
Race			
White	115	104	0.7014
Number (%) of Participants with Events	98 (85.2%)	89 (85.6%)	
Disease Progression (PD)	91 (79.1%)	85 (81.7%)	
Death	7 (6.1%)	4 (3.8%)	
Number (%) of Participants Censored	17 (14.8%)	15 (14.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.93 (4.93, 8.34)	5.49 (4.21, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.746 (0.559, 0.997)		
p-value (Log-Rank Test, Unstratified)	0.0467		
Asian	38	38	
Number (%) of Participants with Events	28 (73.7%)	35 (92.1%)	
Disease Progression (PD)	24 (63.2%)	35 (92.1%)	
Death	4 (10.5%)	0	
Number (%) of Participants Censored	10 (26.3%)	3 (7.9%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.71 (3.88, 15.08)	5.55 (4.04, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.585 (0.352, 0.973)		
p-value (Log-Rank Test, Unstratified)	0.0368		
Other	19	24	
Number (%) of Participants with Events	16 (84.2%)	21 (87.5%)	
Disease Progression (PD)	15 (78.9%)	20 (83.3%)	

label	SG (N=177)	TPC (N=169)	Interaction
Death	1 (5.3%)	1 (4.2%)	
Number (%) of Participants Censored	3 (15.8%)	3 (12.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.36 (2.33, 12.71)	6.01 (4.24, 8.54)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.807 (0.417, 1.559)		
p-value (Log-Rank Test, Unstratified)	0.5276		
Baseline ECOG status			
0	116	106	0.9942
Number (%) of Participants with Events	91 (78.4%)	91 (85.8%)	
Disease Progression (PD)	85 (73.3%)	89 (84.0%)	
Death	6 (5.2%)	2 (1.9%)	
Number (%) of Participants Censored	25 (21.6%)	15 (14.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.07 (6.93, 10.28)	6.87 (5.49, 8.15)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.695 (0.518, 0.933)		
p-value (Log-Rank Test, Unstratified)	0.0147		
1	61	63	
Number (%) of Participants with Events	55 (90.2%)	57 (90.5%)	
Disease Progression (PD)	48 (78.7%)	54 (85.7%)	
Death	7 (11.5%)	3 (4.8%)	
Number (%) of Participants Censored	6 (9.8%)	6 (9.5%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.53 (3.88, 6.14)	4.40 (3.19, 5.52)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.760 (0.522, 1.107)		

label	SG (N=177)	TPC (N=169)	Interaction
p-value (Log-Rank Test, Unstratified)	0.1495		
Physician's choice of chemotherapy			
Taxane	52	45	0.0164
Number (%) of Participants with Events	39 (75.0%)	39 (86.7%)	
Disease Progression (PD)	37 (71.2%)	37 (82.2%)	
Death	2 (3.8%)	2 (4.4%)	
Number (%) of Participants Censored	13 (25.0%)	6 (13.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	9.07 (4.53, 15.21)	4.21 (2.89, 7.16)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.406 (0.252, 0.655)		
p-value (Log-Rank Test, Unstratified)	0.0001		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events	107 (85.6%)	109 (87.9%)	
Disease Progression (PD)	96 (76.8%)	106 (85.5%)	
Death	11 (8.8%)	3 (2.4%)	
Number (%) of Participants Censored	18 (14.4%)	15 (12.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.90 (5.22, 8.34)	5.70 (5.32, 6.90)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.835 (0.639, 1.091)		
p-value (Log-Rank Test, Unstratified)	0.1857		
History of liver metastasis			
Yes	47	39	0.0528
Number (%) of Participants with Events	42 (89.4%)	35 (89.7%)	
Disease Progression (PD)	38 (80.9%)	31 (79.5%)	

label	SG (N=177)	TPC (N=169)	Interaction
Death	4 (8.5%)	4 (10.3%)	
Number (%) of Participants Censored	5 (10.6%)	4 (10.3%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	4.88 (3.15, 8.31)	3.30 (2.20, 4.17)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.488 (0.305, 0.781)		
p-value (Log-Rank Test, Unstratified)	0.0023		
No	130	130	
Number (%) of Participants with Events	104 (80.0%)	113 (86.9%)	
Disease Progression (PD)	95 (73.1%)	112 (86.2%)	
Death	9 (6.9%)	1 (0.8%)	
Number (%) of Participants Censored	26 (20.0%)	17 (13.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.23 (5.55, 9.69)	6.87 (5.59, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.741 (0.567, 0.970)		
p-value (Log-Rank Test, Unstratified)	0.0284		
History of brain metastasis			
Yes	8	9	0.8556
Number (%) of Participants with Events	8 (100.0%)	9 (100.0%)	
Disease Progression (PD)	7 (87.5%)	8 (88.9%)	
Death	1 (12.5%)	1 (11.1%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.72 (0.85, 8.54)	3.19 (0.16, 8.11)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.704 (0.260, 1.902)		

label	SG (N=177)	TPC (N=169)	Interaction
p-value (Log-Rank Test, Unstratified)	0.4864		
No	169	160	
Number (%) of Participants with Events	138 (81.7%)	139 (86.9%)	
Disease Progression (PD)	126 (74.6%)	135 (84.4%)	
Death	12 (7.1%)	4 (2.5%)	
Number (%) of Participants Censored	31 (18.3%)	21 (13.1%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.13 (5.55, 8.77)	5.60 (4.90, 6.74)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.712 (0.561, 0.903)		
p-value (Log-Rank Test, Unstratified)	0.0048		
PD-L1 Status			
CPS < 1	67	59	0.8549
Number (%) of Participants with Events	53 (79.1%)	51 (86.4%)	
Disease Progression (PD)	47 (70.1%)	50 (84.7%)	
Death	6 (9.0%)	1 (1.7%)	
Number (%) of Participants Censored	14 (20.9%)	8 (13.6%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	8.15 (5.36, 9.76)	5.42 (4.07, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.701 (0.475, 1.033)		
p-value (Log-Rank Test, Unstratified)	0.0710		
CPS ≥ 1	109	110	
Number (%) of Participants with Events	93 (85.3%)	97 (88.2%)	
Disease Progression (PD)	86 (78.9%)	93 (84.5%)	
Death	7 (6.4%)	4 (3.6%)	

label	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	16 (14.7%)	13 (11.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	6.74 (4.37, 8.77)	5.65 (4.90, 6.93)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.724 (0.542, 0.966)		
p-value (Log-Rank Test, Unstratified)	0.0270		
BRCA 1/2 status			
Wild-Type	66	65	0.0843
Number (%) of Participants with Events	59 (89.4%)	56 (86.2%)	
Disease Progression (PD)	55 (83.3%)	55 (84.6%)	
Death	4 (6.1%)	1 (1.5%)	
Number (%) of Participants Censored	7 (10.6%)	9 (13.8%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.39 (4.21, 7.92)	4.88 (3.06, 5.65)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.705 (0.487, 1.022)		
p-value (Log-Rank Test, Unstratified)	0.0643		
Mutant	12	10	
Number (%) of Participants with Events	11 (91.7%)	7 (70.0%)	
Disease Progression (PD)	9 (75.0%)	7 (70.0%)	
Death	2 (16.7%)	0	
Number (%) of Participants Censored	1 (8.3%)	3 (30.0%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.20 (1.51, 9.30)	9.00 (2.89, NR)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.730 (0.663, 4.511)		
p-value (Log-Rank Test, Unstratified)	0.2571		

label	SG (N=177)	TPC (N=169)	Interaction
Menopausal status			
Pre-menopausal	37	49	0.5559
Number (%) of Participants with Events	33 (89.2%)	44 (89.8%)	
Disease Progression (PD)	31 (83.8%)	43 (87.8%)	
Death	2 (5.4%)	1 (2.0%)	
Number (%) of Participants Censored	4 (10.8%)	5 (10.2%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	5.85 (4.27, 8.74)	5.42 (4.17, 6.51)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.777 (0.492, 1.225)		
p-value (Log-Rank Test, Unstratified)	0.2786		
Post-menopausal	140	119	
Number (%) of Participants with Events	113 (80.7%)	103 (86.6%)	
Disease Progression (PD)	102 (72.9%)	99 (83.2%)	
Death	11 (7.9%)	4 (3.4%)	
Number (%) of Participants Censored	27 (19.3%)	16 (13.4%)	
Kaplan-Meier Estimate of PFS (Months) (95% CI)			
Median	7.66 (5.55, 9.59)	5.65 (4.40, 7.13)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.696 (0.532, 0.912)		
p-value (Log-Rank Test, Unstratified)	0.0079		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
PFS2 is defined as the time from date of randomization to the first documented progression on next-line therapy based on investigator assessment of PD or death due to any cause, whichever occurs first.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
PFS2 rate is the proportion of participants alive without progression at the next line of therapy. The 95% CI is based on the log-log transformation.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from an unstratified log-rank test.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Data Cut Date: 27 OCT 2025.

5.9. Table 1.1.11: Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel

Parameter	SG (N=177)	TPC (N=169)
Number (%) of Participants with Events	137 (77.4%)	146 (86.4%)
First Subsequent Therapy	103 (58.2%)	121 (71.6%)
Death	34 (19.2%)	25 (14.8%)
Number (%) of Participants Censored	40 (22.6%)	23 (13.6%)
Kaplan-Meier Estimate of TFST (Months) (95% CI) [a]		
Q1	5.39 (4.37, 6.41)	4.96 (3.94, 5.75)
Median	11.40 (9.13, 12.94)	7.66 (6.60, 9.13)
Q3	19.58 (17.84, 21.59)	12.48 (10.84, 15.34)
Absolute Difference in Median TFST, SG vs TPC (Months)	3.75	
Kaplan-Meier Estimate of TFST Rate (95% CI) [b]		
At 3 Months	0.893 (0.837, 0.930)	0.893 (0.835, 0.931)
At 6 Months	0.711 (0.638, 0.772)	0.673 (0.596, 0.738)
At 9 Months	0.586 (0.510, 0.655)	0.440 (0.363, 0.513)
At 12 Months	0.455 (0.380, 0.527)	0.271 (0.206, 0.340)
At 18 Months	0.311 (0.243, 0.381)	0.161 (0.109, 0.221)
At 24 Months	0.162 (0.102, 0.234)	0.119 (0.073, 0.177)
Treatment Comparison		
Log-rank p-value of SG vs TPC [c]	0.0004	
Hazard Ratio of SG vs TPC (95% CI) [d]	0.650 (0.511, 0.826)	

SG = sacituzumab govitecan; TPC = treatment of physician's choice; IWRS = Interactive Web Response System; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomization to the start date of the first subsequent anti-cancer therapy after discontinuation of randomized treatment, or death due to any cause.
[a] Quantile of TFST is from Kaplan-Meier estimate. The 95% CI is based on log-log transformation.
[b] TFST rate is the proportion of participants alive without any subsequent therapy. The 95% CI is based on the log-log transformation.
[c] The two-sided p-value is from stratified log-rank test.
[d] Hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors from Interactive Web Response System (IWRS).
Data Cut Date: 27 OCT 2025.

5.10. Table 1.1.12: Subgroup Analysis of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel

label	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.171
Number (%) of Participants with Events	42 (76.4%)	47 (95.9%)	
First Subsequent Therapy	32 (58.2%)	37 (75.5%)	
Death	10 (18.2%)	10 (20.4%)	
Number (%) of Participants Censored	13 (23.6%)	2 (4.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	13.04 (8.15, 16.85)	6.47 (4.99, 7.85)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.478 (0.311, 0.734)		
p-value (Log-Rank Test, Unstratified)	<0.001		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events	29 (85.3%)	29 (85.3%)	
First Subsequent Therapy	23 (67.6%)	25 (73.5%)	
Death	6 (17.6%)	4 (11.8%)	
Number (%) of Participants Censored	5 (14.7%)	5 (14.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.79 (6.74, 13.01)	7.39 (6.11, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.702 (0.417, 1.180)		
p-value (Log-Rank Test, Unstratified)	0.178		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events	66 (75.0%)	70 (81.4%)	
First Subsequent Therapy	48 (54.5%)	59 (68.6%)	

label	SG (N=177)	TPC (N=169)	Interaction
Death	18 (20.5%)	11 (12.8%)	
Number (%) of Participants Censored	22 (25.0%)	16 (18.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.32 (8.08, 14.09)	9.13 (7.16, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.805 (0.574, 1.128)		
p-value (Log-Rank Test, Unstratified)	0.207		
Geographic region			
US/Canada/Western Europe	56	52	0.224
Number (%) of Participants with Events	45 (80.4%)	48 (92.3%)	
First Subsequent Therapy	37 (66.1%)	41 (78.8%)	
Death	8 (14.3%)	7 (13.5%)	
Number (%) of Participants Censored	11 (19.6%)	4 (7.7%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.43 (8.57, 13.86)	6.75 (5.59, 8.44)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.543 (0.359, 0.823)		
p-value (Log-Rank Test, Unstratified)	0.004		
Rest of the world	121	117	
Number (%) of Participants with Events	92 (76.0%)	98 (83.8%)	
First Subsequent Therapy	66 (54.5%)	80 (68.4%)	
Death	26 (21.5%)	18 (15.4%)	
Number (%) of Participants Censored	29 (24.0%)	19 (16.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.24 (8.87, 14.13)	7.98 (6.77, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.567, 1.005)		

label	SG (N=177)	TPC (N=169)	Interaction
p-value (Log-Rank Test, Unstratified)	0.053		
Age group			
< 65	133	131	0.747
Number (%) of Participants with Events	103 (77.4%)	112 (85.5%)	
First Subsequent Therapy	83 (62.4%)	97 (74.0%)	
Death	20 (15.0%)	15 (11.5%)	
Number (%) of Participants Censored	30 (22.6%)	19 (14.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.79 (9.33, 14.13)	7.39 (6.34, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.665 (0.508, 0.871)		
p-value (Log-Rank Test, Unstratified)	0.003		
>= 65	44	38	
Number (%) of Participants with Events	34 (77.3%)	34 (89.5%)	
First Subsequent Therapy	20 (45.5%)	24 (63.2%)	
Death	14 (31.8%)	10 (26.3%)	
Number (%) of Participants Censored	10 (22.7%)	4 (10.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.74 (4.73, 14.09)	8.33 (6.24, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.764 (0.472, 1.237)		
p-value (Log-Rank Test, Unstratified)	0.273		
Race			
White	115	104	0.686
Number (%) of Participants with Events	94 (81.7%)	89 (85.6%)	
First Subsequent Therapy	70 (60.9%)	72 (69.2%)	

label	SG (N=177)	TPC (N=169)	Interaction
Death	24 (20.9%)	17 (16.3%)	
Number (%) of Participants Censored	21 (18.3%)	15 (14.4%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.38 (8.87, 12.75)	7.59 (6.11, 9.00)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.736 (0.550, 0.985)		
p-value (Log-Rank Test, Unstratified)	0.039		
Asian	38	38	
Number (%) of Participants with Events	26 (68.4%)	33 (86.8%)	
First Subsequent Therapy	21 (55.3%)	32 (84.2%)	
Death	5 (13.2%)	1 (2.6%)	
Number (%) of Participants Censored	12 (31.6%)	5 (13.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	12.32 (4.90, 18.46)	8.13 (6.21, 9.46)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.619 (0.366, 1.047)		
p-value (Log-Rank Test, Unstratified)	0.072		
Other	19	24	
Number (%) of Participants with Events	13 (68.4%)	21 (87.5%)	
First Subsequent Therapy	9 (47.4%)	15 (62.5%)	
Death	4 (21.1%)	6 (25.0%)	
Number (%) of Participants Censored	6 (31.6%)	3 (12.5%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.52 (7.26, 19.15)	9.26 (6.34, 11.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.469 (0.229, 0.958)		
p-value (Log-Rank Test, Unstratified)	0.035		

label	SG (N=177)	TPC (N=169)	Interaction
Baseline ECOG status			
0	116	106	0.801
Number (%) of Participants with Events	84 (72.4%)	88 (83.0%)	
First Subsequent Therapy	66 (56.9%)	77 (72.6%)	
Death	18 (15.5%)	11 (10.4%)	
Number (%) of Participants Censored	32 (27.6%)	18 (17.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	14.09 (11.24, 16.85)	9.30 (7.39, 11.04)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.659 (0.488, 0.890)		
p-value (Log-Rank Test, Unstratified)	0.006		
1	61	63	
Number (%) of Participants with Events	53 (86.9%)	58 (92.1%)	
First Subsequent Therapy	37 (60.7%)	44 (69.8%)	
Death	16 (26.2%)	14 (22.2%)	
Number (%) of Participants Censored	8 (13.1%)	5 (7.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	7.26 (4.80, 10.15)	6.24 (5.29, 7.20)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.751 (0.515, 1.096)		
p-value (Log-Rank Test, Unstratified)	0.136		
Physician's choice of chemotherapy			
Taxane	52	45	0.010
Number (%) of Participants with Events	36 (69.2%)	41 (91.1%)	
First Subsequent Therapy	29 (55.8%)	32 (71.1%)	
Death	7 (13.5%)	9 (20.0%)	

label	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	16 (30.8%)	4 (8.9%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	15.87 (11.66, 18.96)	7.59 (5.59, 9.53)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.365 (0.227, 0.588)		
p-value (Log-Rank Test, Unstratified)	<0.001		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events	101 (80.8%)	105 (84.7%)	
First Subsequent Therapy	74 (59.2%)	89 (71.8%)	
Death	27 (21.6%)	16 (12.9%)	
Number (%) of Participants Censored	24 (19.2%)	19 (15.3%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.69 (7.43, 11.40)	7.79 (6.54, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.836 (0.636, 1.100)		
p-value (Log-Rank Test, Unstratified)	0.200		
History of liver metastasis			
Yes	47	39	0.284
Number (%) of Participants with Events	41 (87.2%)	37 (94.9%)	
First Subsequent Therapy	28 (59.6%)	28 (71.8%)	
Death	13 (27.7%)	9 (23.1%)	
Number (%) of Participants Censored	6 (12.8%)	2 (5.1%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.87 (4.86, 9.76)	5.13 (3.91, 6.01)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.543 (0.344, 0.857)		
p-value (Log-Rank Test, Unstratified)	0.008		

label	SG (N=177)	TPC (N=169)	Interaction
No	130	130	
Number (%) of Participants with Events	96 (73.8%)	109 (83.8%)	
First Subsequent Therapy	75 (57.7%)	93 (71.5%)	
Death	21 (16.2%)	16 (12.3%)	
Number (%) of Participants Censored	34 (26.2%)	21 (16.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	12.68 (10.38, 16.03)	9.13 (7.62, 9.99)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.688 (0.521, 0.907)		
p-value (Log-Rank Test, Unstratified)	0.008		
History of brain metastasis			
Yes	8	9	0.557
Number (%) of Participants with Events	8 (100.0%)	9 (100.0%)	
First Subsequent Therapy	7 (87.5%)	6 (66.7%)	
Death	1 (12.5%)	3 (33.3%)	
Number (%) of Participants Censored	0	0	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	6.85 (0.85, 11.24)	7.20 (0.16, 9.30)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.813 (0.301, 2.198)		
p-value (Log-Rank Test, Unstratified)	0.682		
No	169	160	
Number (%) of Participants with Events	129 (76.3%)	137 (85.6%)	
First Subsequent Therapy	96 (56.8%)	115 (71.9%)	
Death	33 (19.5%)	22 (13.8%)	
Number (%) of Participants Censored	40 (23.7%)	23 (14.4%)	

label	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.60 (9.33, 14.09)	7.69 (6.60, 9.36)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.680 (0.534, 0.867)		
p-value (Log-Rank Test, Unstratified)	0.002		
PD-L1 Status			
CPS < 1	67	59	0.839
Number (%) of Participants with Events	53 (79.1%)	51 (86.4%)	
First Subsequent Therapy	41 (61.2%)	41 (69.5%)	
Death	12 (17.9%)	10 (16.9%)	
Number (%) of Participants Censored	14 (20.9%)	8 (13.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.60 (9.03, 14.09)	7.13 (5.59, 8.48)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.666 (0.452, 0.980)		
p-value (Log-Rank Test, Unstratified)	0.038		
CPS ≥ 1	109	110	
Number (%) of Participants with Events	84 (77.1%)	95 (86.4%)	
First Subsequent Therapy	62 (56.9%)	80 (72.7%)	
Death	22 (20.2%)	15 (13.6%)	
Number (%) of Participants Censored	25 (22.9%)	15 (13.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	10.74 (7.26, 14.13)	7.98 (6.60, 9.69)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.705 (0.524, 0.948)		
p-value (Log-Rank Test, Unstratified)	0.020		
BRCA 1/2 status			

label	SG (N=177)	TPC (N=169)	Interaction
Wild-Type	66	65	0.045
Number (%) of Participants with Events	55 (83.3%)	59 (90.8%)	
First Subsequent Therapy	43 (65.2%)	49 (75.4%)	
Death	12 (18.2%)	10 (15.4%)	
Number (%) of Participants Censored	11 (16.7%)	6 (9.2%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.73 (6.74, 14.92)	6.24 (5.36, 7.85)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.593 (0.408, 0.862)		
p-value (Log-Rank Test, Unstratified)	0.006		
Mutant	12	10	
Number (%) of Participants with Events	11 (91.7%)	8 (80.0%)	
First Subsequent Therapy	8 (66.7%)	7 (70.0%)	
Death	3 (25.0%)	1 (10.0%)	
Number (%) of Participants Censored	1 (8.3%)	2 (20.0%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	8.33 (3.15, 16.39)	11.27 (4.99, 16.62)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.562 (0.626, 3.893)		
p-value (Log-Rank Test, Unstratified)	0.335		
Menopausal status			
Pre-menopausal	37	49	0.251
Number (%) of Participants with Events	30 (81.1%)	41 (83.7%)	
First Subsequent Therapy	27 (73.0%)	38 (77.6%)	
Death	3 (8.1%)	3 (6.1%)	
Number (%) of Participants Censored	7 (18.9%)	8 (16.3%)	

label	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	9.03 (5.85, 12.68)	6.74 (6.21, 8.38)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.898 (0.559, 1.443)		
p-value (Log-Rank Test, Unstratified)	0.660		
Post-menopausal	140	119	
Number (%) of Participants with Events	107 (76.4%)	104 (87.4%)	
First Subsequent Therapy	76 (54.3%)	82 (68.9%)	
Death	31 (22.1%)	22 (18.5%)	
Number (%) of Participants Censored	33 (23.6%)	15 (12.6%)	
Kaplan-Meier Estimate of TFST (Months) (95% CI)			
Median	11.60 (9.33, 14.13)	7.98 (6.80, 9.40)	
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.636 (0.484, 0.835)		
p-value (Log-Rank Test, Unstratified)	0.001		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Time to first subsequent therapy is defined as the time from randomisation to the start date of the first subsequent anti-cancer therapy after discontinuation of randomised treatment, or death due to any cause.
TFST rate is the proportion of participants alive without any subsequent therapy.
Hazard ratio and 95% CIs calculated using unstratified Cox proportional hazards model. Efron method used to handle ties. Reference arm = TPC.
Log-rank p-value is from an unstratified log-rank test.
[1] Interaction p-value: likelihood ratio test from Cox model with treatment + subgroup + treatment×subgroup interaction terms; shown once per subgroup variable at first category level.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Data Cut Date: 27 OCT 2025.

6. Safety - mSAF — Excluding patients preselected to receive nab-paclitaxel

6.1. Table 1.1.1: Summary of Treatment Exposure - Treatment Duration (months) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	Gemcitabine (N=122)	Carboplatin (N=122)	Gem/Carbo (N=122)	Taxane (N=44)	Any TPC (N=166)
Total Duration of Exposure to Study Drug						
Duration (months)						
N	175	122	122	122	44	166
Mean (StD)	9.66 (7.464)	7.82 (6.426)	7.10 (5.533)	7.01 (5.499)	5.40 (4.243)	6.59 (5.232)
Median	8.08	6.09	5.77	5.77	4.76	5.42
Q1, Q3	3.73, 16.23	3.76, 9.68	3.50, 9.49	3.50, 9.20	2.17, 7.68	2.82, 8.39
Min, Max	0.20, 34.76	0.03, 27.86	0.03, 27.73	0.03, 27.73	0.03, 17.91	0.03, 27.73
Cumulative Number (%) of Participants						
Exposed to Study Drug						
>= 3 months, n, (%)	140 (80.0%)	95 (77.9%)	95 (77.9%)	95 (77.9%)	28 (63.6%)	123 (74.1%)
>= 6 months, n, (%)	102 (58.3%)	62 (50.8%)	58 (47.5%)	58 (47.5%)	16 (36.4%)	74 (44.6%)
>= 12 months, n, (%)	58 (33.1%)	24 (19.7%)	18 (14.8%)	17 (13.9%)	3 (6.8%)	20 (12.0%)
>= 24 months, n, (%)	7 (4.0%)	6 (4.9%)	4 (3.3%)	4 (3.3%)	0 (0.0%)	4 (2.4%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, Gem = gemcitabine, Carbo = carboplatin.
Safety Analysis Set includes randomized participants who have received at least one dose of any study drug. Taxane includes participants who have received Paclitaxel. TPC column includes participants who have received any of Gem, Carbo or Paclitaxel.
Duration of exposure to study drug (months) = (last dosing date − first dosing date + 1)/30.4375.

6.2. Table 1.1.2: Observation Period (Months) for Safety — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Total (N=341)
Observation Period (months) for Safety [a]			
N	175	166	341
Mean (StD)	10.49 (7.306)	8.18 (5.935)	9.37 (6.764)
Median	9.07	6.59	7.46
Q1, Q3	4.71, 16.69	3.90, 10.34	4.50, 13.21
Min, Max	0.46, 34.96	0.10, 28.71	0.10, 34.96

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
[a] Observation period is defined as the time from first dose until Data cutoff date, study treatment discontinuation +30 days for any AE and any serious AE, or death, whichever comes first and stops the collection of endpoint data.

6.3. Table 1.1.3: Analysis of Time to First Treatment-Emergent Adverse Event (TEAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	175 (100.0%)	163 (98.2%)
Patients (%) Without Events (Censored)	0 (0.0%)	3 (1.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.10 (0.10, 0.16)	0.18 (0.10, 0.23)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.246 (1.002, 1.548)
p-value		0.0424

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=175)	TPC (N=166)

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.4. Table 1.1.4: Subgroup Analysis of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.5106
De novo			
Total Patients	55	48	
Patients (%) With Events	55 (100.0%)	47 (97.9%)	
Patients (%) Without Events (Censored)	0	1 (2.1%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.16)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.239 (0.831, 1.848)	
p-value		0.2759	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	34 (100.0%)	33 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.21 (0.10, 0.26)	0.20 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.003 (0.616, 1.633)	
p-value		0.9957	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	86 (100.0%)	83 (97.6%)	
Patients (%) Without Events (Censored)	0	2 (2.4%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.417 (1.037, 1.935)	
p-value		0.0271	
Geographic region			0.4926
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	55 (100.0%)	49 (98.0%)	
Patients (%) Without Events (Censored)	0	1 (2.0%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.07, 0.20)	0.18 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.165 (0.790, 1.719)	
p-value		0.4318	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	120 (100.0%)	114 (98.3%)	
Patients (%) Without Events (Censored)	0	2 (1.7%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.20)	0.18 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.316 (1.008, 1.717)	
p-value		0.0384	
Age group			0.6875
< 65			
Total Patients	132	128	
Patients (%) With Events	132 (100.0%)	125 (97.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	0	3 (2.3%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.262 (0.984, 1.620)	
p-value		0.0681	
>= 65			
Total Patients	43	38	
Patients (%) With Events	43 (100.0%)	38 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.13 (0.07, 0.20)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.167 (0.746, 1.824)	
p-value		0.4318	
Race			0.9199
White			
Total Patients	114	101	
Patients (%) With Events	114 (100.0%)	98 (97.0%)	
Patients (%) Without Events (Censored)	0	3 (3.0%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.23)	0.20 (0.13, 0.23)	
Hazard Ratio (95% CI)		1.220 (0.929, 1.603)	
p-value		0.1311	
Asian			
Total Patients	38	38	
Patients (%) With Events	38 (100.0%)	38 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.10 (0.07, 0.20)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.273 (0.789, 2.054)	
p-value		0.3570	
Other			
Total Patients	18	24	
Patients (%) With Events	18 (100.0%)	24 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.07, 0.26)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.120 (0.594, 2.112)	
p-value		0.6710	
Baseline ECOG status			0.7199
0			
Total Patients	115	104	
Patients (%) With Events	115 (100.0%)	102 (98.1%)	
Patients (%) Without Events (Censored)	0	2 (1.9%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.20)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.270 (0.967, 1.668)	
p-value		0.0842	
1			
Total Patients	60	62	
Patients (%) With Events	60 (100.0%)	61 (98.4%)	
Patients (%) Without Events (Censored)	0	1 (1.6%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.23)	0.20 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.194 (0.832, 1.714)	
p-value		0.3083	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.9140
Taxane			
Total Patients	51	44	
Patients (%) With Events	51 (100.0%)	42 (95.5%)	
Patients (%) Without Events (Censored)	0	2 (4.5%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.26)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.267 (0.826, 1.944)	
p-value		0.2754	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	124 (100.0%)	121 (99.2%)	
Patients (%) Without Events (Censored)	0	1 (0.8%)	
Median Time to First TEAE, months (95% CI)	0.11 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.244 (0.965, 1.604)	
p-value		0.0771	
History of liver metastasis			0.6446
Yes			
Total Patients	47	37	
Patients (%) With Events	47 (100.0%)	34 (91.9%)	
Patients (%) Without Events (Censored)	0	3 (8.1%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.20)	0.13 (0.07, 0.26)	
Hazard Ratio (95% CI)		1.287 (0.819, 2.023)	
p-value		0.2383	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	128 (100.0%)	129 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.215 (0.947, 1.558)	
p-value		0.1155	
History of brain metastasis			0.3238
Yes			
Total Patients	8	9	
Patients (%) With Events	8 (100.0%)	9 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.11 (0.03, 0.26)	0.20 (0.03, 1.64)	
Hazard Ratio (95% CI)		1.754 (0.633, 4.859)	
p-value		0.2560	
No			
Total Patients	167	157	
Patients (%) With Events	167 (100.0%)	154 (98.1%)	
Patients (%) Without Events (Censored)	0	3 (1.9%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.16)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.216 (0.973, 1.519)	
p-value		0.0758	
PD-L1 Status			0.6591
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	66 (100.0%)	57 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.13)	0.16 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.403 (0.966, 2.037)	
p-value		0.0634	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	109 (100.0%)	106 (97.2%)	
Patients (%) Without Events (Censored)	0	3 (2.8%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.23)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.183 (0.902, 1.551)	
p-value		0.2338	
BRCA 1/2 status			0.4180
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	65 (100.0%)	61 (96.8%)	
Patients (%) Without Events (Censored)	0	2 (3.2%)	
Median Time to First TEAE, months (95% CI)	0.10 (0.10, 0.23)	0.23 (0.10, 0.26)	
Hazard Ratio (95% CI)		1.219 (0.856, 1.735)	
p-value		0.2506	
Mutant			
Total Patients	12	10	
Patients (%) With Events	12 (100.0%)	10 (100.0%)	
Patients (%) Without Events (Censored)	0	0	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.18 (0.07, 0.26)	0.10 (0.03, 0.26)	
Hazard Ratio (95% CI)		0.834 (0.351, 1.984)	
p-value		0.5450	
Menopausal status			0.5787
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	37 (100.0%)	48 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Median Time to First TEAE, months (95% CI)	0.10 (0.07, 0.23)	0.13 (0.07, 0.23)	
Hazard Ratio (95% CI)		1.418 (0.905, 2.222)	
p-value		0.1343	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	138 (100.0%)	114 (97.4%)	
Patients (%) Without Events (Censored)	0	3 (2.6%)	
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.20)	0.20 (0.10, 0.23)	
Hazard Ratio (95% CI)		1.202 (0.935, 1.546)	
p-value		0.1285	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.5. Table 1.1.5: Analysis of Time to First Serious Treatment-Emergent Adverse Event (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	52 (29.7%)	50 (30.1%)
Patients (%) Without Events (Censored)	123 (70.3%)	116 (69.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	18.92 (12.22, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.896 (0.606, 1.327)
p-value		0.5757

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.6. Table 1.1.6: Subgroup Analysis of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.5527
De novo			
Total Patients	55	48	
Patients (%) With Events	20 (36.4%)	15 (31.2%)	
Patients (%) Without Events (Censored)	35 (63.6%)	33 (68.8%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (13.14, NR)	NR (5.98, NR)	
Hazard Ratio (95% CI)		1.005 (0.507, 1.990)	
p-value		0.9925	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	9 (26.5%)	6 (18.2%)	
Patients (%) Without Events (Censored)	25 (73.5%)	27 (81.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (11.10, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.342 (0.473, 3.808)	
p-value		0.5786	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	23 (26.7%)	29 (34.1%)	
Patients (%) Without Events (Censored)	63 (73.3%)	56 (65.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (7.36, NR)	
Hazard Ratio (95% CI)		0.717 (0.413, 1.244)	
p-value		0.2300	
Geographic region			0.5988
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	18 (32.7%)	14 (28.0%)	
Patients (%) Without Events (Censored)	37 (67.3%)	36 (72.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (6.57, NR)	12.22 (12.22, NR)	
Hazard Ratio (95% CI)		1.101 (0.545, 2.227)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.8008	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	34 (28.3%)	36 (31.0%)	
Patients (%) Without Events (Censored)	86 (71.7%)	80 (69.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.823 (0.513, 1.321)	
p-value		0.4157	
Age group			0.0311
< 65			
Total Patients	132	128	
Patients (%) With Events	33 (25.0%)	39 (30.5%)	
Patients (%) Without Events (Censored)	99 (75.0%)	89 (69.5%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (9.76, NR)	
Hazard Ratio (95% CI)		0.685 (0.429, 1.096)	
p-value		0.1109	
>= 65			
Total Patients	43	38	
Patients (%) With Events	19 (44.2%)	11 (28.9%)	
Patients (%) Without Events (Censored)	24 (55.8%)	27 (71.1%)	
Median Time to First Serious TEAE, months (95% CI)	11.40 (1.31, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		1.744 (0.826, 3.684)	
p-value		0.1422	
Race			0.1492

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
White			
Total Patients	114	101	
Patients (%) With Events	32 (28.1%)	33 (32.7%)	
Patients (%) Without Events (Censored)	82 (71.9%)	68 (67.3%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.772 (0.473, 1.261)	
p-value		0.2932	
Asian			
Total Patients	38	38	
Patients (%) With Events	9 (23.7%)	11 (28.9%)	
Patients (%) Without Events (Censored)	29 (76.3%)	27 (71.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.725 (0.296, 1.776)	
p-value		0.4795	
Other			
Total Patients	18	24	
Patients (%) With Events	10 (55.6%)	6 (25.0%)	
Patients (%) Without Events (Censored)	8 (44.4%)	18 (75.0%)	
Median Time to First Serious TEAE, months (95% CI)	12.11 (0.66, NR)	NR (5.62, NR)	
Hazard Ratio (95% CI)		2.271 (0.817, 6.308)	
p-value		0.1076	
Baseline ECOG status			0.9490
0			
Total Patients	115	104	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	31 (27.0%)	29 (27.9%)	
Patients (%) Without Events (Censored)	84 (73.0%)	75 (72.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (18.92, NR)	
Hazard Ratio (95% CI)		0.894 (0.537, 1.489)	
p-value		0.6593	
1			
Total Patients	60	62	
Patients (%) With Events	21 (35.0%)	21 (33.9%)	
Patients (%) Without Events (Censored)	39 (65.0%)	41 (66.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	12.22 (7.36, NR)	
Hazard Ratio (95% CI)		0.920 (0.498, 1.700)	
p-value		0.7841	
The physician's choice of chemotherapy selected prior to randomization			0.6873
Taxane			
Total Patients	51	44	
Patients (%) With Events	12 (23.5%)	8 (18.2%)	
Patients (%) Without Events (Censored)	39 (76.5%)	36 (81.8%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.234 (0.504, 3.024)	
p-value		0.6547	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	40 (32.3%)	42 (34.4%)	
Patients (%) Without Events (Censored)	84 (67.7%)	80 (65.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	18.92 (9.76, NR)	
Hazard Ratio (95% CI)		0.864 (0.559, 1.337)	
p-value		0.5072	
History of liver metastasis			0.7214
Yes			
Total Patients	47	37	
Patients (%) With Events	18 (38.3%)	12 (32.4%)	
Patients (%) Without Events (Censored)	29 (61.7%)	25 (67.6%)	
Median Time to First Serious TEAE, months (95% CI)	18.66 (5.36, NR)	12.22 (3.06, NR)	
Hazard Ratio (95% CI)		0.938 (0.439, 2.005)	
p-value		0.8391	
No			
Total Patients	128	129	
Patients (%) With Events	34 (26.6%)	38 (29.5%)	
Patients (%) Without Events (Censored)	94 (73.4%)	91 (70.5%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (18.92, NR)	
Hazard Ratio (95% CI)		0.840 (0.527, 1.337)	
p-value		0.4604	
History of brain metastasis			0.7408
Yes			
Total Patients	8	9	
Patients (%) With Events	4 (50.0%)	4 (44.4%)	
Patients (%) Without Events (Censored)	4 (50.0%)	5 (55.6%)	
Median Time to First Serious TEAE, months (95% CI)	6.46 (0.26, NR)	NR (0.03, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.990 (0.247, 3.965)	
p-value		0.9881	
No			
Total Patients	167	157	
Patients (%) With Events	48 (28.7%)	46 (29.3%)	
Patients (%) Without Events (Censored)	119 (71.3%)	111 (70.7%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		0.884 (0.587, 1.330)	
p-value		0.5464	
PD-L1 Status			0.0170
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	17 (25.8%)	24 (42.1%)	
Patients (%) Without Events (Censored)	49 (74.2%)	33 (57.9%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	12.22 (4.63, NR)	
Hazard Ratio (95% CI)		0.487 (0.259, 0.915)	
p-value		0.0214	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	35 (32.1%)	26 (23.9%)	
Patients (%) Without Events (Censored)	74 (67.9%)	83 (76.1%)	
Median Time to First Serious TEAE, months (95% CI)	NR (18.66, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.332 (0.800, 2.219)	
p-value		0.2717	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
BRCA 1/2 status			0.0127
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	15 (23.1%)	15 (23.8%)	
Patients (%) Without Events (Censored)	50 (76.9%)	48 (76.2%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (12.22, NR)	
Hazard Ratio (95% CI)		0.819 (0.398, 1.685)	
p-value		0.5828	
Mutant			
Total Patients	12	10	
Patients (%) With Events	6 (50.0%)	1 (10.0%)	
Patients (%) Without Events (Censored)	6 (50.0%)	9 (90.0%)	
Median Time to First Serious TEAE, months (95% CI)	9.38 (0.23, NR)	21.42 (18.92, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0108	
Menopausal status			0.9009
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	9 (24.3%)	12 (25.0%)	
Patients (%) Without Events (Censored)	28 (75.7%)	36 (75.0%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	NR (7.36, NR)	
Hazard Ratio (95% CI)		0.890 (0.372, 2.131)	
p-value		0.7915	
Post-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	138	117	
Patients (%) With Events	43 (31.2%)	38 (32.5%)	
Patients (%) Without Events (Censored)	95 (68.8%)	79 (67.5%)	
Median Time to First Serious TEAE, months (95% CI)	NR (NR, NR)	18.92 (12.22, NR)	
Hazard Ratio (95% CI)		0.865 (0.557, 1.343)	
p-value		0.5107	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
NC = Not Calculable: the hazard ratio and 95% CI are not estimable by the Cox model.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.7. Table 1.1.7: Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	121 (69.1%)	127 (76.5%)
Patients (%) Without Events (Censored)	54 (30.9%)	39 (23.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.61 (0.95, 3.52)	1.71 (1.15, 2.27)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.824 (0.639, 1.061)
p-value		0.1248

	SG (N=175)	TPC (N=166)

SG = sacituzumab govitecan, TPC = treatment of physician's code.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.8. Table 1.1.8: Subgroup Analysis of Time to First Severe TEAE (CTCAE Grade 3 and above) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.5183
De novo			
Total Patients	55	48	
Patients (%) With Events	39 (70.9%)	32 (66.7%)	
Patients (%) Without Events (Censored)	16 (29.1%)	16 (33.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.72, 3.48)	1.97 (0.85, 3.48)	
Hazard Ratio (95% CI)		1.076 (0.671, 1.724)	
p-value		0.7583	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	25 (73.5%)	29 (87.9%)	
Patients (%) Without Events (Censored)	9 (26.5%)	4 (12.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.79 (0.43, 4.14)	0.95 (0.85, 1.64)	
Hazard Ratio (95% CI)		0.809 (0.467, 1.403)	
p-value		0.4232	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	57 (66.3%)	66 (77.6%)	
Patients (%) Without Events (Censored)	29 (33.7%)	19 (22.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.52 (0.95, 6.28)	1.84 (1.35, 2.99)	
Hazard Ratio (95% CI)		0.724 (0.504, 1.039)	
p-value		0.0746	
Geographic region			0.7226
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	36 (65.5%)	35 (70.0%)	
Patients (%) Without Events (Censored)	19 (34.5%)	15 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.38 (0.92, 10.58)	1.97 (1.05, 3.48)	
Hazard Ratio (95% CI)		0.883 (0.551, 1.416)	
p-value		0.5931	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	85 (70.8%)	92 (79.3%)	
Patients (%) Without Events (Censored)	35 (29.2%)	24 (20.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.77 (0.72, 3.68)	1.64 (0.95, 2.30)	
Hazard Ratio (95% CI)		0.806 (0.597, 1.089)	
p-value		0.1489	
Age group			0.1433
< 65			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	132	128	
Patients (%) With Events	87 (65.9%)	97 (75.8%)	
Patients (%) Without Events (Censored)	45 (34.1%)	31 (24.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.56 (1.25, 4.83)	1.64 (0.99, 2.30)	
Hazard Ratio (95% CI)		0.750 (0.559, 1.006)	
p-value		0.0504	
>= 65			
Total Patients	43	38	
Patients (%) With Events	34 (79.1%)	30 (78.9%)	
Patients (%) Without Events (Censored)	9 (20.9%)	8 (21.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.66 (0.43, 1.61)	1.71 (0.92, 3.81)	
Hazard Ratio (95% CI)		1.105 (0.666, 1.831)	
p-value		0.7158	
Race			0.2450
White			
Total Patients	114	101	
Patients (%) With Events	71 (62.3%)	77 (76.2%)	
Patients (%) Without Events (Censored)	43 (37.7%)	24 (23.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.37 (1.25, 6.41)	1.61 (1.05, 2.33)	
Hazard Ratio (95% CI)		0.712 (0.514, 0.987)	
p-value		0.0393	
Asian			
Total Patients	38	38	
Patients (%) With Events	29 (76.3%)	27 (71.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	9 (23.7%)	11 (28.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.56, 5.39)	1.77 (0.92, 5.39)	
Hazard Ratio (95% CI)		1.093 (0.643, 1.859)	
p-value		0.7825	
Other			
Total Patients	18	24	
Patients (%) With Events	17 (94.4%)	22 (91.7%)	
Patients (%) Without Events (Censored)	1 (5.6%)	2 (8.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.43 (0.30, 0.69)	0.97 (0.72, 3.88)	
Hazard Ratio (95% CI)		1.133 (0.575, 2.234)	
p-value		0.7354	
Baseline ECOG status			0.8748
0			
Total Patients	115	104	
Patients (%) With Events	77 (67.0%)	80 (76.9%)	
Patients (%) Without Events (Censored)	38 (33.0%)	24 (23.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.41 (0.72, 3.68)	1.84 (1.15, 2.50)	
Hazard Ratio (95% CI)		0.861 (0.628, 1.182)	
p-value		0.3369	
1			
Total Patients	60	62	
Patients (%) With Events	44 (73.3%)	47 (75.8%)	
Patients (%) Without Events (Censored)	16 (26.7%)	15 (24.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.07 (0.89, 5.39)	1.41 (0.76, 2.63)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.769 (0.503, 1.176)	
p-value		0.2205	
The physician's choice of chemotherapy selected prior to randomization			0.0008
Taxane			
Total Patients	51	44	
Patients (%) With Events	34 (66.7%)	18 (40.9%)	
Patients (%) Without Events (Censored)	17 (33.3%)	26 (59.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.79, 6.41)	7.79 (2.27, NR)	
Hazard Ratio (95% CI)		1.827 (1.028, 3.249)	
p-value		0.0375	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	87 (70.2%)	109 (89.3%)	
Patients (%) Without Events (Censored)	37 (29.8%)	13 (10.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.51 (0.72, 3.68)	1.18 (0.95, 1.77)	
Hazard Ratio (95% CI)		0.632 (0.472, 0.847)	
p-value		0.0017	
History of liver metastasis			0.7442
Yes			
Total Patients	47	37	
Patients (%) With Events	33 (70.2%)	27 (73.0%)	
Patients (%) Without Events (Censored)	14 (29.8%)	10 (27.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.49, 3.81)	1.41 (0.92, 2.99)	
Hazard Ratio (95% CI)		0.927 (0.551, 1.560)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.7533	
No			
Total Patients	128	129	
Patients (%) With Events	88 (68.8%)	100 (77.5%)	
Patients (%) Without Events (Censored)	40 (31.2%)	29 (22.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.91 (0.95, 4.14)	1.77 (1.15, 2.37)	
Hazard Ratio (95% CI)		0.792 (0.591, 1.060)	
p-value		0.1100	
History of brain metastasis			0.9420
Yes			
Total Patients	8	9	
Patients (%) With Events	6 (75.0%)	8 (88.9%)	
Patients (%) Without Events (Censored)	2 (25.0%)	1 (11.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.84 (0.20, NR)	1.64 (0.07, 2.50)	
Hazard Ratio (95% CI)		0.813 (0.276, 2.394)	
p-value		0.7050	
No			
Total Patients	167	157	
Patients (%) With Events	115 (68.9%)	119 (75.8%)	
Patients (%) Without Events (Censored)	52 (31.1%)	38 (24.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.61 (0.95, 3.58)	1.71 (1.05, 2.37)	
Hazard Ratio (95% CI)		0.825 (0.635, 1.071)	
p-value		0.1403	
PD-L1 Status			0.2740

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	43 (65.2%)	47 (82.5%)	
Patients (%) Without Events (Censored)	23 (34.8%)	10 (17.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.59 (0.72, 4.14)	1.41 (0.95, 2.17)	
Hazard Ratio (95% CI)		0.709 (0.465, 1.081)	
p-value		0.1042	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	78 (71.6%)	80 (73.4%)	
Patients (%) Without Events (Censored)	31 (28.4%)	29 (26.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.71 (0.95, 3.68)	1.84 (0.99, 3.02)	
Hazard Ratio (95% CI)		0.901 (0.656, 1.238)	
p-value		0.5068	
BRCA 1/2 status			0.0104
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	45 (69.2%)	44 (69.8%)	
Patients (%) Without Events (Censored)	20 (30.8%)	19 (30.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.04 (0.92, 4.83)	1.41 (0.92, 3.09)	
Hazard Ratio (95% CI)		0.818 (0.535, 1.249)	
p-value		0.3486	
Mutant			
Total Patients	12	10	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	11 (91.7%)	7 (70.0%)	
Patients (%) Without Events (Censored)	1 (8.3%)	3 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.48 (0.23, 0.95)	3.48 (0.72, NR)	
Hazard Ratio (95% CI)		3.539 (1.278, 9.802)	
p-value		0.0110	
Menopausal status			0.8446
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	24 (64.9%)	35 (72.9%)	
Patients (%) Without Events (Censored)	13 (35.1%)	13 (27.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.20 (0.72, 8.05)	1.84 (0.95, 3.02)	
Hazard Ratio (95% CI)		0.855 (0.507, 1.439)	
p-value		0.5470	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	97 (70.3%)	92 (78.6%)	
Patients (%) Without Events (Censored)	41 (29.7%)	25 (21.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.59 (0.95, 3.68)	1.61 (0.99, 2.50)	
Hazard Ratio (95% CI)		0.793 (0.592, 1.061)	
p-value		0.1095	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.9. Table 1.1.9: Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Number of patients at risk	175 (100.0%)	166 (100.0%)
Number of patients with events	9 (5.1%)	28 (16.9%)
Sacituzumab Govitecan	9 (5.1%)	0
Paclitaxel	0	6 (3.6%)
Gemcitabine	0	11 (6.6%)
Carboplatin	0	21 (12.7%)
Number of patients censored	166 (94.9%)	138 (83.1%)
Probability of being event-free [a] [95% CI] [b] at:		
Month 3	96.5 [92.4, 98.4]	94.9 [90.0, 97.4]
Month 6	95.1 [90.5, 97.5]	90.8 [84.6, 94.6]
Month 9	95.1 [90.5, 97.5]	79.8 [70.4, 86.6]
Month 12	95.1 [90.5, 97.5]	71.2 [57.6, 81.1]
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (14.55, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.224 (0.104, 0.480)
p-value		<0.0001

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[a] Estimated from the Kaplan-Meier method.
[b] Calculated using the log-log transformation (Brookmeyer-Crowley method).

	SG (N=175)	TPC (N=166)

[c] Median 95% CI based on Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties. p-value is from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm in the Safety Analysis Set.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.10. Table 1.1.10: Subgroup Analysis of Time to First TEAE leading to Study Drug Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.3993
De novo			
Total Patients	55	48	
Patients (%) With Events	5 (9.1%)	7 (14.6%)	
Patients (%) Without Events (Censored)	50 (90.9%)	41 (85.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.505 (0.157, 1.629)	
p-value		0.2450	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	1 (2.9%)	4 (12.1%)	
Patients (%) Without Events (Censored)	33 (97.1%)	29 (87.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.73, NR)	
Hazard Ratio (95% CI)		0.155 (0.016, 1.475)	
p-value		0.0683	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	3 (3.5%)	17 (20.0%)	
Patients (%) Without Events (Censored)	83 (96.5%)	68 (80.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (12.06, NR)	
Hazard Ratio (95% CI)		0.133 (0.039, 0.459)	
p-value		0.0002	
Geographic region			0.6954
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	3 (5.5%)	10 (20.0%)	
Patients (%) Without Events (Censored)	52 (94.5%)	40 (80.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.93, NR)	
Hazard Ratio (95% CI)		0.211 (0.058, 0.770)	
p-value		0.0095	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	6 (5.0%)	18 (15.5%)	
Patients (%) Without Events (Censored)	114 (95.0%)	98 (84.5%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.231 (0.090, 0.593)	
p-value		0.0010	
Age group			0.0136
< 65			
Total Patients	132	128	
Patients (%) With Events	4 (3.0%)	23 (18.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	128 (97.0%)	105 (82.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (12.06, NR)	
Hazard Ratio (95% CI)		0.106 (0.036, 0.313)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	5 (11.6%)	5 (13.2%)	
Patients (%) Without Events (Censored)	38 (88.4%)	33 (86.8%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (19.61, NR)	
Hazard Ratio (95% CI)		0.888 (0.253, 3.120)	
p-value		0.8531	
Race			0.0687
White			
Total Patients	114	101	
Patients (%) With Events	4 (3.5%)	21 (20.8%)	
Patients (%) Without Events (Censored)	110 (96.5%)	80 (79.2%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (11.73, NR)	
Hazard Ratio (95% CI)		0.120 (0.041, 0.352)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	3 (7.9%)	
Patients (%) Without Events (Censored)	34 (89.5%)	35 (92.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.054 (0.229, 4.846)	
p-value		0.9457	
Other			
Total Patients	18	24	
Patients (%) With Events	1 (5.6%)	4 (16.7%)	
Patients (%) Without Events (Censored)	17 (94.4%)	20 (83.3%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	14.55 (14.55, NR)	
Hazard Ratio (95% CI)		0.222 (0.023, 2.137)	
p-value		0.1607	
Baseline ECOG status			0.5546
0			
Total Patients	115	104	
Patients (%) With Events	7 (6.1%)	19 (18.3%)	
Patients (%) Without Events (Censored)	108 (93.9%)	85 (81.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (14.55, NR)	
Hazard Ratio (95% CI)		0.248 (0.103, 0.597)	
p-value		0.0008	
1			
Total Patients	60	62	
Patients (%) With Events	2 (3.3%)	9 (14.5%)	
Patients (%) Without Events (Censored)	58 (96.7%)	53 (85.5%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (8.48, NR)	
Hazard Ratio (95% CI)		0.172 (0.037, 0.808)	
p-value		0.0121	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.4581
Taxane			
Total Patients	51	44	
Patients (%) With Events	4 (7.8%)	6 (13.6%)	
Patients (%) Without Events (Censored)	47 (92.2%)	38 (86.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.450 (0.126, 1.611)	
p-value		0.2086	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	5 (4.0%)	22 (18.0%)	
Patients (%) Without Events (Censored)	119 (96.0%)	100 (82.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.170 (0.064, 0.454)	
p-value		0.0001	
History of liver metastasis			0.0897
Yes			
Total Patients	47	37	
Patients (%) With Events	0	3 (8.1%)	
Patients (%) Without Events (Censored)	47 (100.0%)	34 (91.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (6.44, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0060	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	9 (7.0%)	25 (19.4%)	
Patients (%) Without Events (Censored)	119 (93.0%)	104 (80.6%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.284 (0.131, 0.615)	
p-value		0.0007	
History of brain metastasis			0.9652
Yes			
Total Patients	8	9	
Patients (%) With Events	1 (12.5%)	4 (44.4%)	
Patients (%) Without Events (Censored)	7 (87.5%)	5 (55.6%)	
Median Time to Discontinuation, months (95% CI)	NR (1.58, NR)	8.57 (0.20, NR)	
Hazard Ratio (95% CI)		0.269 (0.030, 2.409)	
p-value		0.2077	
No			
Total Patients	167	157	
Patients (%) With Events	8 (4.8%)	24 (15.3%)	
Patients (%) Without Events (Censored)	159 (95.2%)	133 (84.7%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.223 (0.099, 0.502)	
p-value		0.0001	
PD-L1 Status			0.0042
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	1 (1.5%)	16 (28.1%)	
Patients (%) Without Events (Censored)	65 (98.5%)	41 (71.9%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	12.06 (8.48, NR)	
Hazard Ratio (95% CI)		0.036 (0.005, 0.275)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	8 (7.3%)	12 (11.0%)	
Patients (%) Without Events (Censored)	101 (92.7%)	97 (89.0%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.526 (0.212, 1.308)	
p-value		0.1603	
BRCA 1/2 status			0.7310
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	3 (4.6%)	6 (9.5%)	
Patients (%) Without Events (Censored)	62 (95.4%)	57 (90.5%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.403 (0.101, 1.616)	
p-value		0.1847	
Mutant			
Total Patients	12	10	
Patients (%) With Events	1 (8.3%)	2 (20.0%)	
Patients (%) Without Events (Censored)	11 (91.7%)	8 (80.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	19.61 (6.93, NR)	
Hazard Ratio (95% CI)		0.953 (0.060, 15.255)	
p-value		0.9731	
Menopausal status			0.7079
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	1 (2.7%)	7 (14.6%)	
Patients (%) Without Events (Censored)	36 (97.3%)	41 (85.4%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (14.55, NR)	
Hazard Ratio (95% CI)		0.148 (0.018, 1.221)	
p-value		0.0413	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	8 (5.8%)	21 (17.9%)	
Patients (%) Without Events (Censored)	130 (94.2%)	96 (82.1%)	
Median Time to Discontinuation, months (95% CI)	NR (NR, NR)	NR (11.93, NR)	
Hazard Ratio (95% CI)		0.230 (0.100, 0.525)	
p-value		0.0002	

SG = sacituzumab govitecan, TPC = treatment of physician's choice.
NR = Not Reached. NC = Not Calculable (HR is NC when one treatment arm has zero events; log-rank p-value remains valid).
Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if all categories contain ≥10 patients across both arms combined.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

6.11. Table 1.1.11: Analysis of Time to First TEAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Blood and lymphatic system disorders		
Total Patients	175	166
Patients (%) With Events	133 (76.0%)	136 (81.9%)
Patients (%) Without Events (Censored)	42 (24.0%)	30 (18.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.72 (0.69, 0.92)	0.72 (0.69, 0.95)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.852 (0.670, 1.084)
p-value		0.1732
Anaemia		
Total Patients	175	166
Patients (%) With Events	68 (38.9%)	95 (57.2%)
Patients (%) Without Events (Censored)	107 (61.1%)	71 (42.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (10.32, NR)	2.73 (2.10, 4.30)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.535 (0.391, 0.734)
p-value		0.0001
Febrile neutropenia		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	3 (1.8%)
Patients (%) Without Events (Censored)	167 (95.4%)	163 (98.2%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.570 (0.682, 9.687)
p-value		0.1478
Leukopenia		
Total Patients	175	166
Patients (%) With Events	48 (27.4%)	56 (33.7%)
Patients (%) Without Events (Censored)	127 (72.6%)	110 (66.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	29.90 (23.66, NR)	15.90 (9.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.722 (0.489, 1.066)
p-value		0.0991
Lymphopenia		
Total Patients	175	166
Patients (%) With Events	24 (13.7%)	24 (14.5%)
Patients (%) Without Events (Censored)	151 (86.3%)	142 (85.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.868 (0.491, 1.534)
p-value		0.6244
Neutropenia		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	116 (66.3%)	116 (69.9%)
Patients (%) Without Events (Censored)	59 (33.7%)	50 (30.1%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.02 (0.72, 2.60)	1.25 (0.92, 1.87)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.910 (0.703, 1.179)
p-value		0.4435
Thrombocytopenia		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	71 (42.8%)
Patients (%) Without Events (Censored)	170 (97.1%)	95 (57.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	6.93 (5.39, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.045 (0.018, 0.113)
p-value		<0.0001
Cardiac disorders		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	15 (9.0%)
Patients (%) Without Events (Censored)	157 (89.7%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (23.92, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.042 (0.523, 2.077)
p-value		0.9078
Ear and labyrinth disorders		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	7 (4.2%)
Patients (%) Without Events (Censored)	168 (96.0%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.889 (0.311, 2.541)
p-value		0.8263
Eye disorders		
Total Patients	175	166
Patients (%) With Events	27 (15.4%)	10 (6.0%)
Patients (%) Without Events (Censored)	148 (84.6%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (20.76, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.277 (1.098, 4.724)
p-value		0.0231
Dry eye		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	2 (1.2%)
Patients (%) Without Events (Censored)	165 (94.3%)	164 (98.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.971 (0.866, 18.219)
p-value		0.0555
Gastrointestinal disorders		
Total Patients	175	166
Patients (%) With Events	162 (92.6%)	119 (71.7%)
Patients (%) Without Events (Censored)	13 (7.4%)	47 (28.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.26 (0.16, 0.30)	0.80 (0.39, 1.74)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.849 (1.454, 2.350)
p-value		<0.0001
Abdominal distension		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	5 (3.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.859 (0.246, 2.997)
p-value		0.8117
Abdominal pain		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	29 (16.6%)	12 (7.2%)
Patients (%) Without Events (Censored)	146 (83.4%)	154 (92.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.218 (1.129, 4.357)
p-value		0.0178
Abdominal pain upper		
Total Patients	175	166
Patients (%) With Events	16 (9.1%)	10 (6.0%)
Patients (%) Without Events (Censored)	159 (90.9%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.423 (0.644, 3.144)
p-value		0.3806
Constipation		
Total Patients	175	166
Patients (%) With Events	73 (41.7%)	50 (30.1%)
Patients (%) Without Events (Censored)	102 (58.3%)	116 (69.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (6.05, NR)	NR (14.75, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.430 (0.997, 2.051)
p-value		0.0504
Diarrhoea		
Total Patients	175	166
Patients (%) With Events	102 (58.3%)	37 (22.3%)
Patients (%) Without Events (Censored)	73 (41.7%)	129 (77.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	3.32 (1.25, 7.33)	NR (20.96, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.382 (2.318, 4.935)
p-value		<0.0001
Dyspepsia		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	7 (4.2%)
Patients (%) Without Events (Censored)	161 (92.0%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.557 (0.622, 3.899)
p-value		0.3401
Gastrooesophageal reflux disease		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	2 (1.2%)
Patients (%) Without Events (Censored)	164 (93.7%)	164 (98.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		4.804 (1.062, 21.738)
p-value		0.0244
Nausea		
Total Patients	175	166
Patients (%) With Events	111 (63.4%)	70 (42.2%)
Patients (%) Without Events (Censored)	64 (36.6%)	96 (57.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	2.53 (0.95, 3.98)	15.54 (9.23, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.750 (1.297, 2.362)
p-value		0.0002
Stomatitis		
Total Patients	175	166
Patients (%) With Events	30 (17.1%)	8 (4.8%)
Patients (%) Without Events (Censored)	145 (82.9%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.302 (1.510, 7.218)
p-value		0.0015
Vomiting		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	52 (29.7%)	27 (16.3%)
Patients (%) Without Events (Censored)	123 (70.3%)	139 (83.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.795 (1.126, 2.860)
p-value		0.0125
General disorders and administration site conditions		
Total Patients	175	166
Patients (%) With Events	119 (68.0%)	101 (60.8%)
Patients (%) Without Events (Censored)	56 (32.0%)	65 (39.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.81 (1.35, 2.86)	3.55 (1.94, 4.44)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.165 (0.893, 1.520)
p-value		0.2616
Chest pain		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	3 (1.8%)
Patients (%) Without Events (Censored)	167 (95.4%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		2.323 (0.615, 8.778)
p-value		0.2006
Fatigue		
Total Patients	175	166
Patients (%) With Events	91 (52.0%)	82 (49.4%)
Patients (%) Without Events (Censored)	84 (48.0%)	84 (50.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	4.90 (2.53, NR)	7.26 (3.78, 17.51)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.071 (0.794, 1.443)
p-value		0.6580
Malaise		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	5 (3.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.854 (0.633, 5.431)
p-value		0.2527
Oedema peripheral		
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	13 (7.8%)
Patients (%) Without Events (Censored)	158 (90.3%)	153 (92.2%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.090 (0.527, 2.253)
p-value		0.8153
Pain		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	4 (2.4%)
Patients (%) Without Events (Censored)	168 (96.0%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.455 (0.422, 5.022)
p-value		0.5504
Pyrexia		
Total Patients	175	166
Patients (%) With Events	20 (11.4%)	21 (12.7%)
Patients (%) Without Events (Censored)	155 (88.6%)	145 (87.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.766 (0.413, 1.420)
p-value		0.3954
Hepatobiliary disorders		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	11 (6.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.676 (0.279, 1.641)
p-value		0.3844
Immune system disorders		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	6 (3.6%)
Patients (%) Without Events (Censored)	168 (96.0%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.008 (0.337, 3.012)
p-value		0.9885
Infections and infestations		
Total Patients	175	166
Patients (%) With Events	101 (57.7%)	85 (51.2%)
Patients (%) Without Events (Censored)	74 (42.3%)	81 (48.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	6.57 (4.76, 7.69)	5.75 (4.37, 9.23)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.038 (0.777, 1.386)
p-value		0.7977
COVID-19		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	9 (5.4%)
Patients (%) Without Events (Censored)	164 (93.7%)	157 (94.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.967 (0.399, 2.346)
p-value		0.9411
Influenza		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	6 (3.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (20.53, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.078 (0.380, 3.057)
p-value		0.8876
Nasopharyngitis		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	9 (5.4%)
Patients (%) Without Events (Censored)	161 (92.0%)	157 (94.6%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (22.97, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.224 (0.528, 2.838)
p-value		0.6367
Pneumonia		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	11 (6.6%)
Patients (%) Without Events (Censored)	165 (94.3%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.587 (0.245, 1.405)
p-value		0.2270
Upper respiratory tract infection		
Total Patients	175	166
Patients (%) With Events	20 (11.4%)	11 (6.6%)
Patients (%) Without Events (Censored)	155 (88.6%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.428 (0.682, 2.991)
p-value		0.3420
Urinary tract infection		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	22 (12.6%)	26 (15.7%)
Patients (%) Without Events (Censored)	153 (87.4%)	140 (84.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.85, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.702 (0.396, 1.243)
p-value		0.2227
Injury, poisoning and procedural complications		
Total Patients	175	166
Patients (%) With Events	19 (10.9%)	29 (17.5%)
Patients (%) Without Events (Censored)	156 (89.1%)	137 (82.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.83, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.498 (0.277, 0.894)
p-value		0.0174
Infusion related reaction		
Total Patients	175	166
Patients (%) With Events	3 (1.7%)	10 (6.0%)
Patients (%) Without Events (Censored)	172 (98.3%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (18.92, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.239 (0.065, 0.883)
p-value		0.0203
Investigations		
Total Patients	175	166
Patients (%) With Events	76 (43.4%)	78 (47.0%)
Patients (%) Without Events (Censored)	99 (56.6%)	88 (53.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	19.35 (7.85, NR)	7.16 (3.25, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.766 (0.557, 1.052)
p-value		0.1020
Alanine aminotransferase increased		
Total Patients	175	166
Patients (%) With Events	35 (20.0%)	59 (35.5%)
Patients (%) Without Events (Censored)	140 (80.0%)	107 (64.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (11.76, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.438 (0.287, 0.668)
p-value		0.0001
Aspartate aminotransferase increased		
Total Patients	175	166
Patients (%) With Events	32 (18.3%)	48 (28.9%)
Patients (%) Without Events (Censored)	143 (81.7%)	118 (71.1%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.526 (0.335, 0.824)
p-value		0.0045
Blood alkaline phosphatase increased		
Total Patients	175	166
Patients (%) With Events	25 (14.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	150 (85.7%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.986 (0.973, 4.052)
p-value		0.0548
Blood creatinine increased		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	5 (3.0%)
Patients (%) Without Events (Censored)	169 (96.6%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.073 (0.327, 3.518)
p-value		0.9086
Gamma-glutamyltransferase increased		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	10 (6.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.861 (0.357, 2.074)
p-value		0.7403
Weight decreased		
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	6 (3.6%)
Patients (%) Without Events (Censored)	158 (90.3%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.626 (1.034, 6.674)
p-value		0.0350
Metabolism and nutrition disorders		
Total Patients	175	166
Patients (%) With Events	76 (43.4%)	57 (34.3%)
Patients (%) Without Events (Censored)	99 (56.6%)	109 (65.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	12.88 (7.13, NR)	15.44 (12.32, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.281 (0.908, 1.807)
p-value		0.1581
Decreased appetite		
Total Patients	175	166
Patients (%) With Events	35 (20.0%)	22 (13.3%)
Patients (%) Without Events (Censored)	140 (80.0%)	144 (86.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.423 (0.834, 2.430)
p-value		0.1938
Hyperglycaemia		
Total Patients	175	166
Patients (%) With Events	15 (8.6%)	16 (9.6%)
Patients (%) Without Events (Censored)	160 (91.4%)	150 (90.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.823 (0.406, 1.671)
p-value		0.5874
Hyperkalaemia		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	4 (2.4%)
Patients (%) Without Events (Censored)	169 (96.6%)	162 (97.6%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.335 (0.376, 4.737)
p-value		0.6546
Hypoalbuminaemia		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	4 (2.4%)
Patients (%) Without Events (Censored)	169 (96.6%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.336 (0.375, 4.754)
p-value		0.6539
Hypocalcaemia		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	8 (4.8%)
Patients (%) Without Events (Censored)	165 (94.3%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	26.48 (26.48, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.024 (0.400, 2.620)
p-value		0.9583
Hypokalaemia		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	11 (6.6%)
Patients (%) Without Events (Censored)	158 (90.3%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.314 (0.611, 2.824)
p-value		0.4850
Hypomagnesaemia		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	10 (6.0%)
Patients (%) Without Events (Censored)	163 (93.1%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (21.19, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.881 (0.376, 2.062)
p-value		0.7694
Hyponatraemia		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	8 (4.8%)
Patients (%) Without Events (Censored)	164 (93.7%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.305 (0.525, 3.245)
p-value		0.5645
Musculoskeletal and connective tissue disorders		
Total Patients	175	166
Patients (%) With Events	67 (38.3%)	62 (37.3%)
Patients (%) Without Events (Censored)	108 (61.7%)	104 (62.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.13 (10.41, NR)	13.50 (8.77, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.876 (0.618, 1.242)
p-value		0.4573
Arthralgia		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	18 (10.8%)
Patients (%) Without Events (Censored)	157 (89.7%)	148 (89.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.746 (0.384, 1.449)
p-value		0.3843
Back pain		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	17 (10.2%)
Patients (%) Without Events (Censored)	157 (89.7%)	149 (89.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.68, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.857 (0.439, 1.672)
p-value		0.6499
Bone pain		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	1 (0.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	165 (99.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		7.197 (0.907, 57.089)
p-value		0.0293
Myalgia		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	18 (10.8%)
Patients (%) Without Events (Censored)	161 (92.0%)	148 (89.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.06, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.615 (0.303, 1.247)
p-value		0.1735
Pain in extremity		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	14 (8.4%)
Patients (%) Without Events (Censored)	168 (96.0%)	152 (91.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (24.44, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.389 (0.156, 0.971)
p-value		0.0363
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	2 (1.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.859 (0.599, 13.640)
p-value		0.1688
Nervous system disorders		
Total Patients	175	166
Patients (%) With Events	69 (39.4%)	66 (39.8%)
Patients (%) Without Events (Censored)	106 (60.6%)	100 (60.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	14.29 (10.64, NR)	12.58 (6.44, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.876 (0.624, 1.229)
p-value		0.4447
Dizziness		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	164 (93.7%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (25.26, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.831 (0.358, 1.926)
p-value		0.6657
Dysgeusia		
Total Patients	175	166
Patients (%) With Events	14 (8.0%)	12 (7.2%)
Patients (%) Without Events (Censored)	161 (92.0%)	154 (92.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.046 (0.483, 2.267)
p-value		0.9088
Headache		
Total Patients	175	166
Patients (%) With Events	27 (15.4%)	25 (15.1%)
Patients (%) Without Events (Censored)	148 (84.6%)	141 (84.9%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.918 (0.531, 1.587)
p-value		0.7597
Neuropathy peripheral		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	15 (9.0%)
Patients (%) Without Events (Censored)	166 (94.9%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.460 (0.200, 1.056)
p-value		0.0608
Peripheral sensory neuropathy		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	15 (9.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.270 (0.098, 0.745)
p-value		0.0068
Psychiatric disorders		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	24 (13.7%)	19 (11.4%)
Patients (%) Without Events (Censored)	151 (86.3%)	147 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.123 (0.613, 2.057)
p-value		0.7075
Anxiety		
Total Patients	175	166
Patients (%) With Events	6 (3.4%)	6 (3.6%)
Patients (%) Without Events (Censored)	169 (96.6%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.851 (0.273, 2.648)
p-value		0.7801
Depression		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	2 (1.2%)
Patients (%) Without Events (Censored)	164 (93.7%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		4.900 (1.084, 22.157)
p-value		0.0223
Insomnia		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	7 (4.2%)
Patients (%) Without Events (Censored)	166 (94.9%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.108 (0.409, 3.001)
p-value		0.8393
Renal and urinary disorders		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	14 (8.4%)
Patients (%) Without Events (Censored)	154 (88.0%)	152 (91.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.296 (0.657, 2.557)
p-value		0.4540
Reproductive system and breast disorders		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	17 (10.2%)
Patients (%) Without Events (Censored)	154 (88.0%)	149 (89.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.995 (0.523, 1.893)
p-value		0.9861
Breast pain		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	164 (93.7%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.774 (0.333, 1.797)
p-value		0.5494
Respiratory, thoracic and mediastinal disorders		
Total Patients	175	166
Patients (%) With Events	66 (37.7%)	51 (30.7%)
Patients (%) Without Events (Censored)	109 (62.3%)	115 (69.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	15.34 (10.68, NR)	22.05 (11.60, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.148 (0.795, 1.658)
p-value		0.4591
Cough		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	33 (18.9%)	15 (9.0%)
Patients (%) Without Events (Censored)	142 (81.1%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (23.92, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.852 (1.003, 3.418)
p-value		0.0453
Dyspnoea		
Total Patients	175	166
Patients (%) With Events	19 (10.9%)	22 (13.3%)
Patients (%) Without Events (Censored)	156 (89.1%)	144 (86.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (22.05, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.753 (0.406, 1.393)
p-value		0.3642
Oropharyngeal pain		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	5 (3.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.805 (0.616, 5.291)
p-value		0.2747
Pulmonary embolism		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	6 (3.6%)
Patients (%) Without Events (Censored)	166 (94.9%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.359 (0.483, 3.827)
p-value		0.5596
Rhinorrhoea		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	2 (1.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.051 (0.645, 14.436)
p-value		0.1392
Skin and subcutaneous tissue disorders		
Total Patients	175	166
Patients (%) With Events	120 (68.6%)	67 (40.4%)
Patients (%) Without Events (Censored)	55 (31.4%)	99 (59.6%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	0.95 (0.72, 1.35)	17.08 (6.24, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.468 (1.826, 3.337)
p-value		<0.0001
Alopecia		
Total Patients	175	166
Patients (%) With Events	97 (55.4%)	34 (20.5%)
Patients (%) Without Events (Censored)	78 (44.6%)	132 (79.5%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	1.41 (0.92, 11.93)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		3.799 (2.566, 5.623)
p-value		<0.0001
Dry skin		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	3 (1.8%)
Patients (%) Without Events (Censored)	166 (94.9%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (23.56, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.378 (0.637, 8.876)
p-value		0.1840
Eczema		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	3 (1.7%)	7 (4.2%)
Patients (%) Without Events (Censored)	172 (98.3%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.370 (0.095, 1.439)
p-value		0.1356
Pruritus		
Total Patients	175	166
Patients (%) With Events	17 (9.7%)	6 (3.6%)
Patients (%) Without Events (Censored)	158 (90.3%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.340 (0.918, 5.963)
p-value		0.0668
Rash		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	15 (9.0%)
Patients (%) Without Events (Censored)	154 (88.0%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		1.191 (0.612, 2.320)
p-value		0.6063
Vascular disorders		
Total Patients	175	166
Patients (%) With Events	28 (16.0%)	27 (16.3%)
Patients (%) Without Events (Censored)	147 (84.0%)	139 (83.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	25.56 (18.73, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.840 (0.493, 1.431)
p-value		0.5221
Hot flush		
Total Patients	175	166
Patients (%) With Events	9 (5.1%)	4 (2.4%)
Patients (%) Without Events (Censored)	166 (94.9%)	162 (97.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.002 (0.615, 6.516)
p-value		0.2394

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=175)	TPC (N=166)

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.12. Table 1.1.12.1: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
History of brain metastasis			0.3896
Yes			
Total Patients	8	9	
Patients (%) With Events	1 (12.5%)	0 (0.0%)	
Patients (%) Without Events (Censored)	7 (87.5%)	9 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (5.06, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.3613	
No			
Total Patients	167	157	
Patients (%) With Events	26 (15.6%)	10 (6.4%)	
Patients (%) Without Events (Censored)	141 (84.4%)	147 (93.6%)	
Median Time to First TEAE, months (95% CI)	NR (20.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.176 (1.045, 4.532)	
p-value		0.0333	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.13. Table 1.1.12.2: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.2400
De novo			
Total Patients	55	48	
Patients (%) With Events	52 (94.5%)	31 (64.6%)	
Patients (%) Without Events (Censored)	3 (5.5%)	17 (35.4%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.10, 0.36)	0.76 (0.30, 5.19)	
Hazard Ratio (95% CI)		2.332 (1.478, 3.679)	
p-value		0.0002	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	30 (88.2%)	24 (72.7%)	
Patients (%) Without Events (Censored)	4 (11.8%)	9 (27.3%)	
Median Time to First TEAE, months (95% CI)	0.38 (0.16, 1.45)	0.95 (0.26, 3.29)	
Hazard Ratio (95% CI)		1.292 (0.749, 2.229)	
p-value		0.3484	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	86	85	
Patients (%) With Events	80 (93.0%)	64 (75.3%)	
Patients (%) Without Events (Censored)	6 (7.0%)	21 (24.7%)	
Median Time to First TEAE, months (95% CI)	0.21 (0.10, 0.30)	0.82 (0.20, 2.04)	
Hazard Ratio (95% CI)		1.873 (1.338, 2.621)	
p-value		0.0002	
Geographic region			0.6345
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	52 (94.5%)	36 (72.0%)	
Patients (%) Without Events (Censored)	3 (5.5%)	14 (28.0%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.36)	0.90 (0.30, 2.89)	
Hazard Ratio (95% CI)		2.279 (1.470, 3.534)	
p-value		0.0002	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	110 (91.7%)	83 (71.6%)	
Patients (%) Without Events (Censored)	10 (8.3%)	33 (28.4%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.33)	0.74 (0.30, 2.04)	
Hazard Ratio (95% CI)		1.737 (1.300, 2.320)	
p-value		0.0001	
Age group			0.2301
< 65			
Total Patients	132	128	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	121 (91.7%)	90 (70.3%)	
Patients (%) Without Events (Censored)	11 (8.3%)	38 (29.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.36)	0.77 (0.30, 1.74)	
Hazard Ratio (95% CI)		1.699 (1.290, 2.238)	
p-value		0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	41 (95.3%)	29 (76.3%)	
Patients (%) Without Events (Censored)	2 (4.7%)	9 (23.7%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.26)	1.08 (0.26, 5.03)	
Hazard Ratio (95% CI)		2.767 (1.638, 4.674)	
p-value		0.0001	
Race			0.4510
White			
Total Patients	114	101	
Patients (%) With Events	105 (92.1%)	69 (68.3%)	
Patients (%) Without Events (Censored)	9 (7.9%)	32 (31.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	1.61 (0.72, 3.29)	
Hazard Ratio (95% CI)		2.001 (1.470, 2.723)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	36 (94.7%)	26 (68.4%)	
Patients (%) Without Events (Censored)	2 (5.3%)	12 (31.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.13 (0.10, 0.36)	0.28 (0.10, 7.59)	
Hazard Ratio (95% CI)		1.714 (1.022, 2.874)	
p-value		0.0325	
Other			
Total Patients	18	24	
Patients (%) With Events	16 (88.9%)	21 (87.5%)	
Patients (%) Without Events (Censored)	2 (11.1%)	3 (12.5%)	
Median Time to First TEAE, months (95% CI)	0.31 (0.07, 0.59)	0.59 (0.10, 0.82)	
Hazard Ratio (95% CI)		1.398 (0.721, 2.709)	
p-value		0.3261	
Baseline ECOG status			0.6508
0			
Total Patients	115	104	
Patients (%) With Events	105 (91.3%)	73 (70.2%)	
Patients (%) Without Events (Censored)	10 (8.7%)	31 (29.8%)	
Median Time to First TEAE, months (95% CI)	0.20 (0.13, 0.36)	0.90 (0.30, 2.89)	
Hazard Ratio (95% CI)		1.893 (1.399, 2.562)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	57 (95.0%)	46 (74.2%)	
Patients (%) Without Events (Censored)	3 (5.0%)	16 (25.8%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.13, 0.30)	0.72 (0.23, 2.73)	
Hazard Ratio (95% CI)		1.803 (1.214, 2.678)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0029	
The physician's choice of chemotherapy selected prior to randomization			0.1004
Taxane			
Total Patients	51	44	
Patients (%) With Events	49 (96.1%)	24 (54.5%)	
Patients (%) Without Events (Censored)	2 (3.9%)	20 (45.5%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.10, 0.43)	2.89 (0.26, NR)	
Hazard Ratio (95% CI)		2.663 (1.614, 4.392)	
p-value		0.0001	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	113 (91.1%)	95 (77.9%)	
Patients (%) Without Events (Censored)	11 (8.9%)	27 (22.1%)	
Median Time to First TEAE, months (95% CI)	0.23 (0.13, 0.30)	0.72 (0.30, 1.05)	
Hazard Ratio (95% CI)		1.638 (1.243, 2.160)	
p-value		0.0003	
History of liver metastasis			0.8623
Yes			
Total Patients	47	37	
Patients (%) With Events	44 (93.6%)	25 (67.6%)	
Patients (%) Without Events (Censored)	3 (6.4%)	12 (32.4%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.10, 0.33)	0.33 (0.10, 3.29)	
Hazard Ratio (95% CI)		1.659 (1.010, 2.723)	
p-value		0.0364	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
No			
Total Patients	128	129	
Patients (%) With Events	118 (92.2%)	94 (72.9%)	
Patients (%) Without Events (Censored)	10 (7.8%)	35 (27.1%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	0.95 (0.43, 2.04)	
Hazard Ratio (95% CI)		1.883 (1.430, 2.480)	
p-value		<0.0001	
History of brain metastasis			0.7348
Yes			
Total Patients	8	9	
Patients (%) With Events	8 (100.0%)	7 (77.8%)	
Patients (%) Without Events (Censored)	0 (0.0%)	2 (22.2%)	
Median Time to First TEAE, months (95% CI)	0.28 (0.07, 0.53)	2.73 (0.03, NR)	
Hazard Ratio (95% CI)		2.889 (0.843, 9.901)	
p-value		0.0750	
No			
Total Patients	167	157	
Patients (%) With Events	154 (92.2%)	112 (71.3%)	
Patients (%) Without Events (Censored)	13 (7.8%)	45 (28.7%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.30)	0.79 (0.39, 1.74)	
Hazard Ratio (95% CI)		1.827 (1.428, 2.337)	
p-value		<0.0001	
PD-L1 Status			0.8168
CPS < 1			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	66	57	
Patients (%) With Events	63 (95.5%)	44 (77.2%)	
Patients (%) Without Events (Censored)	3 (4.5%)	13 (22.8%)	
Median Time to First TEAE, months (95% CI)	0.28 (0.10, 0.36)	0.76 (0.13, 3.29)	
Hazard Ratio (95% CI)		1.828 (1.234, 2.706)	
p-value		0.0020	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	99 (90.8%)	75 (68.8%)	
Patients (%) Without Events (Censored)	10 (9.2%)	34 (31.2%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.30)	0.82 (0.39, 1.61)	
Hazard Ratio (95% CI)		1.880 (1.387, 2.548)	
p-value		<0.0001	
BRCA 1/2 status			0.0284
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	62 (95.4%)	42 (66.7%)	
Patients (%) Without Events (Censored)	3 (4.6%)	21 (33.3%)	
Median Time to First TEAE, months (95% CI)	0.30 (0.13, 0.36)	1.87 (0.36, 4.57)	
Hazard Ratio (95% CI)		2.313 (1.545, 3.463)	
p-value		<0.0001	
Mutant			
Total Patients	12	10	
Patients (%) With Events	9 (75.0%)	9 (90.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	3 (25.0%)	1 (10.0%)	
Median Time to First TEAE, months (95% CI)	0.38 (0.13, 5.39)	0.30 (0.03, 3.52)	
Hazard Ratio (95% CI)		0.739 (0.293, 1.867)	
p-value		0.5190	
Menopausal status			0.9291
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	34 (91.9%)	34 (70.8%)	
Patients (%) Without Events (Censored)	3 (8.1%)	14 (29.2%)	
Median Time to First TEAE, months (95% CI)	0.16 (0.07, 0.49)	0.72 (0.13, 3.29)	
Hazard Ratio (95% CI)		1.765 (1.086, 2.868)	
p-value		0.0195	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	128 (92.8%)	84 (71.8%)	
Patients (%) Without Events (Censored)	10 (7.2%)	33 (28.2%)	
Median Time to First TEAE, months (95% CI)	0.26 (0.16, 0.33)	0.85 (0.43, 2.37)	
Hazard Ratio (95% CI)		1.898 (1.435, 2.510)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.14. Table 1.1.12.3: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Injury, poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.1069
De novo			
Total Patients	55	48	
Patients (%) With Events	9 (16.4%)	10 (20.8%)	
Patients (%) Without Events (Censored)	46 (83.6%)	38 (79.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.586 (0.228, 1.501)	
p-value		0.2624	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	0 (0.0%)	4 (12.1%)	
Patients (%) Without Events (Censored)	34 (100.0%)	29 (87.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0297	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	10 (11.6%)	15 (17.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	76 (88.4%)	70 (82.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (18.83, NR)	
Hazard Ratio (95% CI)		0.560 (0.250, 1.254)	
p-value		0.1530	
Geographic region			0.4466
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	7 (12.7%)	12 (24.0%)	
Patients (%) Without Events (Censored)	48 (87.3%)	38 (76.0%)	
Median Time to First TEAE, months (95% CI)	NR (17.68, NR)	18.83 (11.76, NR)	
Hazard Ratio (95% CI)		0.320 (0.119, 0.855)	
p-value		0.0179	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	12 (10.0%)	17 (14.7%)	
Patients (%) Without Events (Censored)	108 (90.0%)	99 (85.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (18.92, NR)	
Hazard Ratio (95% CI)		0.609 (0.290, 1.279)	
p-value		0.1858	
Age group			0.9560
< 65			
Total Patients	132	128	
Patients (%) With Events	12 (9.1%)	17 (13.3%)	
Patients (%) Without Events (Censored)	120 (90.9%)	111 (86.7%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.551 (0.261, 1.161)	
p-value		0.1125	
>= 65			
Total Patients	43	38	
Patients (%) With Events	7 (16.3%)	12 (31.6%)	
Patients (%) Without Events (Censored)	36 (83.7%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	NR (9.95, NR)	18.83 (11.76, NR)	
Hazard Ratio (95% CI)		0.480 (0.187, 1.229)	
p-value		0.1181	
Race			0.5073
White			
Total Patients	114	101	
Patients (%) With Events	13 (11.4%)	16 (15.8%)	
Patients (%) Without Events (Censored)	101 (88.6%)	85 (84.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	18.92 (18.83, NR)	
Hazard Ratio (95% CI)		0.534 (0.254, 1.124)	
p-value		0.0938	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	11 (28.9%)	
Patients (%) Without Events (Censored)	34 (89.5%)	27 (71.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (7.03, NR)	
Hazard Ratio (95% CI)		0.325 (0.102, 1.037)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0463	
Other			
Total Patients	18	24	
Patients (%) With Events	1 (5.6%)	1 (4.2%)	
Patients (%) Without Events (Censored)	17 (94.4%)	23 (95.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.240 (0.077, 19.866)	
p-value		0.8788	
Baseline ECOG status			0.7767
0			
Total Patients	115	104	
Patients (%) With Events	11 (9.6%)	17 (16.3%)	
Patients (%) Without Events (Censored)	104 (90.4%)	87 (83.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (18.83, NR)	
Hazard Ratio (95% CI)		0.459 (0.213, 0.991)	
p-value		0.0426	
1			
Total Patients	60	62	
Patients (%) With Events	8 (13.3%)	12 (19.4%)	
Patients (%) Without Events (Censored)	52 (86.7%)	50 (80.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.573 (0.232, 1.414)	
p-value		0.2215	
The physician's choice of chemotherapy selected prior to randomization			0.7566

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Taxane			
Total Patients	51	44	
Patients (%) With Events	6 (11.8%)	8 (18.2%)	
Patients (%) Without Events (Censored)	45 (88.2%)	36 (81.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.498 (0.168, 1.473)	
p-value		0.2016	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	13 (10.5%)	21 (17.2%)	
Patients (%) Without Events (Censored)	111 (89.5%)	101 (82.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (18.83, NR)	
Hazard Ratio (95% CI)		0.508 (0.253, 1.021)	
p-value		0.0528	
History of liver metastasis			0.4088
Yes			
Total Patients	47	37	
Patients (%) With Events	5 (10.6%)	3 (8.1%)	
Patients (%) Without Events (Censored)	42 (89.4%)	34 (91.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (11.76, NR)	
Hazard Ratio (95% CI)		0.669 (0.137, 3.262)	
p-value		0.6168	
No			
Total Patients	128	129	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	14 (10.9%)	26 (20.2%)	
Patients (%) Without Events (Censored)	114 (89.1%)	103 (79.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (18.83, NR)	
Hazard Ratio (95% CI)		0.467 (0.242, 0.898)	
p-value		0.0196	
History of brain metastasis			0.4746
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	2 (22.2%)	
Patients (%) Without Events (Censored)	6 (75.0%)	7 (77.8%)	
Median Time to First TEAE, months (95% CI)	NR (1.58, NR)	NR (0.07, NR)	
Hazard Ratio (95% CI)		1.070 (0.151, 7.607)	
p-value		0.9458	
No			
Total Patients	167	157	
Patients (%) With Events	17 (10.2%)	27 (17.2%)	
Patients (%) Without Events (Censored)	150 (89.8%)	130 (82.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (18.83, NR)	
Hazard Ratio (95% CI)		0.467 (0.253, 0.864)	
p-value		0.0132	
PD-L1 Status			0.8547
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	8 (12.1%)	12 (21.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	58 (87.9%)	45 (78.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	18.92 (11.76, NR)	
Hazard Ratio (95% CI)		0.448 (0.182, 1.107)	
p-value		0.0746	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	11 (10.1%)	17 (15.6%)	
Patients (%) Without Events (Censored)	98 (89.9%)	92 (84.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.535 (0.247, 1.156)	
p-value		0.1067	
Menopausal status			0.5202
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	5 (13.5%)	8 (16.7%)	
Patients (%) Without Events (Censored)	32 (86.5%)	40 (83.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.745 (0.243, 2.283)	
p-value		0.6065	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	14 (10.1%)	21 (17.9%)	
Patients (%) Without Events (Censored)	124 (89.9%)	96 (82.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	18.92 (18.83, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.427 (0.215, 0.850)	
p-value		0.0127	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.15. Table 1.1.12.4: Subgroup Analysis of Time to First TEAE by SOC and PT — SOC: Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.8197
De novo			
Total Patients	55	48	
Patients (%) With Events	40 (72.7%)	23 (47.9%)	
Patients (%) Without Events (Censored)	15 (27.3%)	25 (52.1%)	
Median Time to First TEAE, months (95% CI)	0.79 (0.56, 1.41)	6.24 (1.91, NR)	
Hazard Ratio (95% CI)		2.174 (1.294, 3.653)	
p-value		0.0028	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	20 (58.8%)	10 (30.3%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	14 (41.2%)	23 (69.7%)	
Median Time to First TEAE, months (95% CI)	1.51 (0.72, NR)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.494 (1.162, 5.353)	
p-value		0.0152	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	60 (69.8%)	34 (40.0%)	
Patients (%) Without Events (Censored)	26 (30.2%)	51 (60.0%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.66, 1.35)	17.08 (5.09, NR)	
Hazard Ratio (95% CI)		2.664 (1.740, 4.077)	
p-value		<0.0001	
Geographic region			0.3011
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	37 (67.3%)	22 (44.0%)	
Patients (%) Without Events (Censored)	18 (32.7%)	28 (56.0%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.76, 3.02)	5.09 (2.37, NR)	
Hazard Ratio (95% CI)		2.107 (1.238, 3.586)	
p-value		0.0053	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	83 (69.2%)	45 (38.8%)	
Patients (%) Without Events (Censored)	37 (30.8%)	71 (61.2%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.59, 1.12)	23.56 (6.74, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.611 (1.809, 3.767)	
p-value		<0.0001	
Age group			0.2051
< 65			
Total Patients	132	128	
Patients (%) With Events	96 (72.7%)	49 (38.3%)	
Patients (%) Without Events (Censored)	36 (27.3%)	79 (61.7%)	
Median Time to First TEAE, months (95% CI)	0.87 (0.72, 1.15)	23.56 (6.47, NR)	
Hazard Ratio (95% CI)		2.705 (1.913, 3.827)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	24 (55.8%)	18 (47.4%)	
Patients (%) Without Events (Censored)	19 (44.2%)	20 (52.6%)	
Median Time to First TEAE, months (95% CI)	1.48 (0.62, NR)	5.45 (1.97, NR)	
Hazard Ratio (95% CI)		1.791 (0.966, 3.321)	
p-value		0.0618	
Race			0.5855
White			
Total Patients	114	101	
Patients (%) With Events	74 (64.9%)	33 (32.7%)	
Patients (%) Without Events (Censored)	40 (35.1%)	68 (67.3%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.76, 1.74)	NR (17.08, NR)	
Hazard Ratio (95% CI)		2.943 (1.948, 4.449)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	32 (84.2%)	23 (60.5%)	
Patients (%) Without Events (Censored)	6 (15.8%)	15 (39.5%)	
Median Time to First TEAE, months (95% CI)	0.57 (0.49, 0.92)	2.86 (0.49, NR)	
Hazard Ratio (95% CI)		1.944 (1.121, 3.370)	
p-value		0.0166	
Other			
Total Patients	18	24	
Patients (%) With Events	12 (66.7%)	8 (33.3%)	
Patients (%) Without Events (Censored)	6 (33.3%)	16 (66.7%)	
Median Time to First TEAE, months (95% CI)	1.05 (0.53, NR)	23.56 (2.43, NR)	
Hazard Ratio (95% CI)		3.510 (1.366, 9.020)	
p-value		0.0056	
Baseline ECOG status			0.7495
0			
Total Patients	115	104	
Patients (%) With Events	82 (71.3%)	46 (44.2%)	
Patients (%) Without Events (Censored)	33 (28.7%)	58 (55.8%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.69, 1.41)	17.08 (5.09, NR)	
Hazard Ratio (95% CI)		2.377 (1.651, 3.421)	
p-value		<0.0001	
1			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	60	62	
Patients (%) With Events	38 (63.3%)	21 (33.9%)	
Patients (%) Without Events (Censored)	22 (36.7%)	41 (66.1%)	
Median Time to First TEAE, months (95% CI)	0.85 (0.72, 2.20)	NR (3.38, NR)	
Hazard Ratio (95% CI)		2.613 (1.527, 4.471)	
p-value		0.0003	
The physician's choice of chemotherapy selected prior to randomization			0.0445
Taxane			
Total Patients	51	44	
Patients (%) With Events	35 (68.6%)	22 (50.0%)	
Patients (%) Without Events (Censored)	16 (31.4%)	22 (50.0%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 2.20)	3.29 (0.92, NR)	
Hazard Ratio (95% CI)		1.539 (0.901, 2.628)	
p-value		0.1101	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	85 (68.5%)	45 (36.9%)	
Patients (%) Without Events (Censored)	39 (31.5%)	77 (63.1%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.69, 1.15)	23.56 (6.74, NR)	
Hazard Ratio (95% CI)		2.949 (2.045, 4.252)	
p-value		<0.0001	
History of liver metastasis			0.7234
Yes			
Total Patients	47	37	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	29 (61.7%)	12 (32.4%)	
Patients (%) Without Events (Censored)	18 (38.3%)	25 (67.6%)	
Median Time to First TEAE, months (95% CI)	1.48 (0.66, 9.43)	NR (3.02, NR)	
Hazard Ratio (95% CI)		2.226 (1.134, 4.369)	
p-value		0.0167	
No			
Total Patients	128	129	
Patients (%) With Events	91 (71.1%)	55 (42.6%)	
Patients (%) Without Events (Censored)	37 (28.9%)	74 (57.4%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 1.12)	17.08 (5.45, NR)	
Hazard Ratio (95% CI)		2.620 (1.867, 3.676)	
p-value		<0.0001	
History of brain metastasis			0.7679
Yes			
Total Patients	8	9	
Patients (%) With Events	5 (62.5%)	3 (33.3%)	
Patients (%) Without Events (Censored)	3 (37.5%)	6 (66.7%)	
Median Time to First TEAE, months (95% CI)	2.89 (0.13, NR)	NR (0.36, NR)	
Hazard Ratio (95% CI)		1.936 (0.459, 8.173)	
p-value		0.3600	
No			
Total Patients	167	157	
Patients (%) With Events	115 (68.9%)	64 (40.8%)	
Patients (%) Without Events (Censored)	52 (31.1%)	93 (59.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.92 (0.72, 1.15)	17.08 (6.24, NR)	
Hazard Ratio (95% CI)		2.492 (1.831, 3.393)	
p-value		<0.0001	
PD-L1 Status			0.9149
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	47 (71.2%)	26 (45.6%)	
Patients (%) Without Events (Censored)	19 (28.8%)	31 (54.4%)	
Median Time to First TEAE, months (95% CI)	0.92 (0.59, 1.41)	6.54 (4.73, NR)	
Hazard Ratio (95% CI)		2.444 (1.504, 3.973)	
p-value		0.0002	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	73 (67.0%)	41 (37.6%)	
Patients (%) Without Events (Censored)	36 (33.0%)	68 (62.4%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 1.41)	NR (6.24, NR)	
Hazard Ratio (95% CI)		2.434 (1.656, 3.577)	
p-value		<0.0001	
BRCA 1/2 status			0.1401
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	47 (72.3%)	28 (44.4%)	
Patients (%) Without Events (Censored)	18 (27.7%)	35 (55.6%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.49, 1.41)	6.47 (2.37, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.281 (1.424, 3.653)	
p-value		0.0005	
Mutant			
Total Patients	12	10	
Patients (%) With Events	6 (50.0%)	7 (70.0%)	
Patients (%) Without Events (Censored)	6 (50.0%)	3 (30.0%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.56, NR)	10.17 (0.07, NR)	
Hazard Ratio (95% CI)		0.994 (0.316, 3.125)	
p-value		0.9928	
Menopausal status			0.6776
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	28 (75.7%)	21 (43.8%)	
Patients (%) Without Events (Censored)	9 (24.3%)	27 (56.2%)	
Median Time to First TEAE, months (95% CI)	0.72 (0.46, 1.41)	23.56 (3.48, NR)	
Hazard Ratio (95% CI)		2.678 (1.498, 4.787)	
p-value		0.0006	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	92 (66.7%)	46 (39.3%)	
Patients (%) Without Events (Censored)	46 (33.3%)	71 (60.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 1.41)	17.08 (5.45, NR)	
Hazard Ratio (95% CI)		2.445 (1.712, 3.492)	
p-value		<0.0001	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.16. Table 1.1.12.5: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Anaemia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.0886
De novo			
Total Patients	55	48	
Patients (%) With Events	23 (41.8%)	21 (43.8%)	
Patients (%) Without Events (Censored)	32 (58.2%)	27 (56.2%)	
Median Time to First TEAE, months (95% CI)	NR (3.65, NR)	6.47 (2.33, NR)	
Hazard Ratio (95% CI)		0.882 (0.484, 1.607)	
p-value		0.6704	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	14 (41.2%)	17 (51.5%)	
Patients (%) Without Events (Censored)	20 (58.8%)	16 (48.5%)	
Median Time to First TEAE, months (95% CI)	10.68 (5.13, NR)	4.34 (1.71, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.575 (0.278, 1.187)	
p-value		0.1303	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	31 (36.0%)	57 (67.1%)	
Patients (%) Without Events (Censored)	55 (64.0%)	28 (32.9%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.74, NR)	2.14 (1.25, 2.63)	
Hazard Ratio (95% CI)		0.397 (0.256, 0.617)	
p-value		<0.0001	
Geographic region			0.9181
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	16 (29.1%)	22 (44.0%)	
Patients (%) Without Events (Censored)	39 (70.9%)	28 (56.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	4.34 (2.33, NR)	
Hazard Ratio (95% CI)		0.591 (0.310, 1.127)	
p-value		0.1046	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	52 (43.3%)	73 (62.9%)	
Patients (%) Without Events (Censored)	68 (56.7%)	43 (37.1%)	
Median Time to First TEAE, months (95% CI)	10.74 (6.93, NR)	2.27 (1.84, 3.25)	
Hazard Ratio (95% CI)		0.518 (0.361, 0.744)	
p-value		0.0003	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Age group			0.7074
< 65			
Total Patients	132	128	
Patients (%) With Events	53 (40.2%)	71 (55.5%)	
Patients (%) Without Events (Censored)	79 (59.8%)	57 (44.5%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	3.02 (2.20, 5.52)	
Hazard Ratio (95% CI)		0.542 (0.377, 0.778)	
p-value		0.0008	
>= 65			
Total Patients	43	38	
Patients (%) With Events	15 (34.9%)	24 (63.2%)	
Patients (%) Without Events (Censored)	28 (65.1%)	14 (36.8%)	
Median Time to First TEAE, months (95% CI)	NR (2.79, NR)	2.14 (0.92, 4.34)	
Hazard Ratio (95% CI)		0.506 (0.265, 0.966)	
p-value		0.0348	
Race			0.9988
White			
Total Patients	114	101	
Patients (%) With Events	48 (42.1%)	62 (61.4%)	
Patients (%) Without Events (Censored)	66 (57.9%)	39 (38.6%)	
Median Time to First TEAE, months (95% CI)	10.74 (4.90, NR)	2.30 (1.64, 3.94)	
Hazard Ratio (95% CI)		0.524 (0.358, 0.766)	
p-value		0.0008	
Asian			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	38	38	
Patients (%) With Events	11 (28.9%)	19 (50.0%)	
Patients (%) Without Events (Censored)	27 (71.1%)	19 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	6.47 (2.10, NR)	
Hazard Ratio (95% CI)		0.540 (0.254, 1.145)	
p-value		0.1003	
Other			
Total Patients	18	24	
Patients (%) With Events	8 (44.4%)	14 (58.3%)	
Patients (%) Without Events (Censored)	10 (55.6%)	10 (41.7%)	
Median Time to First TEAE, months (95% CI)	10.68 (2.10, NR)	2.30 (1.64, 4.63)	
Hazard Ratio (95% CI)		0.435 (0.177, 1.067)	
p-value		0.0625	
Baseline ECOG status			0.1053
0			
Total Patients	115	104	
Patients (%) With Events	39 (33.9%)	61 (58.7%)	
Patients (%) Without Events (Censored)	76 (66.1%)	43 (41.3%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.73 (2.10, 5.26)	
Hazard Ratio (95% CI)		0.449 (0.299, 0.674)	
p-value		0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	29 (48.3%)	34 (54.8%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	31 (51.7%)	28 (45.2%)	
Median Time to First TEAE, months (95% CI)	9.63 (2.14, NR)	3.25 (1.18, NR)	
Hazard Ratio (95% CI)		0.703 (0.421, 1.172)	
p-value		0.1749	
The physician's choice of chemotherapy selected prior to randomization			0.0003
Taxane			
Total Patients	51	44	
Patients (%) With Events	22 (43.1%)	12 (27.3%)	
Patients (%) Without Events (Censored)	29 (56.9%)	32 (72.7%)	
Median Time to First TEAE, months (95% CI)	NR (2.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.600 (0.789, 3.247)	
p-value		0.1912	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	46 (37.1%)	83 (68.0%)	
Patients (%) Without Events (Censored)	78 (62.9%)	39 (32.0%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.68, NR)	2.10 (1.71, 2.73)	
Hazard Ratio (95% CI)		0.381 (0.265, 0.549)	
p-value		<0.0001	
History of liver metastasis			0.5396
Yes			
Total Patients	47	37	
Patients (%) With Events	16 (34.0%)	19 (51.4%)	
Patients (%) Without Events (Censored)	31 (66.0%)	18 (48.6%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (4.17, NR)	1.84 (0.99, NR)	
Hazard Ratio (95% CI)		0.470 (0.238, 0.930)	
p-value		0.0273	
No			
Total Patients	128	129	
Patients (%) With Events	52 (40.6%)	76 (58.9%)	
Patients (%) Without Events (Censored)	76 (59.4%)	53 (41.1%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.09, NR)	3.02 (2.14, 4.34)	
Hazard Ratio (95% CI)		0.561 (0.393, 0.802)	
p-value		0.0013	
History of brain metastasis			0.1260
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	6 (66.7%)	
Patients (%) Without Events (Censored)	6 (75.0%)	3 (33.3%)	
Median Time to First TEAE, months (95% CI)	NR (2.14, NR)	1.41 (0.26, NR)	
Hazard Ratio (95% CI)		0.147 (0.028, 0.771)	
p-value		0.0106	
No			
Total Patients	167	157	
Patients (%) With Events	66 (39.5%)	89 (56.7%)	
Patients (%) Without Events (Censored)	101 (60.5%)	68 (43.3%)	
Median Time to First TEAE, months (95% CI)	NR (10.32, NR)	3.02 (2.20, 4.63)	
Hazard Ratio (95% CI)		0.563 (0.408, 0.777)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0004	
PD-L1 Status			0.0242
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	21 (31.8%)	38 (66.7%)	
Patients (%) Without Events (Censored)	45 (68.2%)	19 (33.3%)	
Median Time to First TEAE, months (95% CI)	NR (16.99, NR)	2.33 (0.95, 4.30)	
Hazard Ratio (95% CI)		0.325 (0.189, 0.559)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	47 (43.1%)	57 (52.3%)	
Patients (%) Without Events (Censored)	62 (56.9%)	52 (47.7%)	
Median Time to First TEAE, months (95% CI)	10.74 (4.17, NR)	2.76 (2.10, NR)	
Hazard Ratio (95% CI)		0.704 (0.476, 1.040)	
p-value		0.0770	
BRCA 1/2 status			0.0685
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	16 (24.6%)	29 (46.0%)	
Patients (%) Without Events (Censored)	49 (75.4%)	34 (54.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	5.26 (2.10, NR)	
Hazard Ratio (95% CI)		0.435 (0.236, 0.803)	
p-value		0.0062	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Mutant			
Total Patients	12	10	
Patients (%) With Events	5 (41.7%)	3 (30.0%)	
Patients (%) Without Events (Censored)	7 (58.3%)	7 (70.0%)	
Median Time to First TEAE, months (95% CI)	10.74 (1.15, NR)	NR (2.23, NR)	
Hazard Ratio (95% CI)		1.617 (0.383, 6.833)	
p-value		0.5096	
Menopausal status			0.6862
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	13 (35.1%)	24 (50.0%)	
Patients (%) Without Events (Censored)	24 (64.9%)	24 (50.0%)	
Median Time to First TEAE, months (95% CI)	NR (4.17, NR)	5.26 (1.94, NR)	
Hazard Ratio (95% CI)		0.602 (0.306, 1.183)	
p-value		0.1343	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	55 (39.9%)	70 (59.8%)	
Patients (%) Without Events (Censored)	83 (60.1%)	47 (40.2%)	
Median Time to First TEAE, months (95% CI)	16.99 (10.32, NR)	2.33 (1.87, 3.38)	
Hazard Ratio (95% CI)		0.513 (0.359, 0.735)	
p-value		0.0002	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.17. Table 1.1.12.6: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Abdominal pain (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Age group			0.2652
< 65			
Total Patients	132	128	
Patients (%) With Events	23 (17.4%)	11 (8.6%)	
Patients (%) Without Events (Censored)	109 (82.6%)	117 (91.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (19.02, NR)	
Hazard Ratio (95% CI)		1.896 (0.921, 3.900)	
p-value		0.0777	
>= 65			
Total Patients	43	38	
Patients (%) With Events	6 (14.0%)	1 (2.6%)	
Patients (%) Without Events (Censored)	37 (86.0%)	37 (97.4%)	
Median Time to First TEAE, months (95% CI)	NR (16.69, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.904 (0.700, 49.784)	
p-value		0.0654	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Baseline ECOG status			0.3574
0			
Total Patients	115	104	
Patients (%) With Events	21 (18.3%)	10 (9.6%)	
Patients (%) Without Events (Censored)	94 (81.7%)	94 (90.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (19.02, NR)	
Hazard Ratio (95% CI)		1.835 (0.862, 3.905)	
p-value		0.1101	
1			
Total Patients	60	62	
Patients (%) With Events	8 (13.3%)	2 (3.2%)	
Patients (%) Without Events (Censored)	52 (86.7%)	60 (96.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.306 (0.914, 20.280)	
p-value		0.0446	
History of liver metastasis			0.0183
Yes			
Total Patients	47	37	
Patients (%) With Events	9 (19.1%)	0 (0.0%)	
Patients (%) Without Events (Censored)	38 (80.9%)	37 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0102	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	20 (15.6%)	12 (9.3%)	
Patients (%) Without Events (Censored)	108 (84.4%)	117 (90.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.655 (0.807, 3.394)	
p-value		0.1658	
History of brain metastasis			0.9999
Yes			
Total Patients	8	9	
Patients (%) With Events	0 (0.0%)	0 (0.0%)	
Patients (%) Without Events (Censored)	8 (100.0%)	9 (100.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		1.0000	
No			
Total Patients	167	157	
Patients (%) With Events	29 (17.4%)	12 (7.6%)	
Patients (%) Without Events (Censored)	138 (82.6%)	145 (92.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.215 (1.128, 4.352)	
p-value		0.0180	
PD-L1 Status			0.5543
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	8 (12.1%)	2 (3.5%)	
Patients (%) Without Events (Censored)	58 (87.9%)	55 (96.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (19.02, NR)	
Hazard Ratio (95% CI)		3.198 (0.676, 15.132)	
p-value		0.1219	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	21 (19.3%)	10 (9.2%)	
Patients (%) Without Events (Censored)	88 (80.7%)	99 (90.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.131 (1.002, 4.532)	
p-value		0.0445	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.18. Table 1.1.12.7: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Diarrhoea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.0176

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
De novo			
Total Patients	55	48	
Patients (%) With Events	32 (58.2%)	15 (31.2%)	
Patients (%) Without Events (Censored)	23 (41.8%)	33 (68.8%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.72, NR)	NR (6.21, NR)	
Hazard Ratio (95% CI)		2.372 (1.279, 4.397)	
p-value		0.0049	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	16 (47.1%)	9 (27.3%)	
Patients (%) Without Events (Censored)	18 (52.9%)	24 (72.7%)	
Median Time to First TEAE, months (95% CI)	13.54 (1.97, NR)	23.56 (NR, NR)	
Hazard Ratio (95% CI)		1.724 (0.758, 3.918)	
p-value		0.1904	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	54 (62.8%)	13 (15.3%)	
Patients (%) Without Events (Censored)	32 (37.2%)	72 (84.7%)	
Median Time to First TEAE, months (95% CI)	2.50 (0.59, 6.54)	NR (20.96, NR)	
Hazard Ratio (95% CI)		5.987 (3.250, 11.029)	
p-value		<0.0001	
Geographic region			0.3872
US/Canada/Western Europe			
Total Patients	55	50	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	41 (74.5%)	12 (24.0%)	
Patients (%) Without Events (Censored)	14 (25.5%)	38 (76.0%)	
Median Time to First TEAE, months (95% CI)	0.89 (0.46, 2.60)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.341 (2.274, 8.287)	
p-value		<0.0001	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	61 (50.8%)	25 (21.6%)	
Patients (%) Without Events (Censored)	59 (49.2%)	91 (78.4%)	
Median Time to First TEAE, months (95% CI)	5.39 (2.50, NR)	23.56 (20.96, NR)	
Hazard Ratio (95% CI)		2.955 (1.852, 4.715)	
p-value		<0.0001	
Age group			0.9857
< 65			
Total Patients	132	128	
Patients (%) With Events	74 (56.1%)	25 (19.5%)	
Patients (%) Without Events (Censored)	58 (43.9%)	103 (80.5%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.97, 13.54)	23.56 (20.96, NR)	
Hazard Ratio (95% CI)		3.471 (2.202, 5.470)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	28 (65.1%)	12 (31.6%)	
Patients (%) Without Events (Censored)	15 (34.9%)	26 (68.4%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	0.53 (0.33, 3.61)	NR (3.52, NR)	
Hazard Ratio (95% CI)		3.270 (1.645, 6.501)	
p-value		0.0004	
Race			0.4649
White			
Total Patients	114	101	
Patients (%) With Events	66 (57.9%)	19 (18.8%)	
Patients (%) Without Events (Censored)	48 (42.1%)	82 (81.2%)	
Median Time to First TEAE, months (95% CI)	4.37 (1.22, 11.56)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.842 (2.301, 6.414)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	18 (47.4%)	10 (26.3%)	
Patients (%) Without Events (Censored)	20 (52.6%)	28 (73.7%)	
Median Time to First TEAE, months (95% CI)	17.35 (0.46, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.126 (0.976, 4.632)	
p-value		0.0524	
Other			
Total Patients	18	24	
Patients (%) With Events	13 (72.2%)	7 (29.2%)	
Patients (%) Without Events (Censored)	5 (27.8%)	17 (70.8%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.30, 3.25)	23.56 (3.29, NR)	
Hazard Ratio (95% CI)		4.459 (1.681, 11.830)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0011	
Baseline ECOG status			0.6278
0			
Total Patients	115	104	
Patients (%) With Events	63 (54.8%)	20 (19.2%)	
Patients (%) Without Events (Censored)	52 (45.2%)	84 (80.8%)	
Median Time to First TEAE, months (95% CI)	4.57 (1.58, 16.82)	NR (23.56, NR)	
Hazard Ratio (95% CI)		3.584 (2.163, 5.939)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	39 (65.0%)	17 (27.4%)	
Patients (%) Without Events (Censored)	21 (35.0%)	45 (72.6%)	
Median Time to First TEAE, months (95% CI)	1.74 (0.66, 4.90)	20.96 (NR, NR)	
Hazard Ratio (95% CI)		3.340 (1.863, 5.990)	
p-value		<0.0001	
The physician's choice of chemotherapy selected prior to randomization			0.6521
Taxane			
Total Patients	51	44	
Patients (%) With Events	31 (60.8%)	10 (22.7%)	
Patients (%) Without Events (Censored)	20 (39.2%)	34 (77.3%)	
Median Time to First TEAE, months (95% CI)	1.74 (0.72, 17.35)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.012 (1.469, 6.175)	
p-value		0.0016	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	71 (57.3%)	27 (22.1%)	
Patients (%) Without Events (Censored)	53 (42.7%)	95 (77.9%)	
Median Time to First TEAE, months (95% CI)	3.52 (1.58, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.576 (2.286, 5.594)	
p-value		<0.0001	
History of liver metastasis			0.4559
Yes			
Total Patients	47	37	
Patients (%) With Events	28 (59.6%)	6 (16.2%)	
Patients (%) Without Events (Censored)	19 (40.4%)	31 (83.8%)	
Median Time to First TEAE, months (95% CI)	1.58 (0.36, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.483 (1.849, 10.867)	
p-value		0.0003	
No			
Total Patients	128	129	
Patients (%) With Events	74 (57.8%)	31 (24.0%)	
Patients (%) Without Events (Censored)	54 (42.2%)	98 (76.0%)	
Median Time to First TEAE, months (95% CI)	4.37 (1.97, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.218 (2.108, 4.912)	
p-value		<0.0001	
History of brain metastasis			0.3099
Yes			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	8	9	
Patients (%) With Events	6 (75.0%)	1 (11.1%)	
Patients (%) Without Events (Censored)	2 (25.0%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	1.61 (0.10, 6.54)	NR (2.50, NR)	
Hazard Ratio (95% CI)		11.033 (1.300, 93.603)	
p-value		0.0066	
No			
Total Patients	167	157	
Patients (%) With Events	96 (57.5%)	36 (22.9%)	
Patients (%) Without Events (Censored)	71 (42.5%)	121 (77.1%)	
Median Time to First TEAE, months (95% CI)	3.52 (1.25, 11.04)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.230 (2.198, 4.747)	
p-value		<0.0001	
PD-L1 Status			0.8558
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	38 (57.6%)	12 (21.1%)	
Patients (%) Without Events (Censored)	28 (42.4%)	45 (78.9%)	
Median Time to First TEAE, months (95% CI)	3.52 (0.89, 17.35)	23.56 (23.56, NR)	
Hazard Ratio (95% CI)		3.565 (1.859, 6.838)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	64 (58.7%)	25 (22.9%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	45 (41.3%)	84 (77.1%)	
Median Time to First TEAE, months (95% CI)	3.06 (1.05, 7.33)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.346 (2.090, 5.357)	
p-value		<0.0001	
BRCA 1/2 status			0.1566
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	43 (66.2%)	10 (15.9%)	
Patients (%) Without Events (Censored)	22 (33.8%)	53 (84.1%)	
Median Time to First TEAE, months (95% CI)	2.27 (0.89, 4.53)	20.96 (20.96, NR)	
Hazard Ratio (95% CI)		5.373 (2.693, 10.721)	
p-value		<0.0001	
Mutant			
Total Patients	12	10	
Patients (%) With Events	7 (58.3%)	5 (50.0%)	
Patients (%) Without Events (Censored)	5 (41.7%)	5 (50.0%)	
Median Time to First TEAE, months (95% CI)	3.86 (0.26, NR)	23.56 (0.03, NR)	
Hazard Ratio (95% CI)		2.010 (0.579, 6.983)	
p-value		0.2752	
Menopausal status			0.3317
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	17 (45.9%)	11 (22.9%)	
Patients (%) Without Events (Censored)	20 (54.1%)	37 (77.1%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (1.25, NR)	23.56 (23.56, NR)	
Hazard Ratio (95% CI)		2.613 (1.194, 5.718)	
p-value		0.0125	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	85 (61.6%)	25 (21.4%)	
Patients (%) Without Events (Censored)	53 (38.4%)	92 (78.6%)	
Median Time to First TEAE, months (95% CI)	2.60 (0.92, 5.39)	NR (20.96, NR)	
Hazard Ratio (95% CI)		3.804 (2.431, 5.951)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.19. Table 1.1.12.8: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Nausea (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.6285
De novo			
Total Patients	55	48	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	41 (74.5%)	20 (41.7%)	
Patients (%) Without Events (Censored)	14 (25.5%)	28 (58.3%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.26, 3.48)	NR (1.61, NR)	
Hazard Ratio (95% CI)		2.218 (1.291, 3.811)	
p-value		0.0029	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	17 (50.0%)	12 (36.4%)	
Patients (%) Without Events (Censored)	17 (50.0%)	21 (63.6%)	
Median Time to First TEAE, months (95% CI)	9.43 (0.49, NR)	NR (3.09, NR)	
Hazard Ratio (95% CI)		1.448 (0.690, 3.040)	
p-value		0.3227	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	53 (61.6%)	38 (44.7%)	
Patients (%) Without Events (Censored)	33 (38.4%)	47 (55.3%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.33, 7.20)	9.82 (3.09, NR)	
Hazard Ratio (95% CI)		1.660 (1.093, 2.521)	
p-value		0.0160	
Geographic region			0.8275
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	41 (74.5%)	25 (50.0%)	
Patients (%) Without Events (Censored)	14 (25.5%)	25 (50.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	1.18 (0.26, 2.89)	9.23 (1.41, NR)	
Hazard Ratio (95% CI)		1.866 (1.134, 3.072)	
p-value		0.0126	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	70 (58.3%)	45 (38.8%)	
Patients (%) Without Events (Censored)	50 (41.7%)	71 (61.2%)	
Median Time to First TEAE, months (95% CI)	3.48 (1.02, 6.47)	NR (9.33, NR)	
Hazard Ratio (95% CI)		1.691 (1.162, 2.462)	
p-value		0.0051	
Age group			0.9748
< 65			
Total Patients	132	128	
Patients (%) With Events	83 (62.9%)	53 (41.4%)	
Patients (%) Without Events (Censored)	49 (37.1%)	75 (58.6%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.59, 5.09)	NR (6.11, NR)	
Hazard Ratio (95% CI)		1.738 (1.231, 2.454)	
p-value		0.0015	
>= 65			
Total Patients	43	38	
Patients (%) With Events	28 (65.1%)	17 (44.7%)	
Patients (%) Without Events (Censored)	15 (34.9%)	21 (55.3%)	
Median Time to First TEAE, months (95% CI)	2.33 (0.49, 3.48)	9.82 (3.09, NR)	
Hazard Ratio (95% CI)		1.921 (1.043, 3.536)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0321	
Race			0.7956
White			
Total Patients	114	101	
Patients (%) With Events	73 (64.0%)	43 (42.6%)	
Patients (%) Without Events (Censored)	41 (36.0%)	58 (57.4%)	
Median Time to First TEAE, months (95% CI)	2.92 (0.82, 4.47)	15.54 (3.29, NR)	
Hazard Ratio (95% CI)		1.703 (1.167, 2.483)	
p-value		0.0051	
Asian			
Total Patients	38	38	
Patients (%) With Events	21 (55.3%)	12 (31.6%)	
Patients (%) Without Events (Censored)	17 (44.7%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	3.19 (0.16, NR)	NR (9.33, NR)	
Hazard Ratio (95% CI)		1.945 (0.954, 3.968)	
p-value		0.0582	
Other			
Total Patients	18	24	
Patients (%) With Events	13 (72.2%)	14 (58.3%)	
Patients (%) Without Events (Censored)	5 (27.8%)	10 (41.7%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.16, 5.59)	1.74 (0.30, NR)	
Hazard Ratio (95% CI)		1.478 (0.691, 3.161)	
p-value		0.3106	
Baseline ECOG status			0.3365

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
0			
Total Patients	115	104	
Patients (%) With Events	73 (63.5%)	42 (40.4%)	
Patients (%) Without Events (Censored)	42 (36.5%)	62 (59.6%)	
Median Time to First TEAE, months (95% CI)	2.92 (0.59, 4.47)	NR (9.23, NR)	
Hazard Ratio (95% CI)		1.963 (1.342, 2.871)	
p-value		0.0004	
1			
Total Patients	60	62	
Patients (%) With Events	38 (63.3%)	28 (45.2%)	
Patients (%) Without Events (Censored)	22 (36.7%)	34 (54.8%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.36, 5.39)	9.82 (1.05, NR)	
Hazard Ratio (95% CI)		1.438 (0.880, 2.348)	
p-value		0.1364	
The physician's choice of chemotherapy selected prior to randomization			0.2226
Taxane			
Total Patients	51	44	
Patients (%) With Events	31 (60.8%)	12 (27.3%)	
Patients (%) Without Events (Censored)	20 (39.2%)	32 (72.7%)	
Median Time to First TEAE, months (95% CI)	2.83 (0.95, 5.09)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.586 (1.327, 5.039)	
p-value		0.0036	
Gemcitabine/Carboplatin			
Total Patients	124	122	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	80 (64.5%)	58 (47.5%)	
Patients (%) Without Events (Censored)	44 (35.5%)	64 (52.5%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.36, 4.47)	9.33 (3.09, NR)	
Hazard Ratio (95% CI)		1.591 (1.134, 2.234)	
p-value		0.0064	
History of liver metastasis			0.8991
Yes			
Total Patients	47	37	
Patients (%) With Events	33 (70.2%)	16 (43.2%)	
Patients (%) Without Events (Censored)	14 (29.8%)	21 (56.8%)	
Median Time to First TEAE, months (95% CI)	0.82 (0.16, 3.48)	9.23 (0.30, NR)	
Hazard Ratio (95% CI)		1.761 (0.967, 3.210)	
p-value		0.0594	
No			
Total Patients	128	129	
Patients (%) With Events	78 (60.9%)	54 (41.9%)	
Patients (%) Without Events (Censored)	50 (39.1%)	75 (58.1%)	
Median Time to First TEAE, months (95% CI)	3.06 (1.48, 5.59)	15.54 (6.11, NR)	
Hazard Ratio (95% CI)		1.712 (1.209, 2.424)	
p-value		0.0021	
History of brain metastasis			0.4259
Yes			
Total Patients	8	9	
Patients (%) With Events	5 (62.5%)	2 (22.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	3 (37.5%)	7 (77.8%)	
Median Time to First TEAE, months (95% CI)	4.88 (0.10, NR)	NR (0.10, NR)	
Hazard Ratio (95% CI)		2.472 (0.450, 13.571)	
p-value		0.2771	
No			
Total Patients	167	157	
Patients (%) With Events	106 (63.5%)	68 (43.3%)	
Patients (%) Without Events (Censored)	61 (36.5%)	89 (56.7%)	
Median Time to First TEAE, months (95% CI)	2.53 (0.99, 3.98)	15.54 (6.11, NR)	
Hazard Ratio (95% CI)		1.707 (1.258, 2.317)	
p-value		0.0005	
PD-L1 Status			0.8611
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	39 (59.1%)	23 (40.4%)	
Patients (%) Without Events (Censored)	27 (40.9%)	34 (59.6%)	
Median Time to First TEAE, months (95% CI)	3.58 (0.53, 10.28)	15.54 (3.29, NR)	
Hazard Ratio (95% CI)		1.673 (0.998, 2.803)	
p-value		0.0489	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	72 (66.1%)	47 (43.1%)	
Patients (%) Without Events (Censored)	37 (33.9%)	62 (56.9%)	
Median Time to First TEAE, months (95% CI)	2.14 (0.49, 3.88)	9.82 (3.25, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.815 (1.255, 2.624)	
p-value		0.0012	
BRCA 1/2 status			0.8955
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	39 (60.0%)	27 (42.9%)	
Patients (%) Without Events (Censored)	26 (40.0%)	36 (57.1%)	
Median Time to First TEAE, months (95% CI)	3.19 (0.59, 7.23)	9.33 (3.09, NR)	
Hazard Ratio (95% CI)		1.644 (1.006, 2.689)	
p-value		0.0459	
Mutant			
Total Patients	12	10	
Patients (%) With Events	6 (50.0%)	4 (40.0%)	
Patients (%) Without Events (Censored)	6 (50.0%)	6 (60.0%)	
Median Time to First TEAE, months (95% CI)	7.20 (0.13, NR)	15.54 (0.03, NR)	
Hazard Ratio (95% CI)		1.469 (0.413, 5.228)	
p-value		0.5479	
Menopausal status			0.6596
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	25 (67.6%)	23 (47.9%)	
Patients (%) Without Events (Censored)	12 (32.4%)	25 (52.1%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.16, 5.09)	6.11 (0.82, NR)	
Hazard Ratio (95% CI)		1.598 (0.905, 2.819)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0975	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	86 (62.3%)	46 (39.3%)	
Patients (%) Without Events (Censored)	52 (37.7%)	71 (60.7%)	
Median Time to First TEAE, months (95% CI)	2.83 (0.99, 4.47)	15.54 (9.23, NR)	
Hazard Ratio (95% CI)		1.880 (1.313, 2.691)	
p-value		0.0005	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.20. Table 1.1.12.9: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Vomiting (SOC: Gastrointestinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.1759
De novo			
Total Patients	55	48	
Patients (%) With Events	18 (32.7%)	8 (16.7%)	
Patients (%) Without Events (Censored)	37 (67.3%)	40 (83.3%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (15.01, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.005 (0.868, 4.631)	
p-value		0.0966	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	11 (32.4%)	2 (6.1%)	
Patients (%) Without Events (Censored)	23 (67.6%)	31 (93.9%)	
Median Time to First TEAE, months (95% CI)	NR (8.31, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.542 (1.227, 25.042)	
p-value		0.0122	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	23 (26.7%)	17 (20.0%)	
Patients (%) Without Events (Censored)	63 (73.3%)	68 (80.0%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.312 (0.701, 2.455)	
p-value		0.3941	
Geographic region			0.1950
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	21 (38.2%)	7 (14.0%)	
Patients (%) Without Events (Censored)	34 (61.8%)	43 (86.0%)	
Median Time to First TEAE, months (95% CI)	NR (4.60, NR)	NR (9.89, NR)	
Hazard Ratio (95% CI)		2.908 (1.235, 6.848)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0104	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	31 (25.8%)	20 (17.2%)	
Patients (%) Without Events (Censored)	89 (74.2%)	96 (82.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.432 (0.815, 2.517)	
p-value		0.2082	
Age group			0.3301
< 65			
Total Patients	132	128	
Patients (%) With Events	39 (29.5%)	22 (17.2%)	
Patients (%) Without Events (Censored)	93 (70.5%)	106 (82.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.559 (0.922, 2.634)	
p-value		0.0943	
>= 65			
Total Patients	43	38	
Patients (%) With Events	13 (30.2%)	5 (13.2%)	
Patients (%) Without Events (Censored)	30 (69.8%)	33 (86.8%)	
Median Time to First TEAE, months (95% CI)	NR (3.29, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.680 (0.954, 7.526)	
p-value		0.0514	
Race			0.7471

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
White			
Total Patients	114	101	
Patients (%) With Events	36 (31.6%)	21 (20.8%)	
Patients (%) Without Events (Censored)	78 (68.4%)	80 (79.2%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.462 (0.853, 2.507)	
p-value		0.1647	
Asian			
Total Patients	38	38	
Patients (%) With Events	6 (15.8%)	3 (7.9%)	
Patients (%) Without Events (Censored)	32 (84.2%)	35 (92.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.040 (0.509, 8.169)	
p-value		0.3045	
Other			
Total Patients	18	24	
Patients (%) With Events	6 (33.3%)	3 (12.5%)	
Patients (%) Without Events (Censored)	12 (66.7%)	21 (87.5%)	
Median Time to First TEAE, months (95% CI)	NR (4.63, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.323 (0.574, 9.391)	
p-value		0.2240	
Baseline ECOG status			0.7819
0			
Total Patients	115	104	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	32 (27.8%)	17 (16.3%)	
Patients (%) Without Events (Censored)	83 (72.2%)	87 (83.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.708 (0.948, 3.077)	
p-value		0.0711	
1			
Total Patients	60	62	
Patients (%) With Events	20 (33.3%)	10 (16.1%)	
Patients (%) Without Events (Censored)	40 (66.7%)	52 (83.9%)	
Median Time to First TEAE, months (95% CI)	NR (8.31, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.893 (0.879, 4.074)	
p-value		0.0971	
The physician's choice of chemotherapy selected prior to randomization			0.6330
Taxane			
Total Patients	51	44	
Patients (%) With Events	14 (27.5%)	5 (11.4%)	
Patients (%) Without Events (Censored)	37 (72.5%)	39 (88.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.469 (0.889, 6.857)	
p-value		0.0725	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	38 (30.6%)	22 (18.0%)	
Patients (%) Without Events (Censored)	86 (69.4%)	100 (82.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (12.68, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.693 (1.000, 2.864)	
p-value		0.0471	
History of liver metastasis			0.1618
Yes			
Total Patients	47	37	
Patients (%) With Events	12 (25.5%)	8 (21.6%)	
Patients (%) Without Events (Censored)	35 (74.5%)	29 (78.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	9.89 (NR, NR)	
Hazard Ratio (95% CI)		1.048 (0.420, 2.615)	
p-value		0.9201	
No			
Total Patients	128	129	
Patients (%) With Events	40 (31.2%)	19 (14.7%)	
Patients (%) Without Events (Censored)	88 (68.8%)	110 (85.3%)	
Median Time to First TEAE, months (95% CI)	NR (15.01, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.141 (1.239, 3.699)	
p-value		0.0052	
History of brain metastasis			0.2710
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	3 (33.3%)	
Patients (%) Without Events (Censored)	6 (75.0%)	6 (66.7%)	
Median Time to First TEAE, months (95% CI)	NR (0.30, NR)	NR (0.03, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.664 (0.111, 3.980)	
p-value		0.6519	
No			
Total Patients	167	157	
Patients (%) With Events	50 (29.9%)	24 (15.3%)	
Patients (%) Without Events (Censored)	117 (70.1%)	133 (84.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.931 (1.186, 3.145)	
p-value		0.0071	
PD-L1 Status			0.2507
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	15 (22.7%)	10 (17.5%)	
Patients (%) Without Events (Censored)	51 (77.3%)	47 (82.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.230 (0.552, 2.742)	
p-value		0.6140	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	37 (33.9%)	17 (15.6%)	
Patients (%) Without Events (Censored)	72 (66.1%)	92 (84.4%)	
Median Time to First TEAE, months (95% CI)	NR (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.182 (1.227, 3.881)	
p-value		0.0064	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Menopausal status			0.4473
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	16 (43.2%)	9 (18.8%)	
Patients (%) Without Events (Censored)	21 (56.8%)	39 (81.2%)	
Median Time to First TEAE, months (95% CI)	15.01 (3.52, NR)	NR (8.15, NR)	
Hazard Ratio (95% CI)		2.387 (1.052, 5.416)	
p-value		0.0317	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	36 (26.1%)	18 (15.4%)	
Patients (%) Without Events (Censored)	102 (73.9%)	99 (84.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.650 (0.936, 2.908)	
p-value		0.0801	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.21. Table 1.1.12.10: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alanine aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.7027
De novo			
Total Patients	55	48	
Patients (%) With Events	12 (21.8%)	16 (33.3%)	
Patients (%) Without Events (Censored)	43 (78.2%)	32 (66.7%)	
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	NR (6.01, NR)	
Hazard Ratio (95% CI)		0.476 (0.220, 1.032)	
p-value		0.0552	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	7 (20.6%)	15 (45.5%)	
Patients (%) Without Events (Censored)	27 (79.4%)	18 (54.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.16, NR)	7.16 (1.64, NR)	
Hazard Ratio (95% CI)		0.272 (0.105, 0.708)	
p-value		0.0049	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	16 (18.6%)	28 (32.9%)	
Patients (%) Without Events (Censored)	70 (81.4%)	57 (67.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.470 (0.254, 0.870)	
p-value		0.0141	
Geographic region			0.6133

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	8 (14.5%)	15 (30.0%)	
Patients (%) Without Events (Censored)	47 (85.5%)	35 (70.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	11.76 (6.60, NR)	
Hazard Ratio (95% CI)		0.369 (0.154, 0.887)	
p-value		0.0210	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	27 (22.5%)	44 (37.9%)	
Patients (%) Without Events (Censored)	93 (77.5%)	72 (62.1%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (6.87, NR)	
Hazard Ratio (95% CI)		0.471 (0.290, 0.763)	
p-value		0.0018	
Age group			0.4565
< 65			
Total Patients	132	128	
Patients (%) With Events	32 (24.2%)	50 (39.1%)	
Patients (%) Without Events (Censored)	100 (75.8%)	78 (60.9%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (6.87, NR)	
Hazard Ratio (95% CI)		0.452 (0.288, 0.709)	
p-value		0.0004	
>= 65			
Total Patients	43	38	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	3 (7.0%)	9 (23.7%)	
Patients (%) Without Events (Censored)	40 (93.0%)	29 (76.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.280 (0.076, 1.034)	
p-value		0.0412	
Race			0.2347
White			
Total Patients	114	101	
Patients (%) With Events	25 (21.9%)	37 (36.6%)	
Patients (%) Without Events (Censored)	89 (78.1%)	64 (63.4%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (6.87, NR)	
Hazard Ratio (95% CI)		0.466 (0.279, 0.777)	
p-value		0.0029	
Asian			
Total Patients	38	38	
Patients (%) With Events	6 (15.8%)	10 (26.3%)	
Patients (%) Without Events (Censored)	32 (84.2%)	28 (73.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.456 (0.162, 1.279)	
p-value		0.1270	
Other			
Total Patients	18	24	
Patients (%) With Events	2 (11.1%)	12 (50.0%)	
Patients (%) Without Events (Censored)	16 (88.9%)	12 (50.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (15.41, NR)	4.14 (0.99, NR)	
Hazard Ratio (95% CI)		0.133 (0.029, 0.608)	
p-value		0.0026	
Baseline ECOG status			0.1079
0			
Total Patients	115	104	
Patients (%) With Events	22 (19.1%)	43 (41.3%)	
Patients (%) Without Events (Censored)	93 (80.9%)	61 (58.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (6.60, NR)	
Hazard Ratio (95% CI)		0.344 (0.205, 0.578)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	13 (21.7%)	16 (25.8%)	
Patients (%) Without Events (Censored)	47 (78.3%)	46 (74.2%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.733 (0.351, 1.532)	
p-value		0.4116	
The physician's choice of chemotherapy selected prior to randomization			0.0047
Taxane			
Total Patients	51	44	
Patients (%) With Events	11 (21.6%)	5 (11.4%)	
Patients (%) Without Events (Censored)	40 (78.4%)	39 (88.6%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.389 (0.469, 4.114)	
p-value		0.5474	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	24 (19.4%)	54 (44.3%)	
Patients (%) Without Events (Censored)	100 (80.6%)	68 (55.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (3.22, NR)	
Hazard Ratio (95% CI)		0.335 (0.207, 0.544)	
p-value		<0.0001	
History of liver metastasis			0.5068
Yes			
Total Patients	47	37	
Patients (%) With Events	14 (29.8%)	15 (40.5%)	
Patients (%) Without Events (Censored)	33 (70.2%)	22 (59.5%)	
Median Time to First TEAE, months (95% CI)	NR (6.24, NR)	11.76 (1.35, NR)	
Hazard Ratio (95% CI)		0.476 (0.224, 1.009)	
p-value		0.0482	
No			
Total Patients	128	129	
Patients (%) With Events	21 (16.4%)	44 (34.1%)	
Patients (%) Without Events (Censored)	107 (83.6%)	85 (65.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.382 (0.226, 0.646)	
p-value		0.0002	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
History of brain metastasis			0.1846
Yes			
Total Patients	8	9	
Patients (%) With Events	3 (37.5%)	2 (22.2%)	
Patients (%) Without Events (Censored)	5 (62.5%)	7 (77.8%)	
Median Time to First TEAE, months (95% CI)	5.49 (3.48, NR)	NR (0.95, NR)	
Hazard Ratio (95% CI)		1.186 (0.194, 7.244)	
p-value		0.8531	
No			
Total Patients	167	157	
Patients (%) With Events	32 (19.2%)	57 (36.3%)	
Patients (%) Without Events (Censored)	135 (80.8%)	100 (63.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.411 (0.266, 0.637)	
p-value		<0.0001	
PD-L1 Status			0.6259
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	14 (21.2%)	24 (42.1%)	
Patients (%) Without Events (Censored)	52 (78.8%)	33 (57.9%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	11.76 (6.01, NR)	
Hazard Ratio (95% CI)		0.385 (0.198, 0.748)	
p-value		0.0036	
CPS ≥ 1			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	109	109	
Patients (%) With Events	21 (19.3%)	35 (32.1%)	
Patients (%) Without Events (Censored)	88 (80.7%)	74 (67.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.485 (0.281, 0.837)	
p-value		0.0080	
Menopausal status			0.7498
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	10 (27.0%)	20 (41.7%)	
Patients (%) Without Events (Censored)	27 (73.0%)	28 (58.3%)	
Median Time to First TEAE, months (95% CI)	15.41 (11.14, NR)	7.16 (4.14, NR)	
Hazard Ratio (95% CI)		0.438 (0.197, 0.973)	
p-value		0.0384	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	25 (18.1%)	38 (32.5%)	
Patients (%) Without Events (Censored)	113 (81.9%)	79 (67.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (11.76, NR)	
Hazard Ratio (95% CI)		0.443 (0.267, 0.737)	
p-value		0.0013	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.22. Table 1.1.12.11: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Aspartate aminotransferase increased (SOC: Investigations) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.9403
De novo			
Total Patients	55	48	
Patients (%) With Events	11 (20.0%)	14 (29.2%)	
Patients (%) Without Events (Censored)	44 (80.0%)	34 (70.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.535 (0.240, 1.193)	
p-value		0.1218	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	7 (20.6%)	10 (30.3%)	
Patients (%) Without Events (Censored)	27 (79.4%)	23 (69.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (7.16, NR)	
Hazard Ratio (95% CI)		0.595 (0.225, 1.577)	
p-value		0.2929	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	14 (16.3%)	24 (28.2%)	
Patients (%) Without Events (Censored)	72 (83.7%)	61 (71.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.478 (0.247, 0.926)	
p-value		0.0256	
Geographic region			0.8137
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	7 (12.7%)	9 (18.0%)	
Patients (%) Without Events (Censored)	48 (87.3%)	41 (82.0%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.616 (0.229, 1.659)	
p-value		0.3324	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	25 (20.8%)	39 (33.6%)	
Patients (%) Without Events (Censored)	95 (79.2%)	77 (66.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.509 (0.307, 0.843)	
p-value		0.0077	
Age group			0.1792
< 65			
Total Patients	132	128	
Patients (%) With Events	30 (22.7%)	40 (31.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	102 (77.3%)	88 (68.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.583 (0.362, 0.940)	
p-value		0.0253	
>= 65			
Total Patients	43	38	
Patients (%) With Events	2 (4.7%)	8 (21.1%)	
Patients (%) Without Events (Censored)	41 (95.3%)	30 (78.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.210 (0.045, 0.990)	
p-value		0.0294	
Race			0.4351
White			
Total Patients	114	101	
Patients (%) With Events	23 (20.2%)	28 (27.7%)	
Patients (%) Without Events (Censored)	91 (79.8%)	73 (72.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.598 (0.343, 1.041)	
p-value		0.0665	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	10 (26.3%)	
Patients (%) Without Events (Censored)	34 (89.5%)	28 (73.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.307 (0.095, 0.994)	
p-value		0.0378	
Other			
Total Patients	18	24	
Patients (%) With Events	3 (16.7%)	10 (41.7%)	
Patients (%) Without Events (Censored)	15 (83.3%)	14 (58.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (2.30, NR)	
Hazard Ratio (95% CI)		0.314 (0.086, 1.147)	
p-value		0.0641	
Baseline ECOG status			0.0653
0			
Total Patients	115	104	
Patients (%) With Events	18 (15.7%)	34 (32.7%)	
Patients (%) Without Events (Censored)	97 (84.3%)	70 (67.3%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.392 (0.221, 0.695)	
p-value		0.0009	
1			
Total Patients	60	62	
Patients (%) With Events	14 (23.3%)	14 (22.6%)	
Patients (%) Without Events (Censored)	46 (76.7%)	48 (77.4%)	
Median Time to First TEAE, months (95% CI)	NR (11.96, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.853 (0.402, 1.810)	
p-value		0.6831	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.0569
Taxane			
Total Patients	51	44	
Patients (%) With Events	9 (17.6%)	5 (11.4%)	
Patients (%) Without Events (Censored)	42 (82.4%)	39 (88.6%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.187 (0.387, 3.644)	
p-value		0.7628	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	23 (18.5%)	43 (35.2%)	
Patients (%) Without Events (Censored)	101 (81.5%)	79 (64.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.436 (0.263, 0.725)	
p-value		0.0010	
History of liver metastasis			0.8946
Yes			
Total Patients	47	37	
Patients (%) With Events	12 (25.5%)	14 (37.8%)	
Patients (%) Without Events (Censored)	35 (74.5%)	23 (62.2%)	
Median Time to First TEAE, months (95% CI)	NR (8.31, NR)	NR (1.91, NR)	
Hazard Ratio (95% CI)		0.429 (0.193, 0.955)	
p-value		0.0339	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	20 (15.6%)	34 (26.4%)	
Patients (%) Without Events (Censored)	108 (84.4%)	95 (73.6%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.512 (0.294, 0.891)	
p-value		0.0160	
History of brain metastasis			0.2691
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	1 (11.1%)	
Patients (%) Without Events (Censored)	6 (75.0%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	NR (3.68, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		1.758 (0.158, 19.572)	
p-value		0.6419	
No			
Total Patients	167	157	
Patients (%) With Events	30 (18.0%)	47 (29.9%)	
Patients (%) Without Events (Censored)	137 (82.0%)	110 (70.1%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.500 (0.316, 0.793)	
p-value		0.0027	
PD-L1 Status			0.6560
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	12 (18.2%)	18 (31.6%)	
Patients (%) Without Events (Censored)	54 (81.8%)	39 (68.4%)	
Median Time to First TEAE, months (95% CI)	NR (19.42, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.466 (0.224, 0.970)	
p-value		0.0373	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	20 (18.3%)	30 (27.5%)	
Patients (%) Without Events (Censored)	89 (81.7%)	79 (72.5%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.585 (0.332, 1.031)	
p-value		0.0606	
BRCA 1/2 status			0.7892
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	10 (15.4%)	14 (22.2%)	
Patients (%) Without Events (Censored)	55 (84.6%)	49 (77.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.597 (0.264, 1.349)	
p-value		0.2106	
Mutant			
Total Patients	12	10	
Patients (%) With Events	1 (8.3%)	2 (20.0%)	
Patients (%) Without Events (Censored)	11 (91.7%)	8 (80.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (0.72, NR)	
Hazard Ratio (95% CI)		0.452 (0.041, 4.988)	
p-value		0.4998	
Menopausal status			0.4085
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	7 (18.9%)	18 (37.5%)	
Patients (%) Without Events (Censored)	30 (81.1%)	30 (62.5%)	
Median Time to First TEAE, months (95% CI)	NR (12.58, NR)	NR (4.14, NR)	
Hazard Ratio (95% CI)		0.390 (0.159, 0.954)	
p-value		0.0329	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	25 (18.1%)	29 (24.8%)	
Patients (%) Without Events (Censored)	113 (81.9%)	88 (75.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.618 (0.361, 1.058)	
p-value		0.0772	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.23. Table 1.1.12.12: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Cough (SOC: Respiratory, thoracic and mediastinal disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Age group			0.0453
< 65			
Total Patients	132	128	
Patients (%) With Events	22 (16.7%)	13 (10.2%)	
Patients (%) Without Events (Censored)	110 (83.3%)	115 (89.8%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.333 (0.669, 2.656)	
p-value		0.4125	
>= 65			
Total Patients	43	38	
Patients (%) With Events	11 (25.6%)	2 (5.3%)	
Patients (%) Without Events (Censored)	32 (74.4%)	36 (94.7%)	
Median Time to First TEAE, months (95% CI)	15.34 (10.61, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.772 (1.277, 26.081)	
p-value		0.0099	
Race			0.7807
White			
Total Patients	114	101	
Patients (%) With Events	28 (24.6%)	12 (11.9%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	86 (75.4%)	89 (88.1%)	
Median Time to First TEAE, months (95% CI)	23.92 (12.09, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.875 (0.952, 3.695)	
p-value		0.0647	
Asian			
Total Patients	38	38	
Patients (%) With Events	4 (10.5%)	1 (2.6%)	
Patients (%) Without Events (Censored)	34 (89.5%)	37 (97.4%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.118 (0.342, 28.397)	
p-value		0.2886	
Other			
Total Patients	18	24	
Patients (%) With Events	1 (5.6%)	1 (4.2%)	
Patients (%) Without Events (Censored)	17 (94.4%)	23 (95.8%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (10.55, NR)	
Hazard Ratio (95% CI)		1.118 (0.070, 17.952)	
p-value		0.9372	
Baseline ECOG status			0.5595
0			
Total Patients	115	104	
Patients (%) With Events	26 (22.6%)	13 (12.5%)	
Patients (%) Without Events (Censored)	89 (77.4%)	91 (87.5%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		1.711 (0.878, 3.336)	
p-value		0.1105	
1			
Total Patients	60	62	
Patients (%) With Events	7 (11.7%)	2 (3.2%)	
Patients (%) Without Events (Censored)	53 (88.3%)	60 (96.8%)	
Median Time to First TEAE, months (95% CI)	23.92 (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.680 (0.550, 13.067)	
p-value		0.2052	
The physician's choice of chemotherapy selected prior to randomization			0.4795
Taxane			
Total Patients	51	44	
Patients (%) With Events	9 (17.6%)	4 (9.1%)	
Patients (%) Without Events (Censored)	42 (82.4%)	40 (90.9%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.406 (0.423, 4.673)	
p-value		0.5761	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	24 (19.4%)	11 (9.0%)	
Patients (%) Without Events (Censored)	100 (80.6%)	111 (91.0%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.088 (1.021, 4.268)	
p-value		0.0391	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
History of liver metastasis			0.1339
Yes			
Total Patients	47	37	
Patients (%) With Events	6 (12.8%)	4 (10.8%)	
Patients (%) Without Events (Censored)	41 (87.2%)	33 (89.2%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	10.32 (10.32, NR)	
Hazard Ratio (95% CI)		0.870 (0.237, 3.194)	
p-value		0.8337	
No			
Total Patients	128	129	
Patients (%) With Events	27 (21.1%)	11 (8.5%)	
Patients (%) Without Events (Censored)	101 (78.9%)	118 (91.5%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.290 (1.134, 4.628)	
p-value		0.0175	
History of brain metastasis			0.7445
Yes			
Total Patients	8	9	
Patients (%) With Events	1 (12.5%)	1 (11.1%)	
Patients (%) Without Events (Censored)	7 (87.5%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	NR (2.99, NR)	NR (7.59, NR)	
Hazard Ratio (95% CI)		1.155 (0.072, 18.594)	
p-value		0.9191	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	167	157	
Patients (%) With Events	32 (19.2%)	14 (8.9%)	
Patients (%) Without Events (Censored)	135 (80.8%)	143 (91.1%)	
Median Time to First TEAE, months (95% CI)	NR (23.92, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		1.904 (1.014, 3.579)	
p-value		0.0417	
Menopausal status			0.1151
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	2 (5.4%)	4 (8.3%)	
Patients (%) Without Events (Censored)	35 (94.6%)	44 (91.7%)	
Median Time to First TEAE, months (95% CI)	NR (NR, NR)	NR (10.55, NR)	
Hazard Ratio (95% CI)		0.540 (0.097, 3.014)	
p-value		0.4761	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	31 (22.5%)	11 (9.4%)	
Patients (%) Without Events (Censored)	107 (77.5%)	106 (90.6%)	
Median Time to First TEAE, months (95% CI)	NR (18.17, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		2.171 (1.089, 4.326)	
p-value		0.0240	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.24. Table 1.1.12.13: Subgroup Analysis of Time to First TEAE by SOC and PT — PT: Alopecia (SOC: Skin and subcutaneous tissue disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.8240
De novo			
Total Patients	55	48	
Patients (%) With Events	34 (61.8%)	13 (27.1%)	
Patients (%) Without Events (Censored)	21 (38.2%)	35 (72.9%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.72, 5.32)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.128 (1.645, 5.949)	
p-value		0.0003	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	16 (47.1%)	5 (15.2%)	
Patients (%) Without Events (Censored)	18 (52.9%)	28 (84.8%)	
Median Time to First TEAE, months (95% CI)	NR (0.85, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.148 (1.516, 11.347)	
p-value		0.0026	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	47 (54.7%)	16 (18.8%)	
Patients (%) Without Events (Censored)	39 (45.3%)	69 (81.2%)	
Median Time to First TEAE, months (95% CI)	1.35 (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.171 (2.359, 7.374)	
p-value		<0.0001	
Geographic region			0.2727
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	31 (56.4%)	13 (26.0%)	
Patients (%) Without Events (Censored)	24 (43.6%)	37 (74.0%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.85, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.025 (1.578, 5.798)	
p-value		0.0005	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	66 (55.0%)	21 (18.1%)	
Patients (%) Without Events (Censored)	54 (45.0%)	95 (81.9%)	
Median Time to First TEAE, months (95% CI)	1.35 (0.79, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.235 (2.587, 6.934)	
p-value		<0.0001	
Age group			0.0385
< 65			
Total Patients	132	128	
Patients (%) With Events	78 (59.1%)	22 (17.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	54 (40.9%)	106 (82.8%)	
Median Time to First TEAE, months (95% CI)	1.18 (0.82, 5.06)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.827 (3.002, 7.761)	
p-value		<0.0001	
>= 65			
Total Patients	43	38	
Patients (%) With Events	19 (44.2%)	12 (31.6%)	
Patients (%) Without Events (Censored)	24 (55.8%)	26 (68.4%)	
Median Time to First TEAE, months (95% CI)	NR (0.76, NR)	NR (5.09, NR)	
Hazard Ratio (95% CI)		1.981 (0.957, 4.100)	
p-value		0.0622	
Race			0.5522
White			
Total Patients	114	101	
Patients (%) With Events	59 (51.8%)	15 (14.9%)	
Patients (%) Without Events (Censored)	55 (48.2%)	86 (85.1%)	
Median Time to First TEAE, months (95% CI)	1.64 (0.95, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.015 (2.839, 8.856)	
p-value		<0.0001	
Asian			
Total Patients	38	38	
Patients (%) With Events	27 (71.1%)	13 (34.2%)	
Patients (%) Without Events (Censored)	11 (28.9%)	25 (65.8%)	
Median Time to First TEAE, months (95% CI)	0.74 (0.49, 1.41)	NR (5.45, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		2.871 (1.474, 5.593)	
p-value		0.0012	
Other			
Total Patients	18	24	
Patients (%) With Events	9 (50.0%)	4 (16.7%)	
Patients (%) Without Events (Censored)	9 (50.0%)	20 (83.3%)	
Median Time to First TEAE, months (95% CI)	2.20 (0.56, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.103 (1.258, 13.385)	
p-value		0.0113	
Baseline ECOG status			0.7889
0			
Total Patients	115	104	
Patients (%) With Events	65 (56.5%)	23 (22.1%)	
Patients (%) Without Events (Censored)	50 (43.5%)	81 (77.9%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.89, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.647 (2.262, 5.879)	
p-value		<0.0001	
1			
Total Patients	60	62	
Patients (%) With Events	32 (53.3%)	11 (17.7%)	
Patients (%) Without Events (Censored)	28 (46.7%)	51 (82.3%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.79, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.025 (2.022, 8.012)	
p-value		<0.0001	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.0036
Taxane			
Total Patients	51	44	
Patients (%) With Events	29 (56.9%)	16 (36.4%)	
Patients (%) Without Events (Censored)	22 (43.1%)	28 (63.6%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.72, NR)	NR (1.84, NR)	
Hazard Ratio (95% CI)		1.717 (0.931, 3.164)	
p-value		0.0788	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	68 (54.8%)	18 (14.8%)	
Patients (%) Without Events (Censored)	56 (45.2%)	104 (85.2%)	
Median Time to First TEAE, months (95% CI)	1.38 (0.82, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.651 (3.353, 9.523)	
p-value		<0.0001	
History of liver metastasis			0.9271
Yes			
Total Patients	47	37	
Patients (%) With Events	23 (48.9%)	6 (16.2%)	
Patients (%) Without Events (Censored)	24 (51.1%)	31 (83.8%)	
Median Time to First TEAE, months (95% CI)	5.32 (0.76, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.411 (1.383, 8.413)	
p-value		0.0046	
No			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	128	129	
Patients (%) With Events	74 (57.8%)	28 (21.7%)	
Patients (%) Without Events (Censored)	54 (42.2%)	101 (78.3%)	
Median Time to First TEAE, months (95% CI)	1.15 (0.85, 3.02)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.961 (2.558, 6.135)	
p-value		<0.0001	
History of brain metastasis			0.6613
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	1 (11.1%)	
Patients (%) Without Events (Censored)	6 (75.0%)	8 (88.9%)	
Median Time to First TEAE, months (95% CI)	NR (0.49, NR)	NR (2.30, NR)	
Hazard Ratio (95% CI)		1.962 (0.177, 21.779)	
p-value		0.5759	
No			
Total Patients	167	157	
Patients (%) With Events	95 (56.9%)	33 (21.0%)	
Patients (%) Without Events (Censored)	72 (43.1%)	124 (79.0%)	
Median Time to First TEAE, months (95% CI)	1.18 (0.85, 5.32)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.869 (2.599, 5.759)	
p-value		<0.0001	
PD-L1 Status			0.4195
CPS < 1			
Total Patients	66	57	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	41 (62.1%)	12 (21.1%)	
Patients (%) Without Events (Censored)	25 (37.9%)	45 (78.9%)	
Median Time to First TEAE, months (95% CI)	1.02 (0.72, 5.06)	NR (NR, NR)	
Hazard Ratio (95% CI)		4.566 (2.391, 8.719)	
p-value		<0.0001	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	56 (51.4%)	22 (20.2%)	
Patients (%) Without Events (Censored)	53 (48.6%)	87 (79.8%)	
Median Time to First TEAE, months (95% CI)	1.64 (0.95, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.344 (2.038, 5.485)	
p-value		<0.0001	
BRCA 1/2 status			0.4181
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	40 (61.5%)	17 (27.0%)	
Patients (%) Without Events (Censored)	25 (38.5%)	46 (73.0%)	
Median Time to First TEAE, months (95% CI)	1.12 (0.72, 3.02)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.216 (1.820, 5.685)	
p-value		<0.0001	
Mutant			
Total Patients	12	10	
Patients (%) With Events	5 (41.7%)	3 (30.0%)	
Patients (%) Without Events (Censored)	7 (58.3%)	7 (70.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First TEAE, months (95% CI)	NR (0.59, NR)	NR (0.43, NR)	
Hazard Ratio (95% CI)		1.533 (0.364, 6.457)	
p-value		0.5578	
Menopausal status			0.1786
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	24 (64.9%)	8 (16.7%)	
Patients (%) Without Events (Censored)	13 (35.1%)	40 (83.3%)	
Median Time to First TEAE, months (95% CI)	0.95 (0.56, 11.93)	NR (NR, NR)	
Hazard Ratio (95% CI)		5.783 (2.587, 12.928)	
p-value		<0.0001	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	73 (52.9%)	26 (22.2%)	
Patients (%) Without Events (Censored)	65 (47.1%)	91 (77.8%)	
Median Time to First TEAE, months (95% CI)	1.41 (0.95, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.278 (2.092, 5.137)	
p-value		<0.0001	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥10% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.25. Table 1.1.13: Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Blood and lymphatic system disorders		
Total Patients	175	166
Patients (%) With Events	85 (48.6%)	110 (66.3%)
Patients (%) Without Events (Censored)	90 (51.4%)	56 (33.7%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	11.17 (3.58, 23.66)	2.53 (1.84, 3.48)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.656 (0.492, 0.875)
p-value		0.0032
Anaemia		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	36 (21.7%)
Patients (%) Without Events (Censored)	170 (97.1%)	130 (78.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.109 (0.042, 0.277)
p-value		<0.0001
Febrile neutropenia		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	3 (1.8%)
Patients (%) Without Events (Censored)	167 (95.4%)	163 (98.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		2.570 (0.682, 9.687)
p-value		0.1478
Leukopenia		
Total Patients	175	166
Patients (%) With Events	12 (6.9%)	31 (18.7%)
Patients (%) Without Events (Censored)	163 (93.1%)	135 (81.3%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (23.66, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.313 (0.160, 0.614)
p-value		0.0004
Lymphopenia		
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	6 (3.6%)
Patients (%) Without Events (Censored)	168 (96.0%)	160 (96.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.959 (0.320, 2.876)
p-value		0.9393
Neutropenia		
Total Patients	175	166
Patients (%) With Events	74 (42.3%)	92 (55.4%)
Patients (%) Without Events (Censored)	101 (57.7%)	74 (44.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	21.39 (7.20, NR)	3.48 (2.37, 8.48)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.688 (0.505, 0.939)
p-value		0.0160
Thrombocytopenia		
Total Patients	175	166
Patients (%) With Events	2 (1.1%)	35 (21.1%)
Patients (%) Without Events (Censored)	173 (98.9%)	131 (78.9%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (17.31, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.039 (0.009, 0.163)
p-value		<0.0001
Gastrointestinal disorders		
Total Patients	175	166
Patients (%) With Events	33 (18.9%)	6 (3.6%)
Patients (%) Without Events (Censored)	142 (81.1%)	160 (96.4%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		5.129 (2.146, 12.257)
p-value		<0.0001
Diarrhoea		
Total Patients	175	166
Patients (%) With Events	18 (10.3%)	2 (1.2%)
Patients (%) Without Events (Censored)	157 (89.7%)	164 (98.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		8.397 (1.946, 36.232)
p-value		0.0006
General disorders and administration site conditions		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	11 (6.6%)
Patients (%) Without Events (Censored)	164 (93.7%)	155 (93.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.782 (0.335, 1.826)
p-value		0.5693
Fatigue		

	SG (N=175)	TPC (N=166)
Total Patients	175	166
Patients (%) With Events	7 (4.0%)	8 (4.8%)
Patients (%) Without Events (Censored)	168 (96.0%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.668 (0.239, 1.867)
p-value		0.4392
Infections and infestations		
Total Patients	175	166
Patients (%) With Events	20 (11.4%)	15 (9.0%)
Patients (%) Without Events (Censored)	155 (88.6%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.134 (0.578, 2.222)
p-value		0.7156
Injury, poisoning and procedural complications		
Total Patients	175	166
Patients (%) With Events	2 (1.1%)	8 (4.8%)
Patients (%) Without Events (Censored)	173 (98.9%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (19.61, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.196 (0.041, 0.933)
p-value		0.0233
Investigations		
Total Patients	175	166
Patients (%) With Events	10 (5.7%)	20 (12.0%)
Patients (%) Without Events (Censored)	165 (94.3%)	146 (88.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.417 (0.194, 0.896)
p-value		0.0208
Alanine aminotransferase increased		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	15 (9.0%)
Patients (%) Without Events (Censored)	167 (95.4%)	151 (91.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.437 (0.184, 1.039)
p-value		0.0545
Metabolism and nutrition disorders		
Total Patients	175	166
Patients (%) With Events	11 (6.3%)	7 (4.2%)
Patients (%) Without Events (Censored)	164 (93.7%)	159 (95.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.286 (0.495, 3.343)
p-value		0.6056
Respiratory, thoracic and mediastinal disorders		
Total Patients	175	166
Patients (%) With Events	13 (7.4%)	10 (6.0%)
Patients (%) Without Events (Censored)	162 (92.6%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.158 (0.507, 2.648)
p-value		0.7269
Pulmonary embolism		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	5 (3.0%)
Patients (%) Without Events (Censored)	170 (97.1%)	161 (97.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.942 (0.273, 3.253)
p-value		0.9243

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=175)	TPC (N=166)

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.26. Table 1.1.14.1: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — SOC: Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.4180
De novo			
Total Patients	55	48	
Patients (%) With Events	25 (45.5%)	25 (52.1%)	
Patients (%) Without Events (Censored)	30 (54.5%)	23 (47.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	7.20 (1.77, NR)	4.60 (2.27, NR)	
Hazard Ratio (95% CI)		0.923 (0.529, 1.610)	
p-value		0.7654	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	22 (64.7%)	27 (81.8%)	
Patients (%) Without Events (Censored)	12 (35.3%)	6 (18.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.97 (0.56, 23.66)	1.18 (0.92, 2.37)	
Hazard Ratio (95% CI)		0.762 (0.428, 1.358)	
p-value		0.3343	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	38 (44.2%)	58 (68.2%)	
Patients (%) Without Events (Censored)	48 (55.8%)	27 (31.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.83, NR)	2.53 (1.71, 3.45)	
Hazard Ratio (95% CI)		0.529 (0.349, 0.801)	
p-value		0.0020	
Geographic region			0.8632
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	22 (40.0%)	27 (54.0%)	
Patients (%) Without Events (Censored)	33 (60.0%)	23 (46.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.14, NR)	3.22 (1.87, NR)	
Hazard Ratio (95% CI)		0.683 (0.388, 1.204)	
p-value		0.1762	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	63 (52.5%)	83 (71.6%)	
Patients (%) Without Events (Censored)	57 (47.5%)	33 (28.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (1.77, 23.66)	2.30 (1.61, 3.09)	
Hazard Ratio (95% CI)		0.647 (0.463, 0.905)	
p-value		0.0090	
Age group			0.3545
< 65			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	132	128	
Patients (%) With Events	62 (47.0%)	85 (66.4%)	
Patients (%) Without Events (Censored)	70 (53.0%)	43 (33.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.14, NR)	2.50 (1.84, 3.22)	
Hazard Ratio (95% CI)		0.614 (0.440, 0.856)	
p-value		0.0032	
>= 65			
Total Patients	43	38	
Patients (%) With Events	23 (53.5%)	25 (65.8%)	
Patients (%) Without Events (Censored)	20 (46.5%)	13 (34.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	5.09 (0.66, 22.34)	3.45 (1.05, 8.97)	
Hazard Ratio (95% CI)		0.806 (0.453, 1.431)	
p-value		0.4446	
Race			0.0268
White			
Total Patients	114	101	
Patients (%) With Events	45 (39.5%)	65 (64.4%)	
Patients (%) Without Events (Censored)	69 (60.5%)	36 (35.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.17, NR)	2.37 (1.61, 3.22)	
Hazard Ratio (95% CI)		0.525 (0.358, 0.771)	
p-value		0.0008	
Asian			
Total Patients	38	38	
Patients (%) With Events	27 (71.1%)	24 (63.2%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) Without Events (Censored)	11 (28.9%)	14 (36.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.56, 6.28)	3.45 (1.71, 9.53)	
Hazard Ratio (95% CI)		1.236 (0.706, 2.164)	
p-value		0.4928	
Other			
Total Patients	18	24	
Patients (%) With Events	12 (66.7%)	20 (83.3%)	
Patients (%) Without Events (Censored)	6 (33.3%)	4 (16.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.03 (0.30, 23.66)	2.30 (0.89, 4.40)	
Hazard Ratio (95% CI)		0.677 (0.316, 1.451)	
p-value		0.3014	
Baseline ECOG status			0.4095
0			
Total Patients	115	104	
Patients (%) With Events	61 (53.0%)	74 (71.2%)	
Patients (%) Without Events (Censored)	54 (47.0%)	30 (28.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	4.34 (1.58, NR)	2.50 (1.64, 3.48)	
Hazard Ratio (95% CI)		0.724 (0.514, 1.019)	
p-value		0.0565	
1			
Total Patients	60	62	
Patients (%) With Events	24 (40.0%)	36 (58.1%)	
Patients (%) Without Events (Censored)	36 (60.0%)	26 (41.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.24, 23.66)	3.02 (1.61, 5.09)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.504 (0.292, 0.873)	
p-value		0.0117	
The physician's choice of chemotherapy selected prior to randomization			<0.0001
Taxane			
Total Patients	51	44	
Patients (%) With Events	24 (47.1%)	7 (15.9%)	
Patients (%) Without Events (Censored)	27 (52.9%)	37 (84.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (2.04, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		3.369 (1.445, 7.858)	
p-value		0.0029	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	61 (49.2%)	103 (84.4%)	
Patients (%) Without Events (Censored)	63 (50.8%)	19 (15.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (2.56, NR)	1.64 (1.05, 2.30)	
Hazard Ratio (95% CI)		0.451 (0.325, 0.624)	
p-value		<0.0001	
History of liver metastasis			0.8445
Yes			
Total Patients	47	37	
Patients (%) With Events	25 (53.2%)	24 (64.9%)	
Patients (%) Without Events (Censored)	22 (46.8%)	13 (35.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	2.92 (0.92, NR)	1.64 (0.95, 3.12)	
Hazard Ratio (95% CI)		0.755 (0.429, 1.330)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.3239	
No			
Total Patients	128	129	
Patients (%) With Events	60 (46.9%)	86 (66.7%)	
Patients (%) Without Events (Censored)	68 (53.1%)	43 (33.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (4.14, 23.66)	3.02 (2.10, 4.60)	
Hazard Ratio (95% CI)		0.621 (0.444, 0.868)	
p-value		0.0041	
History of brain metastasis			0.8507
Yes			
Total Patients	8	9	
Patients (%) With Events	3 (37.5%)	5 (55.6%)	
Patients (%) Without Events (Censored)	5 (62.5%)	4 (44.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.43, NR)	2.10 (0.66, NR)	
Hazard Ratio (95% CI)		0.648 (0.154, 2.730)	
p-value		0.5518	
No			
Total Patients	167	157	
Patients (%) With Events	82 (49.1%)	105 (66.9%)	
Patients (%) Without Events (Censored)	85 (50.9%)	52 (33.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (3.48, 23.66)	2.99 (1.84, 4.27)	
Hazard Ratio (95% CI)		0.660 (0.492, 0.885)	
p-value		0.0044	
PD-L1 Status			0.7180

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	30 (45.5%)	39 (68.4%)	
Patients (%) Without Events (Censored)	36 (54.5%)	18 (31.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.58, NR)	2.37 (1.41, 4.63)	
Hazard Ratio (95% CI)		0.652 (0.404, 1.054)	
p-value		0.0742	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	55 (50.5%)	71 (65.1%)	
Patients (%) Without Events (Censored)	54 (49.5%)	38 (34.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (2.56, 22.34)	3.02 (1.84, 4.40)	
Hazard Ratio (95% CI)		0.653 (0.455, 0.938)	
p-value		0.0176	
BRCA 1/2 status			0.3514
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	33 (50.8%)	38 (60.3%)	
Patients (%) Without Events (Censored)	32 (49.2%)	25 (39.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	6.28 (1.58, NR)	2.10 (1.18, 7.79)	
Hazard Ratio (95% CI)		0.719 (0.447, 1.157)	
p-value		0.1622	
Mutant			
Total Patients	12	10	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	7 (58.3%)	7 (70.0%)	
Patients (%) Without Events (Censored)	5 (41.7%)	3 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.26, NR)	4.63 (0.95, NR)	
Hazard Ratio (95% CI)		1.204 (0.417, 3.481)	
p-value		0.7369	
Menopausal status			0.7923
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	17 (45.9%)	31 (64.6%)	
Patients (%) Without Events (Censored)	20 (54.1%)	17 (35.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.89, NR)	3.02 (1.84, 4.93)	
Hazard Ratio (95% CI)		0.711 (0.393, 1.287)	
p-value		0.2483	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	68 (49.3%)	79 (67.5%)	
Patients (%) Without Events (Censored)	70 (50.7%)	38 (32.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.17 (2.56, 23.66)	2.50 (1.61, 3.88)	
Hazard Ratio (95% CI)		0.632 (0.454, 0.878)	
p-value		0.0051	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.27. Table 1.1.14.2: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — SOC: Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Menopausal status			0.0073
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	0 (0.0%)	9 (18.8%)	
Patients (%) Without Events (Censored)	37 (100.0%)	39 (81.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.0058	
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	10 (7.2%)	11 (9.4%)	
Patients (%) Without Events (Censored)	128 (92.8%)	106 (90.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.682 (0.288, 1.615)	
p-value		0.3822	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.

	SG (N=175)	TPC (N=166)	Interaction p-value[1]

Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.28. Table 1.1.14.3: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Leukopenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
The physician's choice of chemotherapy selected prior to randomization			0.6098
Taxane			
Total Patients	51	44	
Patients (%) With Events	1 (2.0%)	1 (2.3%)	
Patients (%) Without Events (Censored)	50 (98.0%)	43 (97.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.852 (0.053, 13.614)	
p-value		0.9094	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	11 (8.9%)	30 (24.6%)	
Patients (%) Without Events (Censored)	113 (91.1%)	92 (75.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (23.66, NR)	NR (13.63, NR)	
Hazard Ratio (95% CI)		0.316 (0.158, 0.634)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.0006	
History of brain metastasis			0.2651
Yes			
Total Patients	8	9	
Patients (%) With Events	0 (0.0%)	2 (22.2%)	
Patients (%) Without Events (Censored)	8 (100.0%)	7 (77.8%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (NR, NR)	NR (1.64, NR)	
Hazard Ratio (95% CI)		NC	
p-value		0.1161	
No			
Total Patients	167	157	
Patients (%) With Events	12 (7.2%)	29 (18.5%)	
Patients (%) Without Events (Censored)	155 (92.8%)	128 (81.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (23.66, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.334 (0.169, 0.658)	
p-value		0.0009	
Menopausal status			0.2028
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	1 (2.7%)	10 (20.8%)	
Patients (%) Without Events (Censored)	36 (97.3%)	38 (79.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (15.08, NR)	NR (13.63, NR)	
Hazard Ratio (95% CI)		0.085 (0.011, 0.677)	
p-value		0.0038	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Post-menopausal			
Total Patients	138	117	
Patients (%) With Events	11 (8.0%)	21 (17.9%)	
Patients (%) Without Events (Censored)	127 (92.0%)	96 (82.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (23.66, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		0.400 (0.192, 0.832)	
p-value		0.0111	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.29. Table 1.1.14.4: Subgroup Analysis of Time to First TEAE with CTCAE Grade 3 and above by SOC and PT — PT: Neutropenia (SOC: Blood and lymphatic system disorders) — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Disease stratification			0.3907
De novo			
Total Patients	55	48	
Patients (%) With Events	21 (38.2%)	19 (39.6%)	
Patients (%) Without Events (Censored)	34 (61.8%)	29 (60.4%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (2.20, NR)	NR (3.48, NR)	
Hazard Ratio (95% CI)		1.040 (0.559, 1.937)	
p-value		0.9081	
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting			
Total Patients	34	33	
Patients (%) With Events	20 (58.8%)	23 (69.7%)	
Patients (%) Without Events (Censored)	14 (41.2%)	10 (30.3%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.58 (0.69, NR)	1.18 (0.92, 4.40)	
Hazard Ratio (95% CI)		0.776 (0.420, 1.435)	
p-value		0.3989	
Recurrent disease occurring > 12 months from completion of treatment in the curative setting			
Total Patients	86	85	
Patients (%) With Events	33 (38.4%)	50 (58.8%)	
Patients (%) Without Events (Censored)	53 (61.6%)	35 (41.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (6.28, NR)	3.22 (2.10, 9.40)	
Hazard Ratio (95% CI)		0.546 (0.350, 0.852)	
p-value		0.0065	
Geographic region			0.9364
US/Canada/Western Europe			
Total Patients	55	50	
Patients (%) With Events	19 (34.5%)	22 (44.0%)	
Patients (%) Without Events (Censored)	36 (65.5%)	28 (56.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (21.39, NR)	5.82 (3.12, NR)	
Hazard Ratio (95% CI)		0.711 (0.384, 1.316)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
p-value		0.2667	
Rest of the world			
Total Patients	120	116	
Patients (%) With Events	55 (45.8%)	70 (60.3%)	
Patients (%) Without Events (Censored)	65 (54.2%)	46 (39.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.34, NR)	3.02 (1.87, 5.78)	
Hazard Ratio (95% CI)		0.683 (0.476, 0.981)	
p-value		0.0349	
Age group			0.4932
< 65			
Total Patients	132	128	
Patients (%) With Events	55 (41.7%)	71 (55.5%)	
Patients (%) Without Events (Censored)	77 (58.3%)	57 (44.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	23.66 (7.20, NR)	3.22 (2.30, 9.40)	
Hazard Ratio (95% CI)		0.657 (0.460, 0.939)	
p-value		0.0188	
>= 65			
Total Patients	43	38	
Patients (%) With Events	19 (44.2%)	21 (55.3%)	
Patients (%) Without Events (Censored)	24 (55.8%)	17 (44.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (1.61, NR)	4.27 (1.71, 9.69)	
Hazard Ratio (95% CI)		0.805 (0.430, 1.508)	
p-value		0.4848	
Race			0.0148

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
White			
Total Patients	114	101	
Patients (%) With Events	37 (32.5%)	55 (54.5%)	
Patients (%) Without Events (Censored)	77 (67.5%)	46 (45.5%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (21.39, NR)	3.22 (2.10, 9.69)	
Hazard Ratio (95% CI)		0.510 (0.335, 0.777)	
p-value		0.0013	
Asian			
Total Patients	38	38	
Patients (%) With Events	25 (65.8%)	20 (52.6%)	
Patients (%) Without Events (Censored)	13 (34.2%)	18 (47.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	3.48 (0.69, 11.24)	5.78 (1.87, NR)	
Hazard Ratio (95% CI)		1.386 (0.761, 2.524)	
p-value		0.3026	
Other			
Total Patients	18	24	
Patients (%) With Events	11 (61.1%)	17 (70.8%)	
Patients (%) Without Events (Censored)	7 (38.9%)	7 (29.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	1.38 (0.49, NR)	2.50 (0.92, 4.93)	
Hazard Ratio (95% CI)		0.812 (0.368, 1.791)	
p-value		0.5998	
Baseline ECOG status			0.8534
0			
Total Patients	115	104	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Patients (%) With Events	52 (45.2%)	63 (60.6%)	
Patients (%) Without Events (Censored)	63 (54.8%)	41 (39.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (4.14, NR)	3.45 (2.27, 5.82)	
Hazard Ratio (95% CI)		0.715 (0.494, 1.034)	
p-value		0.0678	
1			
Total Patients	60	62	
Patients (%) With Events	22 (36.7%)	29 (46.8%)	
Patients (%) Without Events (Censored)	38 (63.3%)	33 (53.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.24, 23.66)	8.48 (1.87, NR)	
Hazard Ratio (95% CI)		0.603 (0.336, 1.083)	
p-value		0.0848	
The physician's choice of chemotherapy selected prior to randomization			<0.0001
Taxane			
Total Patients	51	44	
Patients (%) With Events	20 (39.2%)	3 (6.8%)	
Patients (%) Without Events (Censored)	31 (60.8%)	41 (93.2%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (3.48, NR)	NR (NR, NR)	
Hazard Ratio (95% CI)		6.331 (1.872, 21.410)	
p-value		0.0007	
Gemcitabine/Carboplatin			
Total Patients	124	122	
Patients (%) With Events	54 (43.5%)	89 (73.0%)	
Patients (%) Without Events (Censored)	70 (56.5%)	33 (27.0%)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (5.09, NR)	2.10 (1.41, 3.02)	
Hazard Ratio (95% CI)		0.482 (0.342, 0.681)	
p-value		<0.0001	
History of liver metastasis			0.6113
Yes			
Total Patients	47	37	
Patients (%) With Events	21 (44.7%)	18 (48.6%)	
Patients (%) Without Events (Censored)	26 (55.3%)	19 (51.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (1.58, NR)	2.99 (1.41, NR)	
Hazard Ratio (95% CI)		0.874 (0.464, 1.647)	
p-value		0.6758	
No			
Total Patients	128	129	
Patients (%) With Events	53 (41.4%)	74 (57.4%)	
Patients (%) Without Events (Censored)	75 (58.6%)	55 (42.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (11.17, NR)	4.40 (2.37, 9.40)	
Hazard Ratio (95% CI)		0.641 (0.448, 0.917)	
p-value		0.0127	
History of brain metastasis			0.3842
Yes			
Total Patients	8	9	
Patients (%) With Events	2 (25.0%)	5 (55.6%)	
Patients (%) Without Events (Censored)	6 (75.0%)	4 (44.4%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.72, NR)	2.50 (0.66, NR)	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Hazard Ratio (95% CI)		0.366 (0.071, 1.896)	
p-value		0.2120	
No			
Total Patients	167	157	
Patients (%) With Events	72 (43.1%)	87 (55.4%)	
Patients (%) Without Events (Censored)	95 (56.9%)	70 (44.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (6.28, NR)	4.27 (2.37, 9.40)	
Hazard Ratio (95% CI)		0.710 (0.517, 0.974)	
p-value		0.0301	
PD-L1 Status			0.5269
CPS < 1			
Total Patients	66	57	
Patients (%) With Events	25 (37.9%)	33 (57.9%)	
Patients (%) Without Events (Censored)	41 (62.1%)	24 (42.1%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (3.48, NR)	3.45 (1.71, 9.69)	
Hazard Ratio (95% CI)		0.646 (0.382, 1.091)	
p-value		0.0968	
CPS ≥ 1			
Total Patients	109	109	
Patients (%) With Events	49 (45.0%)	59 (54.1%)	
Patients (%) Without Events (Censored)	60 (55.0%)	50 (45.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	11.24 (4.86, 23.66)	4.40 (2.30, 9.53)	
Hazard Ratio (95% CI)		0.710 (0.481, 1.046)	
p-value		0.0749	

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
BRCA 1/2 status			0.3895
Wild-Type			
Total Patients	65	63	
Patients (%) With Events	29 (44.6%)	33 (52.4%)	
Patients (%) Without Events (Censored)	36 (55.4%)	30 (47.6%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	22.34 (2.92, NR)	3.48 (1.41, NR)	
Hazard Ratio (95% CI)		0.749 (0.451, 1.242)	
p-value		0.2521	
Mutant			
Total Patients	12	10	
Patients (%) With Events	7 (58.3%)	7 (70.0%)	
Patients (%) Without Events (Censored)	5 (41.7%)	3 (30.0%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	0.95 (0.26, NR)	4.63 (0.95, NR)	
Hazard Ratio (95% CI)		1.204 (0.417, 3.481)	
p-value		0.7369	
Menopausal status			0.4146
Pre-menopausal			
Total Patients	37	48	
Patients (%) With Events	16 (43.2%)	25 (52.1%)	
Patients (%) Without Events (Censored)	21 (56.8%)	23 (47.9%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	NR (0.89, NR)	4.40 (2.27, NR)	
Hazard Ratio (95% CI)		0.899 (0.479, 1.685)	
p-value		0.7246	
Post-menopausal			

	SG (N=175)	TPC (N=166)	Interaction p-value[1]
Total Patients	138	117	
Patients (%) With Events	58 (42.0%)	67 (57.3%)	
Patients (%) Without Events (Censored)	80 (58.0%)	50 (42.7%)	
Median Time to First Grade ≥3 TEAE, months (95% CI)	21.39 (7.20, NR)	3.45 (1.87, 8.48)	
Hazard Ratio (95% CI)		0.629 (0.440, 0.898)	
p-value		0.0091	

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.
NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
[1]Interaction p-value from likelihood ratio test: Cox model with treatment + subgroup + treatment×subgroup interaction vs treatment + subgroup only.
Subgroup presented only if p-value from the Cox model is <0.05 and subgroups with ≥10 events (excluding censored) in at least one category of the subgroup over both arms.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.30. Table 1.1.15: Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

	SG (N=175)	TPC (N=166)
Blood and lymphatic system disorders		
Total Patients	175	166
Patients (%) With Events	13 (7.4%)	19 (11.4%)
Patients (%) Without Events (Censored)	162 (92.6%)	147 (88.6%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		

	SG (N=175)	TPC (N=166)
Hazard Ratio (95% CI)		0.633 (0.313, 1.283)
p-value		0.1991
Neutropenia		
Total Patients	175	166
Patients (%) With Events	5 (2.9%)	8 (4.8%)
Patients (%) Without Events (Censored)	170 (97.1%)	158 (95.2%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		0.576 (0.188, 1.762)
p-value		0.3271
Thrombocytopenia		
Total Patients	175	166
Patients (%) With Events	0 (0.0%)	10 (6.0%)
Patients (%) Without Events (Censored)	175 (100.0%)	156 (94.0%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		NC
p-value		0.0009
Gastrointestinal disorders		
Total Patients	175	166
Patients (%) With Events	16 (9.1%)	2 (1.2%)
Patients (%) Without Events (Censored)	159 (90.9%)	164 (98.8%)

	SG (N=175)	TPC (N=166)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		7.405 (1.700, 32.246)
p-value		0.0017
Infections and infestations		
Total Patients	175	166
Patients (%) With Events	21 (12.0%)	16 (9.6%)
Patients (%) Without Events (Censored)	154 (88.0%)	150 (90.4%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.130 (0.588, 2.173)
p-value		0.7149
Respiratory, thoracic and mediastinal disorders		
Total Patients	175	166
Patients (%) With Events	8 (4.6%)	7 (4.2%)
Patients (%) Without Events (Censored)	167 (95.4%)	159 (95.8%)
Kaplan-Meier Quartiles of Time to Event (months)		
Median (95% CI)	NR (NR, NR)	NR (NR, NR)
Analysis SG vs. TPC		
Hazard Ratio (95% CI)		1.006 (0.363, 2.786)
p-value		0.9907

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Rule 1 = Events occurring in ≥5% of subjects in at least one arm; Rule 2 = Events occurring in ≥10 subjects overall (SG + TPC combined) and ≥1% in at least one arm. SOC and PT meeting Rule 1 OR Rule 2 are shown.

	SG (N=175)	TPC (N=166)

NR = Not Reached. Duration (months) = (date of event/censoring − date of first dose + 1)/30.4375.
Median Time-to-Event is from Kaplan-Meier estimate. 95% CI is computed using the Brookmeyer-Crowley method.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
p-value from unstratified log-rank test.
Denominator of percentages is the number of participants in each treatment arm.
Adverse events were coded according to MedDRA Version 28.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

6.31. Table 1.1.16: Subgroup Analysis of Time to First SAE by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

No Eligible Subgroups

6.32. Table 1.1.17: Incidence of TEAE leading to Study Drug Discontinuation by SOC and PT — mSAF — Excluding patients preselected to receive nab-paclitaxel

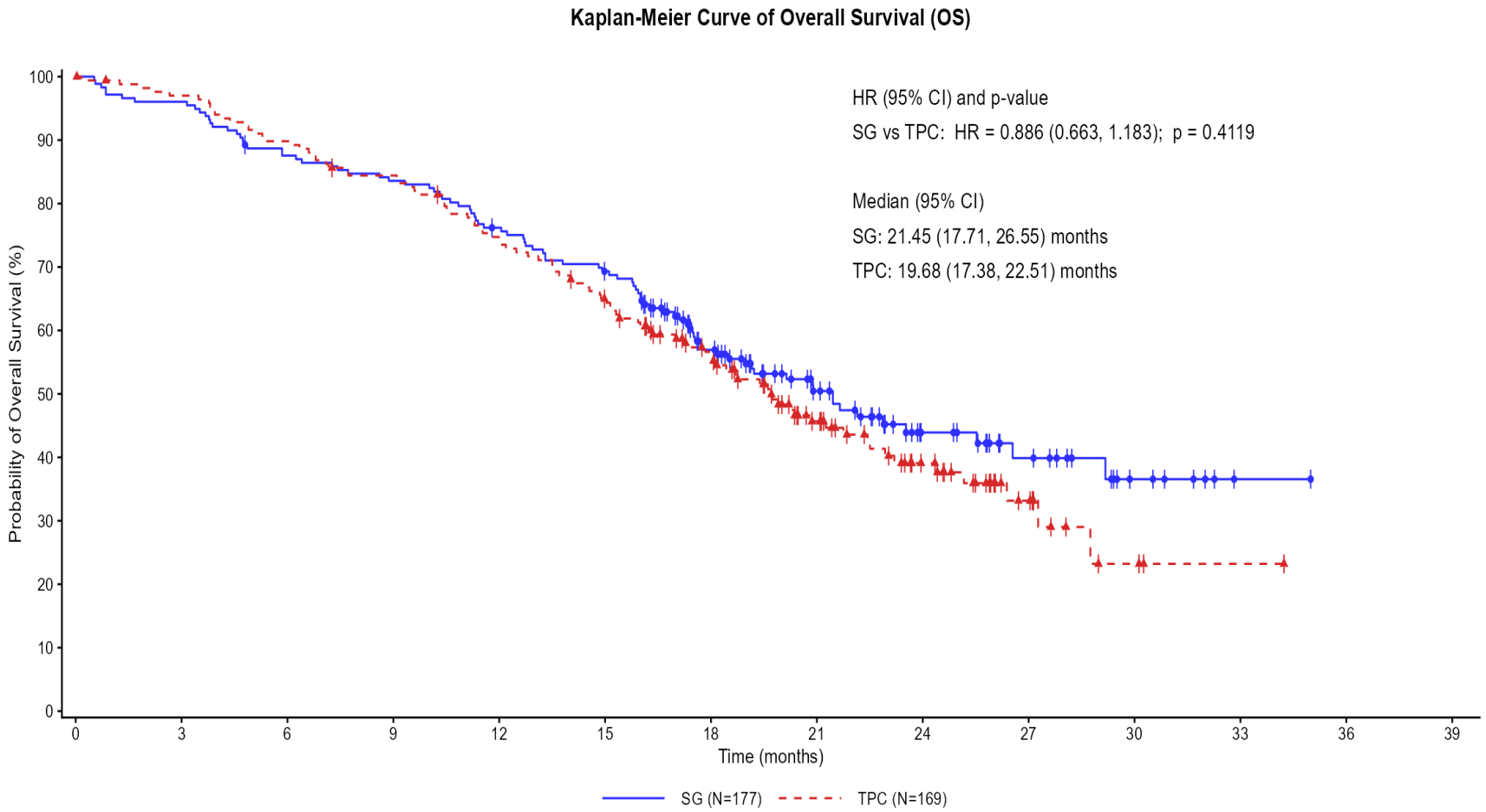
	SG (N=175)	TPC (N=166)
Number (%) of Participants with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	9 (5.1%)	28 (16.9%)
Blood and lymphatic system disorders	1 (0.6%)	14 (8.4%)
Thrombocytopenia	0	9 (5.4%)
Neutropenia	0	3 (1.8%)
Anaemia	0	2 (1.2%)
Febrile neutropenia	1 (0.6%)	0
Cardiac disorders	0	1 (0.6%)
Cardiac failure congestive	0	1 (0.6%)
Gastrointestinal disorders	2 (1.1%)	0
Diarrhoea	1 (0.6%)	0
Neutropenic colitis	1 (0.6%)	0
General disorders and administration site conditions	0	2 (1.2%)
Fatigue	0	2 (1.2%)
Hepatobiliary disorders	0	1 (0.6%)
Hypertransaminasaemia	0	1 (0.6%)
Immune system disorders	0	2 (1.2%)
Hypersensitivity	0	2 (1.2%)
Infections and infestations	1 (0.6%)	1 (0.6%)
Nail bed infection	0	1 (0.6%)
Urosepsis	1 (0.6%)	0
Injury, poisoning and procedural complications	1 (0.6%)	3 (1.8%)
Infusion related reaction	1 (0.6%)	3 (1.8%)
Musculoskeletal and connective tissue disorders	0	1 (0.6%)
Musculoskeletal pain	0	1 (0.6%)
Nervous system disorders	0	1 (0.6%)
Neuropathy peripheral	0	1 (0.6%)
Psychiatric disorders	1 (0.6%)	0
Restlessness	1 (0.6%)	0
Respiratory, thoracic and mediastinal disorders	3 (1.7%)	1 (0.6%)

	SG (N=175)	TPC (N=166)
Interstitial lung disease	2 (1.1%)	0
Pneumonitis	1 (0.6%)	0
Pulmonary embolism	0	1 (0.6%)
Skin and subcutaneous tissue disorders	0	2 (1.2%)
Eczema	0	1 (0.6%)
Skin oedema	0	1 (0.6%)

SG = sacituzumab govitecan, TPC = treatment of physician's choice, SOC = System Organ Class, PT = Preferred Term.
Adverse events were coded according to MedDRA Version 27.1.
Treatment-emergent adverse event (AE) defined as any AE occurring on or after the first dose date of study drug, and up to and including 30 days after last dose date of study drug or the day prior to initiation of subsequent anticancer therapy (including crossover treatment), whichever occurs first.
SOCs were presented alphabetically and PTs within SOC were presented by descending order of the total frequencies.
The following terms are mapped: Neutrophil count decreased → Neutropenia, White blood cell count decreased → Leukopenia, Lymphocyte count decreased → Lymphopenia, Haemoglobin decreased → Anaemia, Red blood cell count decreased → Anaemia, Platelet count decreased → Thrombocytopenia, Asthenia → Fatigue, Typhlitis → Neutropenic colitis, Dyspnoea exertional → Dyspnoea.

7. Efficacy - KM FIGURES — ALL- mITT

7.1. Figure 1.1.1: Kaplan-Meier Curve of Overall Survival (OS) — mITT — Excluding patients preselected to receive nab-paclitaxel

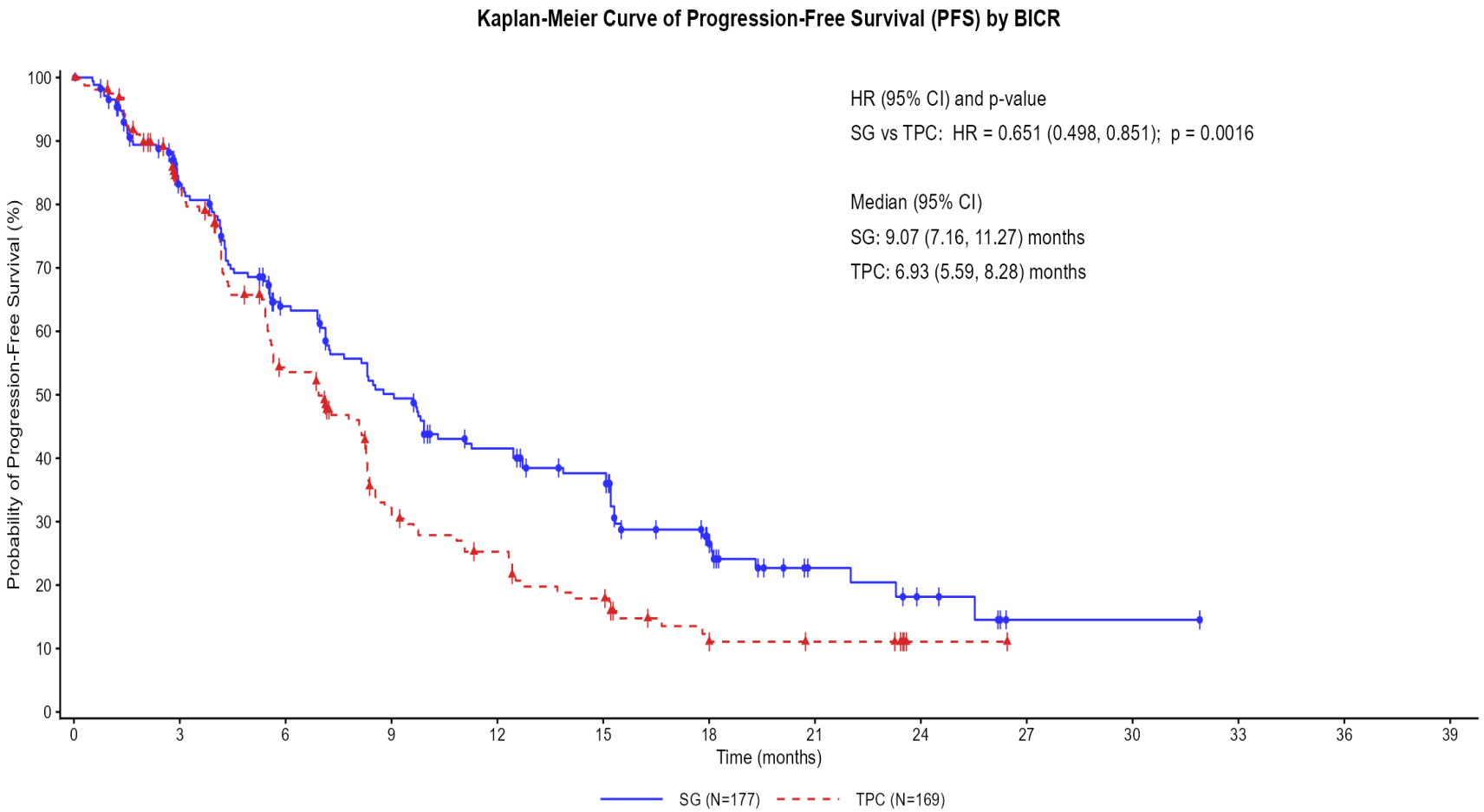


N at Risk (Cumulative Events)

177 (0)	170 (7)	154 (22)	147 (29)	133 (42)	120 (54)	83 (74)	53 (82)	29 (88)	17 (90)	7 (91)	1 (91)	0 (91)	0 (91)
169 (0)	162 (5)	150 (17)	140 (26)	122 (43)	105 (58)	81 (71)	48 (85)	29 (91)	11 (94)	3 (96)	1 (96)	0 (96)	0 (96)

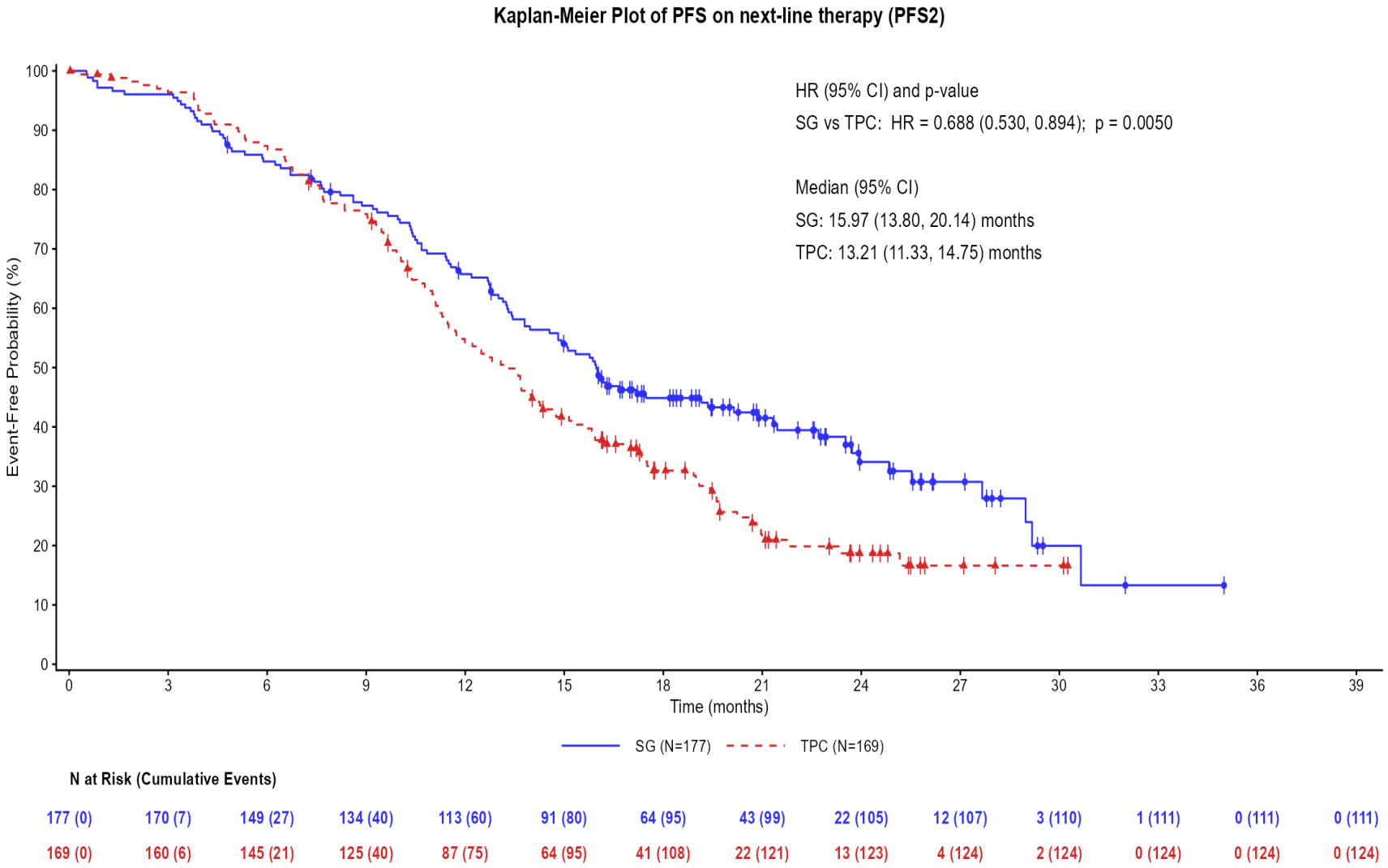
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

7.2. Figure 1.1.2: Kaplan-Meier Curve of Progression-Free Survival (PFS) by BICR — mITT — Excluding patients preselected to receive nab-paclitaxel



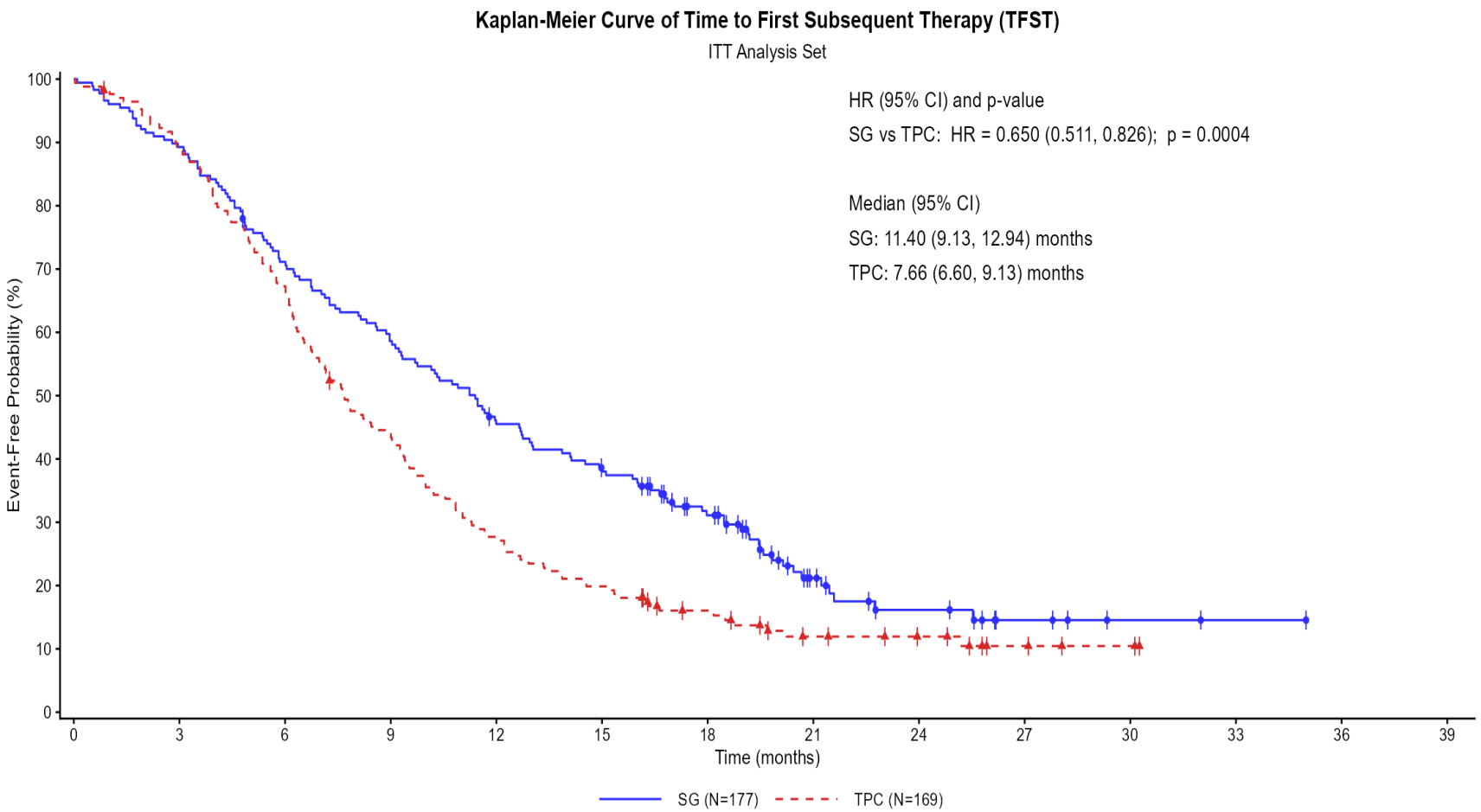
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

7.3. Figure 1.1.3: Kaplan-Meier Plot of PFS on next-line therapy (PFS2) — mITT — Excluding patients preselected to receive nab-paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

7.4. Figure 1.1.4: Kaplan-Meier Curve of Time to First Subsequent Therapy (TFST) — mITT — Excluding patients preselected to receive nab-paclitaxel

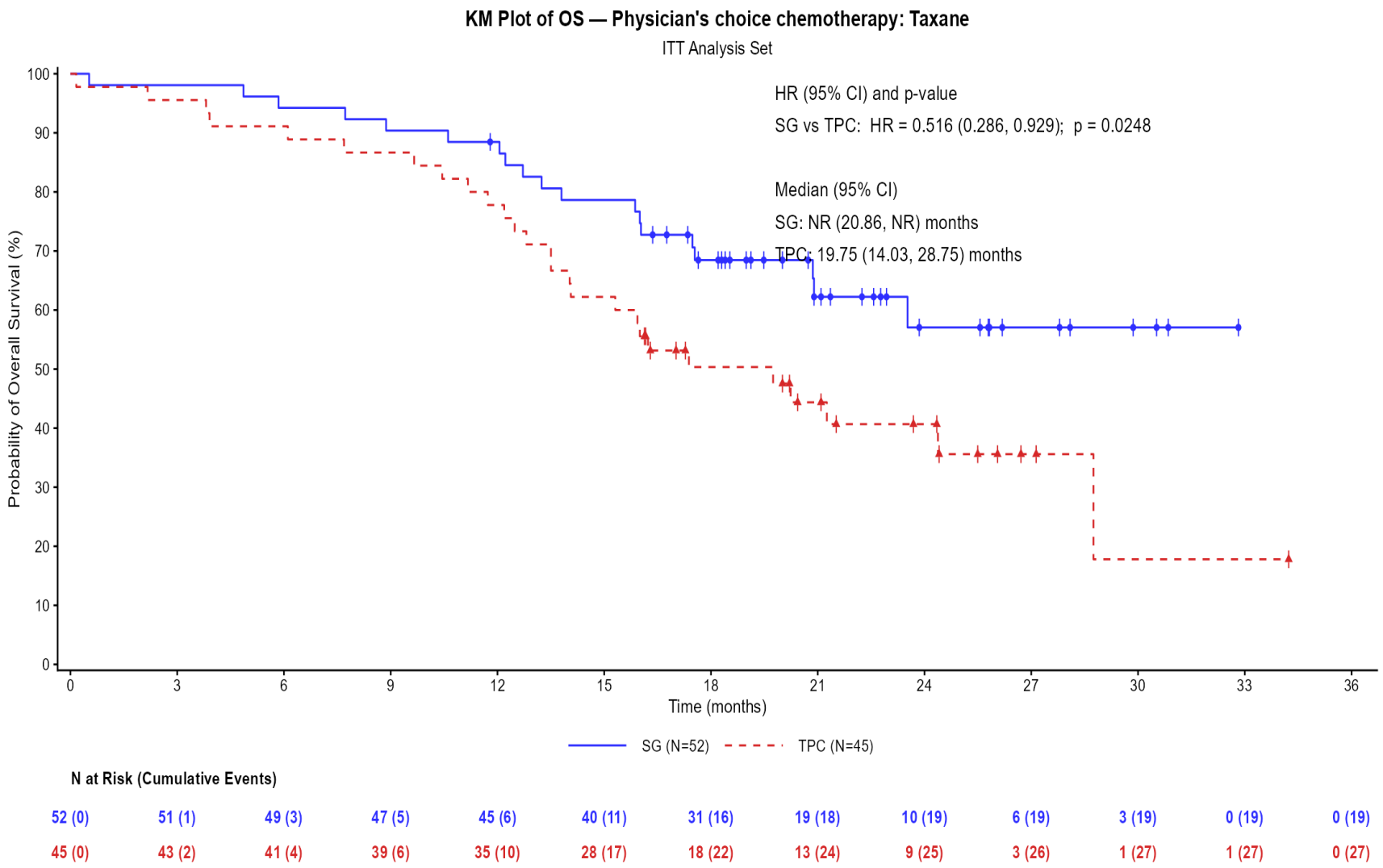


N at Risk (Cumulative Events)

177 (0)	158 (19)	125 (51)	103 (73)	79 (96)	66 (108)	45 (120)	19 (132)	11 (136)	5 (137)	2 (137)	1 (137)	0 (137)	0 (137)
169 (0)	150 (18)	113 (55)	73 (94)	45 (122)	33 (134)	21 (140)	12 (145)	9 (145)	4 (146)	2 (146)	0 (146)	0 (146)	0 (146)

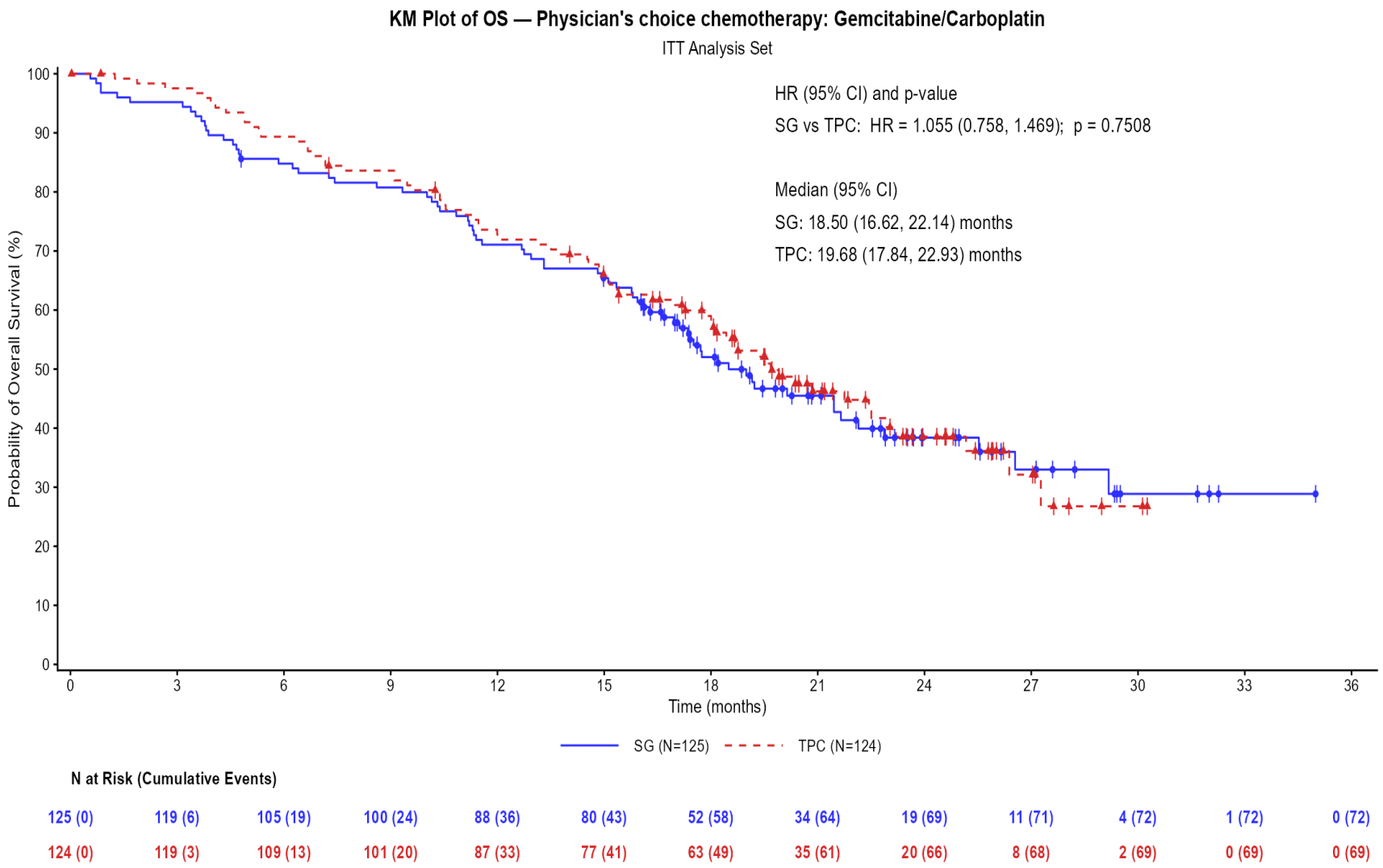
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, adjusted for randomization stratification factors (STRAT1, STRAT2) from IWRS. Efron method for ties. Reference arm = TPC.

7.5. Figure 1.1.6: KM Plot of OS — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



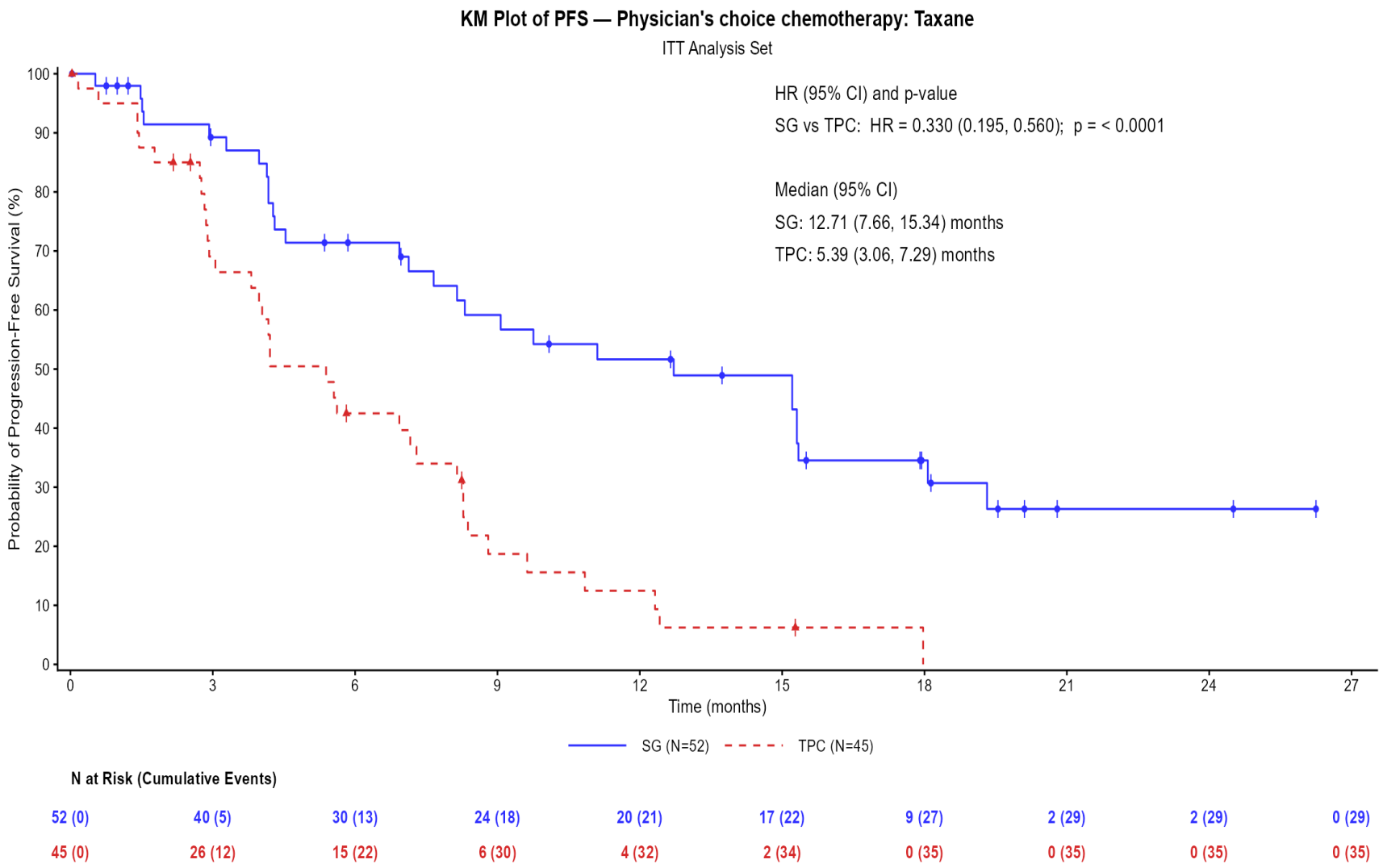
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.6. Figure 1.1.7: KM Plot of OS — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



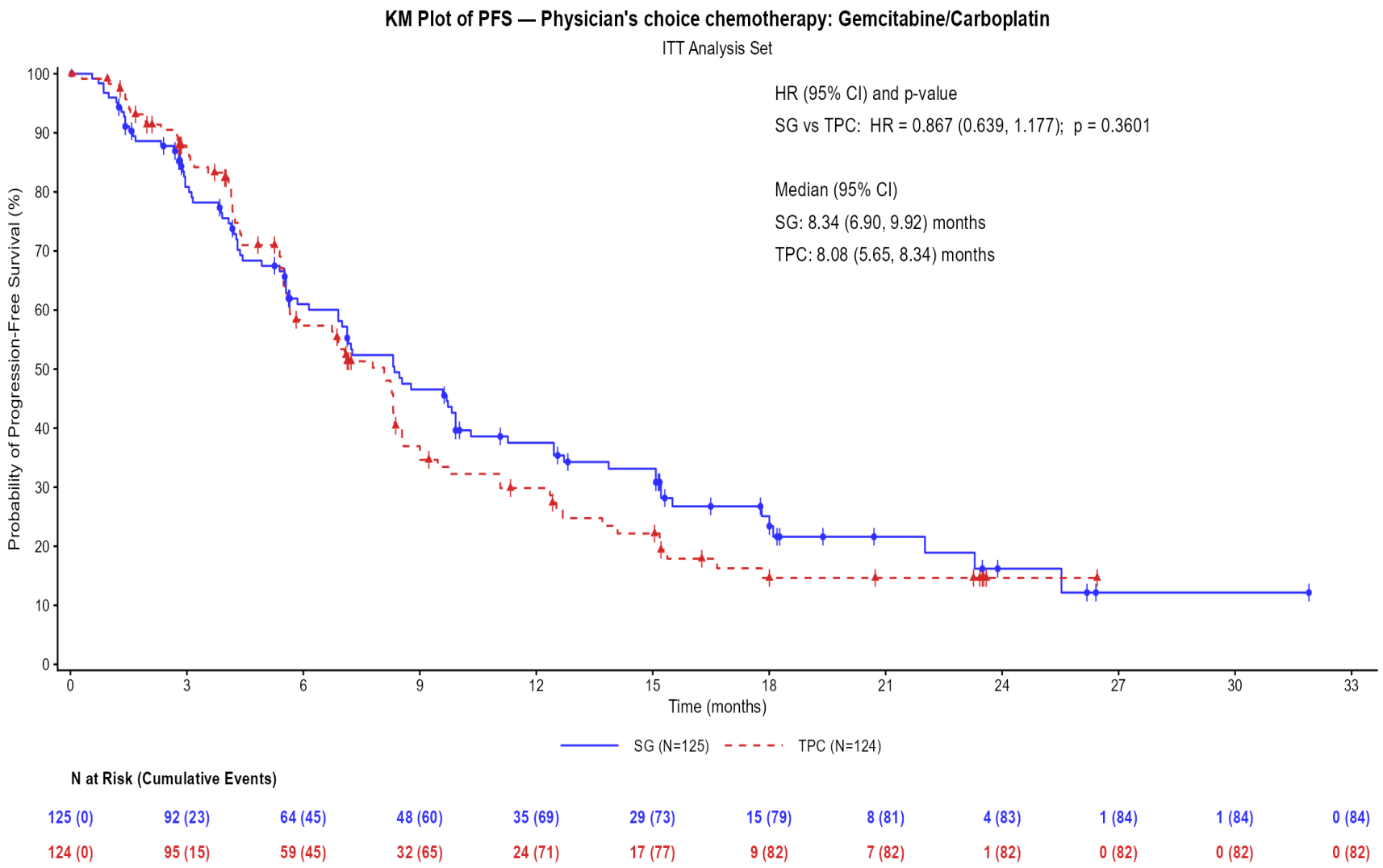
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.7. Figure 1.1.8: KM Plot of PFS — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



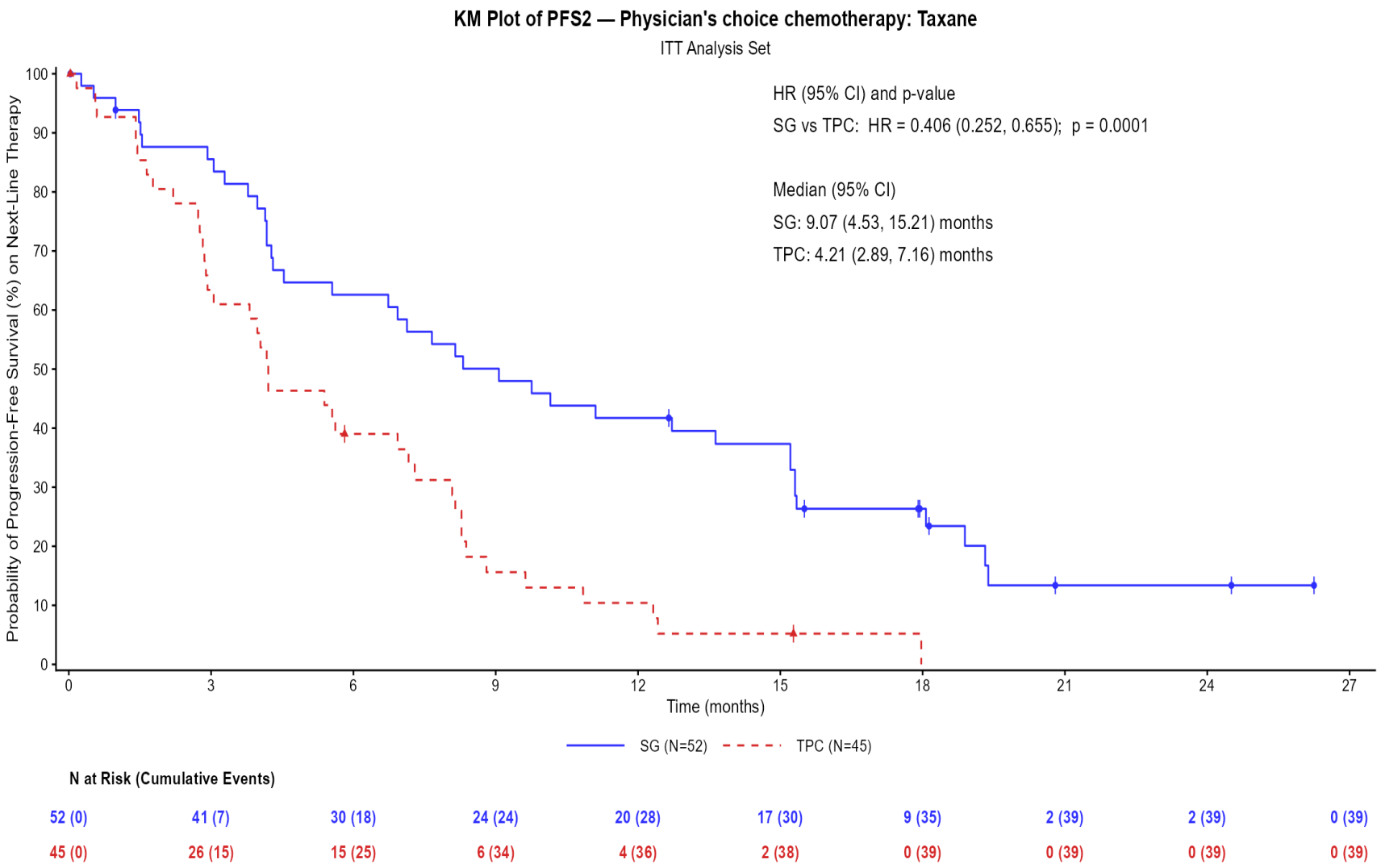
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.8. Figure 1.1.9: KM Plot of PFS — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



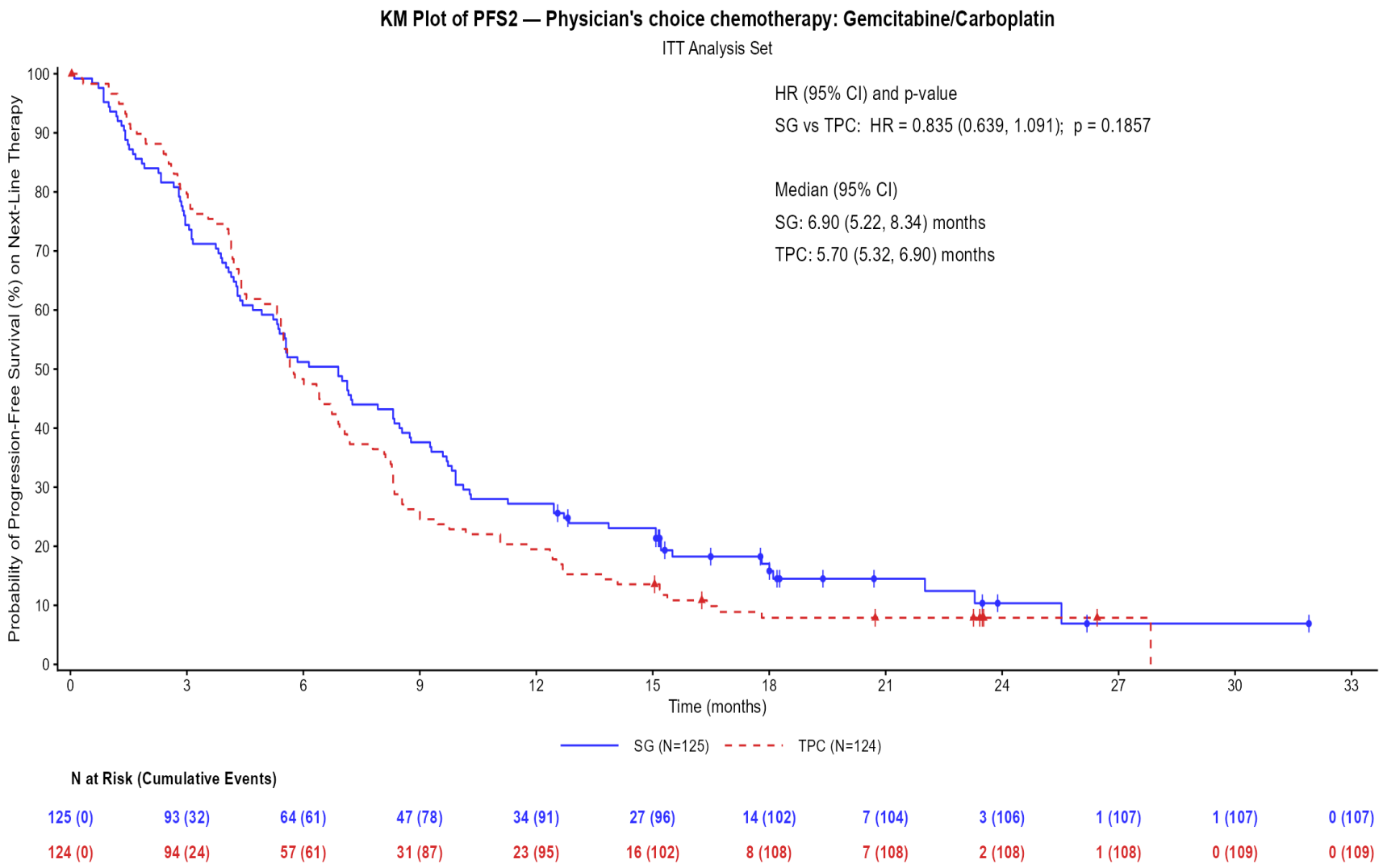
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.9. Figure 1.1.10: KM Plot of PFS2 — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



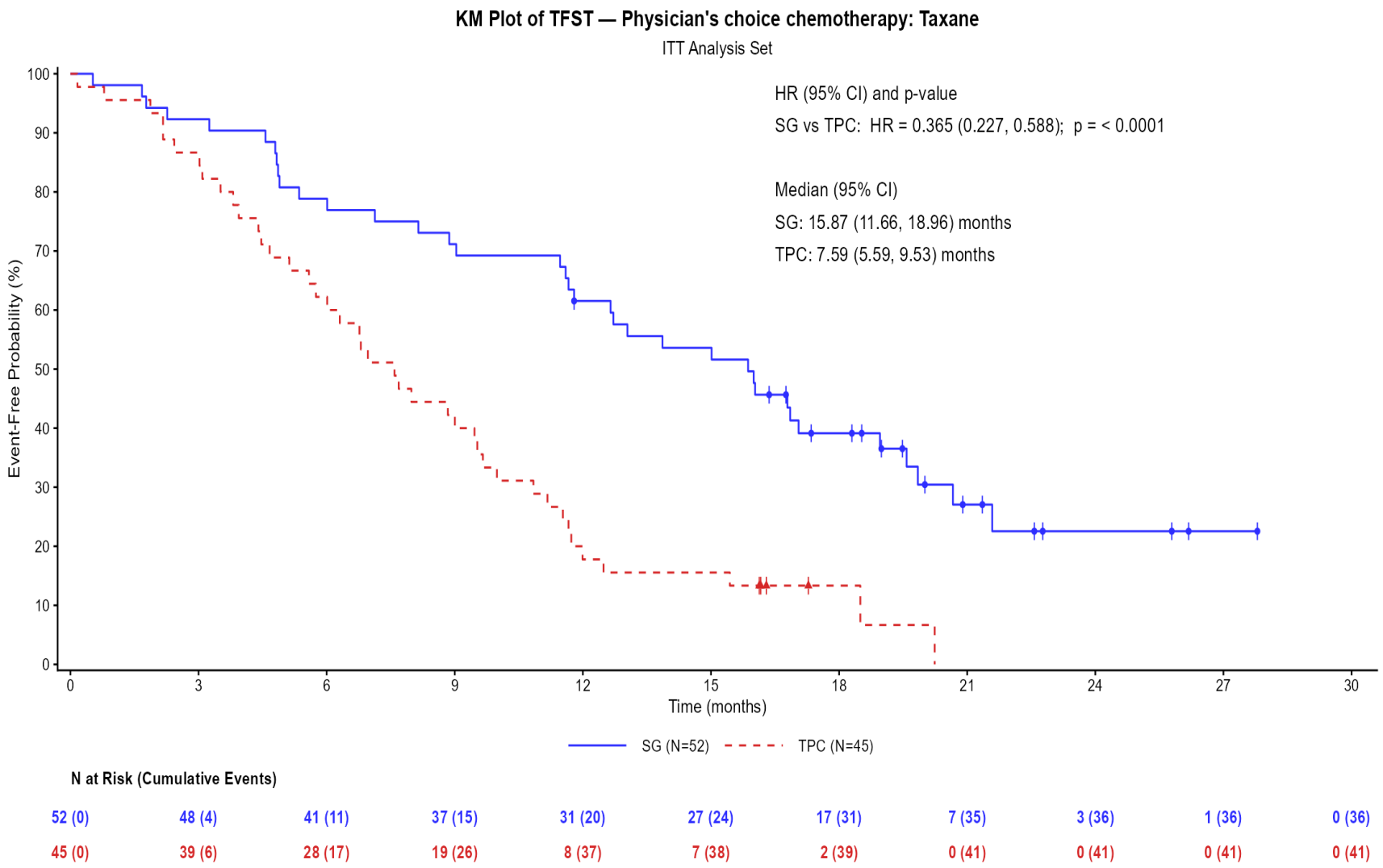
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.10. Figure 1.1.11: KM Plot of PFS2 — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



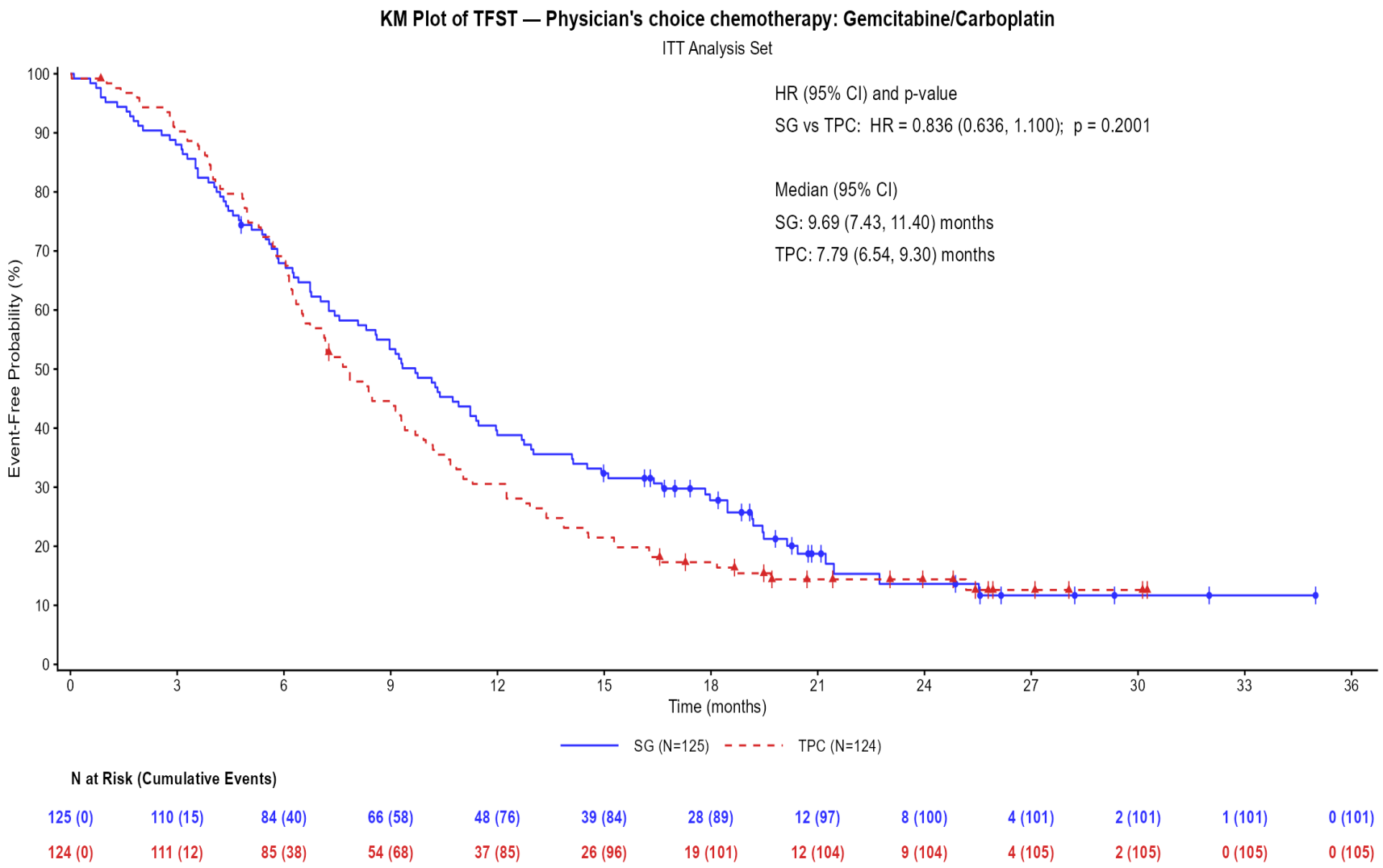
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.11. Figure 1.1.12: KM Plot of TFST — Physician's choice chemotherapy: Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



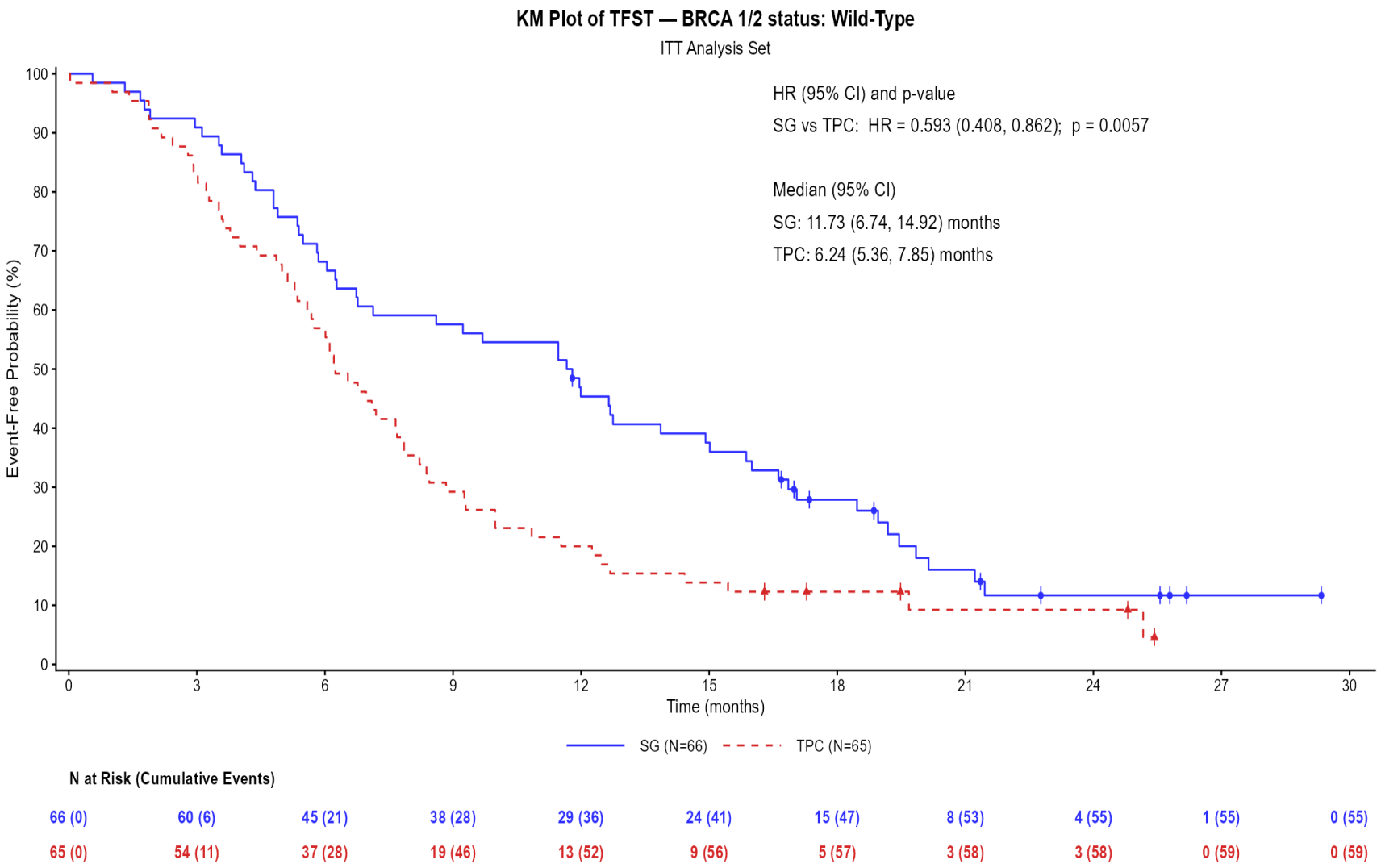
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.12. Figure 1.1.13: KM Plot of TFST — Physician's choice chemotherapy: Gemcitabine/Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



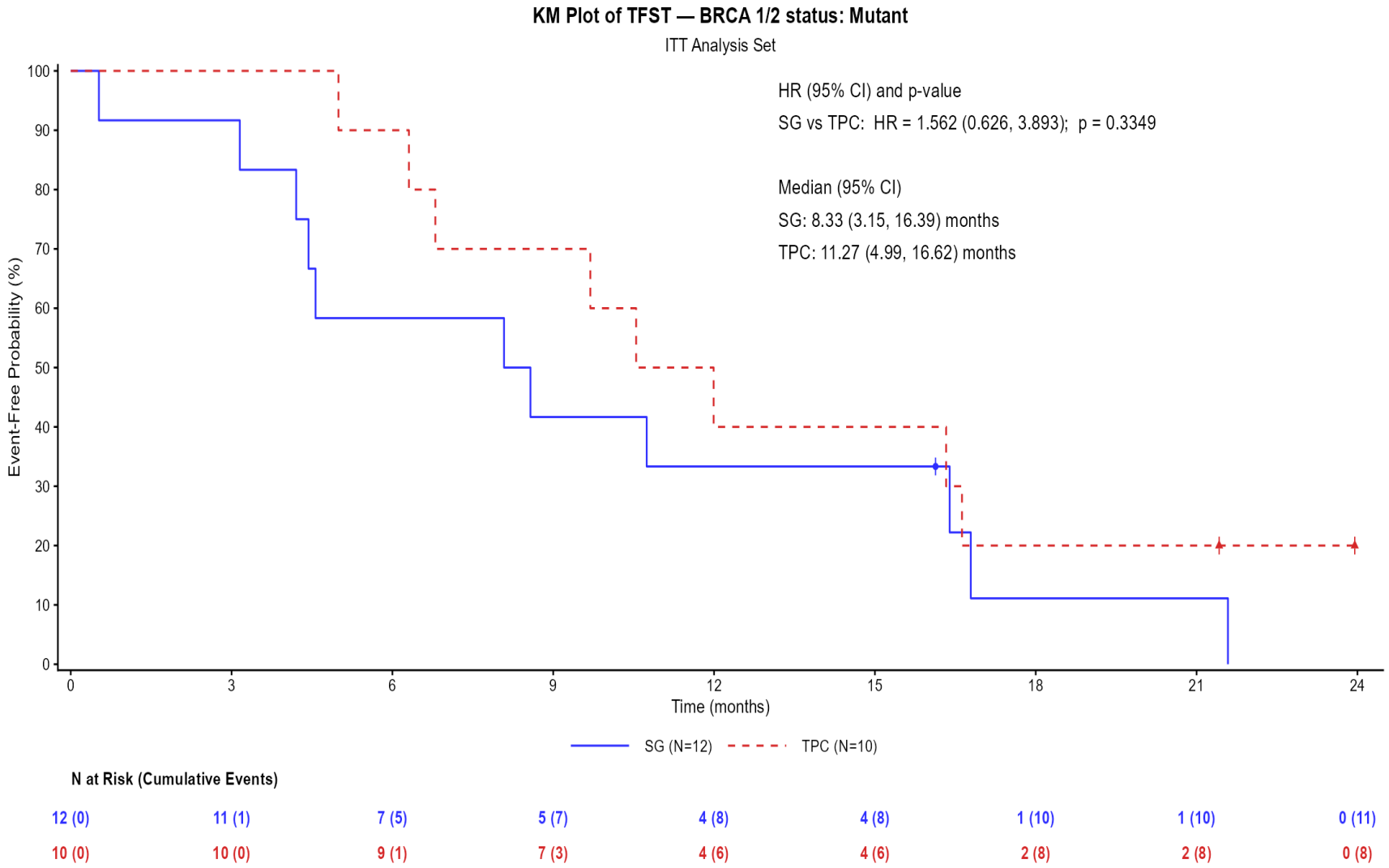
SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

7.13. Figure 1.1.14: KM Plot of TFST — BRCA 1/2 status: Wild-Type — mITT — Excluding patients preselected to receive nab-paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

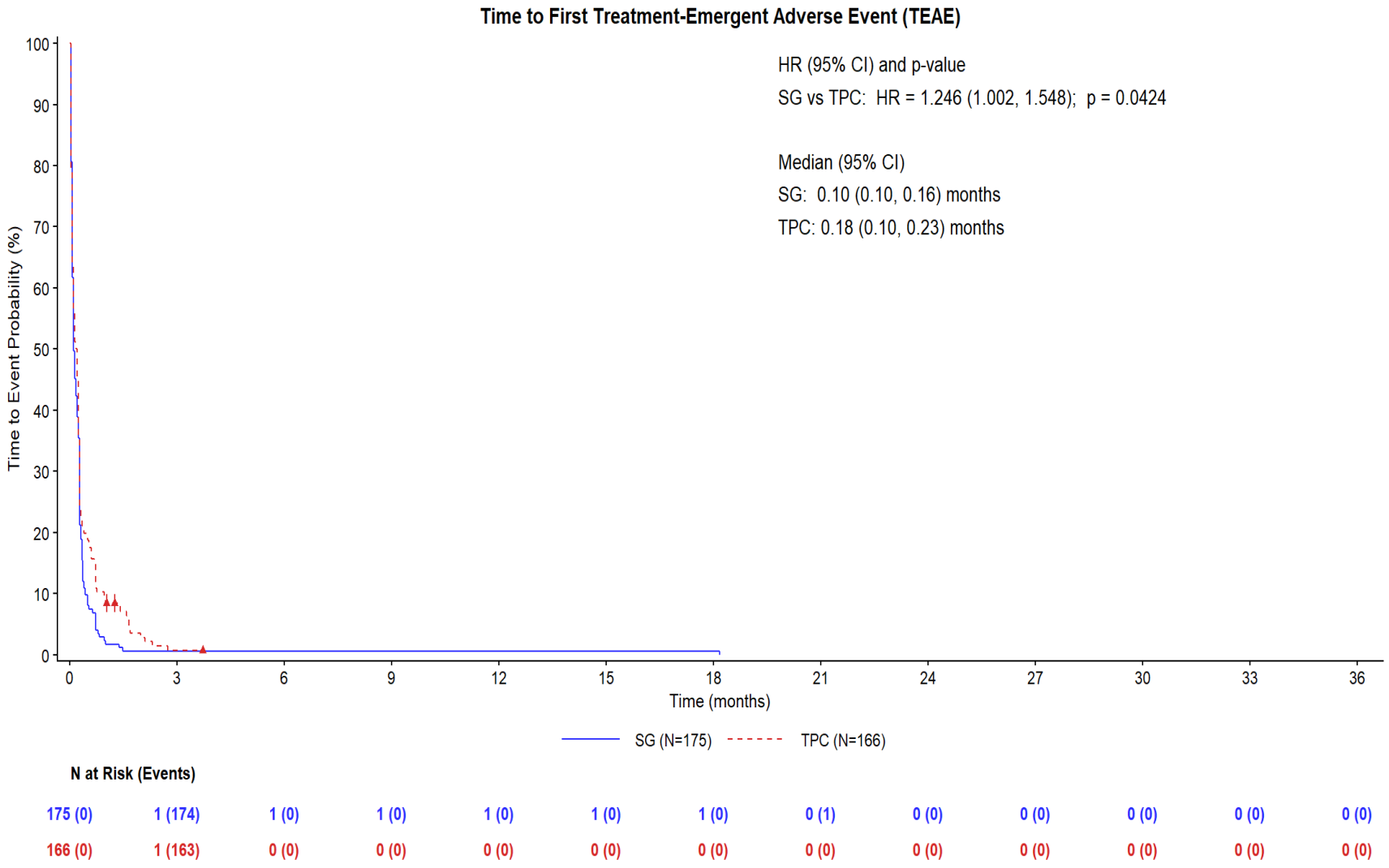
7.14. Figure 1.1.15: KM Plot of TFST — BRCA 1/2 status: Mutant — mITT — Excluding patients preselected to receive nab-paclitaxel



SG = sacituzumab govitecan; TPC = treatment of physician's choice; HR = hazard ratio; CI = confidence interval; NR = Not Reached. ITT Analysis Set includes all participants who were randomized in the study. The two-sided p-value is from stratified log-rank test and the hazard ratio with 95% CIs are calculated using Cox proportional hazards model, unstratified (subgroup analysis). Efron method for ties. Reference arm = TPC.

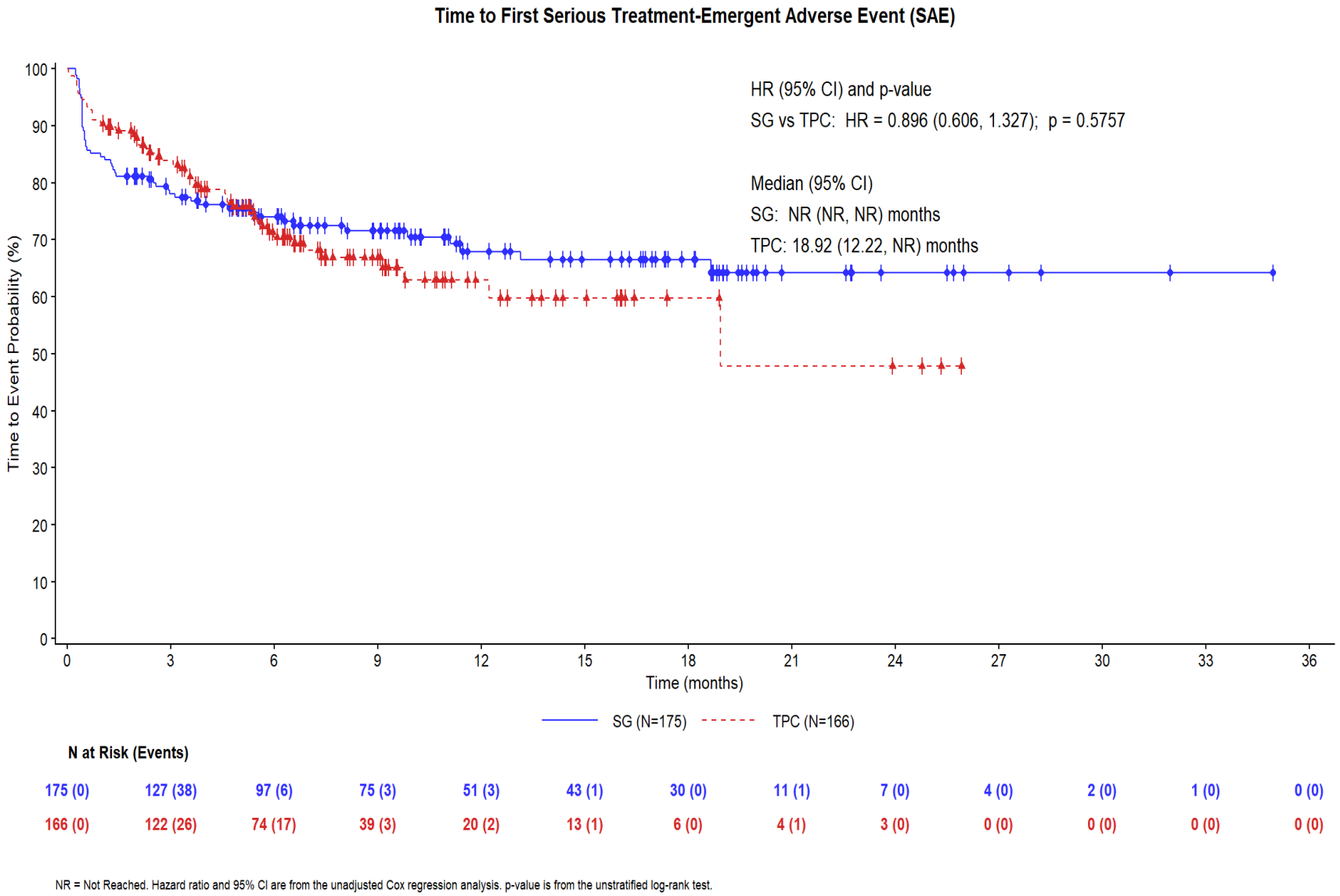
8. Safety - KM FIGURES — ALL

8.1. Figure 1.1.1: Kaplan Meier Plot of Time to First TEAE — mSAF — Excluding patients preselected to receive nab-paclitaxel



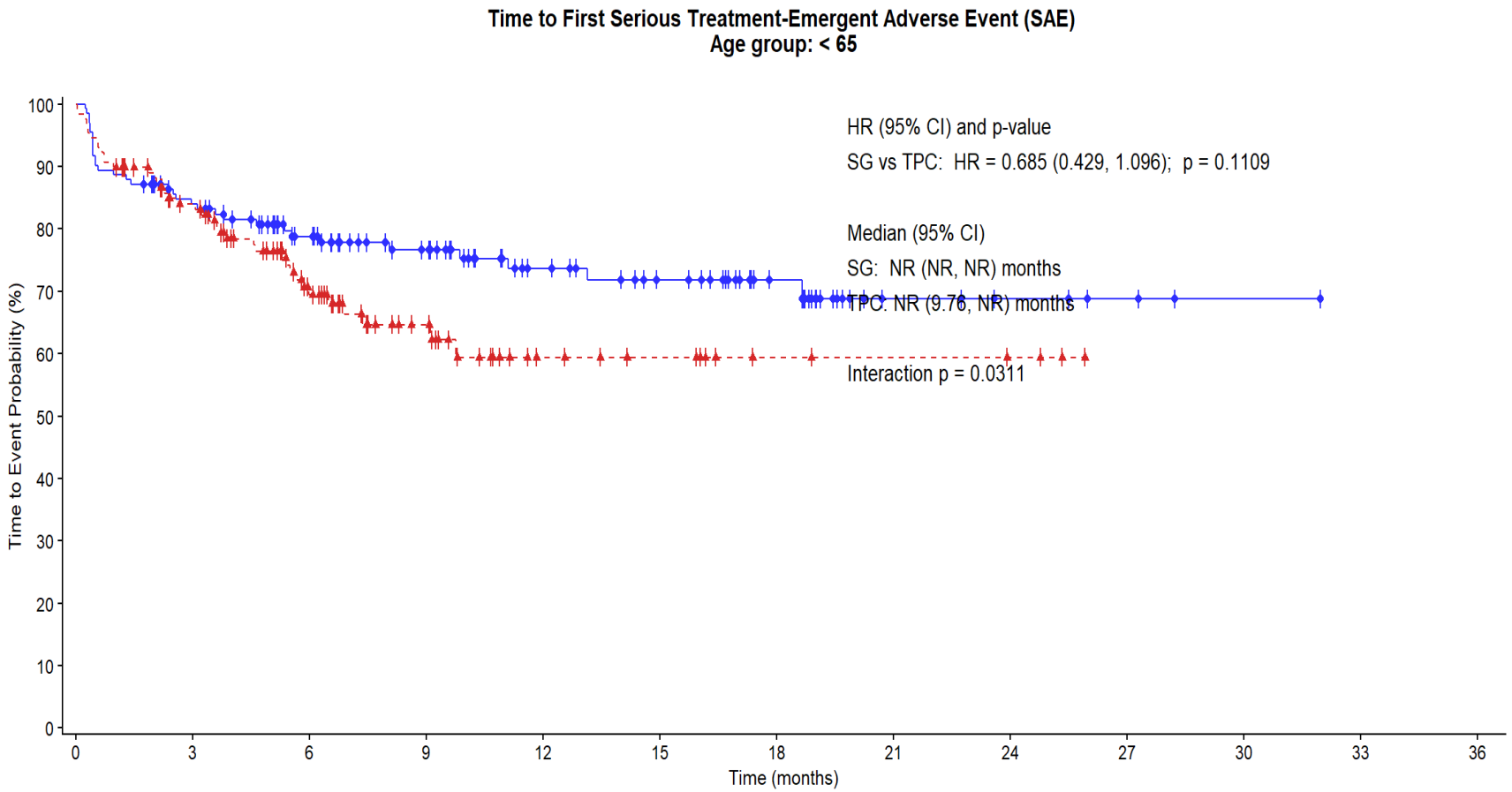
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.2. Figure 1.1.2: Kaplan Meier Plot of Time to First Serious TEAE (SAE) — mSAF — Excluding patients preselected to receive nab-paclitaxel



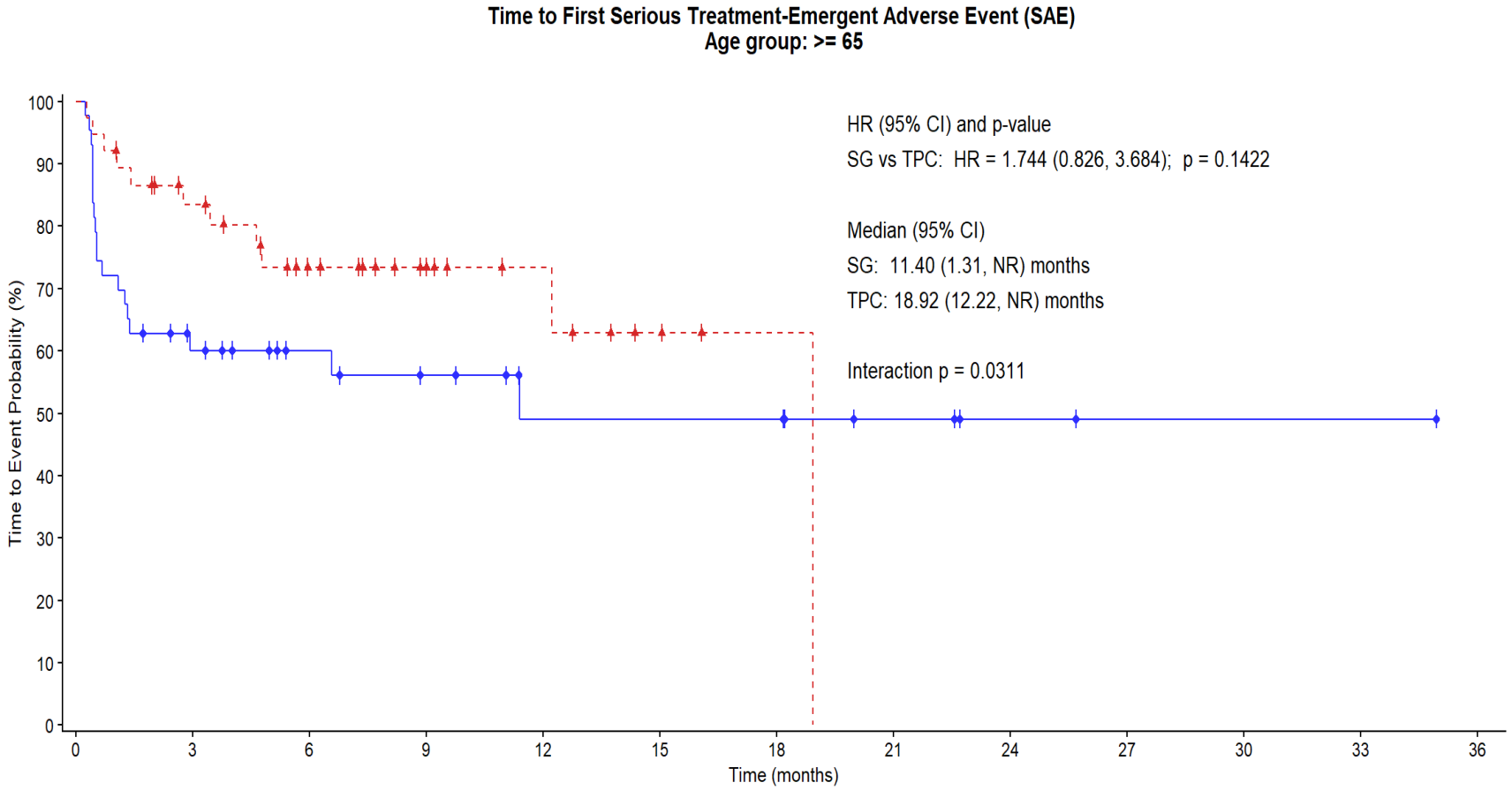
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.3. Figure 1.1.3: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



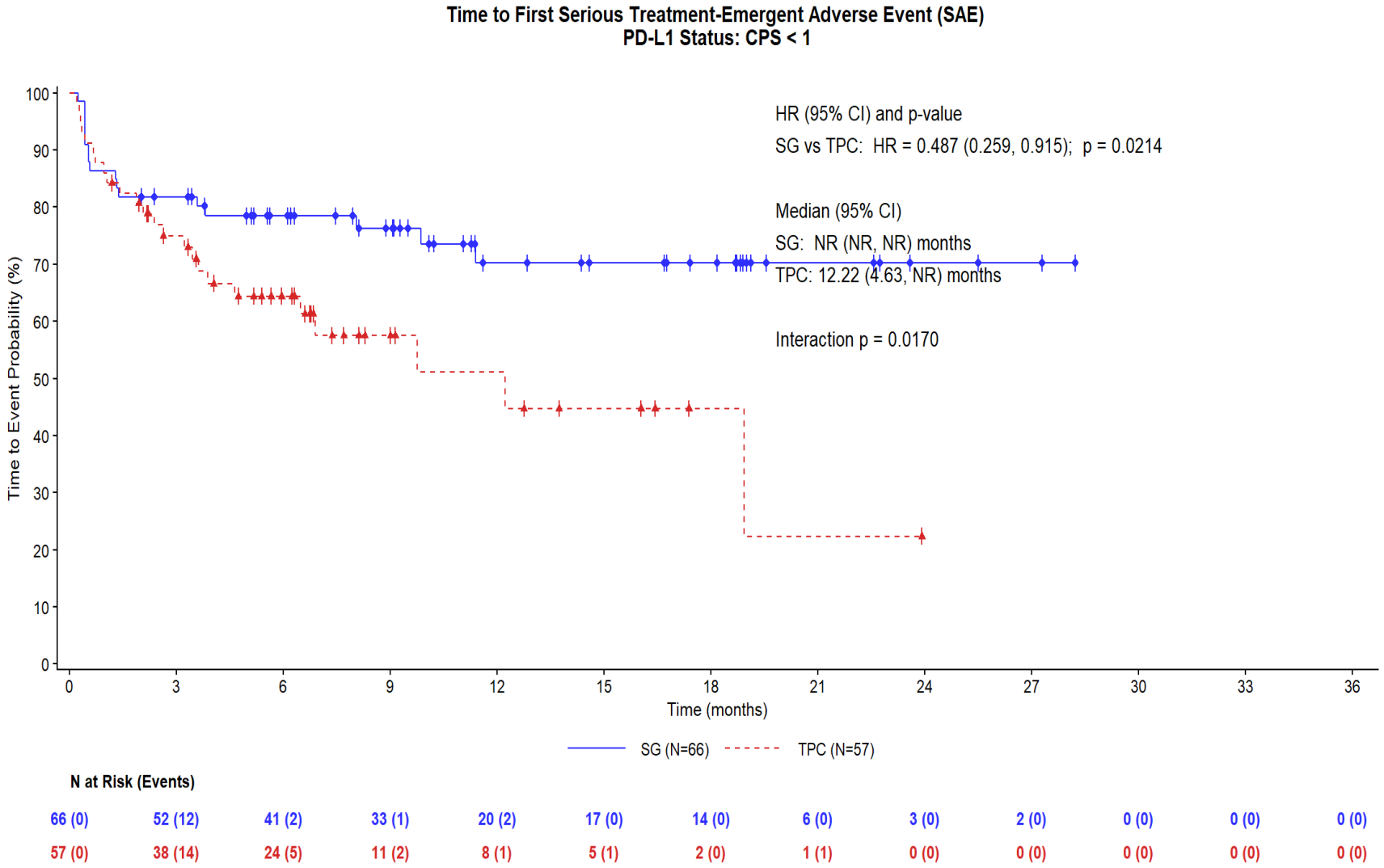
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.4. Figure 1.1.4: Kaplan Meier Plot of Time to First Serious TEAE (SAE) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



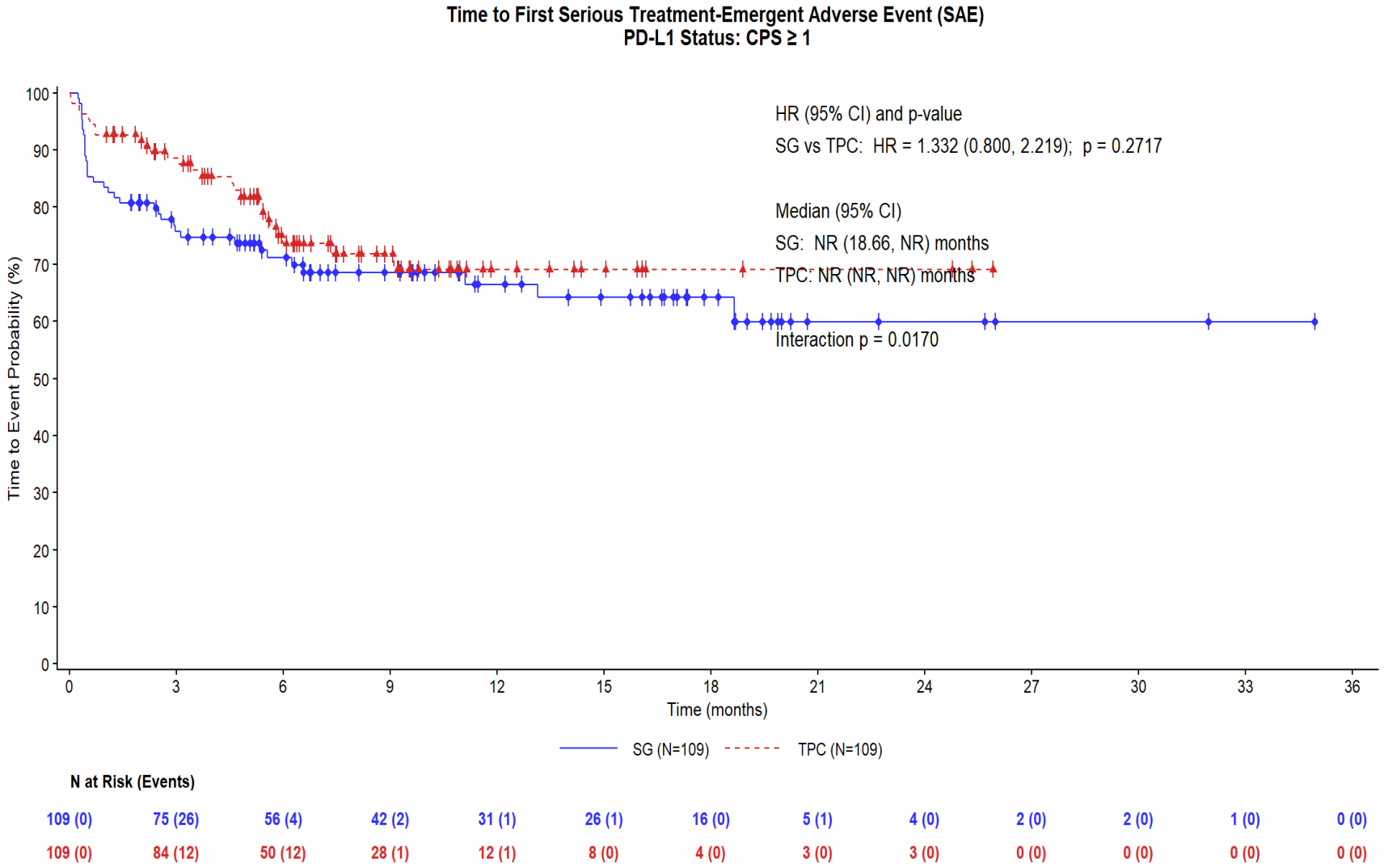
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.5. Figure 1.1.5: Kaplan Meier Plot of Time to First Serious TEAE (SAE) PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



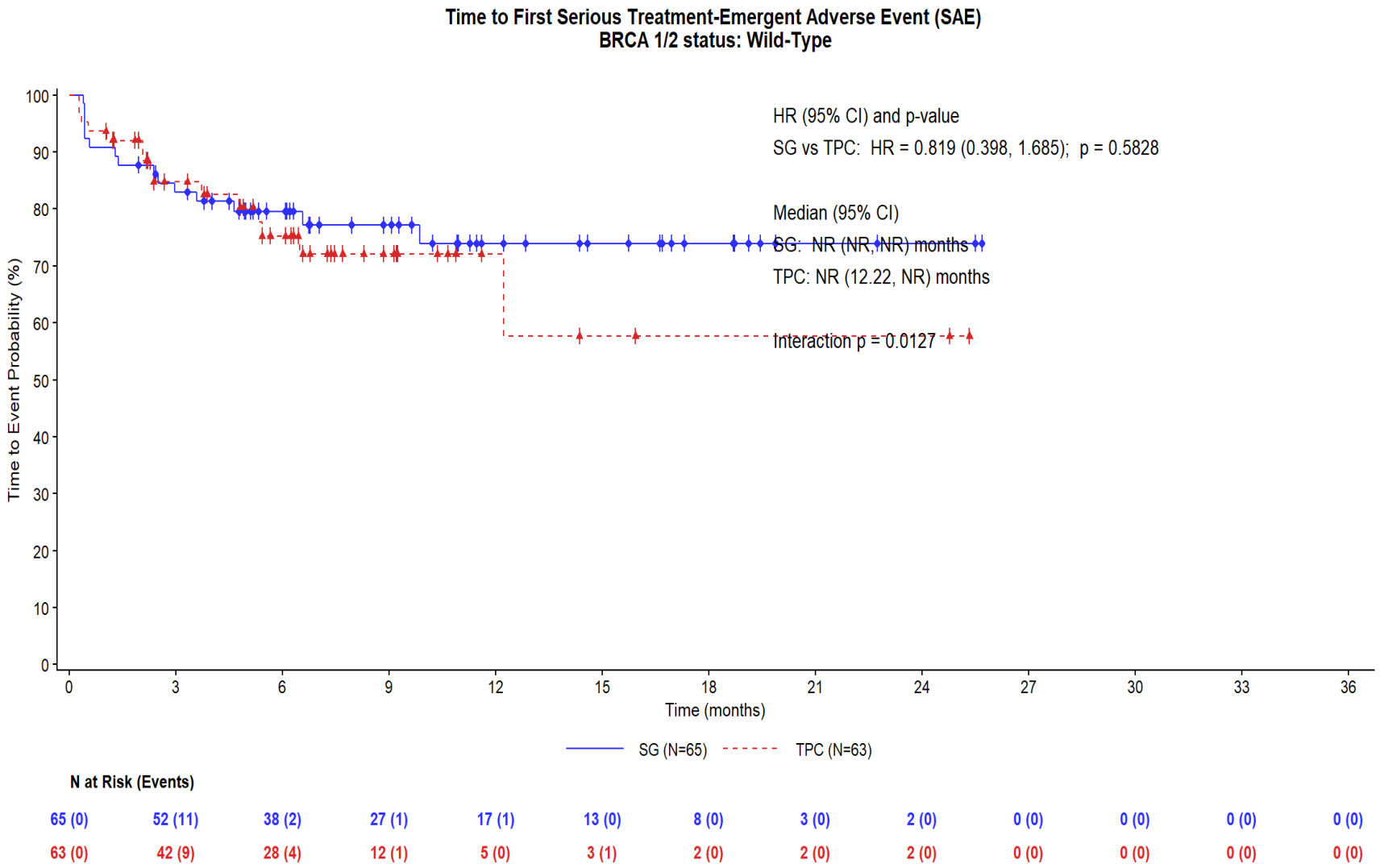
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.6. Figure 1.1.6: Kaplan Meier Plot of Time to First Serious TEAE (SAE) PD L1 Status CPS >= 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



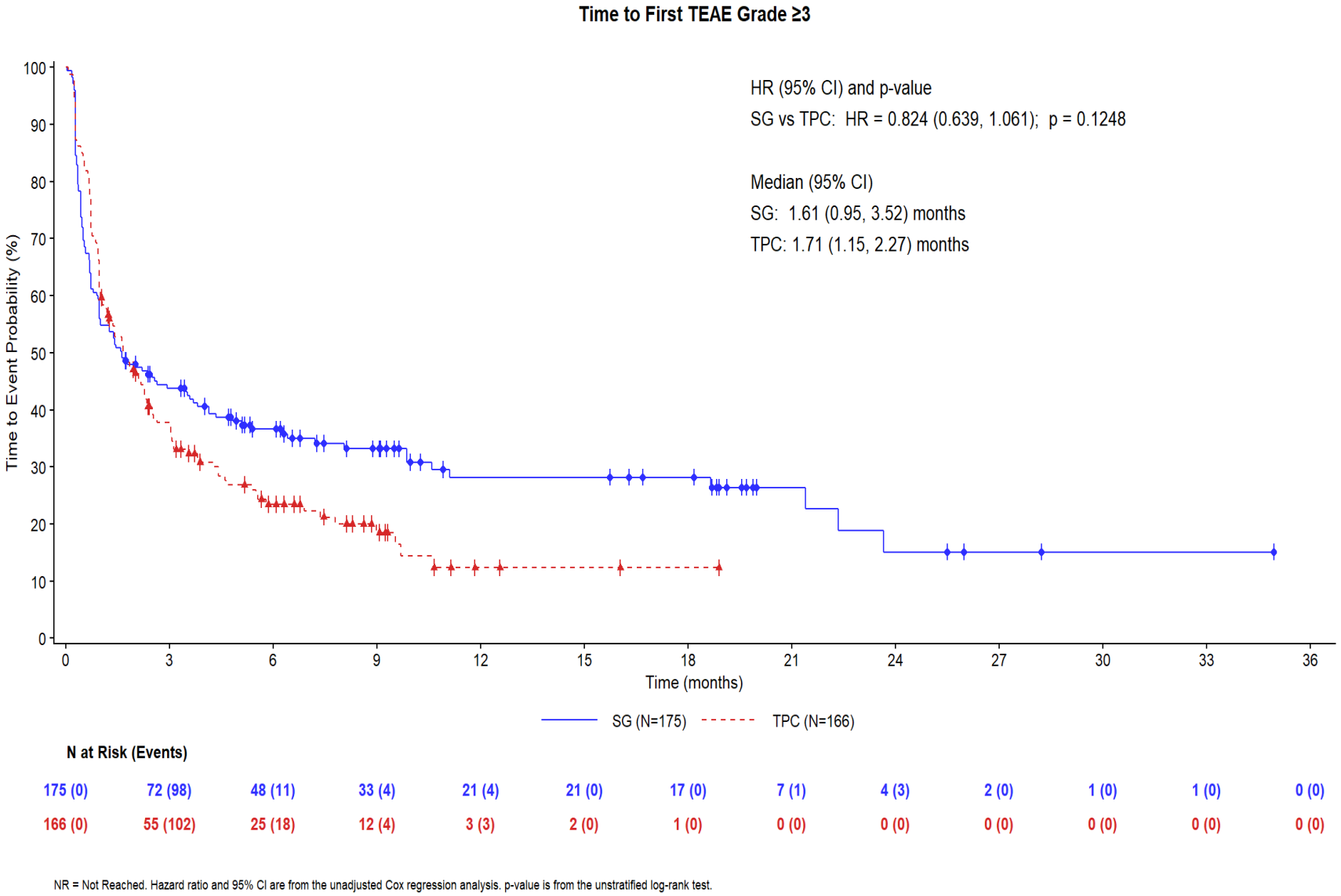
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.7. Figure 1.1.7: Kaplan Meier Plot of Time to First Serious TEAE (SAE) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel



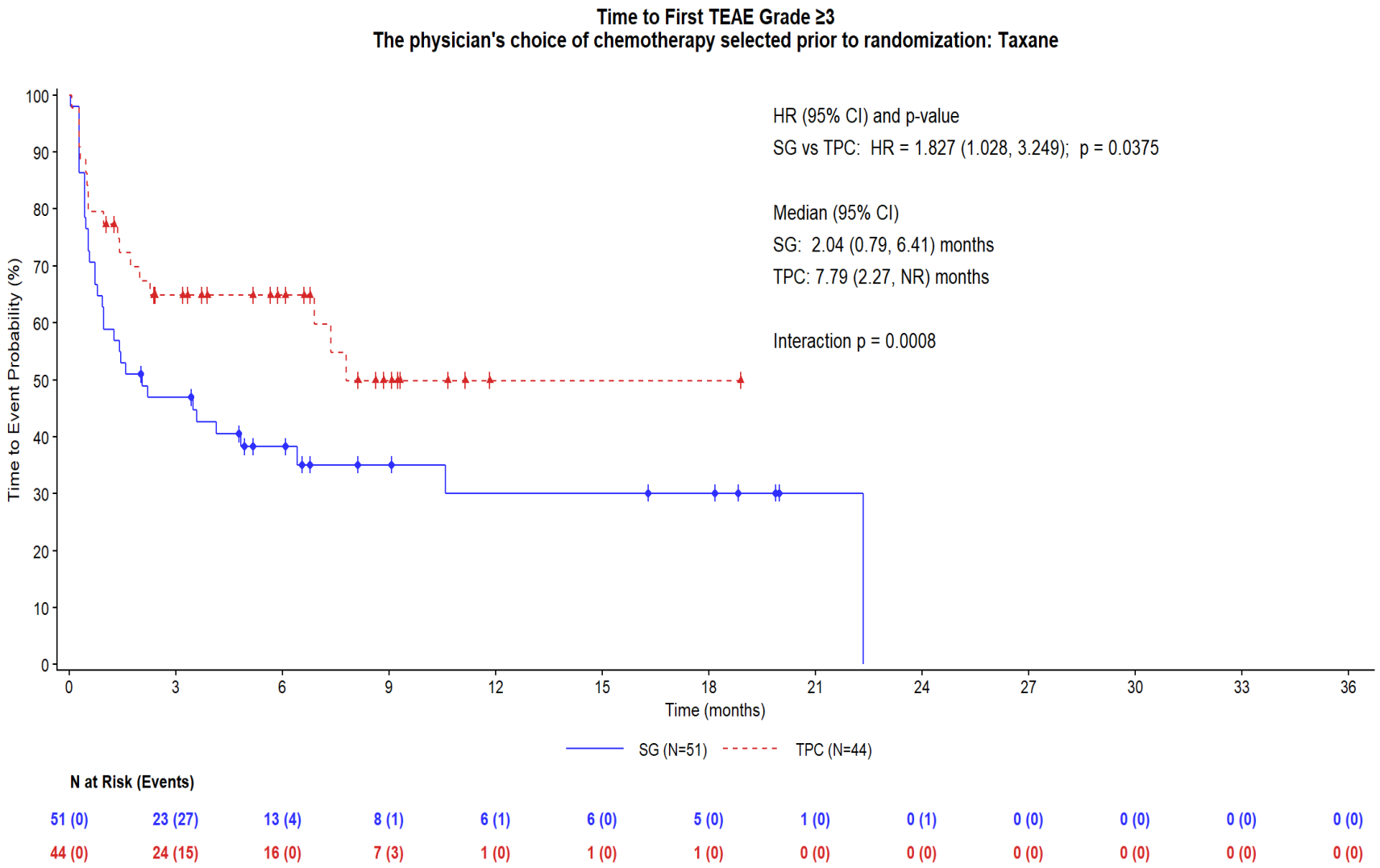
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.8. Figure 1.1.9: Kaplan Meier Plot of Time to First TEAE Grade 3 or higher — mSAF — Excluding patients preselected to receive nab-paclitaxel



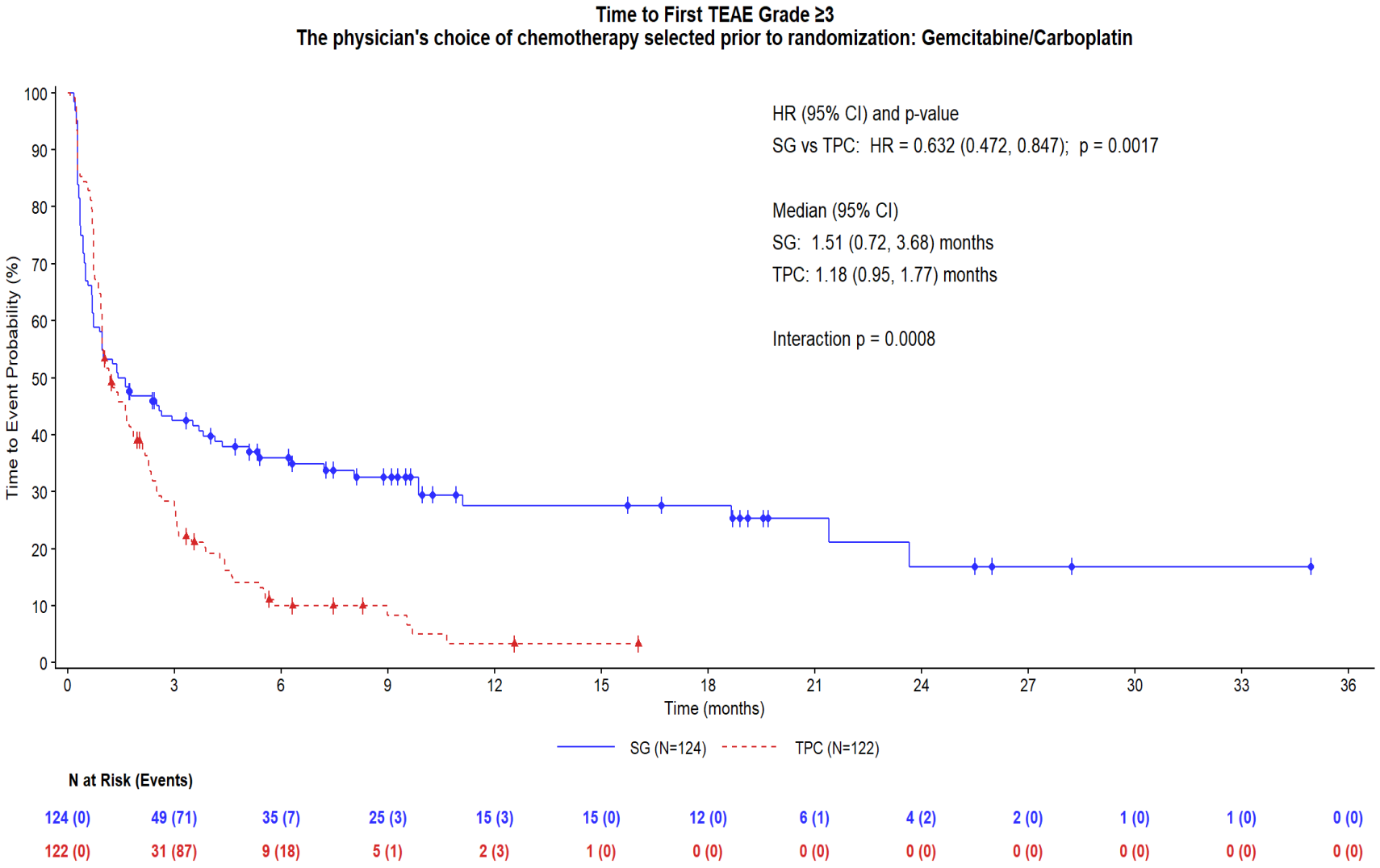
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.9. Figure 1.1.10: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



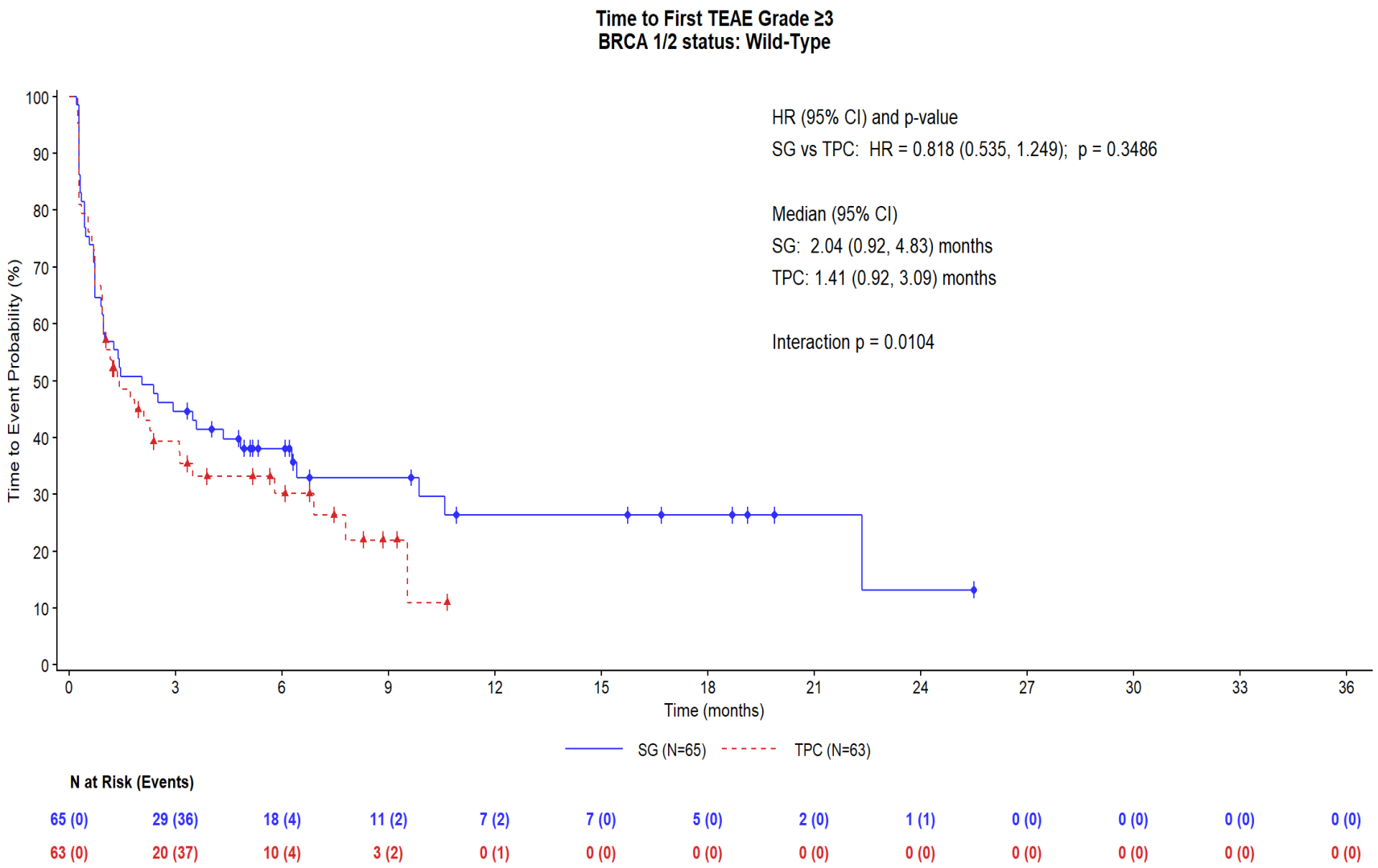
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.10. Figure 1.1.11: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



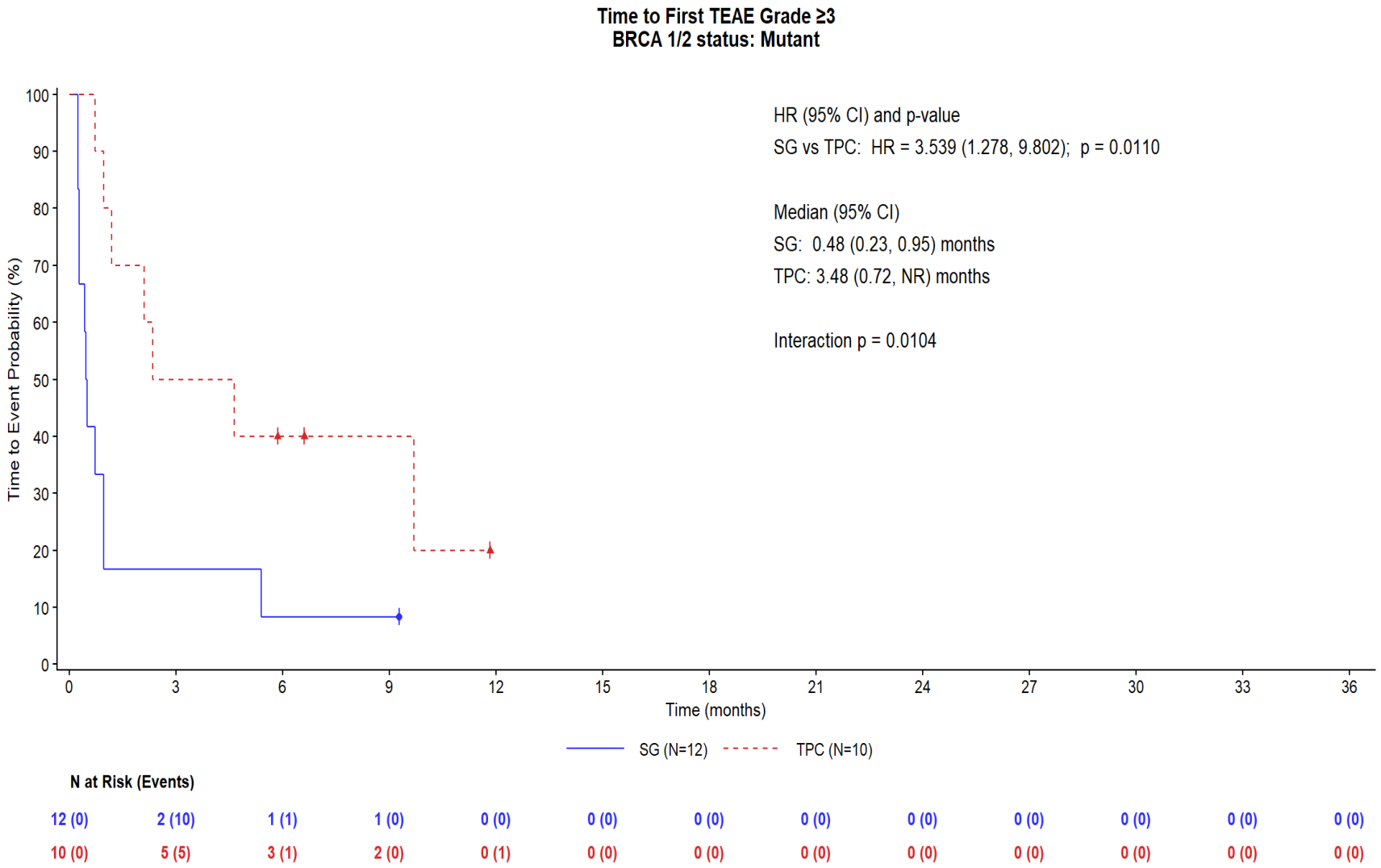
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.11. Figure 1.1.12: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel



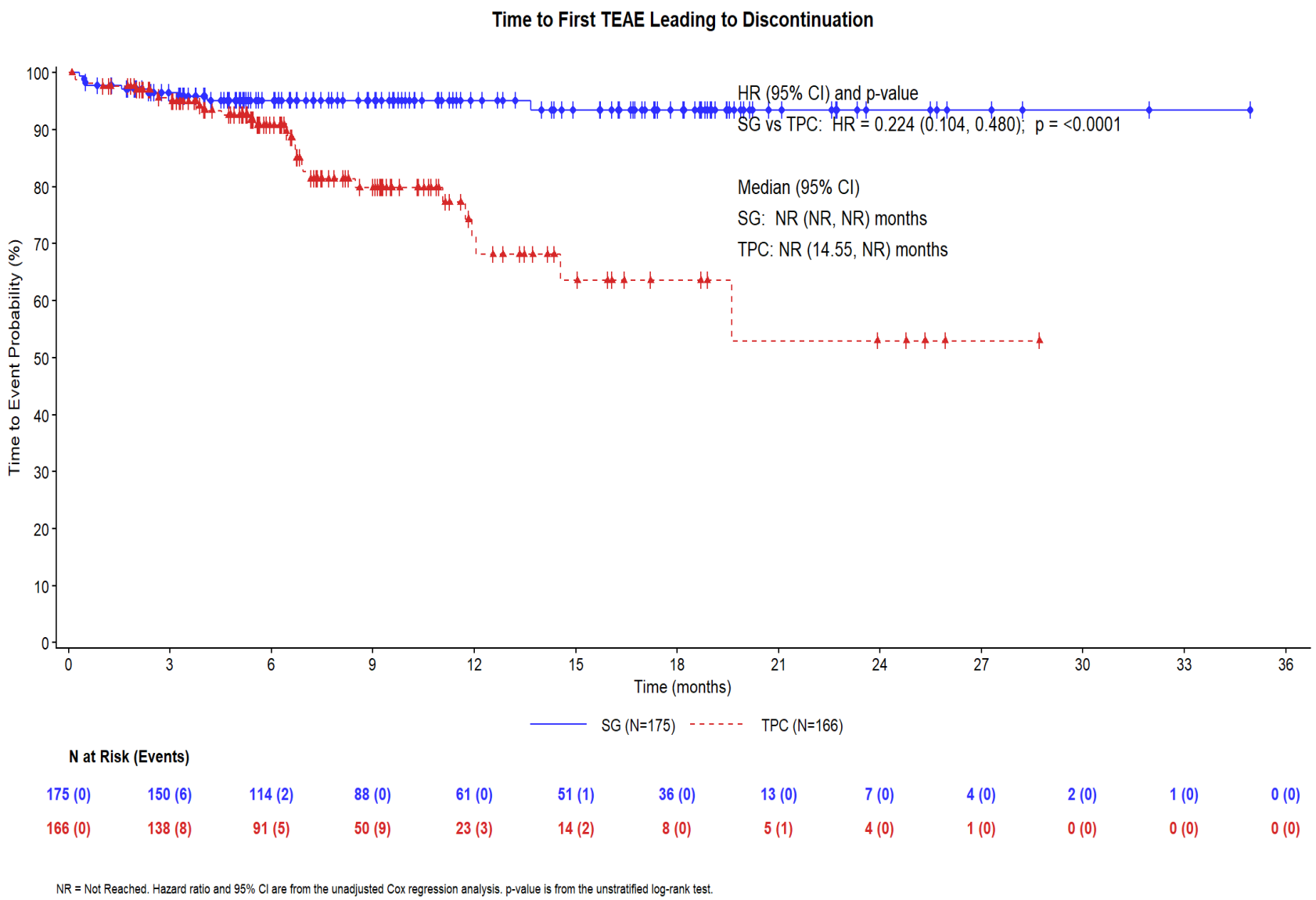
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.12. Figure 1.1.13: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel



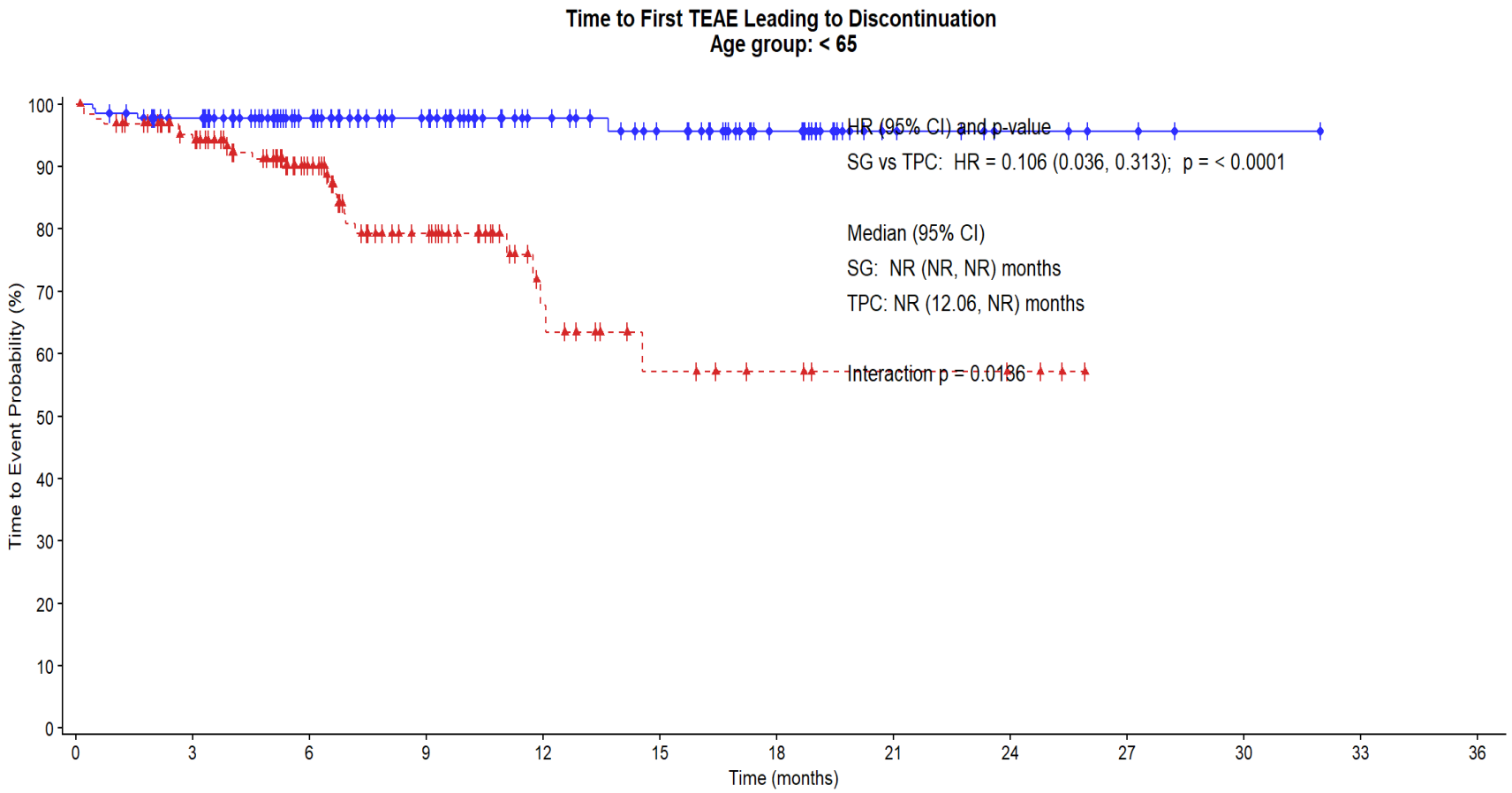
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.13. Figure 1.1.14: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation — mSAF — Excluding patients preselected to receive nab-paclitaxel



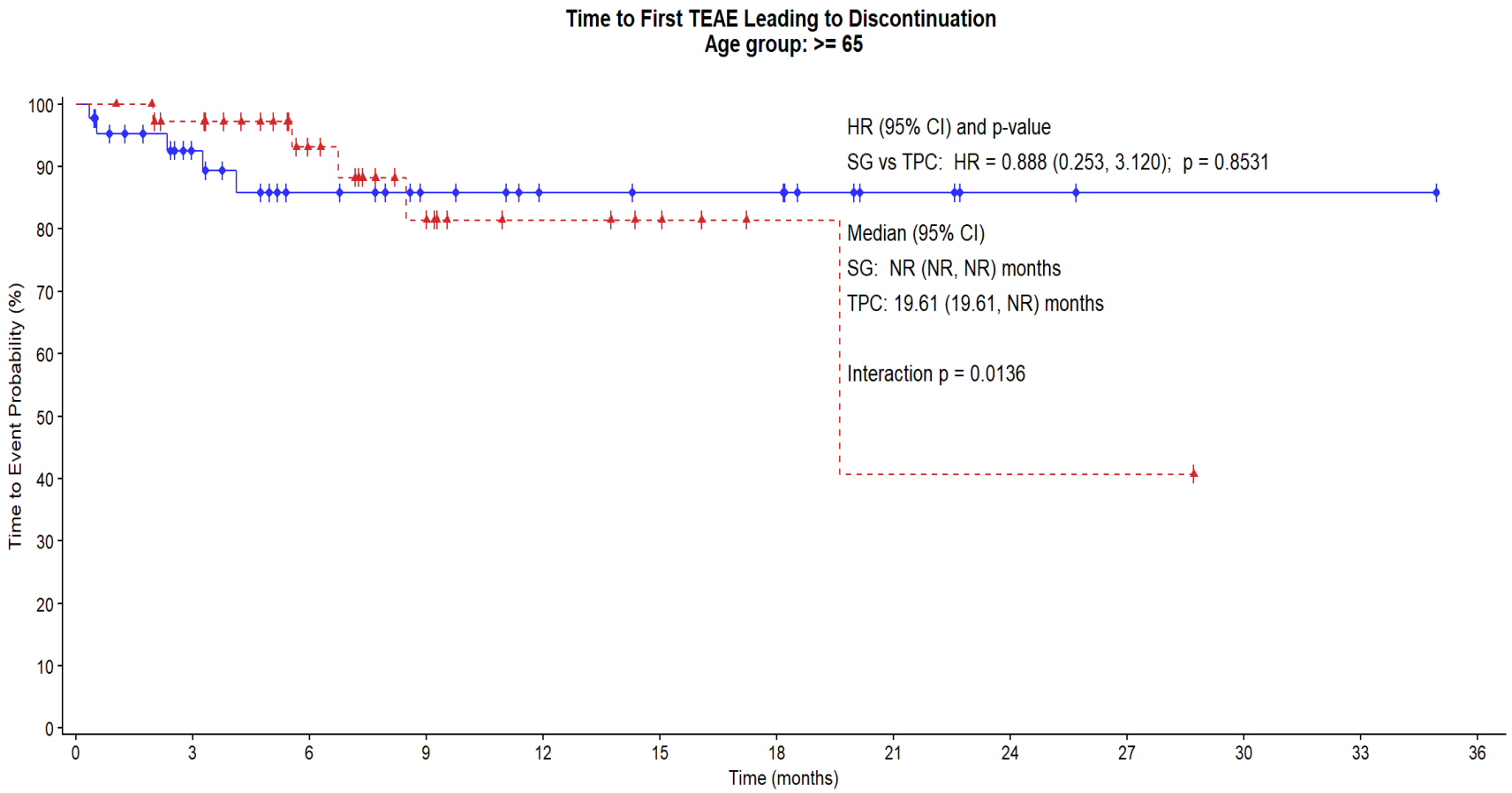
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.14. Figure 1.1.15: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



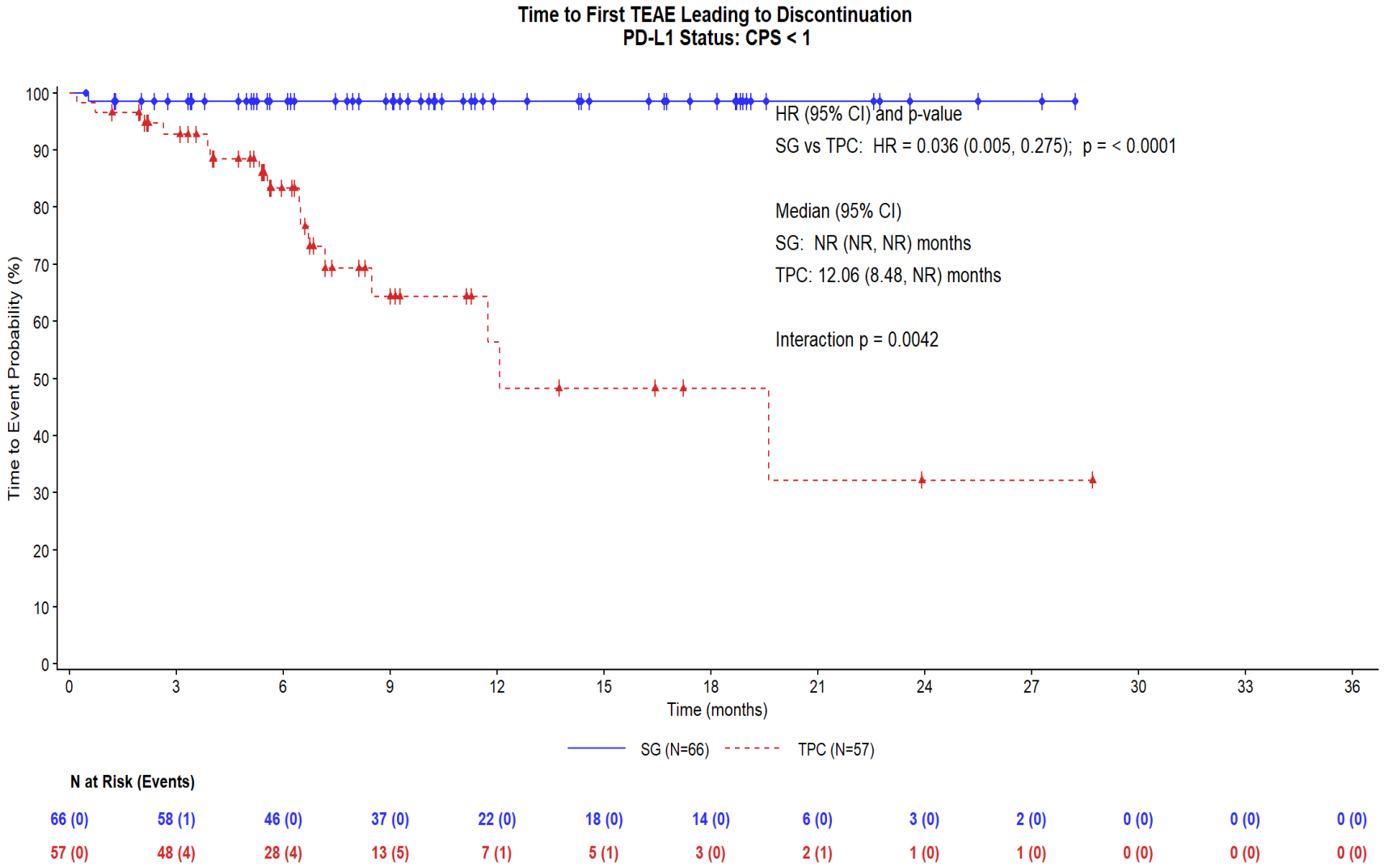
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.15. Figure 1.1.16: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



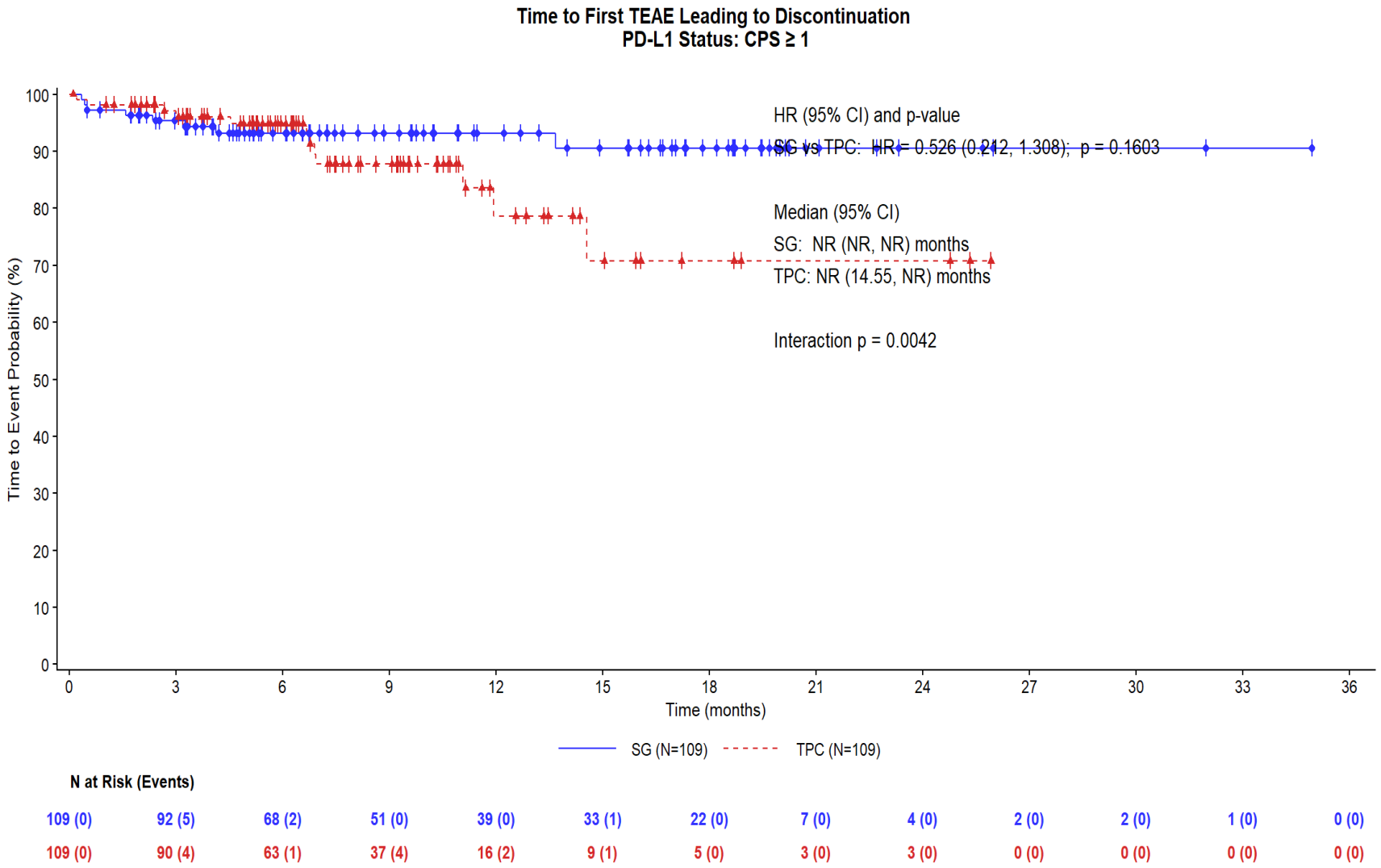
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.16. Figure 1.1.17: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



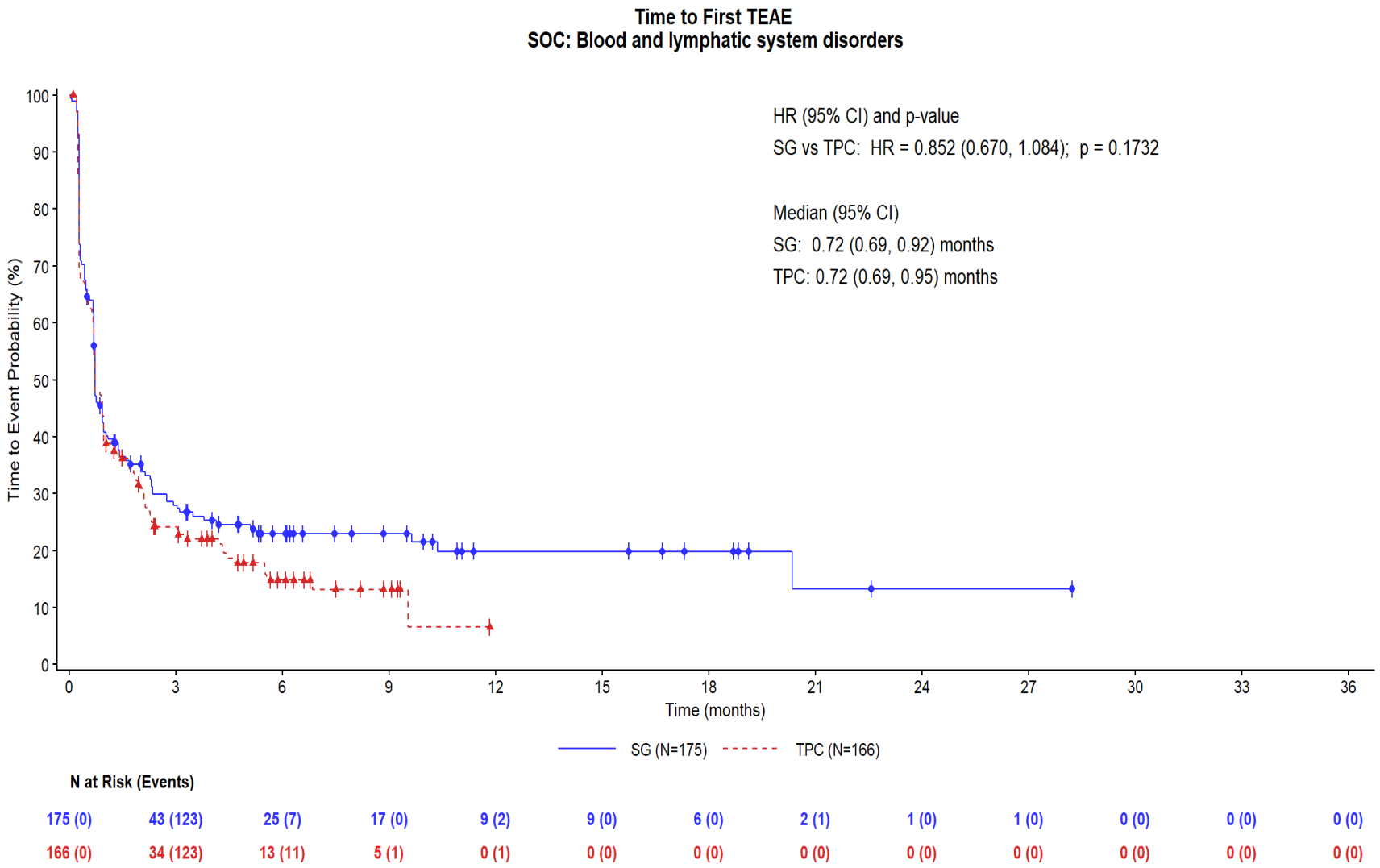
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.17. Figure 1.1.18: Kaplan Meier Plot of Time to First TEAE Leading to Discontinuation PD L1 Status CPS >= 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



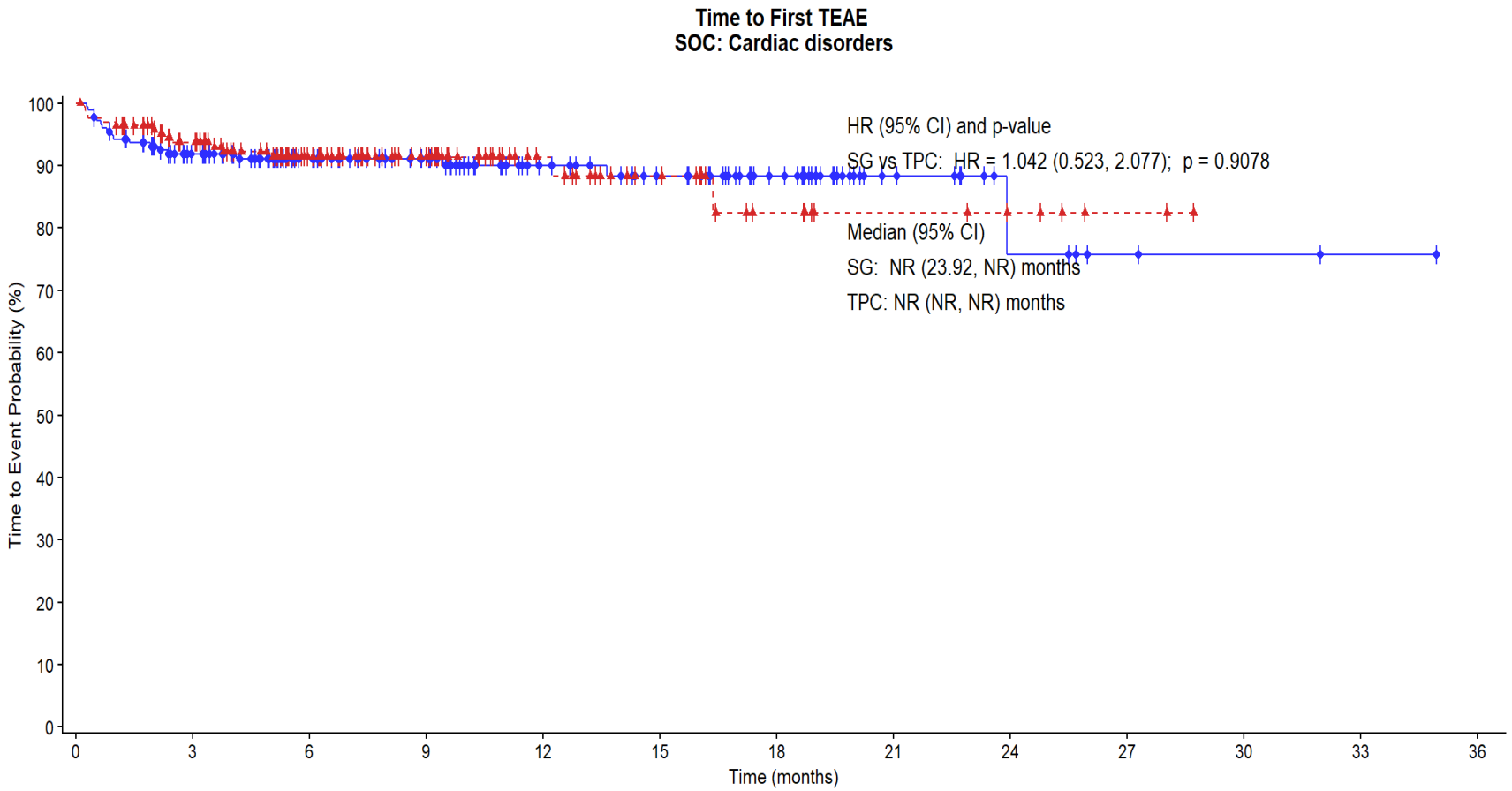
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.18. Figure 1.1.19: Kaplan Meier Plot of Time to First TEAE by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



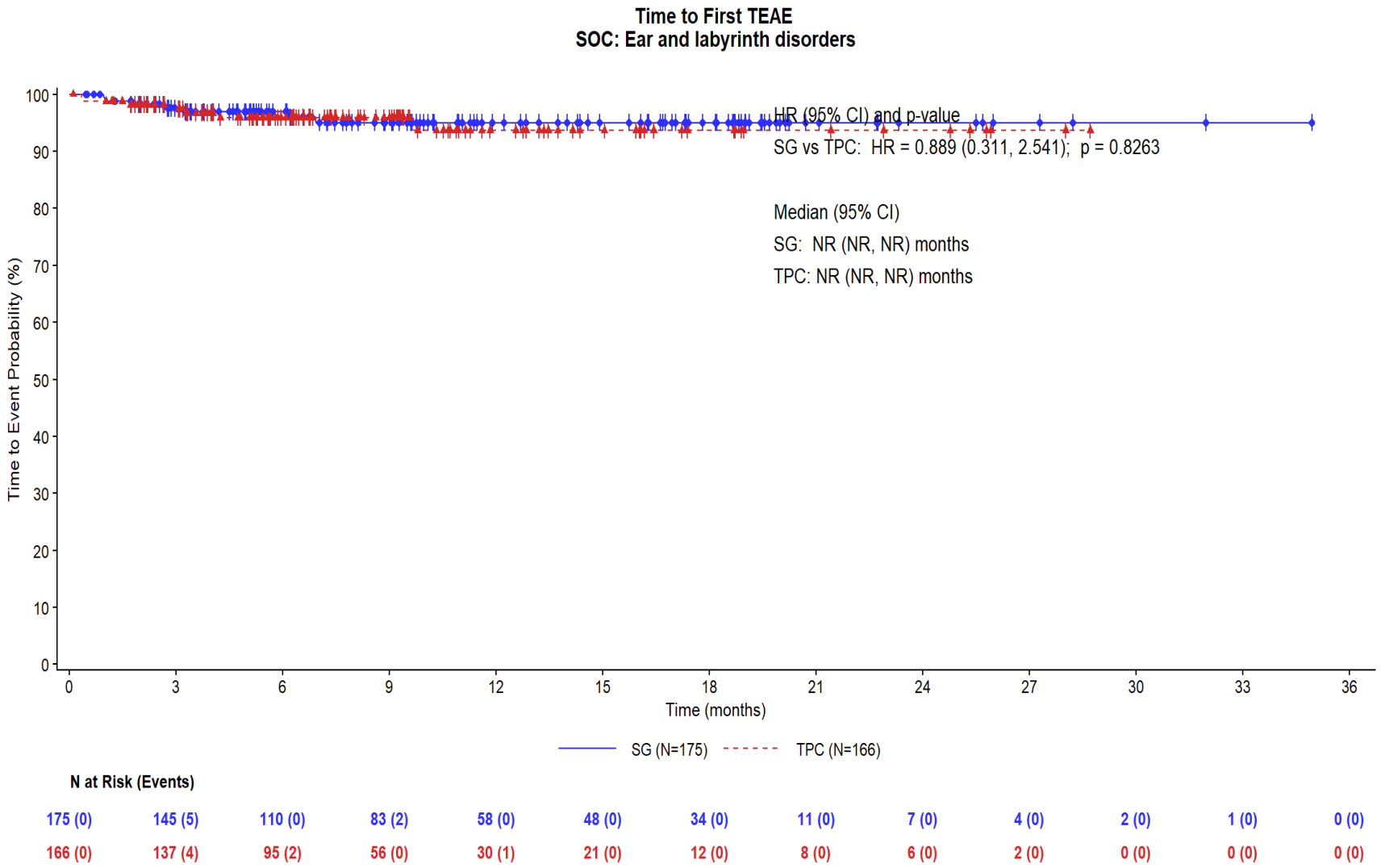
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.19. Figure 1.1.20: Kaplan Meier Plot of Time to First TEAE by SOC Cardiac disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



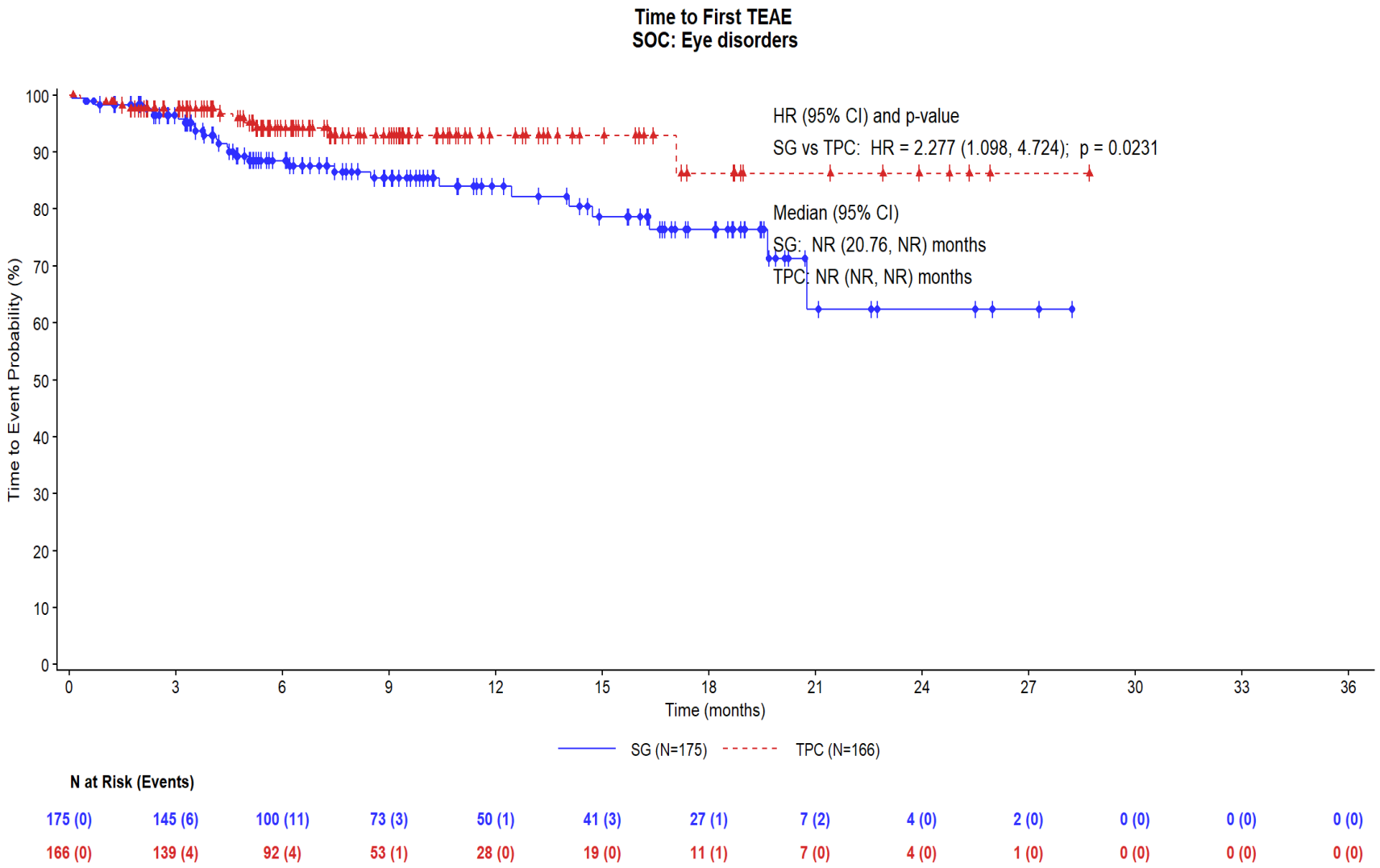
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.20. Figure 1.1.21: Kaplan Meier Plot of Time to First TEAE by SOC Ear and labyrinth disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



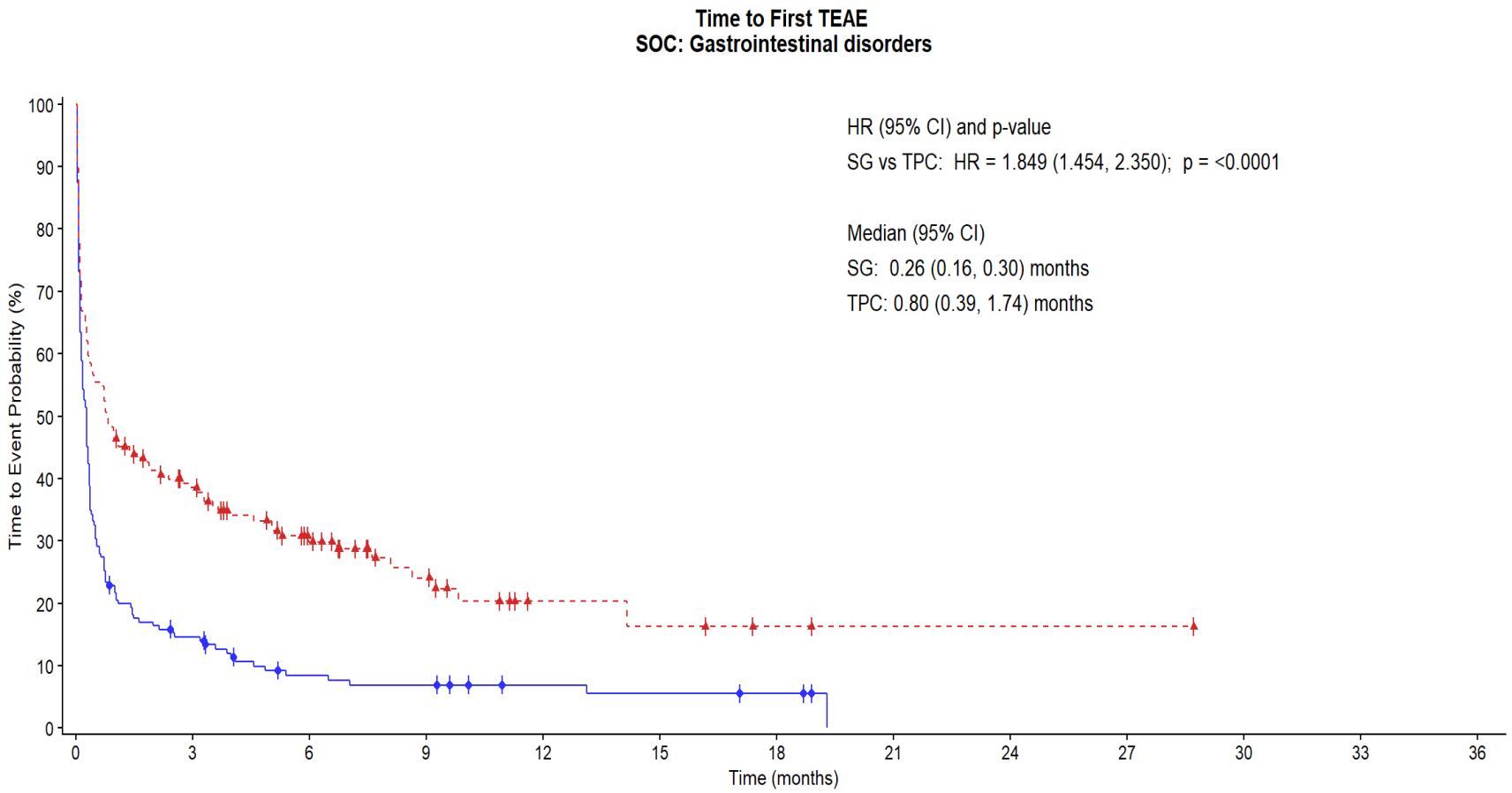
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.21. Figure 1.1.22: Kaplan Meier Plot of Time to First TEAE by SOC Eye disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



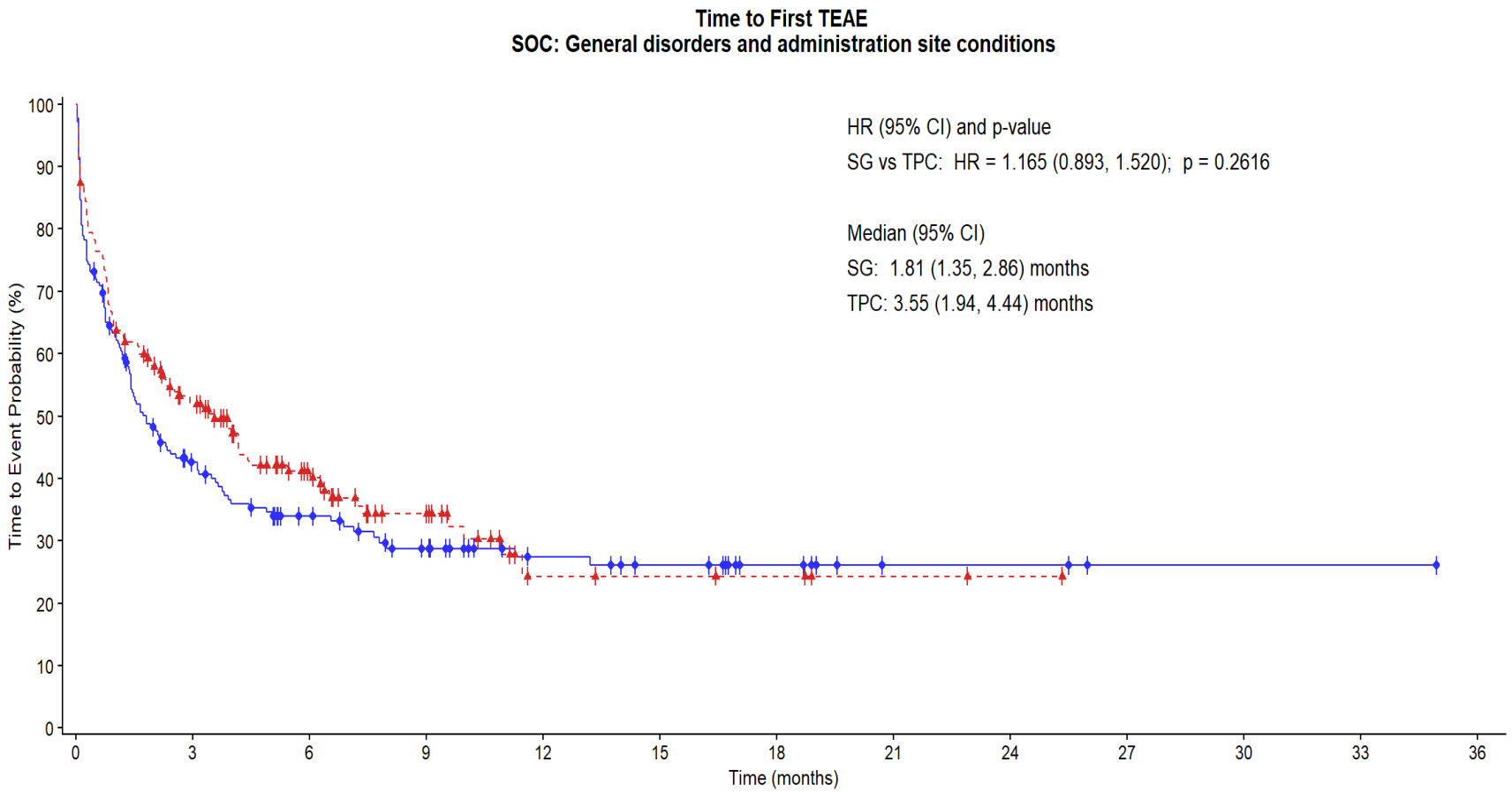
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.22. Figure 1.1.23: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



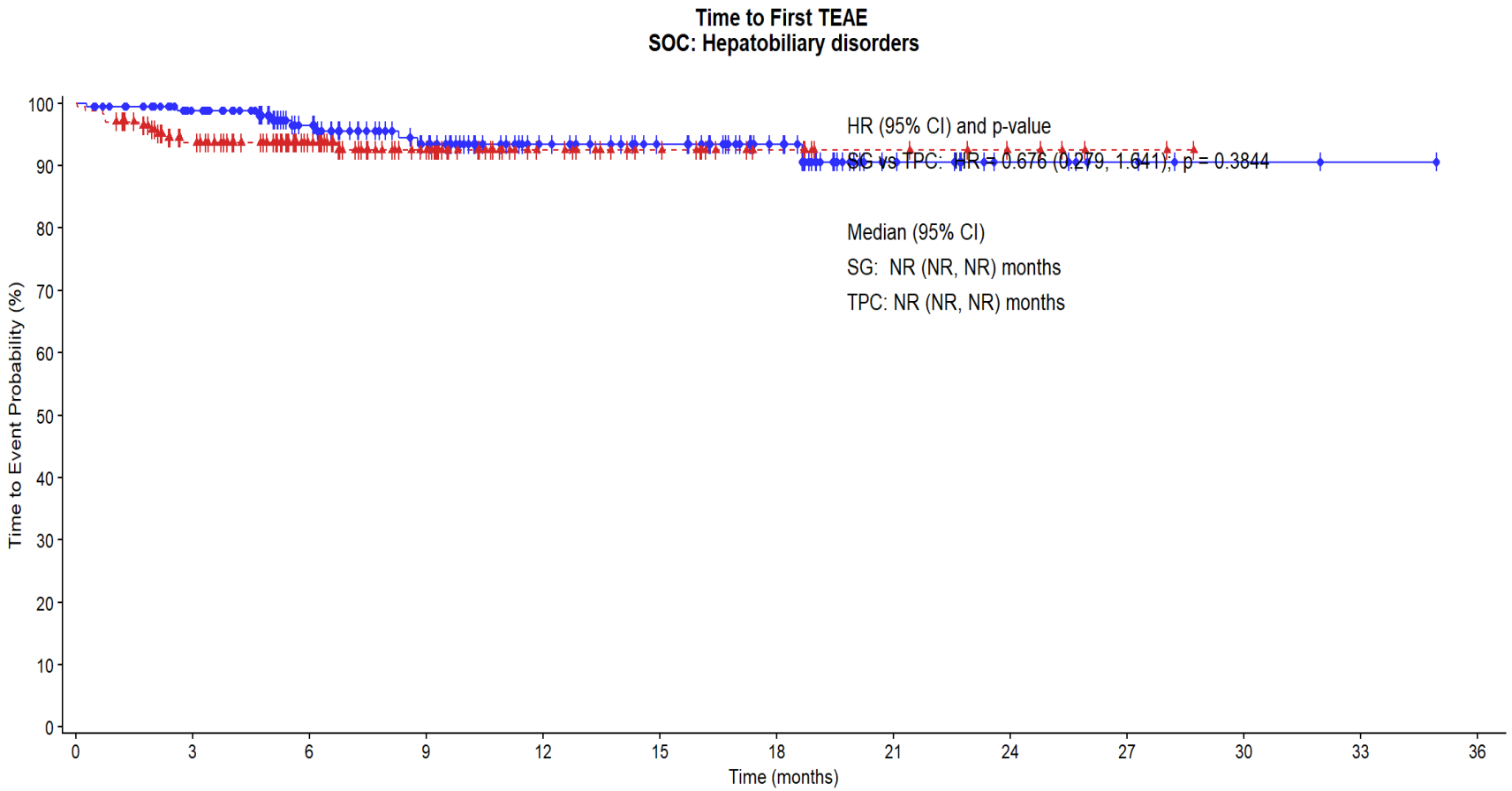
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.23. Figure 1.1.24: Kaplan Meier Plot of Time to First TEAE by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel



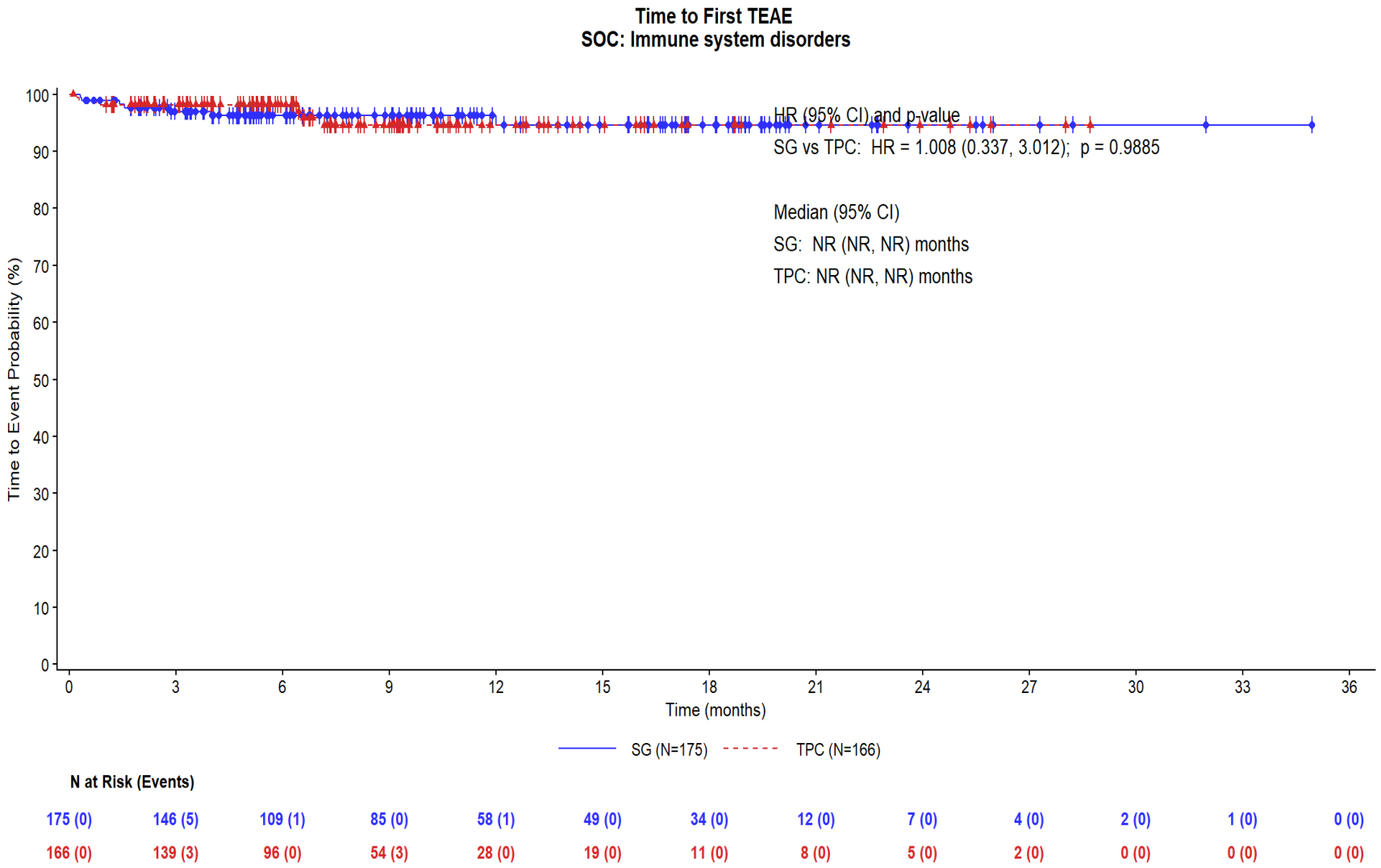
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.24. Figure 1.1.25: Kaplan Meier Plot of Time to First TEAE by SOC Hepatobiliary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



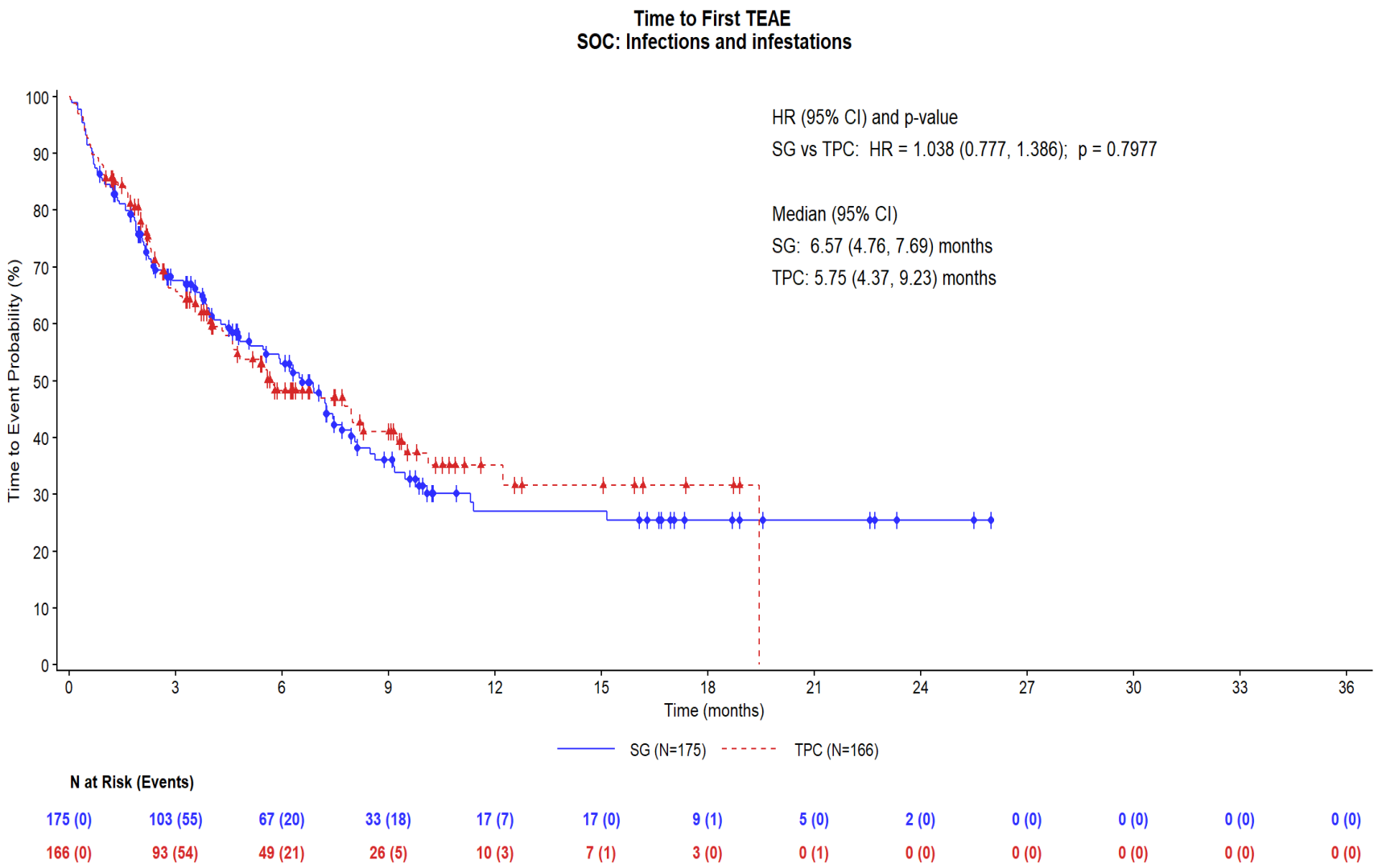
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.25. Figure 1.1.26: Kaplan Meier Plot of Time to First TEAE by SOC Immune system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



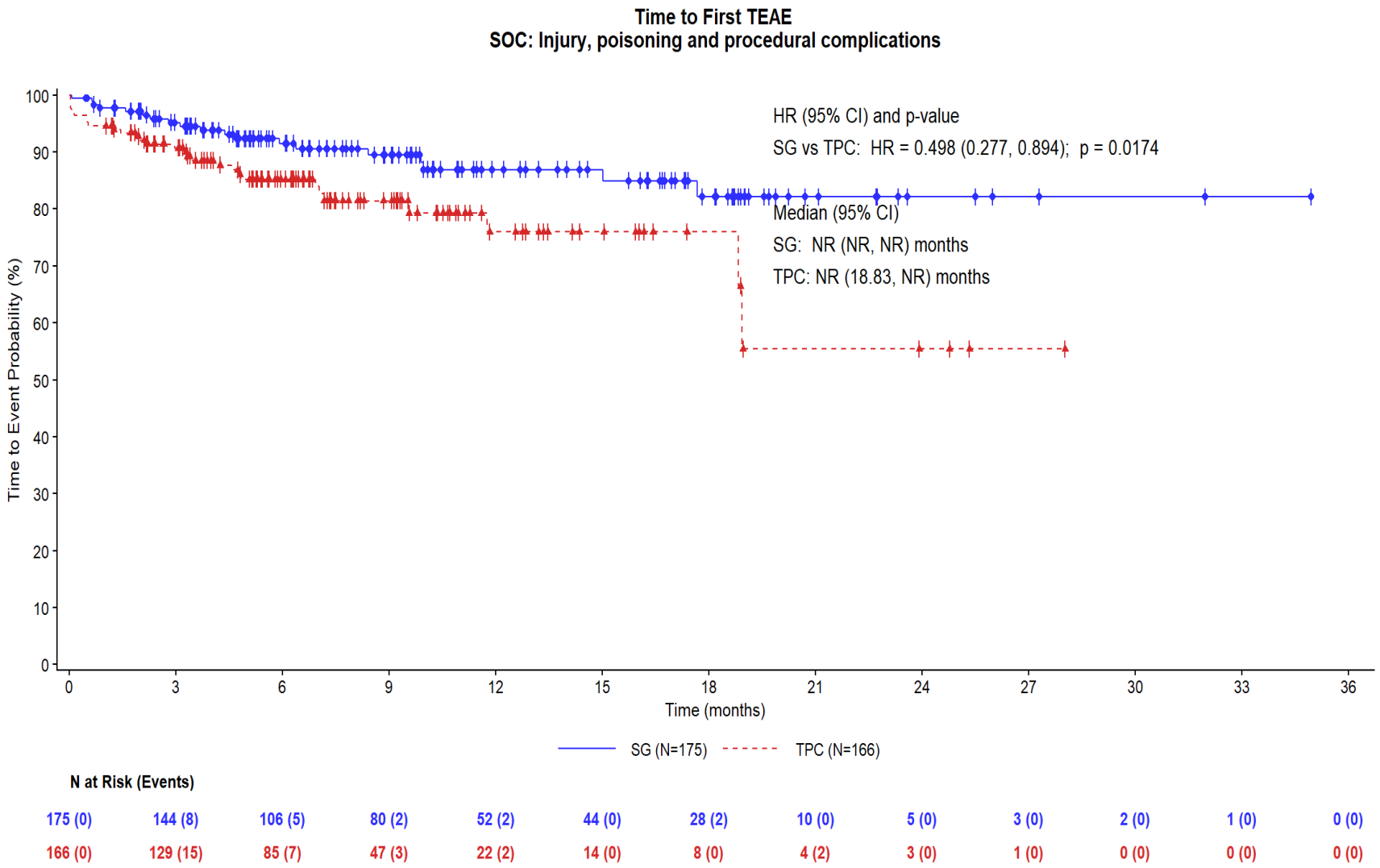
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.26. Figure 1.1.27: Kaplan Meier Plot of Time to First TEAE by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel



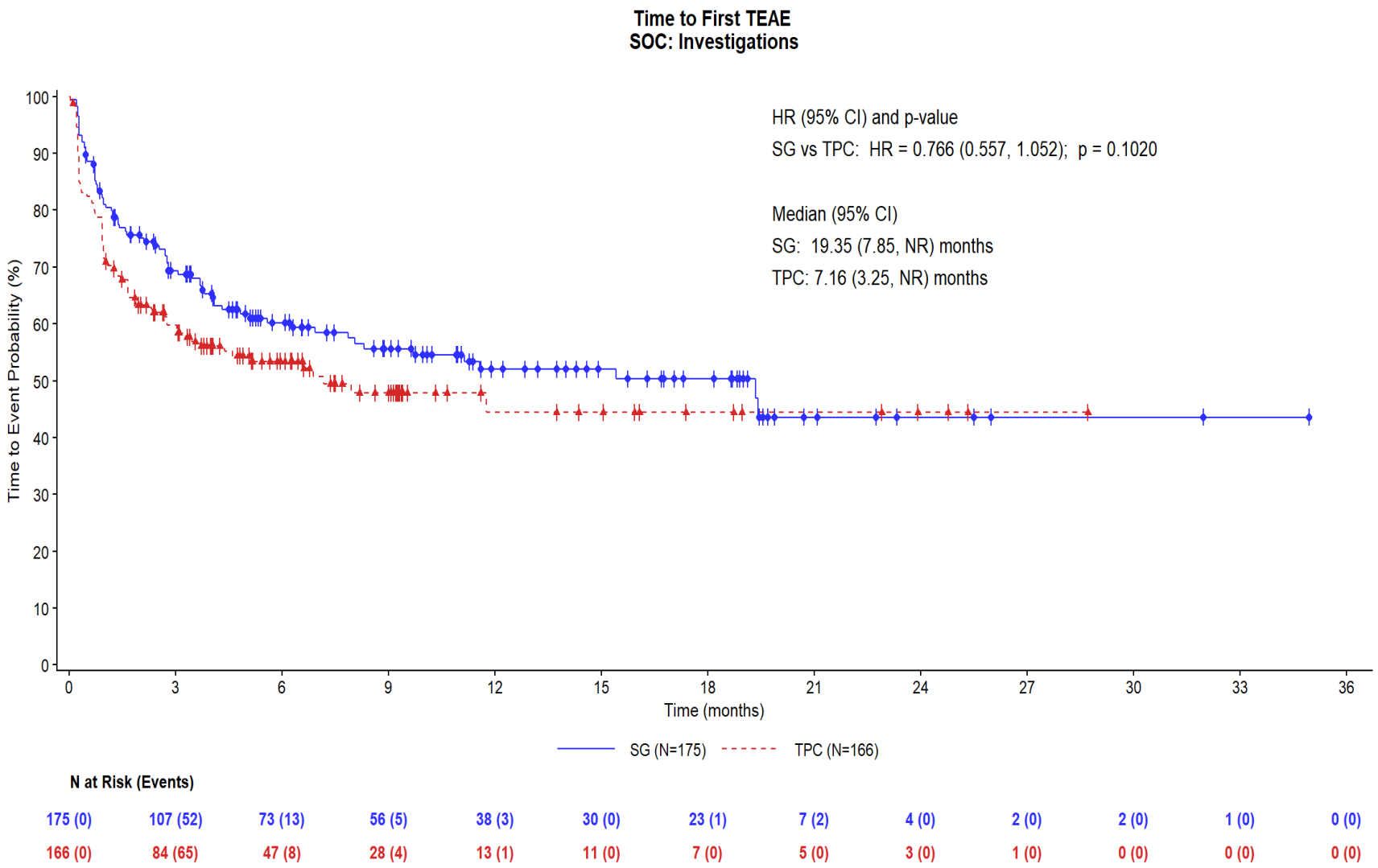
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.27. Figure 1.1.28: Kaplan Meier Plot of Time to First TEAE by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel



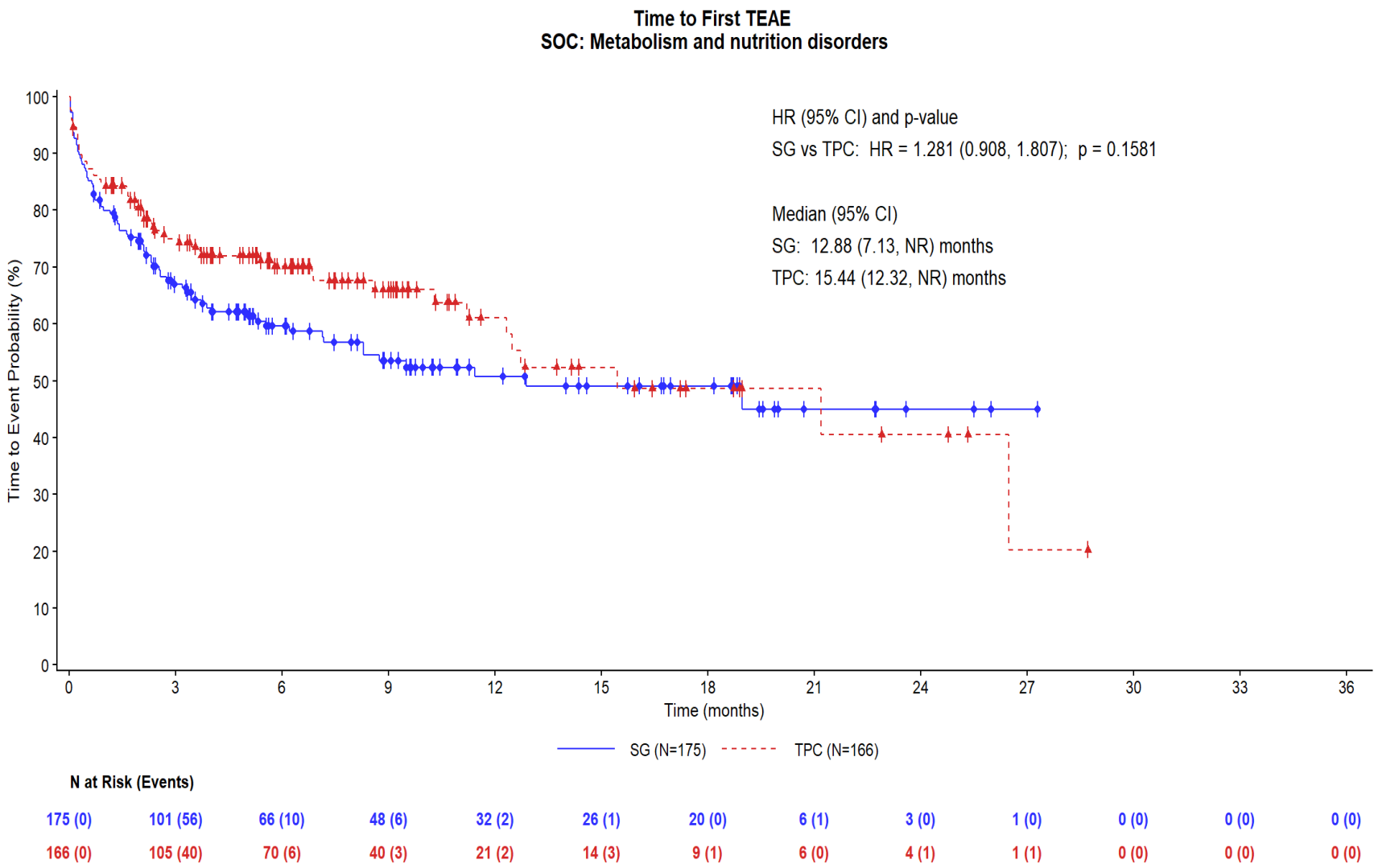
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.28. Figure 1.1.29: Kaplan Meier Plot of Time to First TEAE by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel



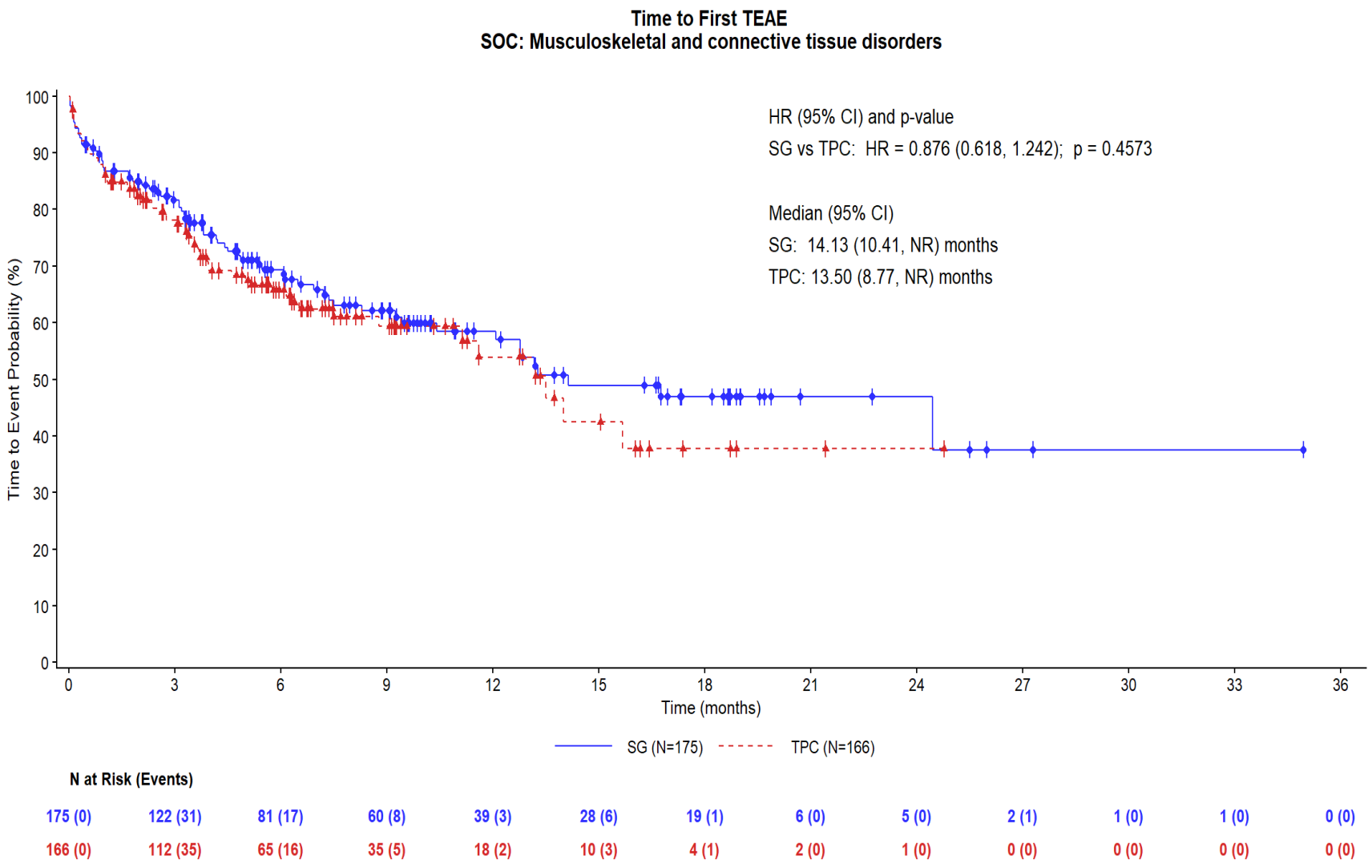
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.29. Figure 1.1.30: Kaplan Meier Plot of Time to First TEAE by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



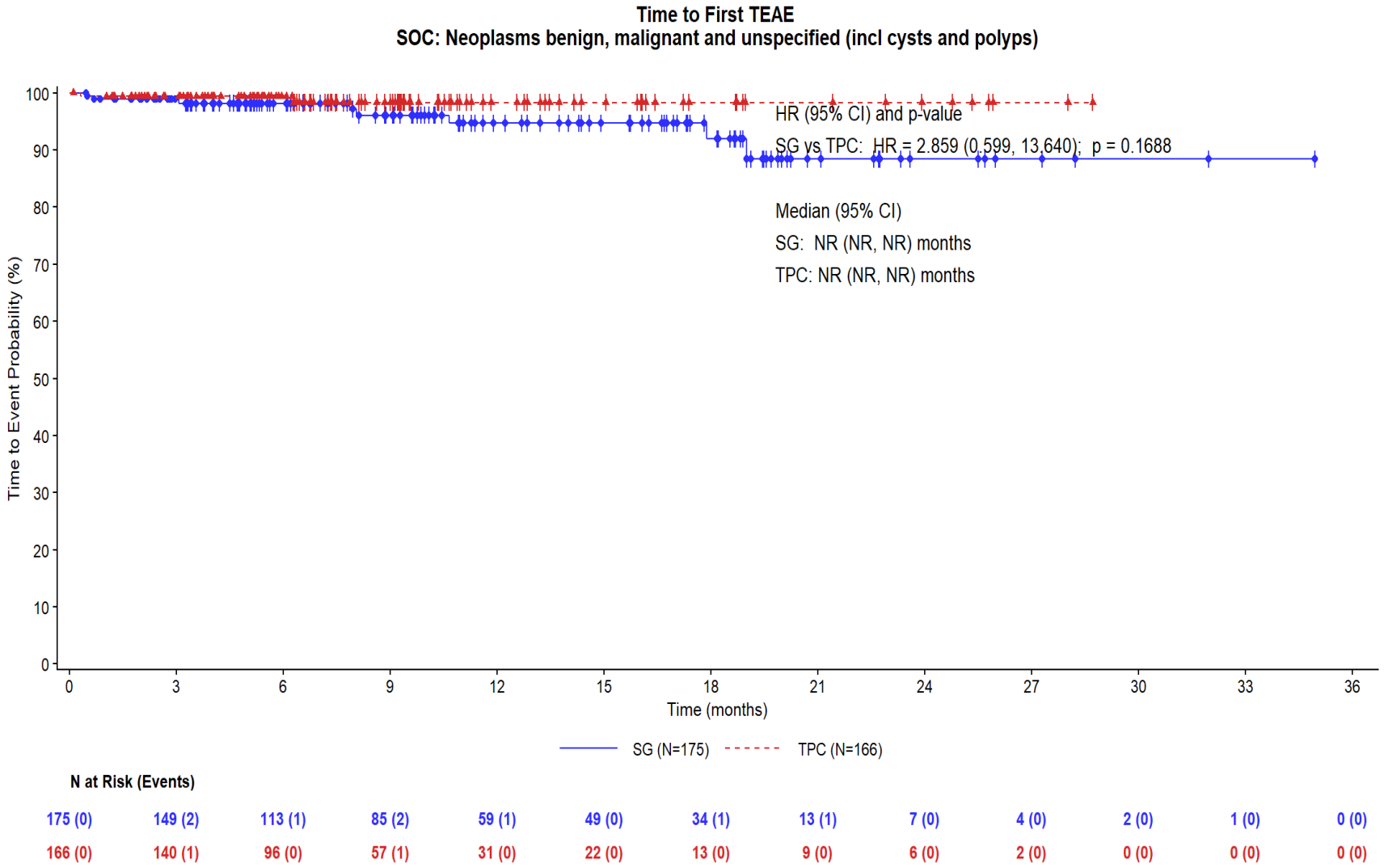
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.30. Figure 1.1.31: Kaplan Meier Plot of Time to First TEAE by SOC Musculoskeletal and connective tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



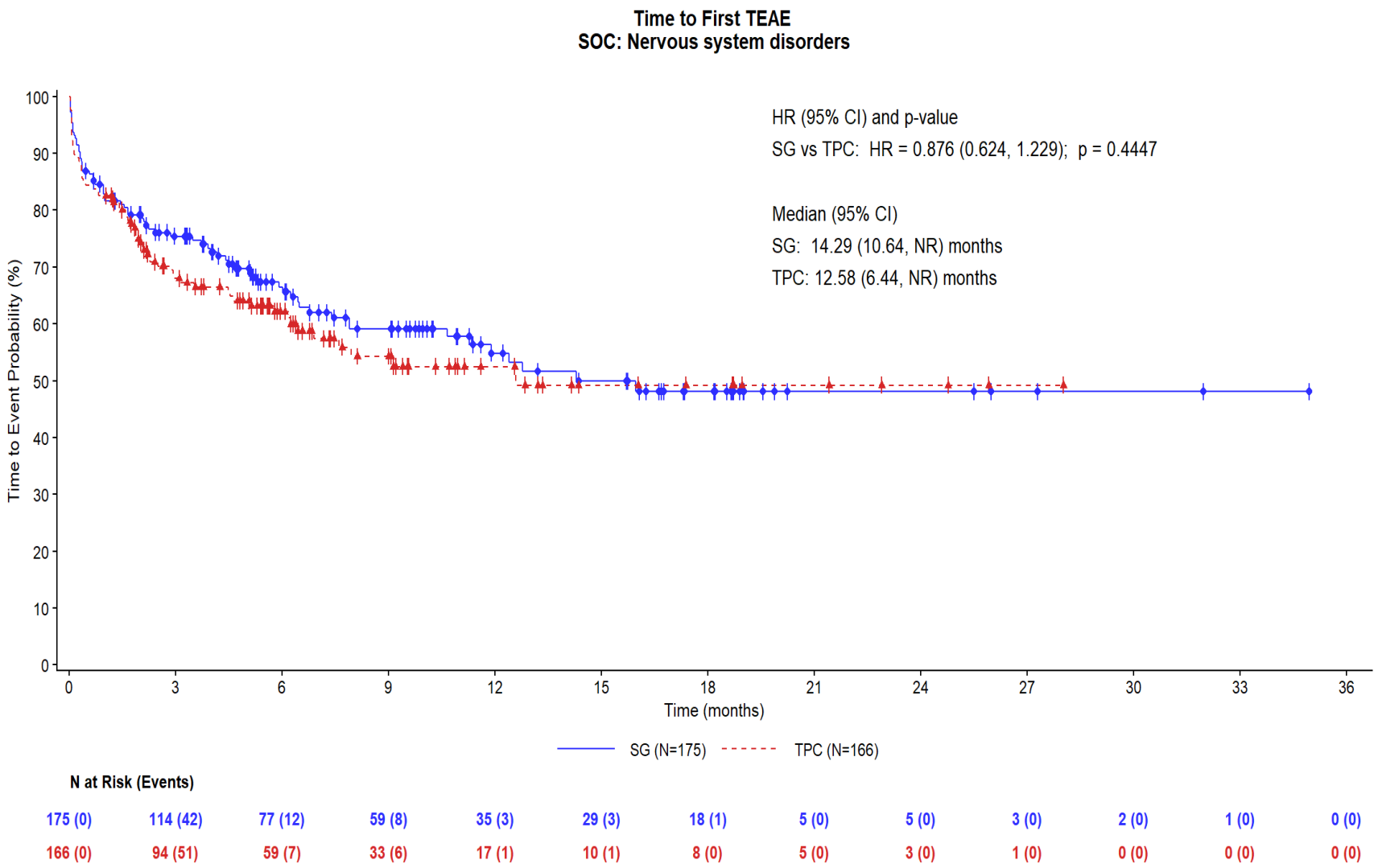
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.31. Figure 1.1.32: Kaplan Meier Plot of Time to First TEAE by SOC Neoplasms benign malignant and unspecified incl cysts and polyps — mSAF — Excluding patients preselected to receive nab-paclitaxel



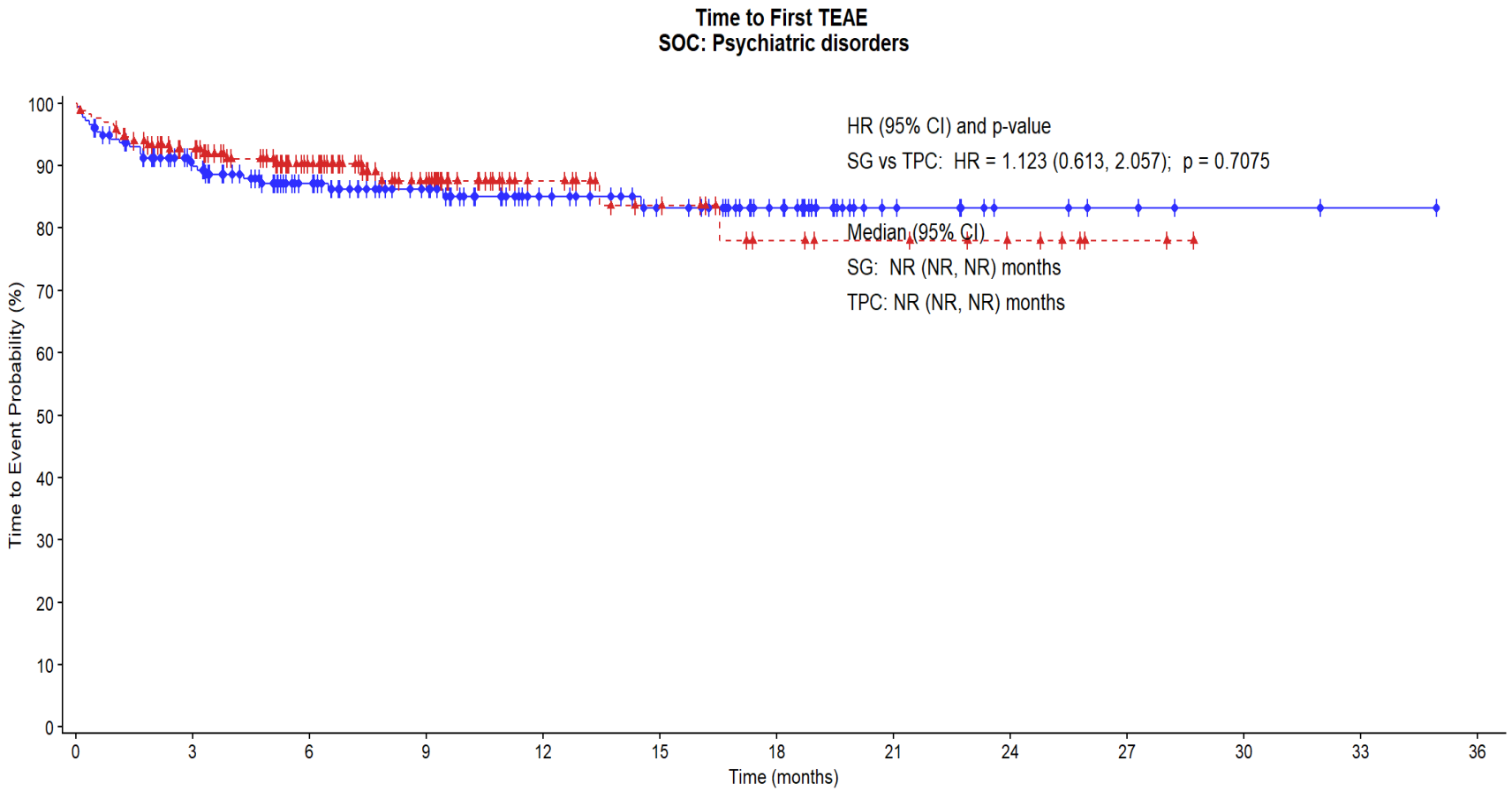
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8.32. Figure 1.1.33: Kaplan Meier Plot of Time to First TEAE by SOC Nervous system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



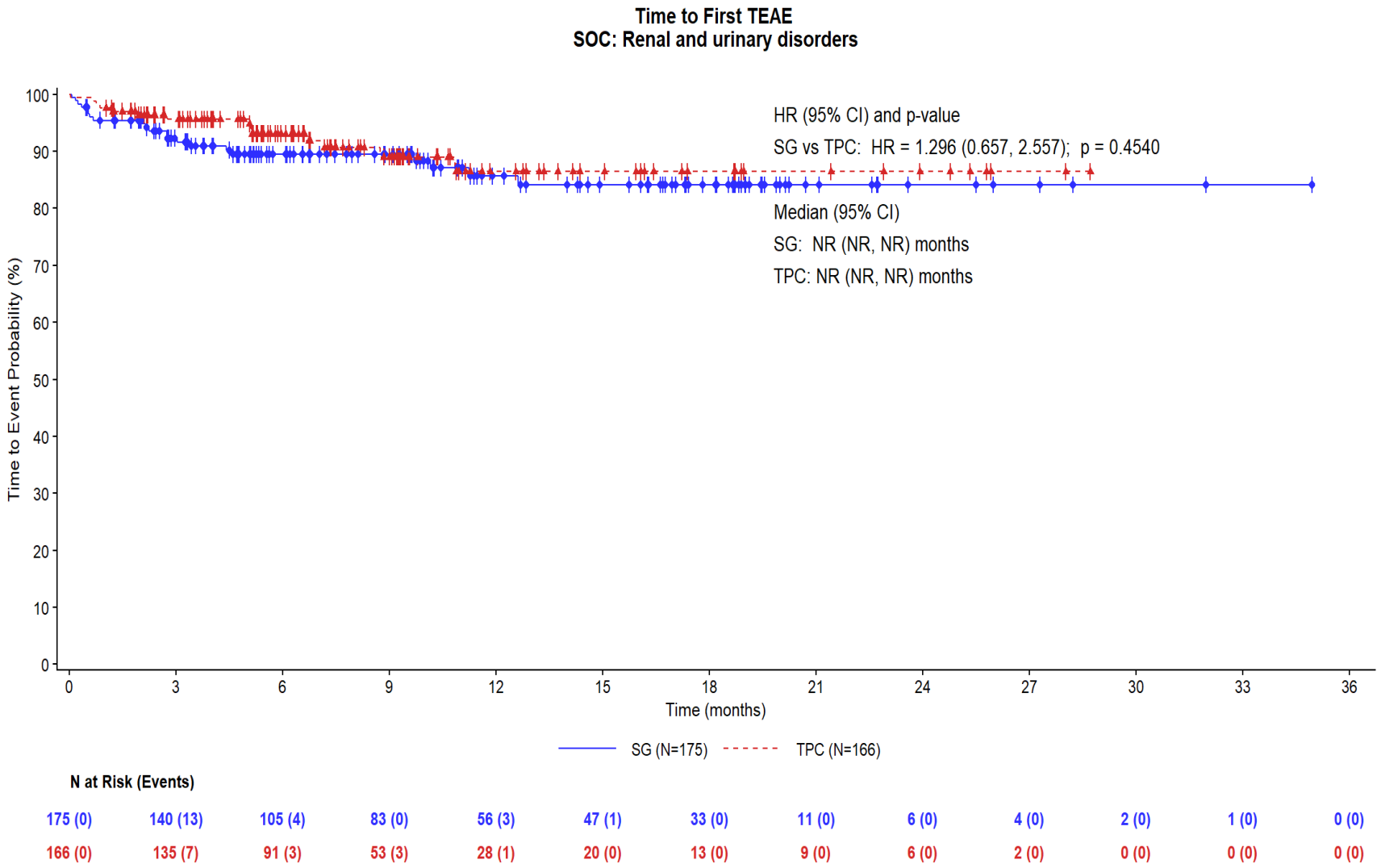
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.33. Figure 1.1.34: Kaplan Meier Plot of Time to First TEAE by SOC Psychiatric disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



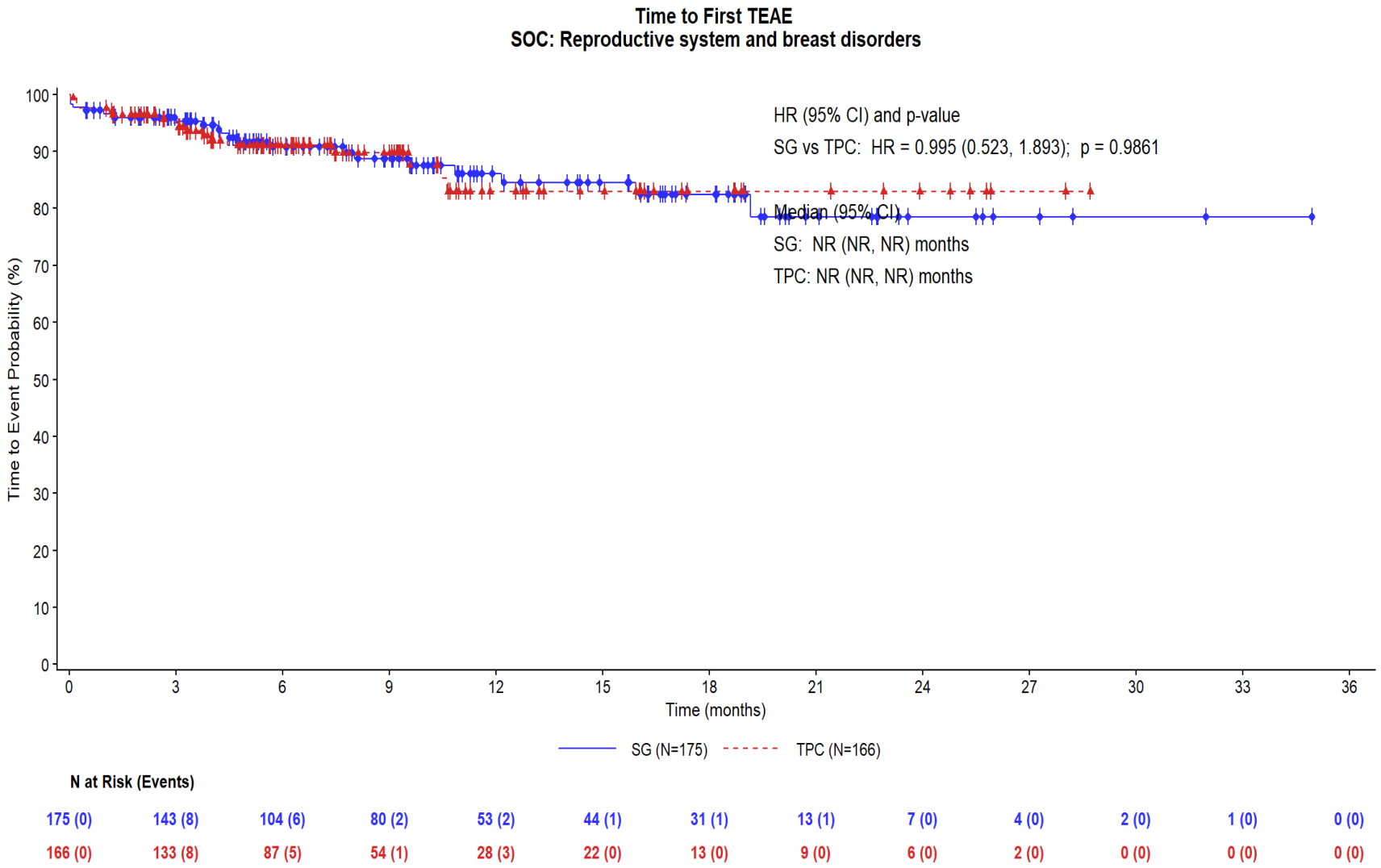
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.34. Figure 1.1.35: Kaplan Meier Plot of Time to First TEAE by SOC Renal and urinary disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



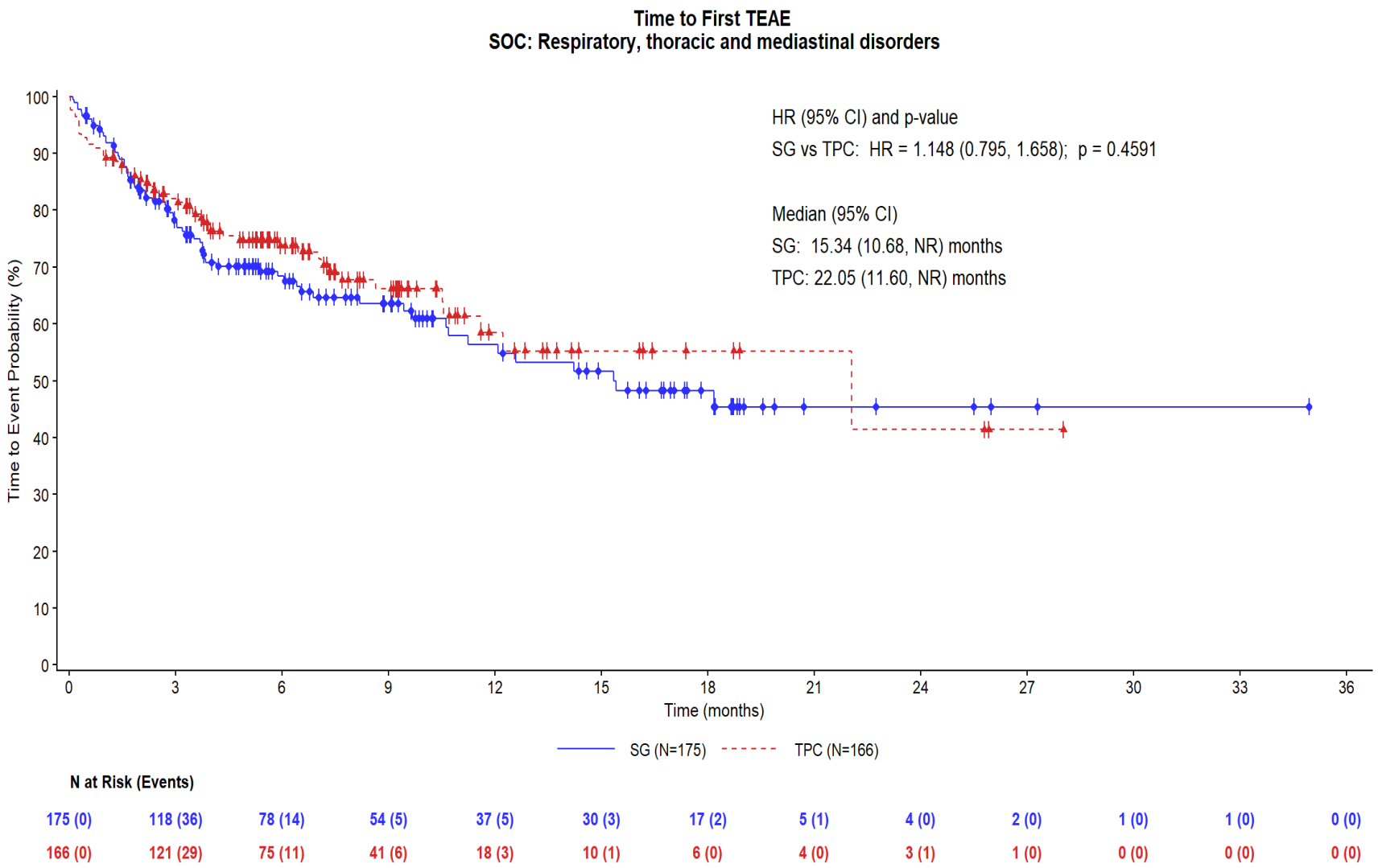
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.35. Figure 1.1.36: Kaplan Meier Plot of Time to First TEAE by SOC Reproductive system and breast disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



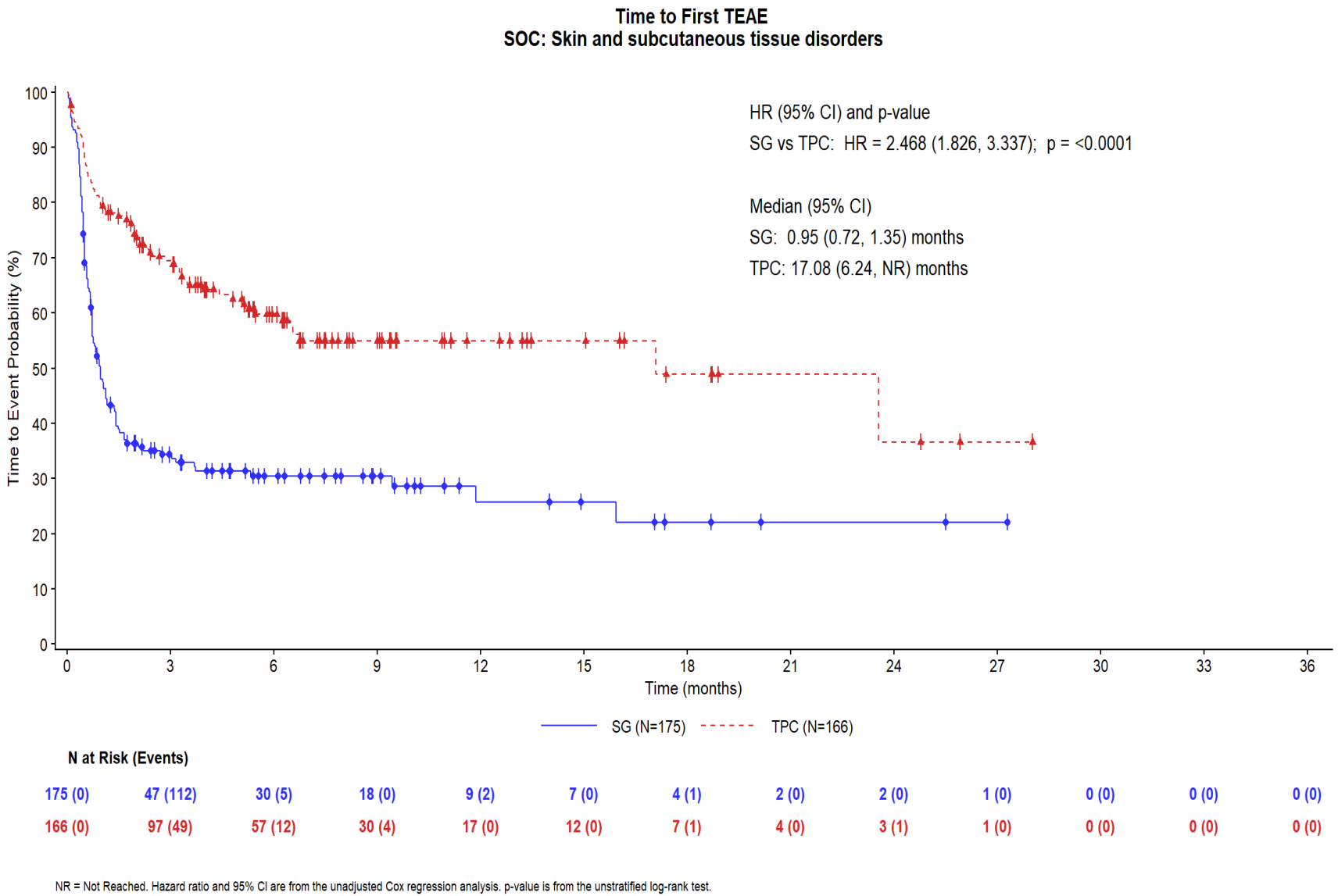
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.36. Figure 1.1.37: Kaplan Meier Plot of Time to First TEAE by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



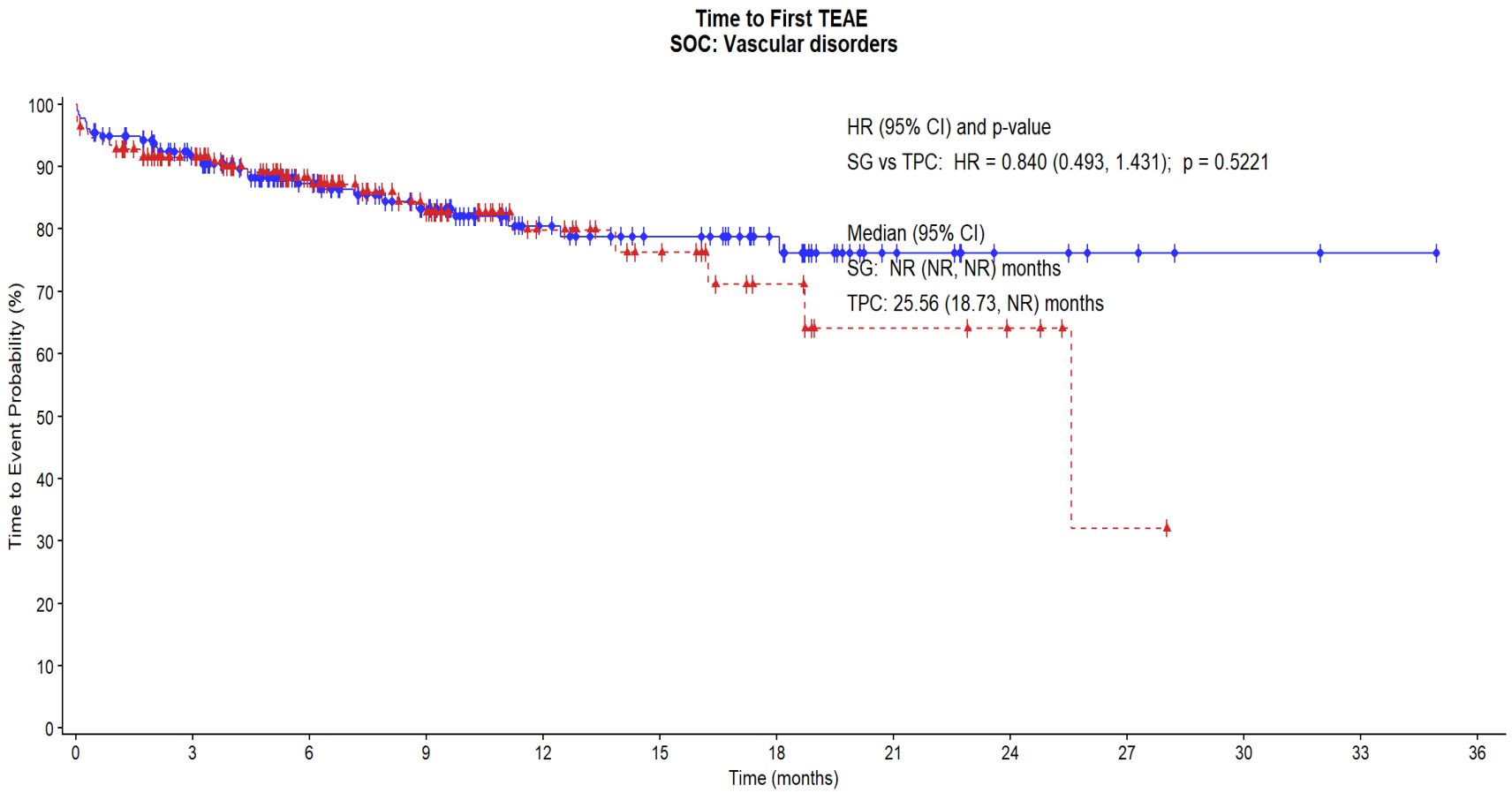
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.37. Figure 1.1.38: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



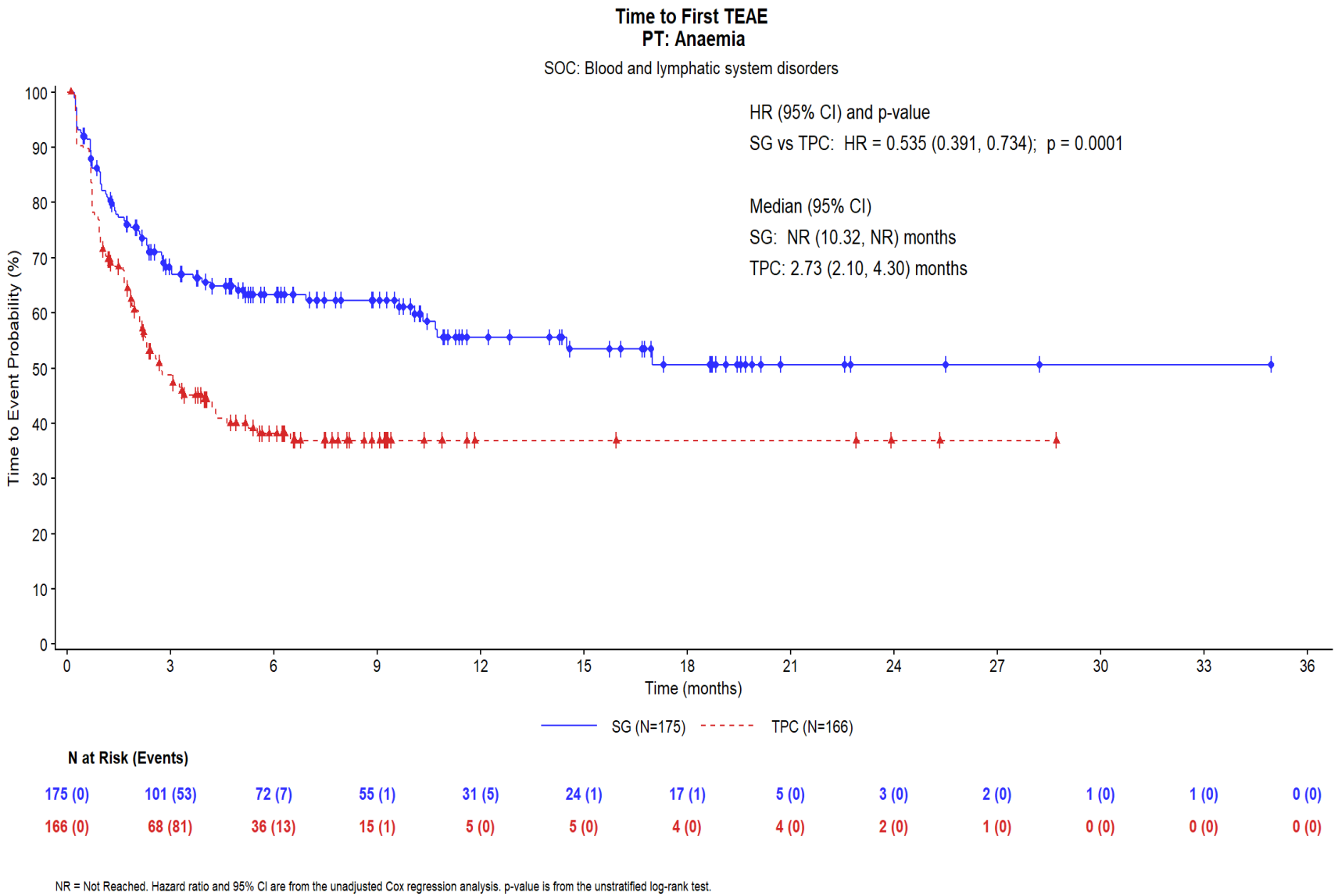
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.38. Figure 1.1.39: Kaplan Meier Plot of Time to First TEAE by SOC Vascular disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



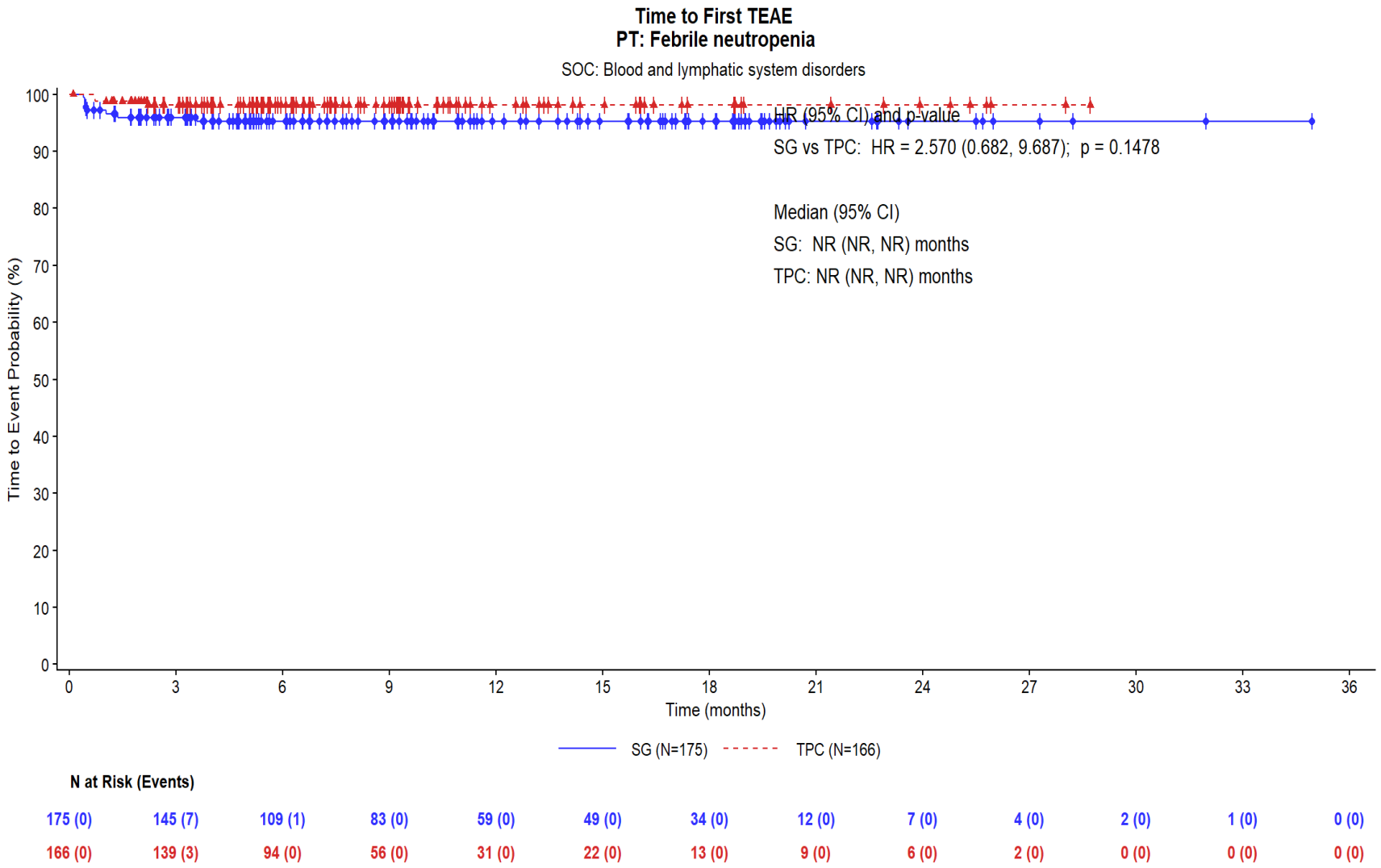
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.39. Figure 1.1.40: Kaplan Meier Plot of Time to First TEAE by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



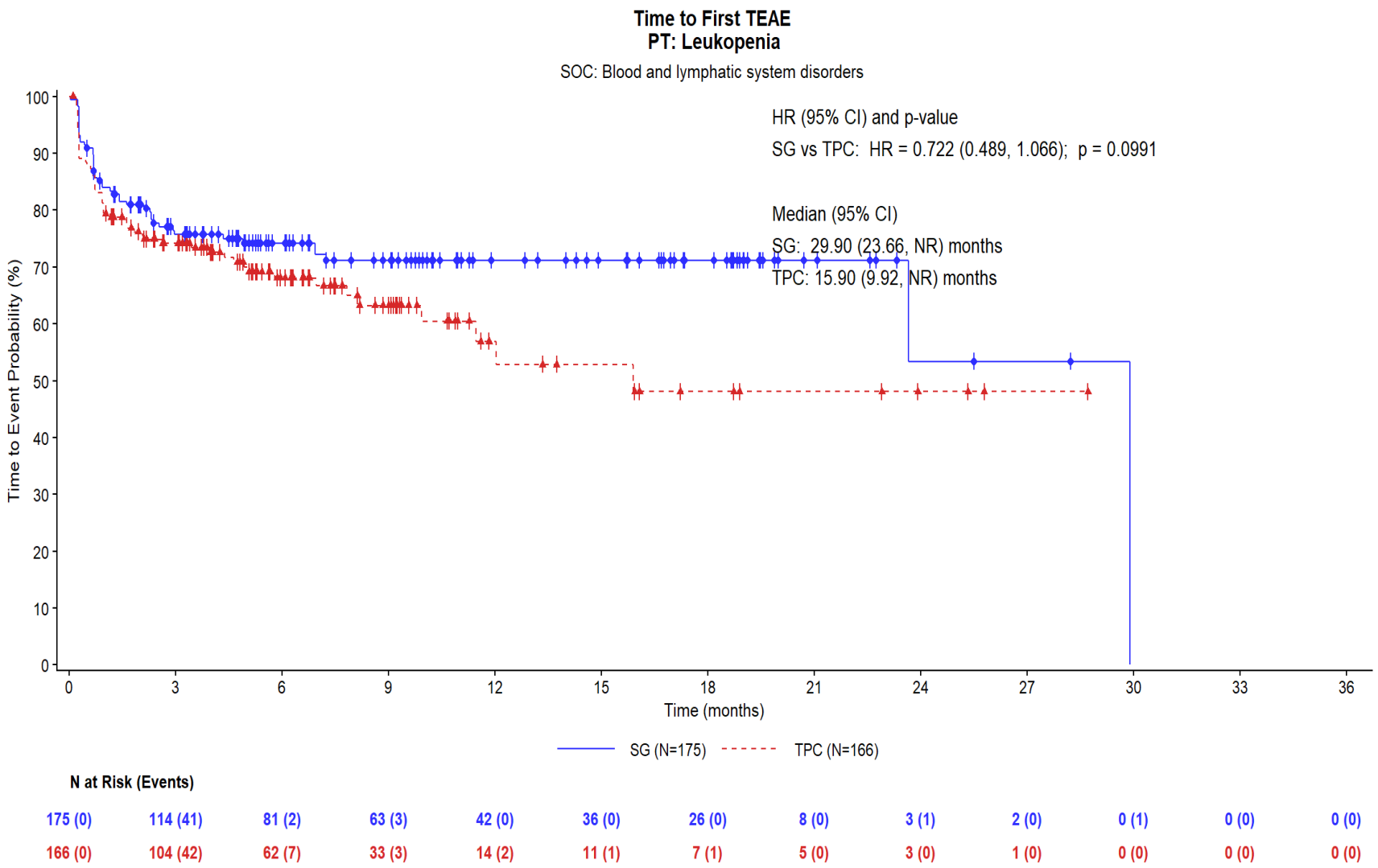
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.40. Figure 1.1.41: Kaplan Meier Plot of Time to First TEAE by PT Febrile neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



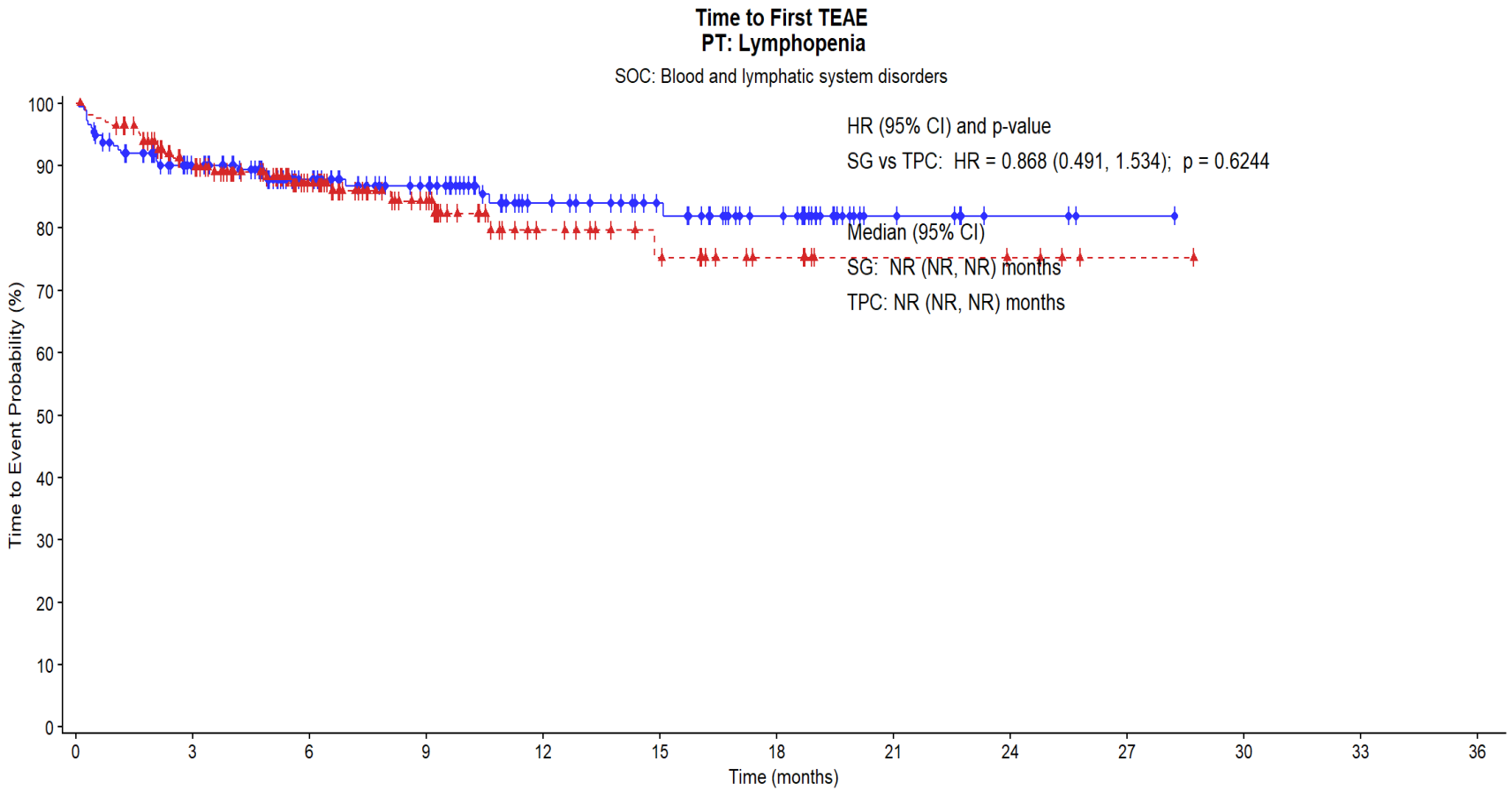
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.41. Figure 1.1.42: Kaplan Meier Plot of Time to First TEAE by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



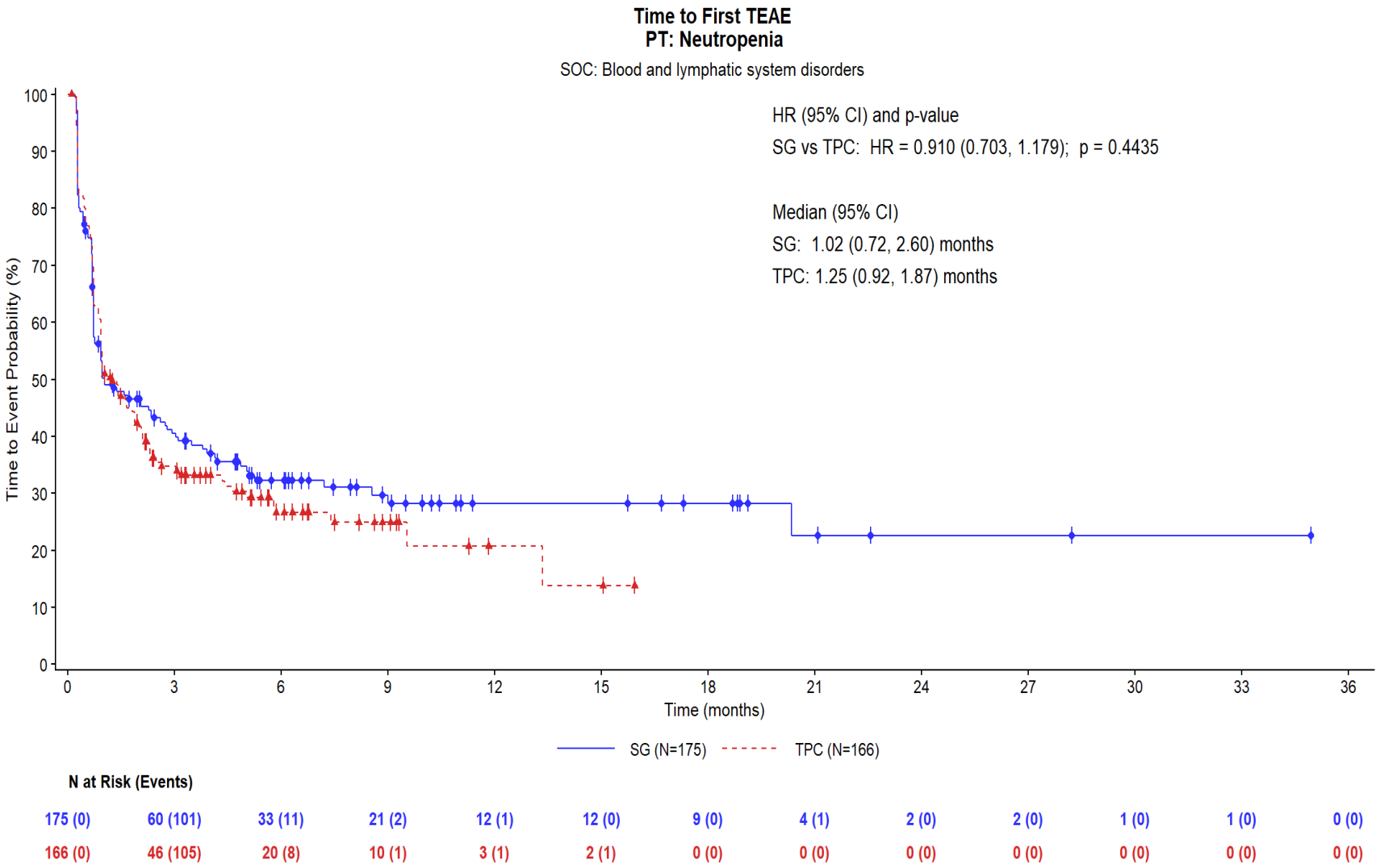
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.42. Figure 1.1.43: Kaplan Meier Plot of Time to First TEAE by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



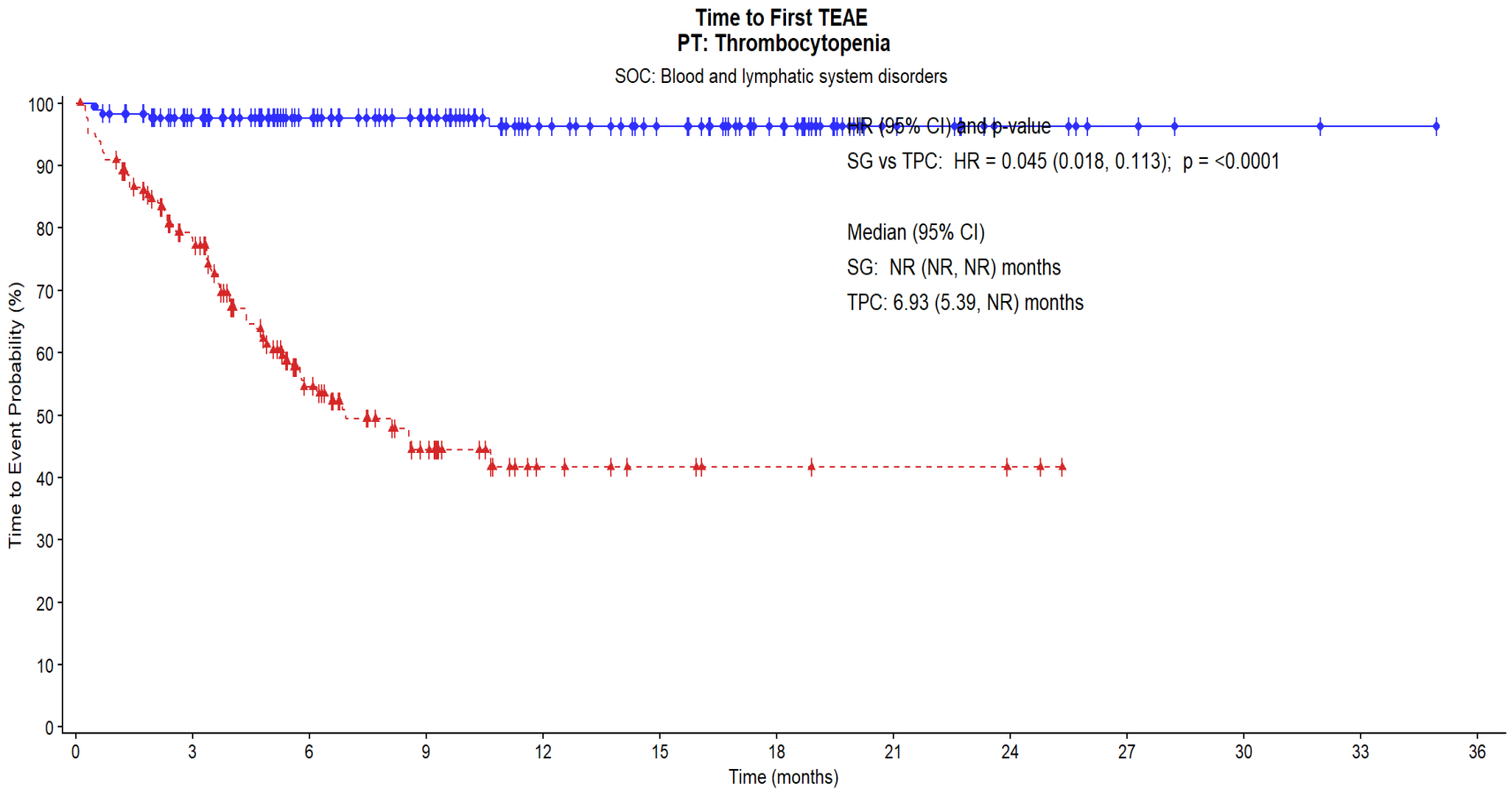
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.43. Figure 1.1.44: Kaplan Meier Plot of Time to First TEAE by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



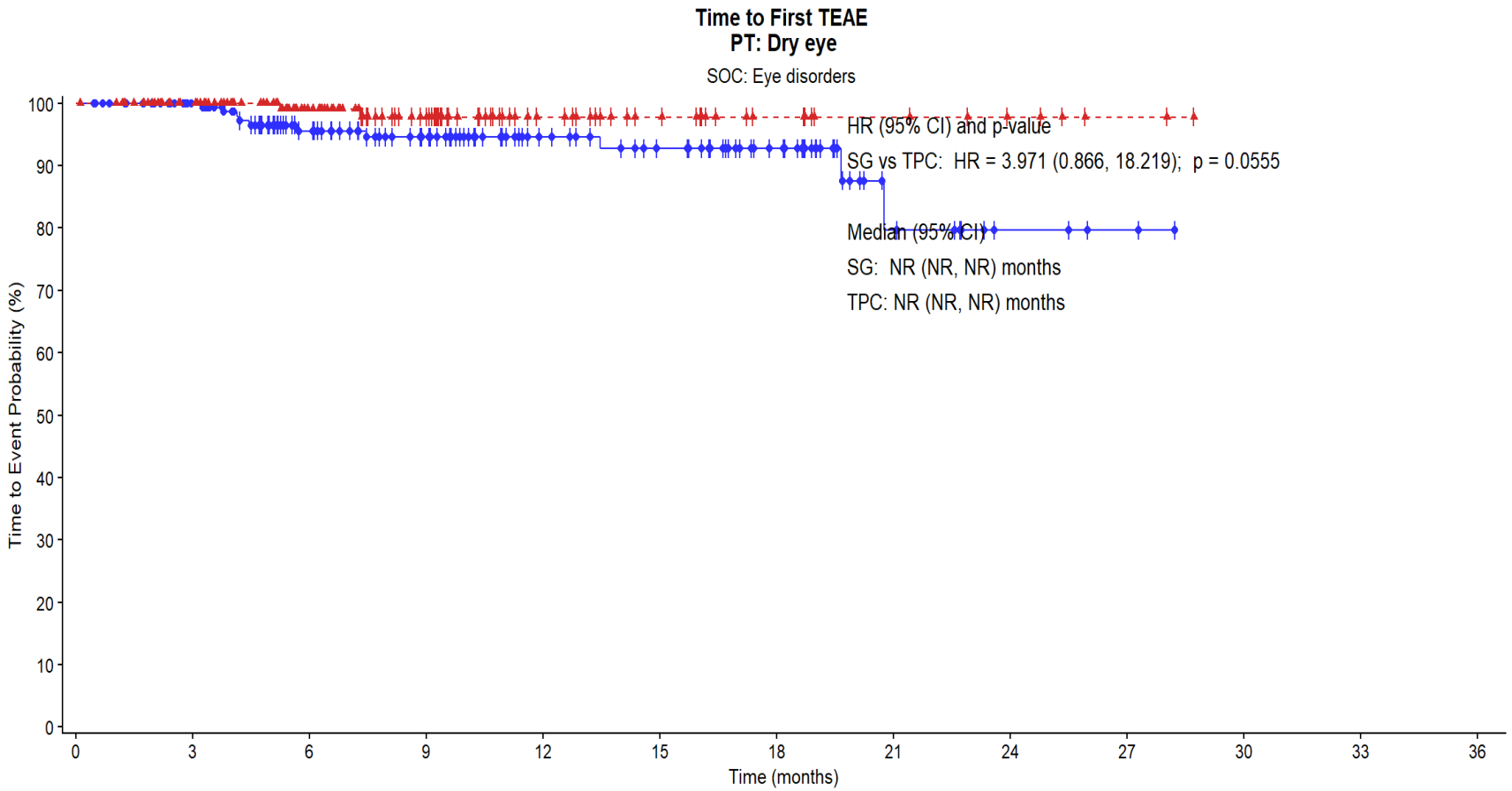
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.44. Figure 1.1.45: Kaplan Meier Plot of Time to First TEAE by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



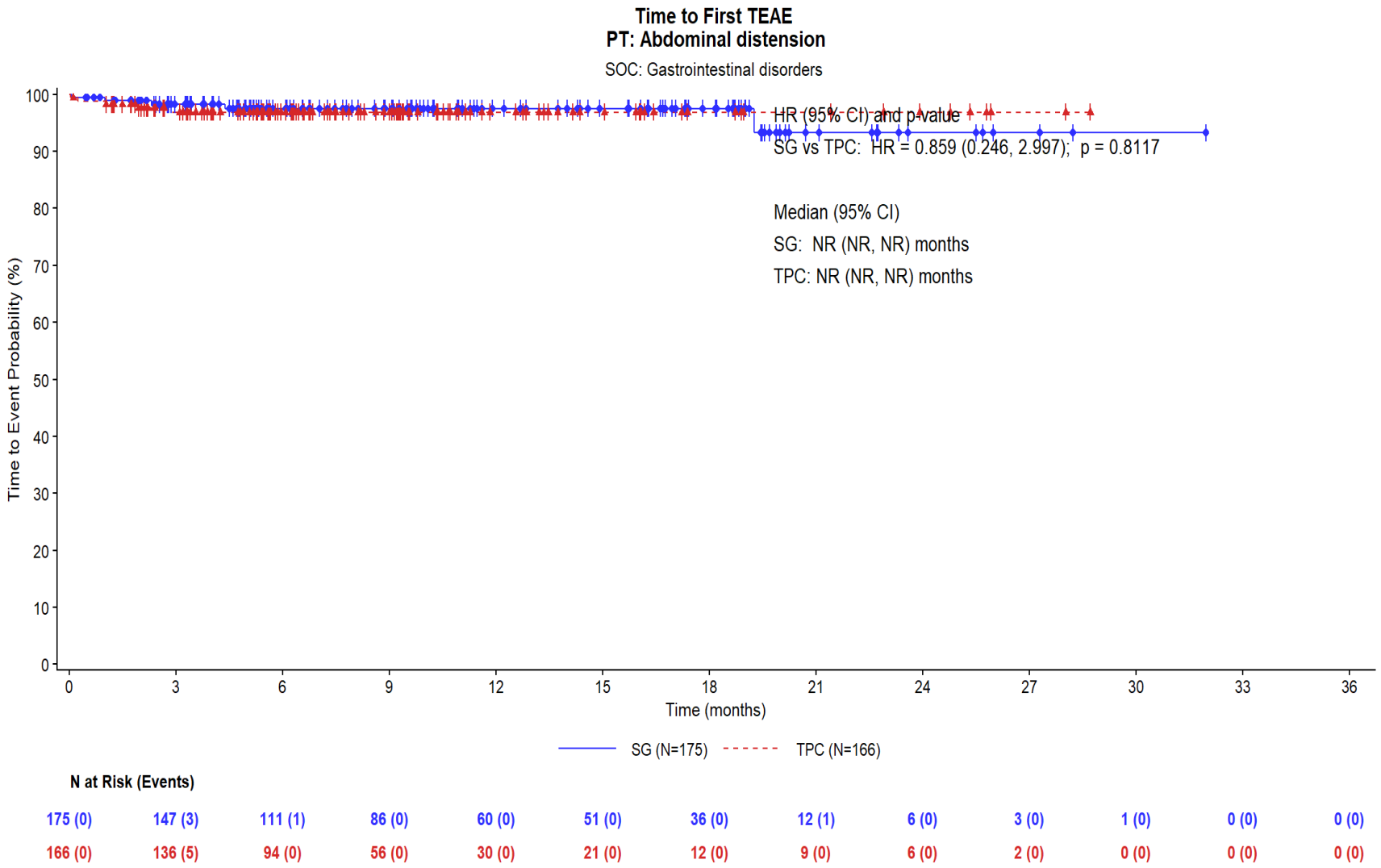
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.45. Figure 1.1.46: Kaplan Meier Plot of Time to First TEAE by PT Dry eye — mSAF — Excluding patients preselected to receive nab-paclitaxel



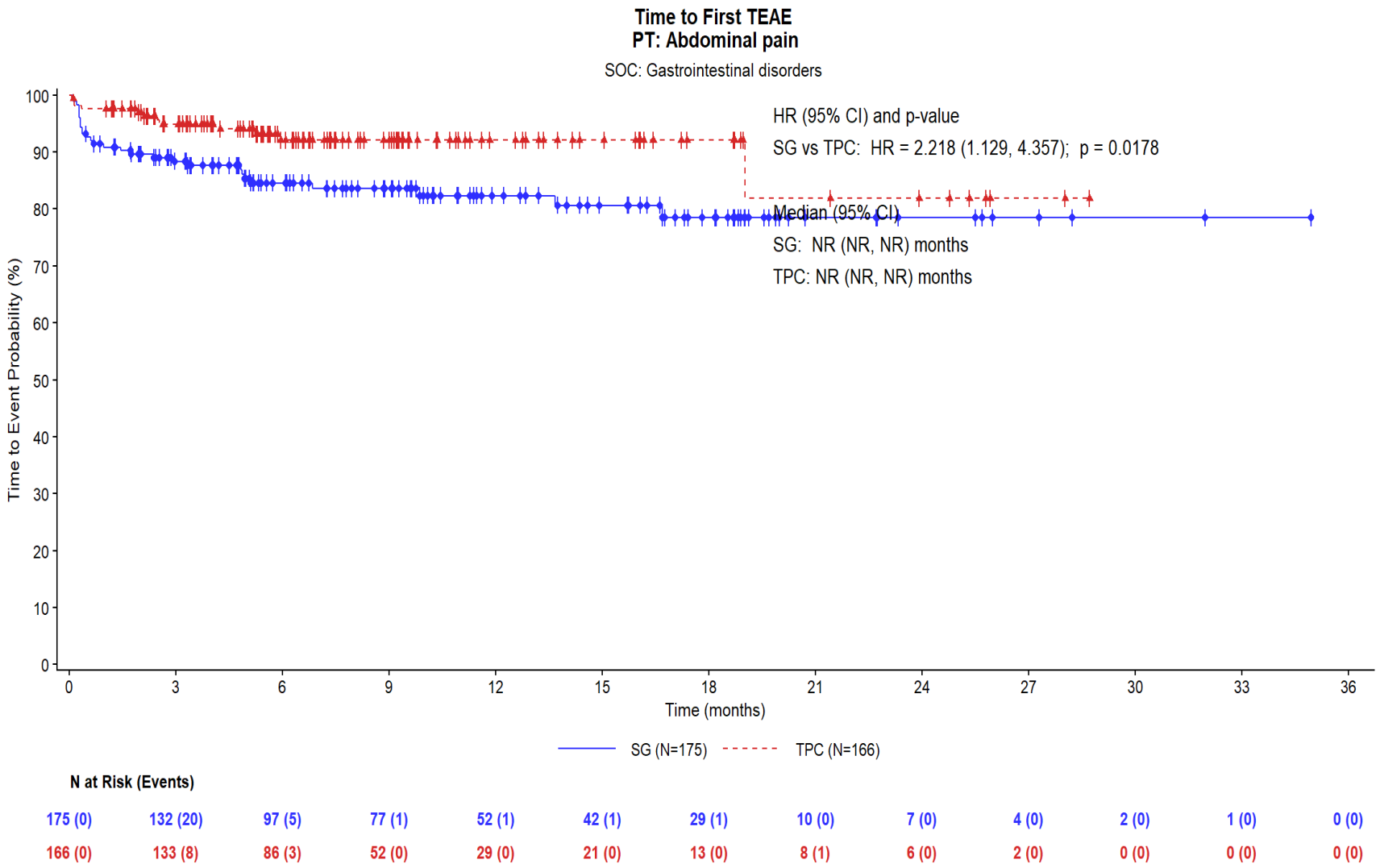
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.46. Figure 1.1.47: Kaplan Meier Plot of Time to First TEAE by PT Abdominal distension — mSAF — Excluding patients preselected to receive nab-paclitaxel



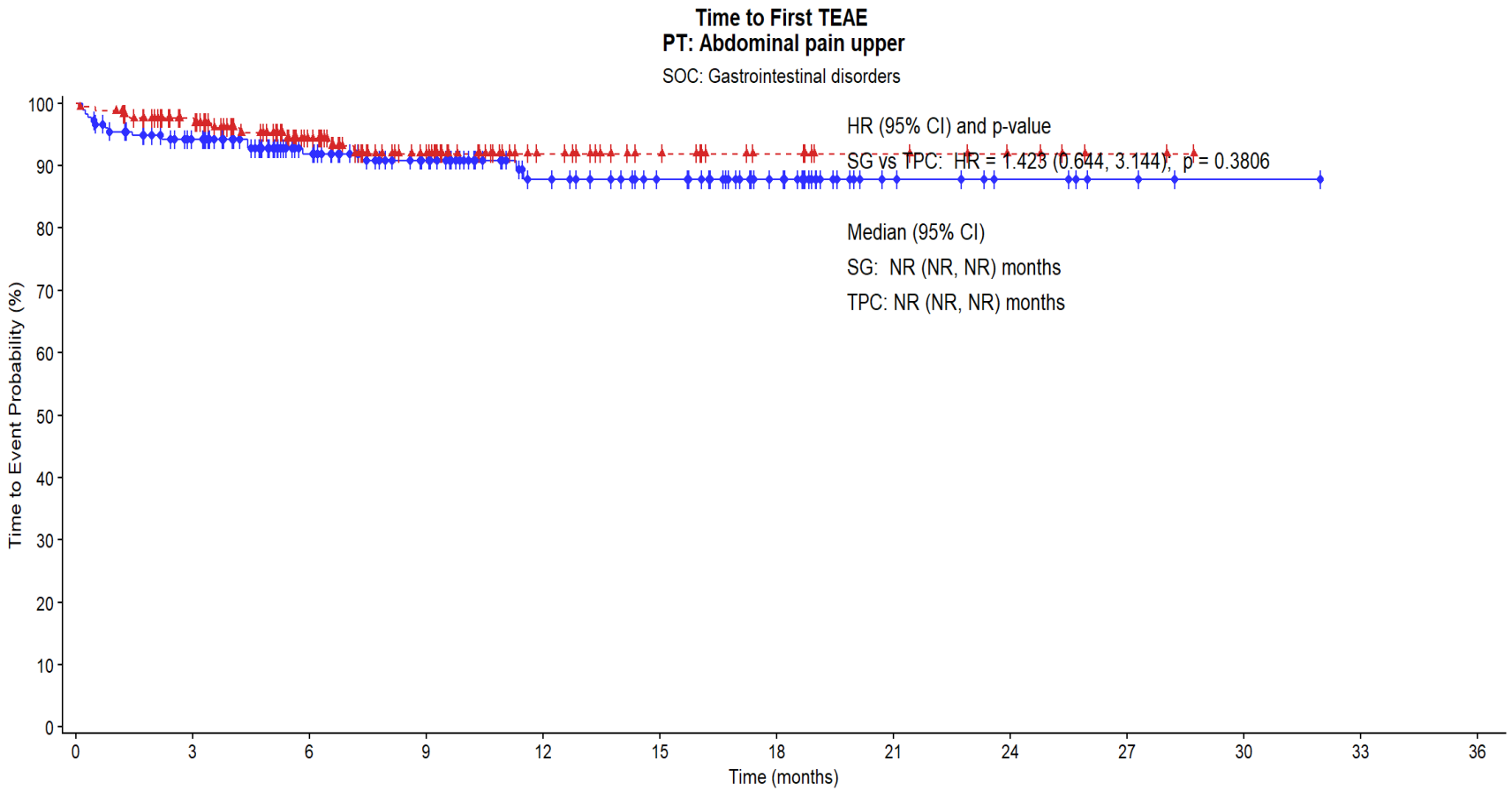
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.47. Figure 1.1.48: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



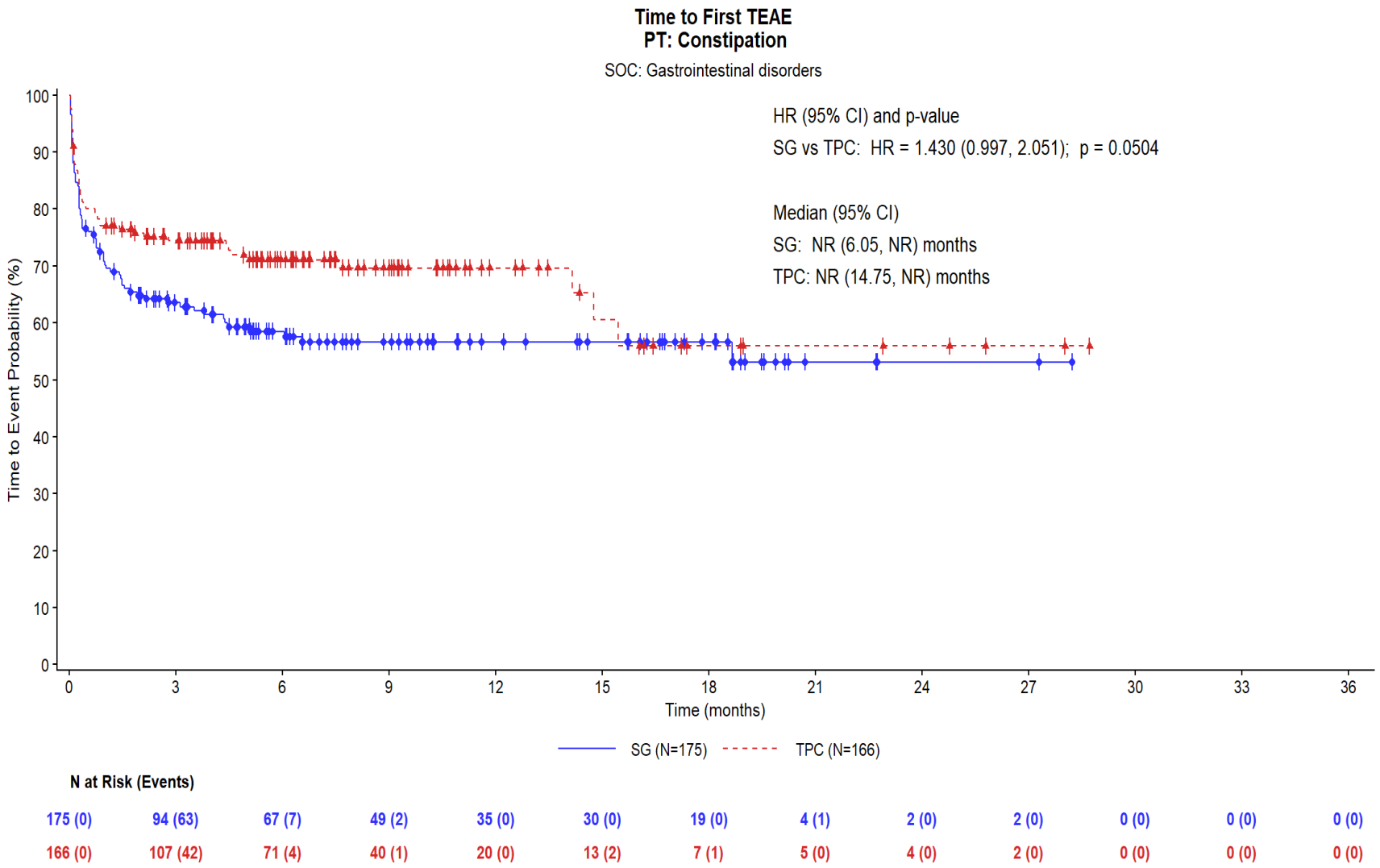
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.48. Figure 1.1.49: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain upper — mSAF — Excluding patients preselected to receive nab-paclitaxel



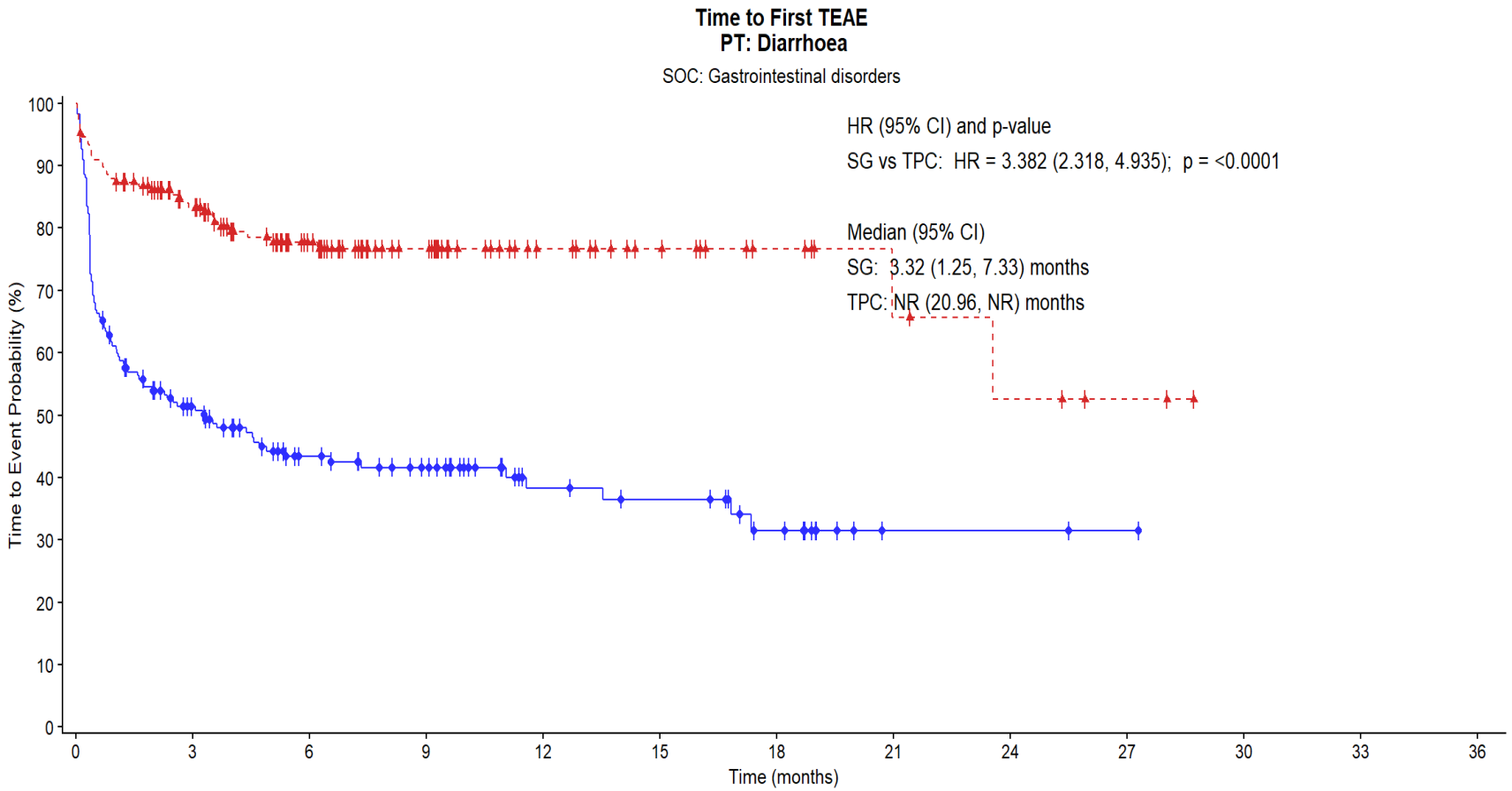
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.49. Figure 1.1.50: Kaplan Meier Plot of Time to First TEAE by PT Constipation — mSAF — Excluding patients preselected to receive nab-paclitaxel



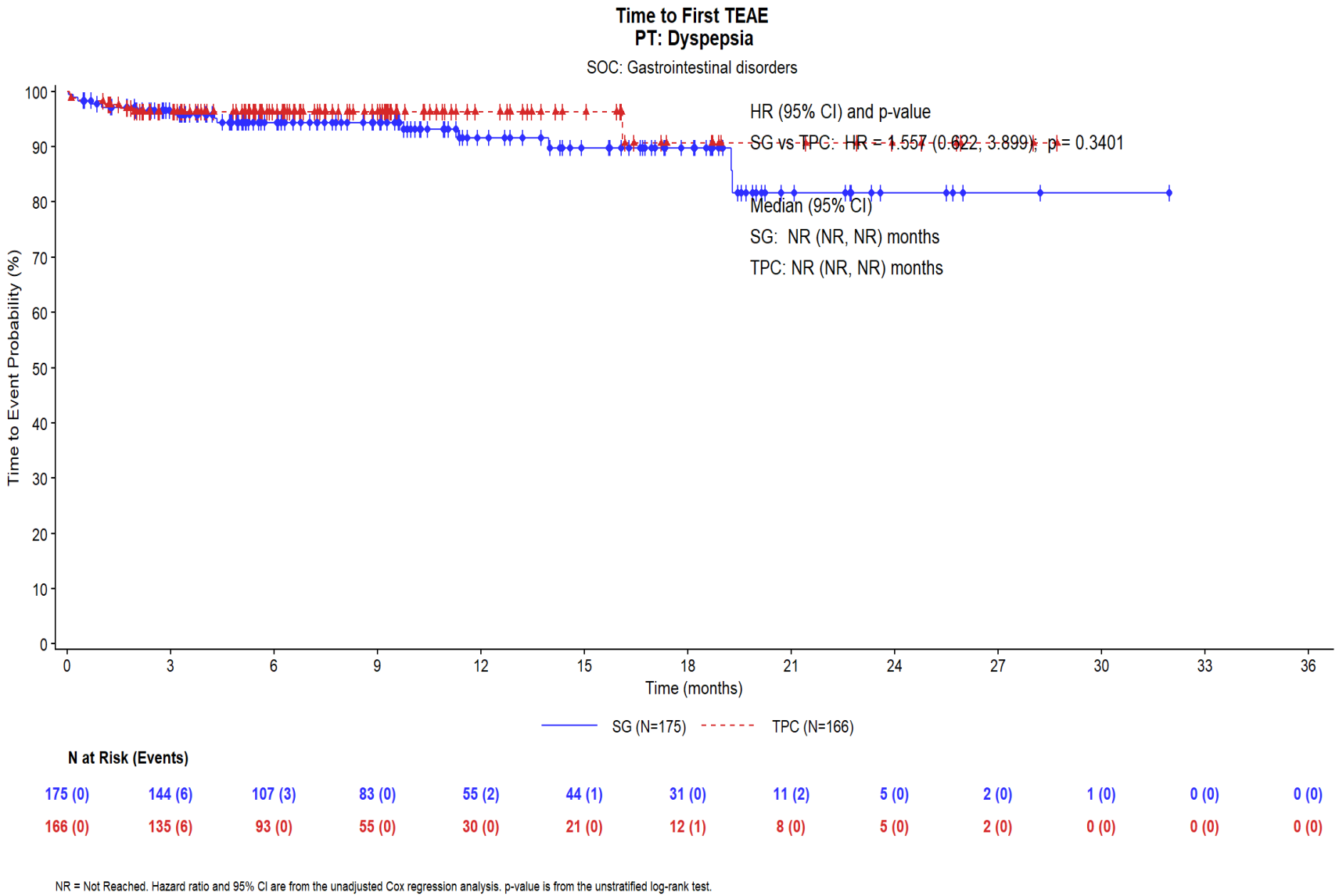
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.50. Figure 1.1.51: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



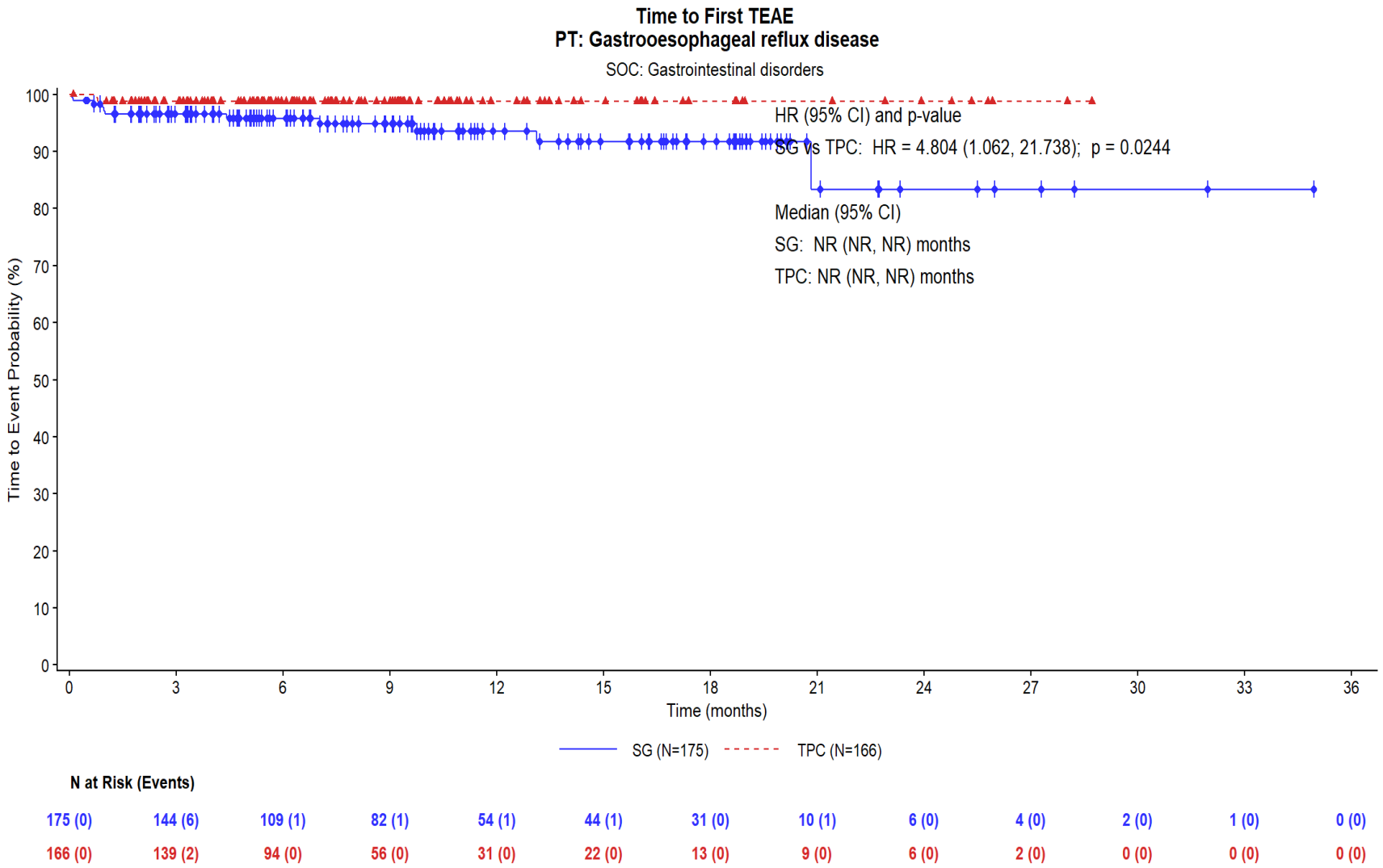
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.51. Figure 1.1.52: Kaplan Meier Plot of Time to First TEAE by PT Dyspepsia — mSAF — Excluding patients preselected to receive nab-paclitaxel



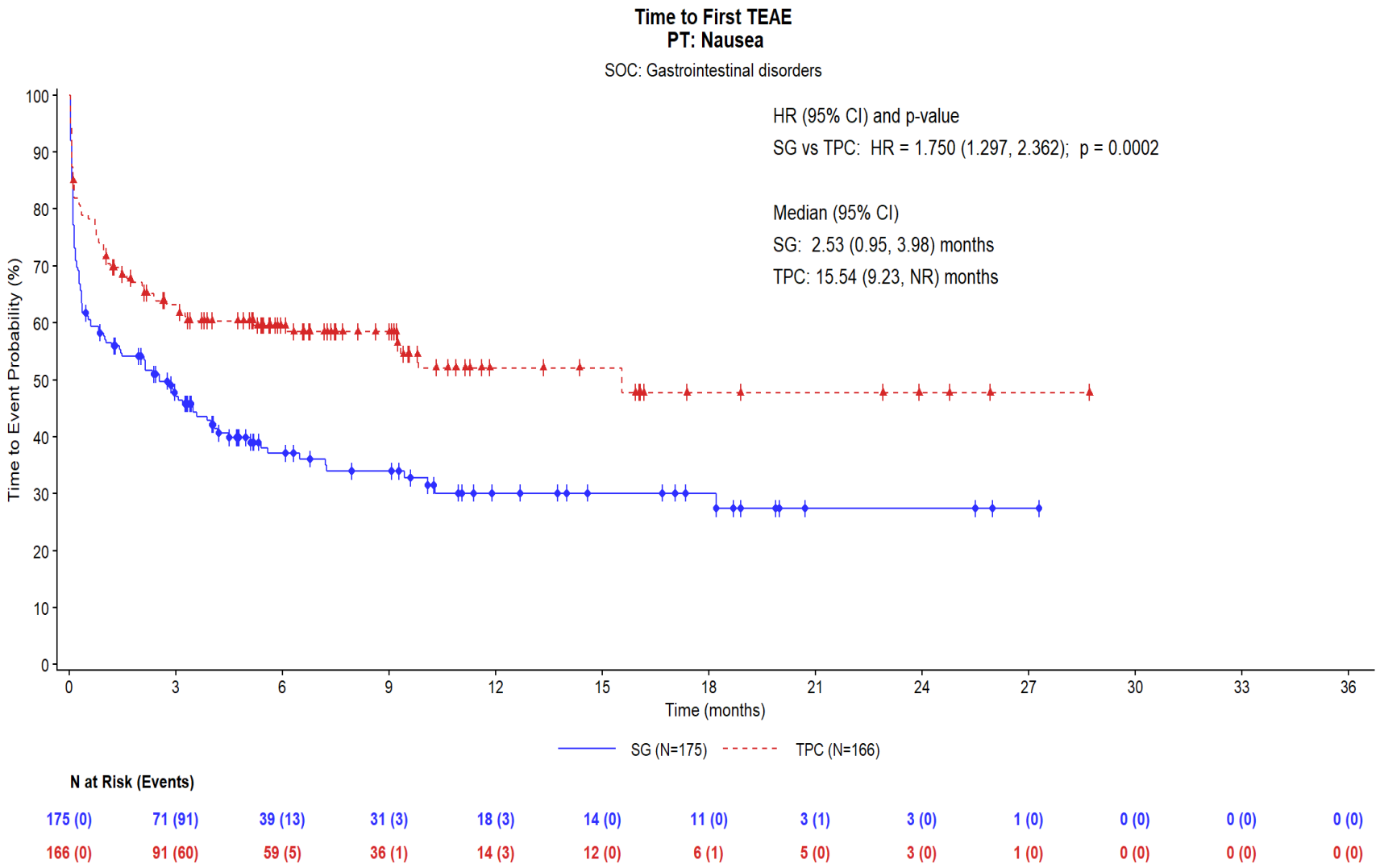
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.52. Figure 1.1.53: Kaplan Meier Plot of Time to First TEAE by PT Gastrooesophageal reflux disease — mSAF — Excluding patients preselected to receive nab-paclitaxel



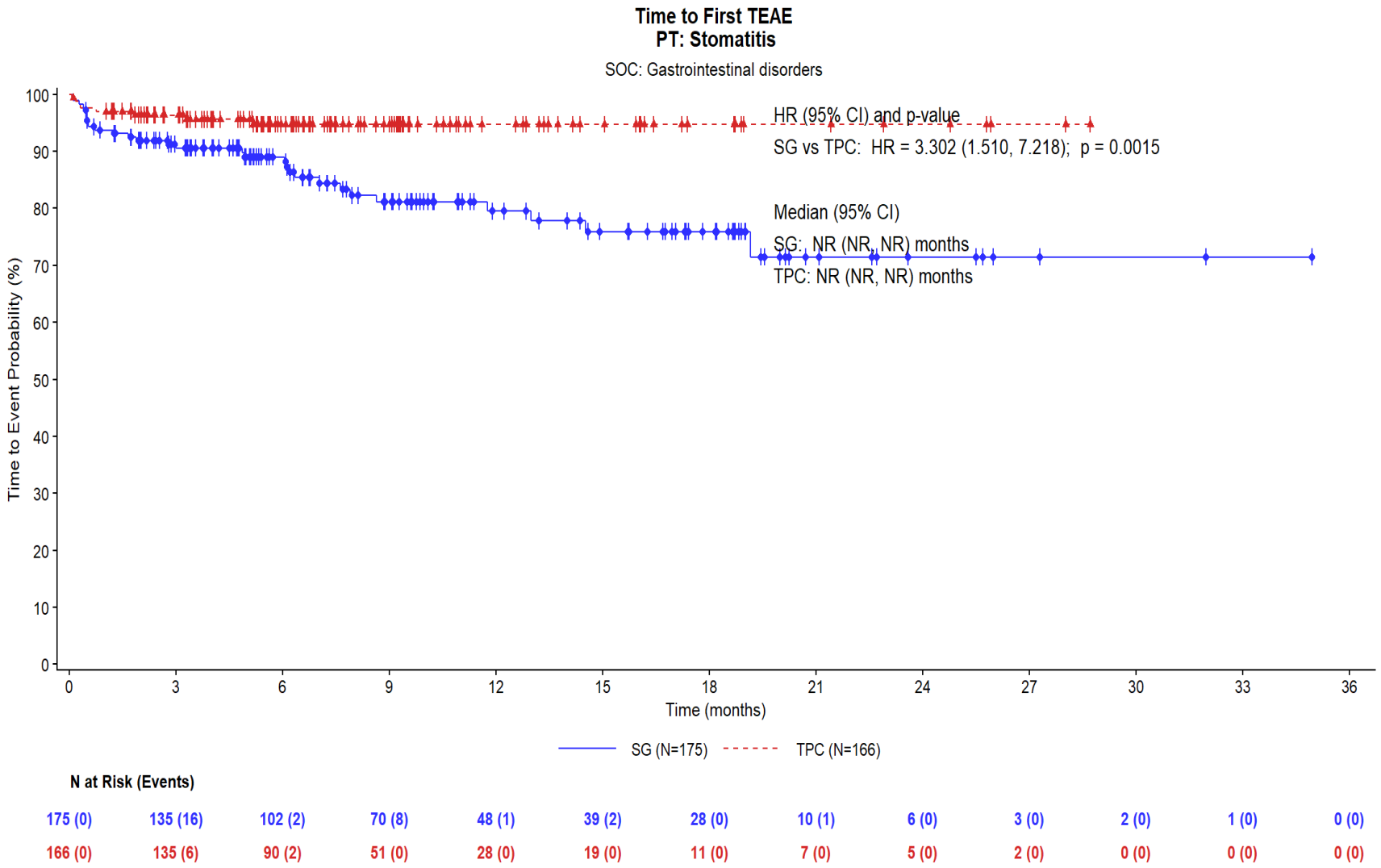
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.53. Figure 1.1.54: Kaplan Meier Plot of Time to First TEAE by PT Nausea — mSAF — Excluding patients preselected to receive nab-paclitaxel



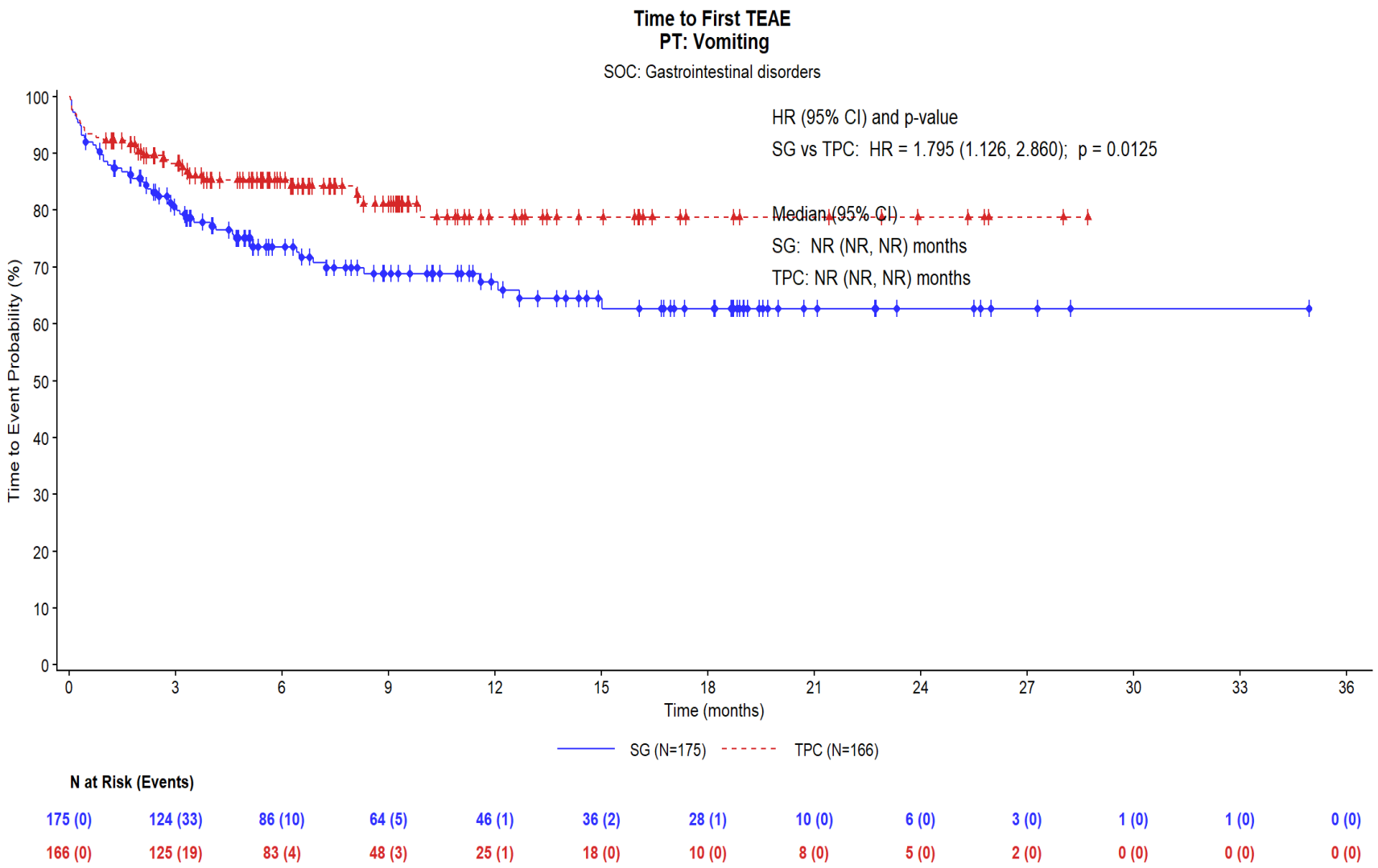
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.54. Figure 1.1.55: Kaplan Meier Plot of Time to First TEAE by PT Stomatitis — mSAF — Excluding patients preselected to receive nab-paclitaxel



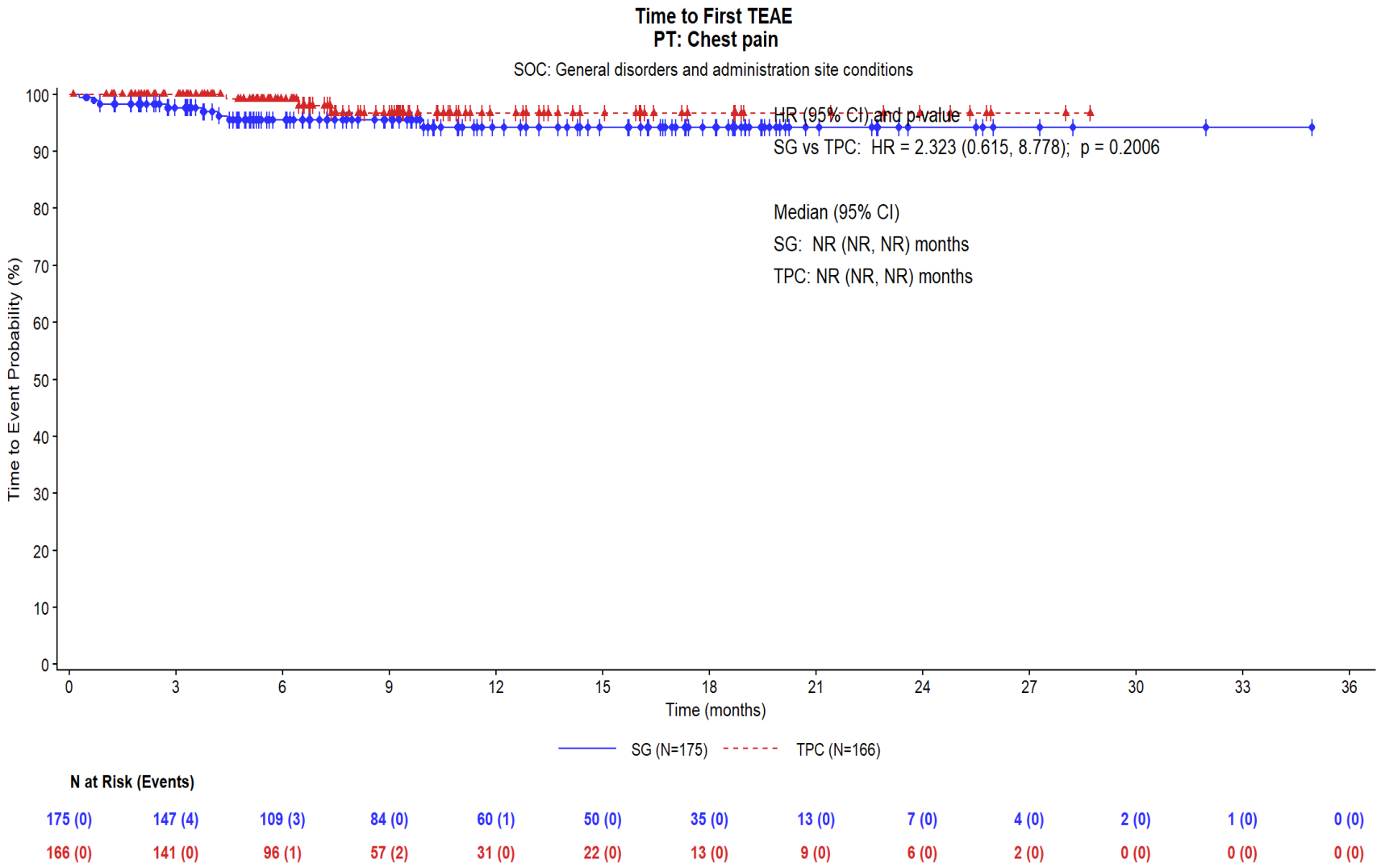
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.55. Figure 1.1.56: Kaplan Meier Plot of Time to First TEAE by PT Vomiting — mSAF — Excluding patients preselected to receive nab-paclitaxel



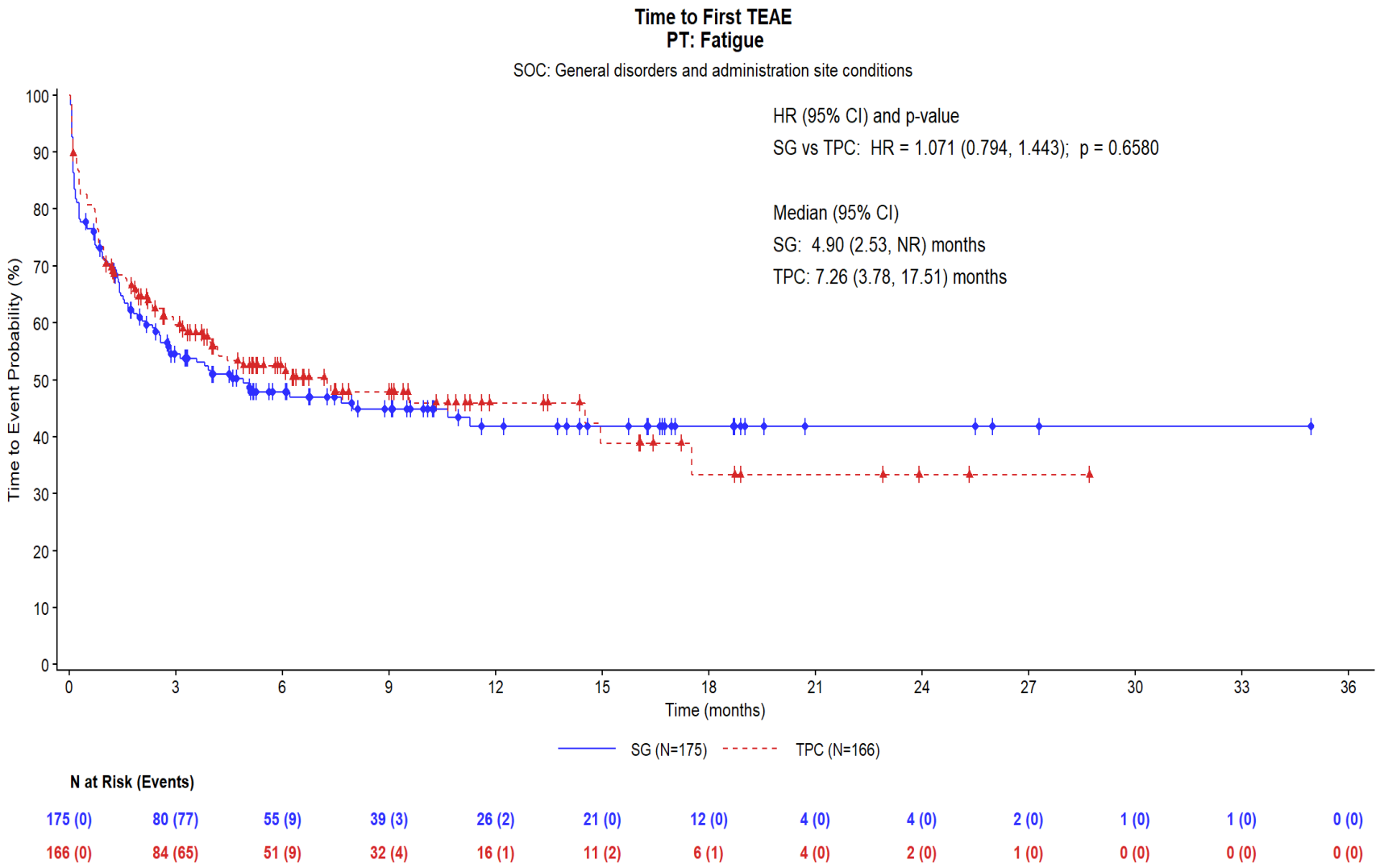
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.56. Figure 1.1.57: Kaplan Meier Plot of Time to First TEAE by PT Chest pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



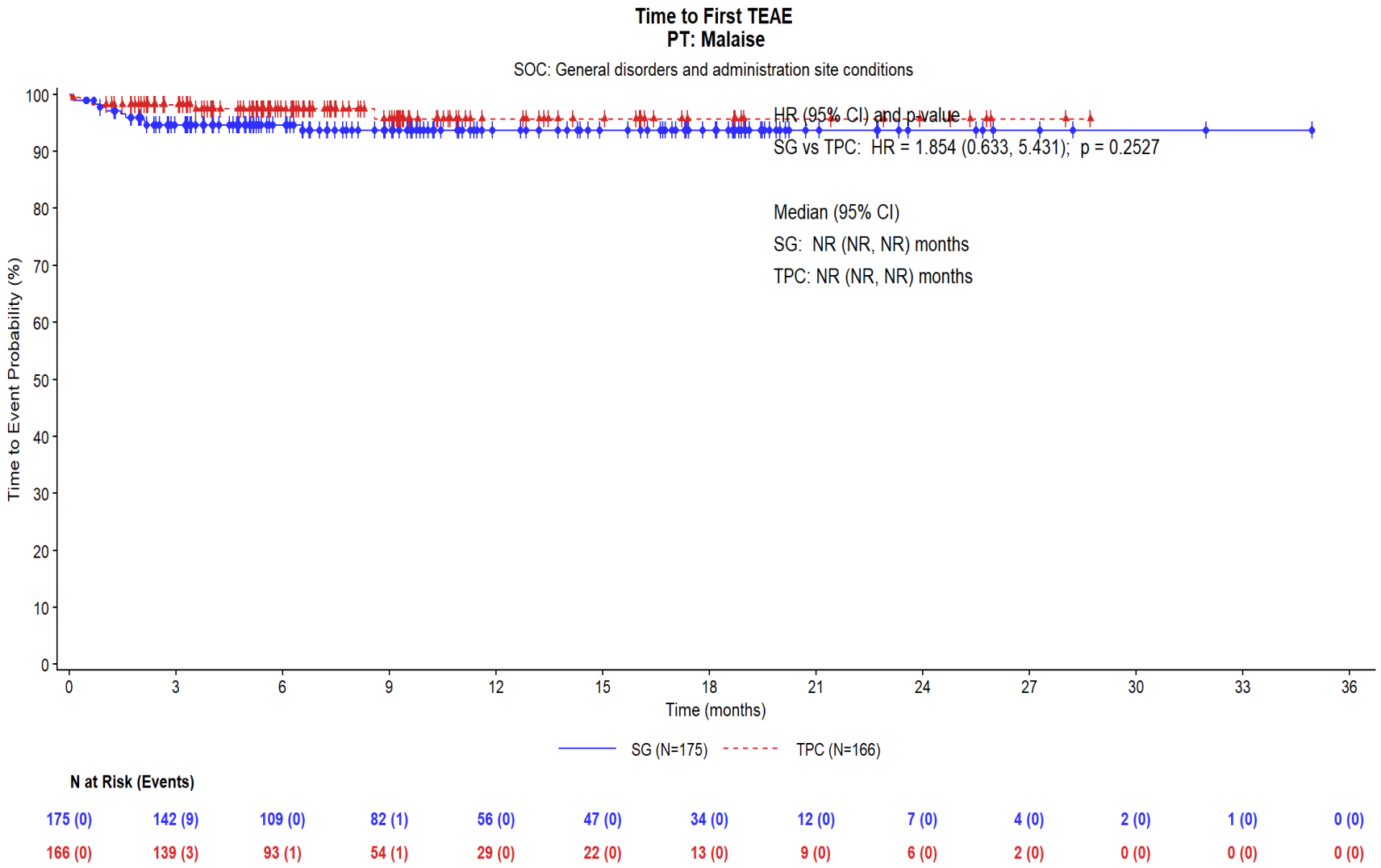
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.57. Figure 1.1.58: Kaplan Meier Plot of Time to First TEAE by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel



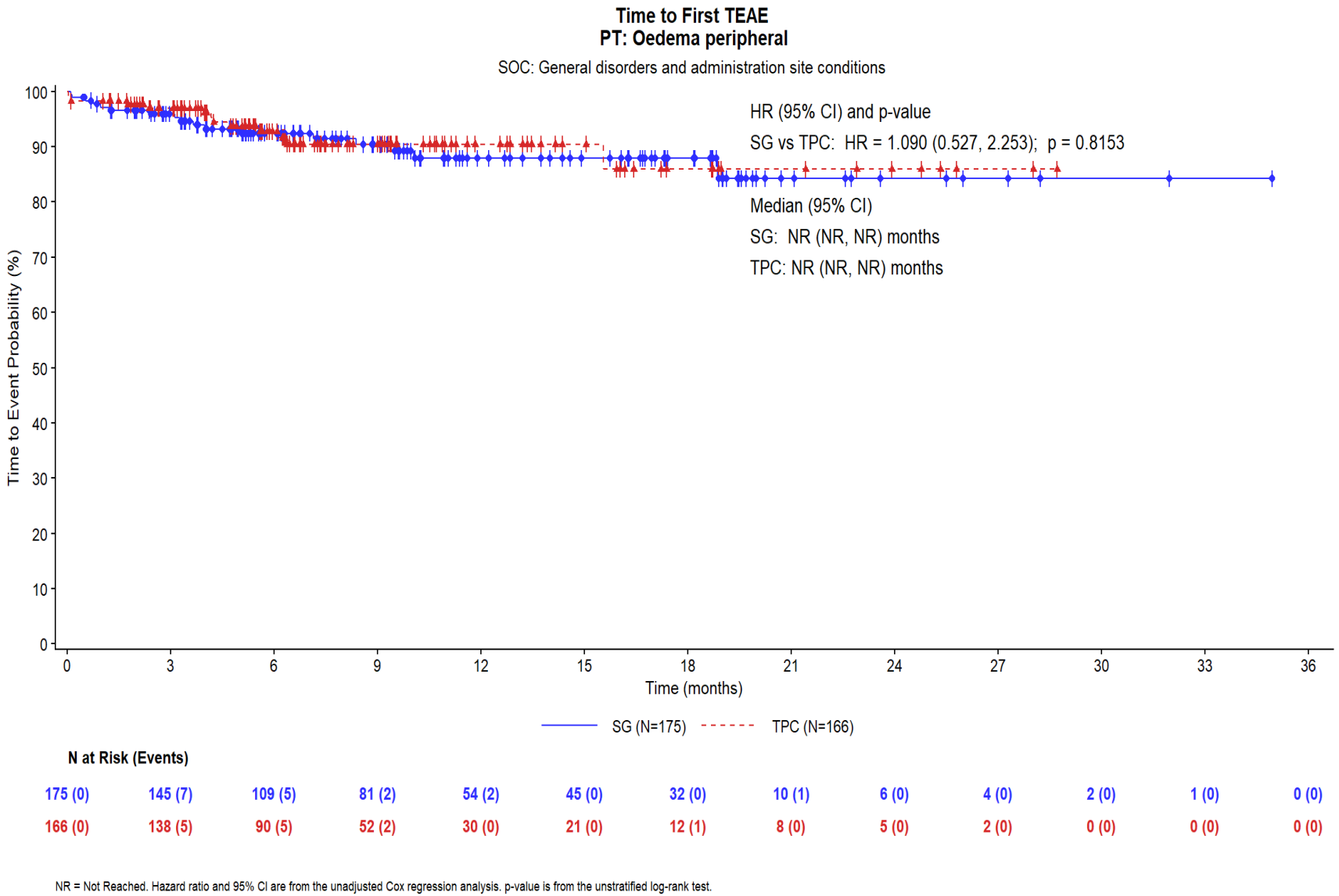
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.58. Figure 1.1.59: Kaplan Meier Plot of Time to First TEAE by PT Malaise — mSAF — Excluding patients preselected to receive nab-paclitaxel



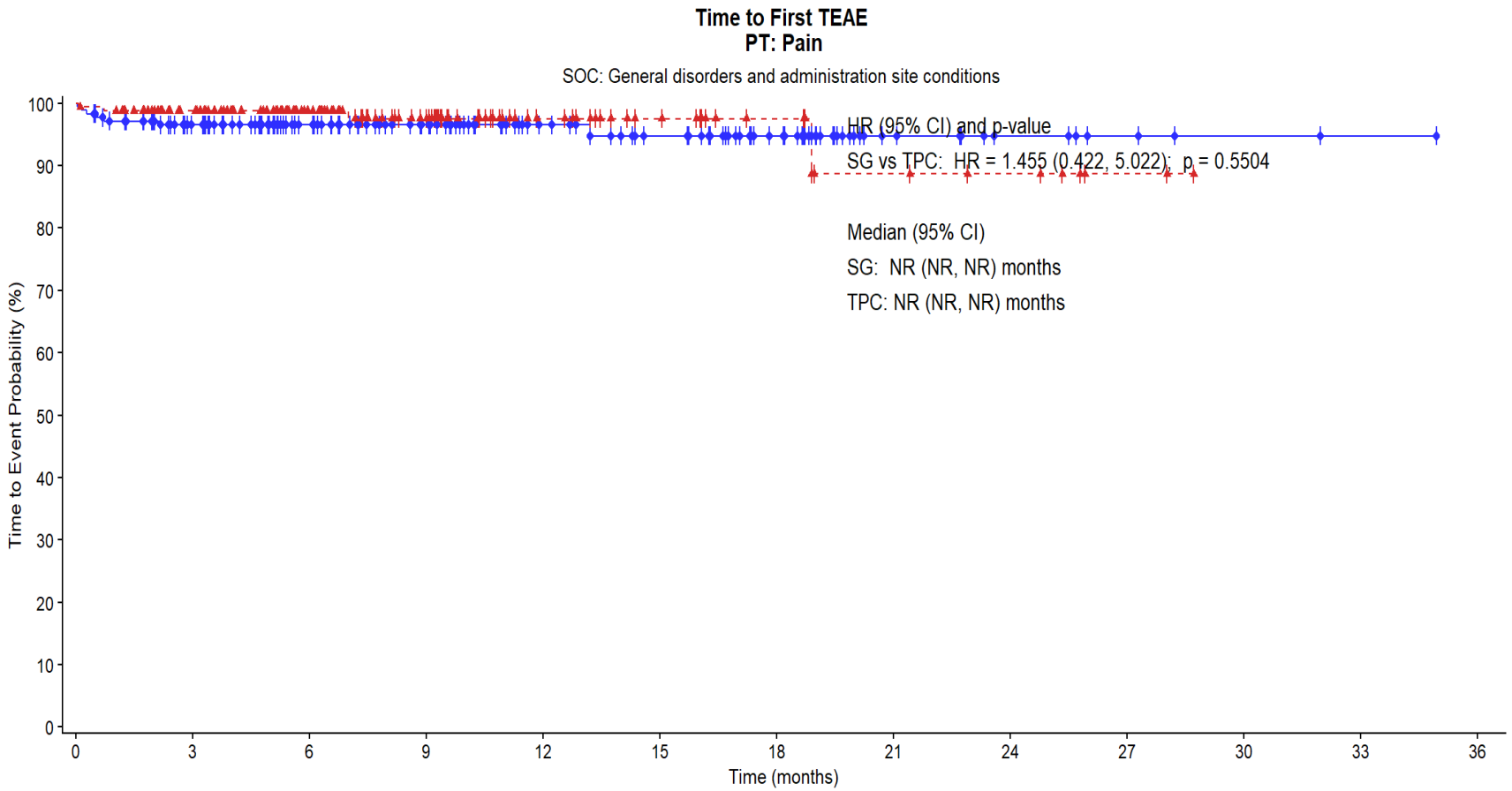
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.59. Figure 1.1.60: Kaplan Meier Plot of Time to First TEAE by PT Oedema peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel



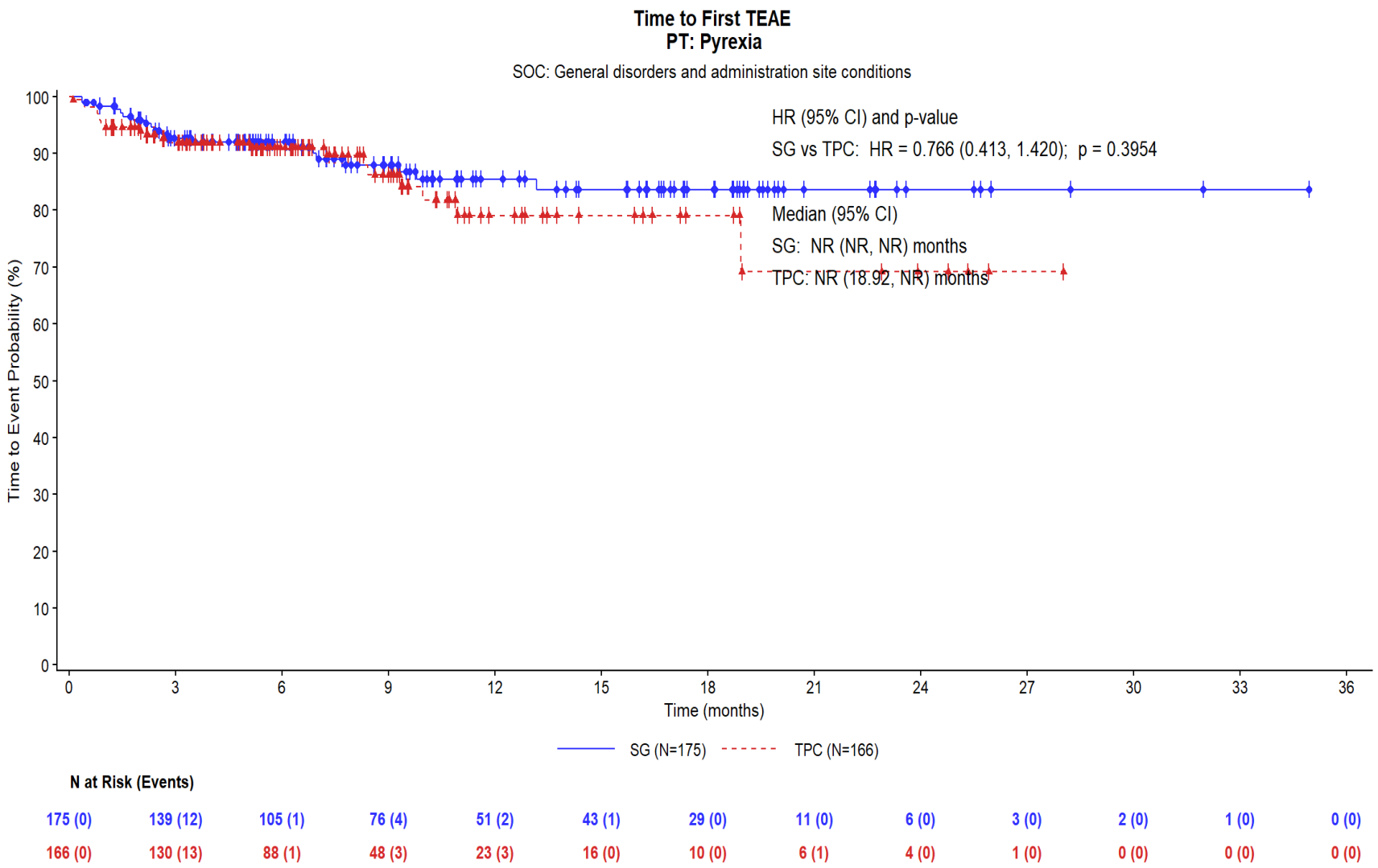
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.60. Figure 1.1.61: Kaplan Meier Plot of Time to First TEAE by PT Pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



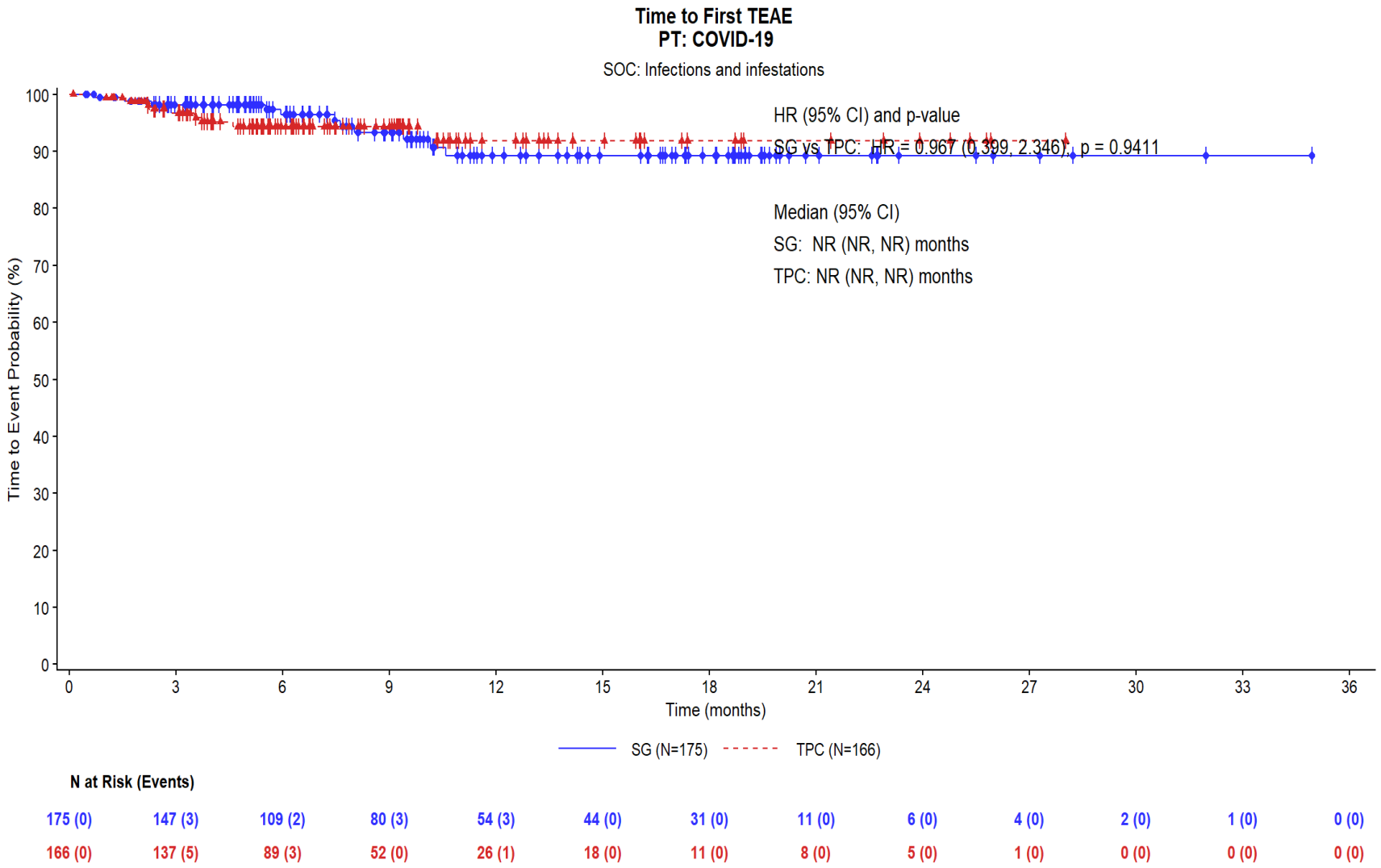
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.61. Figure 1.1.62: Kaplan Meier Plot of Time to First TEAE by PT Pyrexia — mSAF — Excluding patients preselected to receive nab-paclitaxel



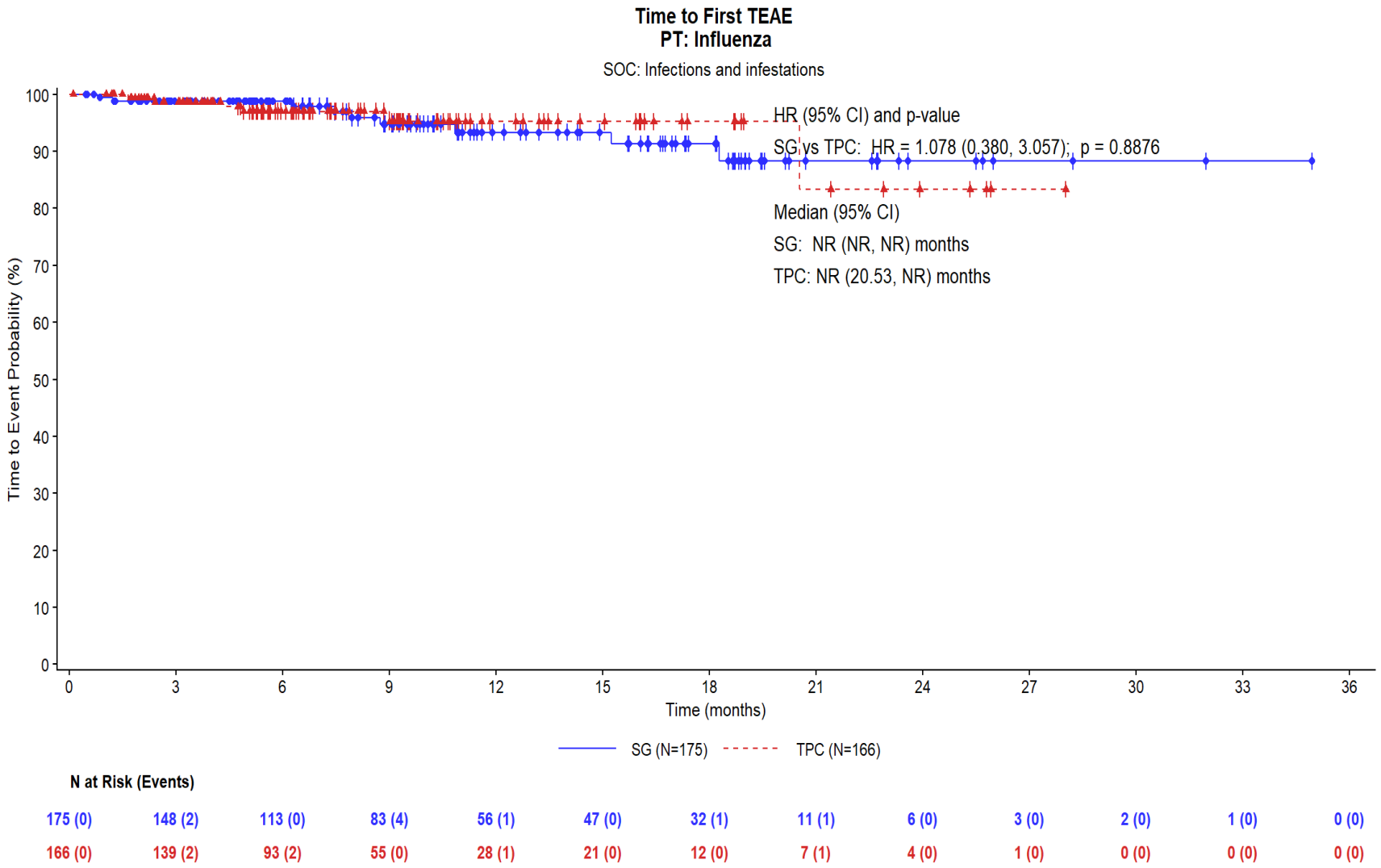
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.62. Figure 1.1.63: Kaplan Meier Plot of Time to First TEAE by PT COVID 19 — mSAF — Excluding patients preselected to receive nab-paclitaxel



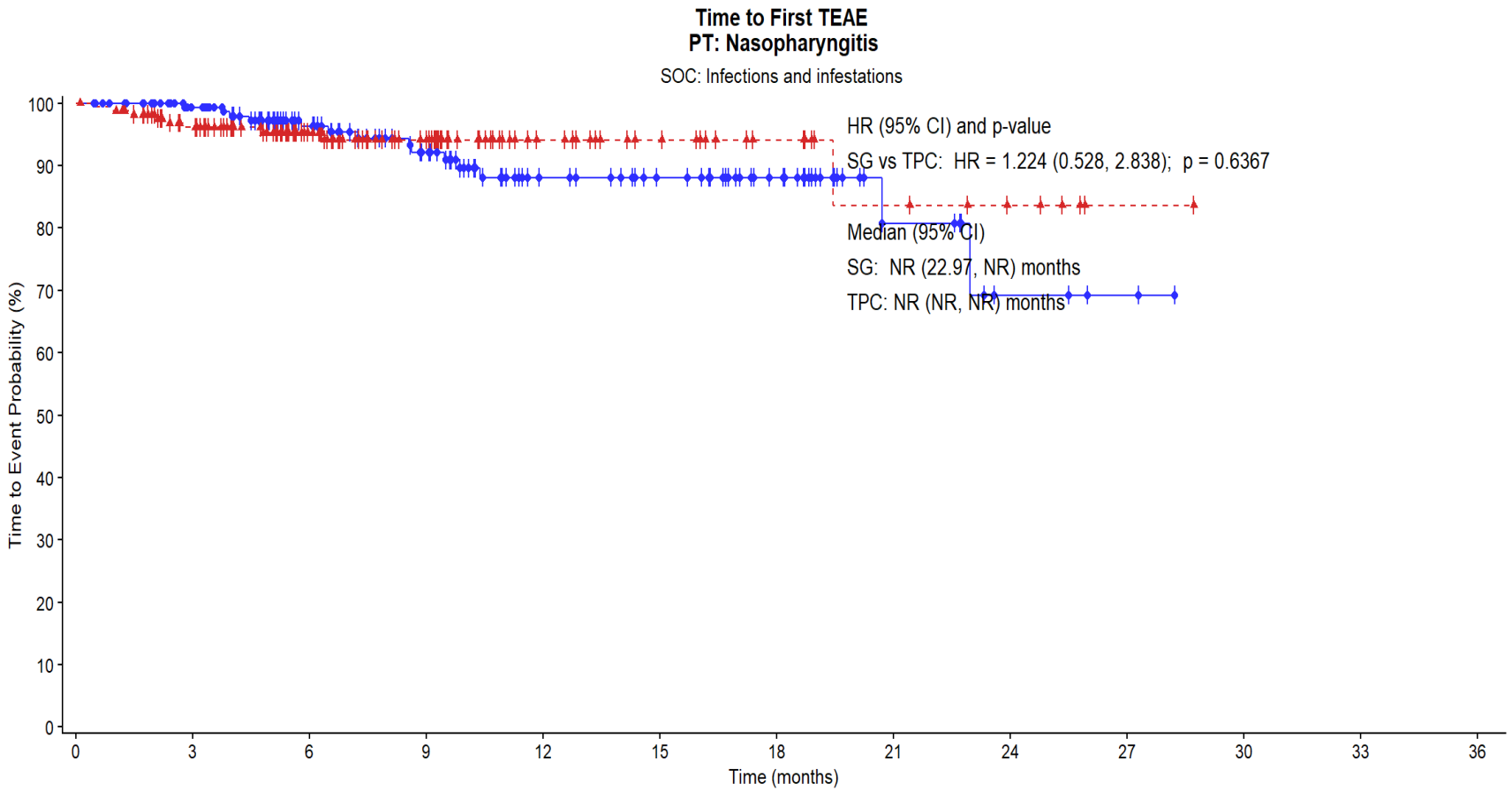
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.63. Figure 1.1.64: Kaplan Meier Plot of Time to First TEAE by PT Influenza — mSAF — Excluding patients preselected to receive nab-paclitaxel



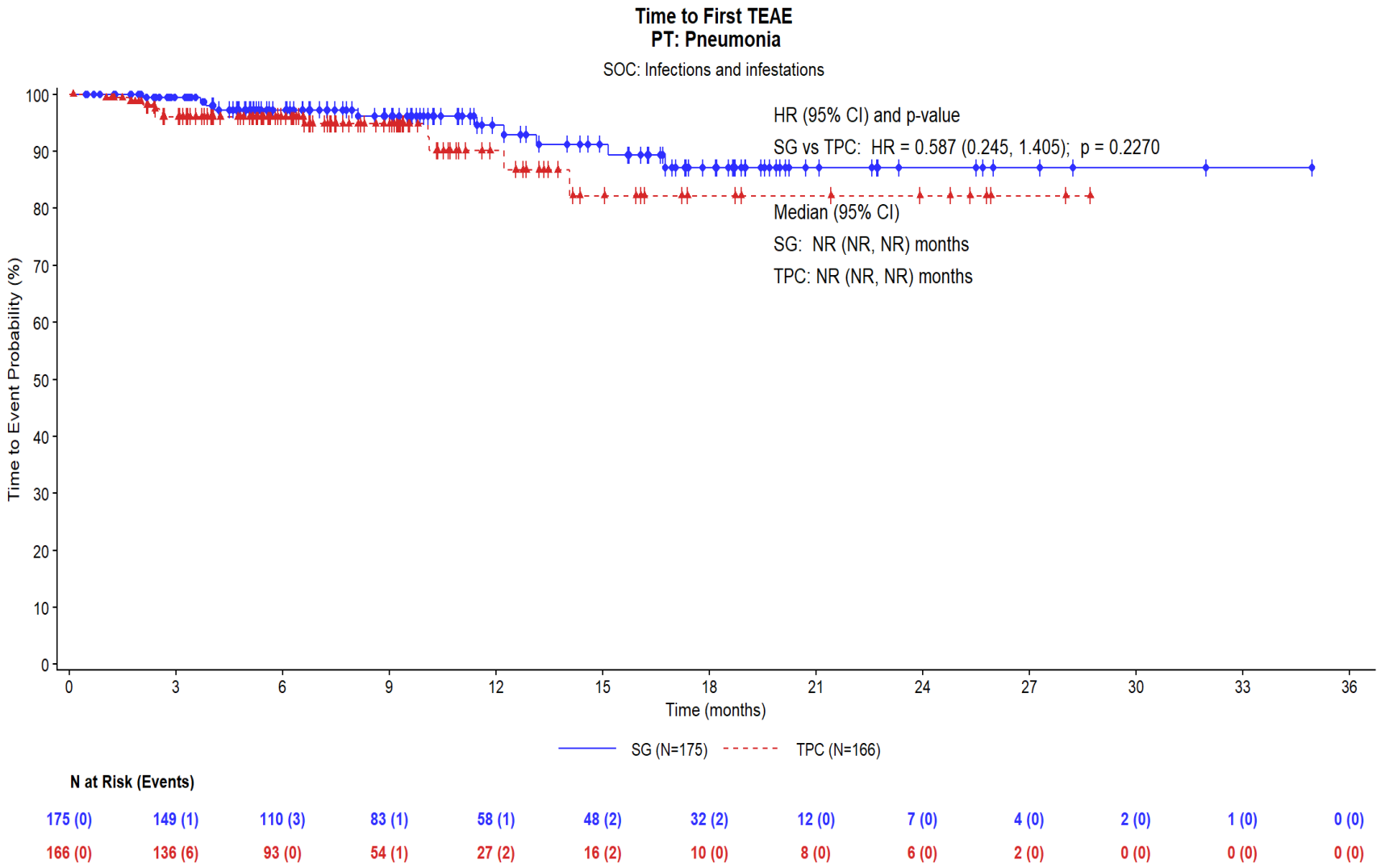
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.64. Figure 1.1.65: Kaplan Meier Plot of Time to First TEAE by PT Nasopharyngitis — mSAF — Excluding patients preselected to receive nab-paclitaxel



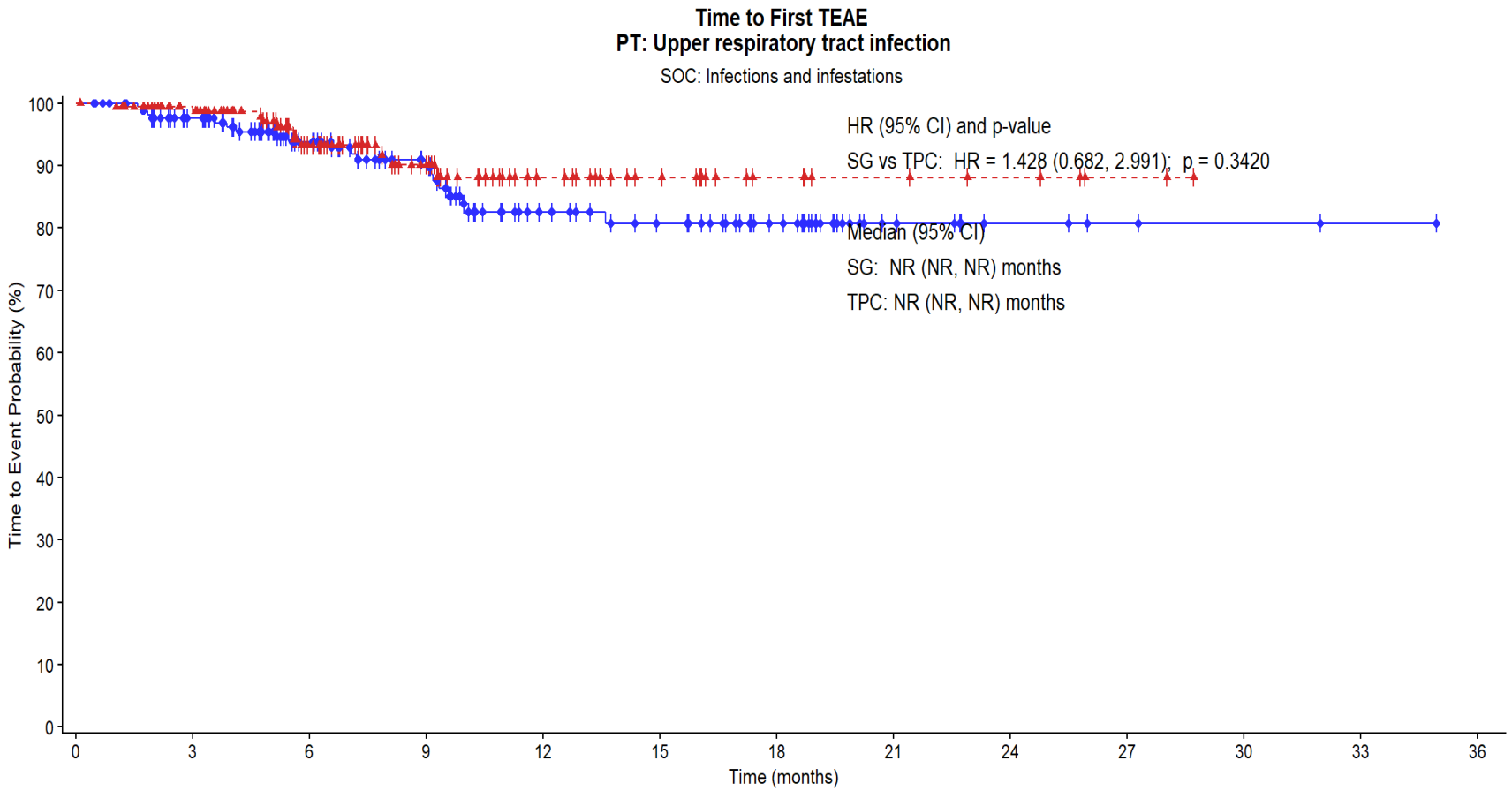
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.65. Figure 1.1.66: Kaplan Meier Plot of Time to First TEAE by PT Pneumonia — mSAF — Excluding patients preselected to receive nab-paclitaxel



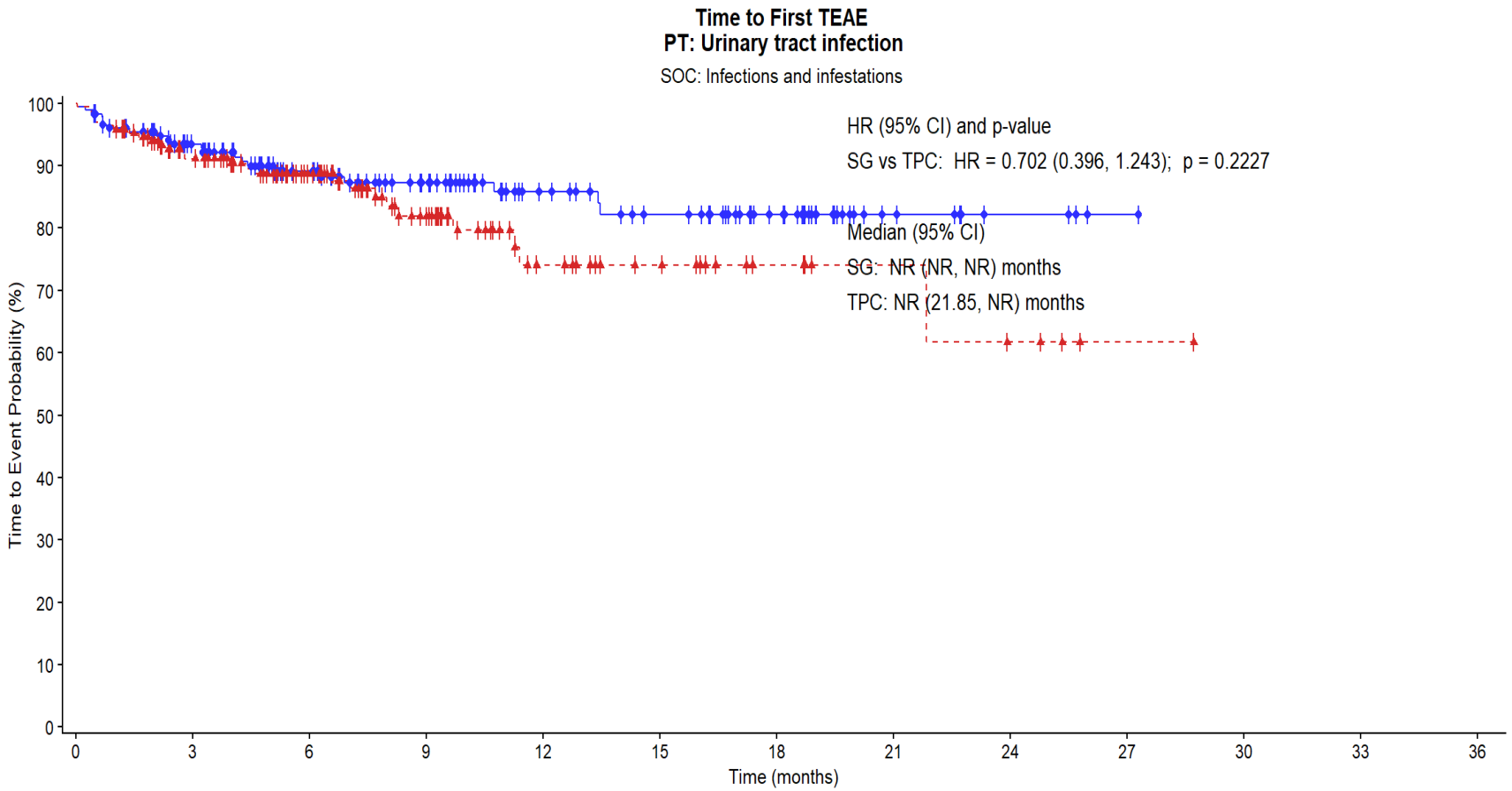
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.66. Figure 1.1.67: Kaplan Meier Plot of Time to First TEAE by PT Upper respiratory tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel



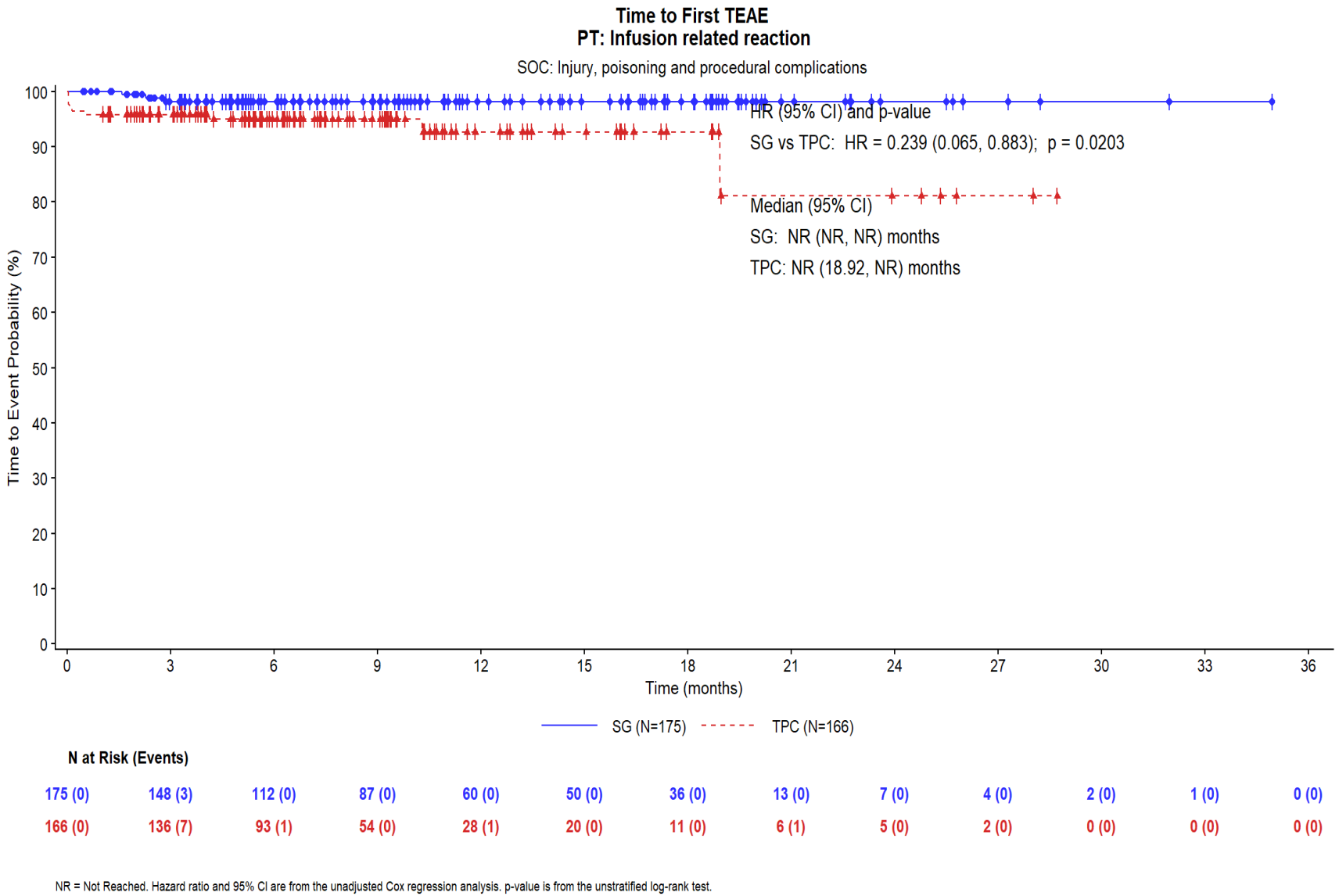
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.67. Figure 1.1.68: Kaplan Meier Plot of Time to First TEAE by PT Urinary tract infection — mSAF — Excluding patients preselected to receive nab-paclitaxel



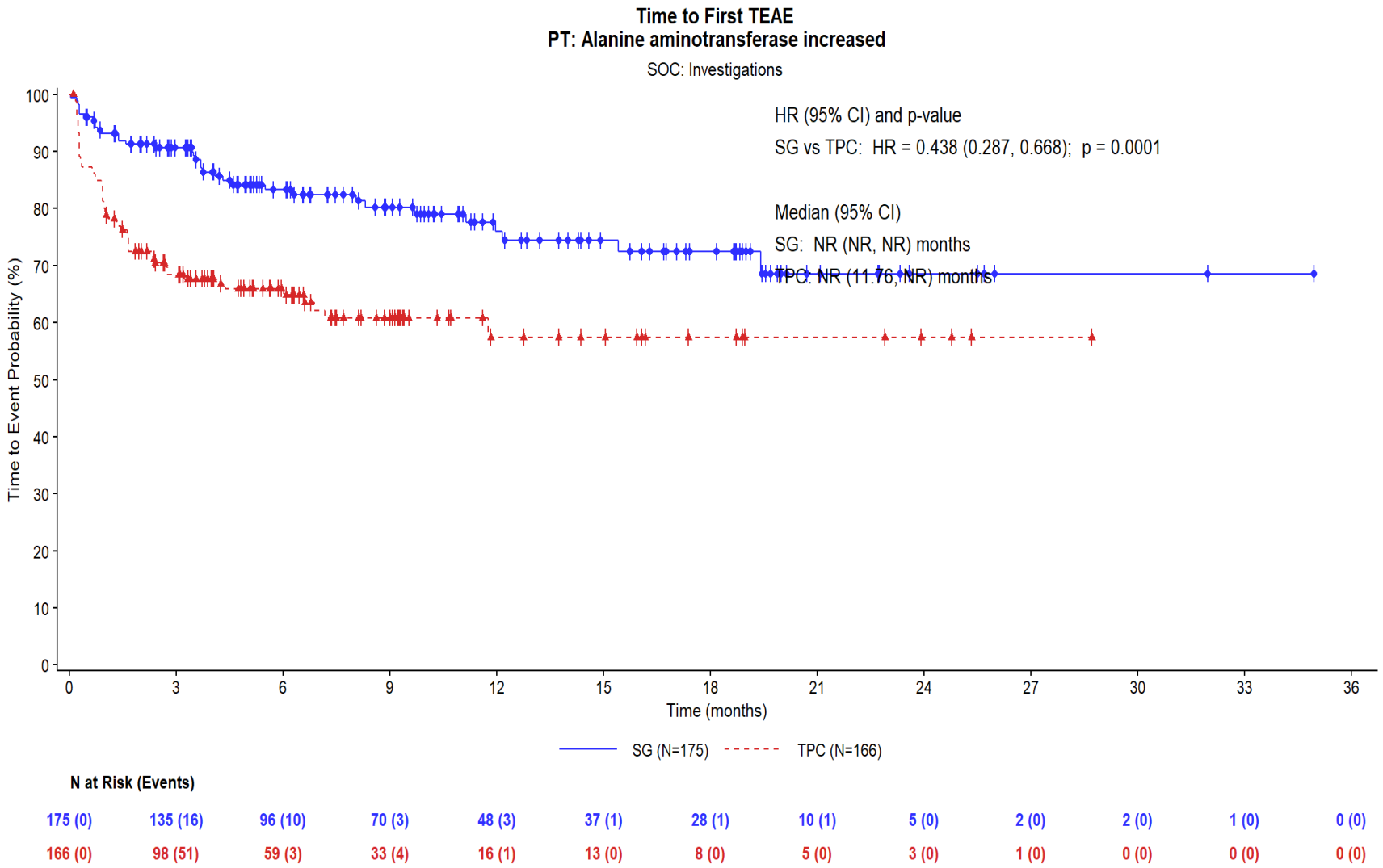
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.68. Figure 1.1.69: Kaplan Meier Plot of Time to First TEAE by PT Infusion related reaction — mSAF — Excluding patients preselected to receive nab-paclitaxel



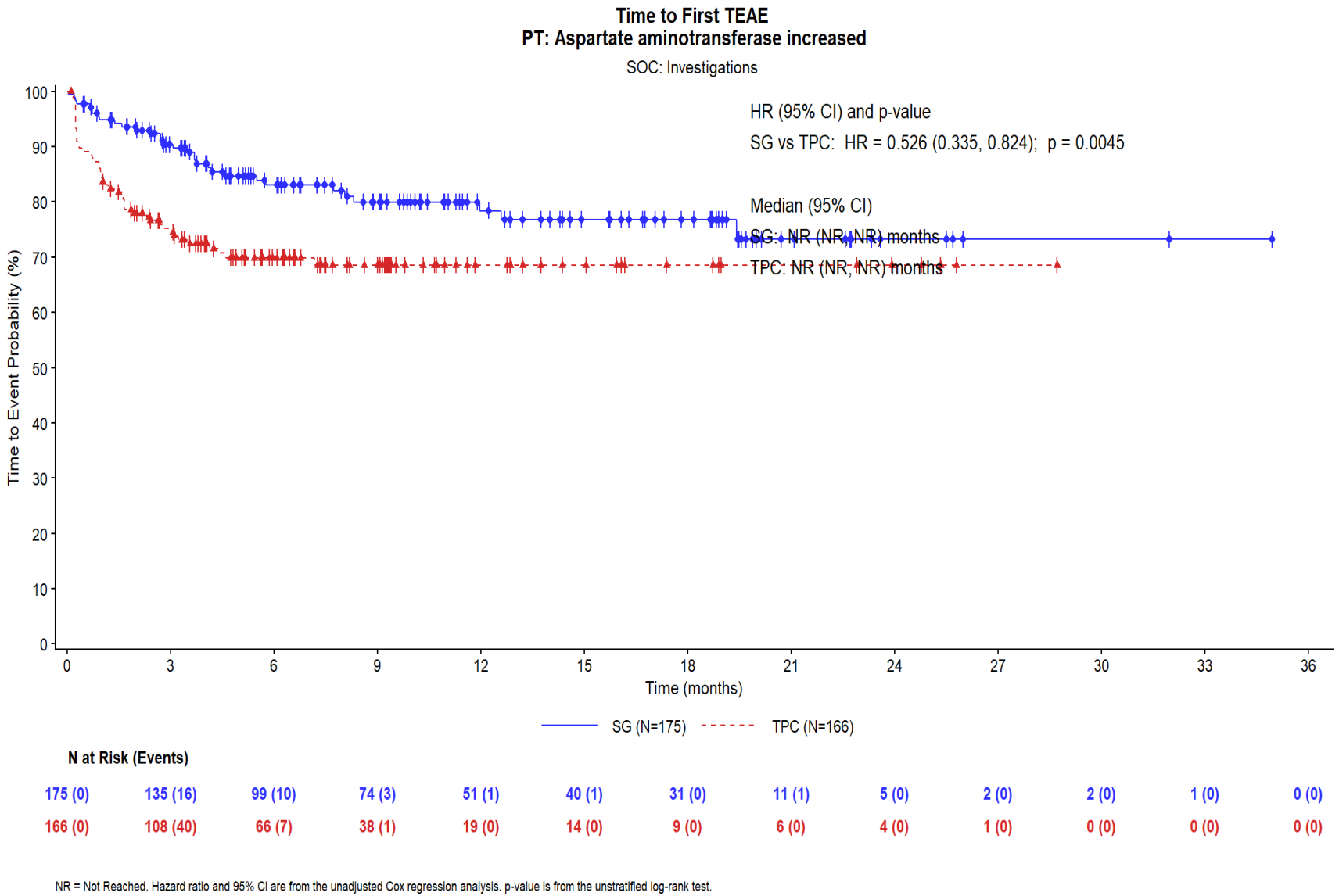
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.69. Figure 1.1.70: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



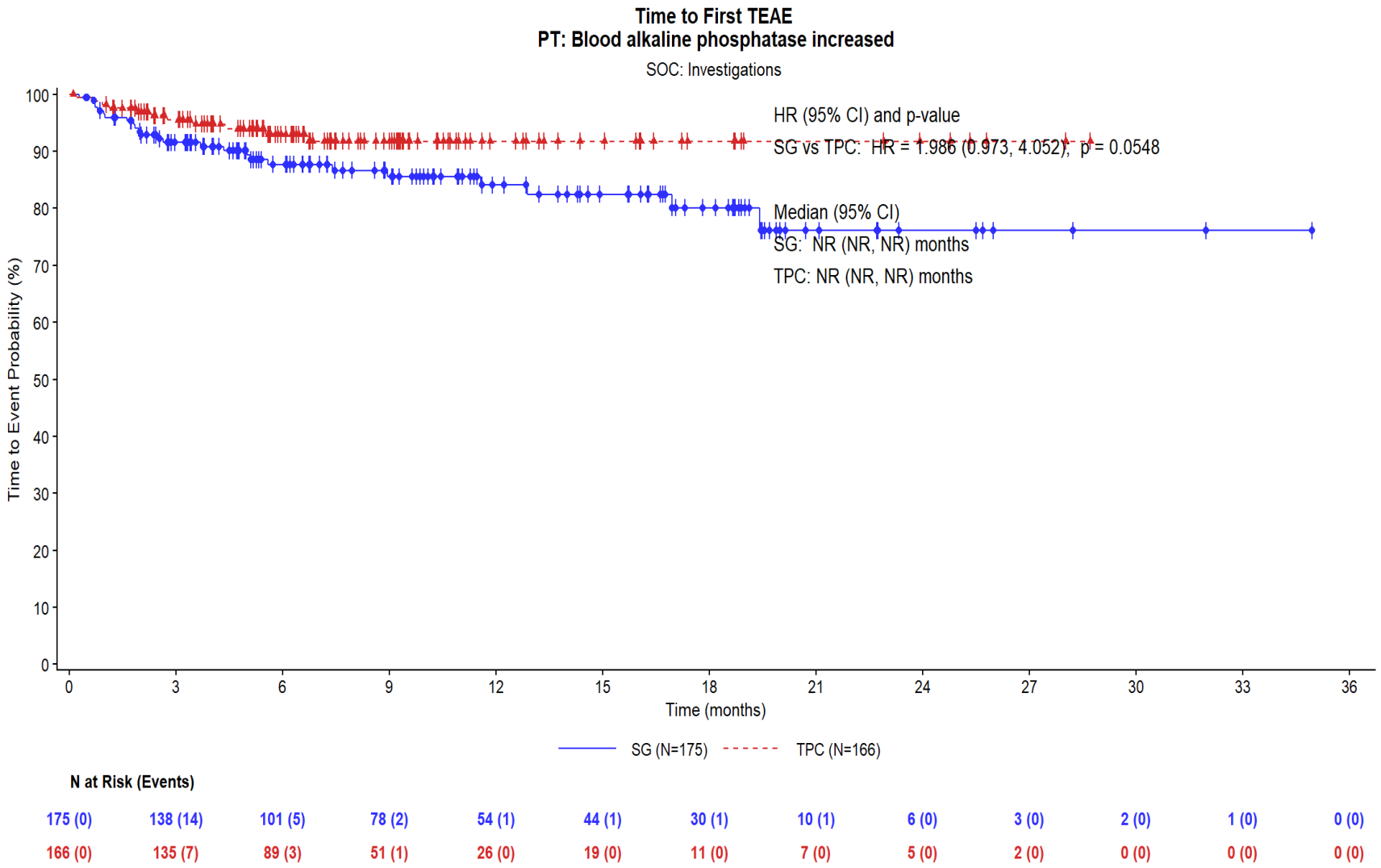
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.70. Figure 1.1.71: Kaplan Meier Plot of Time to First TEAE by PT Aspartate aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



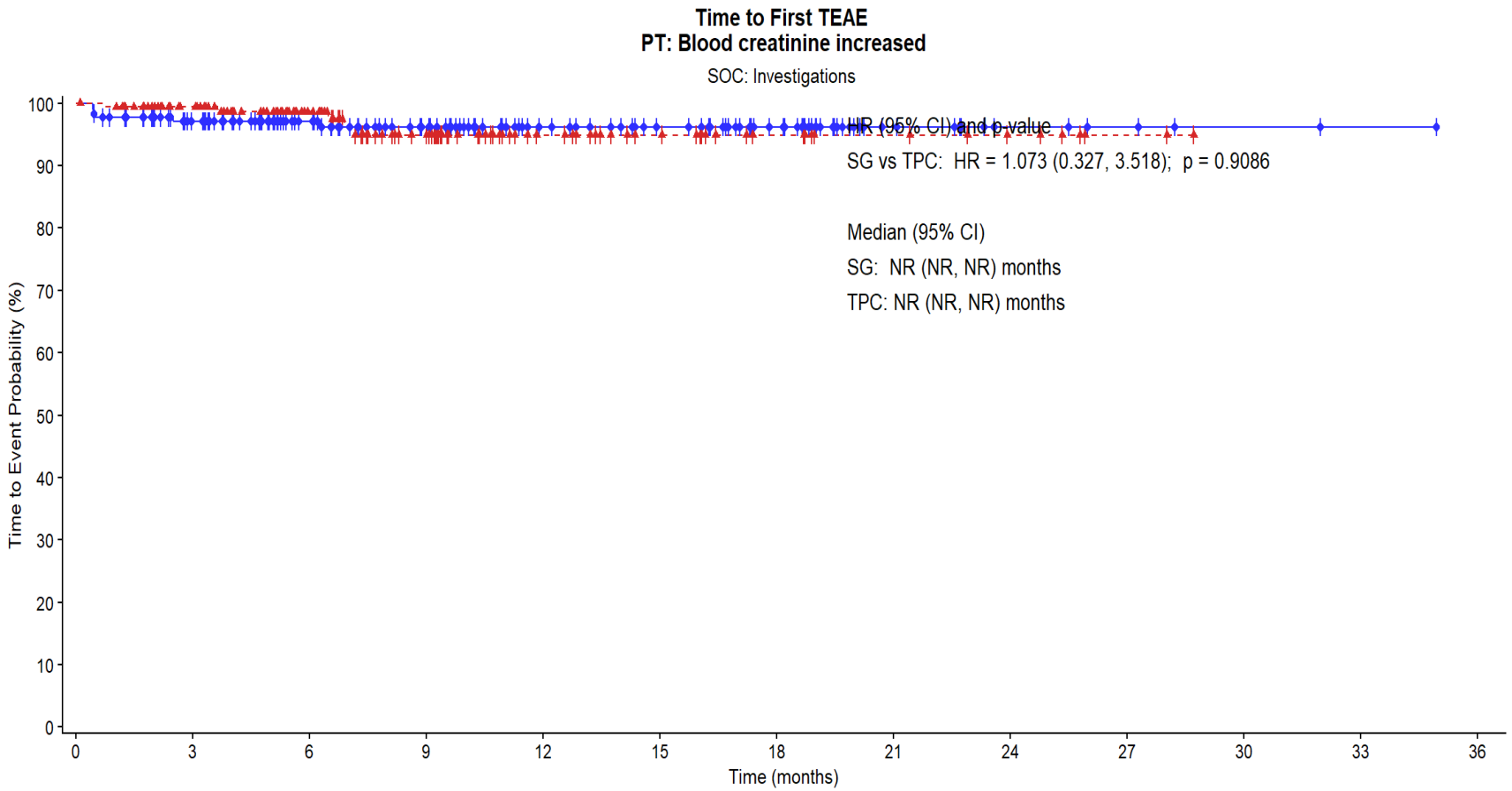
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.71. Figure 1.1.72: Kaplan Meier Plot of Time to First TEAE by PT Blood alkaline phosphatase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



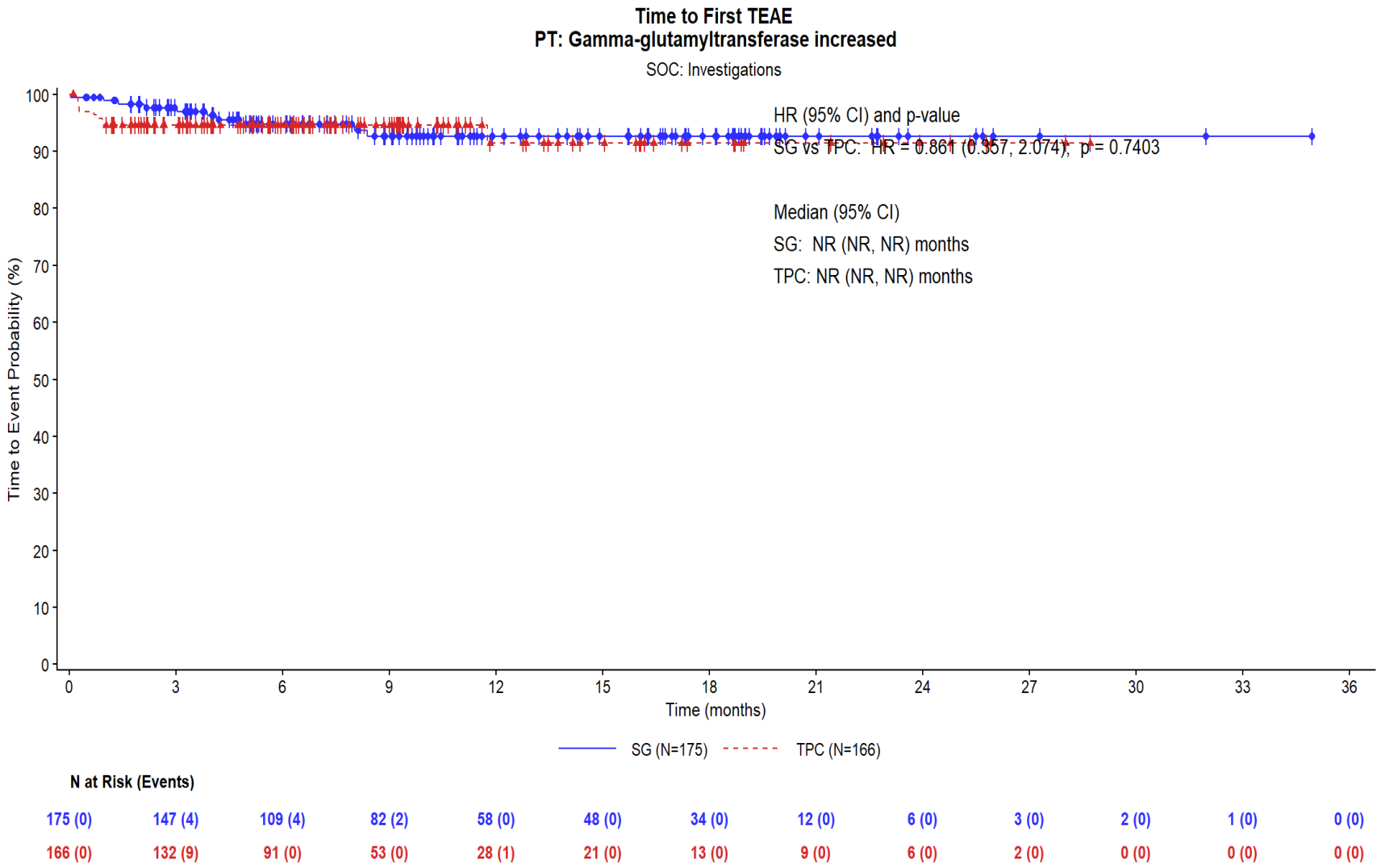
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.72. Figure 1.1.73: Kaplan Meier Plot of Time to First TEAE by PT Blood creatinine increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



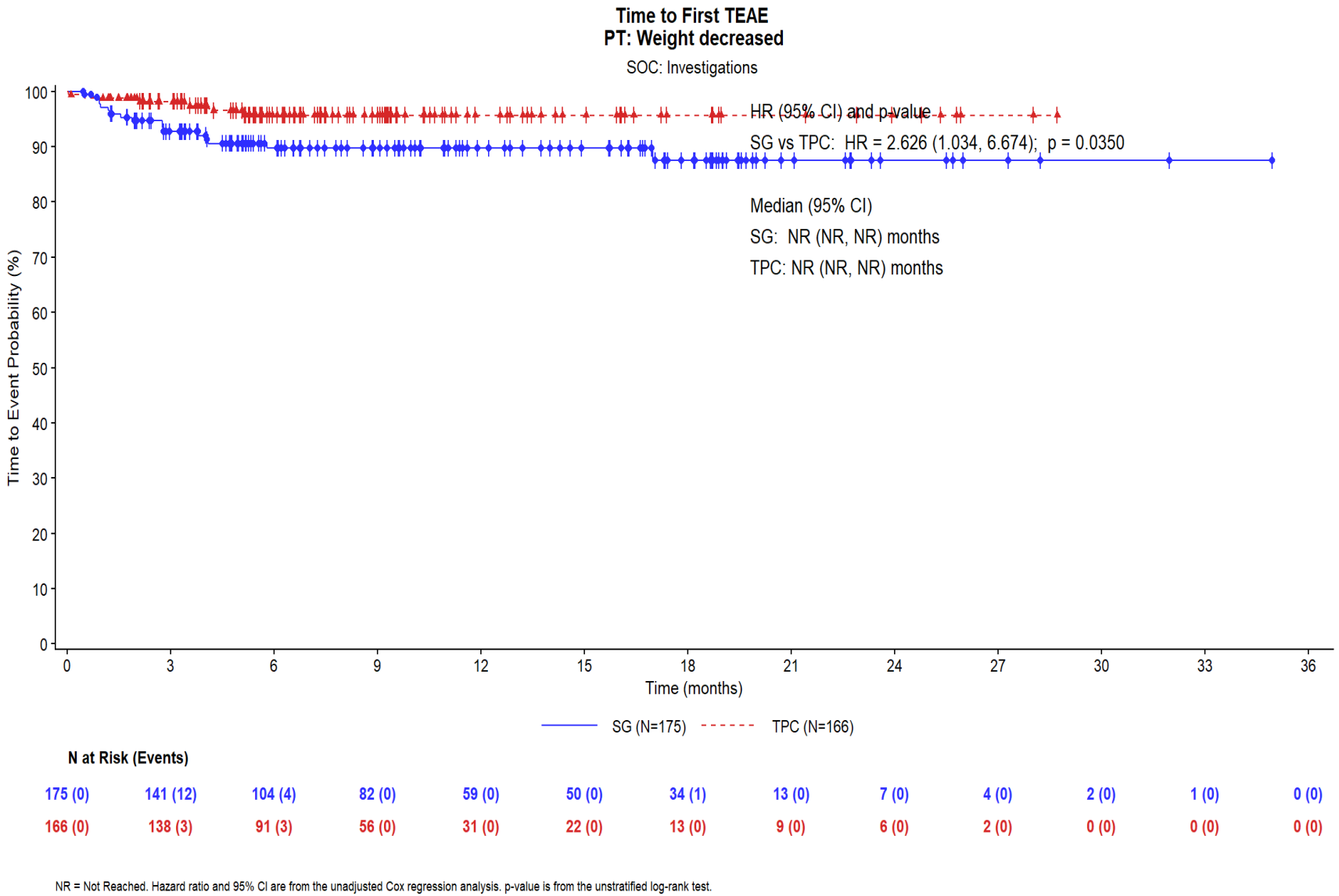
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.73. Figure 1.1.74: Kaplan Meier Plot of Time to First TEAE by PT Gamma glutamyltransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



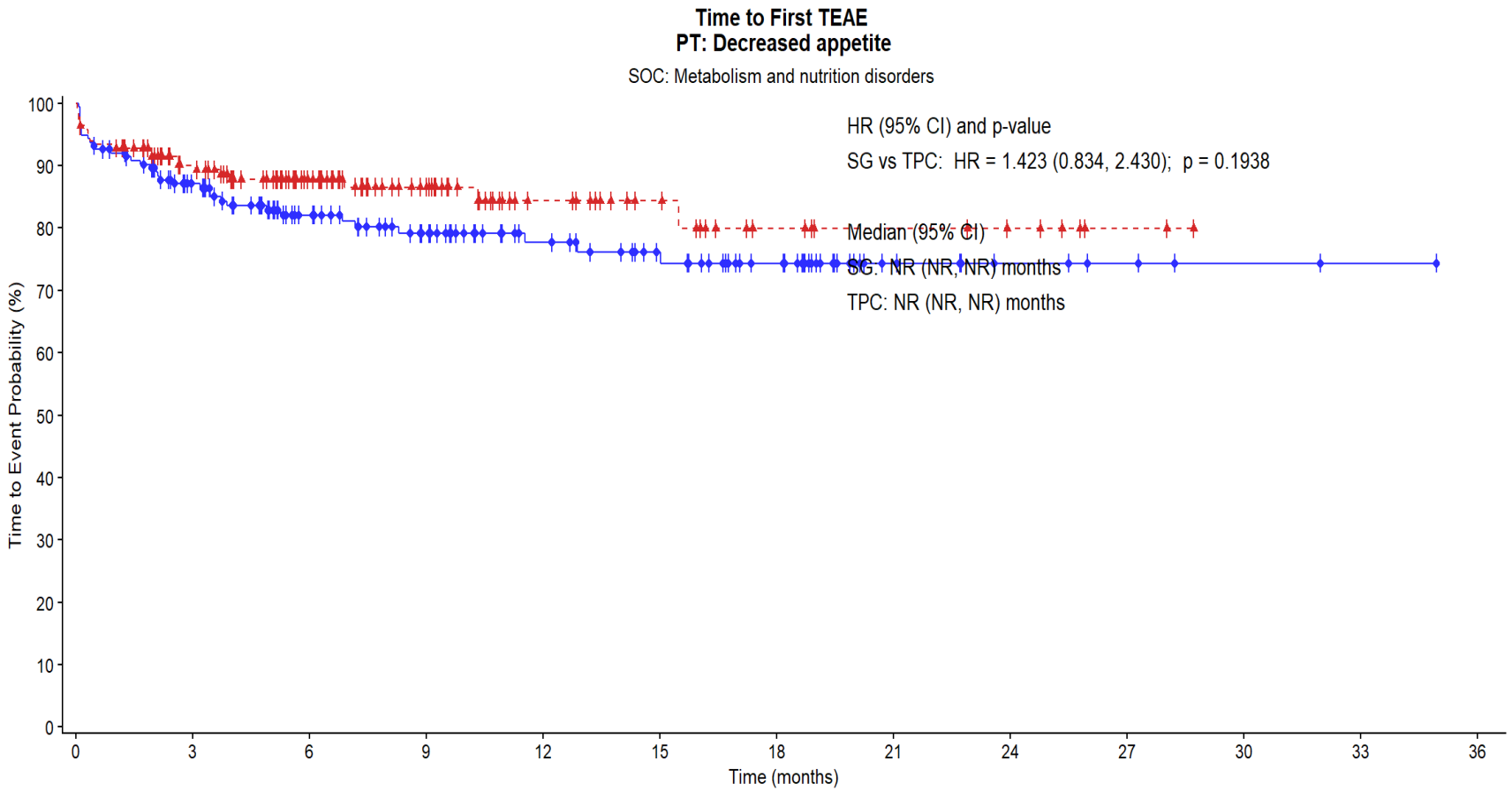
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.74. Figure 1.1.75: Kaplan Meier Plot of Time to First TEAE by PT Weight decreased — mSAF — Excluding patients preselected to receive nab-paclitaxel



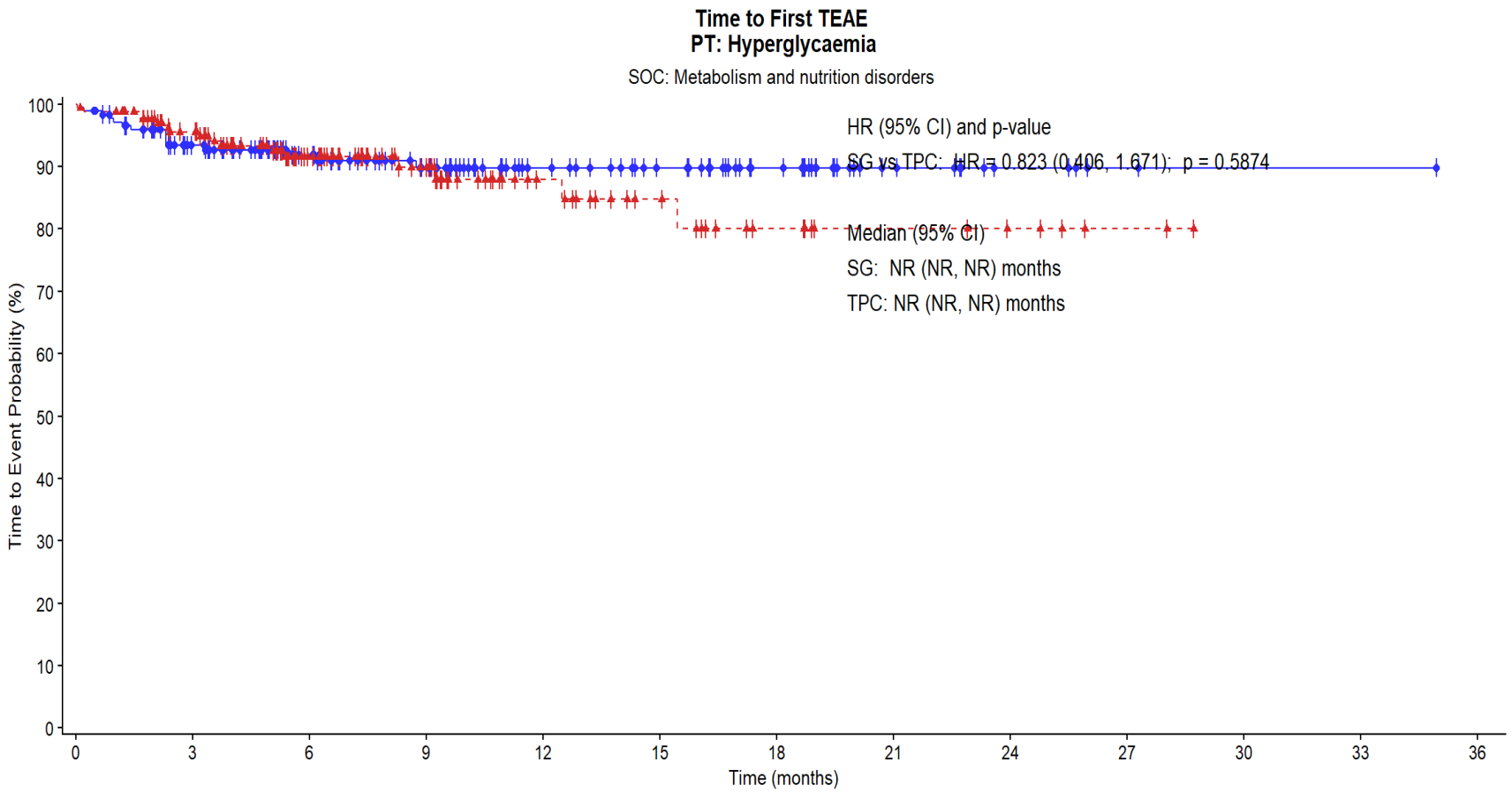
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.75. Figure 1.1.76: Kaplan Meier Plot of Time to First TEAE by PT Decreased appetite — mSAF — Excluding patients preselected to receive nab-paclitaxel



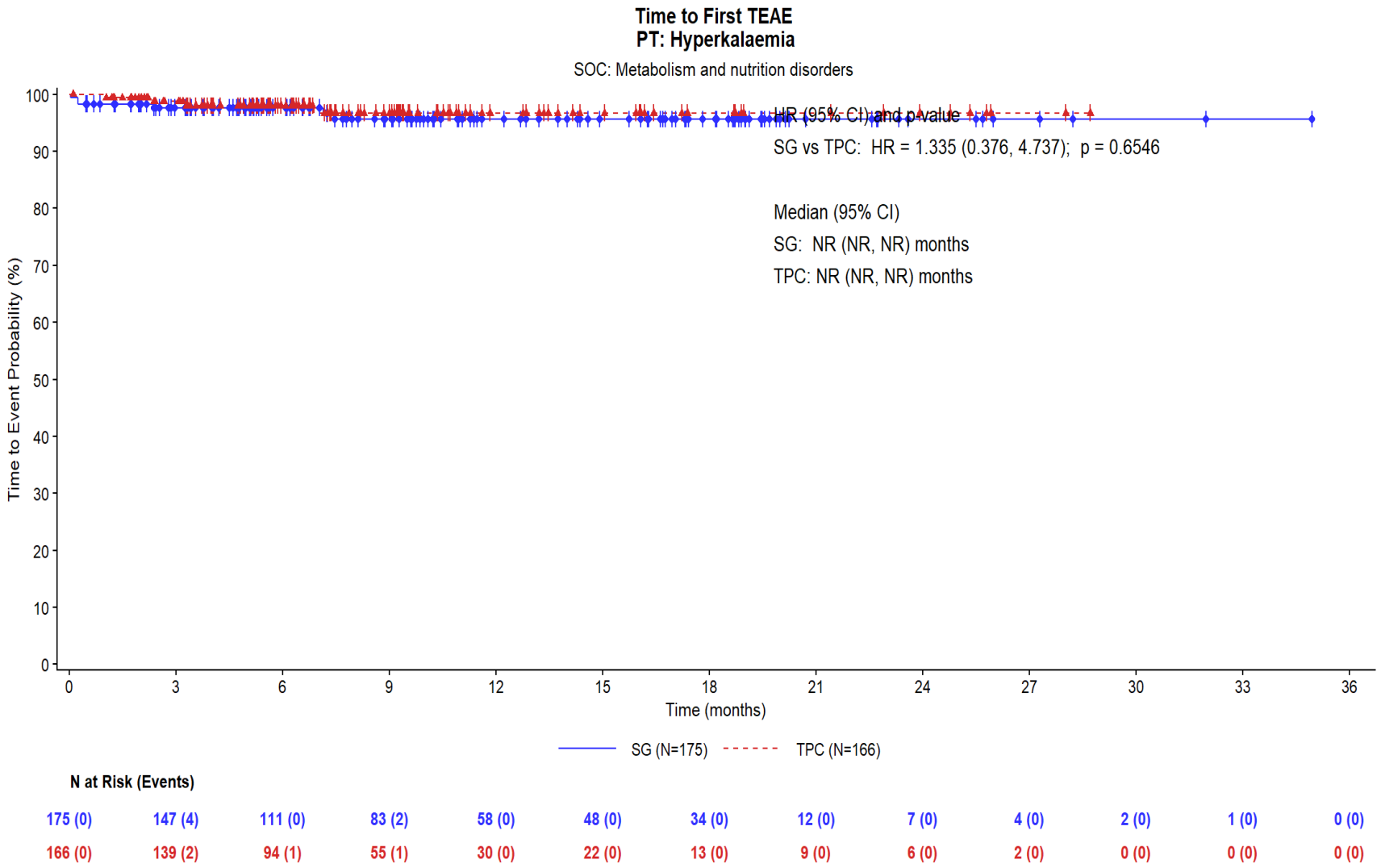
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.76. Figure 1.1.77: Kaplan Meier Plot of Time to First TEAE by PT Hyperglycaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



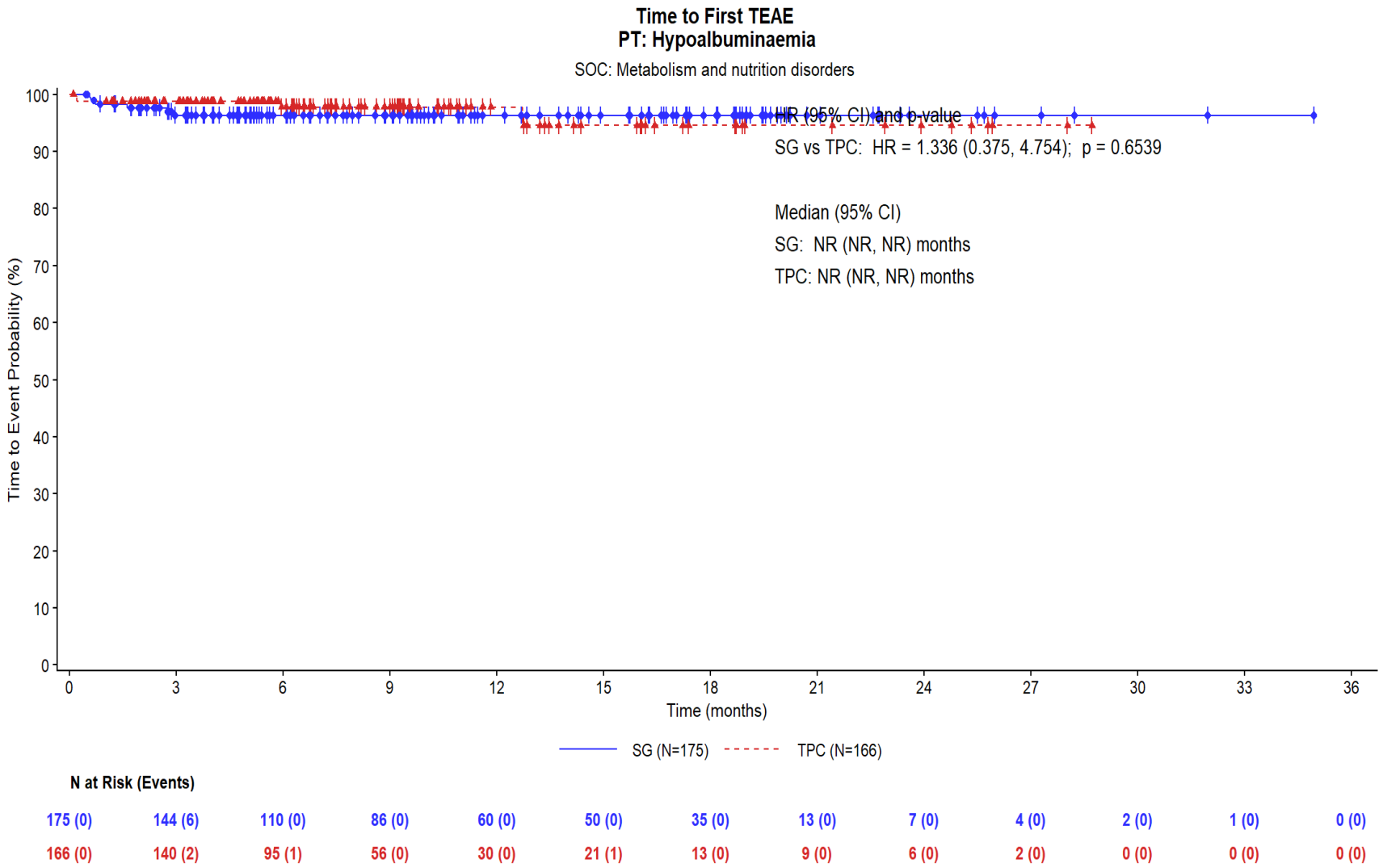
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.77. Figure 1.1.78: Kaplan Meier Plot of Time to First TEAE by PT Hyperkalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



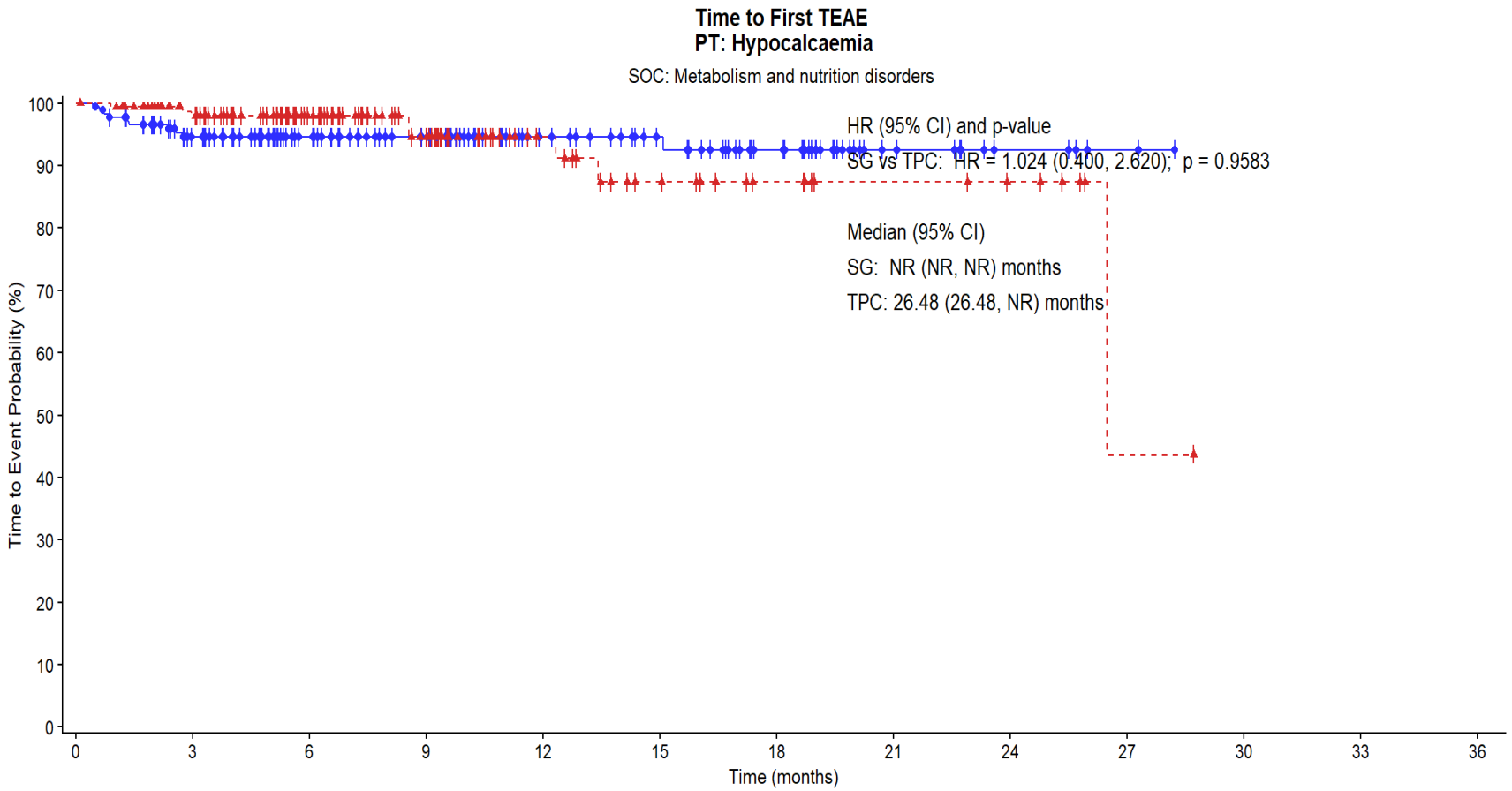
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8.78. Figure 1.1.79: Kaplan Meier Plot of Time to First TEAE by PT Hypoalbuminaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



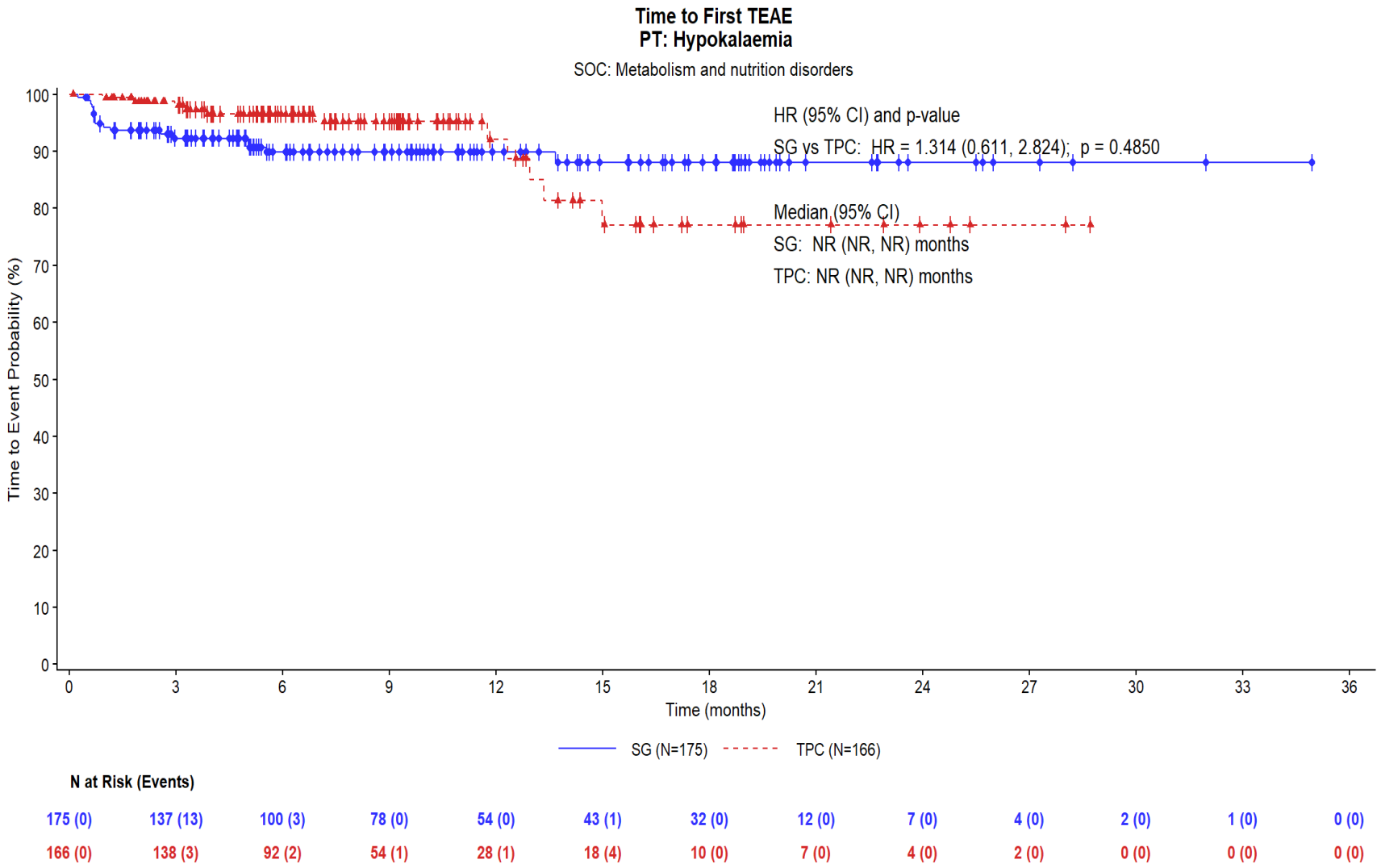
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.79. Figure 1.1.80: Kaplan Meier Plot of Time to First TEAE by PT Hypocalcaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



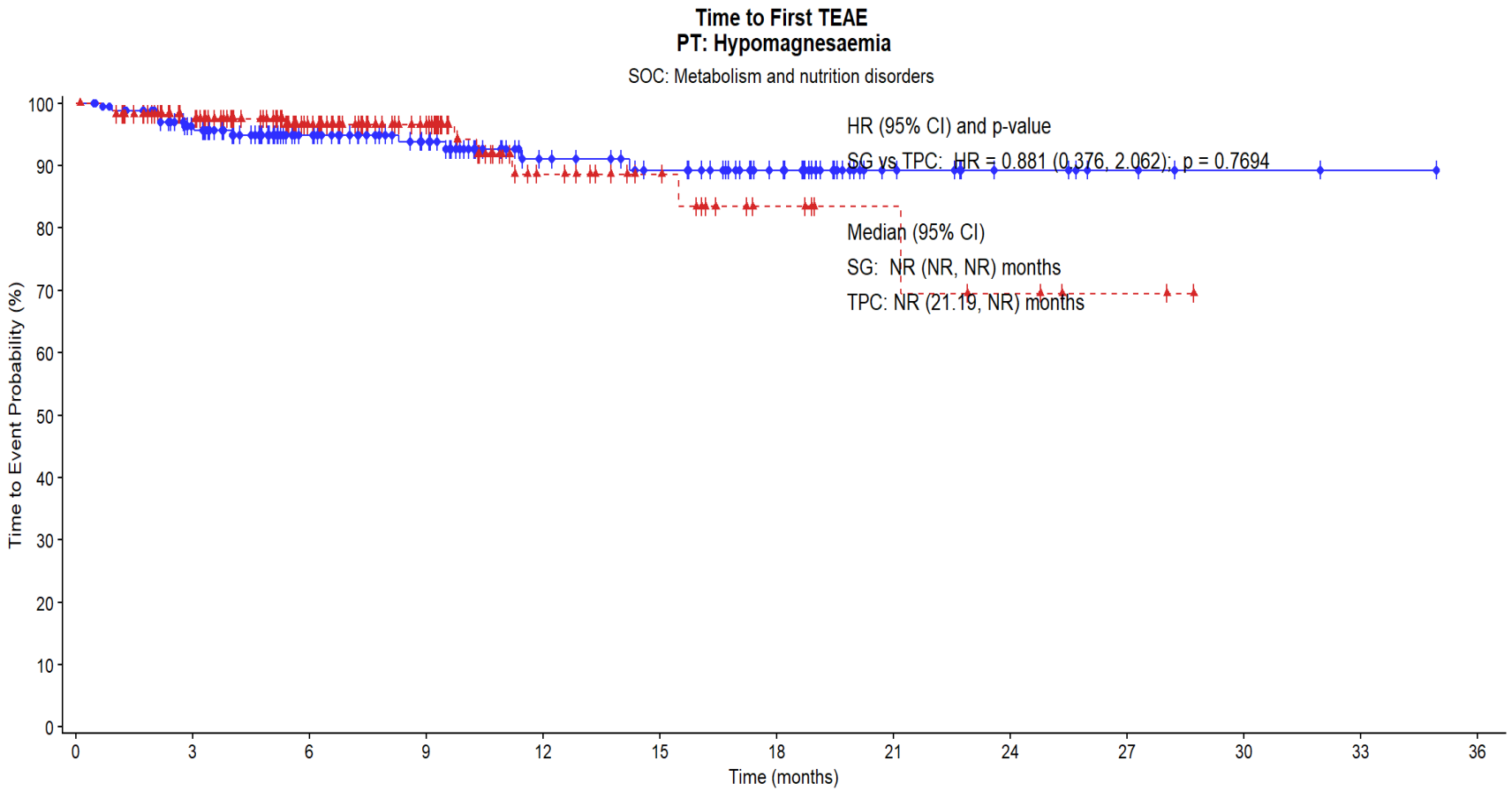
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.80. Figure 1.1.81: Kaplan Meier Plot of Time to First TEAE by PT Hypokalaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



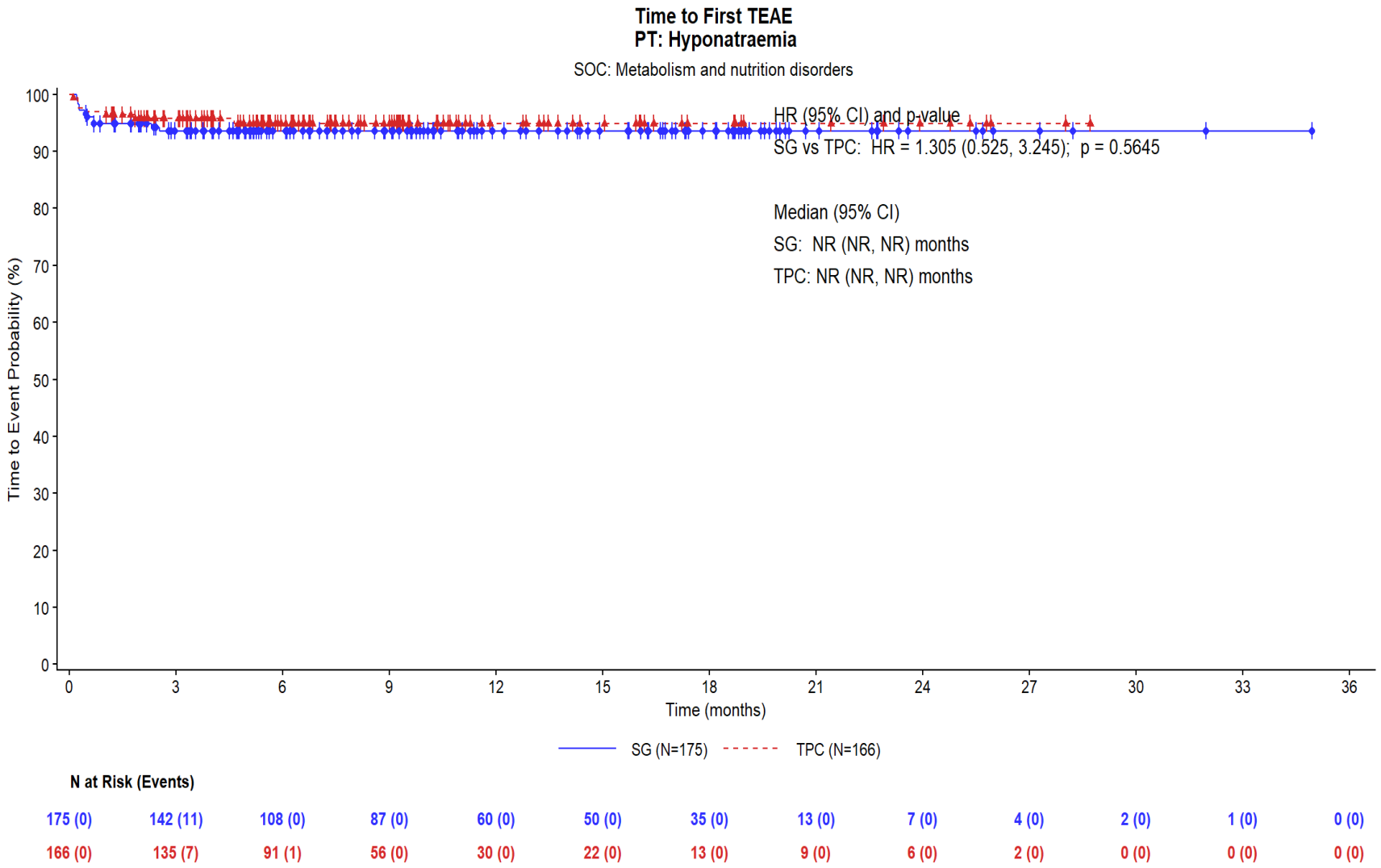
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.81. Figure 1.1.82: Kaplan Meier Plot of Time to First TEAE by PT Hypomagnesaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



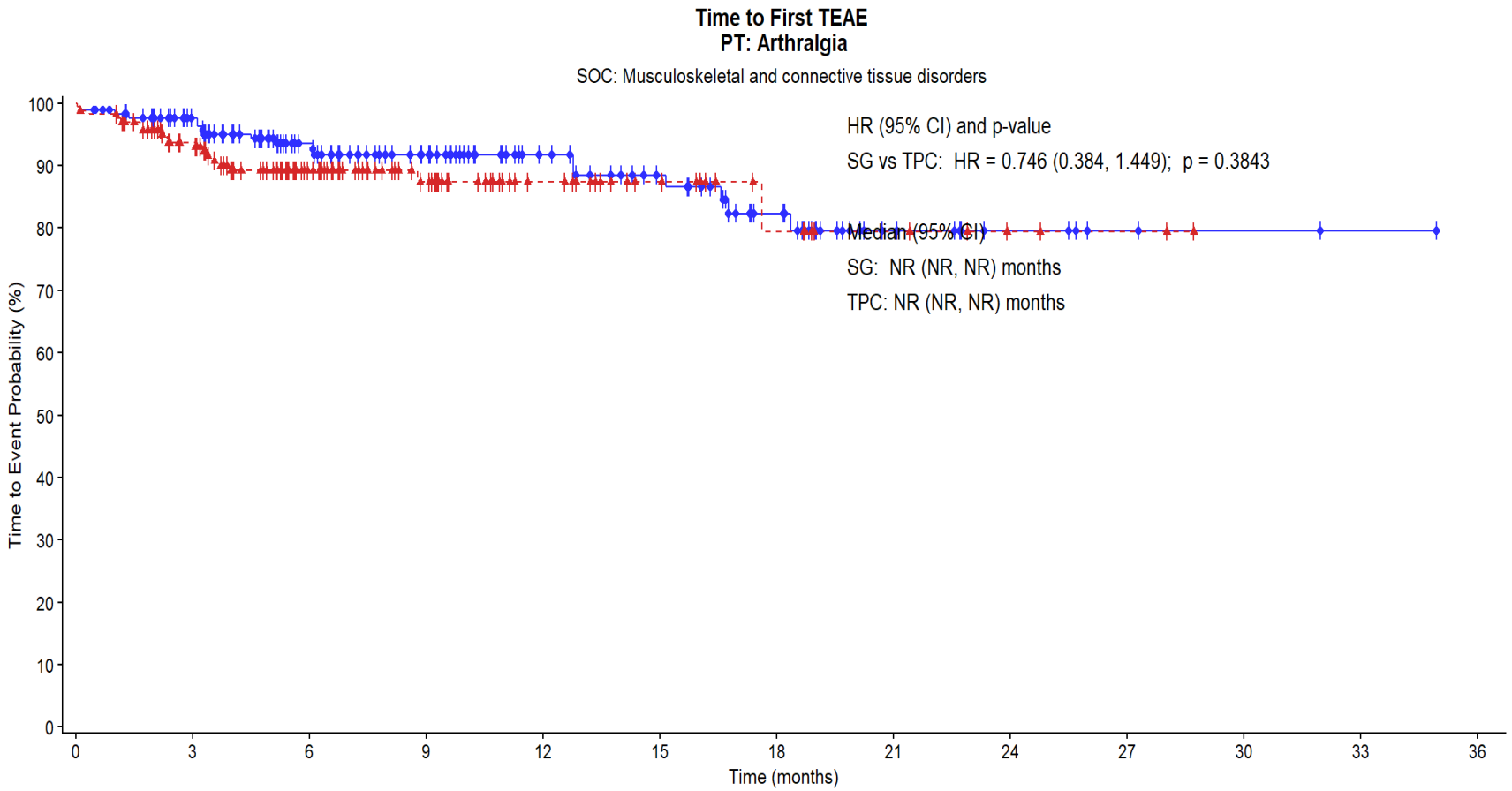
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.82. Figure 1.1.83: Kaplan Meier Plot of Time to First TEAE by PT Hyponatraemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



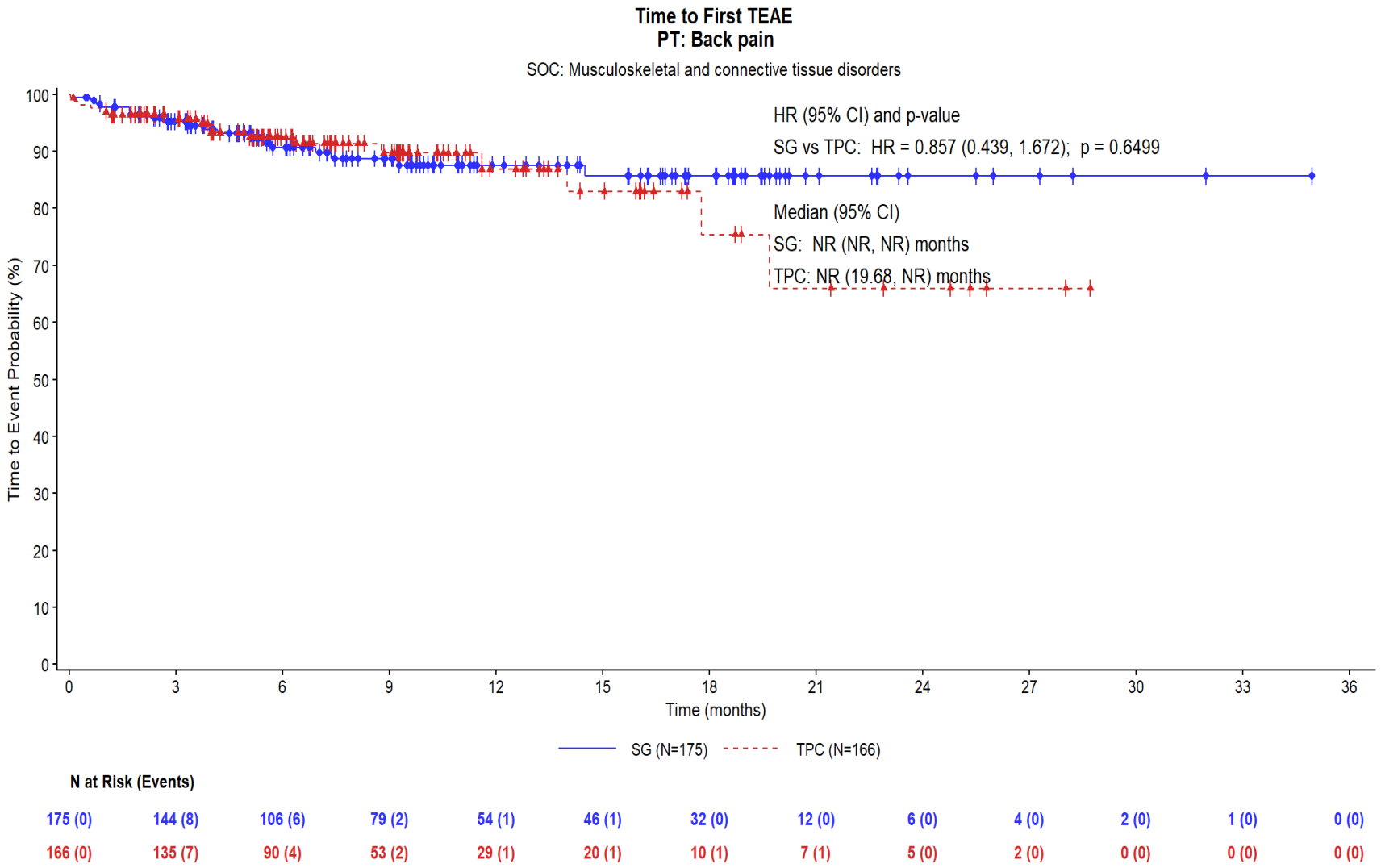
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.83. Figure 1.1.84: Kaplan Meier Plot of Time to First TEAE by PT Arthralgia — mSAF — Excluding patients preselected to receive nab-paclitaxel



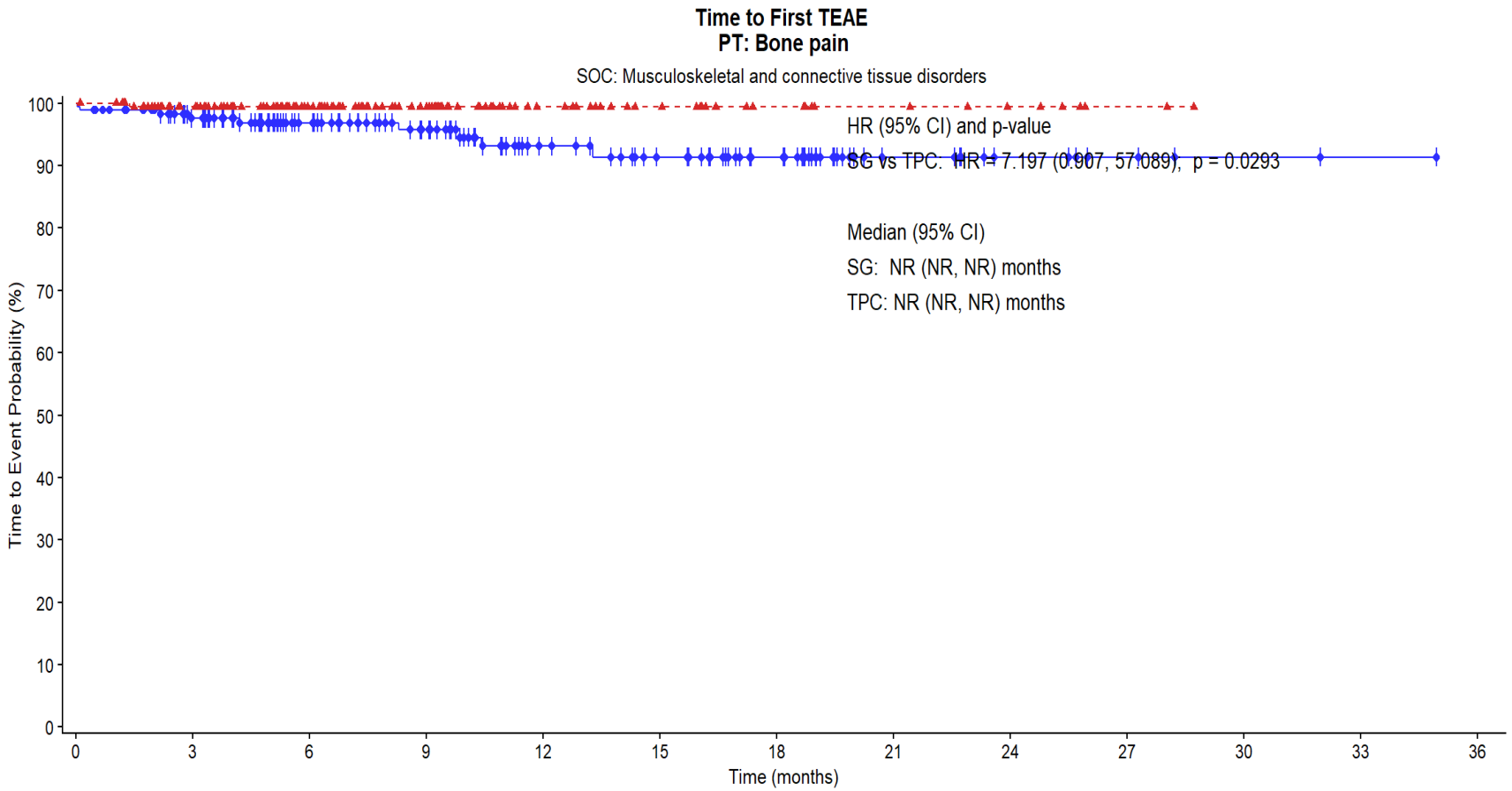
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.84. Figure 1.1.85: Kaplan Meier Plot of Time to First TEAE by PT Back pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



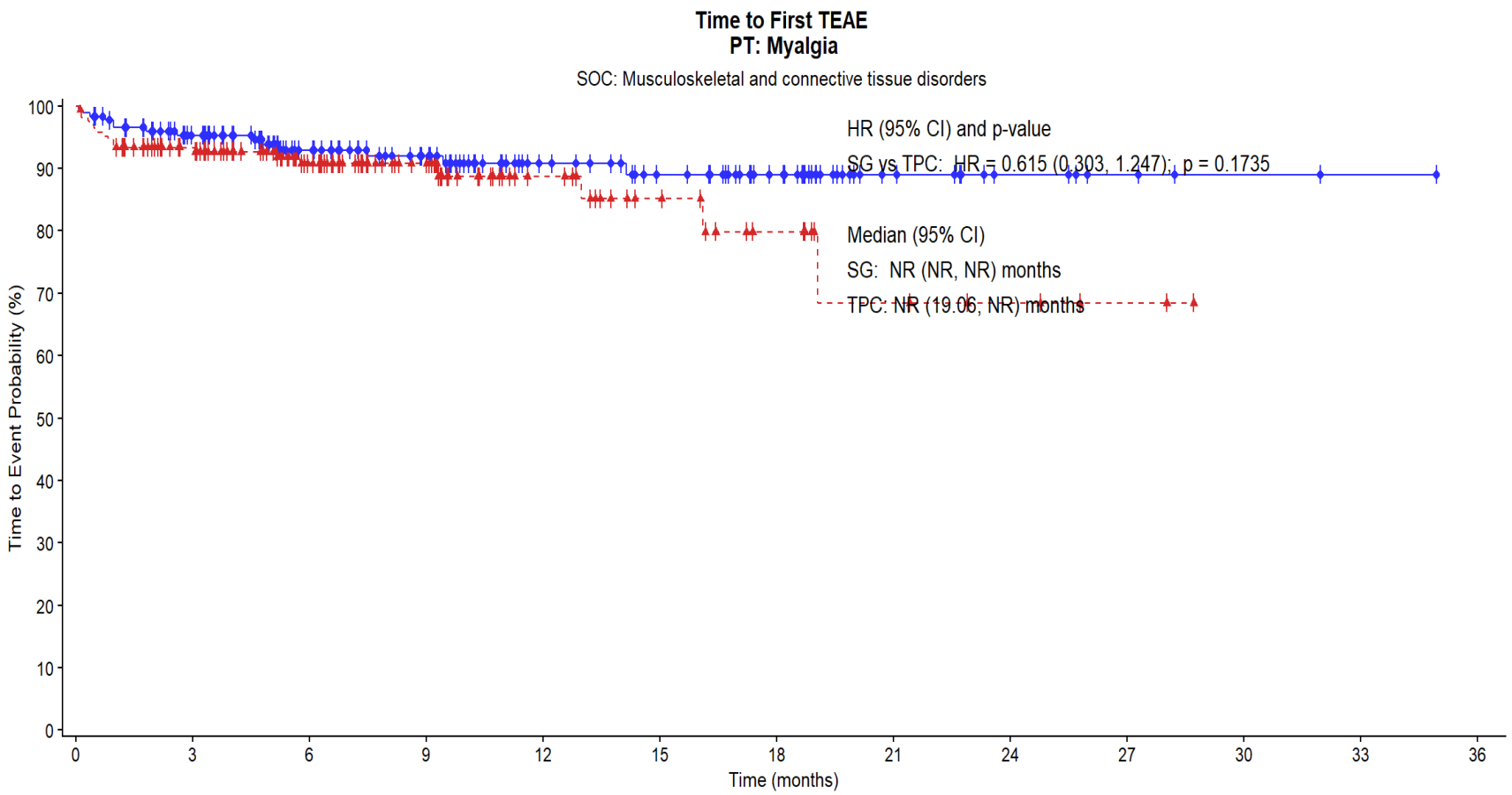
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.85. Figure 1.1.86: Kaplan Meier Plot of Time to First TEAE by PT Bone pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



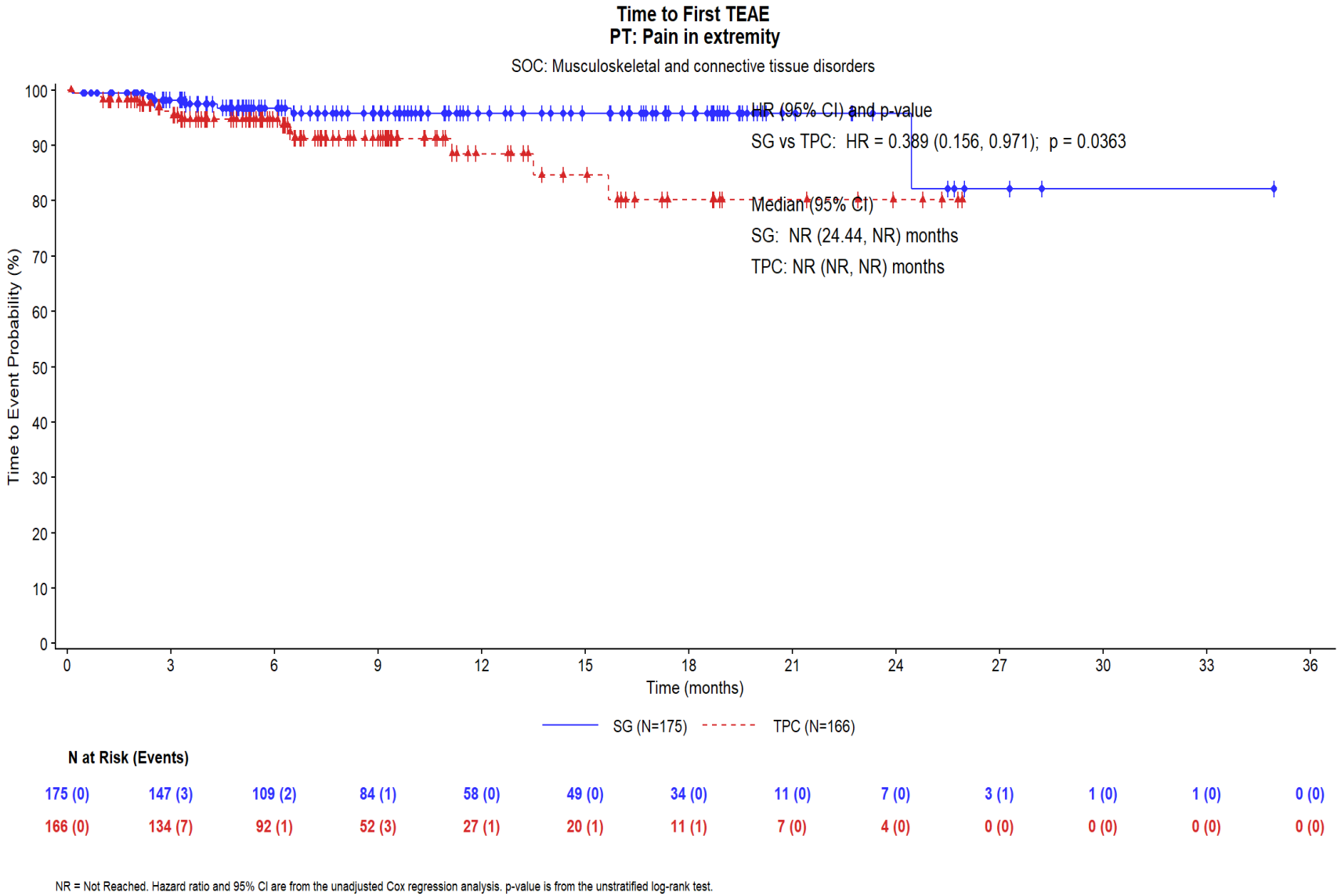
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.86. Figure 1.1.87: Kaplan Meier Plot of Time to First TEAE by PT Myalgia — mSAF — Excluding patients preselected to receive nab-paclitaxel



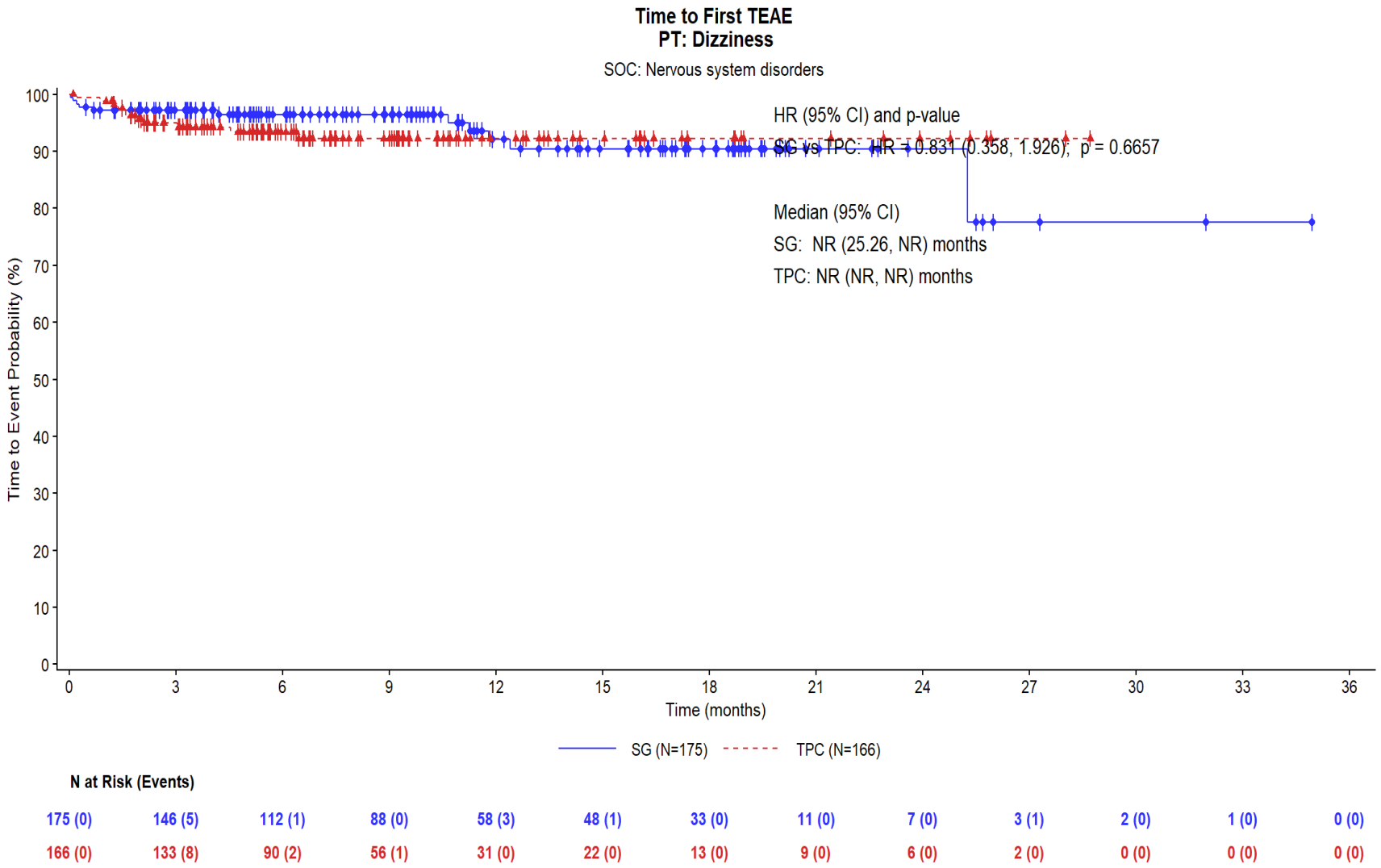
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.87. Figure 1.1.88: Kaplan Meier Plot of Time to First TEAE by PT Pain in extremity — mSAF — Excluding patients preselected to receive nab-paclitaxel



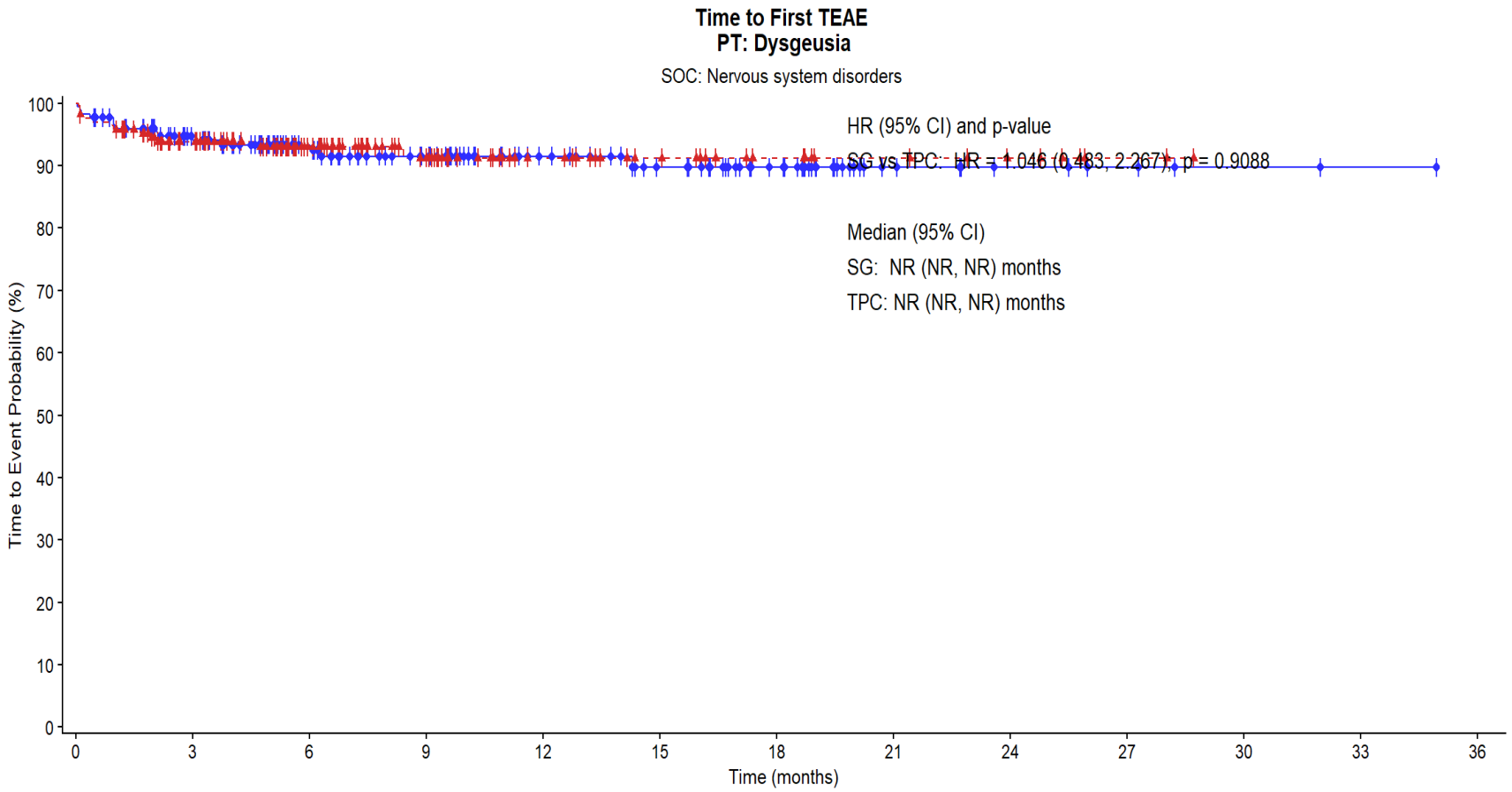
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.88. Figure 1.1.89: Kaplan Meier Plot of Time to First TEAE by PT Dizziness — mSAF — Excluding patients preselected to receive nab-paclitaxel



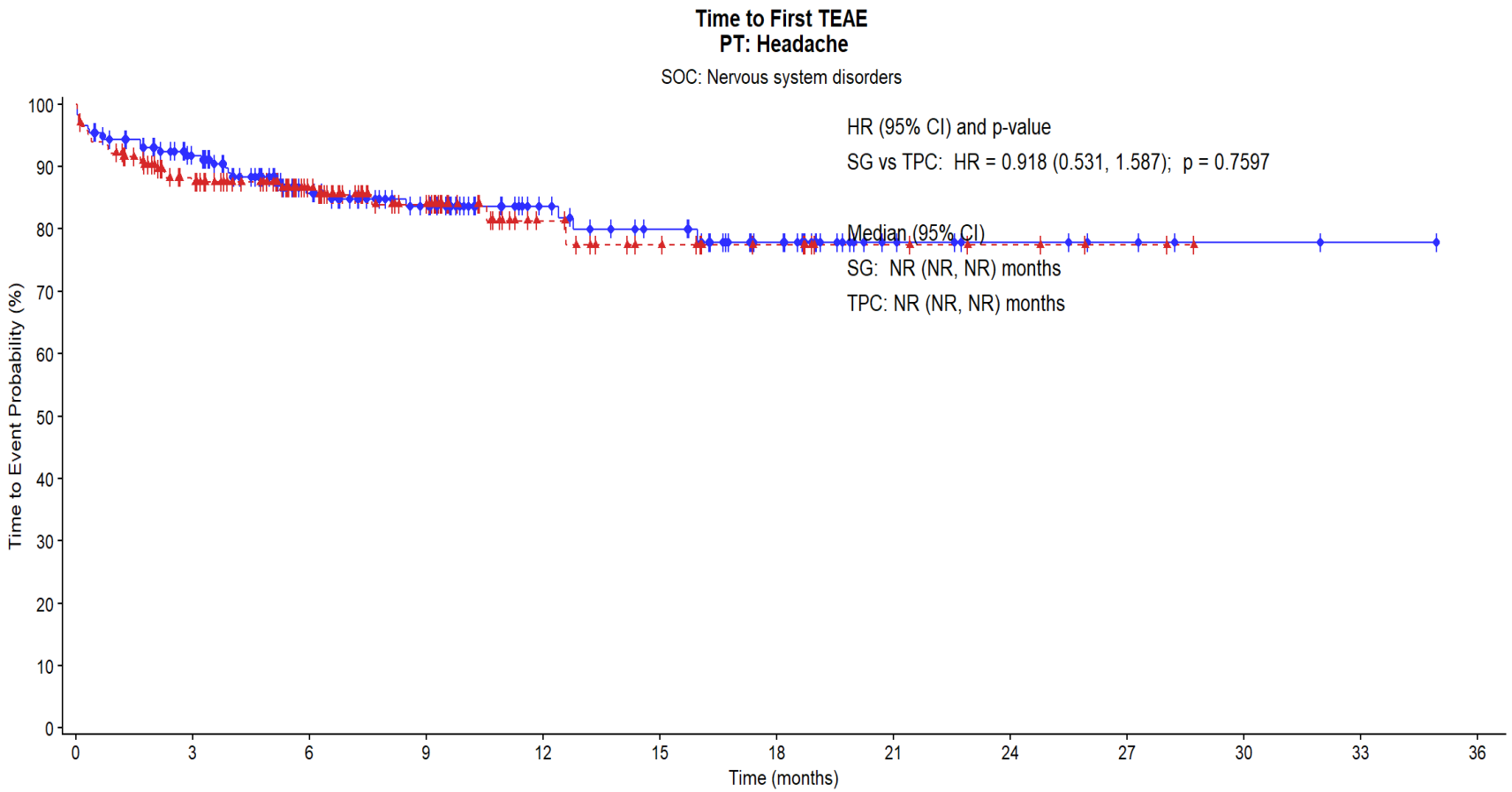
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.89. Figure 1.1.90: Kaplan Meier Plot of Time to First TEAE by PT Dysgeusia — mSAF — Excluding patients preselected to receive nab-paclitaxel



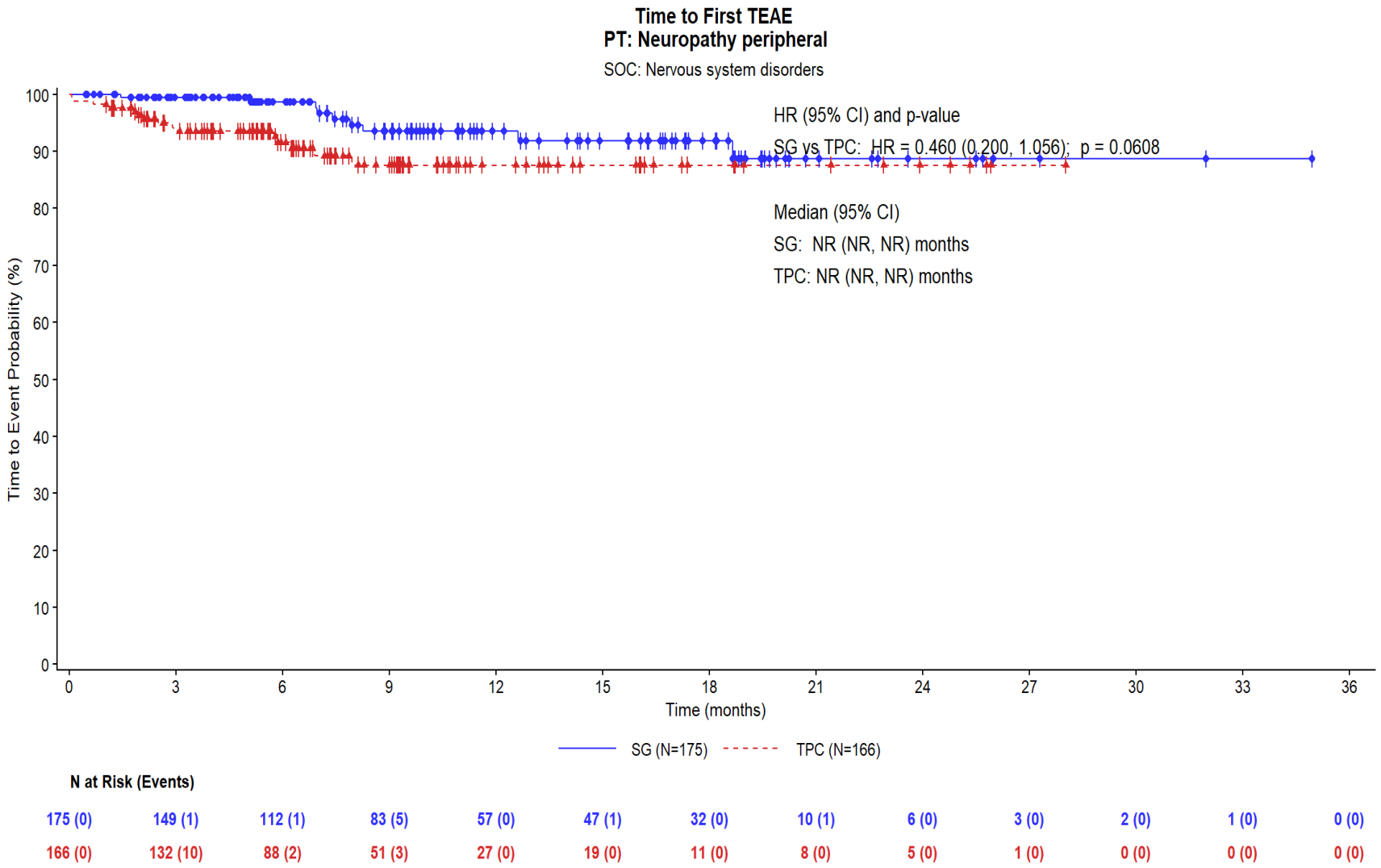
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.90. Figure 1.1.91: Kaplan Meier Plot of Time to First TEAE by PT Headache — mSAF — Excluding patients preselected to receive nab-paclitaxel



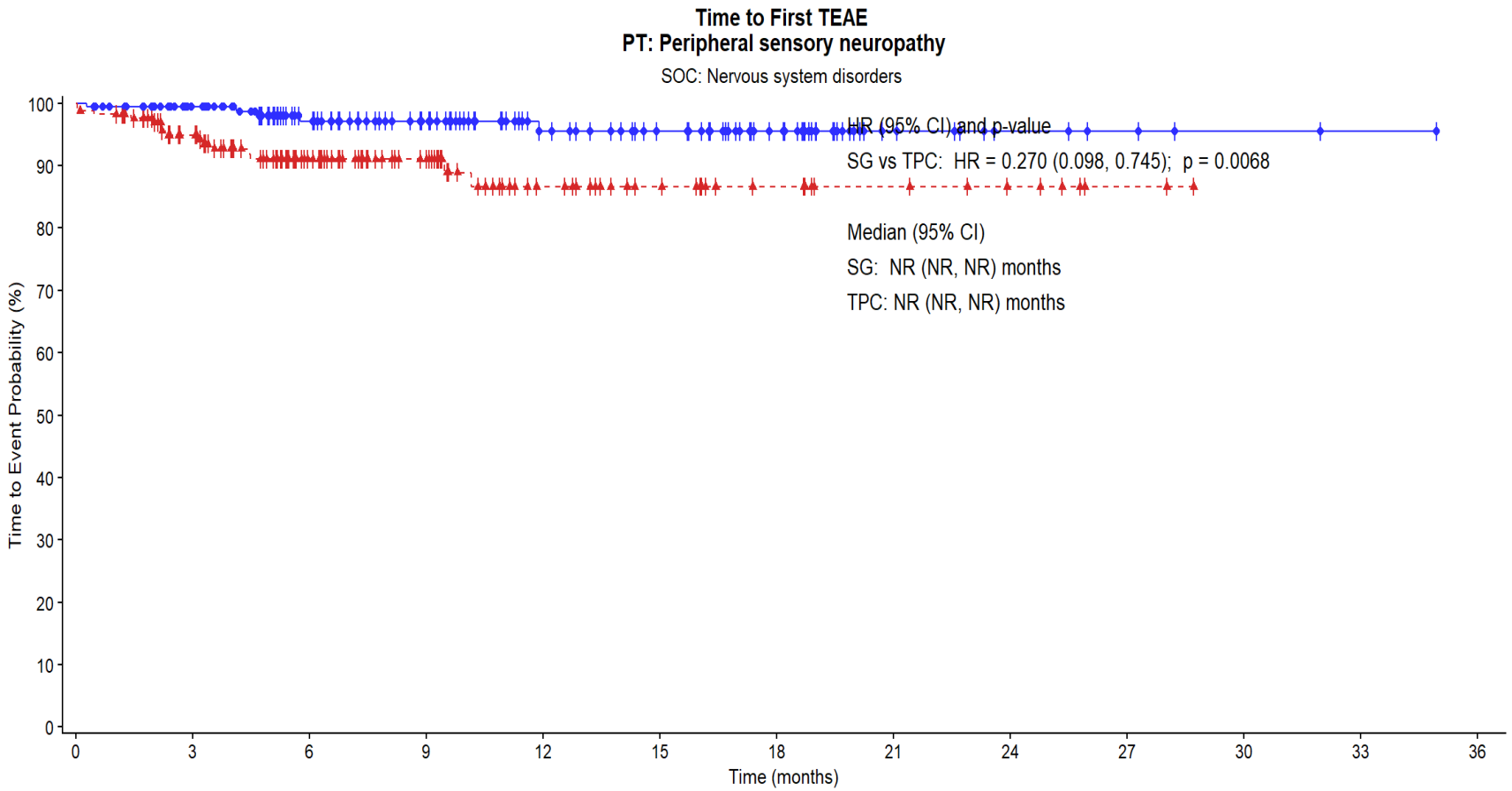
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.91. Figure 1.1.92: Kaplan Meier Plot of Time to First TEAE by PT Neuropathy peripheral — mSAF — Excluding patients preselected to receive nab-paclitaxel



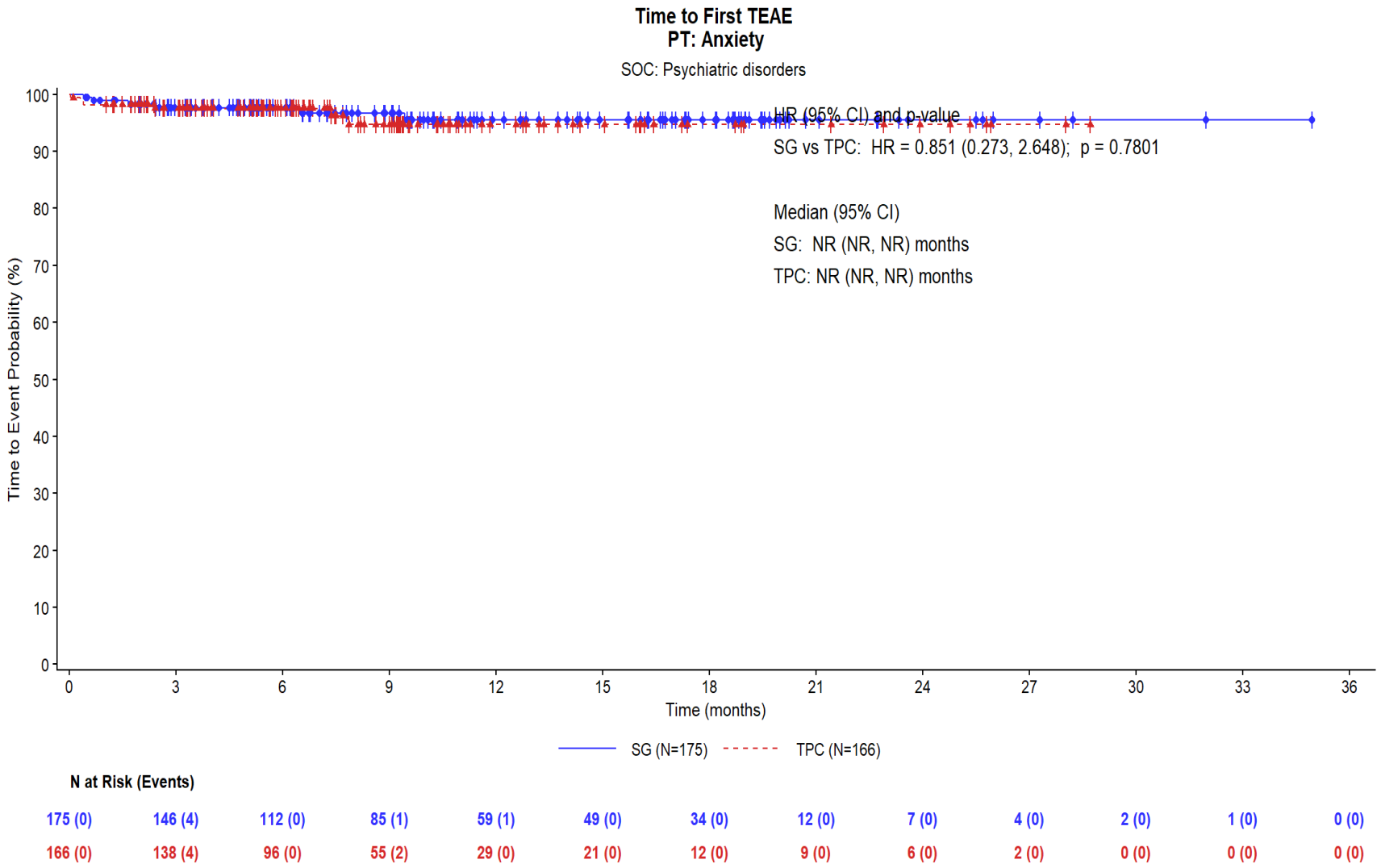
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.92. Figure 1.1.93: Kaplan Meier Plot of Time to First TEAE by PT Peripheral sensory neuropathy — mSAF — Excluding patients preselected to receive nab-paclitaxel



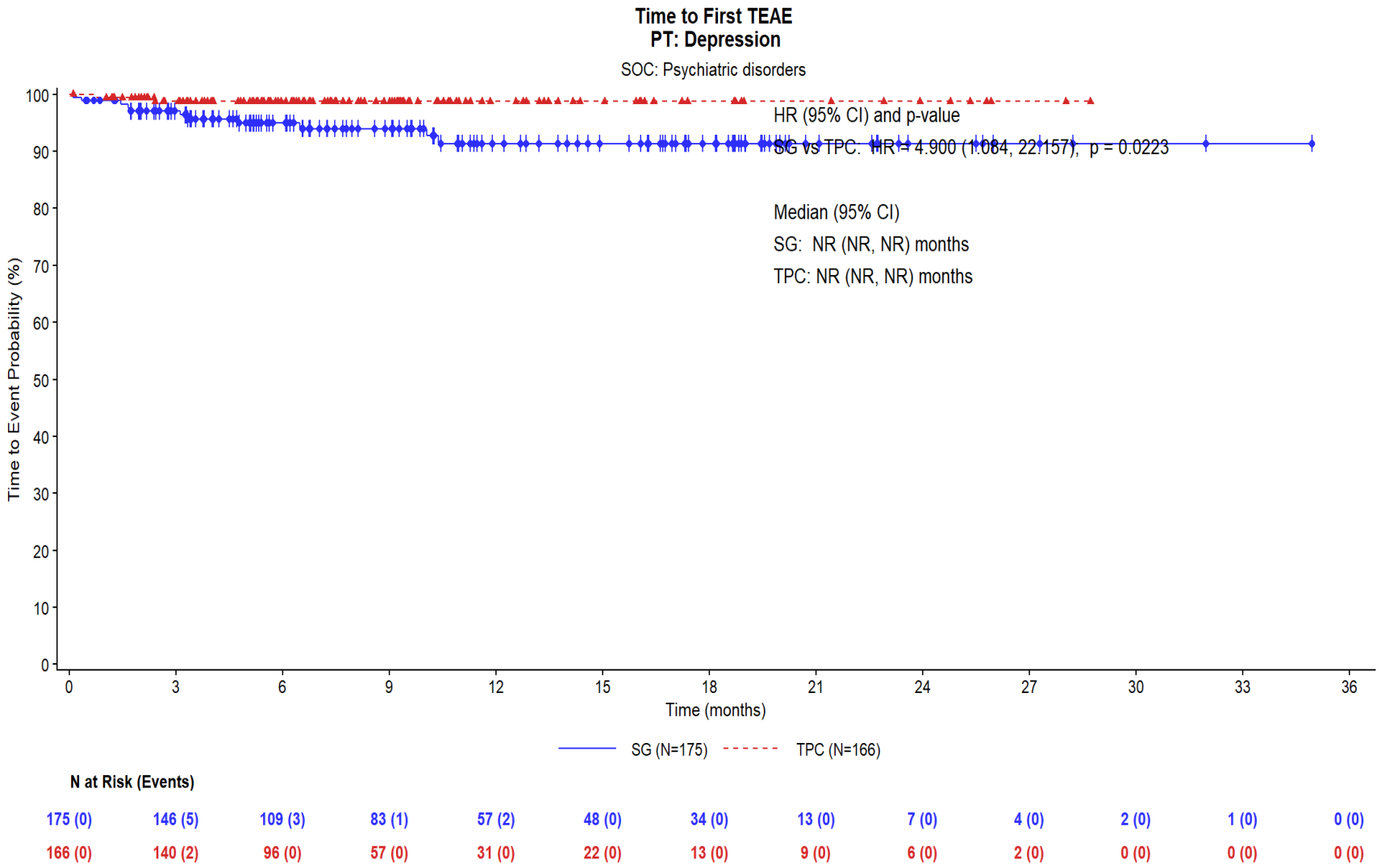
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.93. Figure 1.1.94: Kaplan Meier Plot of Time to First TEAE by PT Anxiety — mSAF — Excluding patients preselected to receive nab-paclitaxel



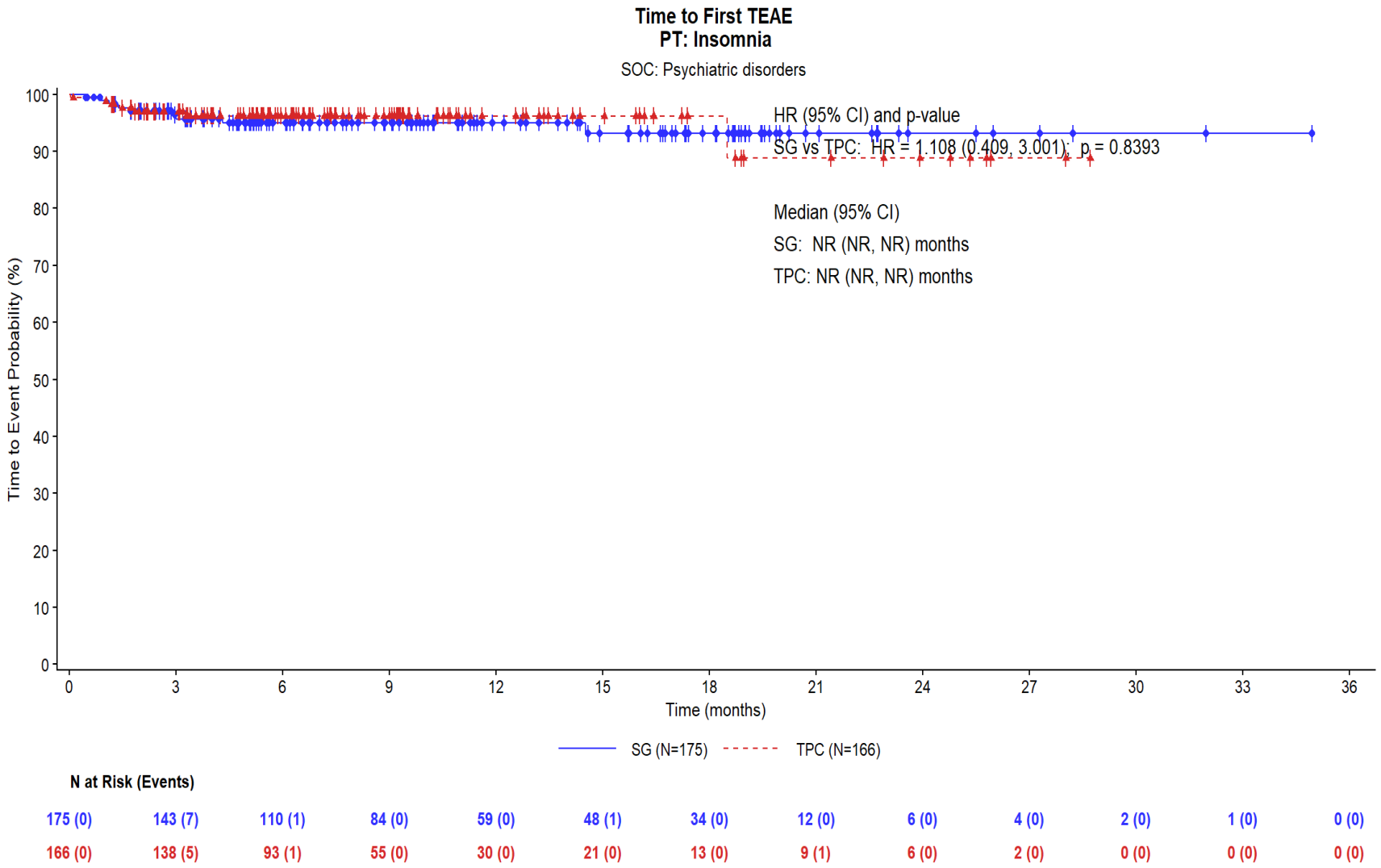
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.94. Figure 1.1.95: Kaplan Meier Plot of Time to First TEAE by PT Depression — mSAF — Excluding patients preselected to receive nab-paclitaxel



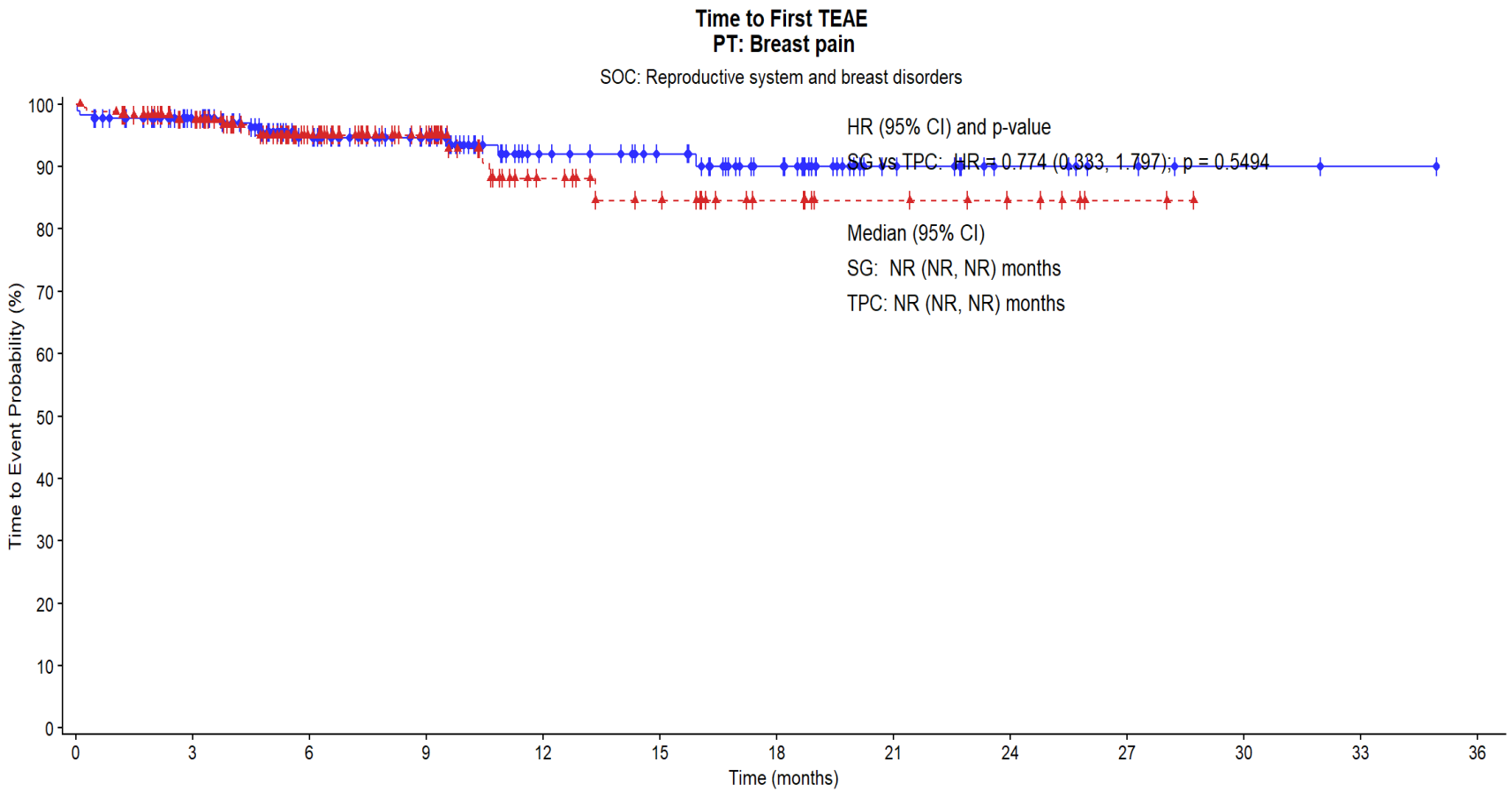
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.95. Figure 1.1.96: Kaplan Meier Plot of Time to First TEAE by PT Insomnia — mSAF — Excluding patients preselected to receive nab-paclitaxel



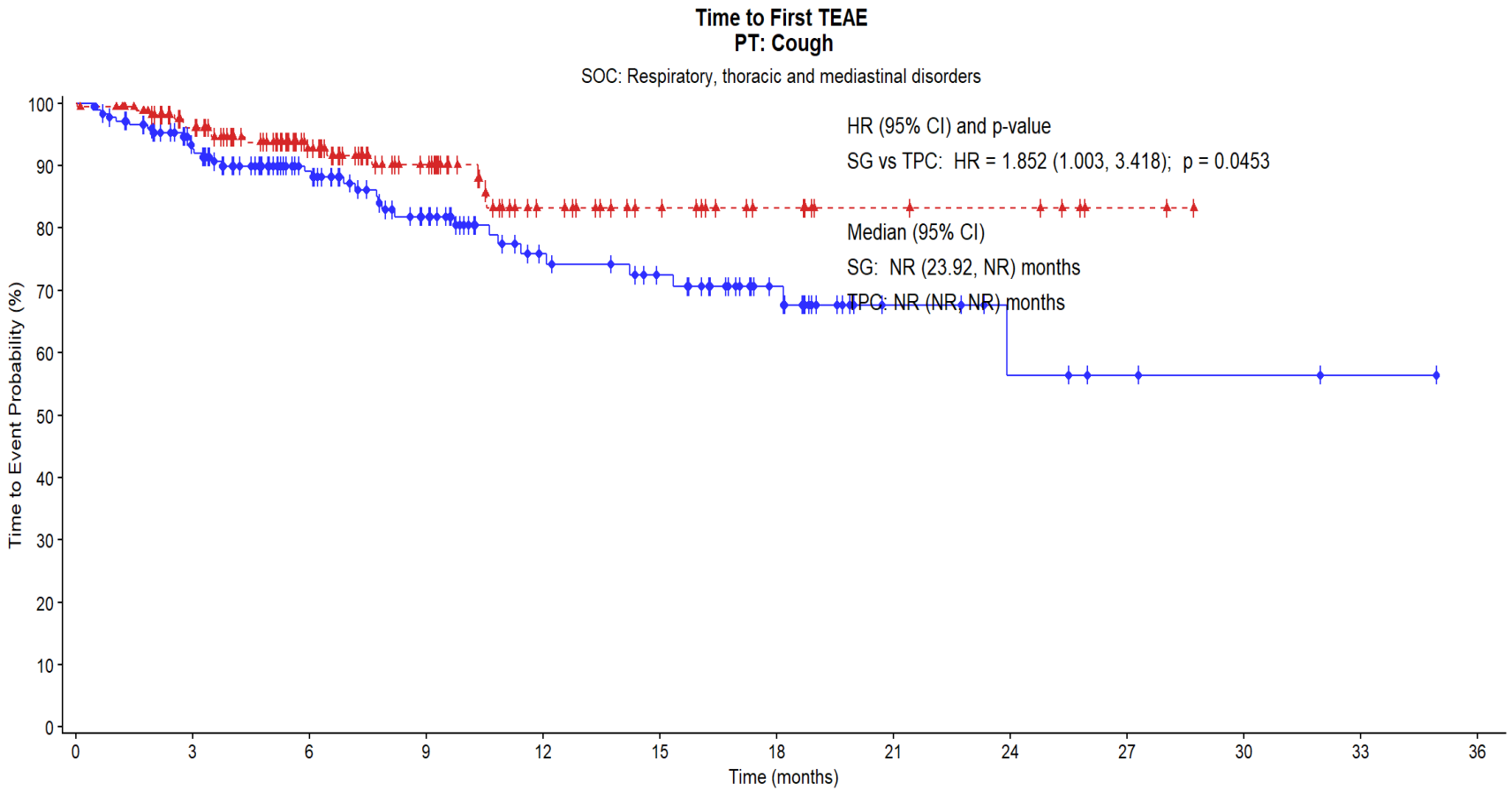
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.96. Figure 1.1.97: Kaplan Meier Plot of Time to First TEAE by PT Breast pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



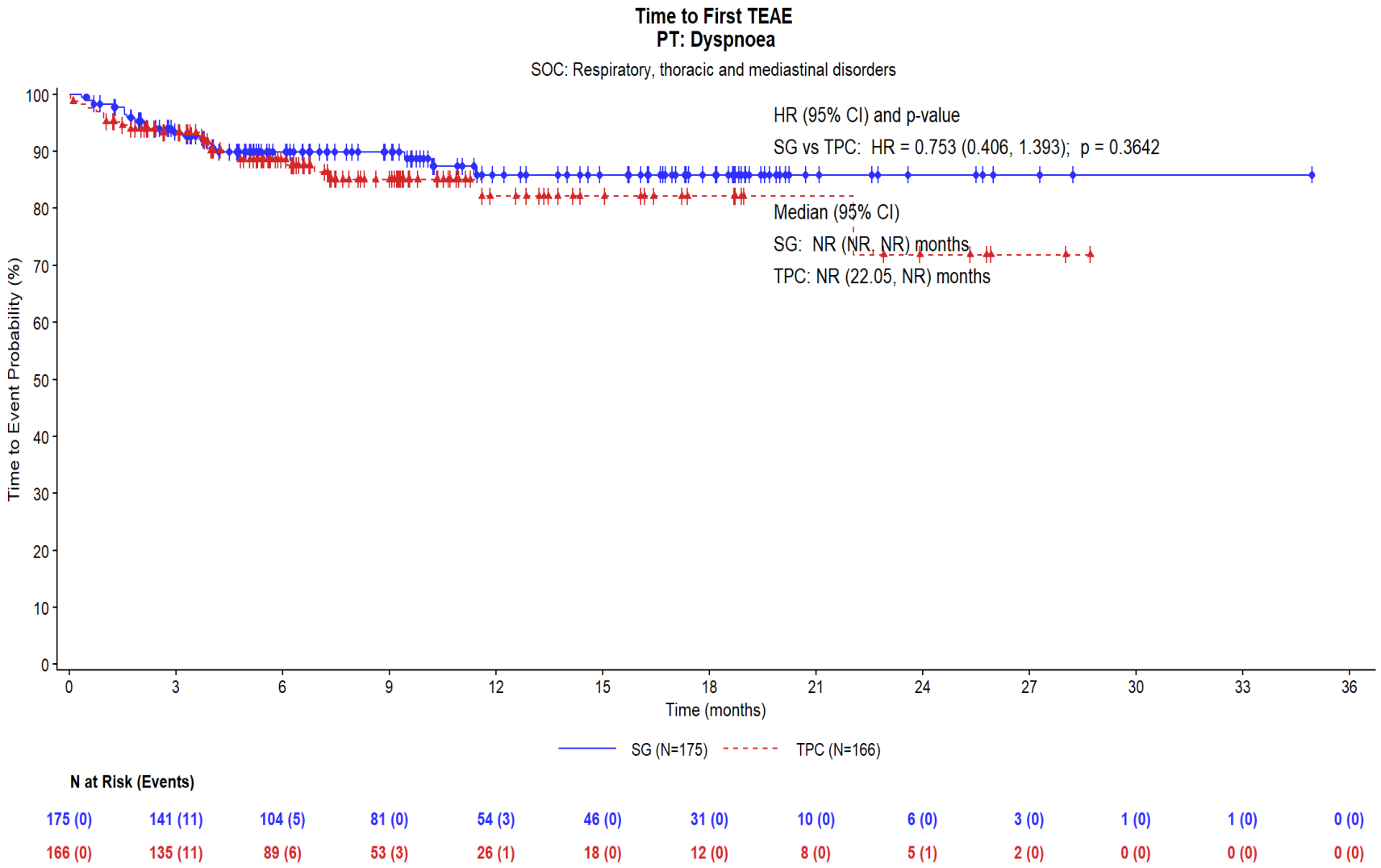
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.97. Figure 1.1.98: Kaplan Meier Plot of Time to First TEAE by PT Cough — mSAF — Excluding patients preselected to receive nab-paclitaxel



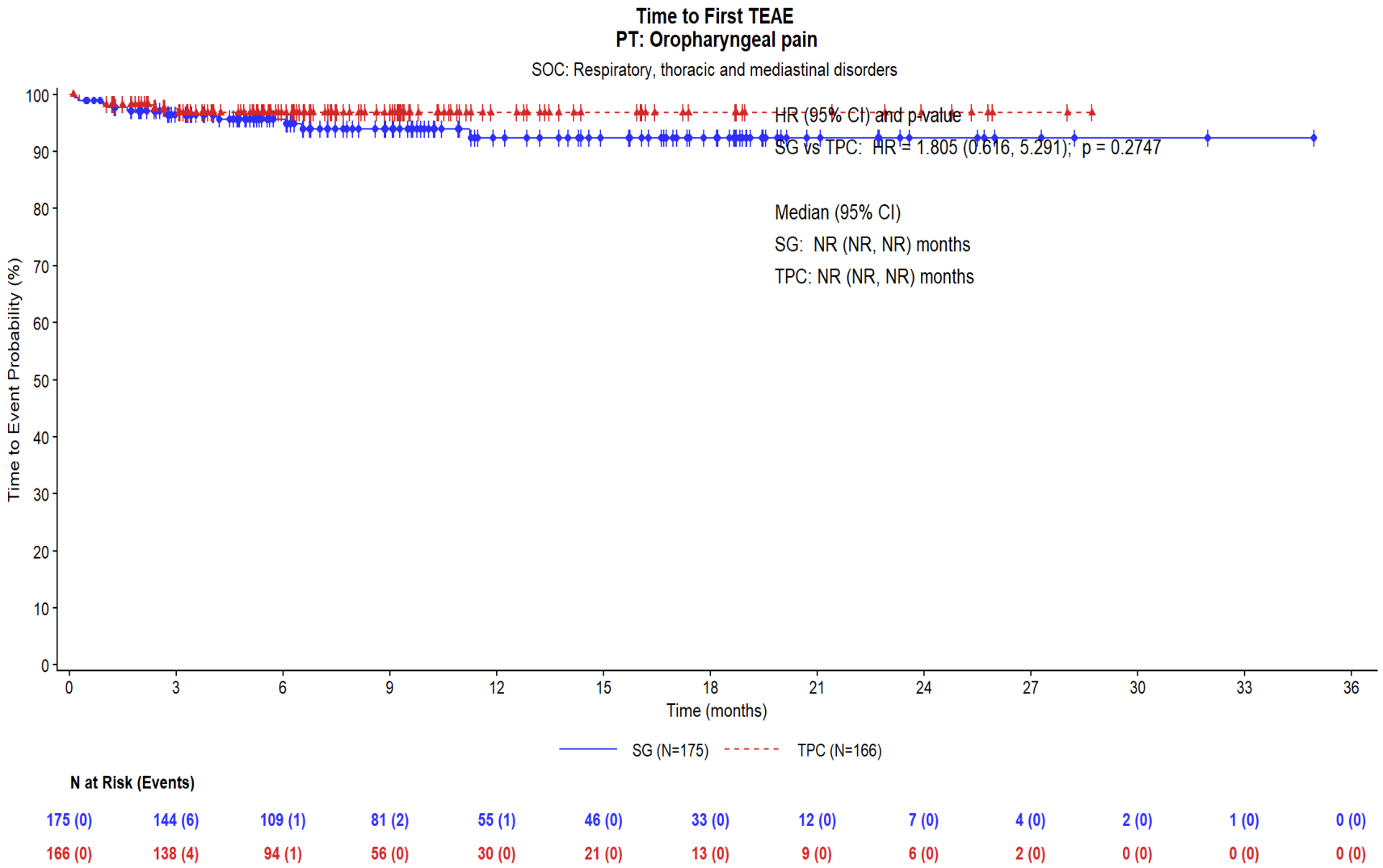
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.98. Figure 1.1.99: Kaplan Meier Plot of Time to First TEAE by PT Dyspnoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



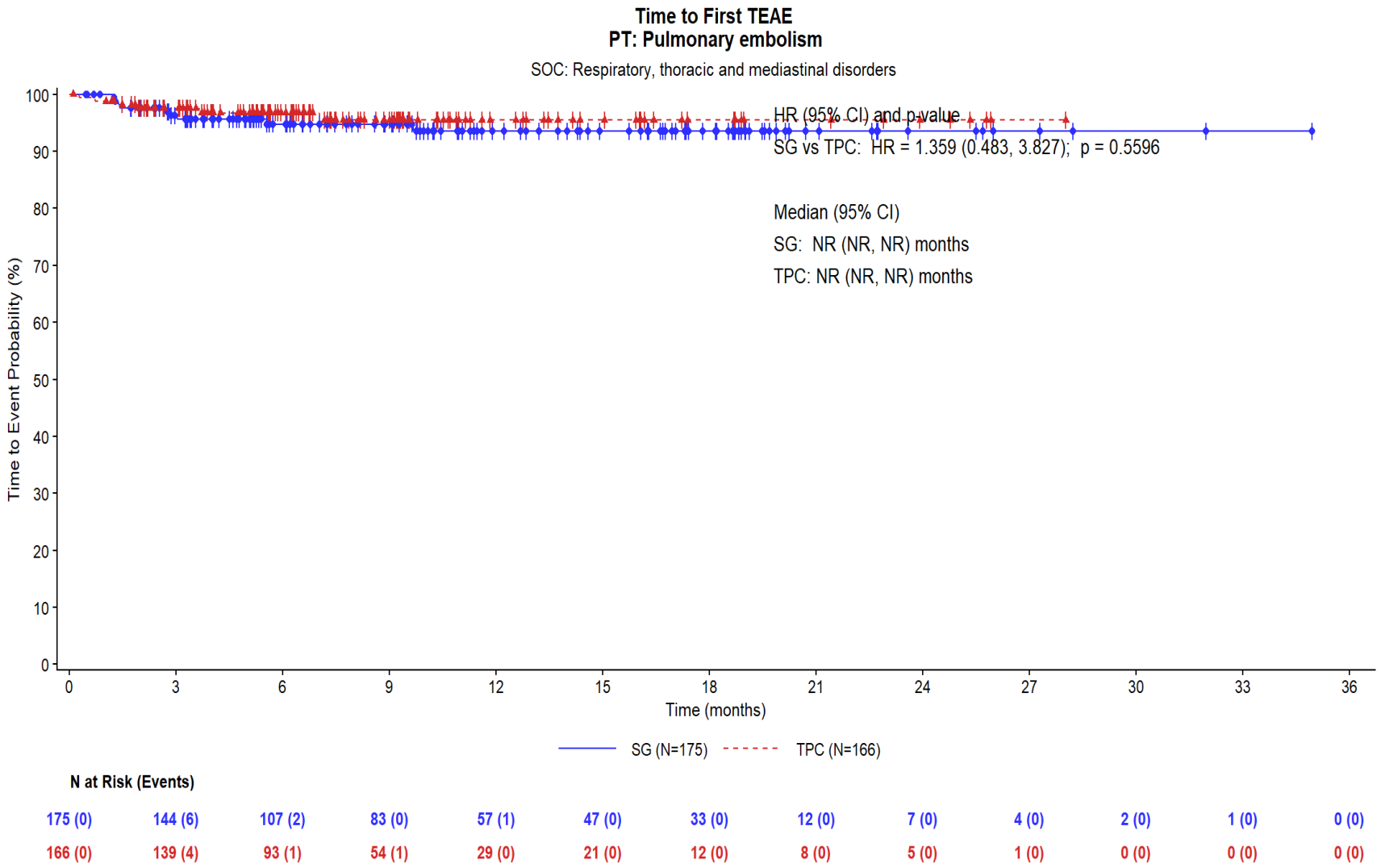
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.99. Figure 1.1.100: Kaplan Meier Plot of Time to First TEAE by PT Oropharyngeal pain — mSAF — Excluding patients preselected to receive nab-paclitaxel



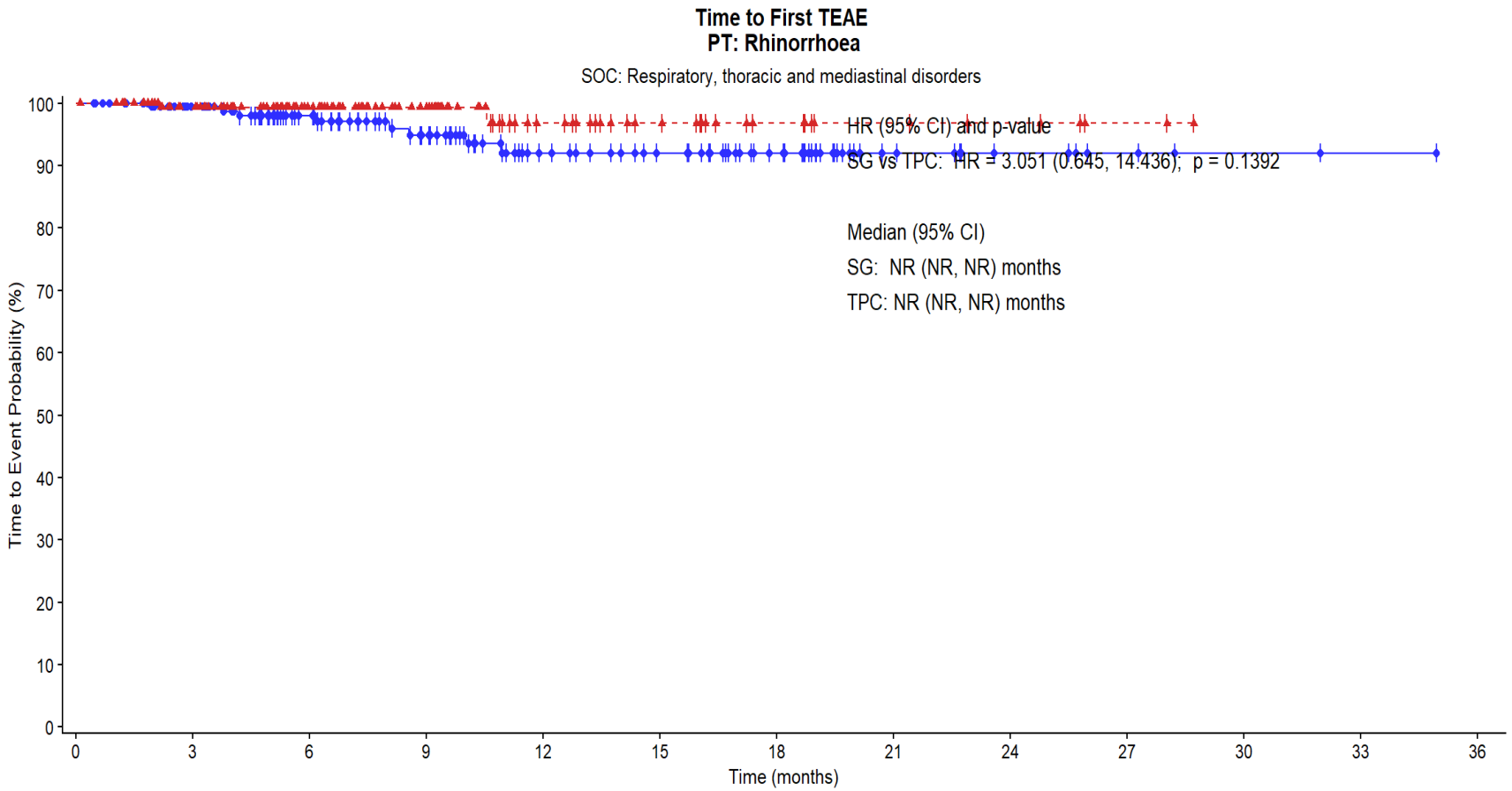
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.100. Figure 1.1.101: Kaplan Meier Plot of Time to First TEAE by PT Pulmonary embolism — mSAF — Excluding patients preselected to receive nab-paclitaxel



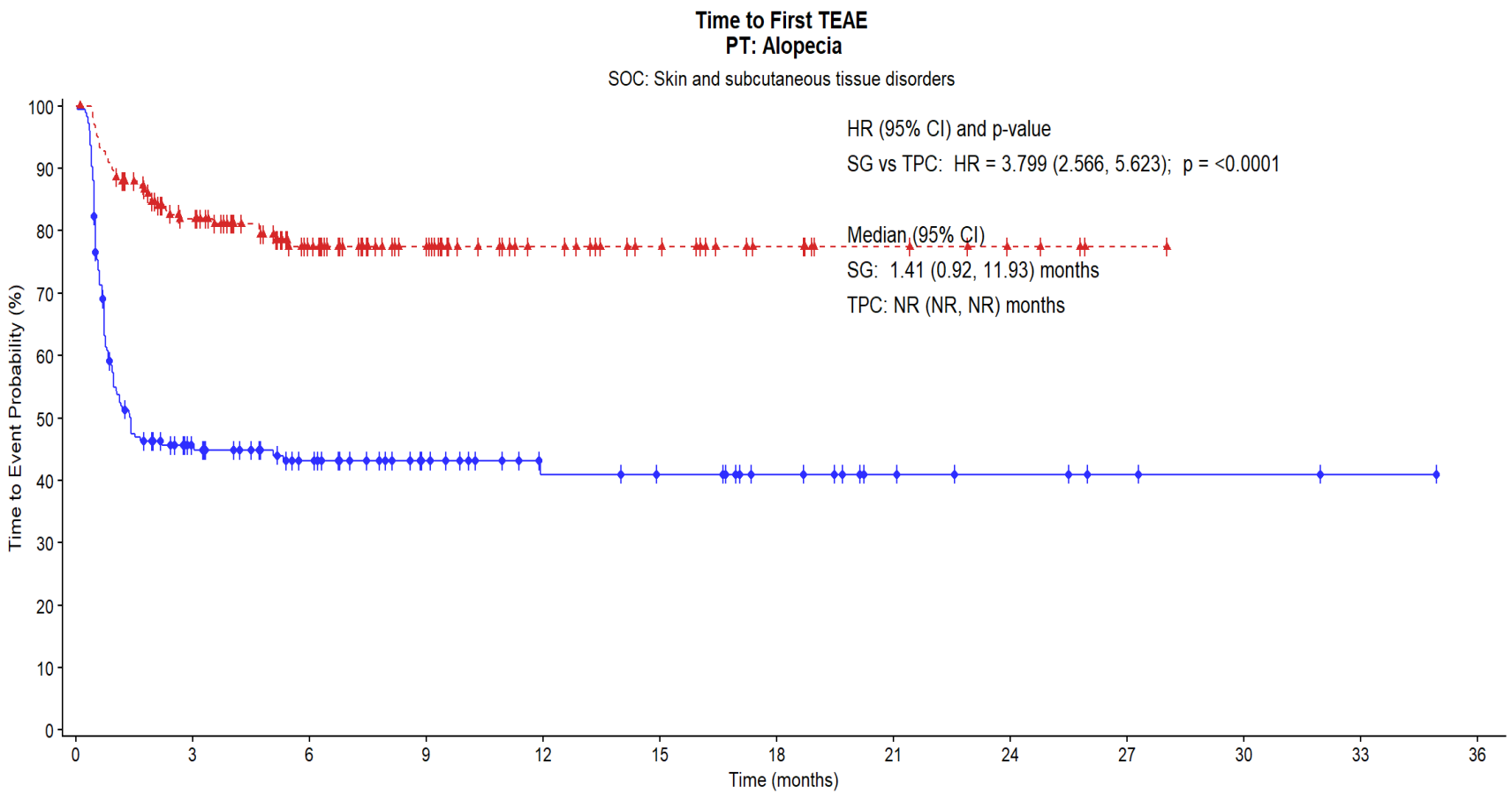
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.101. Figure 1.1.102: Kaplan Meier Plot of Time to First TEAE by PT Rhinorrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



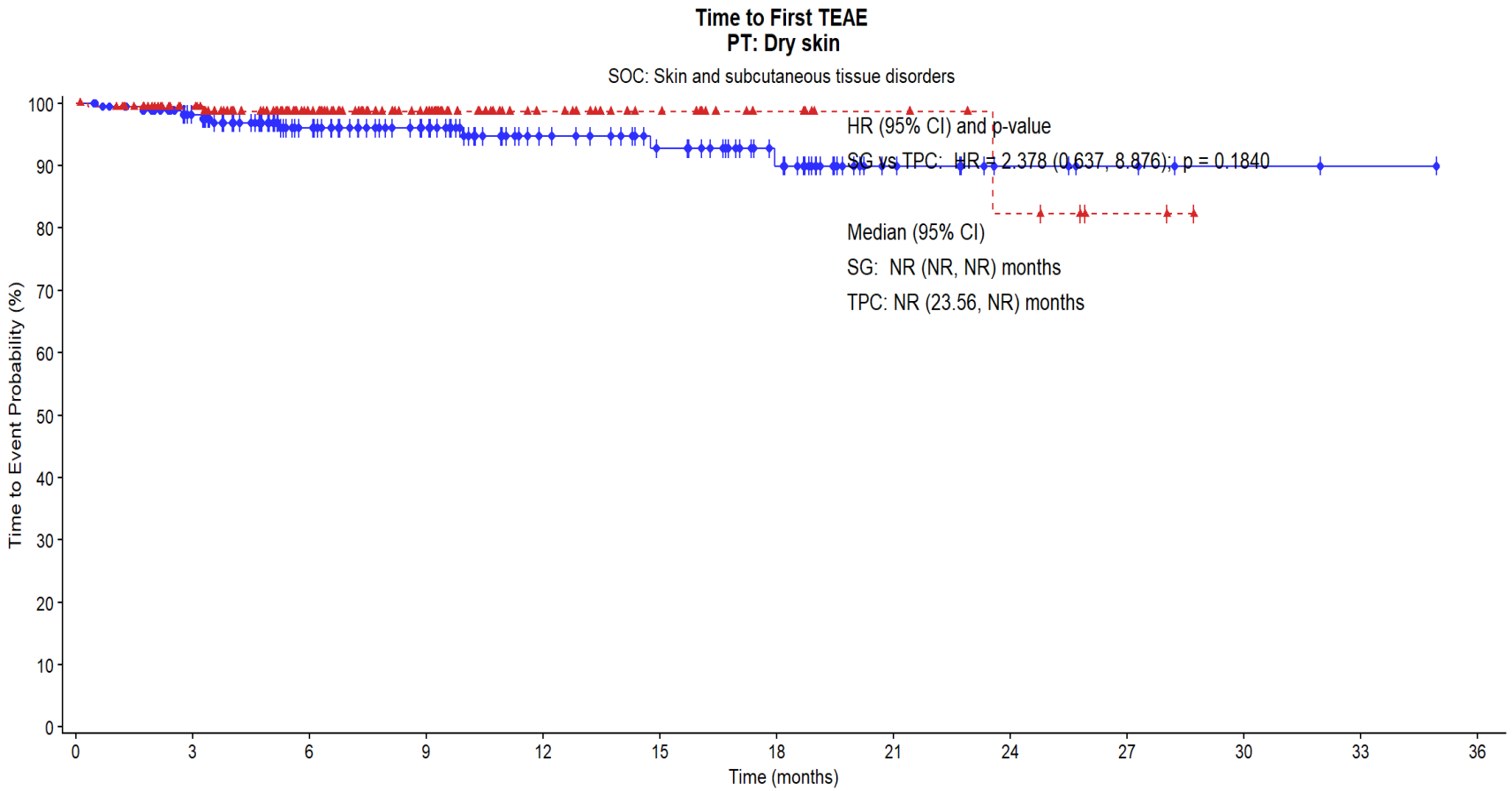
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.102. Figure 1.1.103: Kaplan Meier Plot of Time to First TEAE by PT Alopecia — mSAF — Excluding patients preselected to receive nab-paclitaxel



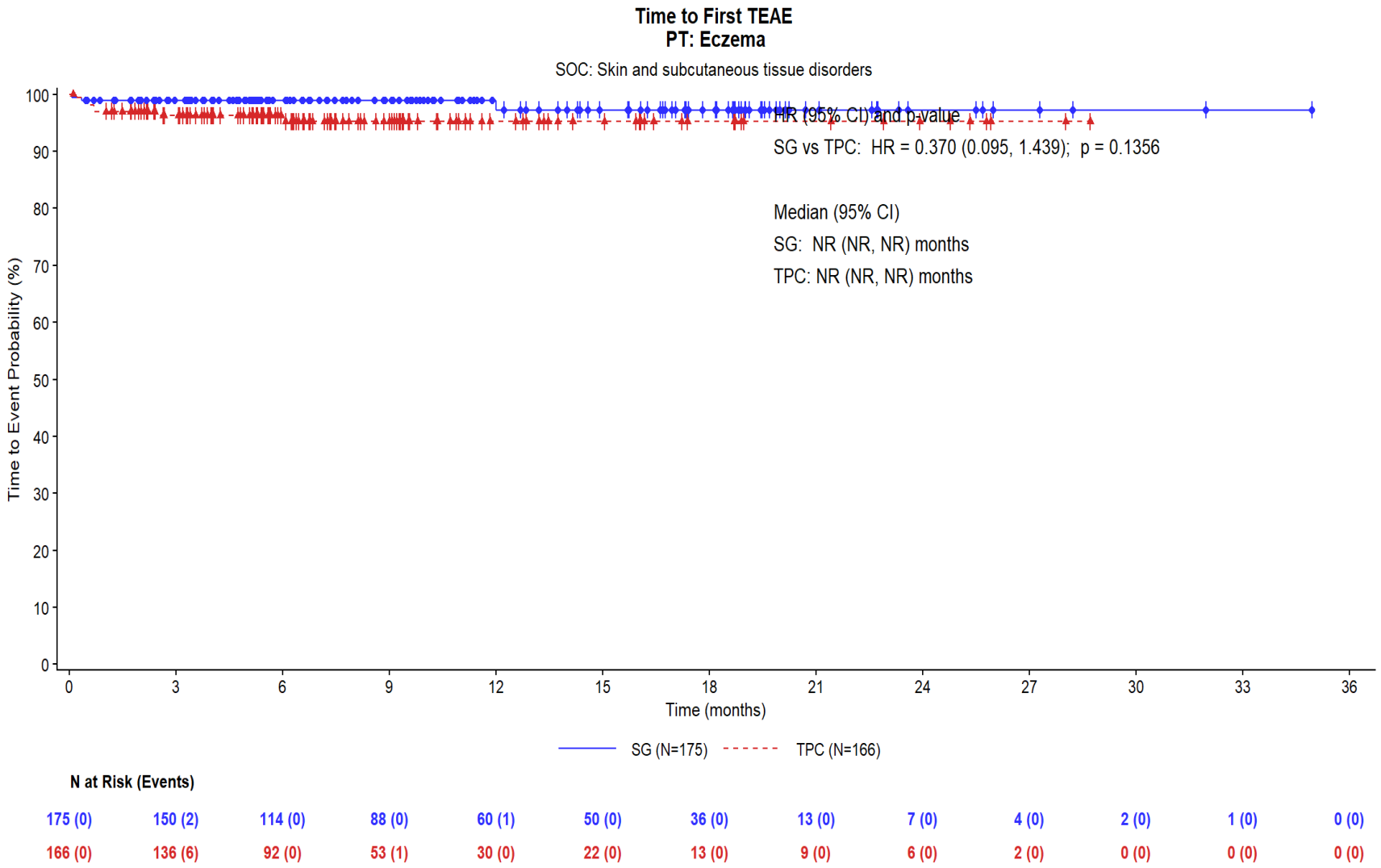
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.103. Figure 1.1.104: Kaplan Meier Plot of Time to First TEAE by PT Dry skin — mSAF — Excluding patients preselected to receive nab-paclitaxel



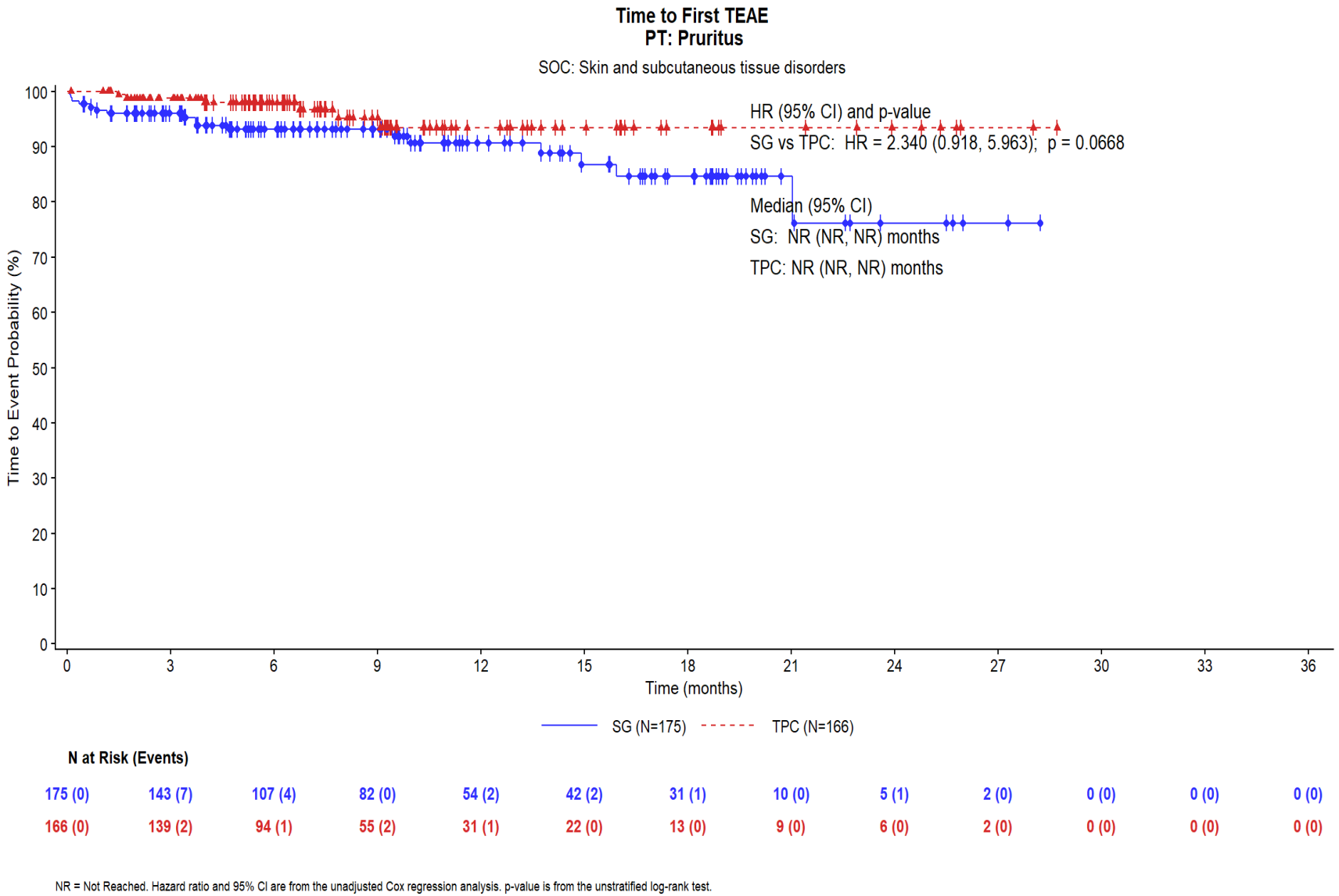
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.104. Figure 1.1.105: Kaplan Meier Plot of Time to First TEAE by PT Eczema — mSAF — Excluding patients preselected to receive nab-paclitaxel



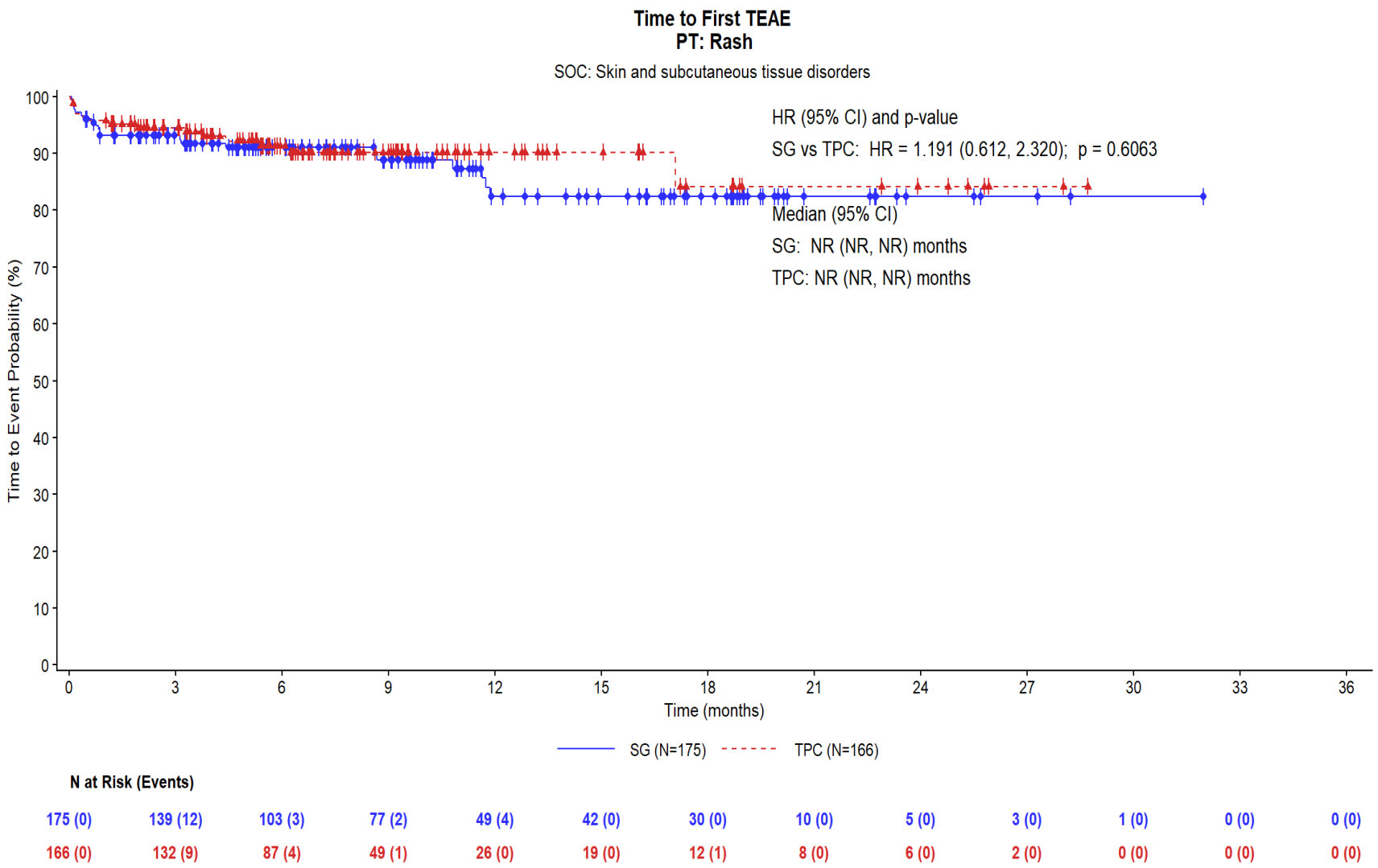
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.105. Figure 1.1.106: Kaplan Meier Plot of Time to First TEAE by PT Pruritus — mSAF — Excluding patients preselected to receive nab-paclitaxel



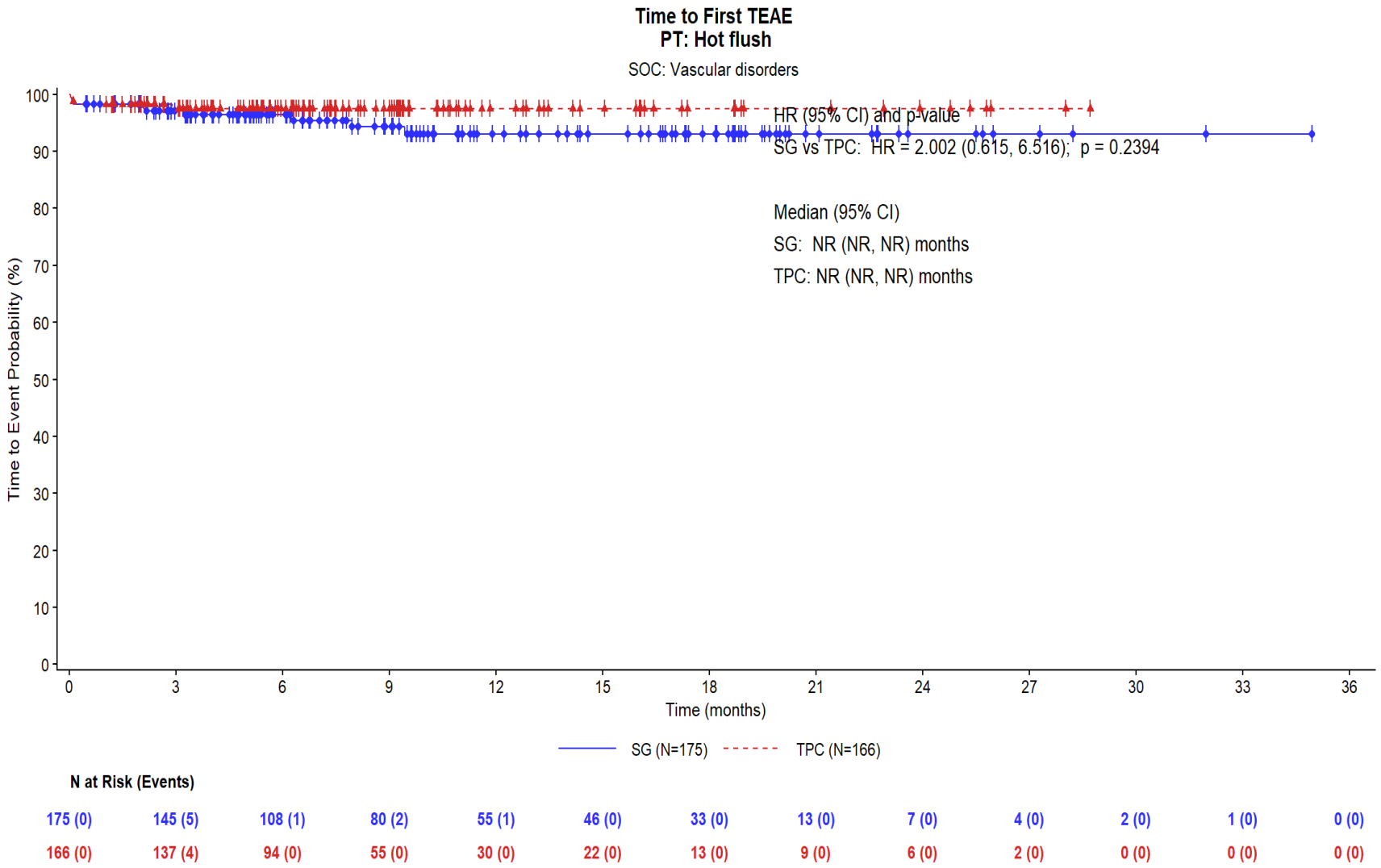
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.106. Figure 1.1.107: Kaplan Meier Plot of Time to First TEAE by PT Rash — mSAF — Excluding patients preselected to receive nab-paclitaxel



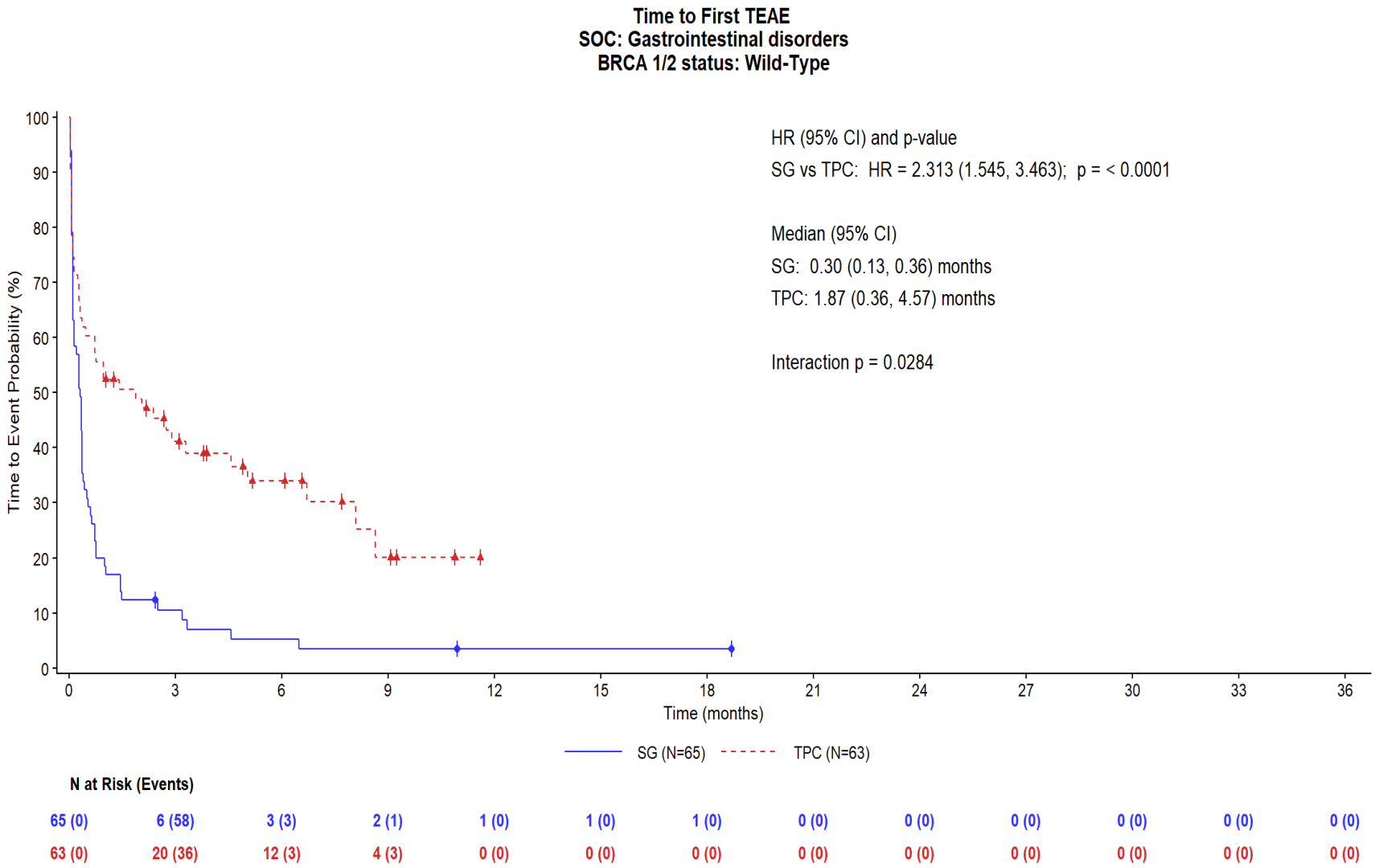
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.107. Figure 1.1.108: Kaplan Meier Plot of Time to First TEAE by PT Hot flush — mSAF — Excluding patients preselected to receive nab-paclitaxel



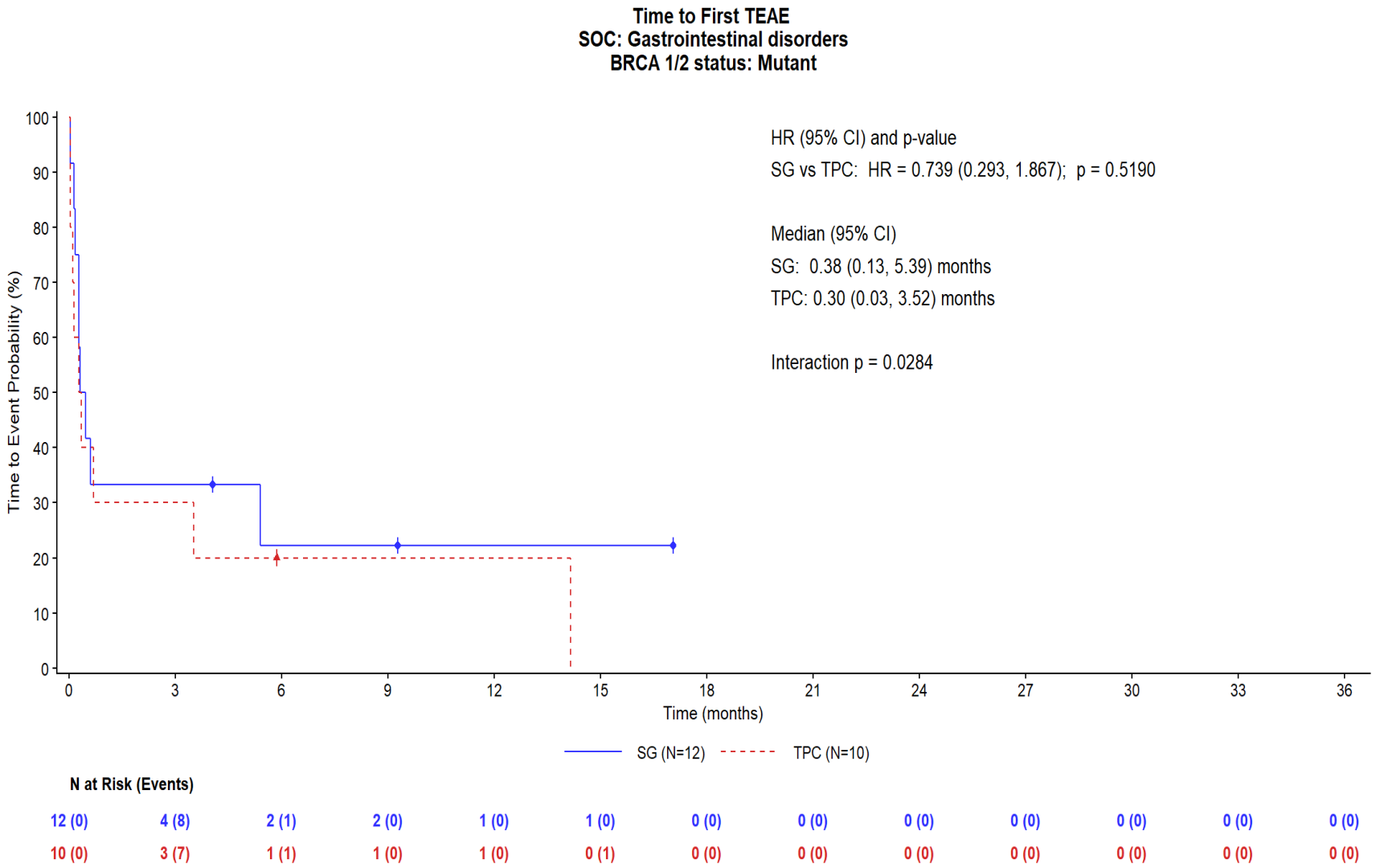
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.108. Figure 1.1.109: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders BRCA 1 2 status Wild Type — mSAF — Excluding patients preselected to receive nab-paclitaxel



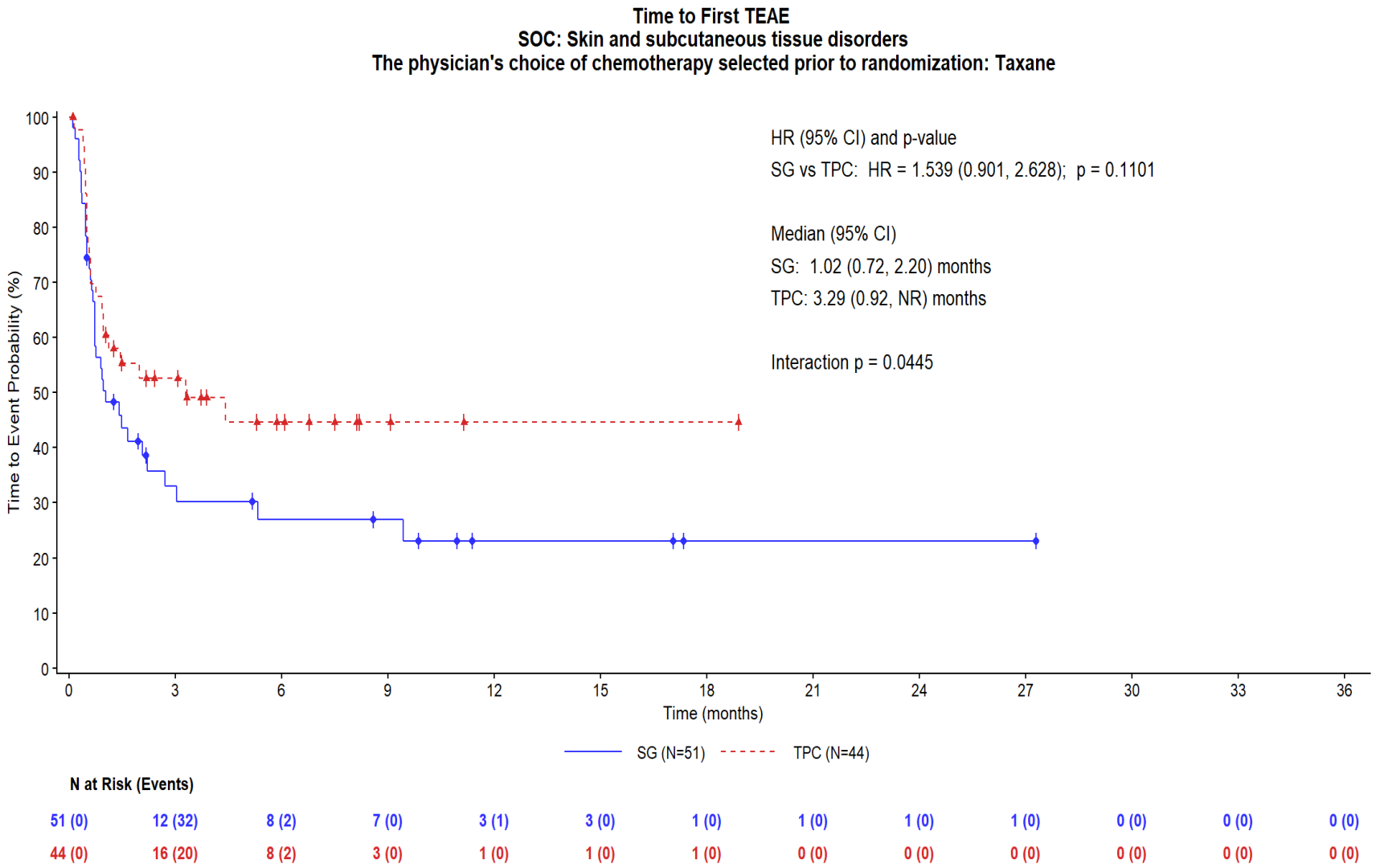
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.109. Figure 1.1.110: Kaplan Meier Plot of Time to First TEAE by SOC Gastrointestinal disorders BRCA 1 2 status Mutant — mSAF — Excluding patients preselected to receive nab-paclitaxel



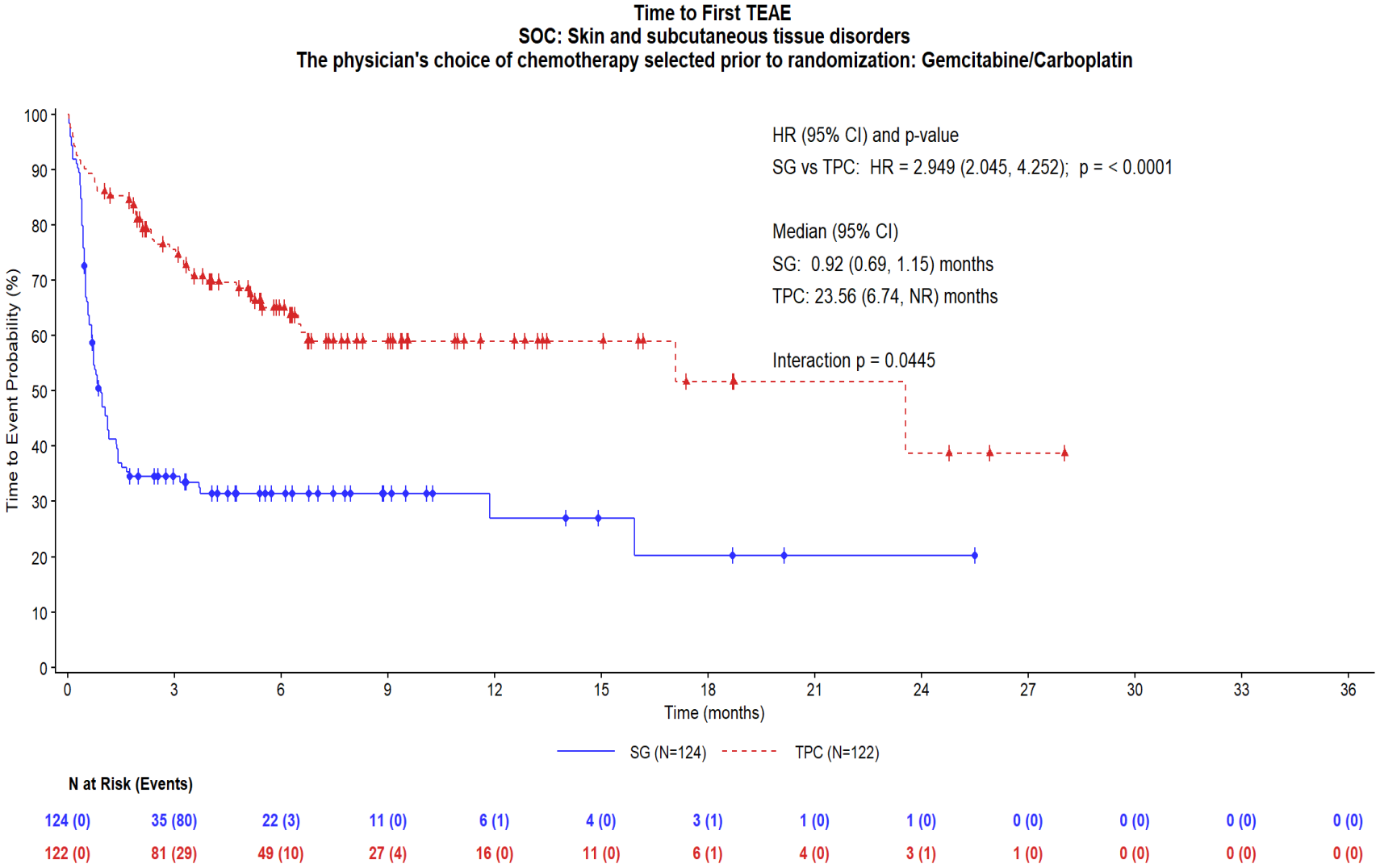
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.110. Figure 1.1.111: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



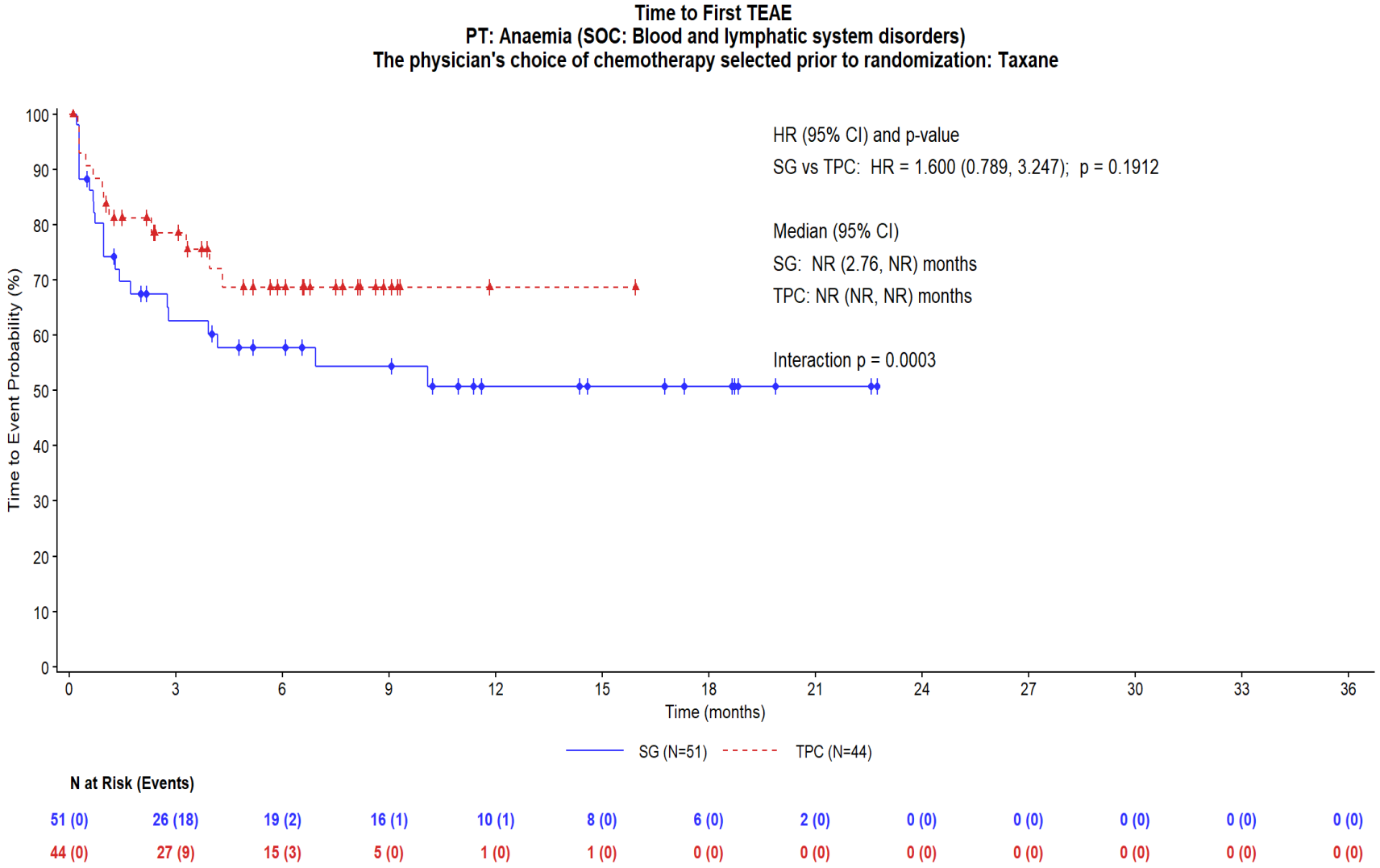
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.111. Figure 1.1.112: Kaplan Meier Plot of Time to First TEAE by SOC Skin and subcutaneous tissue disorders The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



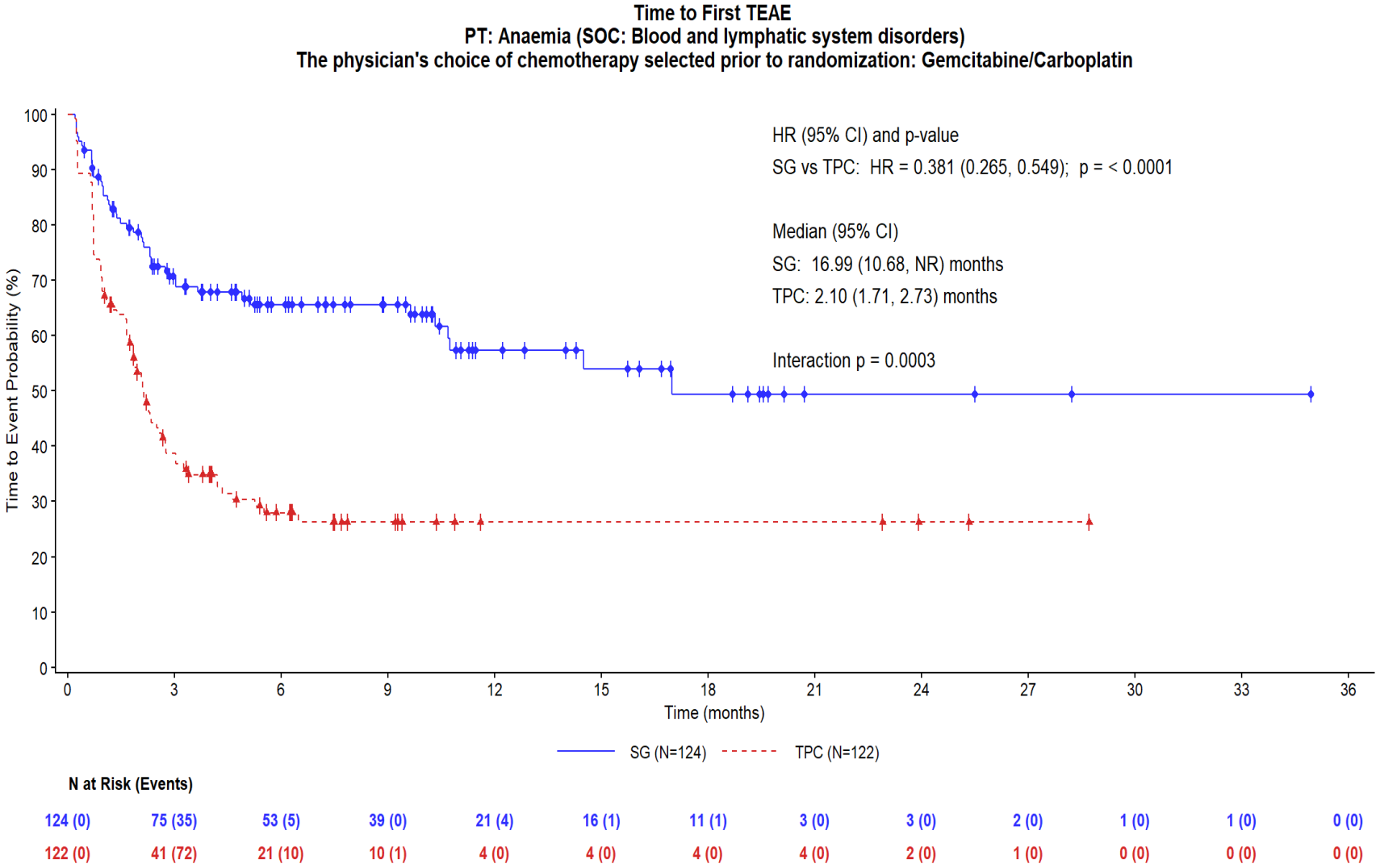
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.112. Figure 1.1.113: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



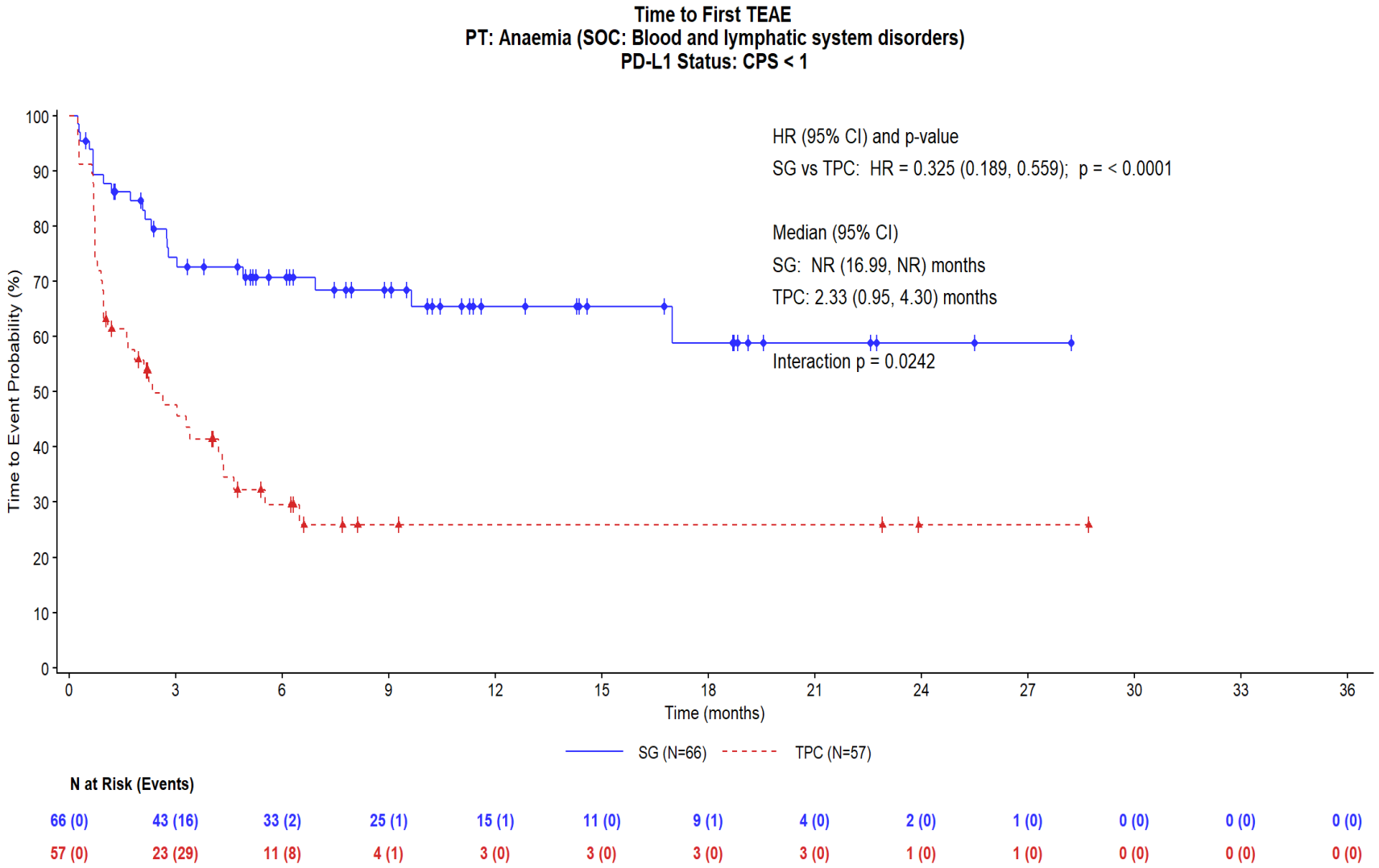
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.113. Figure 1.1.114: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



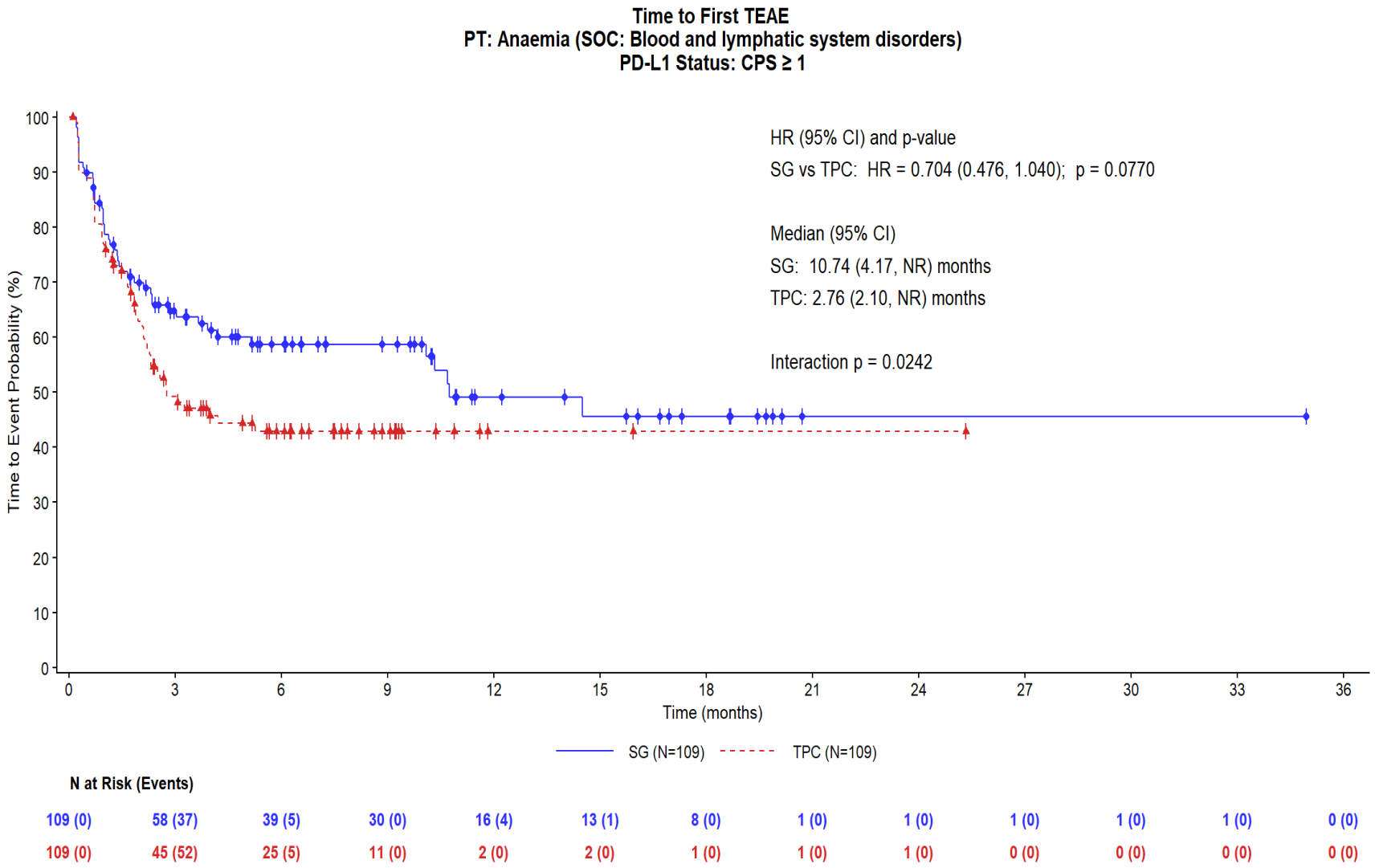
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.114. Figure 1.1.115: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) PD L1 Status CPS less than 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



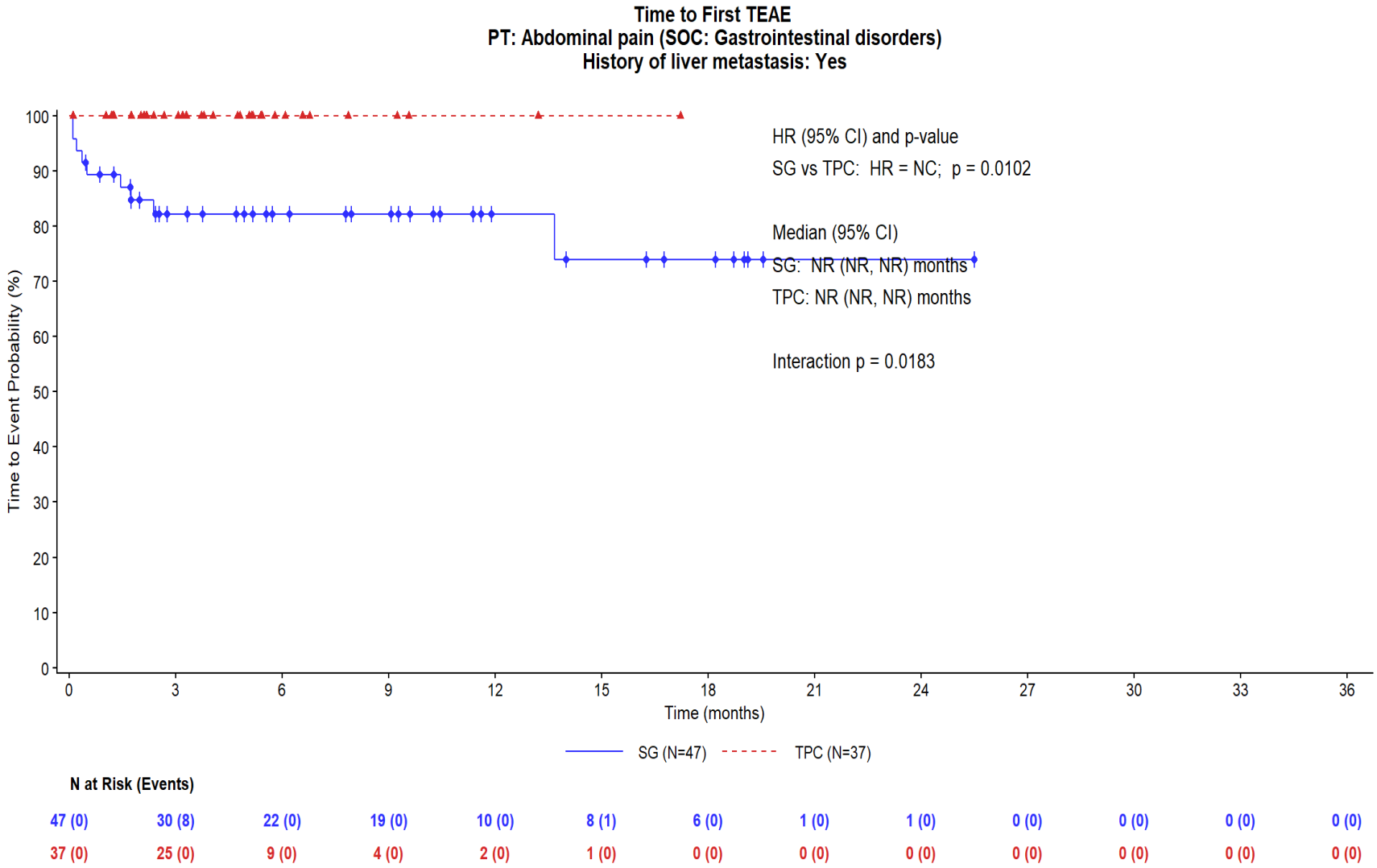
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.115. Figure 1.1.116: Kaplan Meier Plot of Time to First TEAE by PT Anaemia (SOC Blood and lymphatic system disorders) PD L1 Status CPS >= 1 — mSAF — Excluding patients preselected to receive nab-paclitaxel



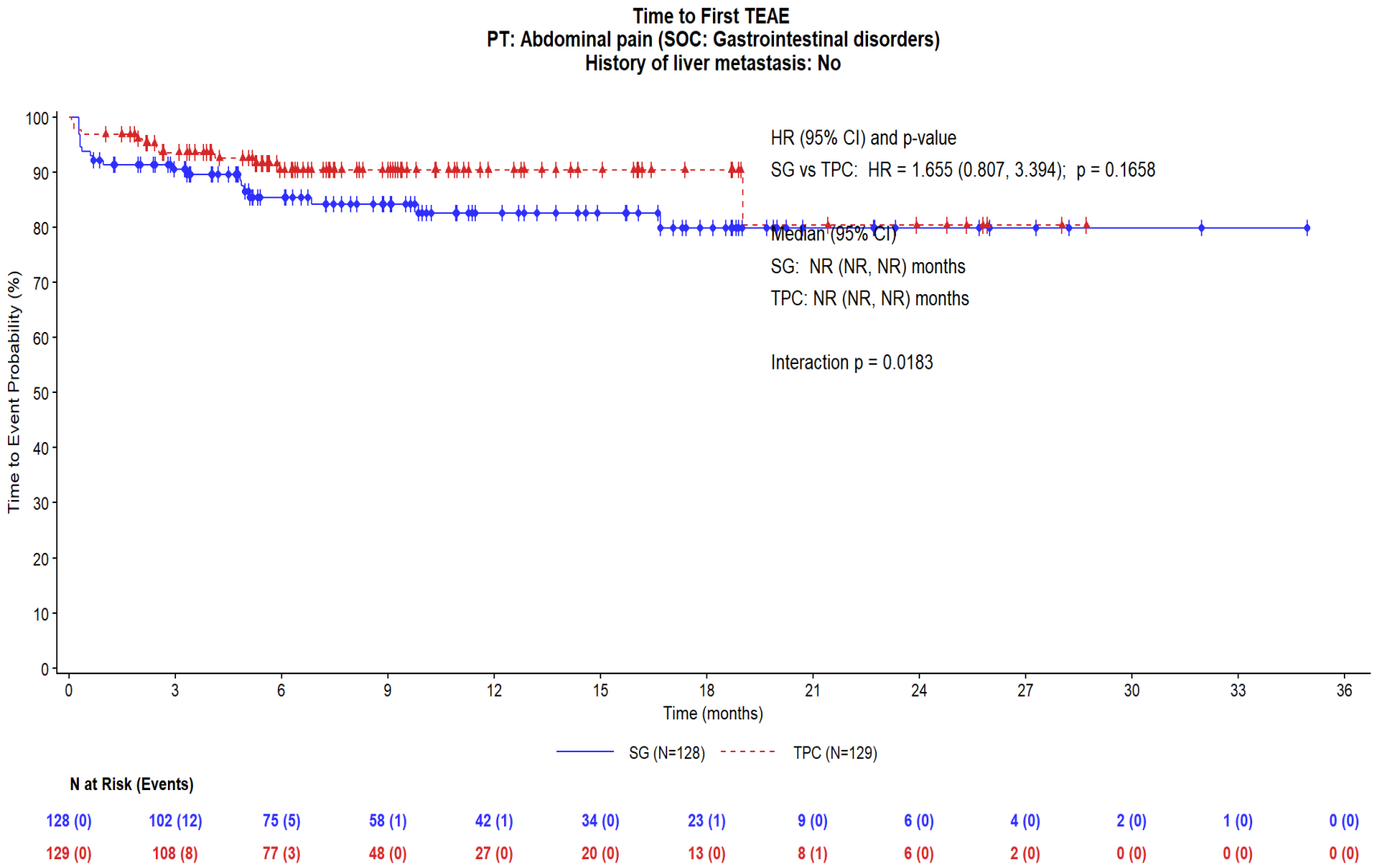
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.116. Figure 1.1.117: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain (SOC Gastrointestinal disorders) History of liver metastasis Yes — mSAF — Excluding patients preselected to receive nab-paclitaxel



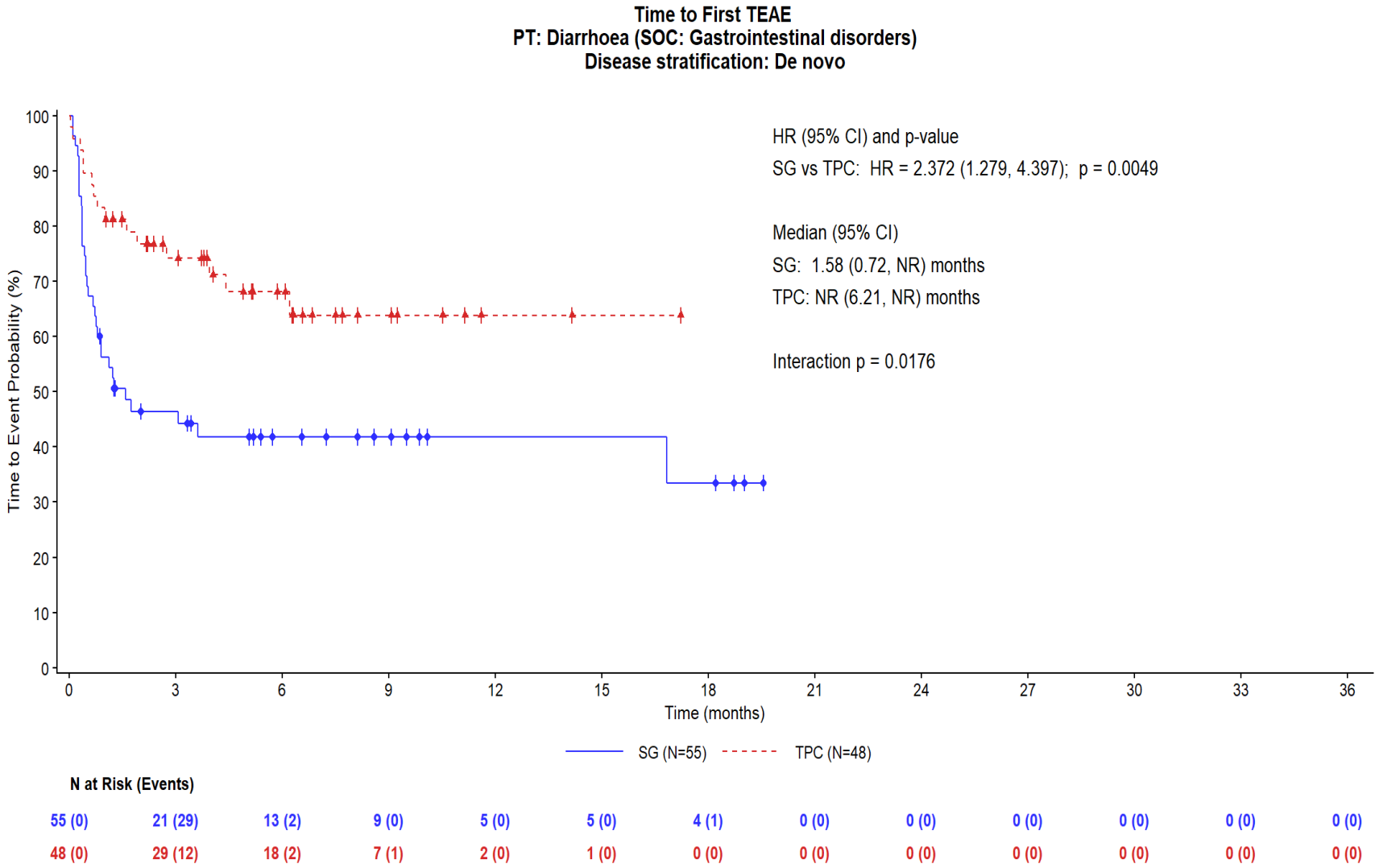
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.117. Figure 1.1.118: Kaplan Meier Plot of Time to First TEAE by PT Abdominal pain (SOC Gastrointestinal disorders) History of liver metastasis No — mSAF — Excluding patients preselected to receive nab-paclitaxel



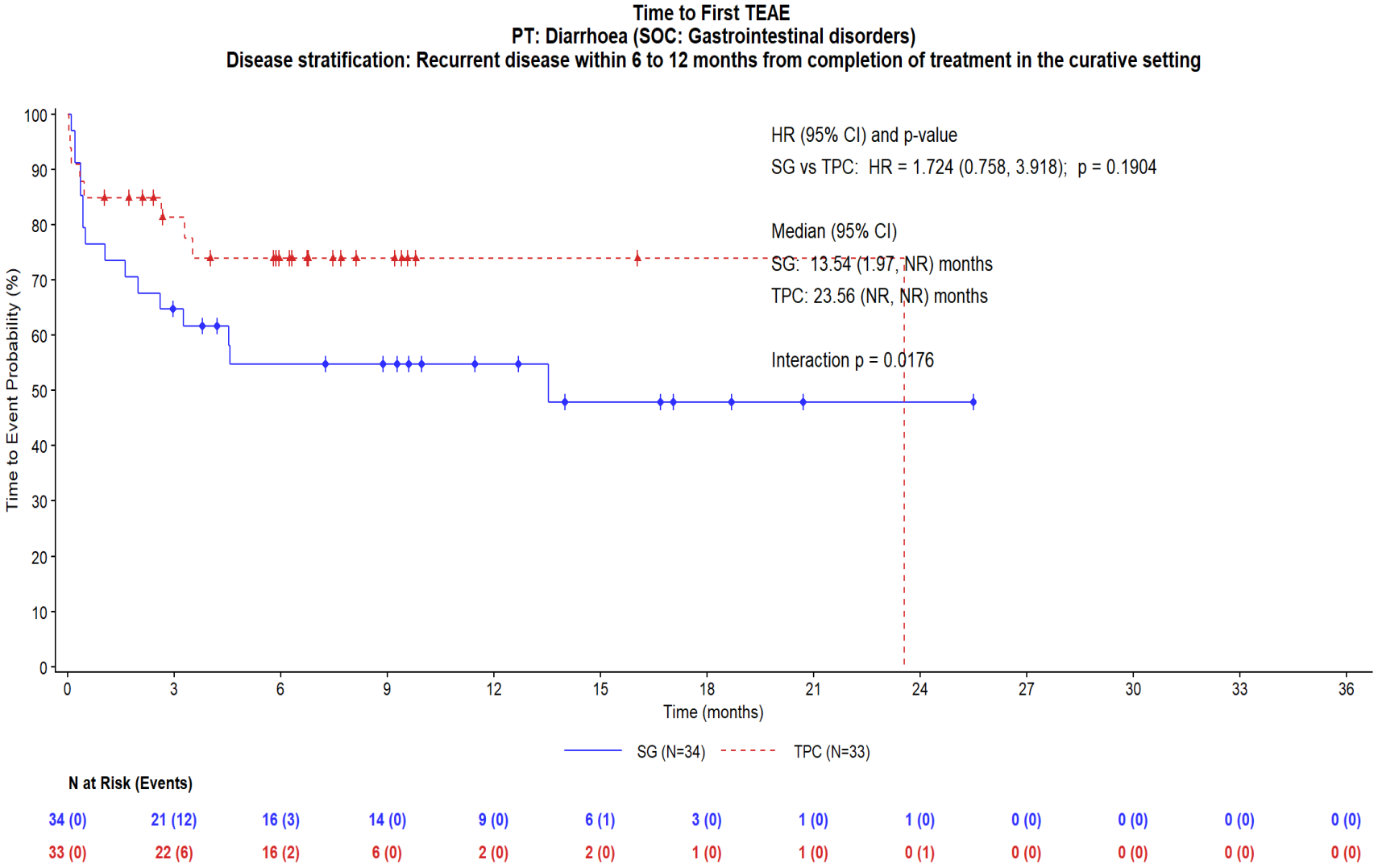
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.118. Figure 1.1.119: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification De novo — mSAF — Excluding patients preselected to receive nab-paclitaxel



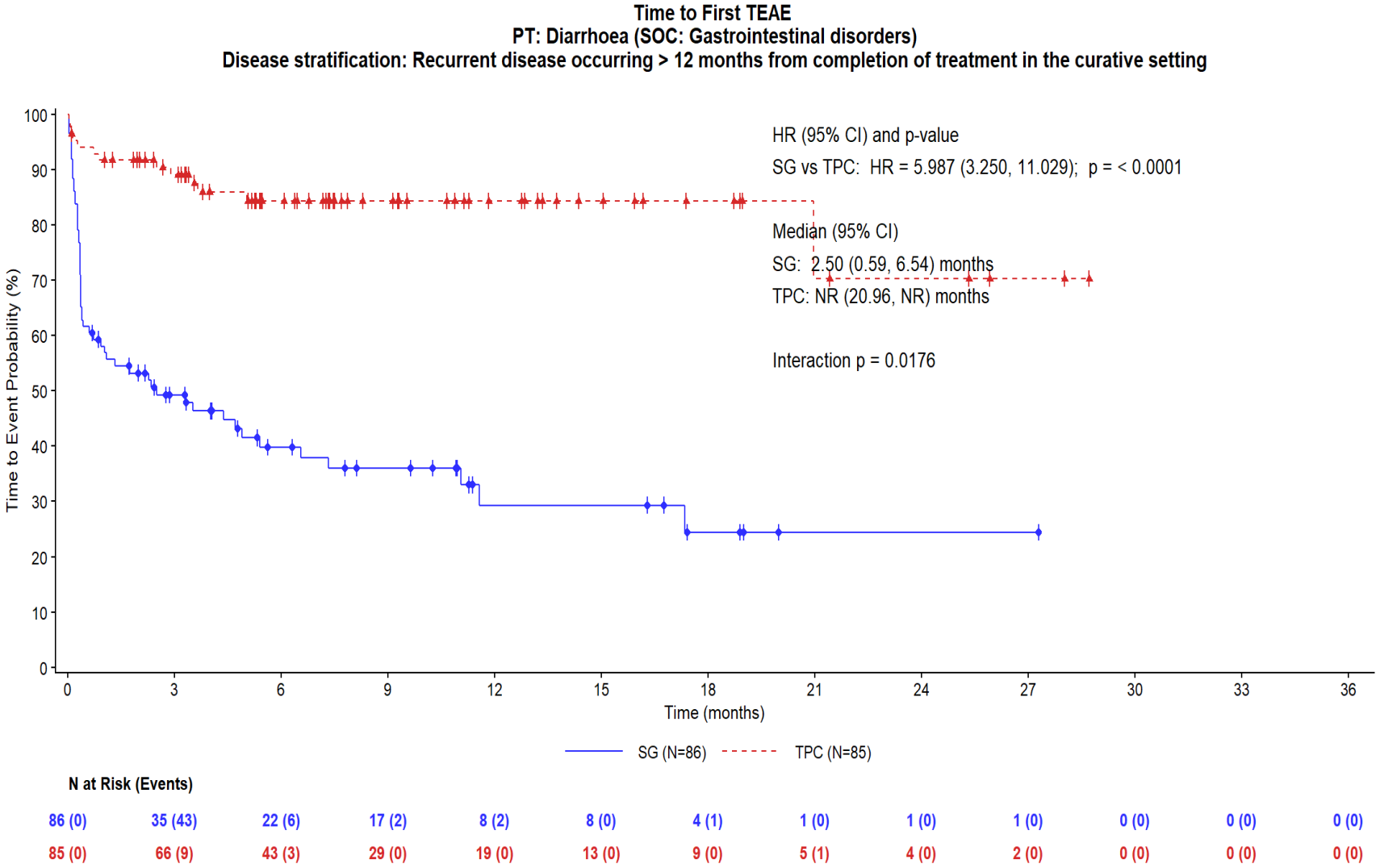
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.119. Figure 1.1.120: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease within 6 to 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel



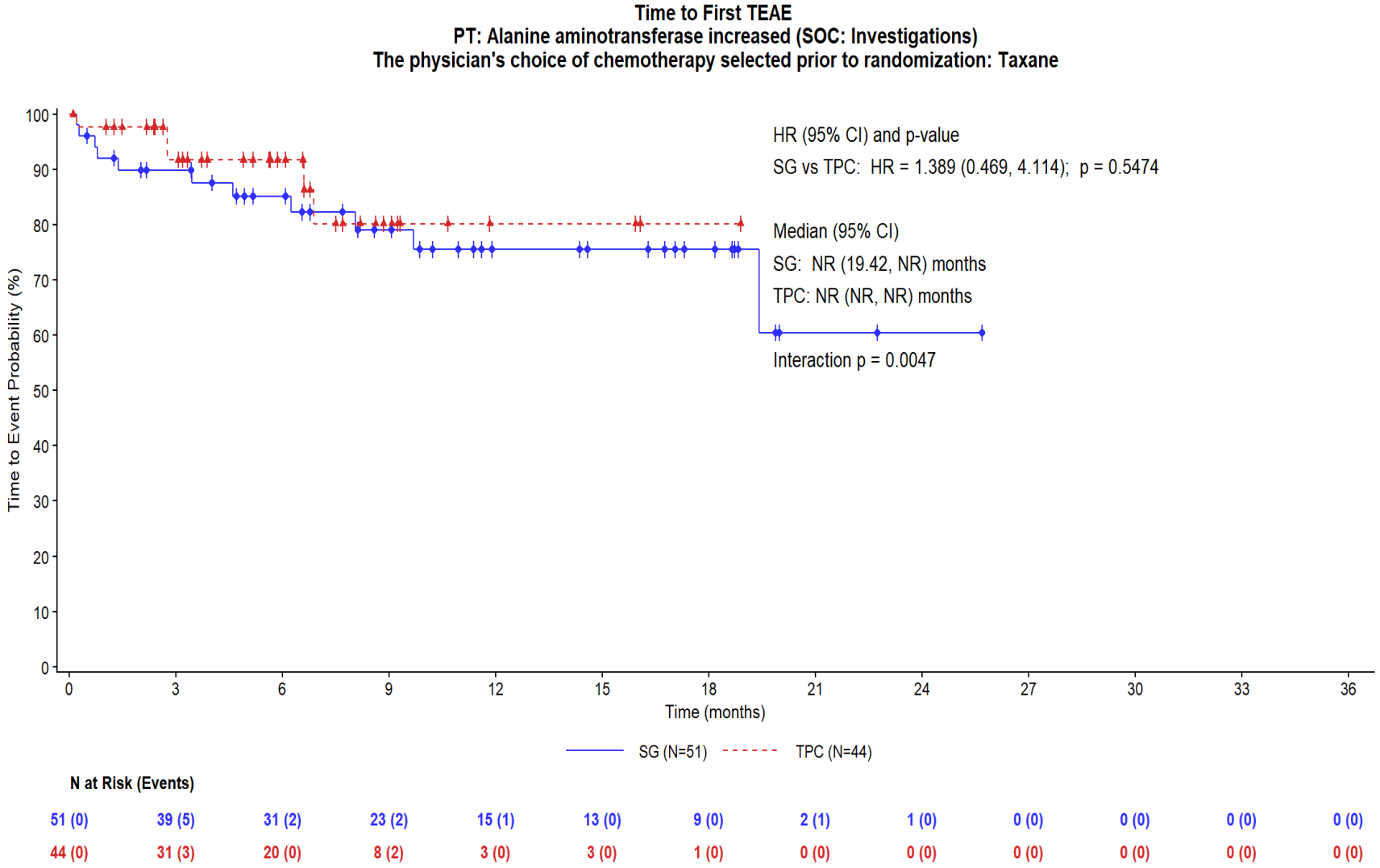
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.120. Figure 1.1.121: Kaplan Meier Plot of Time to First TEAE by PT Diarrhoea (SOC Gastrointestinal disorders) Disease stratification Recurrent disease occurring greater than 12 months from completion of treatment in the curative setting — mSAF — Excluding patients preselected to receive nab-paclitaxel



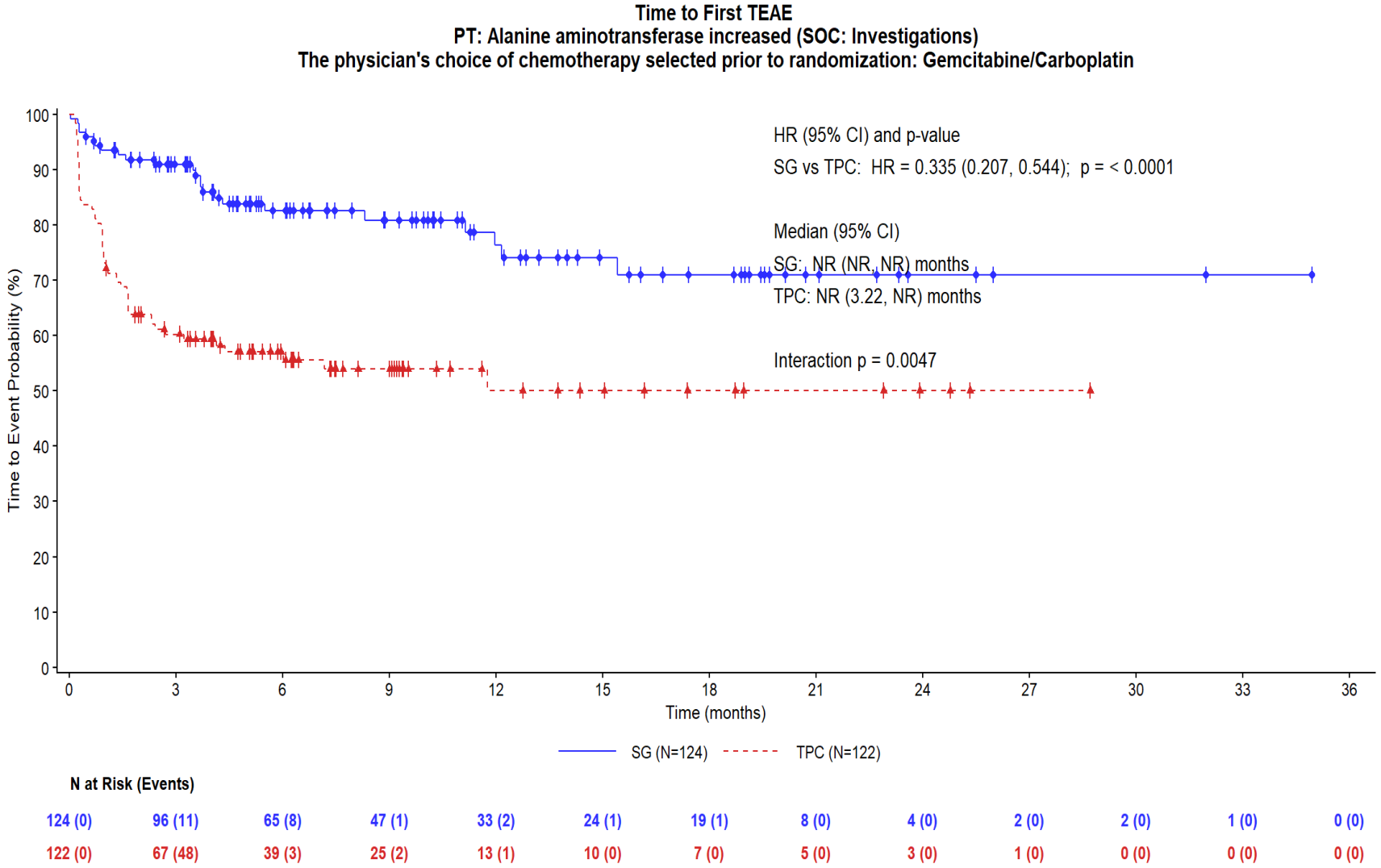
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.121. Figure 1.1.122: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased (SOC Investigations) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



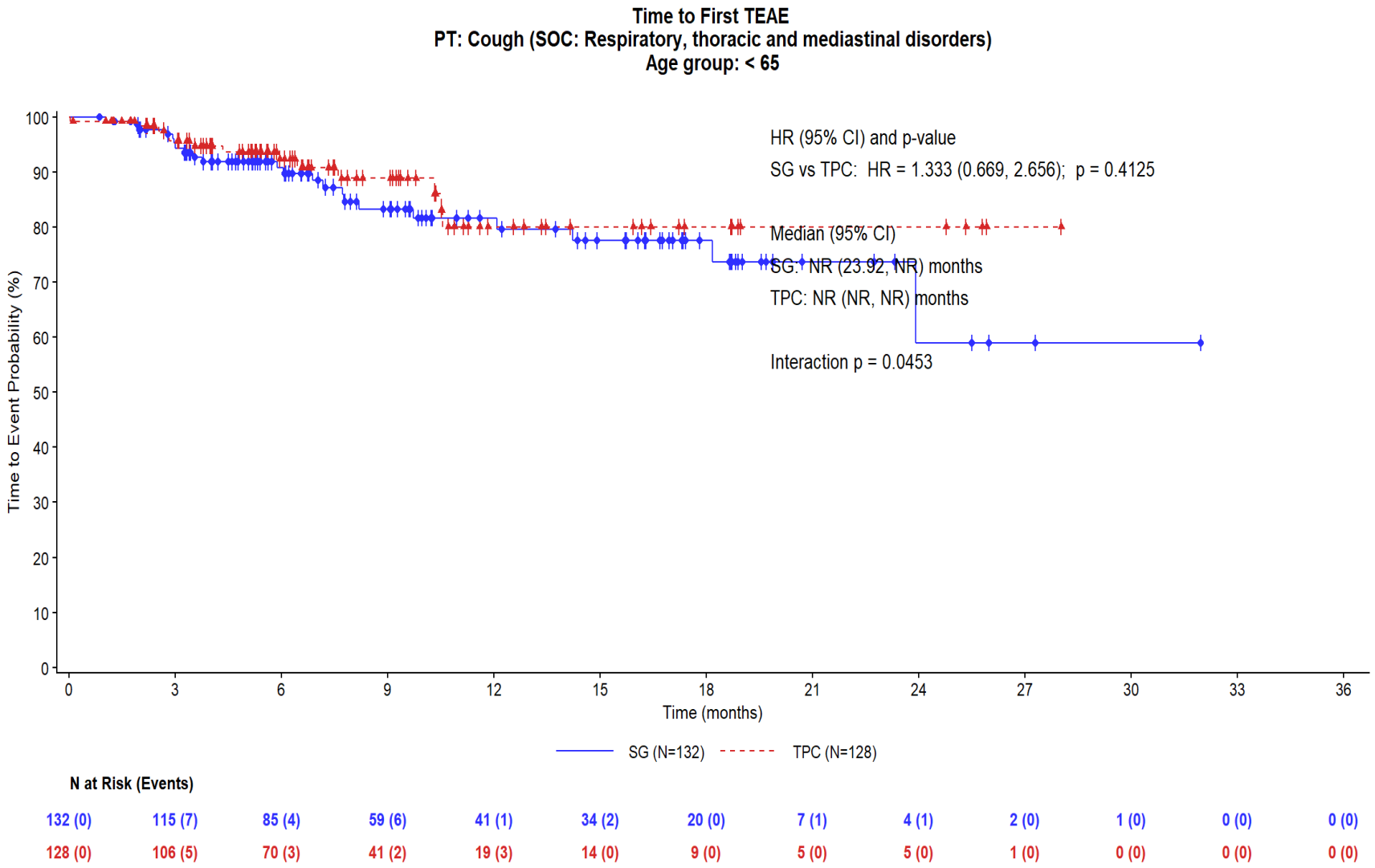
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.122. Figure 1.1.123: Kaplan Meier Plot of Time to First TEAE by PT Alanine aminotransferase increased (SOC Investigations) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



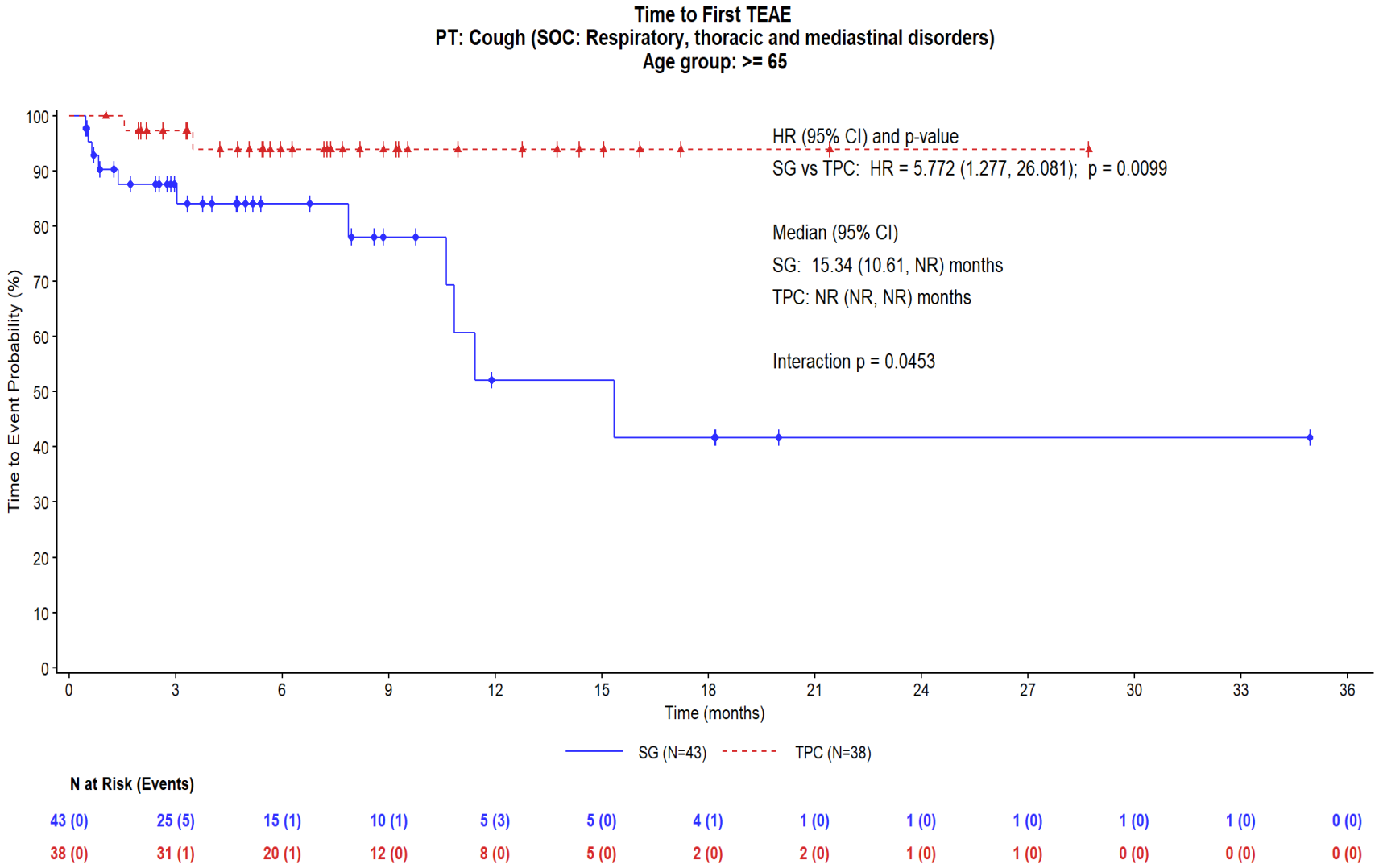
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.123. Figure 1.1.124: Kaplan Meier Plot of Time to First TEAE by PT Cough (SOC Respiratory thoracic and mediastinal disorders) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



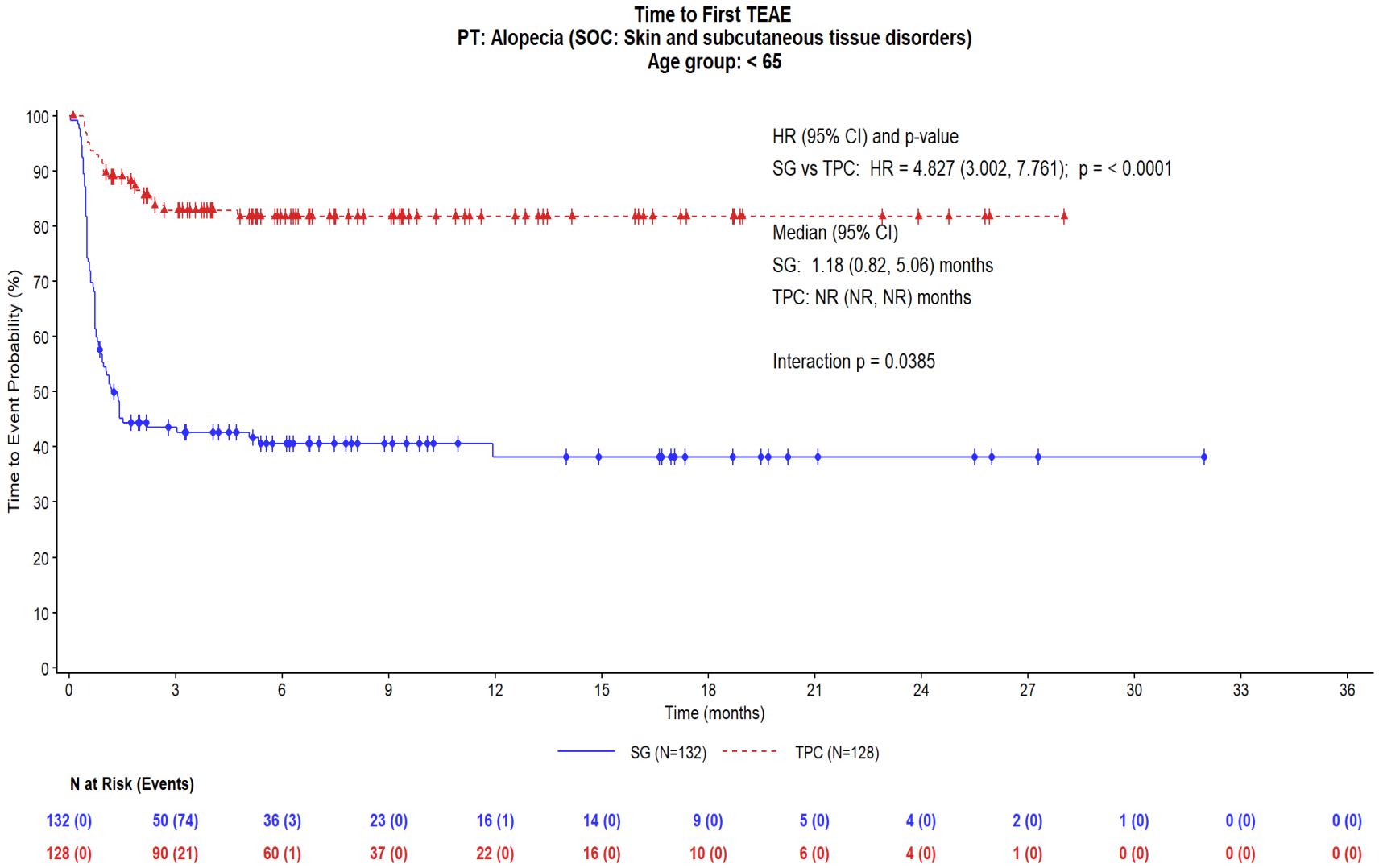
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.124. Figure 1.1.125: Kaplan Meier Plot of Time to First TEAE by PT Cough (SOC Respiratory thoracic and mediastinal disorders) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



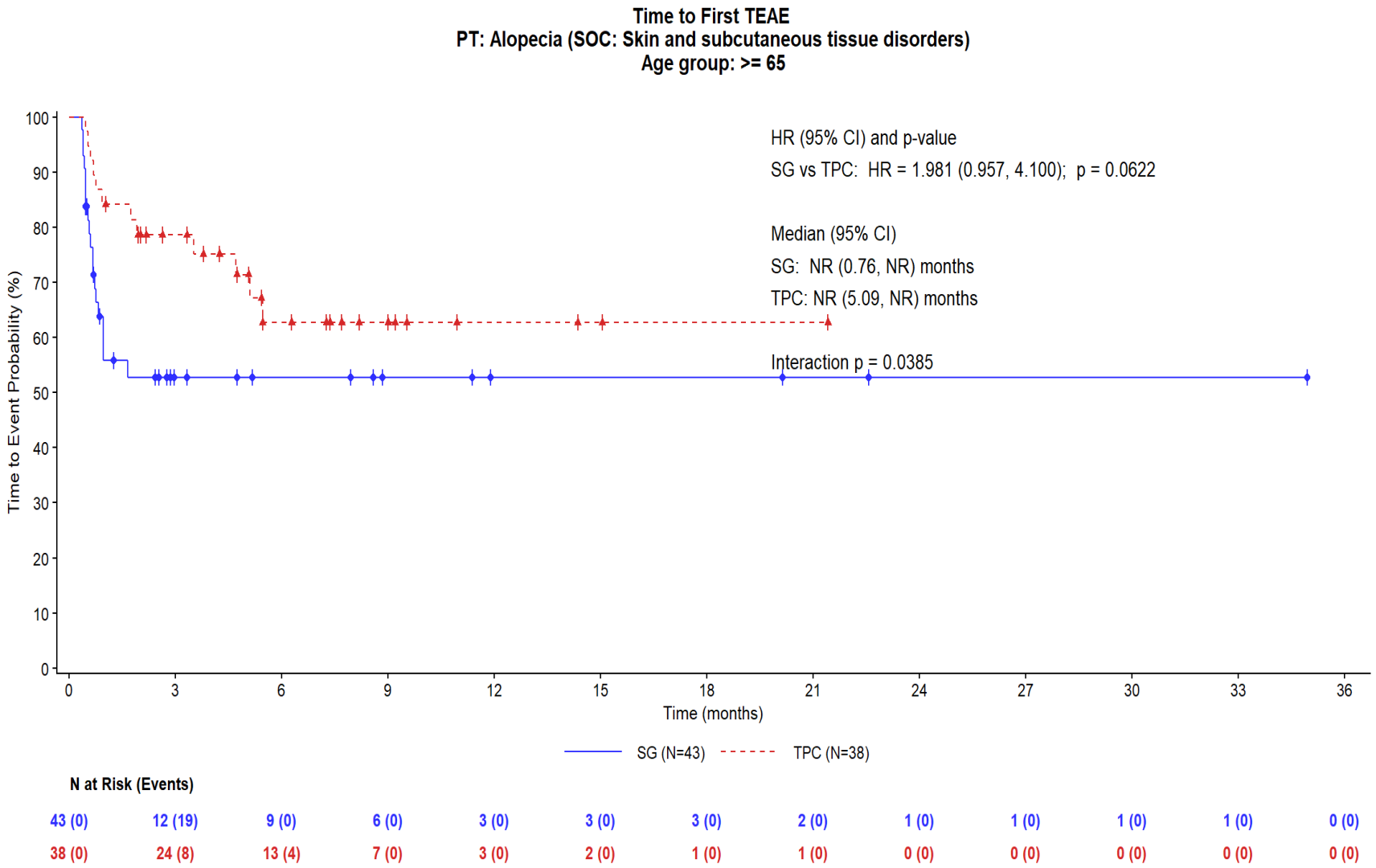
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.125. Figure 1.1.126: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group less than 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



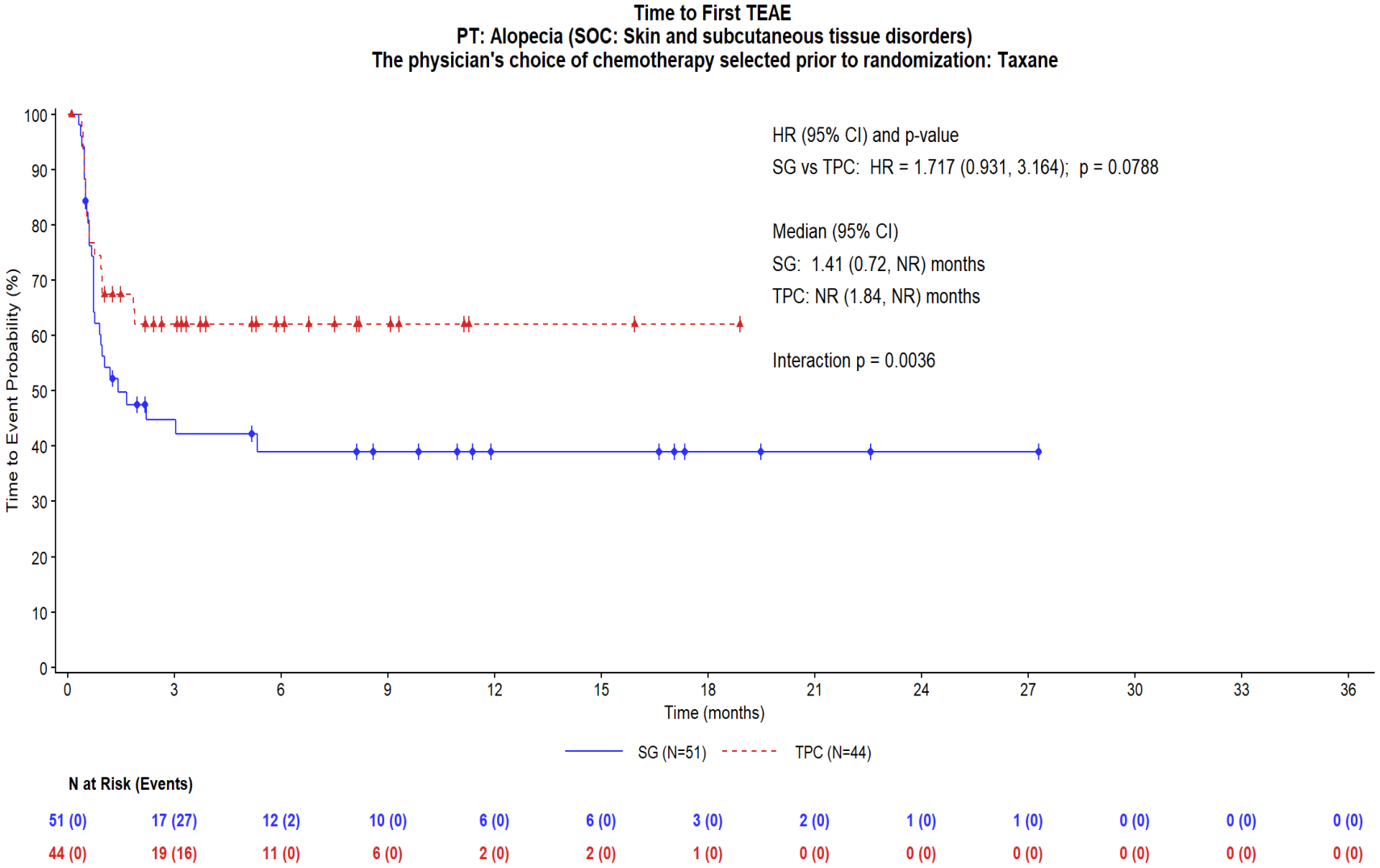
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.126. Figure 1.1.127: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) Age group greater than or equal to 65 — mSAF — Excluding patients preselected to receive nab-paclitaxel



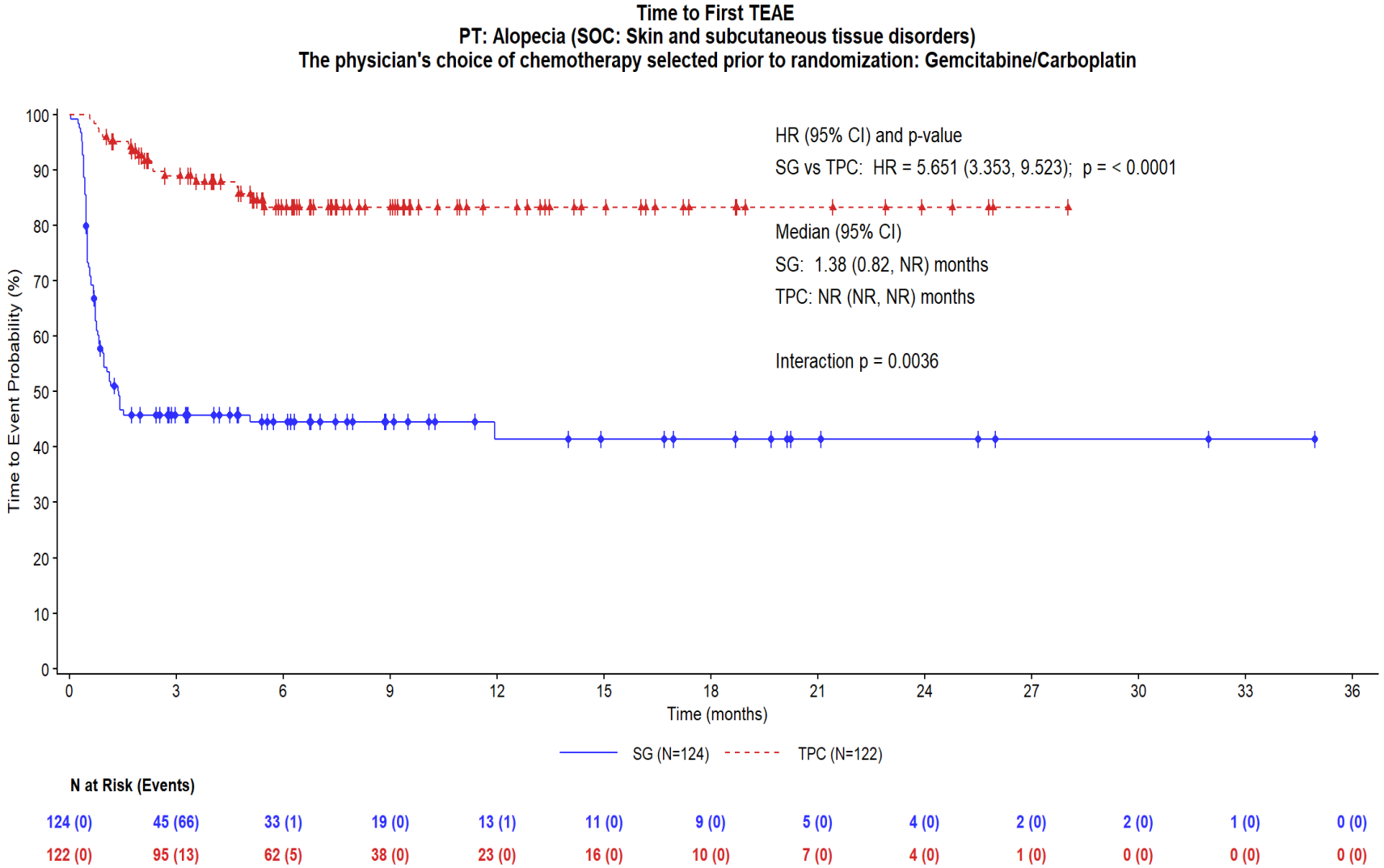
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.127. Figure 1.1.128: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) The physician s choice of chemotherapy selected prior to randomization Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



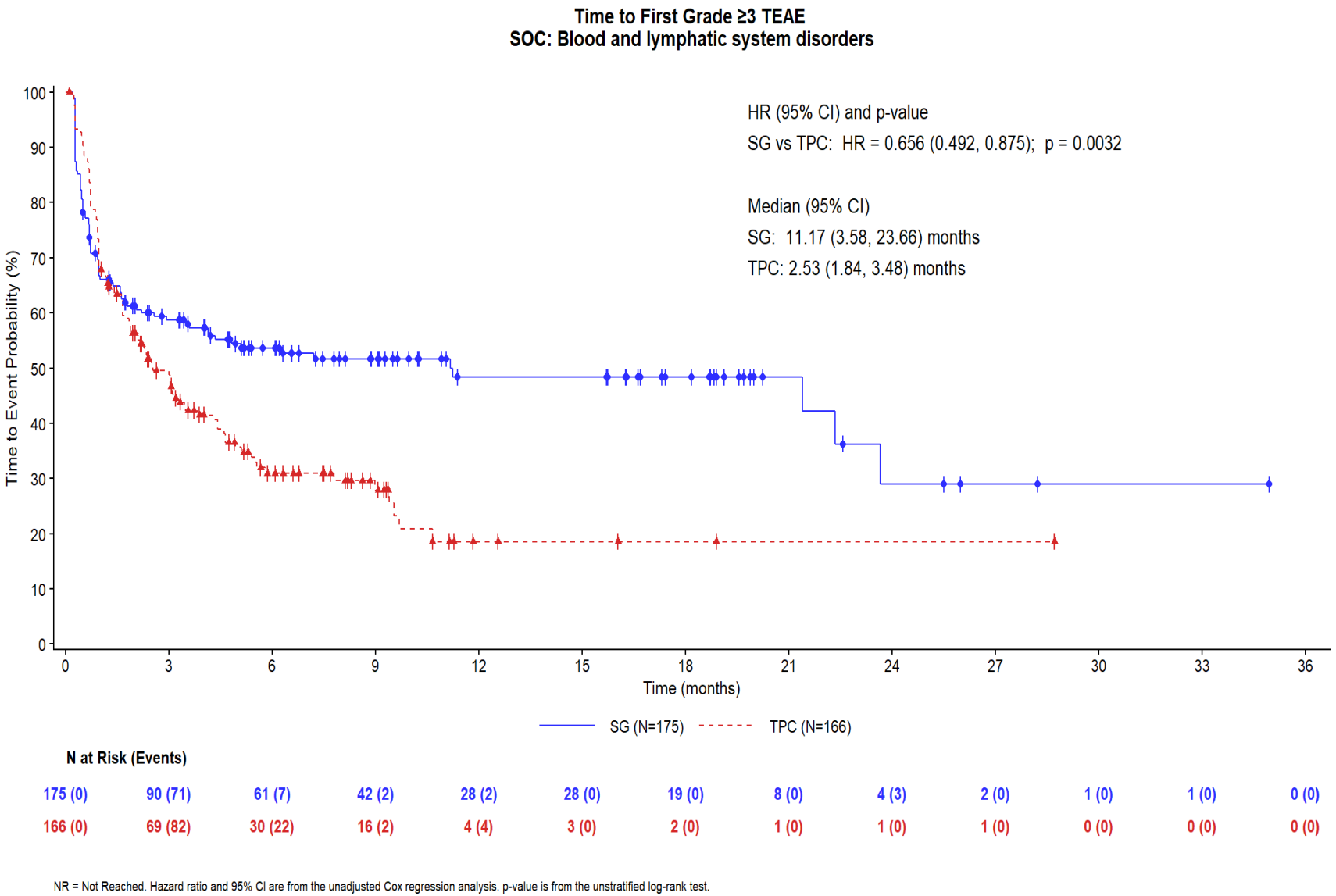
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.128. Figure 1.1.129: Kaplan Meier Plot of Time to First TEAE by PT Alopecia (SOC Skin and subcutaneous tissue disorders) The physician s choice of chemotherapy selected prior to randomization Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



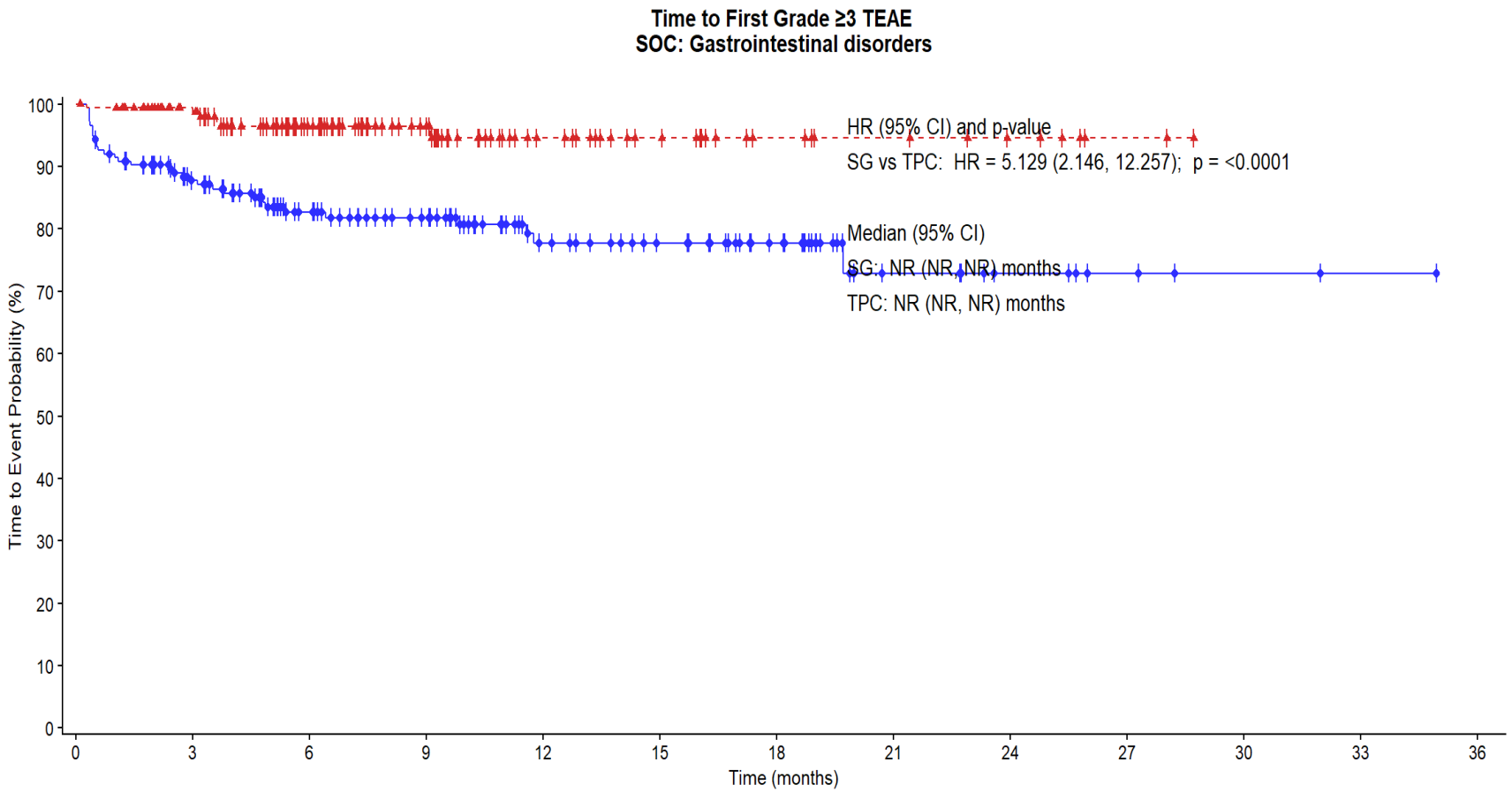
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.129. Figure 1.1.130: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



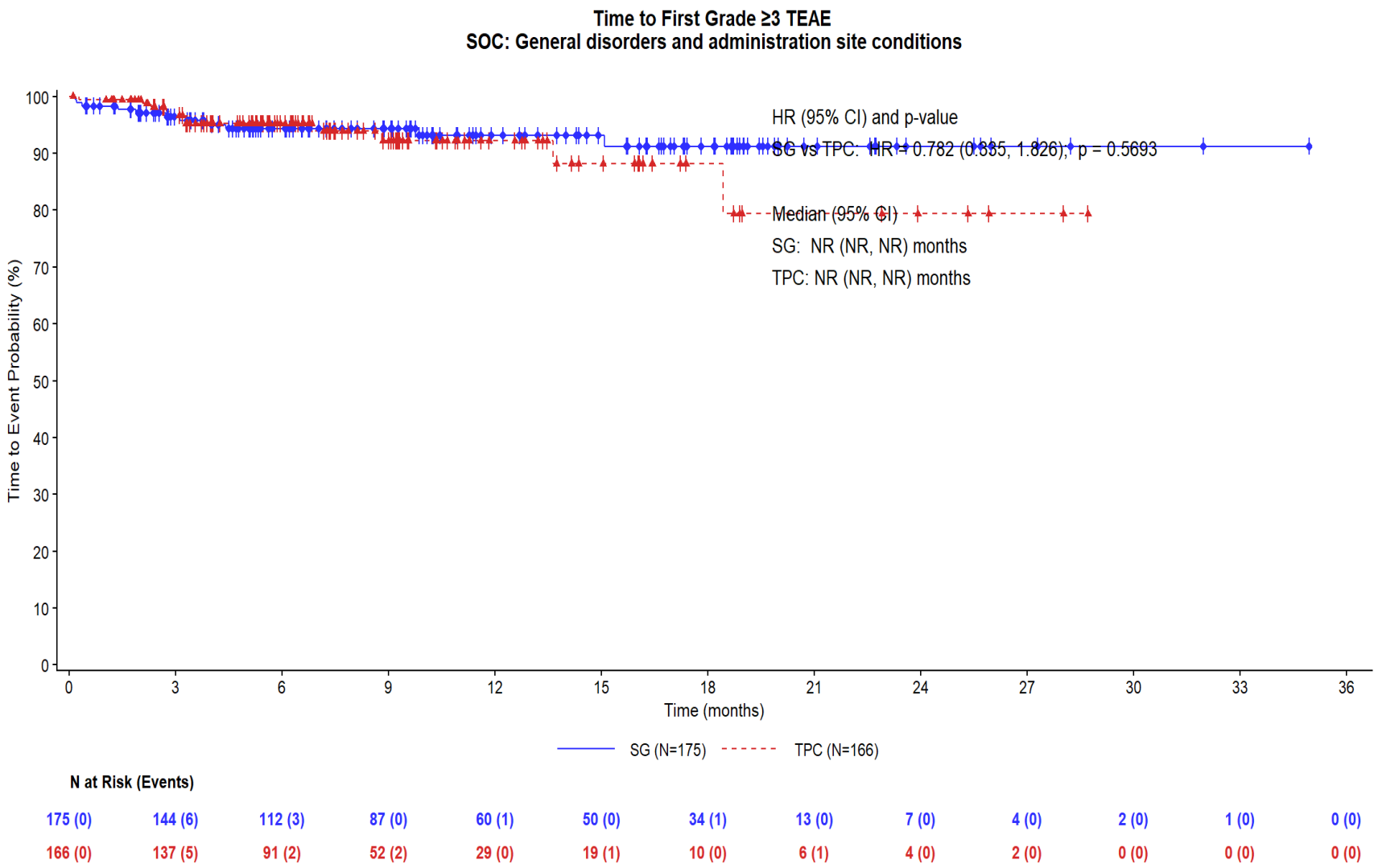
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.130. Figure 1.1.131: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



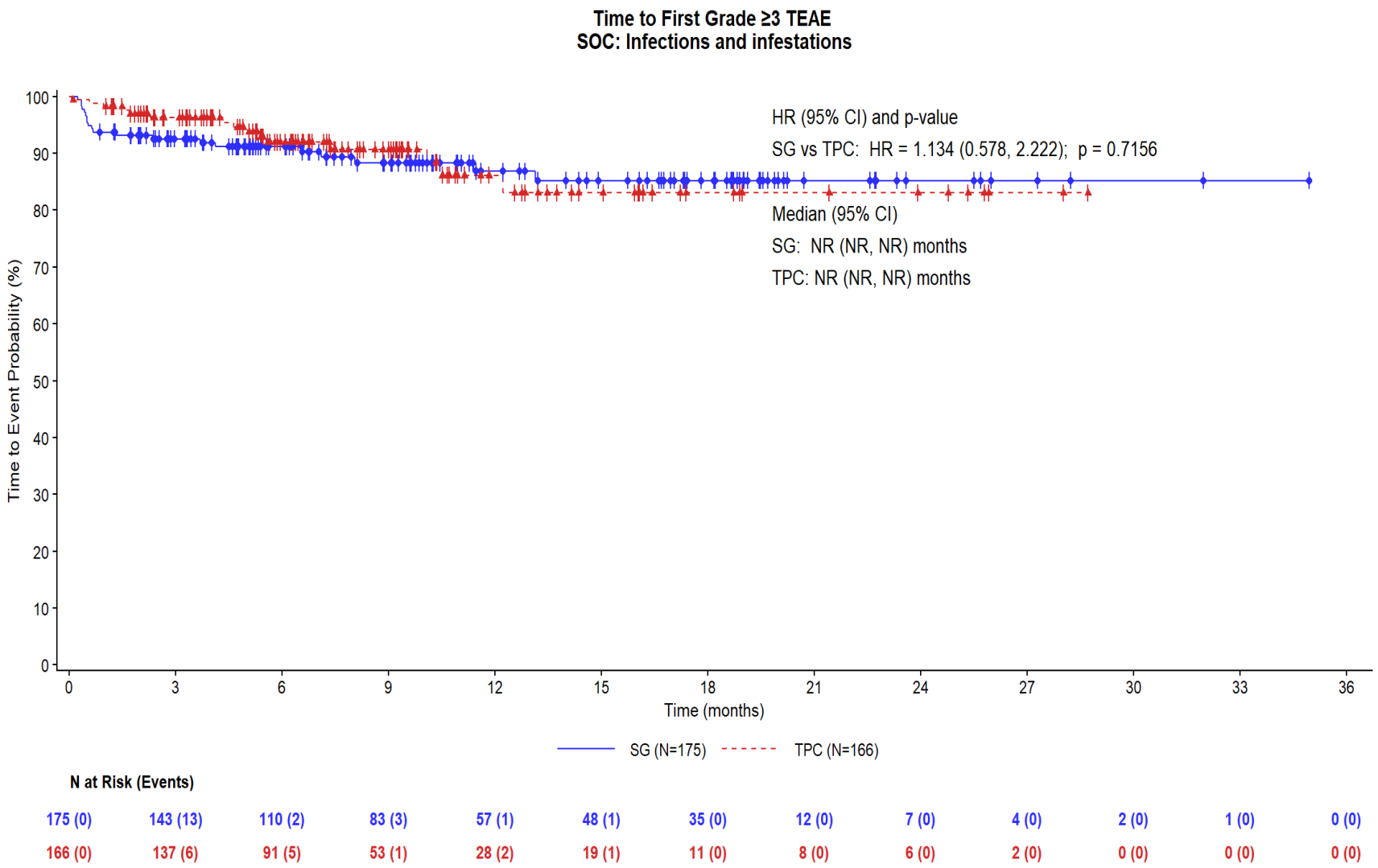
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.131. Figure 1.1.132: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC General disorders and administration site conditions — mSAF — Excluding patients preselected to receive nab-paclitaxel



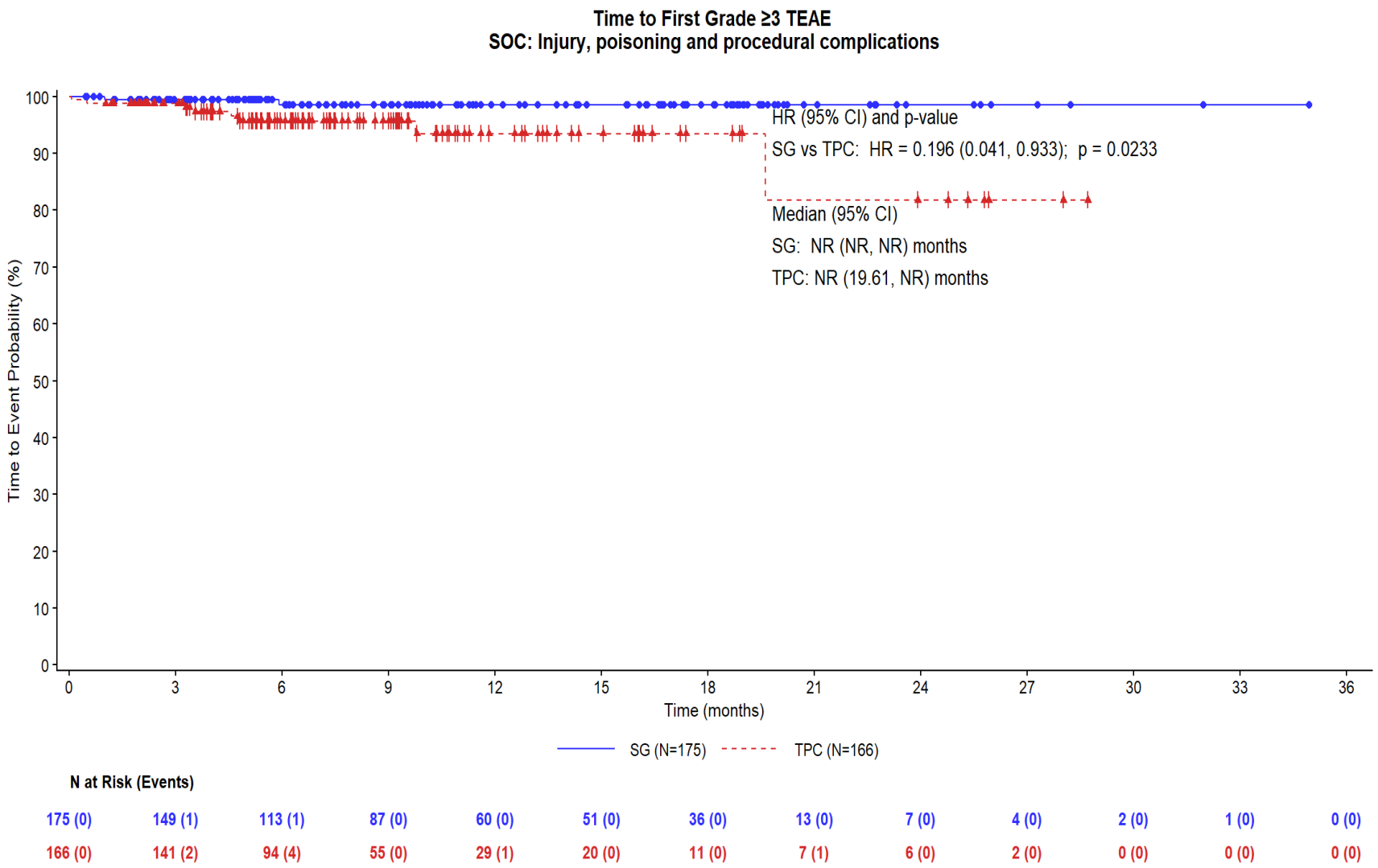
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.132. Figure 1.1.133: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel



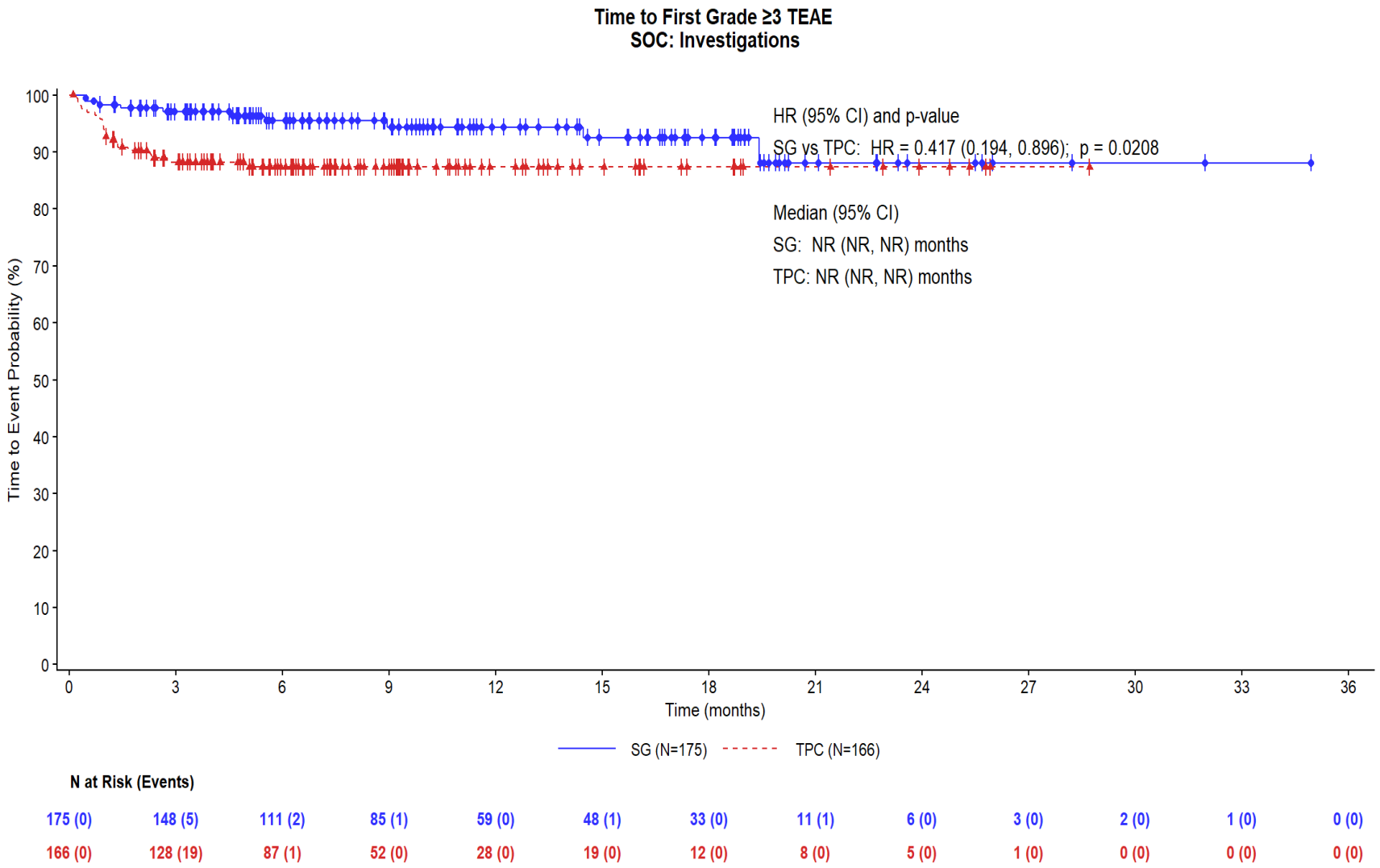
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.133. Figure 1.1.134: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Injury poisoning and procedural complications — mSAF — Excluding patients preselected to receive nab-paclitaxel



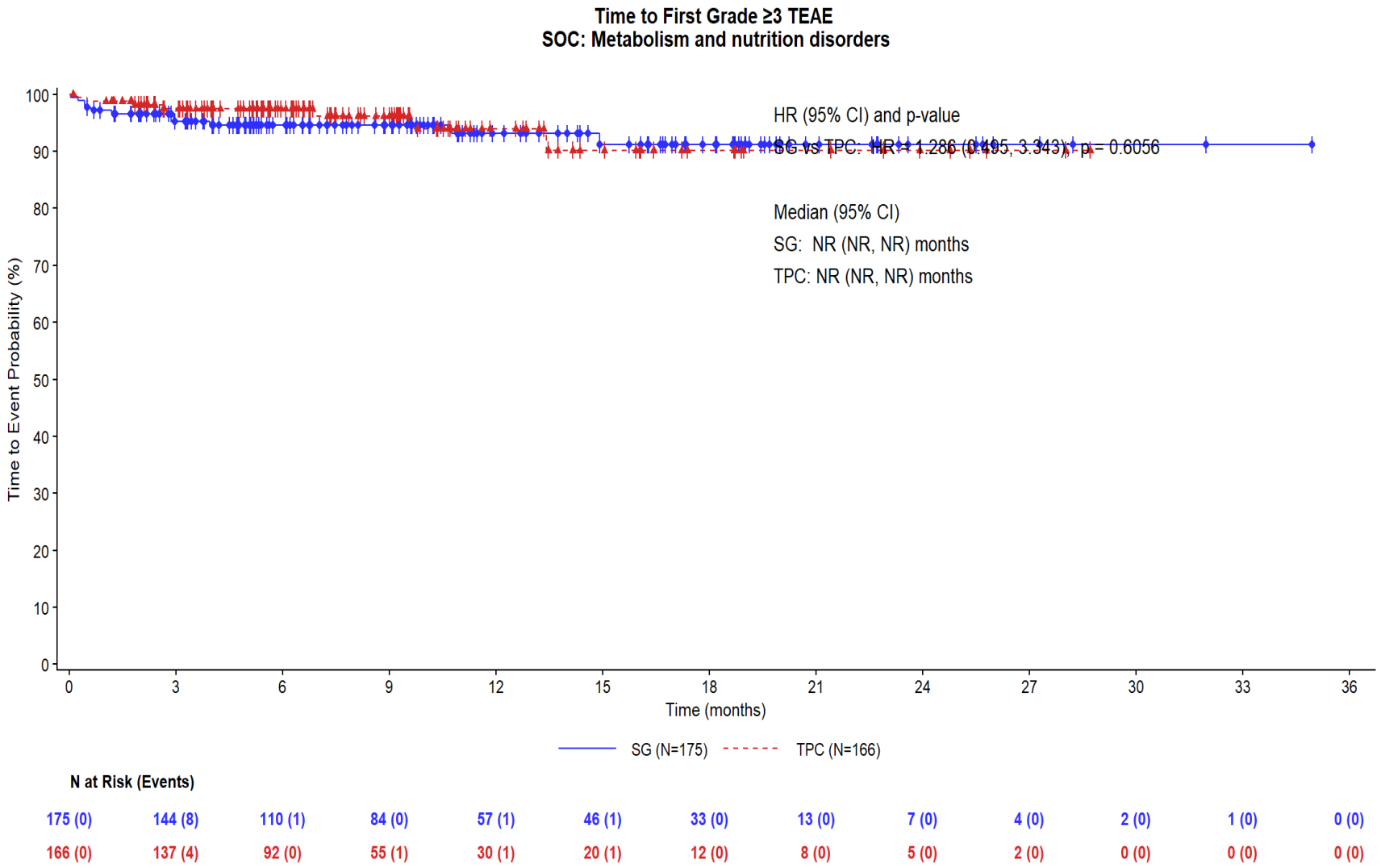
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.134. Figure 1.1.135: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Investigations — mSAF — Excluding patients preselected to receive nab-paclitaxel



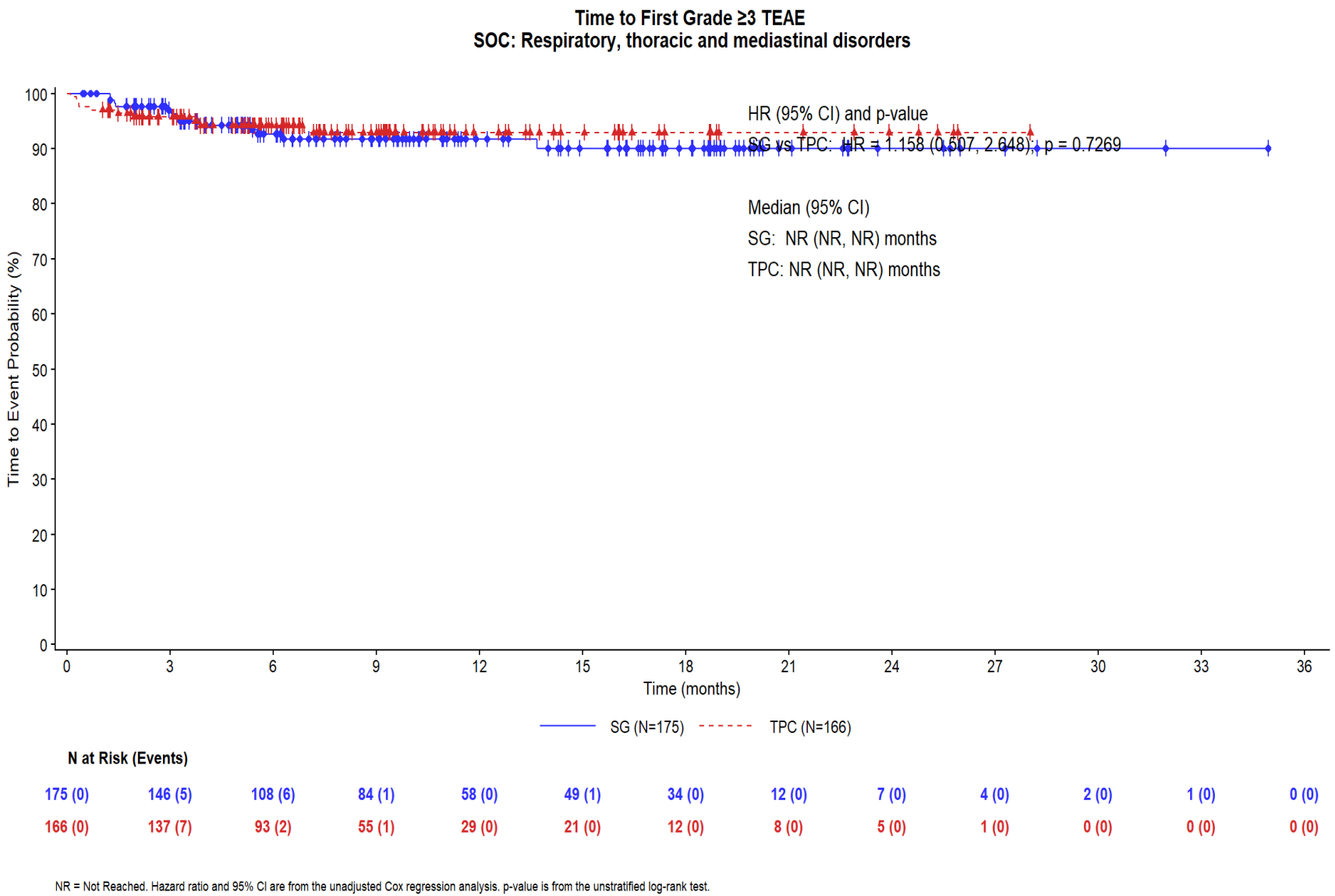
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.135. Figure 1.1.136: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Metabolism and nutrition disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



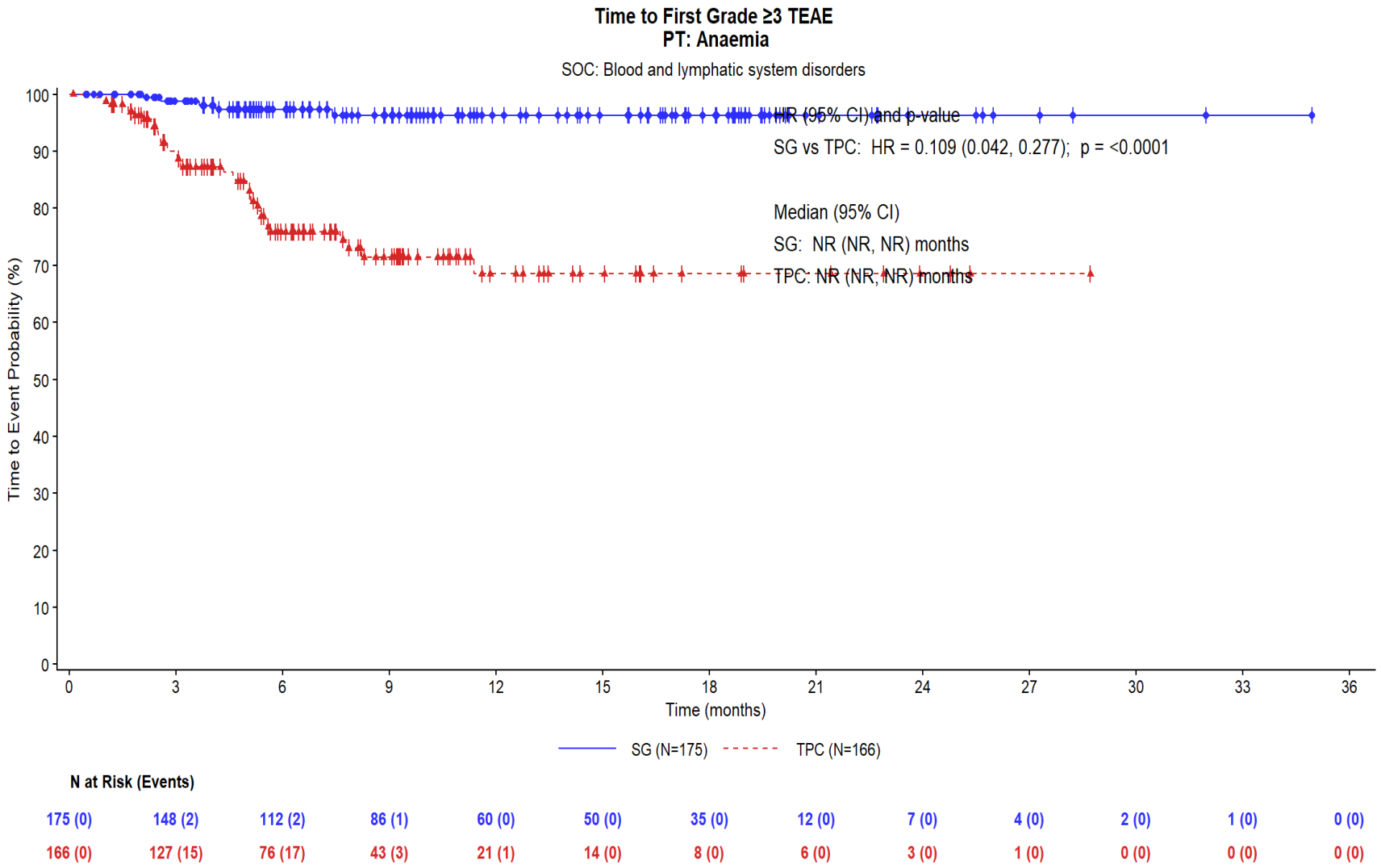
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.136. Figure 1.1.137: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



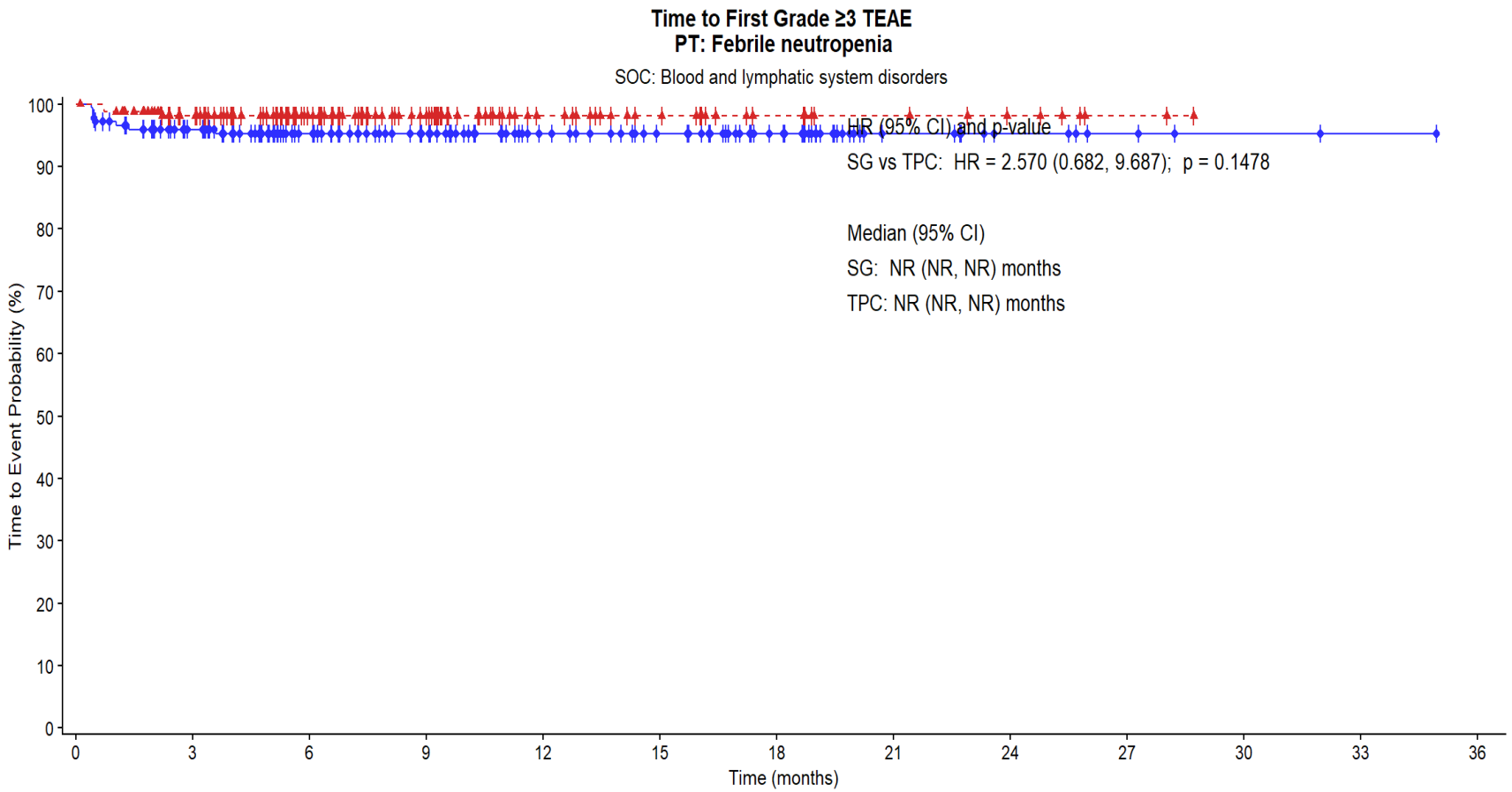
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.137. Figure 1.1.138: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Anaemia — mSAF — Excluding patients preselected to receive nab-paclitaxel



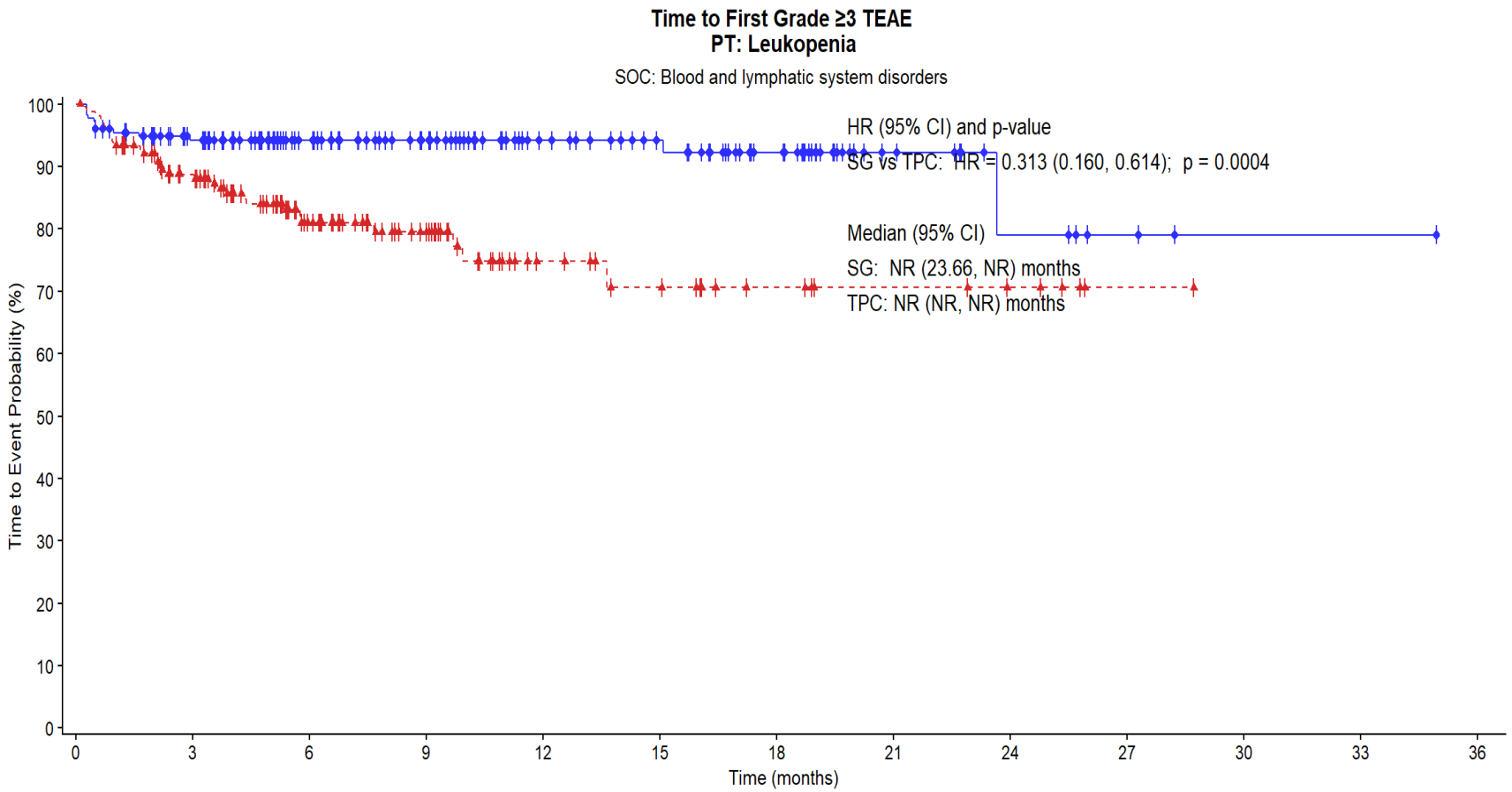
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.138. Figure 1.1.139: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Febrile neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



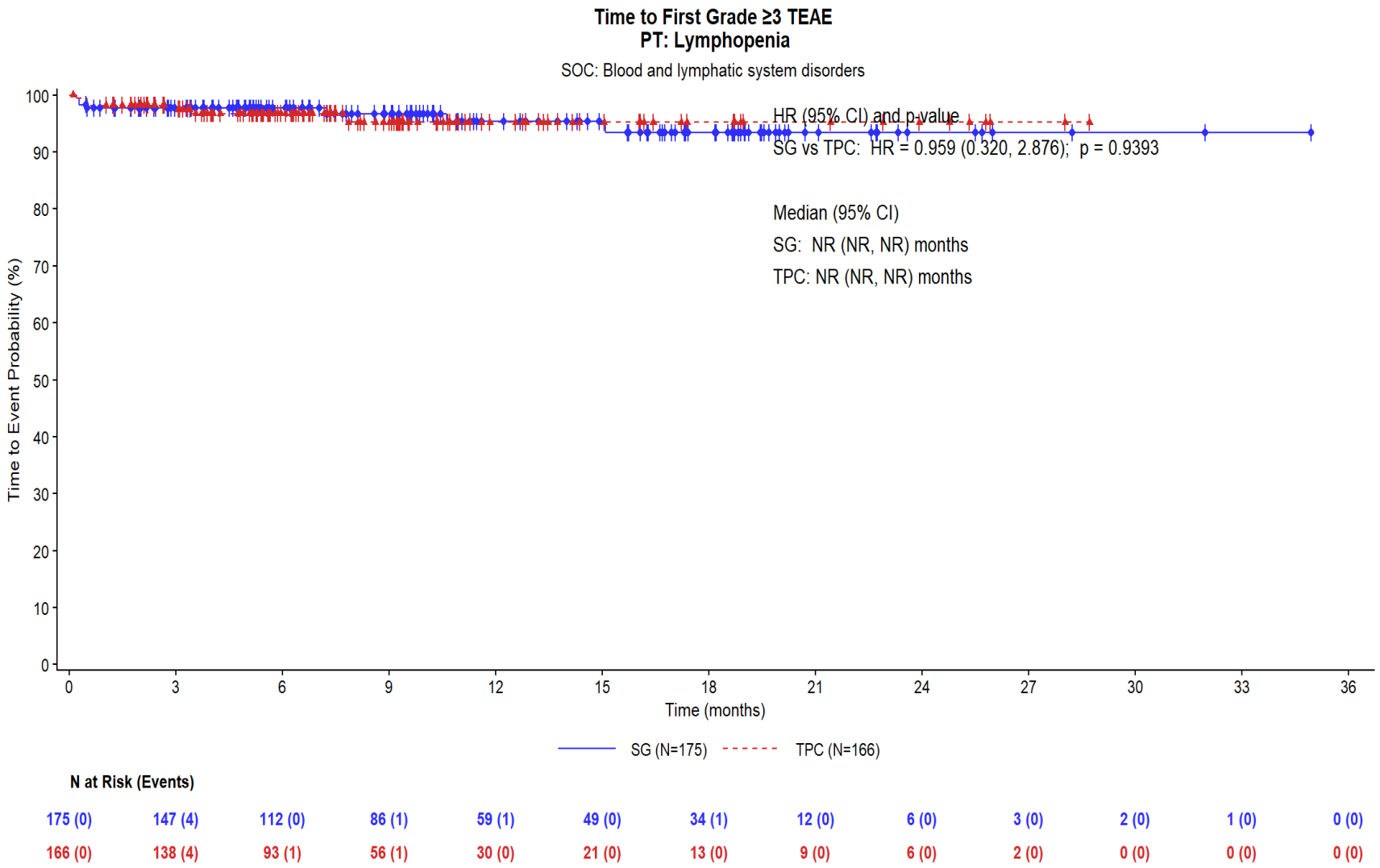
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.139. Figure 1.1.140: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Leukopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



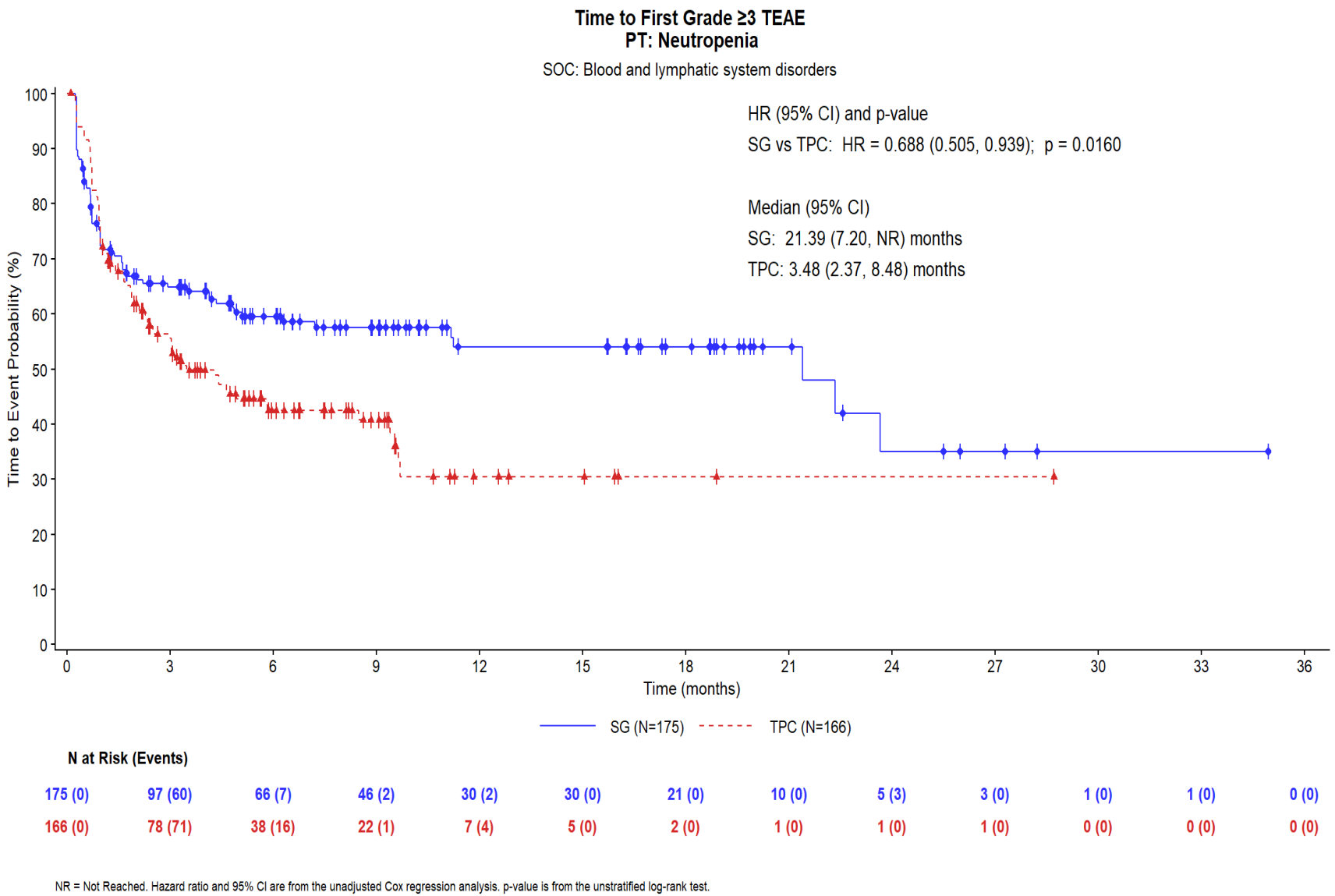
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.140. Figure 1.1.141: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Lymphopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



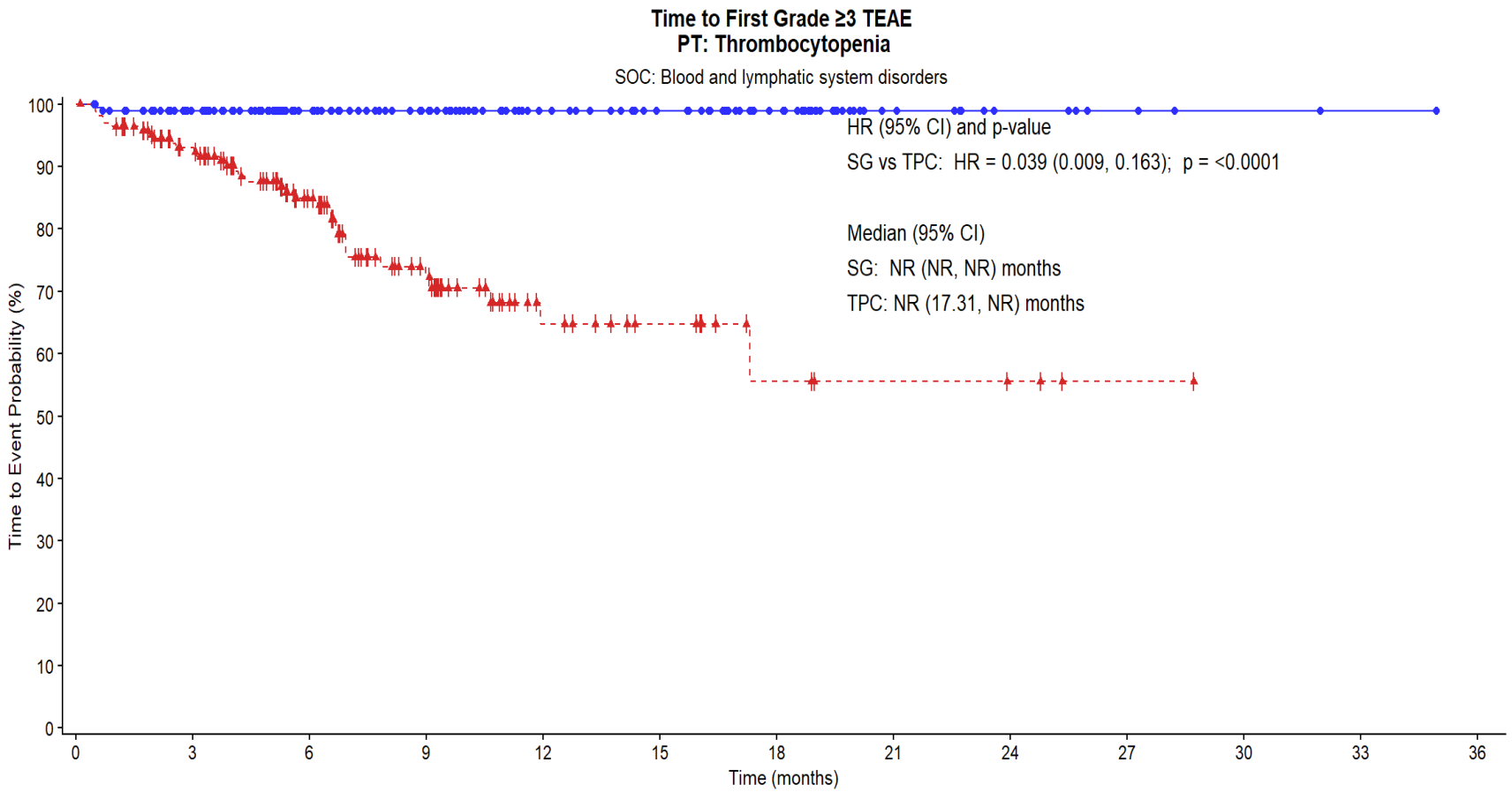
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.141. Figure 1.1.142: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



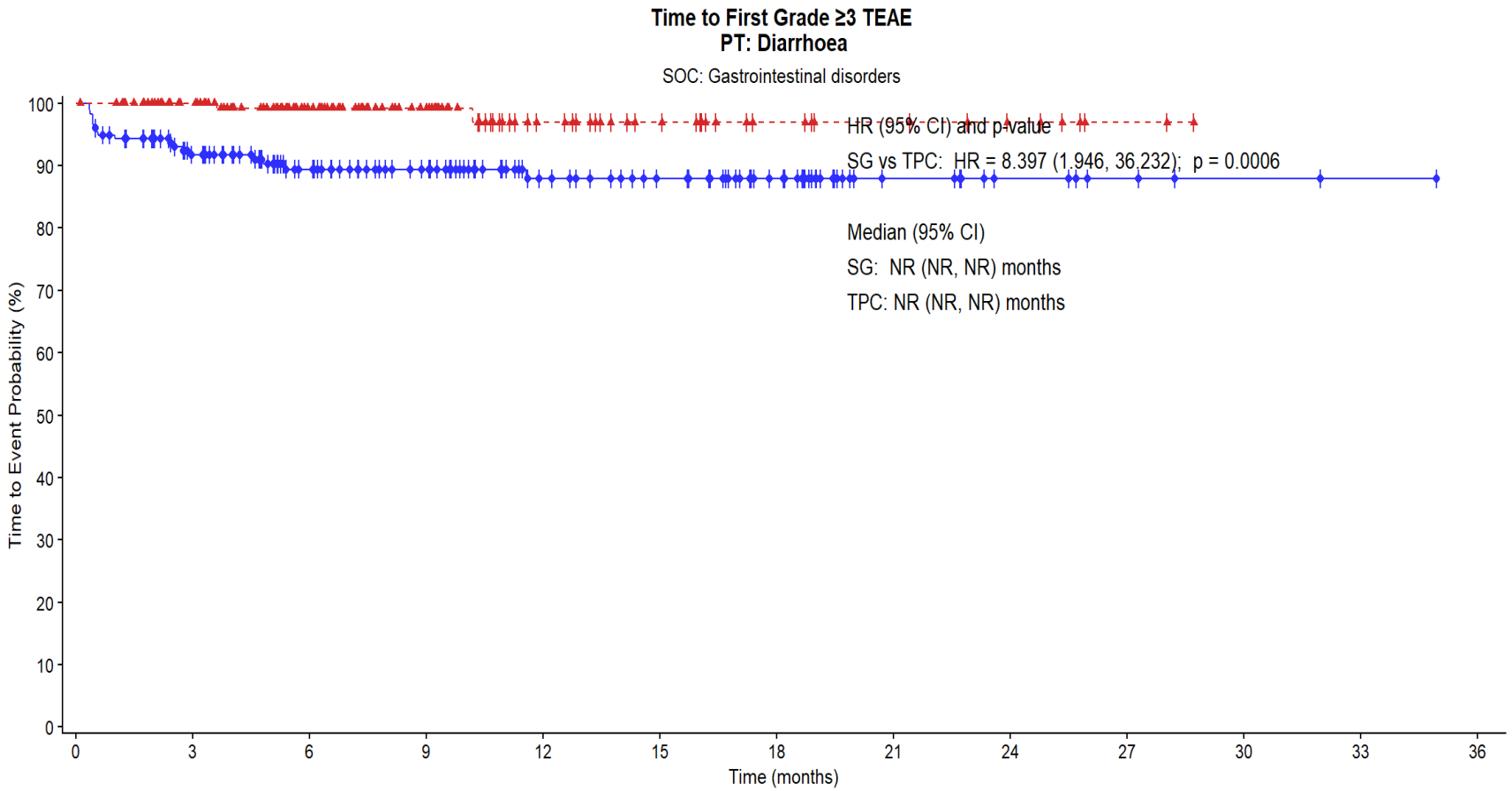
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.142. Figure 1.1.143: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



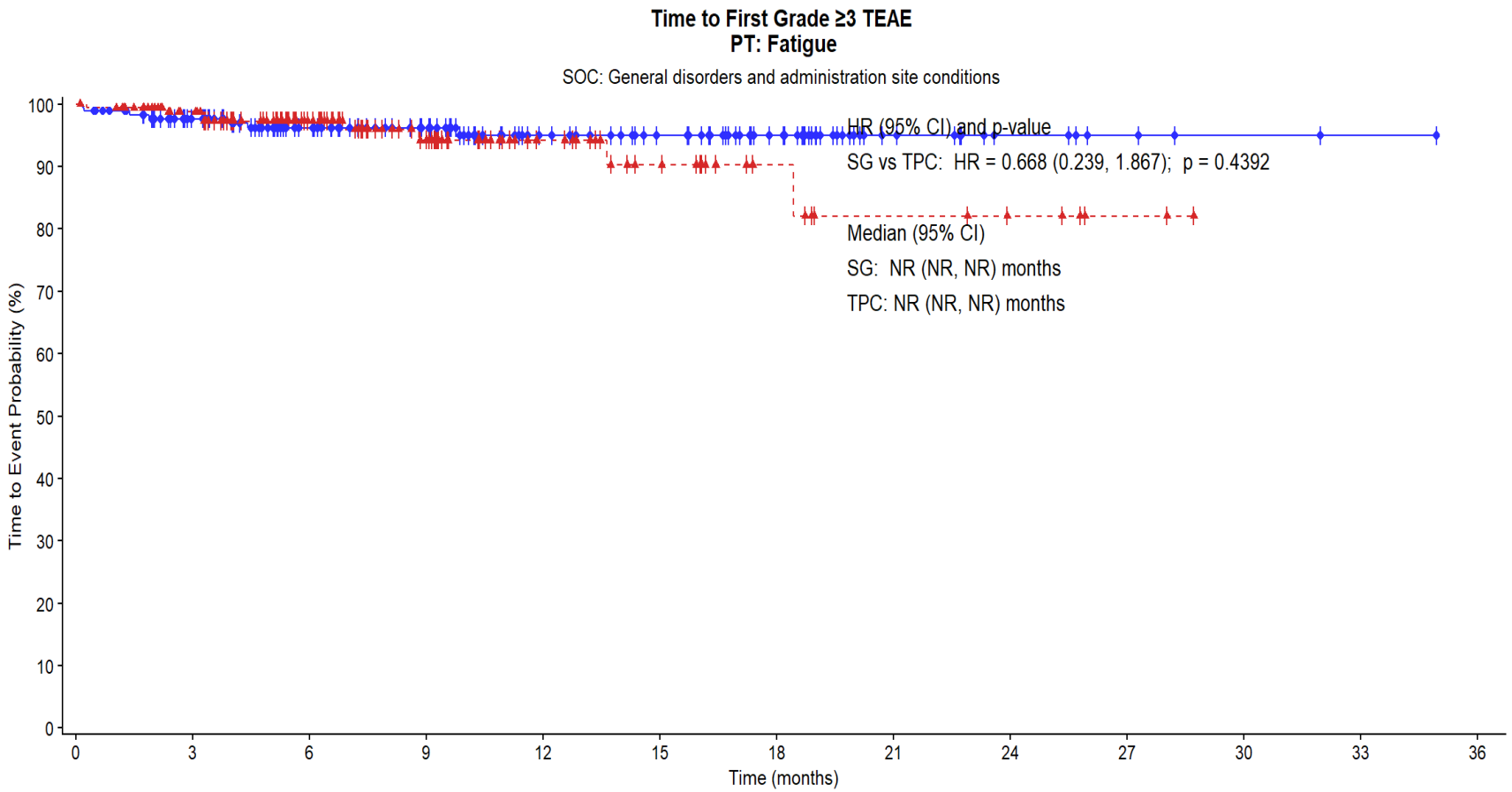
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.143. Figure 1.1.144: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Diarrhoea — mSAF — Excluding patients preselected to receive nab-paclitaxel



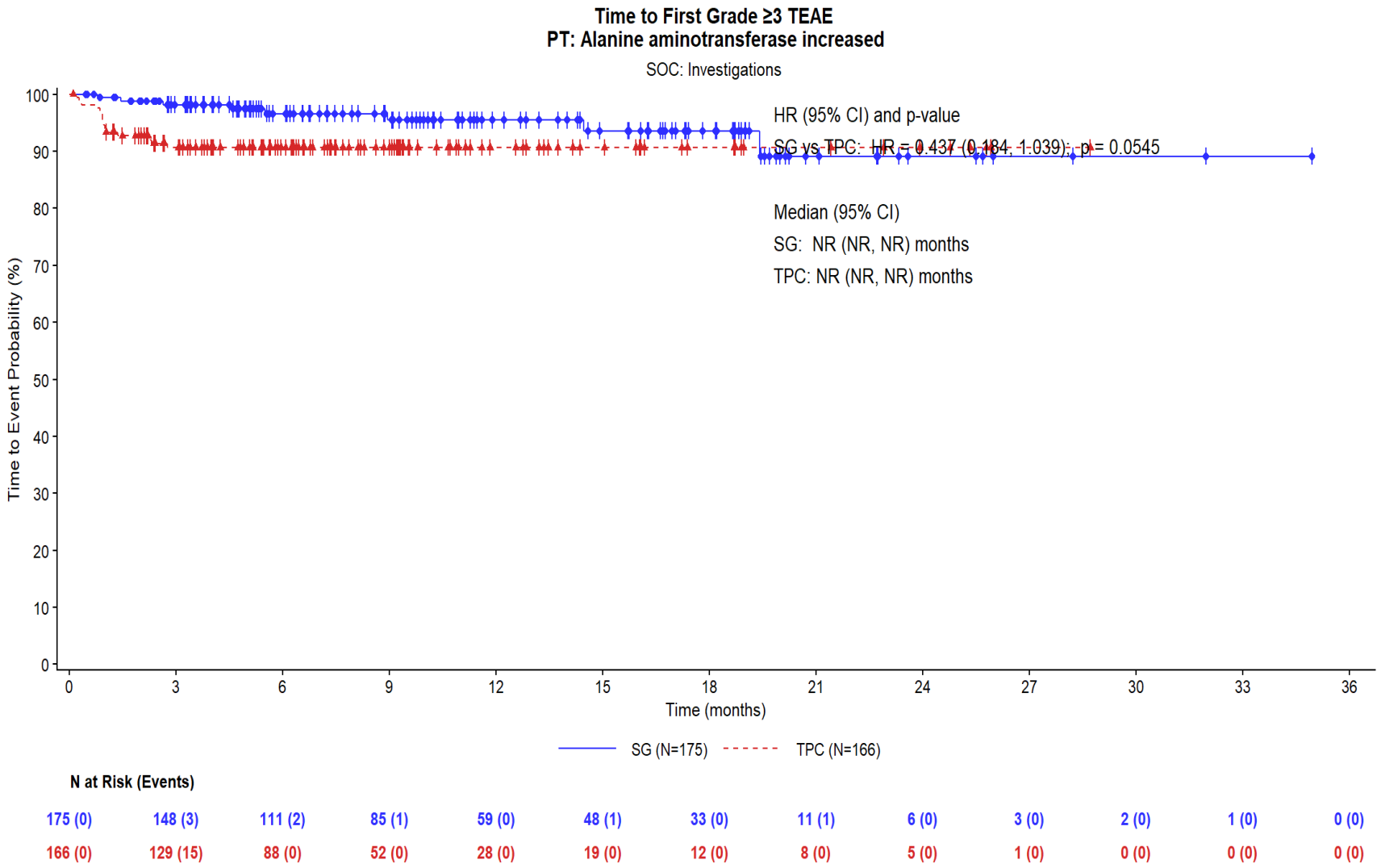
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.144. Figure 1.1.145: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Fatigue — mSAF — Excluding patients preselected to receive nab-paclitaxel



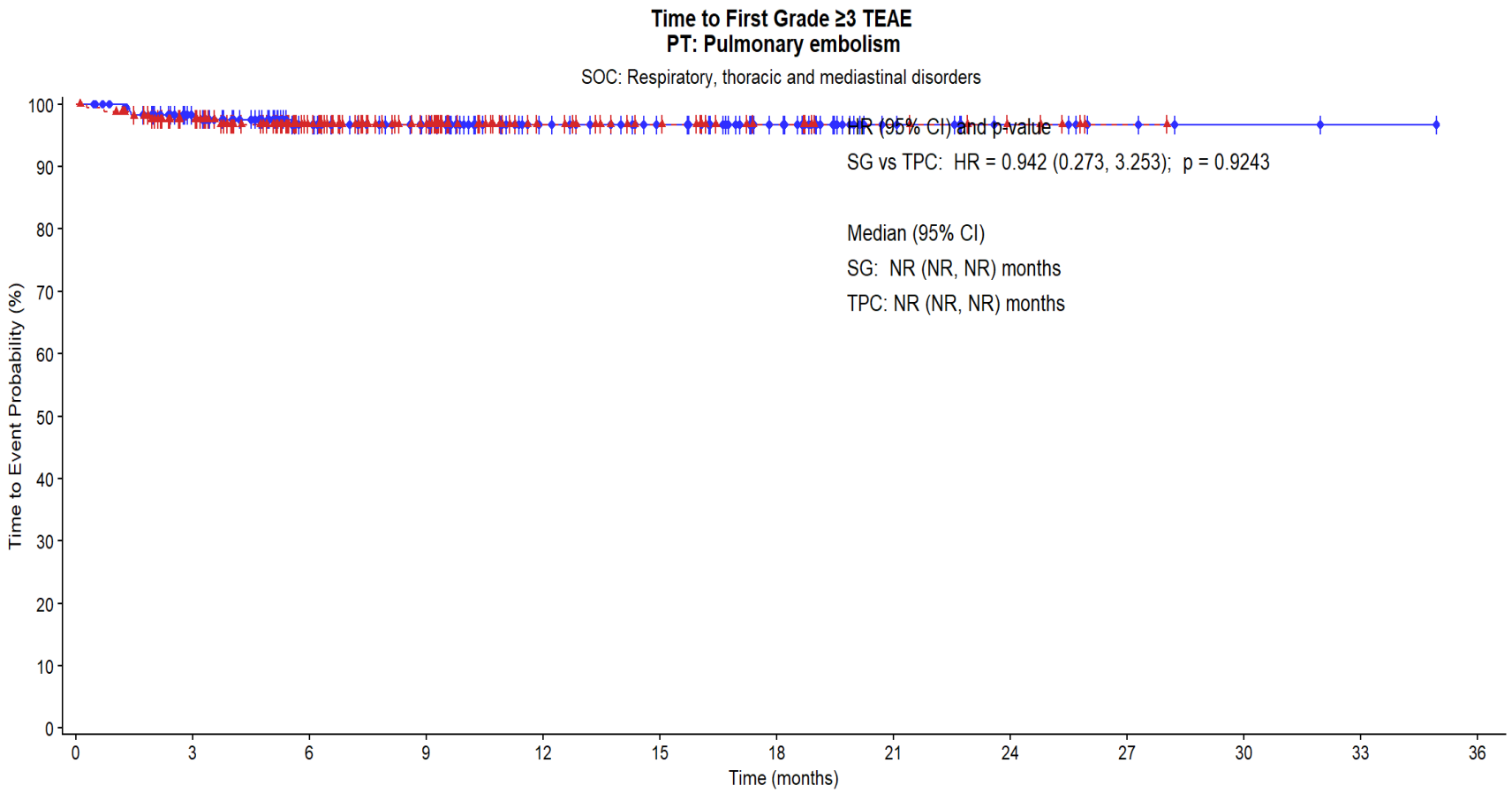
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.145. Figure 1.1.146: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Alanine aminotransferase increased — mSAF — Excluding patients preselected to receive nab-paclitaxel



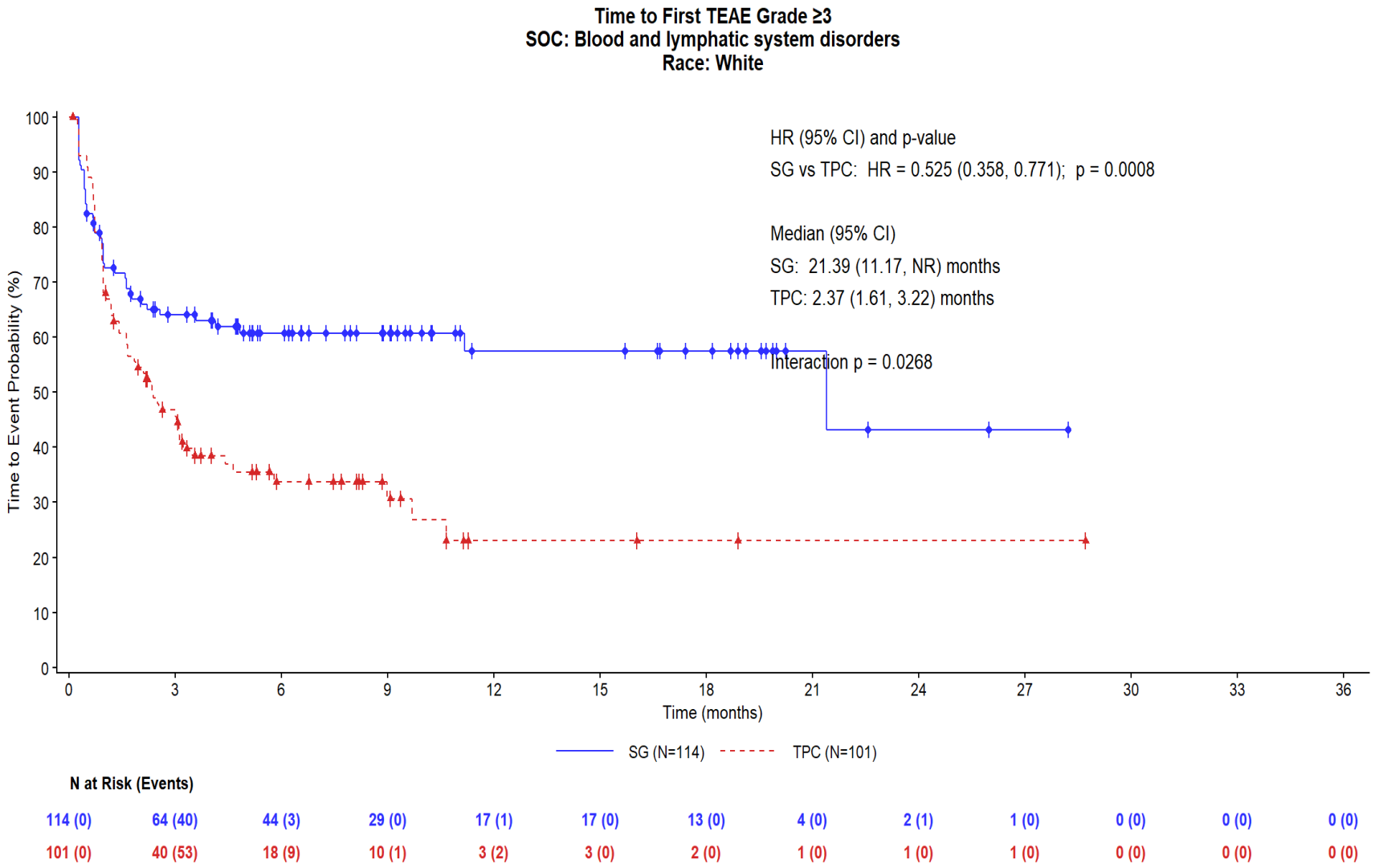
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.146. Figure 1.1.147: Kaplan Meier Plot of Time to First TEAE with CTCAE Grade 3 or higher by PT Pulmonary embolism — mSAF — Excluding patients preselected to receive nab-paclitaxel



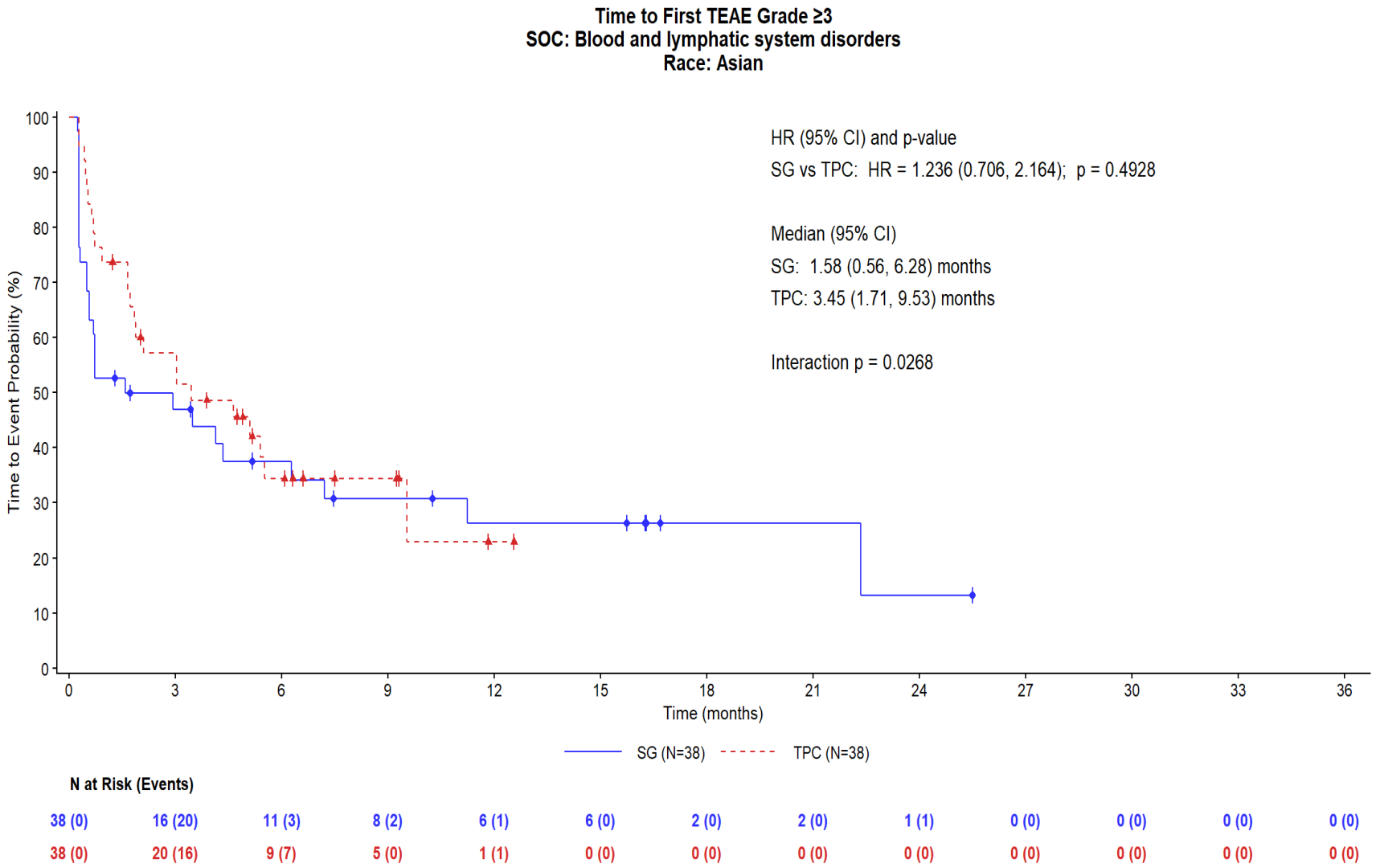
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.147. Figure 1.1.148: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel



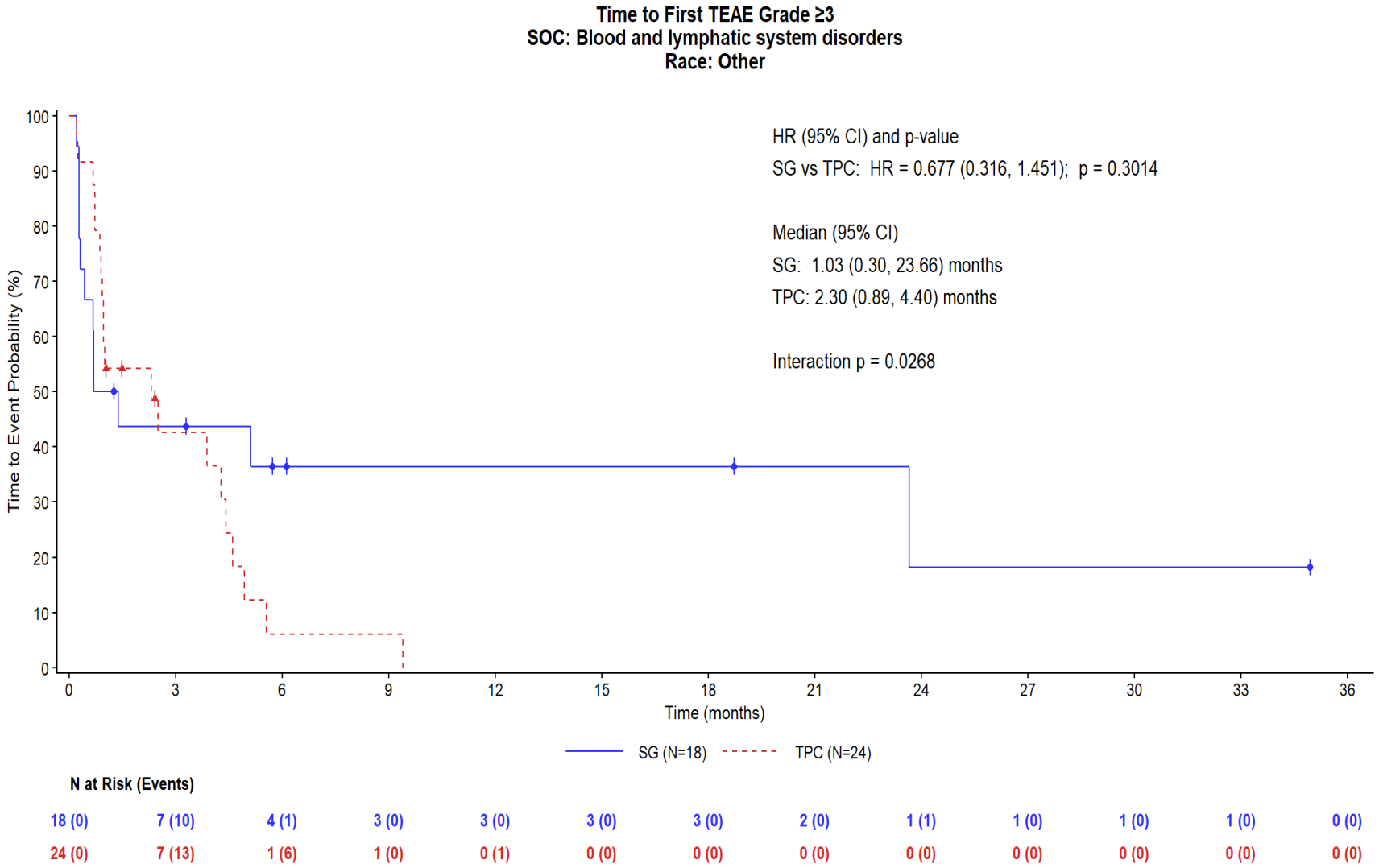
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.148. Figure 1.1.149: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Race Asian — mSAF — Excluding patients preselected to receive nab-paclitaxel



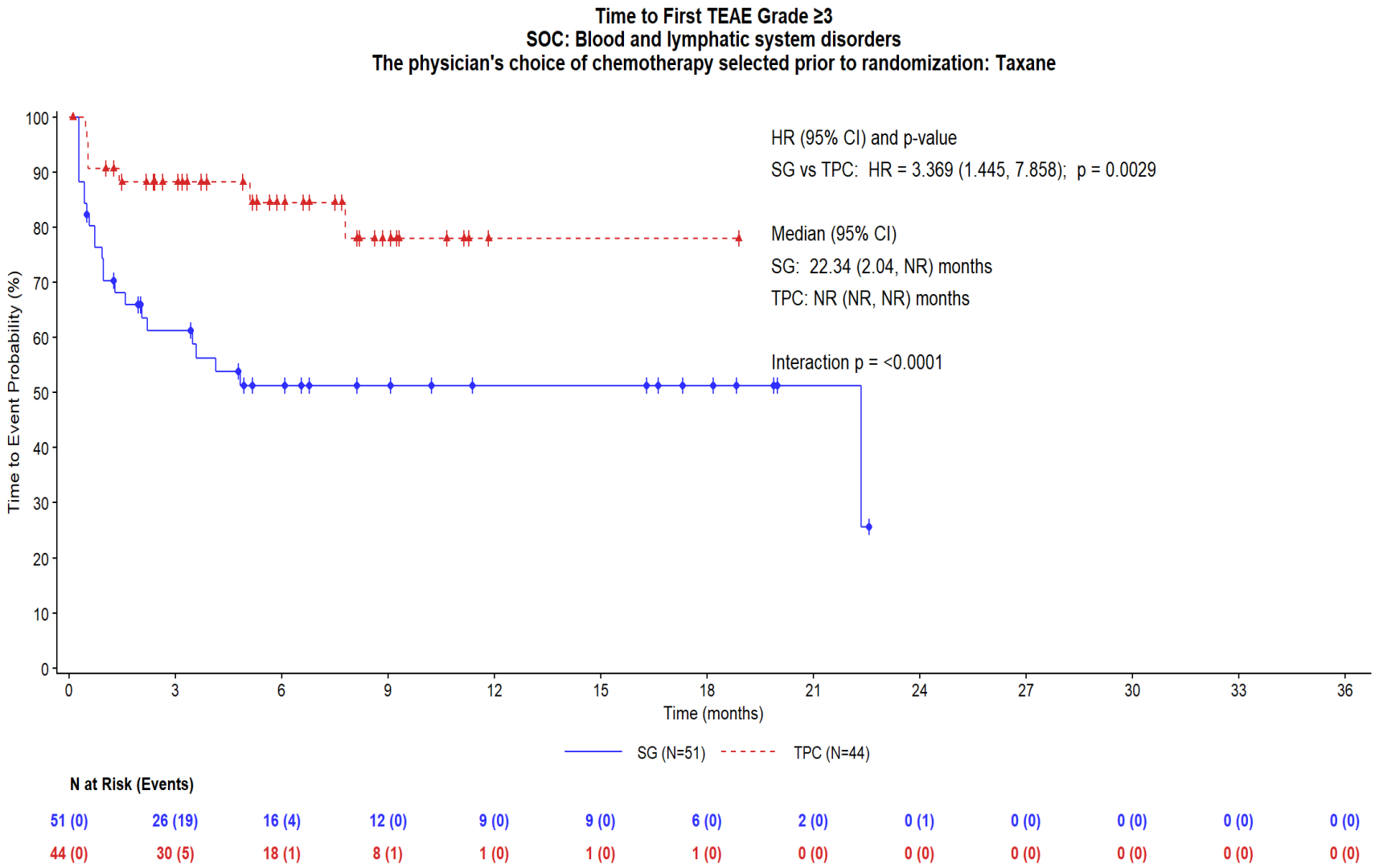
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.149. Figure 1.1.150: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel



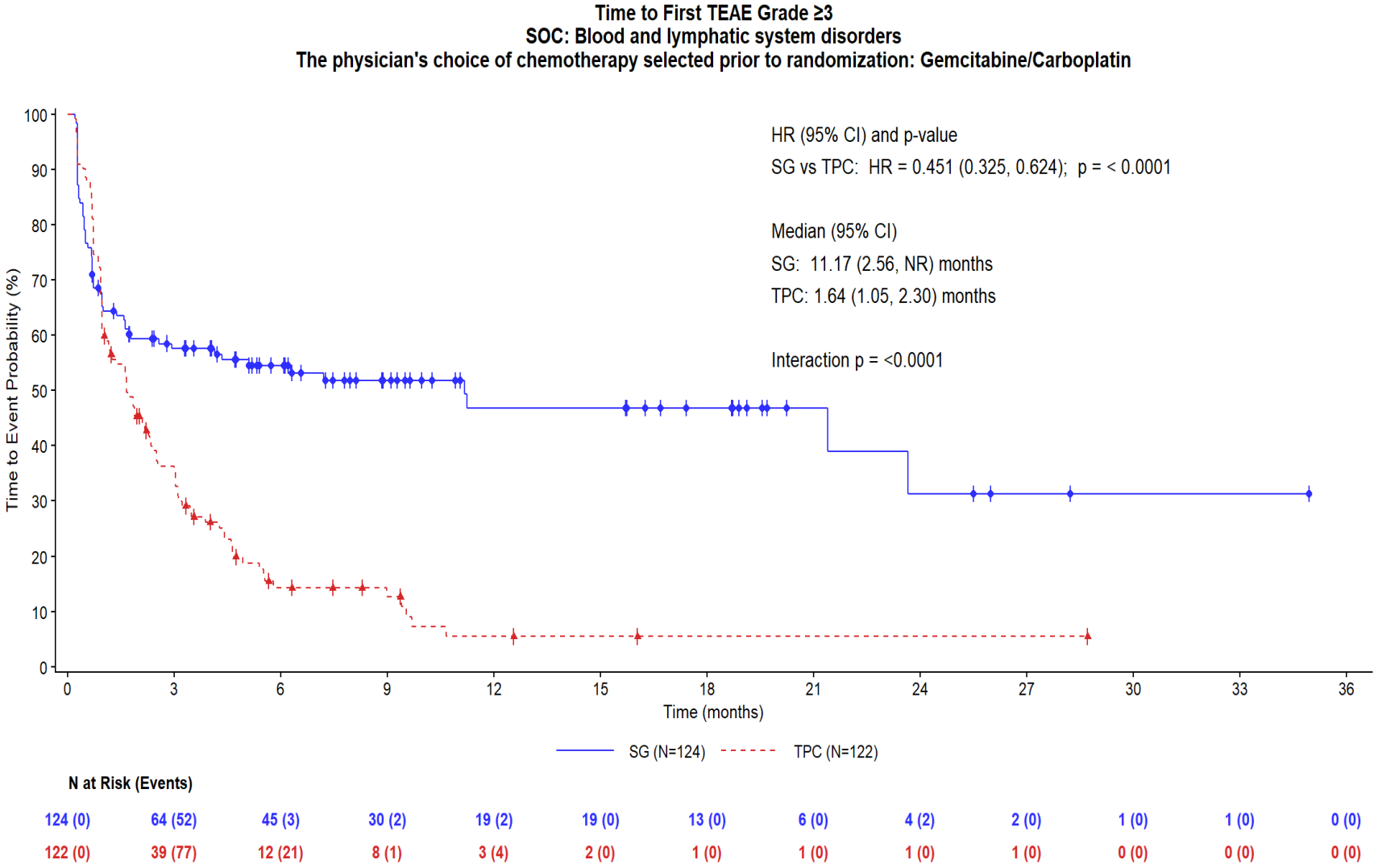
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.150. Figure 1.1.151: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Physician s chemotherapy choice Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



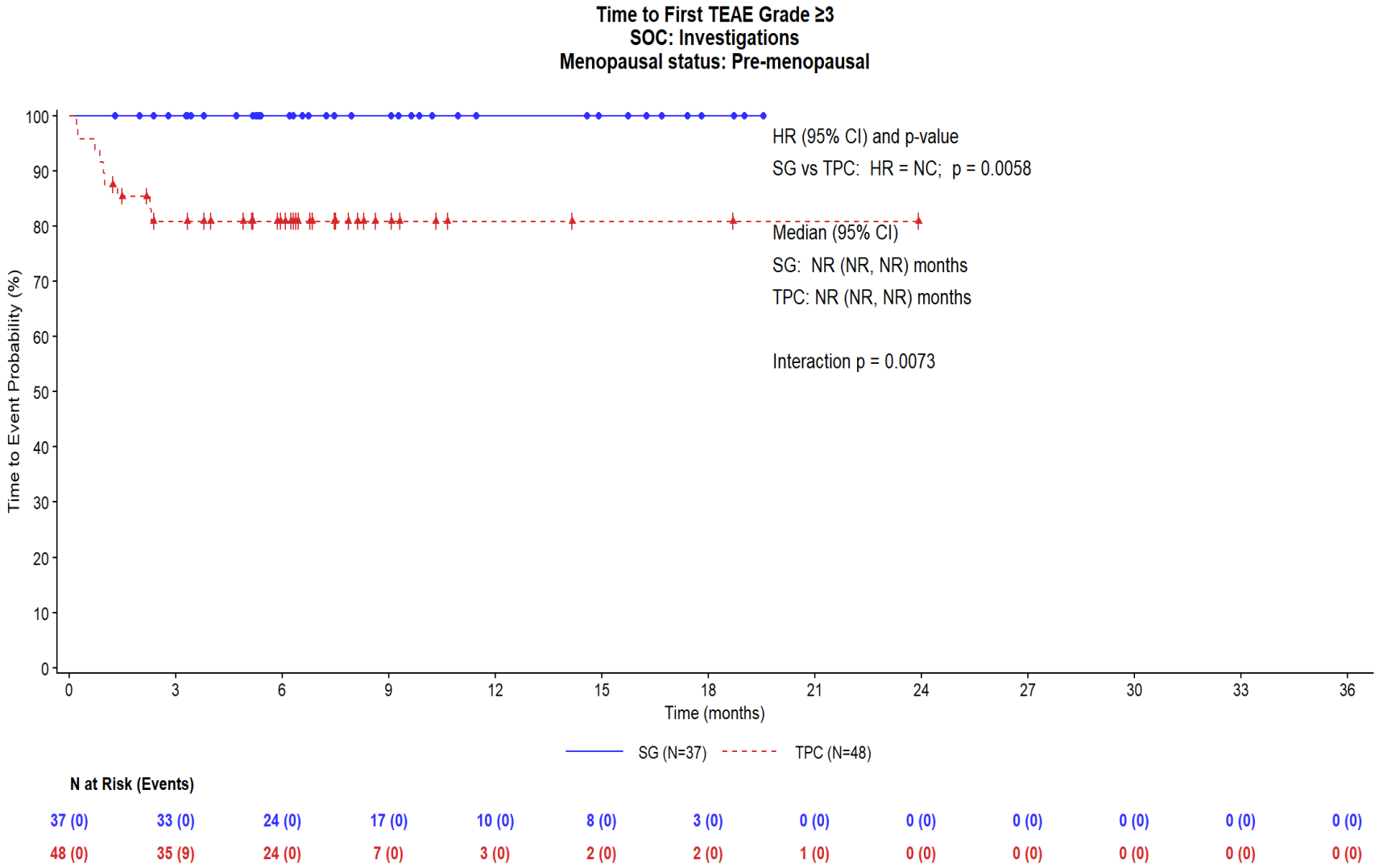
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.151. Figure 1.1.152: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Blood and lymphatic system disorders Physician s chemotherapy choice Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



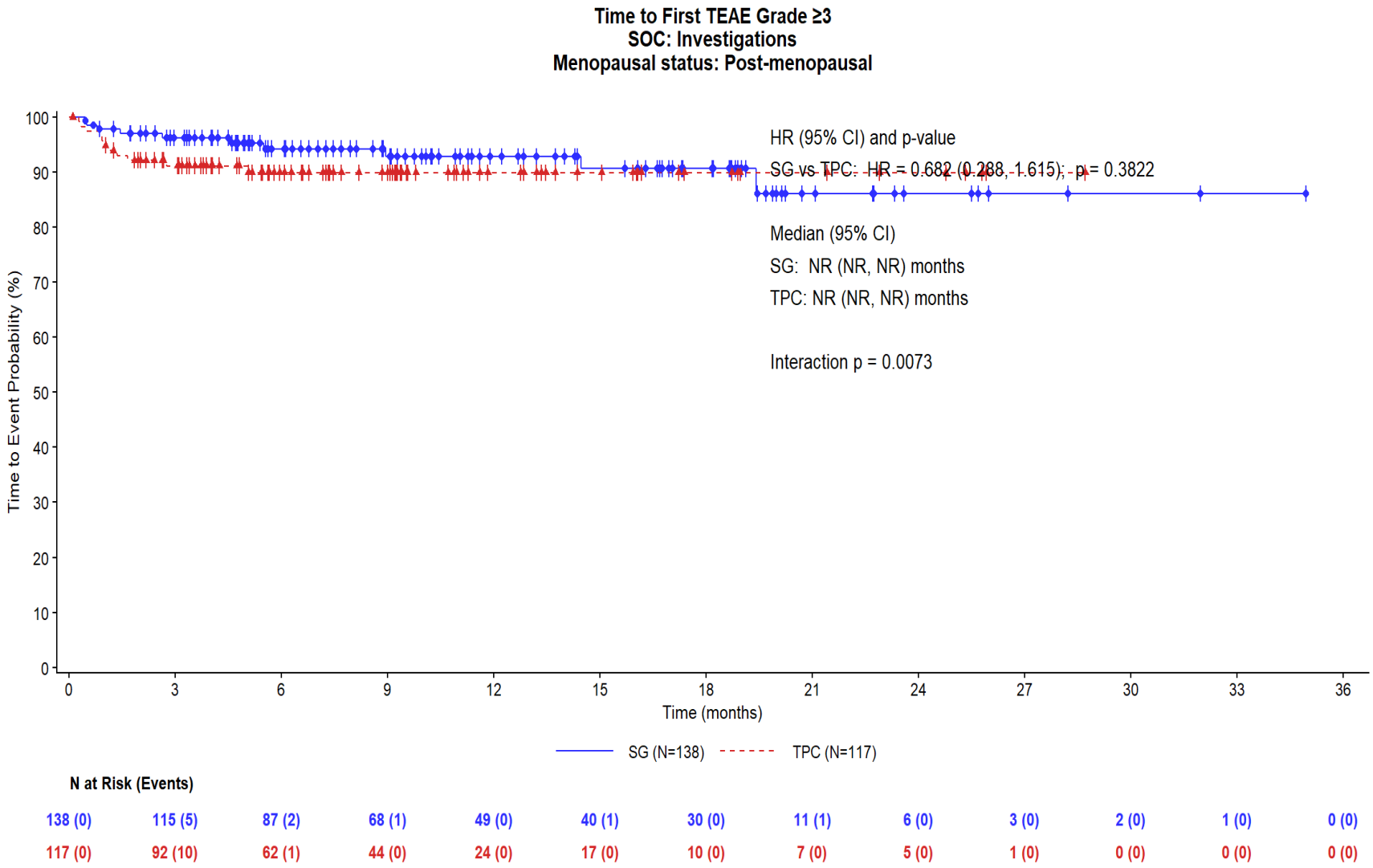
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.152. Figure 1.1.153: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Investigations Menopausal status Pre menopausal — mSAF — Excluding patients preselected to receive nab-paclitaxel



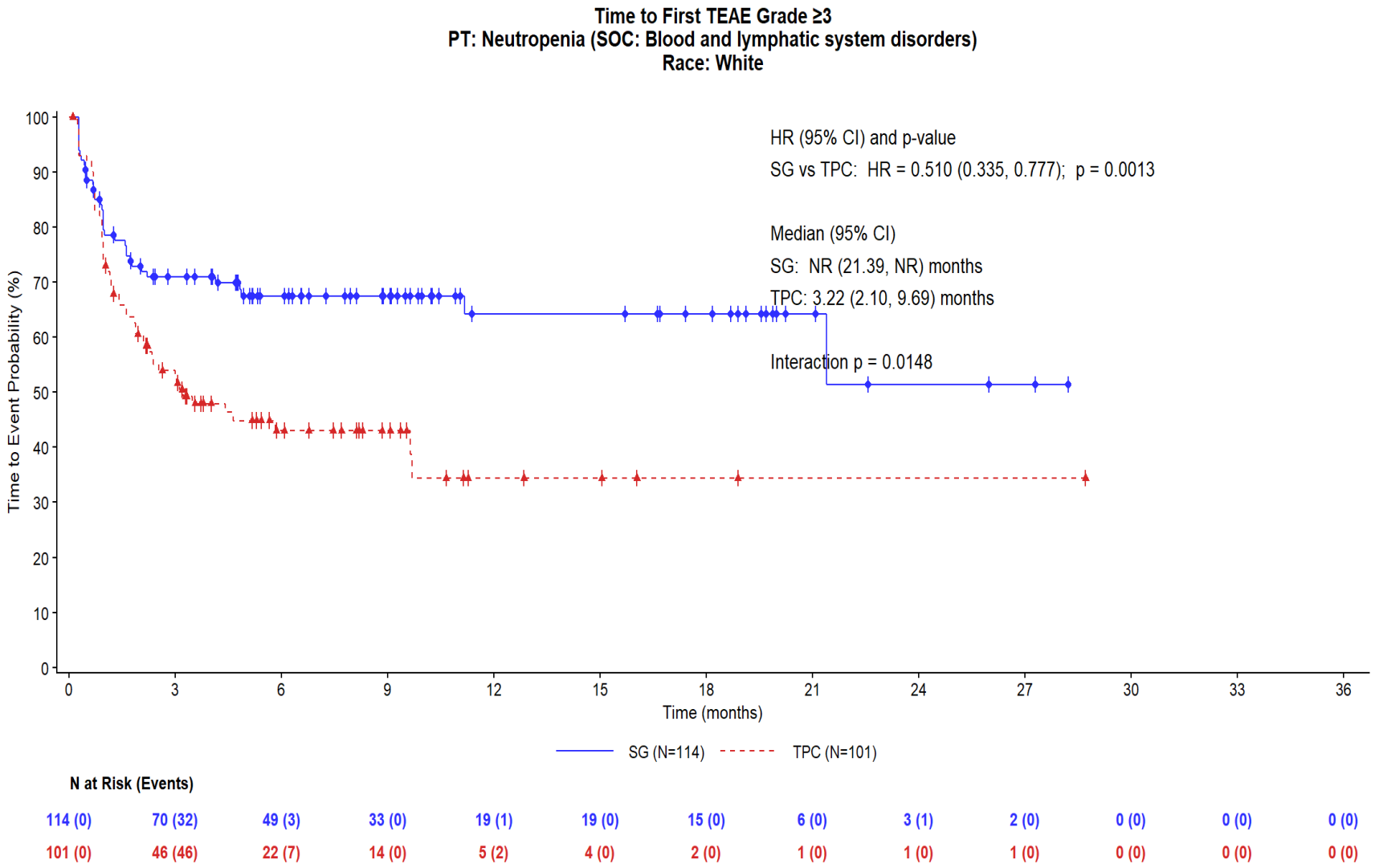
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.153. Figure 1.1.154: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by SOC Investigations Menopausal status Post menopausal — mSAF — Excluding patients preselected to receive nab-paclitaxel



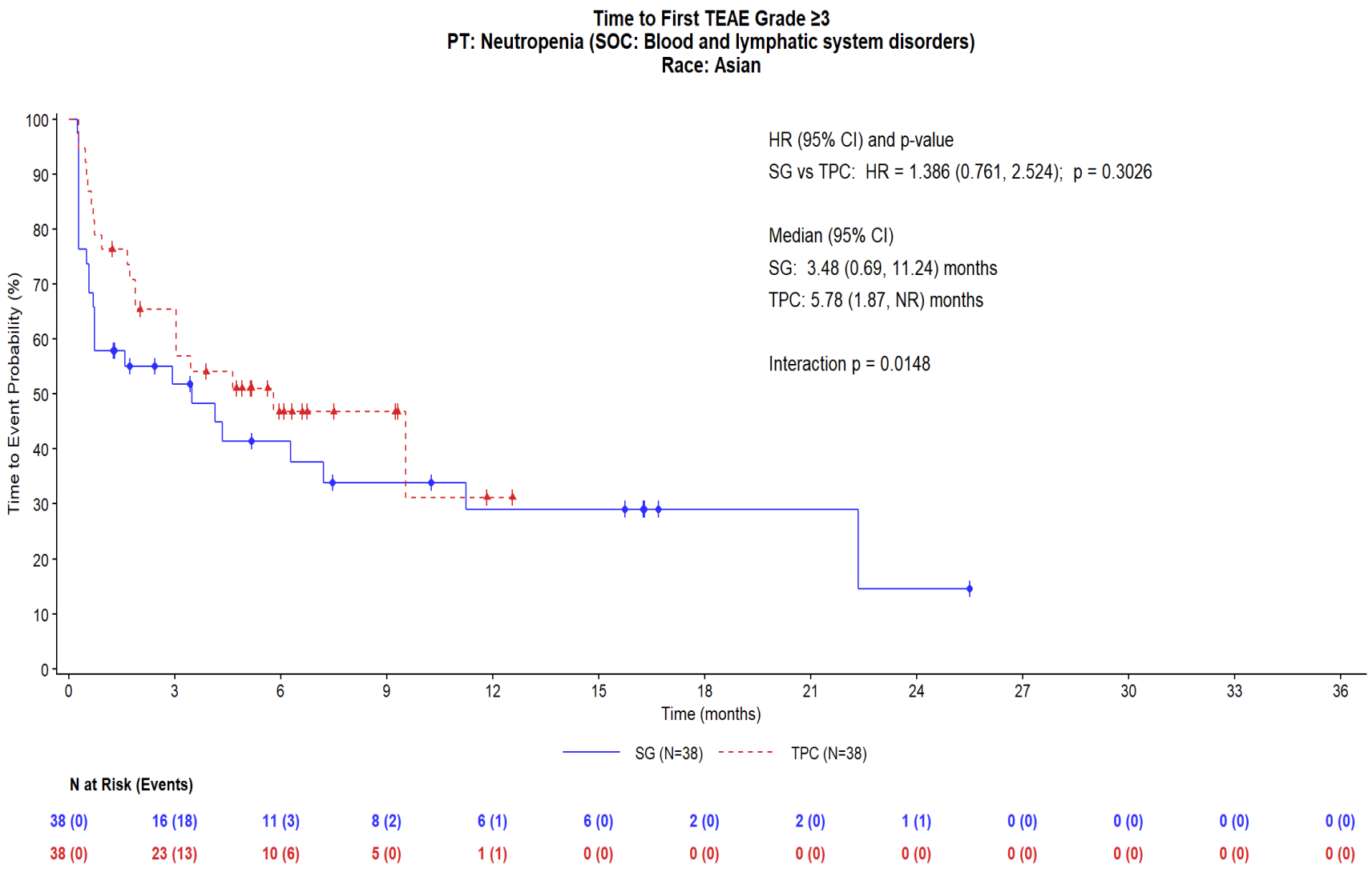
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.154. Figure 1.1.155: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Race White — mSAF — Excluding patients preselected to receive nab-paclitaxel



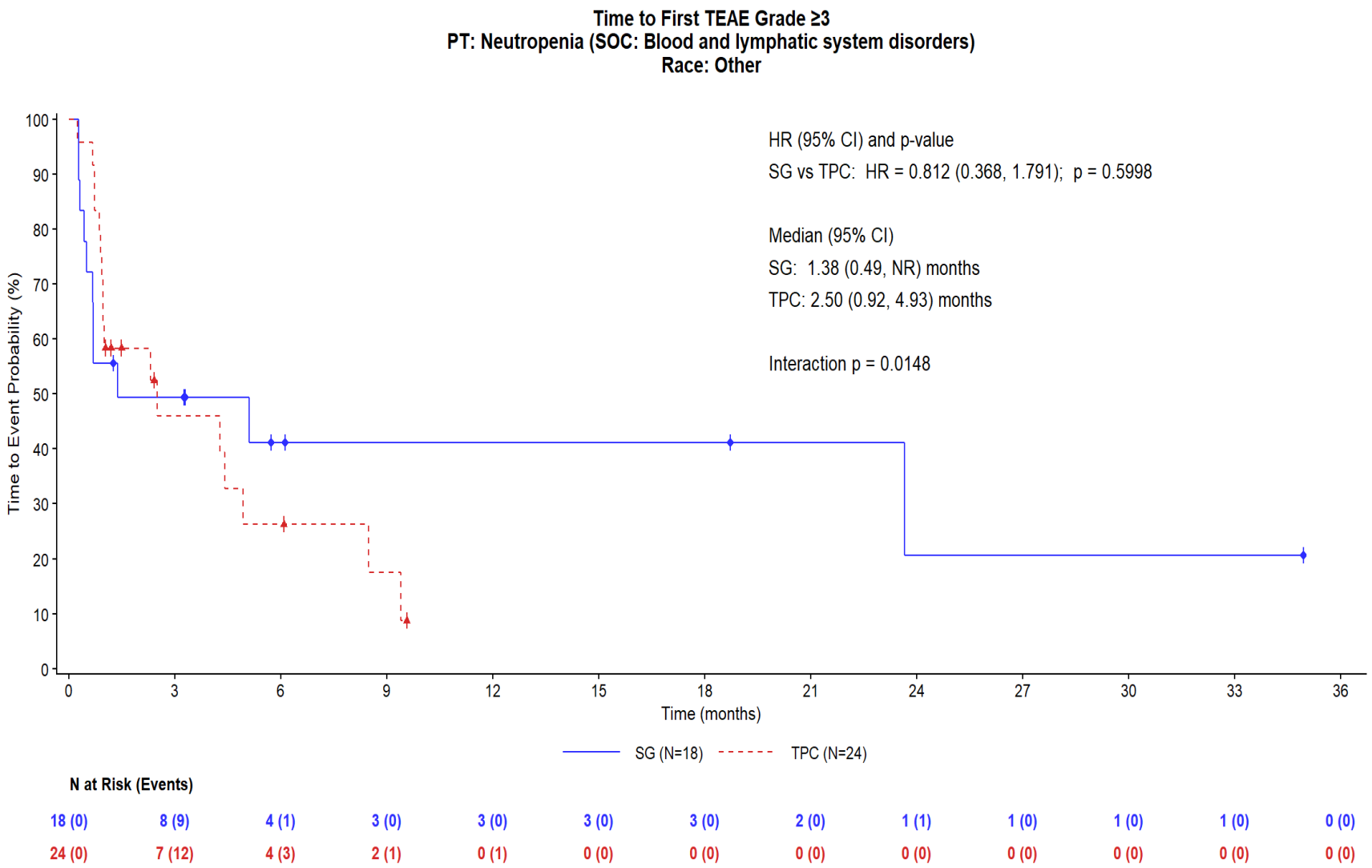
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.155. Figure 1.1.156: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Race Asian — mSAF — Excluding patients preselected to receive nab-paclitaxel



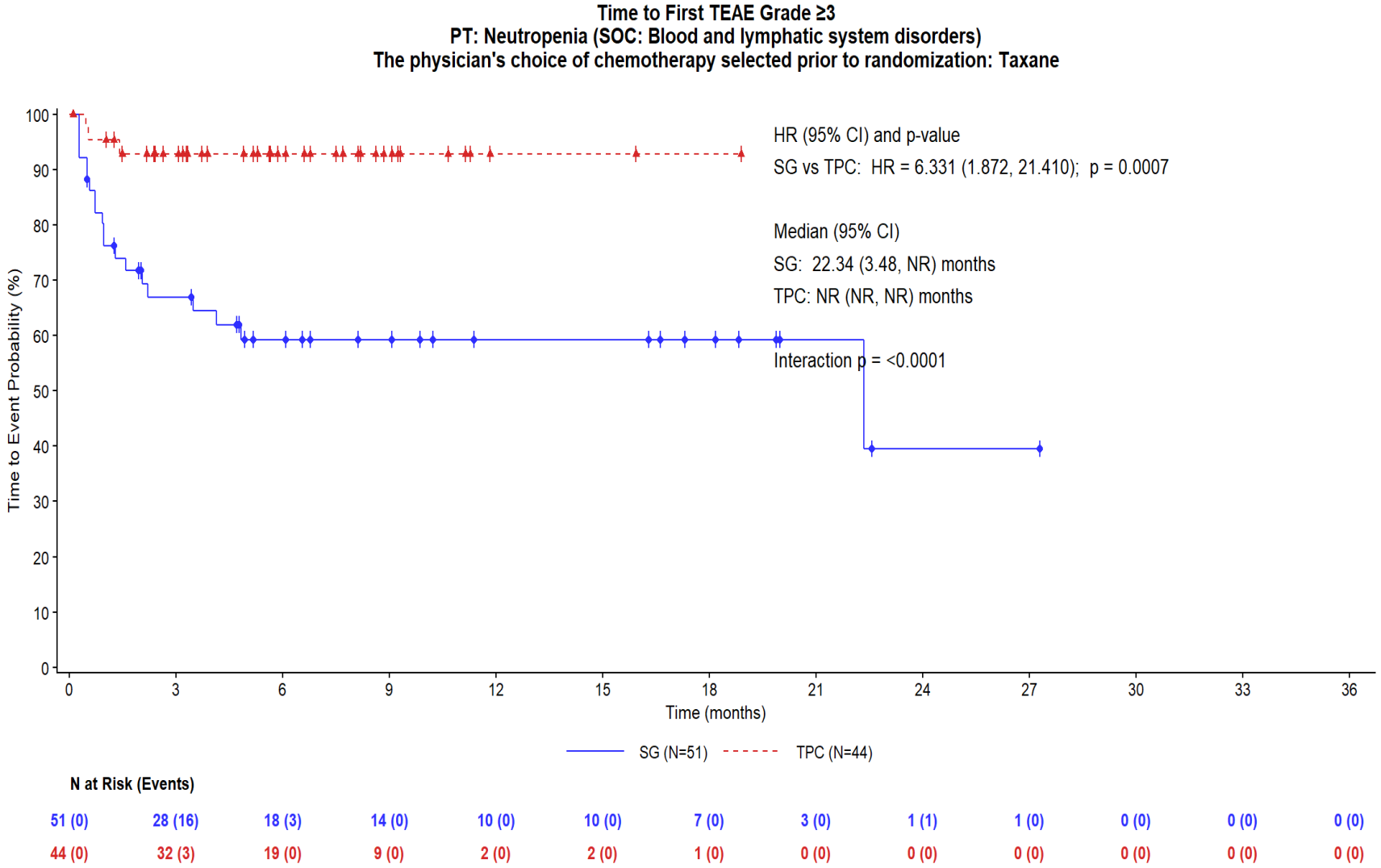
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.156. Figure 1.1.157: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Race Other — mSAF — Excluding patients preselected to receive nab-paclitaxel



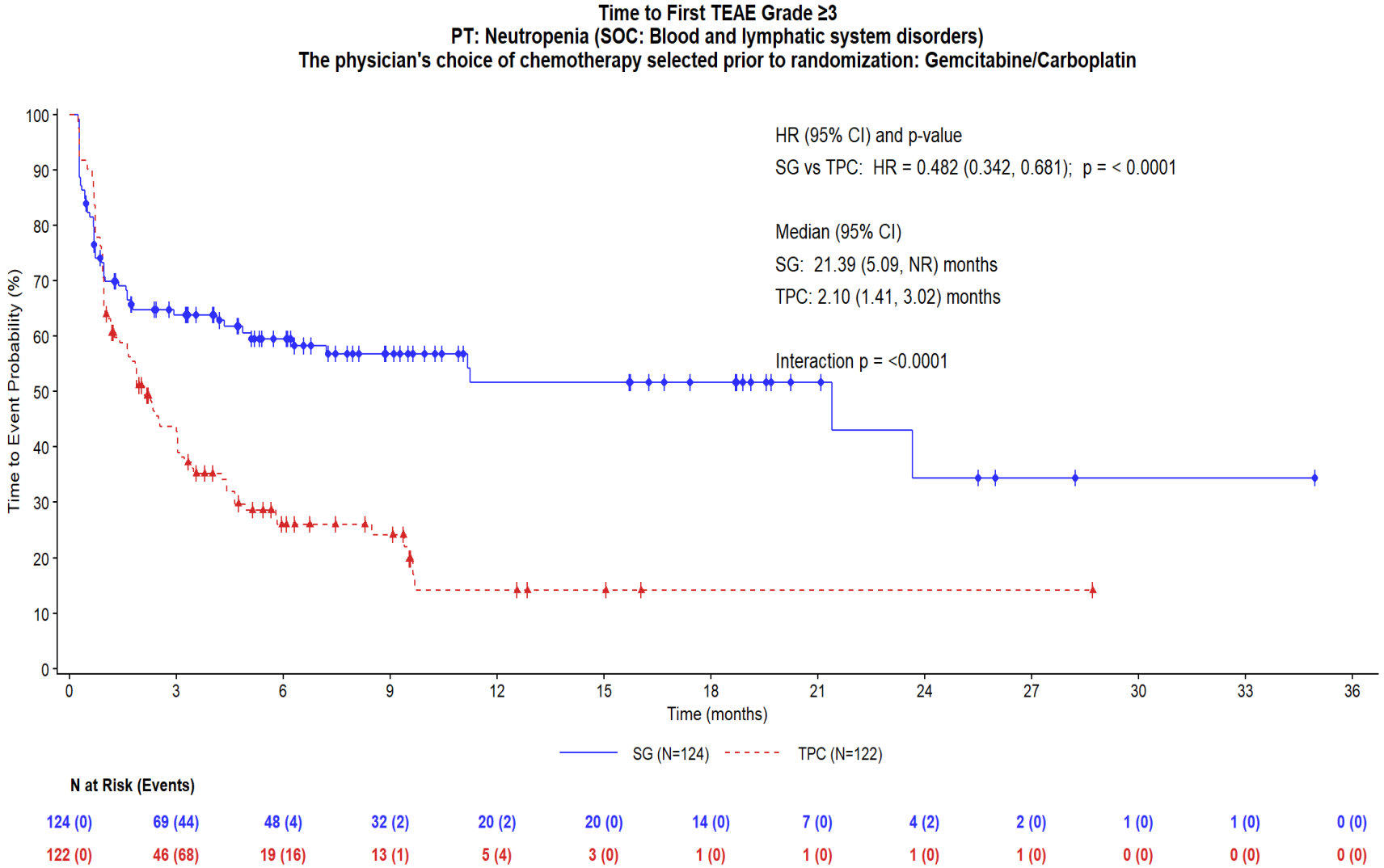
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.157. Figure 1.1.158: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Physician s chemotherapy choice Taxane — mSAF — Excluding patients preselected to receive nab-paclitaxel



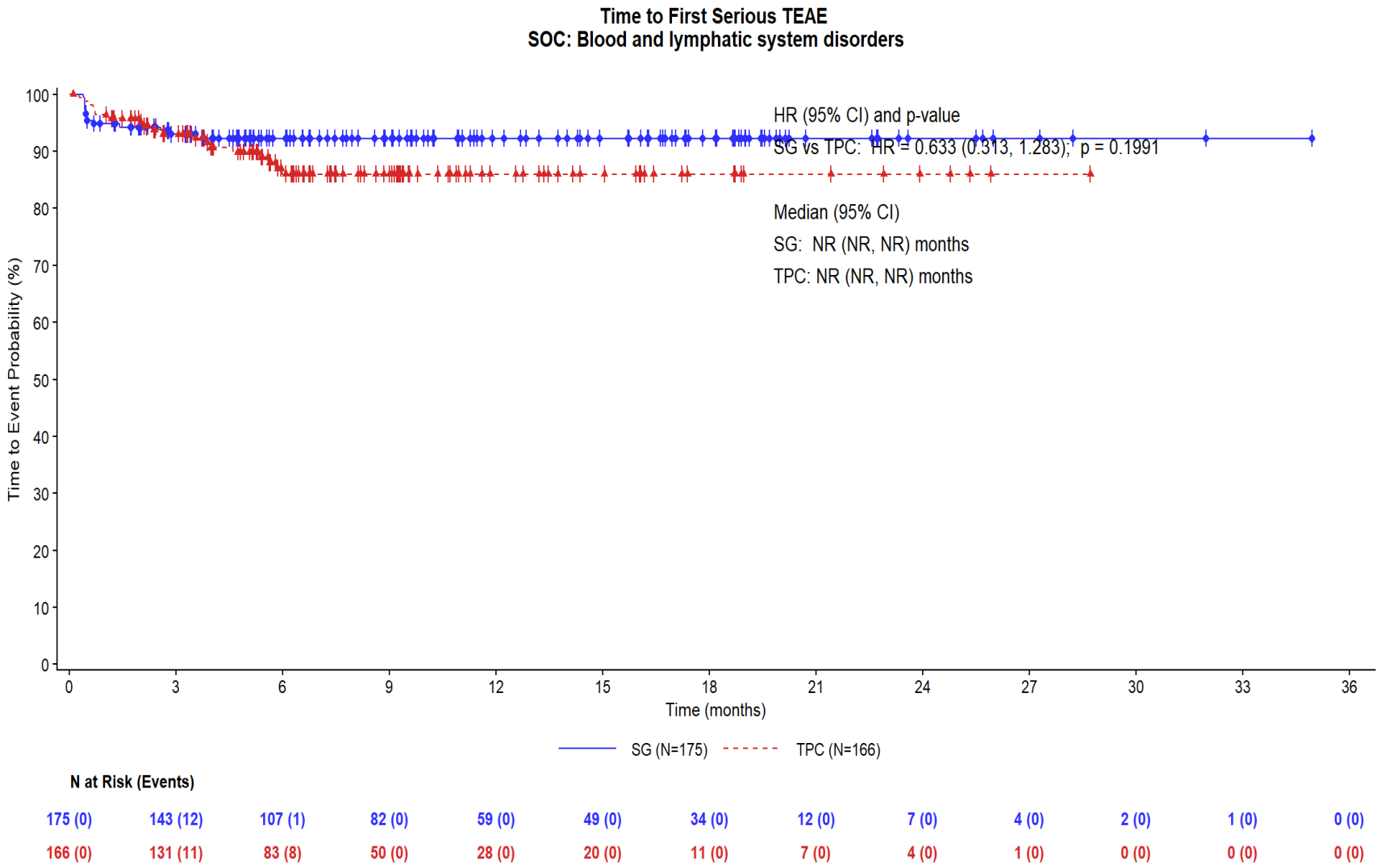
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.158. Figure 1.1.159: Kaplan Meier Plot of Time to First Severe TEAE (CTCAE Grade 3 and above) by PT Neutropenia (SOC Blood and lymphatic system disorders) Physician s chemotherapy choice Gemcitabine Carboplatin — mSAF — Excluding patients preselected to receive nab-paclitaxel



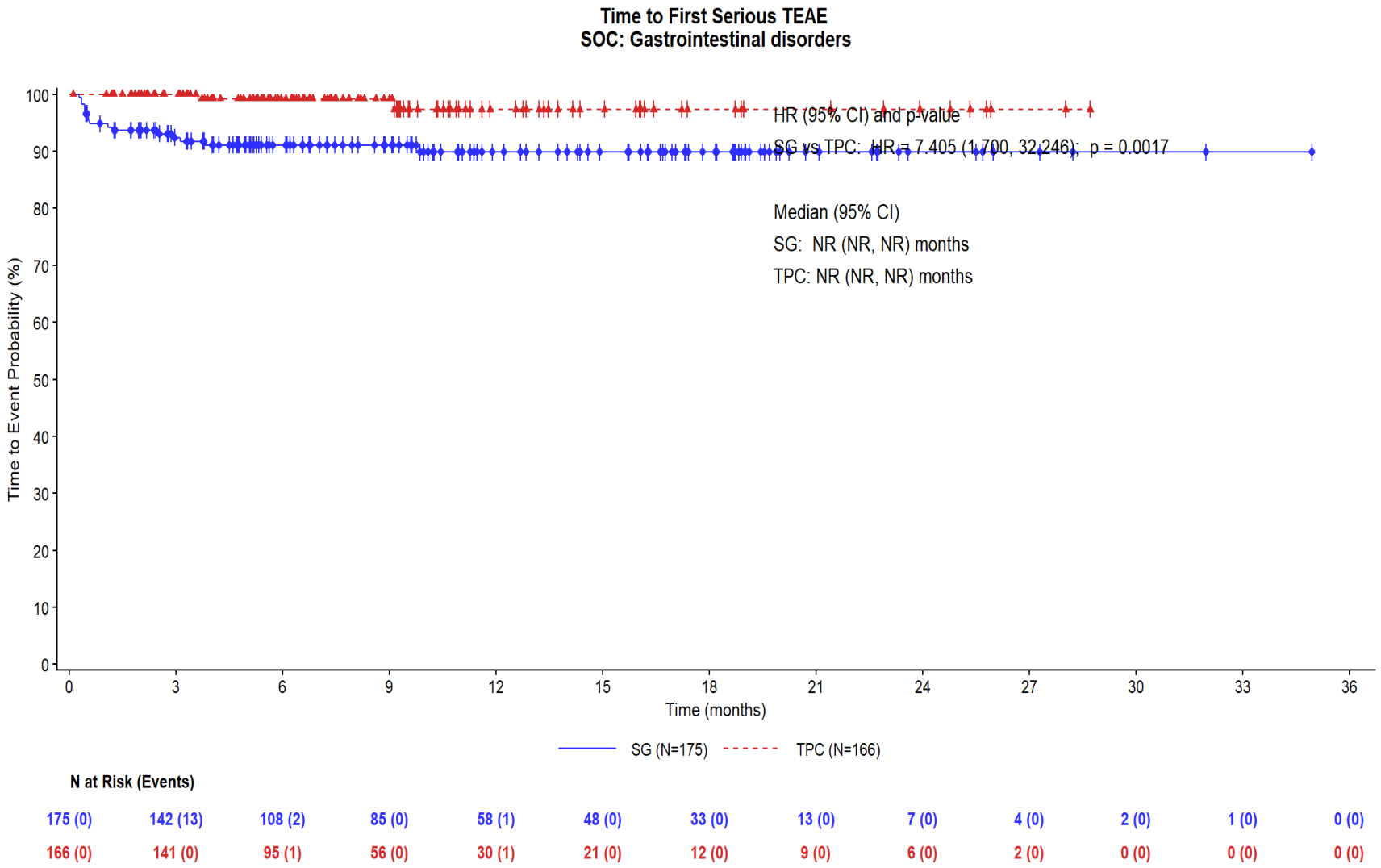
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test. Interaction p-value is from a likelihood ratio test comparing a Cox model with treatment + subgroup + treatment×subgroup interaction versus treatment + subgroup only.

8.159. Figure 1.1.160: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Blood and lymphatic system disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



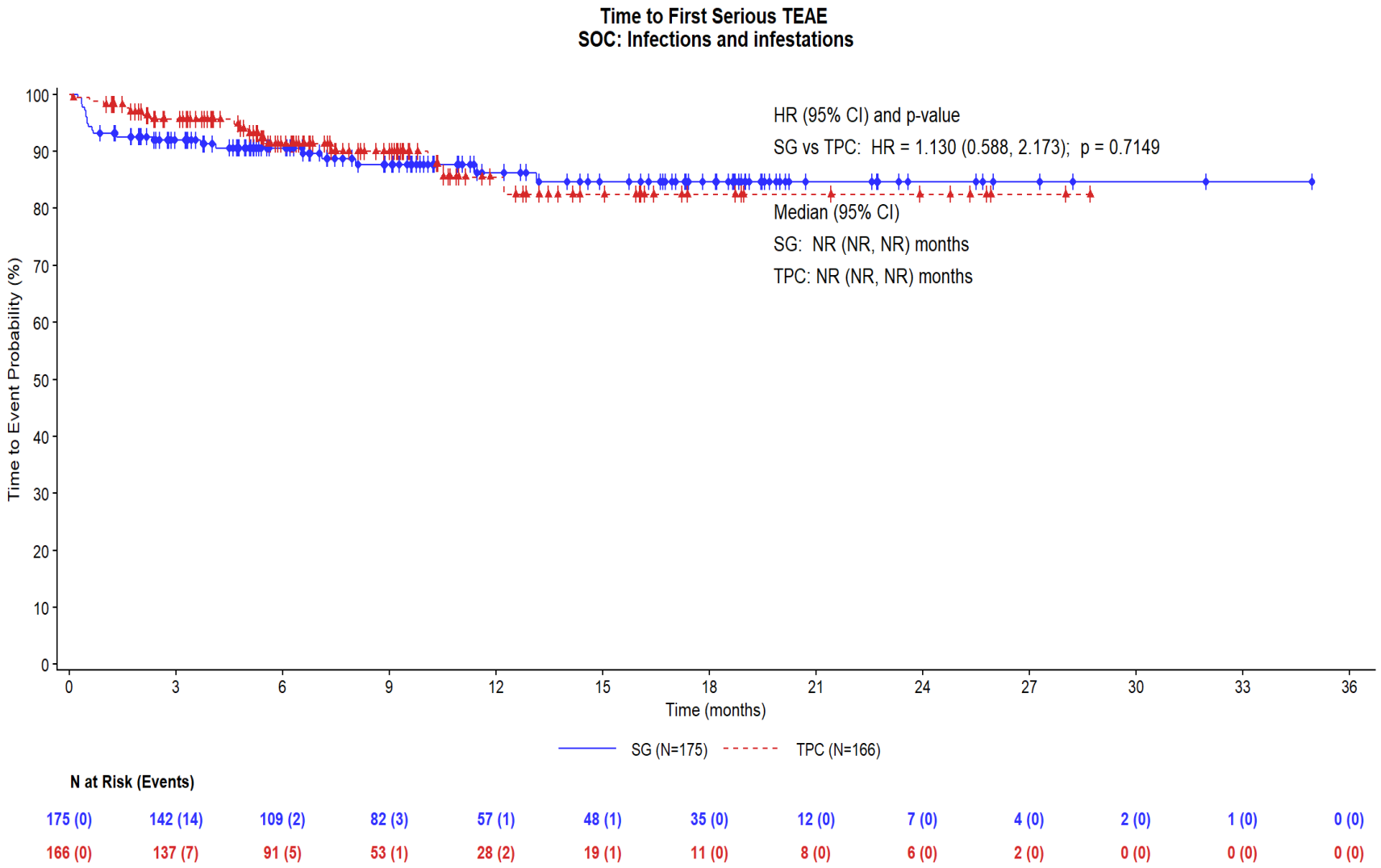
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.160. Figure 1.1.161: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Gastrointestinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



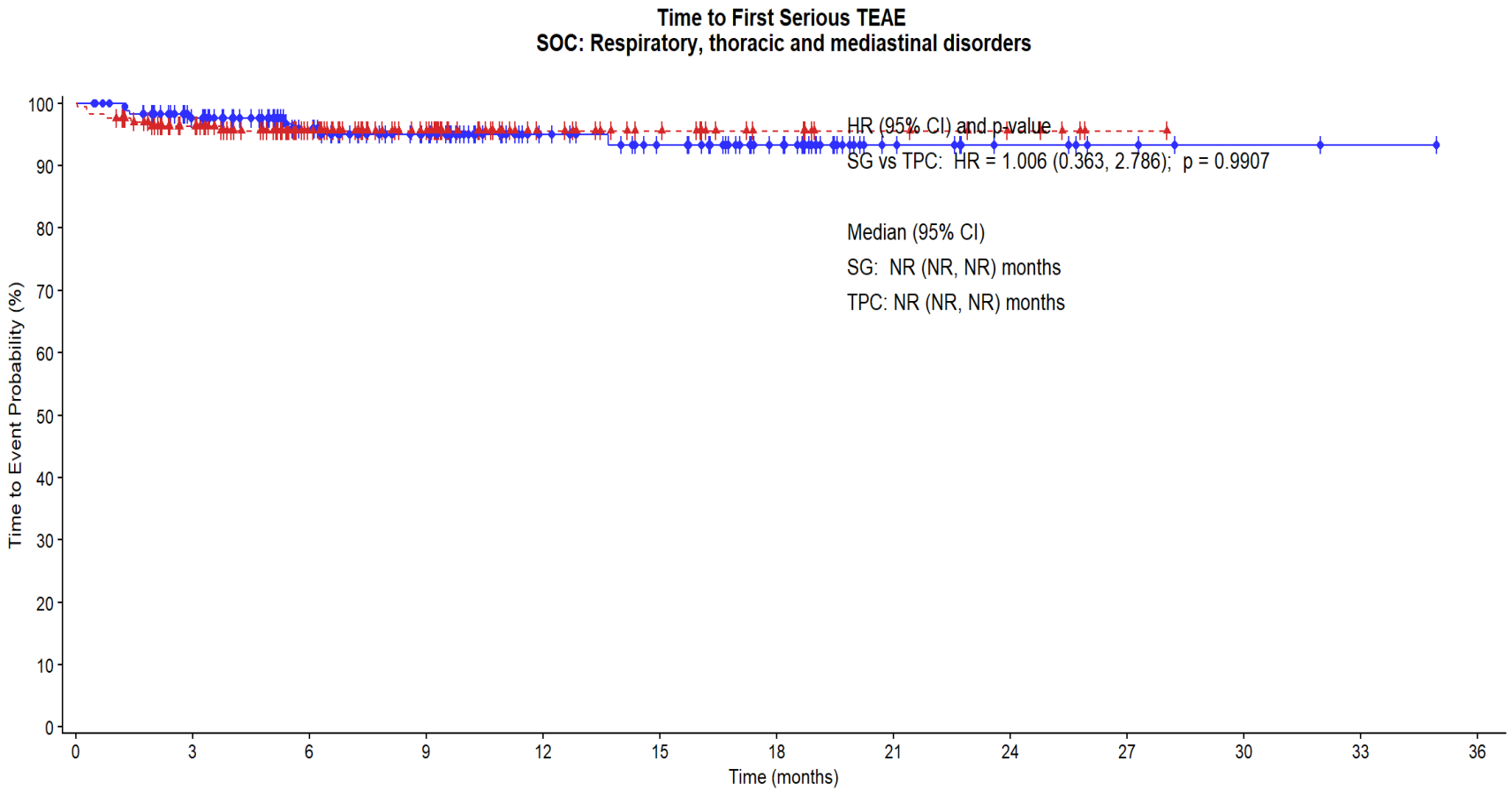
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.161. Figure 1.1.162: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Infections and infestations — mSAF — Excluding patients preselected to receive nab-paclitaxel



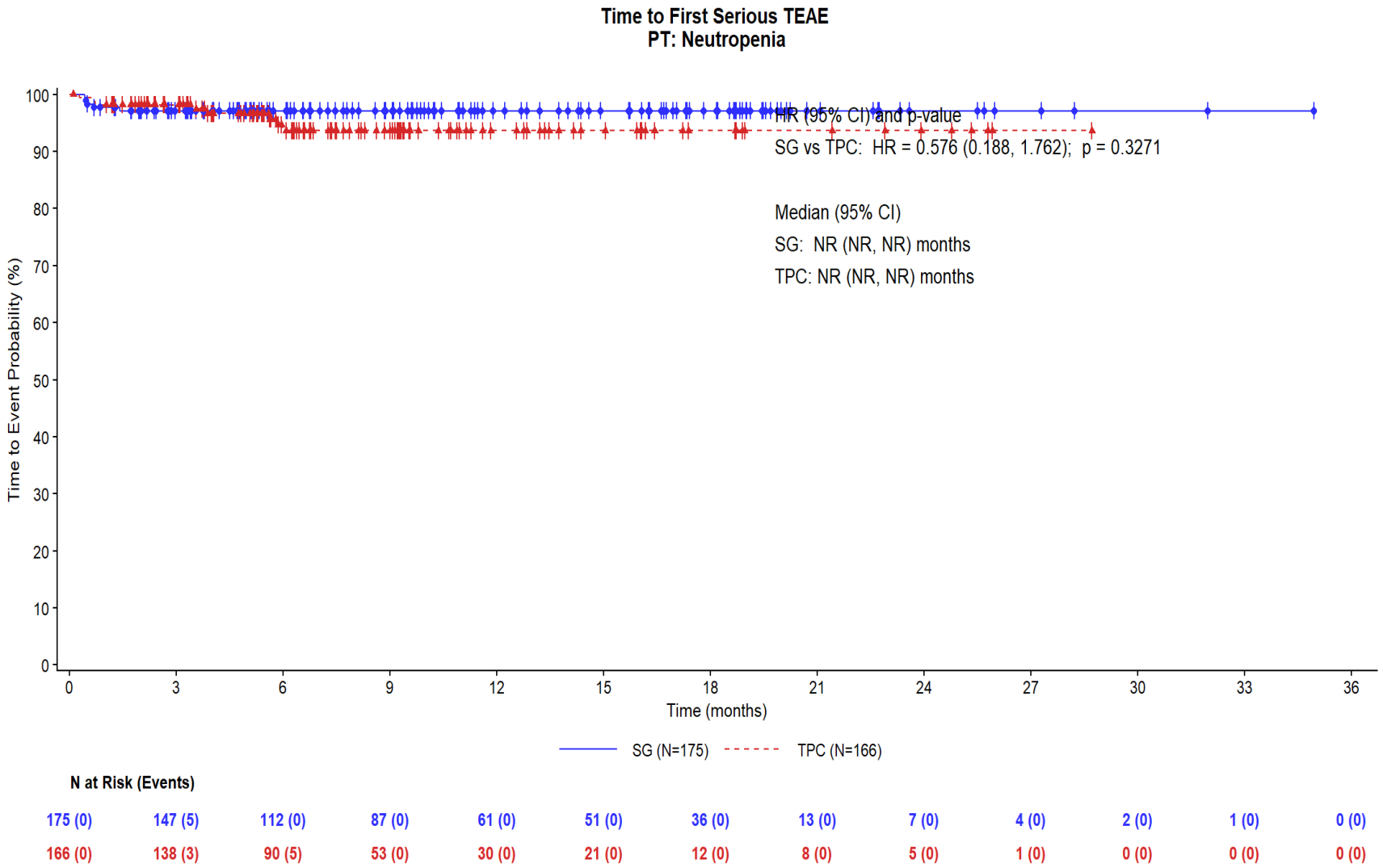
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.162. Figure 1.1.163: Kaplan Meier Plot of Time to First TEAE (SAE) by SOC Respiratory thoracic and mediastinal disorders — mSAF — Excluding patients preselected to receive nab-paclitaxel



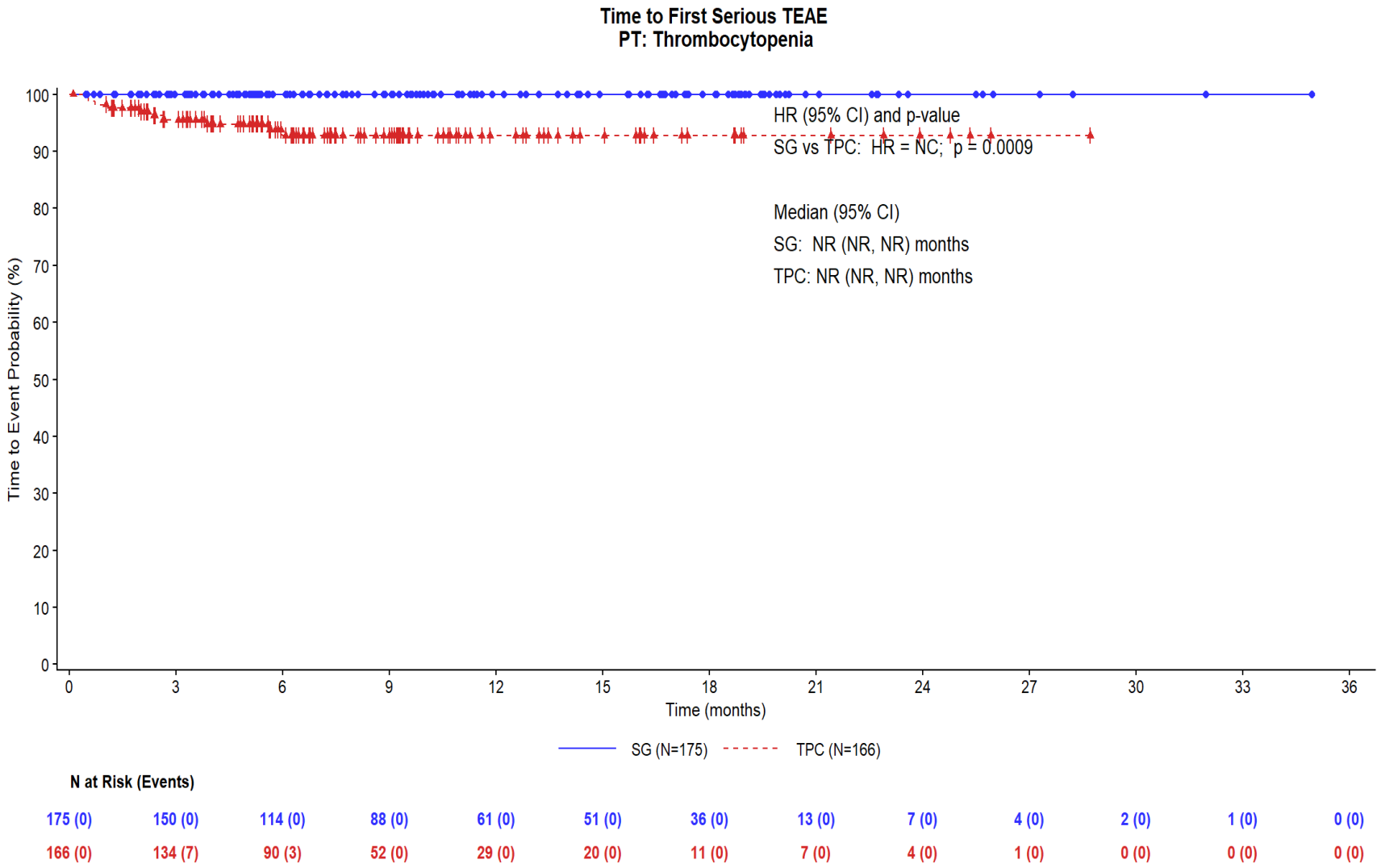
NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.163. Figure 1.1.164: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Neutropenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

8.164. Figure 1.1.165: Kaplan Meier Plot of Time to First TEAE (SAE) by PT Thrombocytopenia — mSAF — Excluding patients preselected to receive nab-paclitaxel



NR = Not Reached. Hazard ratio and 95% CI are from the unadjusted Cox regression analysis. p-value is from the unstratified log-rank test.

Table. Recurrence of diarrhoea TEAE — mSAF: Excluding patients preselected to nab-paclitaxel

	SG (N=175)			TPC (N=166)		
Incidence of diarrhoea TEAE	**1 event**	**2 events**	**>2 events**	**1 event**	**2 events**	**>2 events**
Grade 1	46 (26.3%)	16 (9.1%)	18 (10.3%)	27 (16.3%)	2 (1.2%)	4 (2.4%)
Grade 2	36 (20.6%)	9 (5.1%)	5 (2.9%)	11 (6.6%)	2 (1.2%)	1 (0.6%)
Grade ≥3	17 (9.7%)	1 (0.6%)	0	2 (1.2%)	0	0
Grade 3	18 (10.3%)	0	0	2 (1.2%)	0	0
Grade 4	1 (0.6%)	0	0	0	0	0
Grade 5	0	0	0	0	0	0

n = number of events per patient;

GS-US-592-6238-20788-92106 (SG): 2 diarrhoea episodes at Grade≥3 (1×Grade 3 + 1×Grade 4)

Inhaltsverzeichnis – Patientenberichtete Endpunkte

Studie ASCENT-03 – Datenschnitt: 27. Oktober 2025

(Teil-)Population: Paclitaxel/Carboplatin+Gemcitabin-Population (ergänzend)

- Beobachtungsdauer
- Rücklaufquoten
- Ergebnisse:
    - EORTC QLQ-C30
    - EORTC QLQ-BR23
    - EQ-5D-5L VAS
    - PGI-C
    - PGI-S
- Subgruppenanalysen
- Abbildungen
    - Veränderung zu Baseline
    - Kaplan-Meier-Kurven
    - Kaplan-Meier-Kurven: Subgruppen

Table 1.1.1
Summary of Observation Period (Months) for EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel)

Statistic	SG (N=177)	TPC (N=169)	Overall (N=346)
N	176	167	343
Mean (SD)	9.9 (7.44)	7.8 (5.96)	8.8 (6.83)
95% CI	8.7, 11.0	6.8, 8.7	8.1, 9.6
Median	8.2	6.1	6.9
Q1, Q3	4.2, 16.1	3.7, 9.9	4.1, 12.9
Min, Max	0.0, 34.5	0.0, 27.3	0.0, 34.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 1.1.2
Summary of Observation Period (Months) for EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel)

Statistic	SG (N=177)	TPC (N=169)	Overall (N=346)
N	175	167	342
Mean (SD)	9.8 (7.40)	7.7 (5.98)	8.8 (6.81)
95% CI	8.7, 10.9	6.8, 8.6	8.1, 9.5
Median	7.9	6.1	6.9
Q1, Q3	4.2, 16.1	3.7, 9.9	4.1, 12.6
Min, Max	0.0, 34.5	0.0, 27.3	0.0, 34.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.

CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 1.1.3
Summary of Observation Period (Months) for EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel)

Statistic	SG (N=177)	TPC (N=169)	Overall (N=346)
N	175	167	342
Mean (SD)	9.9 (7.42)	7.7 (5.99)	8.8 (6.84)
95% CI	8.8, 11.0	6.8, 8.6	8.1, 9.6
Median	8.5	6.1	6.9
Q1, Q3	4.2, 16.2	3.7, 9.9	4.1, 12.9
Min, Max	0.0, 34.5	0.0, 27.3	0.0, 34.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 1.1.4
Summary of Observation Period (Months) for PGIC
(mITT excluding patients preselected to receive nab-paclitaxel)

Statistic	SG (N=177)	TPC (N=169)	Overall (N=346)
N	135	131	266
Mean (SD)	5.5 (0.81)	5.3 (1.00)	5.4 (0.91)
95% CI	5.3, 5.6	5.1, 5.5	5.3, 5.5
Median	5.7	5.6	5.6
Q1, Q3	5.2, 6.0	4.7, 6.0	5.1, 6.0
Min, Max	2.8, 6.5	2.8, 6.5	2.8, 6.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 1.1.5
Summary of Observation Period (Months) for PGIS
(mITT excluding patients preselected to receive nab-paclitaxel)

Statistic	SG (N=177)	TPC (N=169)	Overall (N=346)
N	171	166	337
Mean (SD)	4.3 (2.34)	4.2 (2.33)	4.3 (2.33)
95% CI	4.0, 4.7	3.8, 4.5	4.0, 4.5
Median	5.6	5.3	5.5
Q1, Q3	3.6, 5.8	3.0, 5.8	3.5, 5.8
Min, Max	0.0, 6.5	0.0, 6.5	0.0, 6.5

Note: Observation period is defined as the time from the start of treatment to the final study visit and is truncated at the date of the last questionnaire completion if it occurs earlier. If the treatment start date is missing, the randomization date is used. The final study visit is defined as the maximum of Period 01 end date and Period 02 end date.

CI = Confidence Interval; PGIS = Patient Global Impression of Severity; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.2.1
Available Data Rate for the EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	173/177 (97.7%)	165/169 (97.6%)	338/346 (97.7%)
Week 4	144/177 (81.4%)	140/169 (82.8%)	284/346 (82.1%)
Week 7	139/177 (78.5%)	103/169 (60.9%)	242/346 (69.9%)
Week 10	130/177 (73.4%)	122/169 (72.2%)	252/346 (72.8%)
Week 13	119/177 (67.2%)	118/169 (69.8%)	237/346 (68.5%)
Week 16	118/177 (66.7%)	92/169 (54.4%)	210/346 (60.7%)
Week 19	115/177 (65.0%)	89/169 (52.7%)	204/346 (59.0%)
Week 22	102/177 (57.6%)	88/169 (52.1%)	190/346 (54.9%)
Week 25	91/177 (51.4%)	74/169 (43.8%)	165/346 (47.7%)
Week 28	90/177 (50.8%)	62/169 (36.7%)	152/346 (43.9%)
Week 31	86/177 (48.6%)	43/169 (25.4%)	129/346 (37.3%)
Week 34	77/177 (43.5%)	54/169 (32.0%)	131/346 (37.9%)
Week 37	75/177 (42.4%)	40/169 (23.7%)	115/346 (33.2%)
Week 40	68/177 (38.4%)	36/169 (21.3%)	104/346 (30.1%)
Week 43	57/177 (32.2%)	31/169 (18.3%)	88/346 (25.4%)
Week 46	62/177 (35.0%)	25/169 (14.8%)	87/346 (25.1%)
Week 49	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 52	50/177 (28.2%)	26/169 (15.4%)	76/346 (22.0%)
Week 55	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 58	48/177 (27.1%)	21/169 (12.4%)	69/346 (19.9%)
Week 61	41/177 (23.2%)	20/169 (11.8%)	61/346 (17.6%)
Week 64	42/177 (23.7%)	20/169 (11.8%)	62/346 (17.9%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 67	43/177 (24.3%)	15/169 (8.9%)	58/346 (16.8%)
Week 70	43/177 (24.3%)	14/169 (8.3%)	57/346 (16.5%)
Week 73	37/177 (20.9%)	14/169 (8.3%)	51/346 (14.7%)
Week 76	29/177 (16.4%)	11/169 (6.5%)	40/346 (11.6%)
Week 79	26/177 (14.7%)	10/169 (5.9%)	36/346 (10.4%)
Week 82	22/177 (12.4%)	7/169 (4.1%)	29/346 (8.4%)
Week 85	17/177 (9.6%)	7/169 (4.1%)	24/346 (6.9%)
Week 88	13/177 (7.3%)	8/169 (4.7%)	21/346 (6.1%)
Week 91	11/177 (6.2%)	6/169 (3.6%)	17/346 (4.9%)
Week 94	11/177 (6.2%)	6/169 (3.6%)	17/346 (4.9%)
Week 97	10/177 (5.6%)	7/169 (4.1%)	17/346 (4.9%)
Week 100	7/177 (4.0%)	5/169 (3.0%)	12/346 (3.5%)
Week 103	6/177 (3.4%)	5/169 (3.0%)	11/346 (3.2%)
Week 106	7/177 (4.0%)	5/169 (3.0%)	12/346 (3.5%)
Week 109	6/177 (3.4%)	5/169 (3.0%)	11/346 (3.2%)
Week 112	5/177 (2.8%)	2/169 (1.2%)	7/346 (2.0%)
Week 115	5/177 (2.8%)	0/169 (0.0%)	5/346 (1.4%)
Week 118	3/177 (1.7%)	2/169 (1.2%)	5/346 (1.4%)
Week 121	4/177 (2.3%)	1/169 (0.6%)	5/346 (1.4%)
Week 124	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 136	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 139	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 142	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 145	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 148	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 151	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
End of Treatment	86/177 (48.6%)	107/169 (63.3%)	193/346 (55.8%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ITT = intent-to-treat.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.2.2
Available Data Rate for the EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	172/177 (97.2%)	165/169 (97.6%)	337/346 (97.4%)
Week 4	142/177 (80.2%)	138/169 (81.7%)	280/346 (80.9%)
Week 7	137/177 (77.4%)	101/169 (59.8%)	238/346 (68.8%)
Week 10	127/177 (71.8%)	121/169 (71.6%)	248/346 (71.7%)
Week 13	118/177 (66.7%)	117/169 (69.2%)	235/346 (67.9%)
Week 16	118/177 (66.7%)	91/169 (53.8%)	209/346 (60.4%)
Week 19	116/177 (65.5%)	89/169 (52.7%)	205/346 (59.2%)
Week 22	101/177 (57.1%)	87/169 (51.5%)	188/346 (54.3%)
Week 25	92/177 (52.0%)	74/169 (43.8%)	166/346 (48.0%)
Week 28	90/177 (50.8%)	62/169 (36.7%)	152/346 (43.9%)
Week 31	85/177 (48.0%)	43/169 (25.4%)	128/346 (37.0%)
Week 34	75/177 (42.4%)	53/169 (31.4%)	128/346 (37.0%)
Week 37	74/177 (41.8%)	40/169 (23.7%)	114/346 (32.9%)
Week 40	67/177 (37.9%)	36/169 (21.3%)	103/346 (29.8%)
Week 43	56/177 (31.6%)	31/169 (18.3%)	87/346 (25.1%)
Week 46	61/177 (34.5%)	26/169 (15.4%)	87/346 (25.1%)
Week 49	50/177 (28.2%)	22/169 (13.0%)	72/346 (20.8%)
Week 52	50/177 (28.2%)	26/169 (15.4%)	76/346 (22.0%)
Week 55	50/177 (28.2%)	22/169 (13.0%)	72/346 (20.8%)
Week 58	47/177 (26.6%)	21/169 (12.4%)	68/346 (19.7%)
Week 61	40/177 (22.6%)	20/169 (11.8%)	60/346 (17.3%)
Week 64	41/177 (23.2%)	20/169 (11.8%)	61/346 (17.6%)
Week 67	42/177 (23.7%)	15/169 (8.9%)	57/346 (16.5%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 70	43/177 (24.3%)	14/169 (8.3%)	57/346 (16.5%)
Week 73	36/177 (20.3%)	14/169 (8.3%)	50/346 (14.5%)
Week 76	28/177 (15.8%)	11/169 (6.5%)	39/346 (11.3%)
Week 79	25/177 (14.1%)	10/169 (5.9%)	35/346 (10.1%)
Week 82	21/177 (11.9%)	7/169 (4.1%)	28/346 (8.1%)
Week 85	16/177 (9.0%)	7/169 (4.1%)	23/346 (6.6%)
Week 88	12/177 (6.8%)	8/169 (4.7%)	20/346 (5.8%)
Week 91	10/177 (5.6%)	6/169 (3.6%)	16/346 (4.6%)
Week 94	11/177 (6.2%)	6/169 (3.6%)	17/346 (4.9%)
Week 97	9/177 (5.1%)	7/169 (4.1%)	16/346 (4.6%)
Week 100	7/177 (4.0%)	5/169 (3.0%)	12/346 (3.5%)
Week 103	6/177 (3.4%)	5/169 (3.0%)	11/346 (3.2%)
Week 106	7/177 (4.0%)	5/169 (3.0%)	12/346 (3.5%)
Week 109	6/177 (3.4%)	5/169 (3.0%)	11/346 (3.2%)
Week 112	5/177 (2.8%)	2/169 (1.2%)	7/346 (2.0%)
Week 115	5/177 (2.8%)	0/169 (0.0%)	5/346 (1.4%)
Week 118	3/177 (1.7%)	2/169 (1.2%)	5/346 (1.4%)
Week 121	4/177 (2.3%)	1/169 (0.6%)	5/346 (1.4%)
Week 124	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 136	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 139	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 142	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 145	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 148	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 151	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
End of Treatment	87/177 (49.2%)	105/169 (62.1%)	192/346 (55.5%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer Module Questionnaire; ITT = intent-to-treat.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.2.3
Available Data Rate for the EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	171/177 (96.6%)	164/169 (97.0%)	335/346 (96.8%)
Week 4	142/177 (80.2%)	136/169 (80.5%)	278/346 (80.3%)
Week 7	137/177 (77.4%)	101/169 (59.8%)	238/346 (68.8%)
Week 10	127/177 (71.8%)	121/169 (71.6%)	248/346 (71.7%)
Week 13	118/177 (66.7%)	117/169 (69.2%)	235/346 (67.9%)
Week 16	118/177 (66.7%)	91/169 (53.8%)	209/346 (60.4%)
Week 19	116/177 (65.5%)	89/169 (52.7%)	205/346 (59.2%)
Week 22	101/177 (57.1%)	87/169 (51.5%)	188/346 (54.3%)
Week 25	91/177 (51.4%)	74/169 (43.8%)	165/346 (47.7%)
Week 28	91/177 (51.4%)	62/169 (36.7%)	153/346 (44.2%)
Week 31	86/177 (48.6%)	43/169 (25.4%)	129/346 (37.3%)
Week 34	76/177 (42.9%)	53/169 (31.4%)	129/346 (37.3%)
Week 37	75/177 (42.4%)	40/169 (23.7%)	115/346 (33.2%)
Week 40	68/177 (38.4%)	36/169 (21.3%)	104/346 (30.1%)
Week 43	57/177 (32.2%)	31/169 (18.3%)	88/346 (25.4%)
Week 46	62/177 (35.0%)	25/169 (14.8%)	87/346 (25.1%)
Week 49	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 52	50/177 (28.2%)	26/169 (15.4%)	76/346 (22.0%)
Week 55	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 58	48/177 (27.1%)	21/169 (12.4%)	69/346 (19.9%)
Week 61	41/177 (23.2%)	20/169 (11.8%)	61/346 (17.6%)
Week 64	42/177 (23.7%)	20/169 (11.8%)	62/346 (17.9%)
Week 67	43/177 (24.3%)	15/169 (8.9%)	58/346 (16.8%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 70	43/177 (24.3%)	14/169 (8.3%)	57/346 (16.5%)
Week 73	37/177 (20.9%)	14/169 (8.3%)	51/346 (14.7%)
Week 76	29/177 (16.4%)	11/169 (6.5%)	40/346 (11.6%)
Week 79	26/177 (14.7%)	10/169 (5.9%)	36/346 (10.4%)
Week 82	22/177 (12.4%)	7/169 (4.1%)	29/346 (8.4%)
Week 85	17/177 (9.6%)	7/169 (4.1%)	24/346 (6.9%)
Week 88	13/177 (7.3%)	8/169 (4.7%)	21/346 (6.1%)
Week 91	11/177 (6.2%)	6/169 (3.6%)	17/346 (4.9%)
Week 94	11/177 (6.2%)	6/169 (3.6%)	17/346 (4.9%)
Week 97	10/177 (5.6%)	7/169 (4.1%)	17/346 (4.9%)
Week 100	7/177 (4.0%)	5/169 (3.0%)	12/346 (3.5%)
Week 103	6/177 (3.4%)	5/169 (3.0%)	11/346 (3.2%)
Week 106	7/177 (4.0%)	5/169 (3.0%)	12/346 (3.5%)
Week 109	6/177 (3.4%)	5/169 (3.0%)	11/346 (3.2%)
Week 112	5/177 (2.8%)	2/169 (1.2%)	7/346 (2.0%)
Week 115	5/177 (2.8%)	0/169 (0.0%)	5/346 (1.4%)
Week 118	3/177 (1.7%)	2/169 (1.2%)	5/346 (1.4%)
Week 121	4/177 (2.3%)	1/169 (0.6%)	5/346 (1.4%)
Week 124	3/177 (1.7%)	0/169 (0.0%)	3/346 (0.9%)
Week 127	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 130	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 133	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 136	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 139	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 142	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 145	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 148	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 151	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
End of Treatment	85/177 (48.0%)	105/169 (62.1%)	190/346 (54.9%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; VAS = Visual analogue scale.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.2.4
Available Data Rate for the PGIC
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 13	85/177 (48.0%)	85/169 (50.3%)	170/346 (49.1%)
Week 16	114/177 (64.4%)	87/169 (51.5%)	201/346 (58.1%)
Week 19	115/177 (65.0%)	86/169 (50.9%)	201/346 (58.1%)
Week 22	101/177 (57.1%)	86/169 (50.9%)	187/346 (54.0%)
Week 25	93/177 (52.5%)	74/169 (43.8%)	167/346 (48.3%)
Week 28	47/177 (26.6%)	43/169 (25.4%)	90/346 (26.0%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; PGIC = Patient Global Impression of Change.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.2.5
Available Data Rate for the PGIS
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	168/177 (94.9%)	164/169 (97.0%)	332/346 (96.0%)
Week 13	85/177 (48.0%)	85/169 (50.3%)	170/346 (49.1%)
Week 16	114/177 (64.4%)	87/169 (51.5%)	201/346 (58.1%)
Week 19	115/177 (65.0%)	86/169 (50.9%)	201/346 (58.1%)
Week 22	101/177 (57.1%)	86/169 (50.9%)	187/346 (54.0%)
Week 25	93/177 (52.5%)	74/169 (43.8%)	167/346 (48.3%)
Week 28	47/177 (26.6%)	43/169 (25.4%)	90/346 (26.0%)

Note: The available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
ITT = intent-to-treat; PGIS = Patient Global Impression of Severity.

Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.3.1
Modified Available Data Rate for the EORTC QLQ-C30
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	173/177 (97.7%)	165/169 (97.6%)	338/346 (97.7%)
Week 4	144/174 (82.8%)	140/168 (83.3%)	284/342 (83.0%)
Week 7	139/171 (81.3%)	103/167 (61.7%)	242/338 (71.6%)
Week 10	130/170 (76.5%)	122/166 (73.5%)	252/336 (75.0%)
Week 13	119/170 (70.0%)	118/164 (72.0%)	237/334 (71.0%)
Week 16	118/167 (70.7%)	92/163 (56.4%)	210/330 (63.6%)
Week 19	115/163 (70.6%)	89/158 (56.3%)	204/321 (63.6%)
Week 22	102/158 (64.6%)	88/156 (56.4%)	190/314 (60.5%)
Week 25	91/157 (58.0%)	74/152 (48.7%)	165/309 (53.4%)
Week 28	90/154 (58.4%)	62/151 (41.1%)	152/305 (49.8%)
Week 31	86/153 (56.2%)	43/147 (29.3%)	129/300 (43.0%)
Week 34	77/151 (51.0%)	54/144 (37.5%)	131/295 (44.4%)
Week 37	75/150 (50.0%)	40/143 (28.0%)	115/293 (39.2%)
Week 40	68/148 (45.9%)	36/142 (25.4%)	104/290 (35.9%)
Week 43	57/147 (38.8%)	31/138 (22.5%)	88/285 (30.9%)
Week 46	62/144 (43.1%)	25/137 (18.2%)	87/281 (31.0%)
Week 49	51/141 (36.2%)	22/132 (16.7%)	73/273 (26.7%)
Week 52	50/135 (37.0%)	26/127 (20.5%)	76/262 (29.0%)
Week 55	51/133 (38.3%)	22/124 (17.7%)	73/257 (28.4%)
Week 58	48/129 (37.2%)	21/121 (17.4%)	69/250 (27.6%)
Week 61	41/125 (32.8%)	20/117 (17.1%)	61/242 (25.2%)
Week 64	42/125 (33.6%)	20/114 (17.5%)	62/239 (25.9%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 67	43/122 (35.2%)	15/109 (13.8%)	58/231 (25.1%)
Week 70	43/117 (36.8%)	14/105 (13.3%)	57/222 (25.7%)
Week 73	37/112 (33.0%)	14/102 (13.7%)	51/214 (23.8%)
Week 76	29/110 (26.4%)	11/100 (11.0%)	40/210 (19.0%)
Week 79	26/103 (25.2%)	10/97 (10.3%)	36/200 (18.0%)
Week 82	22/101 (21.8%)	7/94 (7.4%)	29/195 (14.9%)
Week 85	17/98 (17.3%)	7/92 (7.6%)	24/190 (12.6%)
Week 88	13/98 (13.3%)	8/87 (9.2%)	21/185 (11.4%)
Week 91	11/96 (11.5%)	6/85 (7.1%)	17/181 (9.4%)
Week 94	11/94 (11.7%)	6/83 (7.2%)	17/177 (9.6%)
Week 97	10/92 (10.9%)	7/82 (8.5%)	17/174 (9.8%)
Week 100	7/91 (7.7%)	5/80 (6.3%)	12/171 (7.0%)
Week 103	6/89 (6.7%)	5/78 (6.4%)	11/167 (6.6%)
Week 106	7/89 (7.9%)	5/78 (6.4%)	12/167 (7.2%)
Week 109	6/89 (6.7%)	5/77 (6.5%)	11/166 (6.6%)
Week 112	5/88 (5.7%)	2/76 (2.6%)	7/164 (4.3%)
Week 115	5/88 (5.7%)	0/76 (0.0%)	5/164 (3.0%)
Week 118	3/87 (3.4%)	2/75 (2.7%)	5/162 (3.1%)
Week 121	4/87 (4.6%)	1/74 (1.4%)	5/161 (3.1%)
Week 124	1/87 (1.1%)	0/74 (0.0%)	1/161 (0.6%)
Week 136	2/86 (2.3%)	0/73 (0.0%)	2/159 (1.3%)
Week 139	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 142	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 145	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 148	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 151	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
End of Treatment	86/136 (63.2%)	107/153 (69.9%)	193/289 (66.8%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ITT = intent-to-treat.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_compliance.sas

Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.3.2
Modified Available Data Rate for the EORTC QLQ-BR23
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	172/177 (97.2%)	165/169 (97.6%)	337/346 (97.4%)
Week 4	142/174 (81.6%)	138/168 (82.1%)	280/342 (81.9%)
Week 7	137/171 (80.1%)	101/167 (60.5%)	238/338 (70.4%)
Week 10	127/170 (74.7%)	121/166 (72.9%)	248/336 (73.8%)
Week 13	118/170 (69.4%)	117/164 (71.3%)	235/334 (70.4%)
Week 16	118/167 (70.7%)	91/163 (55.8%)	209/330 (63.3%)
Week 19	116/163 (71.2%)	89/158 (56.3%)	205/321 (63.9%)
Week 22	101/158 (63.9%)	87/156 (55.8%)	188/314 (59.9%)
Week 25	92/157 (58.6%)	74/152 (48.7%)	166/309 (53.7%)
Week 28	90/154 (58.4%)	62/151 (41.1%)	152/305 (49.8%)
Week 31	85/153 (55.6%)	43/147 (29.3%)	128/300 (42.7%)
Week 34	75/151 (49.7%)	53/144 (36.8%)	128/295 (43.4%)
Week 37	74/150 (49.3%)	40/143 (28.0%)	114/293 (38.9%)
Week 40	67/148 (45.3%)	36/142 (25.4%)	103/290 (35.5%)
Week 43	56/147 (38.1%)	31/138 (22.5%)	87/285 (30.5%)
Week 46	61/144 (42.4%)	26/137 (19.0%)	87/281 (31.0%)
Week 49	50/141 (35.5%)	22/132 (16.7%)	72/273 (26.4%)
Week 52	50/135 (37.0%)	26/127 (20.5%)	76/262 (29.0%)
Week 55	50/133 (37.6%)	22/124 (17.7%)	72/257 (28.0%)
Week 58	47/129 (36.4%)	21/121 (17.4%)	68/250 (27.2%)
Week 61	40/125 (32.0%)	20/117 (17.1%)	60/242 (24.8%)
Week 64	41/125 (32.8%)	20/114 (17.5%)	61/239 (25.5%)
Week 67	42/122 (34.4%)	15/109 (13.8%)	57/231 (24.7%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 70	43/117 (36.8%)	14/105 (13.3%)	57/222 (25.7%)
Week 73	36/112 (32.1%)	14/102 (13.7%)	50/214 (23.4%)
Week 76	28/110 (25.5%)	11/100 (11.0%)	39/210 (18.6%)
Week 79	25/103 (24.3%)	10/97 (10.3%)	35/200 (17.5%)
Week 82	21/101 (20.8%)	7/94 (7.4%)	28/195 (14.4%)
Week 85	16/98 (16.3%)	7/92 (7.6%)	23/190 (12.1%)
Week 88	12/98 (12.2%)	8/87 (9.2%)	20/185 (10.8%)
Week 91	10/96 (10.4%)	6/85 (7.1%)	16/181 (8.8%)
Week 94	11/94 (11.7%)	6/83 (7.2%)	17/177 (9.6%)
Week 97	9/92 (9.8%)	7/82 (8.5%)	16/174 (9.2%)
Week 100	7/91 (7.7%)	5/80 (6.3%)	12/171 (7.0%)
Week 103	6/89 (6.7%)	5/78 (6.4%)	11/167 (6.6%)
Week 106	7/89 (7.9%)	5/78 (6.4%)	12/167 (7.2%)
Week 109	6/89 (6.7%)	5/77 (6.5%)	11/166 (6.6%)
Week 112	5/88 (5.7%)	2/76 (2.6%)	7/164 (4.3%)
Week 115	5/88 (5.7%)	0/76 (0.0%)	5/164 (3.0%)
Week 118	3/87 (3.4%)	2/75 (2.7%)	5/162 (3.1%)
Week 121	4/87 (4.6%)	1/74 (1.4%)	5/161 (3.1%)
Week 124	1/87 (1.1%)	0/74 (0.0%)	1/161 (0.6%)
Week 136	2/86 (2.3%)	0/73 (0.0%)	2/159 (1.3%)
Week 139	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 142	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 145	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 148	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 151	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
End of Treatment	87/136 (64.0%)	105/153 (68.6%)	192/289 (66.4%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer Module Questionnaire; ITT = intent-to-treat.
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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.3.3
Modified Available Data Rate for the EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	171/177 (96.6%)	164/169 (97.0%)	335/346 (96.8%)
Week 4	142/174 (81.6%)	136/168 (81.0%)	278/342 (81.3%)
Week 7	137/171 (80.1%)	101/167 (60.5%)	238/338 (70.4%)
Week 10	127/170 (74.7%)	121/166 (72.9%)	248/336 (73.8%)
Week 13	118/170 (69.4%)	117/164 (71.3%)	235/334 (70.4%)
Week 16	118/167 (70.7%)	91/163 (55.8%)	209/330 (63.3%)
Week 19	116/163 (71.2%)	89/158 (56.3%)	205/321 (63.9%)
Week 22	101/158 (63.9%)	87/156 (55.8%)	188/314 (59.9%)
Week 25	91/157 (58.0%)	74/152 (48.7%)	165/309 (53.4%)
Week 28	91/154 (59.1%)	62/151 (41.1%)	153/305 (50.2%)
Week 31	86/153 (56.2%)	43/147 (29.3%)	129/300 (43.0%)
Week 34	76/151 (50.3%)	53/144 (36.8%)	129/295 (43.7%)
Week 37	75/150 (50.0%)	40/143 (28.0%)	115/293 (39.2%)
Week 40	68/148 (45.9%)	36/142 (25.4%)	104/290 (35.9%)
Week 43	57/147 (38.8%)	31/138 (22.5%)	88/285 (30.9%)
Week 46	62/144 (43.1%)	25/137 (18.2%)	87/281 (31.0%)
Week 49	51/141 (36.2%)	22/132 (16.7%)	73/273 (26.7%)
Week 52	50/135 (37.0%)	26/127 (20.5%)	76/262 (29.0%)
Week 55	51/133 (38.3%)	22/124 (17.7%)	73/257 (28.4%)
Week 58	48/129 (37.2%)	21/121 (17.4%)	69/250 (27.6%)
Week 61	41/125 (32.8%)	20/117 (17.1%)	61/242 (25.2%)
Week 64	42/125 (33.6%)	20/114 (17.5%)	62/239 (25.9%)
Week 67	43/122 (35.2%)	15/109 (13.8%)	58/231 (25.1%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 70	43/117 (36.8%)	14/105 (13.3%)	57/222 (25.7%)
Week 73	37/112 (33.0%)	14/102 (13.7%)	51/214 (23.8%)
Week 76	29/110 (26.4%)	11/100 (11.0%)	40/210 (19.0%)
Week 79	26/103 (25.2%)	10/97 (10.3%)	36/200 (18.0%)
Week 82	22/101 (21.8%)	7/94 (7.4%)	29/195 (14.9%)
Week 85	17/98 (17.3%)	7/92 (7.6%)	24/190 (12.6%)
Week 88	13/98 (13.3%)	8/87 (9.2%)	21/185 (11.4%)
Week 91	11/96 (11.5%)	6/85 (7.1%)	17/181 (9.4%)
Week 94	11/94 (11.7%)	6/83 (7.2%)	17/177 (9.6%)
Week 97	10/92 (10.9%)	7/82 (8.5%)	17/174 (9.8%)
Week 100	7/91 (7.7%)	5/80 (6.3%)	12/171 (7.0%)
Week 103	6/89 (6.7%)	5/78 (6.4%)	11/167 (6.6%)
Week 106	7/89 (7.9%)	5/78 (6.4%)	12/167 (7.2%)
Week 109	6/89 (6.7%)	5/77 (6.5%)	11/166 (6.6%)
Week 112	5/88 (5.7%)	2/76 (2.6%)	7/164 (4.3%)
Week 115	5/88 (5.7%)	0/76 (0.0%)	5/164 (3.0%)
Week 118	3/87 (3.4%)	2/75 (2.7%)	5/162 (3.1%)
Week 121	4/87 (4.6%)	1/74 (1.4%)	5/161 (3.1%)
Week 124	3/87 (3.4%)	0/74 (0.0%)	3/161 (1.9%)
Week 127	1/87 (1.1%)	0/73 (0.0%)	1/160 (0.6%)
Week 130	2/86 (2.3%)	0/73 (0.0%)	2/159 (1.3%)
Week 133	2/86 (2.3%)	0/73 (0.0%)	2/159 (1.3%)
Week 136	2/86 (2.3%)	0/73 (0.0%)	2/159 (1.3%)
Week 139	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 142	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 145	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
Week 148	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 151	1/86 (1.2%)	0/73 (0.0%)	1/159 (0.6%)
End of Treatment	85/136 (62.5%)	105/153 (68.6%)	190/289 (65.7%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; VAS = Visual analogue scale.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.3.4
Modified Available Data Rate for the PGIC
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 13	85/170 (50.0%)	85/164 (51.8%)	170/334 (50.9%)
Week 16	114/167 (68.3%)	87/163 (53.4%)	201/330 (60.9%)
Week 19	115/163 (70.6%)	86/158 (54.4%)	201/321 (62.6%)
Week 22	101/158 (63.9%)	86/156 (55.1%)	187/314 (59.6%)
Week 25	93/157 (59.2%)	74/152 (48.7%)	167/309 (54.0%)
Week 28	47/154 (30.5%)	43/151 (28.5%)	90/305 (29.5%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; PGIC = Patient Global Impression of Change.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 2.1.3.5
Modified Available Data Rate for the PGIS
(mITT excluding patients preselected to receive nab-paclitaxel)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	168/177 (94.9%)	164/169 (97.0%)	332/346 (96.0%)
Week 13	85/170 (50.0%)	85/164 (51.8%)	170/334 (50.9%)
Week 16	114/167 (68.3%)	87/163 (53.4%)	201/330 (60.9%)
Week 19	115/163 (70.6%)	86/158 (54.4%)	201/321 (62.6%)
Week 22	101/158 (63.9%)	86/156 (55.1%)	187/314 (59.6%)
Week 25	93/157 (59.2%)	74/152 (48.7%)	167/309 (54.0%)
Week 28	47/154 (30.5%)	43/151 (28.5%)	90/305 (29.5%)

Note: The modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint (i.e. accounting for deaths).
ITT = intent-to-treat; PGIS = Patient Global Impression of Severity.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 3.1.2.2
Distribution of Responses to PGIC by Visit
(mITT excluding patients preselected to receive nab-paclitaxel)

Item	Visit	Response Level	SG (N=177)	TPC (N=169)	Overall (N=346)
PGIC	Week 13		N=85	N=85	N=170
		Very Much Improved	8 (9.4%)	11 (12.9%)	19 (11.2%)
		Much Improved	28 (32.9%)	25 (29.4%)	53 (31.2%)
		Minimally Improved	22 (25.9%)	23 (27.1%)	45 (26.5%)
		No Change	16 (18.8%)	11 (12.9%)	27 (15.9%)
		Minimally Worsened	9 (10.6%)	12 (14.1%)	21 (12.4%)
		Much Worsened	2 (2.4%)	3 (3.5%)	5 (2.9%)
		Very Much Worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 16		N=114	N=87	N=201
		Very Much Improved	17 (14.9%)	9 (10.3%)	26 (12.9%)
		Much Improved	31 (27.2%)	23 (26.4%)	54 (26.9%)
		Minimally Improved	33 (28.9%)	21 (24.1%)	54 (26.9%)
		No Change	15 (13.2%)	16 (18.4%)	31 (15.4%)
		Minimally Worsened	14 (12.3%)	14 (16.1%)	28 (13.9%)
		Much Worsened	4 (3.5%)	4 (4.6%)	8 (4.0%)
		Very Much Worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 19		N=115	N=86	N=201
		Very Much Improved	11 (9.6%)	8 (9.3%)	19 (9.5%)
		Much Improved	34 (29.6%)	26 (30.2%)	60 (29.9%)
		Minimally Improved	33 (28.7%)	23 (26.7%)	56 (27.9%)
		No Change	21 (18.3%)	18 (20.9%)	39 (19.4%)
		Minimally Worsened	12 (10.4%)	7 (8.1%)	19 (9.5%)
		Much Worsened	4 (3.5%)	3 (3.5%)	7 (3.5%)
		Very Much Worsened	0 (0.0%)	1 (1.2%)	1 (0.5%)
	Week 22		N=101	N=86	N=187
		Very Much Improved	17 (16.8%)	10 (11.6%)	27 (14.4%)
		Much Improved	30 (29.7%)	24 (27.9%)	54 (28.9%)
		Minimally Improved	21 (20.8%)	19 (22.1%)	40 (21.4%)
		No Change	19 (18.8%)	20 (23.3%)	39 (20.9%)
		Minimally Worsened	9 (8.9%)	9 (10.5%)	18 (9.6%)
		Much Worsened	5 (5.0%)	4 (4.7%)	9 (4.8%)
		Very Much Worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 25		N=93	N=74	N=167
		Very Much Improved	10 (10.8%)	5 (6.8%)	15 (9.0%)
		Much Improved	35 (37.6%)	26 (35.1%)	61 (36.5%)
		Minimally Improved	24 (25.8%)	14 (18.9%)	38 (22.8%)
		No Change	15 (16.1%)	13 (17.6%)	28 (16.8%)
		Minimally Worsened	6 (6.5%)	10 (13.5%)	16 (9.6%)
		Much Worsened	3 (3.2%)	5 (6.8%)	8 (4.8%)
		Very Much Worsened	0 (0.0%)	1 (1.4%)	1 (0.6%)

Item	Visit	Response Level	SG (N=177)	TPC (N=169)	Overall (N=346)
	Week 28		N=47	N=43	N=90
		Very Much Improved	6 (12.8%)	6 (14.0%)	12 (13.3%)
		Much Improved	17 (36.2%)	16 (37.2%)	33 (36.7%)
		Minimally Improved	11 (23.4%)	8 (18.6%)	19 (21.1%)
		No Change	7 (14.9%)	4 (9.3%)	11 (12.2%)
		Minimally Worsened	4 (8.5%)	6 (14.0%)	10 (11.1%)
		Much Worsened	1 (2.1%)	3 (7.0%)	4 (4.4%)
		Very Much Worsened	1 (2.1%)	0 (0.0%)	1 (1.1%)

PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 3.1.2.3
Distribution of Responses to PGIS by Visit
(mITT excluding patients preselected to receive nab-paclitaxel)

Item	Visit	Response Level	SG (N=177)	TPC (N=169)	Overall (N=346)
PGIS	Baseline (Week 1)		N=168	N=164	N=332
		Very Poor	5 (3.0%)	5 (3.0%)	10 (3.0%)
		Poor	18 (10.7%)	29 (17.7%)	47 (14.2%)
		Fair	62 (36.9%)	54 (32.9%)	116 (34.9%)
		Good	66 (39.3%)	60 (36.6%)	126 (38.0%)
		Excellent	17 (10.1%)	16 (9.8%)	33 (9.9%)
	Week 13		N=85	N=85	N=170
		Very Poor	1 (1.2%)	2 (2.4%)	3 (1.8%)
		Poor	4 (4.7%)	9 (10.6%)	13 (7.6%)
		Fair	40 (47.1%)	30 (35.3%)	70 (41.2%)
		Good	35 (41.2%)	36 (42.4%)	71 (41.8%)
		Excellent	5 (5.9%)	8 (9.4%)	13 (7.6%)
	Week 16		N=114	N=87	N=201
		Very Poor	2 (1.8%)	0 (0.0%)	2 (1.0%)
		Poor	9 (7.9%)	9 (10.3%)	18 (9.0%)
		Fair	63 (55.3%)	47 (54.0%)	110 (54.7%)
		Good	31 (27.2%)	27 (31.0%)	58 (28.9%)
		Excellent	9 (7.9%)	4 (4.6%)	13 (6.5%)
	Week 19		N=115	N=86	N=201
		Very Poor	1 (0.9%)	2 (2.3%)	3 (1.5%)
		Poor	7 (6.1%)	6 (7.0%)	13 (6.5%)
		Fair	57 (49.6%)	43 (50.0%)	100 (49.8%)
		Good	43 (37.4%)	28 (32.6%)	71 (35.3%)
		Excellent	7 (6.1%)	7 (8.1%)	14 (7.0%)
	Week 22		N=101	N=86	N=187
		Very Poor	2 (2.0%)	1 (1.2%)	3 (1.6%)
		Poor	6 (5.9%)	14 (16.3%)	20 (10.7%)
		Fair	43 (42.6%)	32 (37.2%)	75 (40.1%)
		Good	46 (45.5%)	36 (41.9%)	82 (43.9%)
		Excellent	4 (4.0%)	3 (3.5%)	7 (3.7%)
	Week 25		N=93	N=74	N=167
		Very Poor	0 (0.0%)	3 (4.1%)	3 (1.8%)
		Poor	7 (7.5%)	11 (14.9%)	18 (10.8%)
		Fair	42 (45.2%)	29 (39.2%)	71 (42.5%)
		Good	41 (44.1%)	27 (36.5%)	68 (40.7%)
		Excellent	3 (3.2%)	4 (5.4%)	7 (4.2%)
	Week 28		N=47	N=43	N=90
		Very Poor	1 (2.1%)	0 (0.0%)	1 (1.1%)
		Poor	3 (6.4%)	5 (11.6%)	8 (8.9%)
		Fair	22 (46.8%)	20 (46.5%)	42 (46.7%)
		Good	16 (34.0%)	15 (34.9%)	31 (34.4%)

Item	Visit	Response Level	SG (N=177)	TPC (N=169)	Overall (N=346)
		Excellent	5 (10.6%)	3 (7.0%)	8 (8.9%)

PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Data Source: ADSL ADQSRun Date: 01MAY2026

Table 5.1.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	102 (57.6%)	96 (56.8%)
The number (%) of patients censored [a]	75 (42.4%)	73 (43.2%)
Not at risk at baseline n (%) [a]	2 (1.1%)	5 (3.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	11 (6.2%)	5 (3.0%)
Premature treatment discontinuation n (%) [a]	37 (20.9%)	51 (30.2%)
Others n (%) [a]	9 (5.1%)	2 (1.2%)
Median time to event (95% CI) [b]	3.6 (2.1, 5.7)	4.1 (2.6, 4.9)
Q1	1.0 (0.8, 1.4)	1.0 (0.9, 1.6)
Q3	16.7 (8.3, NE)	13.0 (7.3, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	52.8% (44.6%, 60.3%)	56.6% (48.2%, 64.2%)
by 6 Months, % (95% CI)	41.1% (33.0%, 49.1%)	36.5% (28.1%, 44.9%)
by 12 Months, % (95% CI)	30.5% (22.6%, 38.7%)	28.0% (19.4%, 37.3%)
by 18 Months, % (95% CI)	24.0% (15.4%, 33.6%)	16.0% (6.6%, 29.0%)
by 24 Months, % (95% CI)	24.0% (15.4%, 33.6%)	16.0% (6.6%, 29.0%)
Nominal p-value for stratified log-rank test [c]	0.767	
HR (95% CI) [d]	0.96 (0.72, 1.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	89 (50.3%)	92 (54.4%)
The number (%) of patients censored [a]	88 (49.7%)	77 (45.6%)
Not at risk at baseline n (%) [a]	1 (0.6%)	1 (0.6%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	11 (6.2%)	8 (4.7%)
Premature treatment discontinuation n (%) [a]	51 (28.8%)	56 (33.1%)
Others n (%) [a]	8 (4.5%)	2 (1.2%)
Median time to event (95% CI) [b]	5.6 (3.3, 9.2)	4.6 (2.9, 6.0)
Q1	1.4 (0.8, 1.6)	1.4 (1.1, 1.9)
Q3	21.5 (20.1, NE)	14.0 (11.1, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	60.3% (52.1%, 67.5%)	58.2% (49.8%, 65.7%)
by 6 Months, % (95% CI)	49.7% (41.4%, 57.5%)	41.5% (33.0%, 49.8%)
by 12 Months, % (95% CI)	37.0% (27.9%, 46.2%)	33.2% (23.6%, 43.0%)
by 18 Months, % (95% CI)	34.7% (25.2%, 44.4%)	23.7% (13.4%, 35.8%)
by 24 Months, % (95% CI)	21.7% (8.6%, 38.6%)	19.0% (8.5%, 32.6%)
Nominal p-value for stratified log-rank test [c]	0.571	
HR (95% CI) [d]	0.91 (0.68, 1.22)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	103 (58.2%)	115 (68.0%)
The number (%) of patients censored [a]	74 (41.8%)	54 (32.0%)
Not at risk at baseline n (%) [a]	5 (2.8%)	4 (2.4%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	9 (5.1%)	4 (2.4%)
Premature treatment discontinuation n (%) [a]	37 (20.9%)	35 (20.7%)
Others n (%) [a]	6 (3.4%)	1 (0.6%)
Median time to event (95% CI) [b]	1.6 (1.4, 2.4)	2.8 (1.9, 3.8)
Q1	0.8 (0.8, 1.0)	1.0 (0.9, 1.1)
Q3	20.8 (8.4, NE)	6.9 (5.1, 9.9)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	39.1% (31.2%, 46.8%)	47.9% (39.6%, 55.6%)
by 6 Months, % (95% CI)	35.0% (27.3%, 42.8%)	28.2% (20.9%, 35.9%)
by 12 Months, % (95% CI)	30.0% (22.1%, 38.3%)	13.6% (7.3%, 21.9%)
by 18 Months, % (95% CI)	27.5% (19.1%, 36.5%)	13.6% (7.3%, 21.9%)
by 24 Months, % (95% CI)	22.0% (11.5%, 34.7%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.883	
HR (95% CI) [d]	0.97 (0.74, 1.26)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	82 (46.3%)	68 (40.2%)
The number (%) of patients censored [a]	95 (53.7%)	101 (59.8%)
Not at risk at baseline n (%) [a]	1 (0.6%)	6 (3.6%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	11 (6.2%)	7 (4.1%)
Premature treatment discontinuation n (%) [a]	55 (31.1%)	77 (45.6%)
Others n (%) [a]	12 (6.8%)	1 (0.6%)
Median time to event (95% CI) [b]	8.4 (4.9, 11.4)	9.1 (6.5, 12.3)
Q1	2.8 (1.7, 3.6)	3.5 (2.6, 4.4)
Q3	NE (15.5, NE)	14.0 (12.3, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	74.0% (66.3%, 80.2%)	80.2% (72.6%, 85.9%)
by 6 Months, % (95% CI)	55.4% (46.7%, 63.2%)	60.0% (50.7%, 68.1%)
by 12 Months, % (95% CI)	38.2% (28.7%, 47.7%)	38.0% (25.5%, 50.5%)
by 18 Months, % (95% CI)	31.3% (21.6%, 41.3%)	12.6% (3.1%, 29.3%)
by 24 Months, % (95% CI)	31.3% (21.6%, 41.3%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.732	
HR (95% CI) [d]	1.06 (0.77, 1.48)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	97 (54.8%)	104 (61.5%)
The number (%) of patients censored [a]	80 (45.2%)	65 (38.5%)
Not at risk at baseline n (%) [a]	1 (0.6%)	0 (0.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	10 (5.6%)	6 (3.6%)
Premature treatment discontinuation n (%) [a]	43 (24.3%)	48 (28.4%)
Others n (%) [a]	9 (5.1%)	1 (0.6%)
Median time to event (95% CI) [b]	4.2 (2.9, 5.7)	3.5 (2.4, 4.1)
Q1	1.6 (1.0, 1.8)	1.4 (0.9, 1.9)
Q3	18.5 (12.6, NE)	10.2 (6.5, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	57.4% (49.1%, 64.8%)	53.0% (44.6%, 60.7%)
by 6 Months, % (95% CI)	40.2% (31.8%, 48.4%)	34.3% (26.4%, 42.3%)
by 12 Months, % (95% CI)	33.4% (25.0%, 41.9%)	21.3% (12.9%, 31.2%)
by 18 Months, % (95% CI)	27.3% (18.5%, 36.9%)	18.3% (9.8%, 28.8%)
by 24 Months, % (95% CI)	11.7% (1.4%, 33.8%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.114	
HR (95% CI) [d]	0.81 (0.62, 1.07)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	102 (57.6%)	100 (59.2%)
The number (%) of patients censored [a]	75 (42.4%)	69 (40.8%)
Not at risk at baseline n (%) [a]	5 (2.8%)	1 (0.6%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	10 (5.6%)	8 (4.7%)
Premature treatment discontinuation n (%) [a]	36 (20.3%)	49 (29.0%)
Others n (%) [a]	8 (4.5%)	1 (0.6%)
Median time to event (95% CI) [b]	2.4 (1.5, 3.6)	3.3 (2.2, 4.5)
Q1	1.0 (0.8, 1.1)	0.9 (0.8, 1.0)
Q3	18.2 (12.2, NE)	15.2 (6.3, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	47.8% (39.6%, 55.5%)	53.6% (45.3%, 61.3%)
by 6 Months, % (95% CI)	37.9% (30.0%, 45.8%)	34.0% (25.9%, 42.2%)
by 12 Months, % (95% CI)	33.5% (25.6%, 41.7%)	25.7% (17.1%, 35.1%)
by 18 Months, % (95% CI)	26.6% (17.5%, 36.5%)	21.4% (11.8%, 32.9%)
by 24 Months, % (95% CI)	18.9% (9.0%, 31.6%)	14.3% (4.2%, 30.2%)
Nominal p-value for stratified log-rank test [c]	0.983	
HR (95% CI) [d]	0.96 (0.73, 1.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	119 (67.2%)	124 (73.4%)
The number (%) of patients censored [a]	58 (32.8%)	45 (26.6%)
Not at risk at baseline n (%) [a]	3 (1.7%)	2 (1.2%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	9 (5.1%)	2 (1.2%)
Premature treatment discontinuation n (%) [a]	25 (14.1%)	29 (17.2%)
Others n (%) [a]	5 (2.8%)	2 (1.2%)
Median time to event (95% CI) [b]	1.4 (1.0, 1.7)	1.4 (1.1, 1.9)
Q1	0.8 (0.8, 0.8)	0.9 (0.8, 1.0)
Q3	5.7 (2.6, NE)	4.9 (3.5, 5.6)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	31.9% (24.7%, 39.3%)	36.6% (28.9%, 44.3%)
by 6 Months, % (95% CI)	24.0% (17.4%, 31.2%)	16.5% (10.5%, 23.7%)
by 12 Months, % (95% CI)	21.0% (14.3%, 28.7%)	7.9% (3.2%, 15.4%)
by 18 Months, % (95% CI)	21.0% (14.3%, 28.7%)	7.9% (3.2%, 15.4%)
by 24 Months, % (95% CI)	14.0% (4.7%, 28.4%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.879	
HR (95% CI) [d]	0.98 (0.76, 1.26)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	109 (61.6%)	93 (55.0%)
The number (%) of patients censored [a]	68 (38.4%)	76 (45.0%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	9 (5.1%)	9 (5.3%)
Premature treatment discontinuation n (%) [a]	37 (20.9%)	55 (32.5%)
Others n (%) [a]	5 (2.8%)	2 (1.2%)
Median time to event (95% CI) [b]	1.9 (1.4, 2.8)	2.6 (1.7, 5.6)
Q1	0.8 (0.8, 0.9)	0.9 (0.8, 1.3)
Q3	11.7 (5.7, NE)	19.6 (9.5, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	40.0% (32.2%, 47.6%)	49.1% (40.9%, 56.9%)
by 6 Months, % (95% CI)	31.6% (24.0%, 39.4%)	40.8% (32.5%, 48.8%)
by 12 Months, % (95% CI)	23.4% (15.4%, 32.3%)	32.3% (22.6%, 42.4%)
by 18 Months, % (95% CI)	18.7% (9.4%, 30.3%)	32.3% (22.6%, 42.4%)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.120	
HR (95% CI) [d]	1.26 (0.95, 1.67)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	88 (49.7%)	100 (59.2%)
The number (%) of patients censored [a]	89 (50.3%)	69 (40.8%)
Not at risk at baseline n (%) [a]	11 (6.2%)	5 (3.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	13 (7.3%)	4 (2.4%)
Premature treatment discontinuation n (%) [a]	42 (23.7%)	49 (29.0%)
Others n (%) [a]	7 (4.0%)	1 (0.6%)
Median time to event (95% CI) [b]	5.6 (2.4, 8.8)	3.0 (2.4, 4.4)
Q1	1.2 (0.8, 1.5)	1.1 (1.0, 1.5)
Q3	17.8 (10.8, NE)	10.9 (6.9, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	56.1% (47.6%, 63.9%)	49.4% (41.0%, 57.3%)
by 6 Months, % (95% CI)	48.1% (39.4%, 56.3%)	36.8% (28.7%, 44.9%)
by 12 Months, % (95% CI)	30.8% (21.7%, 40.3%)	23.5% (15.0%, 33.1%)
by 18 Months, % (95% CI)	23.6% (14.2%, 34.4%)	14.7% (5.7%, 27.8%)
by 24 Months, % (95% CI)	23.6% (14.2%, 34.4%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.299	
HR (95% CI) [d]	0.85 (0.64, 1.14)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	65 (36.7%)	89 (52.7%)
The number (%) of patients censored [a]	112 (63.3%)	80 (47.3%)
Not at risk at baseline n (%) [a]	2 (1.1%)	4 (2.4%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	12 (6.8%)	9 (5.3%)
Premature treatment discontinuation n (%) [a]	67 (37.9%)	56 (33.1%)
Others n (%) [a]	14 (7.9%)	1 (0.6%)
Median time to event (95% CI) [b]	12.2 (7.7, NE)	4.7 (2.8, 5.8)
Q1	2.1 (1.4, 3.6)	1.4 (1.0, 1.9)
Q3	NE (NE, NE)	18.5 (8.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	71.3% (63.4%, 77.8%)	58.1% (49.6%, 65.7%)
by 6 Months, % (95% CI)	64.0% (55.6%, 71.3%)	41.5% (32.8%, 49.9%)
by 12 Months, % (95% CI)	50.7% (40.6%, 59.9%)	31.4% (22.3%, 40.8%)
by 18 Months, % (95% CI)	46.9% (36.3%, 56.8%)	28.2% (18.5%, 38.7%)
by 24 Months, % (95% CI)	46.9% (36.3%, 56.8%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	<.001	
HR (95% CI) [d]	0.56 (0.40, 0.77)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	80 (45.2%)	87 (51.5%)
The number (%) of patients censored [a]	97 (54.8%)	82 (48.5%)
Not at risk at baseline n (%) [a]	10 (5.6%)	10 (5.9%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	14 (7.9%)	7 (4.1%)
Premature treatment discontinuation n (%) [a]	50 (28.2%)	53 (31.4%)
Others n (%) [a]	6 (3.4%)	2 (1.2%)
Median time to event (95% CI) [b]	5.5 (3.6, 10.8)	4.2 (3.1, 5.7)
Q1	1.4 (1.0, 2.3)	1.2 (1.0, 1.9)
Q3	19.2 (16.8, NE)	13.8 (9.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	63.8% (55.4%, 71.1%)	60.1% (51.5%, 67.7%)
by 6 Months, % (95% CI)	49.1% (40.2%, 57.4%)	41.4% (32.7%, 49.8%)
by 12 Months, % (95% CI)	39.3% (29.8%, 48.7%)	32.2% (23.2%, 41.4%)
by 18 Months, % (95% CI)	32.6% (21.3%, 44.4%)	23.0% (11.8%, 36.3%)
by 24 Months, % (95% CI)	21.4% (8.5%, 38.0%)	23.0% (11.8%, 36.3%)
Nominal p-value for stratified log-rank test [c]	0.133	
HR (95% CI) [d]	0.80 (0.59, 1.09)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	87 (49.2%)	84 (49.7%)
The number (%) of patients censored [a]	90 (50.8%)	85 (50.3%)
Not at risk at baseline n (%) [a]	3 (1.7%)	6 (3.6%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	14 (7.9%)	7 (4.1%)
Premature treatment discontinuation n (%) [a]	48 (27.1%)	60 (35.5%)
Others n (%) [a]	8 (4.5%)	2 (1.2%)
Median time to event (95% CI) [b]	3.6 (2.1, 8.8)	4.9 (2.4, 7.9)
Q1	0.9 (0.8, 1.4)	1.0 (0.9, 1.4)
Q3	NE (NE, NE)	15.5 (11.1, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	52.7% (44.4%, 60.3%)	56.8% (48.2%, 64.5%)
by 6 Months, % (95% CI)	43.9% (35.7%, 51.9%)	45.5% (36.8%, 53.8%)
by 12 Months, % (95% CI)	39.7% (30.9%, 48.3%)	35.1% (24.2%, 46.2%)
by 18 Months, % (95% CI)	37.0% (27.5%, 46.6%)	18.8% (6.7%, 35.5%)
by 24 Months, % (95% CI)	37.0% (27.5%, 46.6%)	12.5% (2.8%, 30.0%)
Nominal p-value for stratified log-rank test [c]	0.971	
HR (95% CI) [d]	0.99 (0.73, 1.33)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	97 (54.8%)	89 (52.7%)
The number (%) of patients censored [a]	80 (45.2%)	80 (47.3%)
Not at risk at baseline n (%) [a]	4 (2.3%)	6 (3.6%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	9 (5.1%)	8 (4.7%)
Premature treatment discontinuation n (%) [a]	44 (24.9%)	53 (31.4%)
Others n (%) [a]	7 (4.0%)	3 (1.8%)
Median time to event (95% CI) [b]	2.4 (1.7, 3.6)	3.3 (1.9, 6.5)
Q1	1.0 (0.8, 1.4)	0.9 (0.8, 1.1)
Q3	19.4 (12.4, NE)	13.3 (9.0, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	44.4% (36.3%, 52.2%)	50.3% (41.8%, 58.2%)
by 6 Months, % (95% CI)	38.0% (30.1%, 46.0%)	44.0% (35.4%, 52.2%)
by 12 Months, % (95% CI)	35.1% (26.8%, 43.5%)	32.5% (23.3%, 41.9%)
by 18 Months, % (95% CI)	30.4% (21.2%, 40.1%)	24.4% (13.5%, 37.0%)
by 24 Months, % (95% CI)	22.8% (10.1%, 38.5%)	24.4% (13.5%, 37.0%)
Nominal p-value for stratified log-rank test [c]	0.843	
HR (95% CI) [d]	1.01 (0.76, 1.35)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	118 (66.7%)	71 (42.0%)
The number (%) of patients censored [a]	59 (33.3%)	98 (58.0%)
Not at risk at baseline n (%) [a]	1 (0.6%)	0 (0.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	8 (4.5%)	14 (8.3%)
Premature treatment discontinuation n (%) [a]	27 (15.3%)	73 (43.2%)
Others n (%) [a]	6 (3.4%)	1 (0.6%)
Median time to event (95% CI) [b]	1.7 (1.2, 2.2)	6.9 (4.7, NE)
Q1	0.8 (0.8, 0.9)	1.9 (1.4, 2.8)
Q3	5.8 (3.8, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	37.5% (29.9%, 45.1%)	66.6% (58.3%, 73.6%)
by 6 Months, % (95% CI)	24.5% (17.6%, 31.9%)	53.5% (44.5%, 61.6%)
by 12 Months, % (95% CI)	20.7% (13.9%, 28.4%)	43.7% (32.7%, 54.2%)
by 18 Months, % (95% CI)	16.4% (9.5%, 25.0%)	39.3% (26.7%, 51.7%)
by 24 Months, % (95% CI)	16.4% (9.5%, 25.0%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	<.001	
HR (95% CI) [d]	2.36 (1.75, 3.18)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	65 (36.7%)	63 (37.3%)
The number (%) of patients censored [a]	112 (63.3%)	106 (62.7%)
Not at risk at baseline n (%) [a]	10 (5.6%)	10 (5.9%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	10 (5.6%)	12 (7.1%)
Premature treatment discontinuation n (%) [a]	64 (36.2%)	73 (43.2%)
Others n (%) [a]	11 (6.2%)	1 (0.6%)
Median time to event (95% CI) [b]	10.5 (7.4, 27.9)	8.7 (4.6, NE)
Q1	2.9 (1.7, 4.5)	1.9 (1.4, 3.3)
Q3	27.9 (21.5, NE)	19.4 (19.4, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	74.8% (66.8%, 81.2%)	70.7% (62.2%, 77.6%)
by 6 Months, % (95% CI)	63.4% (54.4%, 71.1%)	54.3% (44.9%, 62.7%)
by 12 Months, % (95% CI)	48.8% (38.8%, 58.1%)	46.6% (35.5%, 56.9%)
by 18 Months, % (95% CI)	46.7% (36.3%, 56.4%)	46.6% (35.5%, 56.9%)
by 24 Months, % (95% CI)	35.4% (19.9%, 51.2%)	23.3% (2.2%, 57.4%)
Nominal p-value for stratified log-rank test [c]	0.234	
HR (95% CI) [d]	0.80 (0.56, 1.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	101 (57.1%)	82 (48.5%)
The number (%) of patients censored [a]	76 (42.9%)	87 (51.5%)
Not at risk at baseline n (%) [a]	8 (4.5%)	5 (3.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	7 (4.1%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	9 (5.1%)	7 (4.1%)
Premature treatment discontinuation n (%) [a]	36 (20.3%)	62 (36.7%)
Others n (%) [a]	5 (2.8%)	2 (1.2%)
Median time to event (95% CI) [b]	2.3 (1.7, 3.7)	5.0 (2.8, 7.0)
Q1	1.0 (0.8, 1.4)	1.4 (1.0, 1.7)
Q3	13.2 (6.3, NE)	17.1 (12.7, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	48.2% (39.8%, 56.1%)	57.7% (49.1%, 65.4%)
by 6 Months, % (95% CI)	33.0% (25.1%, 41.1%)	45.2% (36.4%, 53.6%)
by 12 Months, % (95% CI)	28.6% (20.8%, 36.8%)	37.5% (28.0%, 47.1%)
by 18 Months, % (95% CI)	22.6% (14.4%, 31.8%)	21.9% (9.4%, 37.7%)
by 24 Months, % (95% CI)	22.6% (14.4%, 31.8%)	21.9% (9.4%, 37.7%)
Nominal p-value for stratified log-rank test [c]	0.039	
HR (95% CI) [d]	1.39 (1.03, 1.86)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	46 (26.0%)	49 (29.0%)
The number (%) of patients censored [a]	131 (74.0%)	120 (71.0%)
Not at risk at baseline n (%) [a]	1 (0.6%)	0 (0.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	7 (4.1%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	17 (9.6%)	15 (8.9%)
Premature treatment discontinuation n (%) [a]	81 (45.8%)	92 (54.4%)
Others n (%) [a]	14 (7.9%)	2 (1.2%)
Median time to event (95% CI) [b]	NE (18.5, NE)	NE (NE, NE)
Q1	4.5 (3.0, 11.7)	3.0 (1.9, 5.3)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	82.1% (74.9%, 87.4%)	76.3% (68.4%, 82.5%)
by 6 Months, % (95% CI)	73.0% (64.7%, 79.7%)	66.4% (57.5%, 73.9%)
by 12 Months, % (95% CI)	66.5% (56.8%, 74.4%)	60.5% (50.5%, 69.1%)
by 18 Months, % (95% CI)	61.9% (50.8%, 71.2%)	60.5% (50.5%, 69.1%)
by 24 Months, % (95% CI)	57.8% (44.5%, 69.0%)	60.5% (50.5%, 69.1%)
Nominal p-value for stratified log-rank test [c]	0.255	
HR (95% CI) [d]	0.77 (0.51, 1.16)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	7 (4.0%)	9 (5.3%)
The number (%) of patients censored [a]	170 (96.0%)	160 (94.7%)
Not at risk at baseline n (%) [a]	4 (2.3%)	7 (4.1%)
Missing baseline only n (%) [a]	24 (13.6%)	20 (11.8%)
Having baseline but no postbaseline visit n (%) [a]	14 (7.9%)	16 (9.5%)
No baseline or any postbaseline n (%) [a]	93 (52.5%)	79 (46.7%)
Missing PRO for two consecutive visits n (%) [a]	23 (13.0%)	20 (11.8%)
Premature treatment discontinuation n (%) [a]	9 (5.1%)	17 (10.1%)
Others n (%) [a]	3 (1.7%)	1 (0.6%)
Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.2, NE)
Q1	2.7 (0.8, NE)	4.2 (1.0, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	73.9% (52.5%, 86.7%)	79.8% (62.2%, 89.9%)
by 6 Months, % (95% CI)	73.9% (52.5%, 86.7%)	70.1% (49.2%, 83.8%)
by 12 Months, % (95% CI)	73.9% (52.5%, 86.7%)	70.1% (49.2%, 83.8%)
by 18 Months, % (95% CI)	73.9% (52.5%, 86.7%)	70.1% (49.2%, 83.8%)
by 24 Months, % (95% CI)	NE (NE, NE)	70.1% (49.2%, 83.8%)
Nominal p-value for stratified log-rank test [c]	0.829	
HR (95% CI) [d]	1.15 (0.42, 3.17)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	69 (39.0%)	65 (38.5%)
The number (%) of patients censored [a]	108 (61.0%)	104 (61.5%)
Not at risk at baseline n (%) [a]	37 (20.9%)	34 (20.1%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	7 (4.1%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	9 (5.1%)	9 (5.3%)
Premature treatment discontinuation n (%) [a]	35 (19.8%)	48 (28.4%)
Others n (%) [a]	9 (5.1%)	2 (1.2%)
Median time to event (95% CI) [b]	5.6 (3.6, 9.8)	6.3 (3.3, 9.3)
Q1	1.5 (1.1, 2.1)	1.6 (1.0, 2.0)
Q3	27.9 (13.1, NE)	15.2 (10.2, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	62.0% (52.4%, 70.1%)	62.6% (53.1%, 70.8%)
by 6 Months, % (95% CI)	49.2% (39.4%, 58.3%)	51.7% (41.9%, 60.6%)
by 12 Months, % (95% CI)	38.5% (28.6%, 48.3%)	35.2% (23.9%, 46.8%)
by 18 Months, % (95% CI)	33.1% (23.2%, 43.4%)	19.6% (5.5%, 39.9%)
by 24 Months, % (95% CI)	29.5% (18.7%, 41.0%)	19.6% (5.5%, 39.9%)
Nominal p-value for stratified log-rank test [c]	0.815	
HR (95% CI) [d]	0.96 (0.68, 1.35)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	131 (74.0%)	107 (63.3%)
The number (%) of patients censored [a]	46 (26.0%)	62 (36.7%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	13 (7.3%)	7 (4.1%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	5 (2.8%)	4 (2.4%)
Premature treatment discontinuation n (%) [a]	19 (10.7%)	44 (26.0%)
Others n (%) [a]	4 (2.3%)	3 (1.8%)
Median time to event (95% CI) [b]	1.0 (0.8, 1.1)	2.1 (1.4, 3.5)
Q1	0.8 (0.8, 0.8)	1.0 (0.9, 1.0)
Q3	2.2 (1.5, 4.6)	9.2 (5.1, 17.1)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	22.3% (16.2%, 29.2%)	45.8% (37.7%, 53.6%)
by 6 Months, % (95% CI)	16.9% (11.3%, 23.4%)	28.4% (20.8%, 36.5%)
by 12 Months, % (95% CI)	12.5% (7.0%, 19.7%)	20.8% (12.7%, 30.4%)
by 18 Months, % (95% CI)	12.5% (7.0%, 19.7%)	11.1% (3.1%, 25.0%)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	<.001	
HR (95% CI) [d]	1.73 (1.34, 2.24)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	53 (29.9%)	42 (24.9%)
The number (%) of patients censored [a]	124 (70.1%)	127 (75.1%)
Not at risk at baseline n (%) [a]	8 (4.5%)	6 (3.6%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	7 (4.1%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	17 (9.6%)	15 (8.9%)
Premature treatment discontinuation n (%) [a]	66 (37.3%)	91 (53.8%)
Others n (%) [a]	16 (9.0%)	4 (2.4%)
Median time to event (95% CI) [b]	24.7 (10.2, NE)	NE (9.8, NE)
Q1	4.2 (2.2, 7.2)	5.1 (2.8, 8.1)
Q3	NE (24.7, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	78.4% (70.7%, 84.3%)	80.1% (72.3%, 85.9%)
by 6 Months, % (95% CI)	68.9% (60.1%, 76.1%)	72.4% (63.6%, 79.5%)
by 12 Months, % (95% CI)	59.0% (49.0%, 67.6%)	61.3% (49.5%, 71.1%)
by 18 Months, % (95% CI)	53.1% (41.0%, 63.7%)	56.6% (42.2%, 68.6%)
by 24 Months, % (95% CI)	53.1% (41.0%, 63.7%)	56.6% (42.2%, 68.6%)
Nominal p-value for stratified log-rank test [c]	0.684	
HR (95% CI) [d]	1.07 (0.71, 1.61)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	89 (50.3%)	89 (52.7%)
The number (%) of patients censored [a]	88 (49.7%)	80 (47.3%)
Not at risk at baseline n (%) [a]	2 (1.1%)	4 (2.4%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	7 (4.1%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	11 (6.2%)	11 (6.5%)
Premature treatment discontinuation n (%) [a]	50 (28.2%)	53 (31.4%)
Others n (%) [a]	8 (4.5%)	1 (0.6%)
Median time to event (95% CI) [b]	5.6 (4.0, 9.6)	3.8 (2.8, 5.6)
Q1	1.5 (1.1, 2.2)	1.4 (1.0, 1.9)
Q3	16.5 (15.0, NE)	12.7 (7.9, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	64.4% (56.2%, 71.5%)	55.9% (47.2%, 63.7%)
by 6 Months, % (95% CI)	49.9% (41.2%, 57.9%)	39.6% (30.9%, 48.2%)
by 12 Months, % (95% CI)	37.9% (28.8%, 46.9%)	27.1% (17.9%, 37.2%)
by 18 Months, % (95% CI)	24.7% (15.4%, 35.1%)	23.7% (14.0%, 34.8%)
by 24 Months, % (95% CI)	24.7% (15.4%, 35.1%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.140	
HR (95% CI) [d]	0.79 (0.59, 1.07)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	17 (9.6%)	19 (11.2%)
The number (%) of patients censored [a]	160 (90.4%)	150 (88.8%)
Not at risk at baseline n (%) [a]	3 (1.7%)	2 (1.2%)
Missing baseline only n (%) [a]	132 (74.6%)	98 (58.0%)
Having baseline but no postbaseline visit n (%) [a]	3 (1.7%)	6 (3.6%)
No baseline or any postbaseline n (%) [a]	11 (6.2%)	31 (18.3%)
Missing PRO for two consecutive visits n (%) [a]	5 (2.8%)	6 (3.6%)
Premature treatment discontinuation n (%) [a]	5 (2.8%)	7 (4.1%)
Others n (%) [a]	1 (0.6%)	0 (0.0%)
Median time to event (95% CI) [b]	3.5 (0.9, 7.9)	1.4 (1.0, 3.3)
Q1	0.8 (0.7, 1.0)	1.0 (0.8, 1.4)
Q3	NE (3.5, NE)	4.6 (1.5, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	50.5% (30.4%, 67.6%)	36.8% (18.8%, 55.0%)
by 6 Months, % (95% CI)	41.2% (21.9%, 59.5%)	23.8% (9.4%, 41.9%)
by 12 Months, % (95% CI)	29.4% (12.1%, 49.2%)	23.8% (9.4%, 41.9%)
by 18 Months, % (95% CI)	29.4% (12.1%, 49.2%)	NE (NE, NE)
by 24 Months, % (95% CI)	29.4% (12.1%, 49.2%)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.310	
HR (95% CI) [d]	0.83 (0.43, 1.59)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.3
Time to First Meaningful Deterioration for EQ-VAS
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	70 (39.5%)	56 (33.1%)
The number (%) of patients censored [a]	107 (60.5%)	113 (66.9%)
Not at risk at baseline n (%) [a]	1 (0.6%)	1 (0.6%)
Missing baseline only n (%) [a]	4 (2.3%)	3 (1.8%)
Having baseline but no postbaseline visit n (%) [a]	12 (6.8%)	8 (4.7%)
No baseline or any postbaseline n (%) [a]	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits n (%) [a]	15 (8.5%)	12 (7.1%)
Premature treatment discontinuation n (%) [a]	58 (32.8%)	84 (49.7%)
Others n (%) [a]	15 (8.5%)	3 (1.8%)
Median time to event (95% CI) [b]	9.8 (6.3, NE)	13.0 (10.3, NE)
Q1	2.3 (1.3, 3.6)	2.8 (1.6, 4.4)
Q3	NE (NE, NE)	NE (15.4, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	70.9% (63.0%, 77.5%)	73.7% (65.7%, 80.2%)
by 6 Months, % (95% CI)	61.9% (53.2%, 69.4%)	64.4% (55.6%, 71.9%)
by 12 Months, % (95% CI)	46.5% (36.4%, 56.0%)	54.4% (42.1%, 65.1%)
by 18 Months, % (95% CI)	42.5% (32.0%, 52.7%)	38.9% (21.9%, 55.6%)
by 24 Months, % (95% CI)	39.0% (27.4%, 50.4%)	38.9% (21.9%, 55.6%)
Nominal p-value for stratified log-rank test [c]	0.472	
HR (95% CI) [d]	1.14 (0.80, 1.63)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.

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Table 5.1.4
Time to First Meaningful Deterioration for PGIC
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	40 (22.6%)	42 (24.9%)
The number (%) of patients censored [a]	137 (77.4%)	127 (75.1%)
Not at risk at baseline n (%) [a]	0 (0.0%)	0 (0.0%)
Missing baseline only n (%) [a]	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit n (%) [a]	0 (0.0%)	0 (0.0%)
No baseline or any postbaseline n (%) [a]	42 (23.7%)	38 (22.5%)
Missing PRO for two consecutive visits n (%) [a]	4 (2.3%)	2 (1.2%)
Premature treatment discontinuation n (%) [a]	72 (40.7%)	83 (49.1%)
Others n (%) [a]	19 (10.7%)	4 (2.4%)
Median time to event (95% CI) [b]	NE (6.4, NE)	6.5 (6.3, NE)
Q1	5.0 (3.8, 6.0)	4.3 (3.7, 5.6)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	91.8% (85.7%, 95.4%)	91.6% (85.3%, 95.3%)
by 6 Months, % (95% CI)	68.4% (58.8%, 76.2%)	64.8% (54.4%, 73.4%)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.370	
HR (95% CI) [d]	0.82 (0.53, 1.27)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 5.1.5
Time to First Meaningful Deterioration for PGIS
(mITT excluding patients preselected to receive nab-paclitaxel)

Parameter	SG (N=177)	TPC (N=169)
The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	177	169
The number (%) of patients with an event [a]	17 (9.6%)	11 (6.5%)
The number (%) of patients censored [a]	160 (90.4%)	158 (93.5%)
Not at risk at baseline n (%) [a]	18 (10.2%)	25 (14.8%)
Missing baseline only n (%) [a]	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit n (%) [a]	36 (20.3%)	35 (20.7%)
No baseline or any postbaseline n (%) [a]	6 (3.4%)	3 (1.8%)
Missing PRO for two consecutive visits n (%) [a]	11 (6.2%)	13 (7.7%)
Premature treatment discontinuation n (%) [a]	65 (36.7%)	74 (43.8%)
Others n (%) [a]	21 (11.9%)	6 (3.6%)
Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
Q1	NE (5.6, NE)	NE (5.8, NE)
Q3	NE (NE, NE)	NE (NE, NE)
Proportion of patients who are event-free		
by 3 Months, % (95% CI)	97.2% (91.5%, 99.1%)	97.8% (91.4%, 99.4%)
by 6 Months, % (95% CI)	83.2% (74.0%, 89.4%)	83.3% (70.3%, 91.0%)
by 12 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 18 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
by 24 Months, % (95% CI)	NE (NE, NE)	NE (NE, NE)
Nominal p-value for stratified log-rank test [c]	0.672	
HR (95% CI) [d]	1.28 (0.60, 2.75)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[d] HR (95% CI) of SG vs. TPC was estimated using a Cox proportional hazards regression model adjusted for the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 7.1.1.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	28 (50.9%)	23 (46.9%)
	The number (%) of patients censored [a]	27 (49.1%)	26 (53.1%)
	Median time to event (95% CI) [b]	5.7 (3.3, 15.2)	5.8 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.935	
	HR (95% CI) [d]	1.03 (0.59, 1.80)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	22 (64.7%)	23 (67.6%)
	The number (%) of patients censored [a]	12 (35.3%)	11 (32.4%)
	Median time to event (95% CI) [b]	5.4 (1.0, 7.7)	1.9 (0.9, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.247	
	HR (95% CI) [d]	0.71 (0.39, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	52 (59.1%)	50 (58.1%)
	The number (%) of patients censored [a]	36 (40.9%)	36 (41.9%)
	Median time to event (95% CI) [b]	2.2 (1.4, 3.6)	4.1 (2.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.700	
	HR (95% CI) [d]	1.08 (0.73, 1.60)	
	P-value of subgroup*treatment interaction [e]	0.391	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	27 (49.1%)	26 (53.1%)
	The number (%) of patients censored [a]	28 (50.9%)	23 (46.9%)
	Median time to event (95% CI) [b]	5.6 (2.1, 20.1)	2.8 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.408	
	HR (95% CI) [d]	0.79 (0.46, 1.37)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	21 (61.8%)	18 (52.9%)
	The number (%) of patients censored [a]	13 (38.2%)	16 (47.1%)
	Median time to event (95% CI) [b]	3.9 (1.4, 21.5)	5.1 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.881	
	HR (95% CI) [d]	0.95 (0.51, 1.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	41 (46.6%)	48 (55.8%)
	The number (%) of patients censored [a]	47 (53.4%)	38 (44.2%)
	Median time to event (95% CI) [b]	7.2 (2.2, 8.8)	4.9 (3.5, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.972	
	HR (95% CI) [d]	1.01 (0.67, 1.54)	
	P-value of subgroup*treatment interaction [e]	0.766	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	25 (45.5%)	32 (65.3%)
	The number (%) of patients censored [a]	30 (54.5%)	17 (34.7%)
	Median time to event (95% CI) [b]	5.6 (1.5, NE)	2.8 (1.2, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.069	
	HR (95% CI) [d]	0.61 (0.36, 1.05)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	25 (73.5%)	22 (64.7%)
	The number (%) of patients censored [a]	9 (26.5%)	12 (35.3%)
	Median time to event (95% CI) [b]	1.3 (0.8, 3.1)	1.7 (0.9, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.655	
	HR (95% CI) [d]	1.14 (0.64, 2.03)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	53 (60.2%)	61 (70.9%)
	The number (%) of patients censored [a]	35 (39.8%)	25 (29.1%)
	Median time to event (95% CI) [b]	1.5 (1.0, 2.4)	2.8 (1.9, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.554	
	HR (95% CI) [d]	1.12 (0.78, 1.63)	
	P-value of subgroup*treatment interaction [e]	0.163	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	20 (36.4%)	16 (32.7%)
	The number (%) of patients censored [a]	35 (63.6%)	33 (67.3%)
	Median time to event (95% CI) [b]	10.4 (5.0, NE)	10.0 (5.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.618	
	HR (95% CI) [d]	0.84 (0.43, 1.66)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	21 (61.8%)	14 (41.2%)
	The number (%) of patients censored [a]	13 (38.2%)	20 (58.8%)
	Median time to event (95% CI) [b]	4.1 (3.0, 12.2)	6.9 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.582	
	HR (95% CI) [d]	1.21 (0.61, 2.39)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	41 (46.6%)	38 (44.2%)
	The number (%) of patients censored [a]	47 (53.4%)	48 (55.8%)
	Median time to event (95% CI) [b]	6.0 (4.2, 11.4)	10.2 (4.9, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.649	
	HR (95% CI) [d]	1.11 (0.71, 1.73)	
	P-value of subgroup*treatment interaction [e]	0.647	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	31 (56.4%)	33 (67.3%)
	The number (%) of patients censored [a]	24 (43.6%)	16 (32.7%)
	Median time to event (95% CI) [b]	3.5 (1.6, 7.6)	3.1 (1.7, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.207	
	HR (95% CI) [d]	0.72 (0.43, 1.20)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	23 (67.6%)	17 (50.0%)
	The number (%) of patients censored [a]	11 (32.4%)	17 (50.0%)
	Median time to event (95% CI) [b]	3.6 (2.6, 6.4)	7.0 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.595	
	HR (95% CI) [d]	1.19 (0.63, 2.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	43 (48.9%)	54 (62.8%)
	The number (%) of patients censored [a]	45 (51.1%)	32 (37.2%)
	Median time to event (95% CI) [b]	4.6 (2.8, 12.6)	3.3 (1.9, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.123	
	HR (95% CI) [d]	0.73 (0.49, 1.09)	
	P-value of subgroup*treatment interaction [e]	0.362	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	29 (52.7%)	31 (63.3%)
	The number (%) of patients censored [a]	26 (47.3%)	18 (36.7%)
	Median time to event (95% CI) [b]	2.8 (1.5, 18.2)	2.8 (1.4, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.535	
	HR (95% CI) [d]	0.85 (0.51, 1.43)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	21 (61.8%)	23 (67.6%)
	The number (%) of patients censored [a]	13 (38.2%)	11 (32.4%)
	Median time to event (95% CI) [b]	3.2 (1.0, 12.2)	1.4 (0.9, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.126	
	HR (95% CI) [d]	0.62 (0.34, 1.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	52 (59.1%)	46 (53.5%)
	The number (%) of patients censored [a]	36 (40.9%)	40 (46.5%)
	Median time to event (95% CI) [b]	2.2 (1.4, 3.6)	4.1 (2.9, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.244	
	HR (95% CI) [d]	1.26 (0.85, 1.88)	
	P-value of subgroup*treatment interaction [e]	0.128	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	33 (60.0%)	34 (69.4%)
	The number (%) of patients censored [a]	22 (40.0%)	15 (30.6%)
	Median time to event (95% CI) [b]	1.7 (1.0, 4.5)	1.4 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.173	
	HR (95% CI) [d]	0.72 (0.44, 1.17)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	24 (70.6%)	26 (76.5%)
	The number (%) of patients censored [a]	10 (29.4%)	8 (23.5%)
	Median time to event (95% CI) [b]	1.3 (0.8, 1.8)	1.2 (0.9, 3.2)
	Nominal p-value for unstratified log-rank test [c]	0.674	
	HR (95% CI) [d]	0.88 (0.50, 1.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	62 (70.5%)	64 (74.4%)
	The number (%) of patients censored [a]	26 (29.5%)	22 (25.6%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	1.5 (1.0, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.402	
	HR (95% CI) [d]	1.18 (0.83, 1.67)	
	P-value of subgroup*treatment interaction [e]	0.293	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	33 (60.0%)	23 (46.9%)
	The number (%) of patients censored [a]	22 (40.0%)	26 (53.1%)
	Median time to event (95% CI) [b]	2.9 (1.5, 4.2)	2.8 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.478	
	HR (95% CI) [d]	1.21 (0.71, 2.08)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	26 (76.5%)	19 (55.9%)
	The number (%) of patients censored [a]	8 (23.5%)	15 (44.1%)
	Median time to event (95% CI) [b]	1.4 (0.9, 2.6)	1.9 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.285	
	HR (95% CI) [d]	1.38 (0.76, 2.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	50 (56.8%)	51 (59.3%)
	The number (%) of patients censored [a]	38 (43.2%)	35 (40.7%)
	Median time to event (95% CI) [b]	1.9 (1.4, 3.2)	3.8 (1.5, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.316	
	HR (95% CI) [d]	1.23 (0.83, 1.83)	
	P-value of subgroup*treatment interaction [e]	0.871	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	21 (38.2%)	23 (46.9%)
	The number (%) of patients censored [a]	34 (61.8%)	26 (53.1%)
	Median time to event (95% CI) [b]	10.0 (5.6, NE)	3.6 (2.5, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.054	
	HR (95% CI) [d]	0.55 (0.29, 1.02)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	18 (52.9%)	21 (61.8%)
	The number (%) of patients censored [a]	16 (47.1%)	13 (38.2%)
	Median time to event (95% CI) [b]	4.3 (1.4, 7.7)	1.6 (0.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.352	
	HR (95% CI) [d]	0.74 (0.40, 1.40)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	49 (55.7%)	56 (65.1%)
	The number (%) of patients censored [a]	39 (44.3%)	30 (34.9%)
	Median time to event (95% CI) [b]	2.2 (1.4, 6.5)	2.8 (2.2, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.756	
	HR (95% CI) [d]	1.07 (0.73, 1.57)	
	P-value of subgroup*treatment interaction [e]	0.194	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	21 (38.2%)	27 (55.1%)
	The number (%) of patients censored [a]	34 (61.8%)	22 (44.9%)
	Median time to event (95% CI) [b]	10.1 (4.3, NE)	2.8 (1.4, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.52 (0.29, 0.94)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	14 (41.2%)	19 (55.9%)
	The number (%) of patients censored [a]	20 (58.8%)	15 (44.1%)
	Median time to event (95% CI) [b]	12.2 (3.5, NE)	4.9 (2.1, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.46 (0.23, 0.94)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	30 (34.1%)	43 (50.0%)
	The number (%) of patients censored [a]	58 (65.9%)	43 (50.0%)
	Median time to event (95% CI) [b]	NE (7.2, NE)	5.0 (3.4, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.060	
	HR (95% CI) [d]	0.64 (0.40, 1.03)	
	P-value of subgroup*treatment interaction [e]	0.758	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	23 (41.8%)	23 (46.9%)
	The number (%) of patients censored [a]	32 (58.2%)	26 (53.1%)
	Median time to event (95% CI) [b]	9.1 (2.8, 18.0)	4.1 (2.8, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.284	
	HR (95% CI) [d]	0.72 (0.40, 1.31)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	17 (50.0%)	21 (61.8%)
	The number (%) of patients censored [a]	17 (50.0%)	13 (38.2%)
	Median time to event (95% CI) [b]	4.2 (1.5, NE)	1.2 (0.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.107	
	HR (95% CI) [d]	0.58 (0.31, 1.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	40 (45.5%)	43 (50.0%)
	The number (%) of patients censored [a]	48 (54.5%)	43 (50.0%)
	Median time to event (95% CI) [b]	5.1 (2.6, 14.4)	4.6 (3.3, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.885	
	HR (95% CI) [d]	0.97 (0.63, 1.50)	
	P-value of subgroup*treatment interaction [e]	0.456	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	25 (45.5%)	23 (46.9%)
	The number (%) of patients censored [a]	30 (54.5%)	26 (53.1%)
	Median time to event (95% CI) [b]	4.2 (1.5, NE)	3.5 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	0.94 (0.53, 1.65)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	20 (58.8%)	14 (41.2%)
	The number (%) of patients censored [a]	14 (41.2%)	20 (58.8%)
	Median time to event (95% CI) [b]	3.8 (1.0, NE)	NE (1.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.404	
	HR (95% CI) [d]	1.34 (0.68, 2.65)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	42 (47.7%)	47 (54.7%)
	The number (%) of patients censored [a]	46 (52.3%)	39 (45.3%)
	Median time to event (95% CI) [b]	3.6 (1.7, NE)	4.9 (1.8, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.694	
	HR (95% CI) [d]	0.93 (0.61, 1.40)	
	P-value of subgroup*treatment interaction [e]	0.707	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	28 (50.9%)	22 (44.9%)
	The number (%) of patients censored [a]	27 (49.1%)	27 (55.1%)
	Median time to event (95% CI) [b]	3.5 (1.7, 15.9)	6.2 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.974	
	HR (95% CI) [d]	1.01 (0.57, 1.78)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	23 (67.6%)	16 (47.1%)
	The number (%) of patients censored [a]	11 (32.4%)	18 (52.9%)
	Median time to event (95% CI) [b]	2.2 (1.3, 3.7)	2.2 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.536	
	HR (95% CI) [d]	1.22 (0.64, 2.32)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	46 (52.3%)	51 (59.3%)
	The number (%) of patients censored [a]	42 (47.7%)	35 (40.7%)
	Median time to event (95% CI) [b]	2.3 (1.5, 11.4)	2.8 (1.5, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.657	
	HR (95% CI) [d]	0.91 (0.61, 1.36)	
	P-value of subgroup*treatment interaction [e]	0.778	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	30 (54.5%)	28 (57.1%)
	The number (%) of patients censored [a]	25 (45.5%)	21 (42.9%)
	Median time to event (95% CI) [b]	1.7 (1.1, 17.3)	3.3 (1.9, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.573	
	HR (95% CI) [d]	1.16 (0.69, 1.96)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	25 (73.5%)	12 (35.3%)
	The number (%) of patients censored [a]	9 (26.5%)	22 (64.7%)
	Median time to event (95% CI) [b]	2.1 (1.0, 4.1)	6.9 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.019	
	HR (95% CI) [d]	2.24 (1.12, 4.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	63 (71.6%)	31 (36.0%)
	The number (%) of patients censored [a]	25 (28.4%)	55 (64.0%)
	Median time to event (95% CI) [b]	1.2 (0.8, 2.2)	NE (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.61 (2.34, 5.57)	
	P-value of subgroup*treatment interaction [e]	0.004	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	18 (32.7%)	19 (38.8%)
	The number (%) of patients censored [a]	37 (67.3%)	30 (61.2%)
	Median time to event (95% CI) [b]	19.0 (7.4, NE)	5.2 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.064	
	HR (95% CI) [d]	0.54 (0.28, 1.05)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	14 (41.2%)	14 (41.2%)
	The number (%) of patients censored [a]	20 (58.8%)	20 (58.8%)
	Median time to event (95% CI) [b]	21.5 (3.6, NE)	3.1 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.201	
	HR (95% CI) [d]	0.61 (0.29, 1.31)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	33 (37.5%)	30 (34.9%)
	The number (%) of patients censored [a]	55 (62.5%)	56 (65.1%)
	Median time to event (95% CI) [b]	9.8 (5.1, NE)	19.4 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.623	
	HR (95% CI) [d]	1.13 (0.69, 1.87)	
	P-value of subgroup*treatment interaction [e]	0.134	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	30 (54.5%)	22 (44.9%)
	The number (%) of patients censored [a]	25 (45.5%)	27 (55.1%)
	Median time to event (95% CI) [b]	2.1 (1.5, 5.0)	5.1 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.277	
	HR (95% CI) [d]	1.36 (0.78, 2.36)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	19 (55.9%)	14 (41.2%)
	The number (%) of patients censored [a]	15 (44.1%)	20 (58.8%)
	Median time to event (95% CI) [b]	5.0 (1.6, 13.2)	7.0 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.752	
	HR (95% CI) [d]	0.89 (0.44, 1.81)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	52 (59.1%)	46 (53.5%)
	The number (%) of patients censored [a]	36 (40.9%)	40 (46.5%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	4.9 (2.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.023	
	HR (95% CI) [d]	1.59 (1.06, 2.37)	
	P-value of subgroup*treatment interaction [e]	0.423	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	16 (29.1%)	16 (32.7%)
	The number (%) of patients censored [a]	39 (70.9%)	33 (67.3%)
	Median time to event (95% CI) [b]	NE (6.9, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.413	
	HR (95% CI) [d]	0.75 (0.37, 1.50)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	15 (44.1%)	7 (20.6%)
	The number (%) of patients censored [a]	19 (55.9%)	27 (79.4%)
	Median time to event (95% CI) [b]	18.5 (3.6, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.225	
	HR (95% CI) [d]	1.75 (0.71, 4.33)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	15 (17.0%)	26 (30.2%)
	The number (%) of patients censored [a]	73 (83.0%)	60 (69.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.052	
	HR (95% CI) [d]	0.54 (0.28, 1.02)	
	P-value of subgroup*treatment interaction [e]	0.097	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	2 (3.6%)	1 (2.0%)
	The number (%) of patients censored [a]	53 (96.4%)	48 (98.0%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.812	
	HR (95% CI) [d]	1.34 (0.12, 14.74)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	0 (0.0%)	1 (2.9%)
	The number (%) of patients censored [a]	34 (100.0%)	33 (97.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.456	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	5 (5.7%)	7 (8.1%)
	The number (%) of patients censored [a]	83 (94.3%)	79 (91.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.846	
	HR (95% CI) [d]	1.13 (0.36, 3.56)	
	P-value of subgroup*treatment interaction [e]	0.982	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.4

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	20 (36.4%)	18 (36.7%)
	The number (%) of patients censored [a]	35 (63.6%)	31 (63.3%)
	Median time to event (95% CI) [b]	7.0 (2.4, NE)	8.4 (1.9, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.704	
	HR (95% CI) [d]	0.88 (0.46, 1.68)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	16 (47.1%)	15 (44.1%)
	The number (%) of patients censored [a]	18 (52.9%)	19 (55.9%)
	Median time to event (95% CI) [b]	8.4 (1.4, 18.5)	3.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.246	
	HR (95% CI) [d]	0.64 (0.30, 1.37)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	33 (37.5%)	32 (37.2%)
	The number (%) of patients censored [a]	55 (62.5%)	54 (62.8%)
	Median time to event (95% CI) [b]	4.2 (2.1, 9.8)	6.3 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.559	
	HR (95% CI) [d]	1.16 (0.71, 1.89)	
	P-value of subgroup*treatment interaction [e]	0.607	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	41 (74.5%)	36 (73.5%)
	The number (%) of patients censored [a]	14 (25.5%)	13 (26.5%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.6)	1.4 (1.0, 2.3)
	Nominal p-value for unstratified log-rank test [c]	0.311	
	HR (95% CI) [d]	1.26 (0.81, 1.98)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	27 (79.4%)	20 (58.8%)
	The number (%) of patients censored [a]	7 (20.6%)	14 (41.2%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.3)	2.7 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.041	
	HR (95% CI) [d]	1.82 (1.02, 3.26)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	63 (71.6%)	51 (59.3%)
	The number (%) of patients censored [a]	25 (28.4%)	35 (40.7%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.2)	3.5 (1.5, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.10 (1.44, 3.05)	
	P-value of subgroup*treatment interaction [e]	0.194	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	11 (20.0%)	12 (24.5%)
	The number (%) of patients censored [a]	44 (80.0%)	37 (75.5%)
	Median time to event (95% CI) [b]	NE (10.1, NE)	NE (6.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.413	
	HR (95% CI) [d]	0.71 (0.31, 1.63)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	14 (41.2%)	11 (32.4%)
	The number (%) of patients censored [a]	20 (58.8%)	23 (67.6%)
	Median time to event (95% CI) [b]	17.5 (3.9, NE)	12.7 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.608	
	HR (95% CI) [d]	0.81 (0.36, 1.82)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	28 (31.8%)	19 (22.1%)
	The number (%) of patients censored [a]	60 (68.2%)	67 (77.9%)
	Median time to event (95% CI) [b]	17.1 (5.6, NE)	NE (9.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.162	
	HR (95% CI) [d]	1.51 (0.84, 2.71)	
	P-value of subgroup*treatment interaction [e]	0.264	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.1.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	28 (50.9%)	25 (51.0%)
	The number (%) of patients censored [a]	27 (49.1%)	24 (49.0%)
	Median time to event (95% CI) [b]	4.5 (2.9, 15.9)	3.6 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.289	
	HR (95% CI) [d]	0.74 (0.43, 1.29)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	25 (73.5%)	17 (50.0%)
	The number (%) of patients censored [a]	9 (26.5%)	17 (50.0%)
	Median time to event (95% CI) [b]	3.0 (1.5, 5.0)	5.1 (2.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.272	
	HR (95% CI) [d]	1.41 (0.76, 2.63)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	36 (40.9%)	47 (54.7%)
	The number (%) of patients censored [a]	52 (59.1%)	39 (45.3%)
	Median time to event (95% CI) [b]	9.6 (5.6, 15.0)	3.9 (2.8, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.043	
	HR (95% CI) [d]	0.64 (0.41, 0.99)	
	P-value of subgroup*treatment interaction [e]	0.098	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	5 (9.1%)	5 (10.2%)
	The number (%) of patients censored [a]	50 (90.9%)	44 (89.8%)
	Median time to event (95% CI) [b]	7.2 (0.8, NE)	4.6 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.567	
	HR (95% CI) [d]	0.68 (0.19, 2.43)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	3 (8.8%)	4 (11.8%)
	The number (%) of patients censored [a]	31 (91.2%)	30 (88.2%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	1.4 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.647	
	HR (95% CI) [d]	0.71 (0.16, 3.19)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	9 (10.2%)	10 (11.6%)
	The number (%) of patients censored [a]	79 (89.8%)	76 (88.4%)
	Median time to event (95% CI) [b]	1.0 (0.7, NE)	0.9 (0.8, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.806	
	HR (95% CI) [d]	0.87 (0.35, 2.16)	
	P-value of subgroup*treatment interaction [e]	0.785	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	20 (36.4%)	17 (34.7%)
	The number (%) of patients censored [a]	35 (63.6%)	32 (65.3%)
	Median time to event (95% CI) [b]	12.0 (6.3, NE)	10.5 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.747	
	HR (95% CI) [d]	0.90 (0.46, 1.74)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	16 (47.1%)	13 (38.2%)
	The number (%) of patients censored [a]	18 (52.9%)	21 (61.8%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.711	
	HR (95% CI) [d]	1.15 (0.55, 2.40)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.1.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	34 (38.6%)	26 (30.2%)
	The number (%) of patients censored [a]	54 (61.4%)	60 (69.8%)
	Median time to event (95% CI) [b]	9.1 (6.2, 15.5)	13.0 (11.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.211	
	HR (95% CI) [d]	1.38 (0.83, 2.31)	
	P-value of subgroup*treatment interaction [e]	0.548	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.1.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	21 (38.2%)	22 (44.9%)
	The number (%) of patients censored [a]	34 (61.8%)	27 (55.1%)
	Median time to event (95% CI) [b]	18.6 (2.8, NE)	5.6 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.304	
	HR (95% CI) [d]	0.73 (0.40, 1.33)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	14 (41.2%)	13 (38.2%)
	The number (%) of patients censored [a]	20 (58.8%)	21 (61.8%)
	Median time to event (95% CI) [b]	7.0 (3.5, NE)	NE (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.859	
	HR (95% CI) [d]	0.93 (0.44, 1.99)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	40 (45.5%)	28 (32.6%)
	The number (%) of patients censored [a]	48 (54.5%)	58 (67.4%)
	Median time to event (95% CI) [b]	9.1 (2.8, 13.6)	19.4 (9.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.032	
	HR (95% CI) [d]	1.69 (1.04, 2.74)	
	P-value of subgroup*treatment interaction [e]	0.083	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	9 (16.4%)	14 (28.6%)
	The number (%) of patients censored [a]	46 (83.6%)	35 (71.4%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.073	
	HR (95% CI) [d]	0.47 (0.20, 1.09)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	8 (23.5%)	7 (20.6%)
	The number (%) of patients censored [a]	26 (76.5%)	27 (79.4%)
	Median time to event (95% CI) [b]	NE (5.8, NE)	6.5 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.687	
	HR (95% CI) [d]	1.25 (0.43, 3.60)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	23 (26.1%)	21 (24.4%)
	The number (%) of patients censored [a]	65 (73.9%)	65 (75.6%)
	Median time to event (95% CI) [b]	6.4 (5.6, NE)	6.4 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.773	
	HR (95% CI) [d]	1.09 (0.60, 1.97)	
	P-value of subgroup*treatment interaction [e]	0.237	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
De novo	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	55	49
	The number (%) of patients with an event [a]	4 (7.3%)	2 (4.1%)
	The number (%) of patients censored [a]	51 (92.7%)	47 (95.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.701	
	HR (95% CI) [d]	1.39 (0.25, 7.63)	
Recurrent Disease within 6 to 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	34	34
	The number (%) of patients with an event [a]	2 (5.9%)	4 (11.8%)
	The number (%) of patients censored [a]	32 (94.1%)	30 (88.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	0.41 (0.08, 2.26)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.1.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Disease-free Interval
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Recurrent Disease Occurring > 12 Months	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	88	86
	The number (%) of patients with an event [a]	11 (12.5%)	5 (5.8%)
	The number (%) of patients censored [a]	77 (87.5%)	81 (94.2%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.190	
	HR (95% CI) [d]	2.01 (0.69, 5.80)	
	P-value of subgroup*treatment interaction [e]	0.331	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	30 (53.6%)	32 (61.5%)
	The number (%) of patients censored [a]	26 (46.4%)	20 (38.5%)
	Median time to event (95% CI) [b]	3.6 (1.6, 7.6)	3.1 (1.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.108	
	HR (95% CI) [d]	0.66 (0.40, 1.11)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	72 (59.5%)	64 (54.7%)
	The number (%) of patients censored [a]	49 (40.5%)	53 (45.3%)
	Median time to event (95% CI) [b]	3.7 (1.8, 6.3)	4.2 (2.7, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.605	
	HR (95% CI) [d]	1.10 (0.78, 1.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.192	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	28 (50.0%)	30 (57.7%)
	The number (%) of patients censored [a]	28 (50.0%)	22 (42.3%)
	Median time to event (95% CI) [b]	3.9 (1.7, 7.4)	3.3 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.618	
	HR (95% CI) [d]	0.88 (0.52, 1.47)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	61 (50.4%)	62 (53.0%)
	The number (%) of patients censored [a]	60 (49.6%)	55 (47.0%)
	Median time to event (95% CI) [b]	7.2 (3.3, 11.6)	5.4 (3.1, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.690	
	HR (95% CI) [d]	0.93 (0.65, 1.33)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.782	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	31 (55.4%)	39 (75.0%)
	The number (%) of patients censored [a]	25 (44.6%)	13 (25.0%)
	Median time to event (95% CI) [b]	1.4 (0.9, 1.7)	1.9 (1.2, 3.9)
	Nominal p-value for unstratified log-rank test [c]	0.428	
	HR (95% CI) [d]	0.83 (0.51, 1.34)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	72 (59.5%)	76 (65.0%)
	The number (%) of patients censored [a]	49 (40.5%)	41 (35.0%)
	Median time to event (95% CI) [b]	1.9 (1.4, 3.1)	2.8 (1.9, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.988	
	HR (95% CI) [d]	1.01 (0.73, 1.39)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.573	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	24 (42.9%)	18 (34.6%)
	The number (%) of patients censored [a]	32 (57.1%)	34 (65.4%)
	Median time to event (95% CI) [b]	5.5 (3.8, 10.4)	7.6 (5.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.430	
	HR (95% CI) [d]	1.28 (0.69, 2.36)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	58 (47.9%)	50 (42.7%)
	The number (%) of patients censored [a]	63 (52.1%)	67 (57.3%)
	Median time to event (95% CI) [b]	8.8 (4.6, 12.5)	10.0 (5.6, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.771	
	HR (95% CI) [d]	0.95 (0.64, 1.39)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.394	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	29 (51.8%)	32 (61.5%)
	The number (%) of patients censored [a]	27 (48.2%)	20 (38.5%)
	Median time to event (95% CI) [b]	4.3 (2.1, 7.6)	2.7 (1.6, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.253	
	HR (95% CI) [d]	0.75 (0.45, 1.24)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	68 (56.2%)	72 (61.5%)
	The number (%) of patients censored [a]	53 (43.8%)	45 (38.5%)
	Median time to event (95% CI) [b]	4.2 (2.8, 6.0)	3.7 (2.6, 4.7)
	Nominal p-value for unstratified log-rank test [c]	0.370	
	HR (95% CI) [d]	0.86 (0.62, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.635	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	26 (46.4%)	28 (53.8%)
	The number (%) of patients censored [a]	30 (53.6%)	24 (46.2%)
	Median time to event (95% CI) [b]	3.1 (1.4, NE)	3.6 (1.4, 5.3)
	Nominal p-value for unstratified log-rank test [c]	0.914	
	HR (95% CI) [d]	0.97 (0.57, 1.66)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	76 (62.8%)	72 (61.5%)
	The number (%) of patients censored [a]	45 (37.2%)	45 (38.5%)
	Median time to event (95% CI) [b]	2.2 (1.5, 4.2)	3.1 (1.9, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.967	
	HR (95% CI) [d]	0.99 (0.72, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.809	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	35 (62.5%)	40 (76.9%)
	The number (%) of patients censored [a]	21 (37.5%)	12 (23.1%)
	Median time to event (95% CI) [b]	1.3 (0.8, 1.7)	1.4 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.590	
	HR (95% CI) [d]	0.89 (0.56, 1.42)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	84 (69.4%)	84 (71.8%)
	The number (%) of patients censored [a]	37 (30.6%)	33 (28.2%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.8)	1.6 (1.1, 2.3)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	0.99 (0.73, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.780	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	29 (51.8%)	26 (50.0%)
	The number (%) of patients censored [a]	27 (48.2%)	26 (50.0%)
	Median time to event (95% CI) [b]	2.8 (1.5, 6.9)	2.5 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.842	
	HR (95% CI) [d]	1.06 (0.62, 1.81)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	80 (66.1%)	67 (57.3%)
	The number (%) of patients censored [a]	41 (33.9%)	50 (42.7%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.2)	2.6 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.093	
	HR (95% CI) [d]	1.32 (0.95, 1.83)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.484	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	24 (42.9%)	31 (59.6%)
	The number (%) of patients censored [a]	32 (57.1%)	21 (40.4%)
	Median time to event (95% CI) [b]	5.0 (1.7, 16.0)	2.8 (1.5, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.252	
	HR (95% CI) [d]	0.73 (0.42, 1.26)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	64 (52.9%)	69 (59.0%)
	The number (%) of patients censored [a]	57 (47.1%)	48 (41.0%)
	Median time to event (95% CI) [b]	5.6 (2.2, 8.8)	3.4 (2.3, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.342	
	HR (95% CI) [d]	0.85 (0.60, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.674	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	24 (42.9%)	31 (59.6%)
	The number (%) of patients censored [a]	32 (57.1%)	21 (40.4%)
	Median time to event (95% CI) [b]	6.3 (1.6, NE)	3.1 (1.4, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.065	
	HR (95% CI) [d]	0.60 (0.35, 1.04)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	41 (33.9%)	58 (49.6%)
	The number (%) of patients censored [a]	80 (66.1%)	59 (50.4%)
	Median time to event (95% CI) [b]	NE (9.6, NE)	5.0 (3.3, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	0.54 (0.36, 0.81)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.663	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	26 (46.4%)	21 (40.4%)
	The number (%) of patients censored [a]	30 (53.6%)	31 (59.6%)
	Median time to event (95% CI) [b]	5.1 (2.5, 9.1)	6.0 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.331	
	HR (95% CI) [d]	1.33 (0.75, 2.36)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	54 (44.6%)	66 (56.4%)
	The number (%) of patients censored [a]	67 (55.4%)	51 (43.6%)
	Median time to event (95% CI) [b]	8.4 (3.6, 16.8)	3.8 (2.1, 5.2)
	Nominal p-value for unstratified log-rank test [c]	0.031	
	HR (95% CI) [d]	0.67 (0.47, 0.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.051	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	20 (35.7%)	24 (46.2%)
	The number (%) of patients censored [a]	36 (64.3%)	28 (53.8%)
	Median time to event (95% CI) [b]	NE (2.1, NE)	5.2 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.466	
	HR (95% CI) [d]	0.80 (0.44, 1.46)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	67 (55.4%)	60 (51.3%)
	The number (%) of patients censored [a]	54 (44.6%)	57 (48.7%)
	Median time to event (95% CI) [b]	2.8 (1.6, 4.2)	4.9 (1.8, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.774	
	HR (95% CI) [d]	1.06 (0.74, 1.50)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.408	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	29 (51.8%)	27 (51.9%)
	The number (%) of patients censored [a]	27 (48.2%)	25 (48.1%)
	Median time to event (95% CI) [b]	2.8 (1.5, 3.7)	2.7 (1.5, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.725	
	HR (95% CI) [d]	1.10 (0.65, 1.86)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	68 (56.2%)	62 (53.0%)
	The number (%) of patients censored [a]	53 (43.8%)	55 (47.0%)
	Median time to event (95% CI) [b]	2.3 (1.7, 6.9)	3.5 (1.7, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.891	
	HR (95% CI) [d]	0.97 (0.69, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.760	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	40 (71.4%)	19 (36.5%)
	The number (%) of patients censored [a]	16 (28.6%)	33 (63.5%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.4)	10.1 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.07 (1.77, 5.35)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	78 (64.5%)	52 (44.4%)
	The number (%) of patients censored [a]	43 (35.5%)	65 (55.6%)
	Median time to event (95% CI) [b]	1.7 (1.1, 2.8)	6.2 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.03 (1.42, 2.88)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.184	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	20 (35.7%)	18 (34.6%)
	The number (%) of patients censored [a]	36 (64.3%)	34 (65.4%)
	Median time to event (95% CI) [b]	8.3 (3.8, NE)	NE (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.759	
	HR (95% CI) [d]	0.90 (0.47, 1.72)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	45 (37.2%)	45 (38.5%)
	The number (%) of patients censored [a]	76 (62.8%)	72 (61.5%)
	Median time to event (95% CI) [b]	16.1 (7.9, 27.9)	8.7 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.262	
	HR (95% CI) [d]	0.79 (0.52, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.755	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	29 (51.8%)	25 (48.1%)
	The number (%) of patients censored [a]	27 (48.2%)	27 (51.9%)
	Median time to event (95% CI) [b]	1.7 (1.2, 3.5)	2.4 (1.5, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.301	
	HR (95% CI) [d]	1.32 (0.77, 2.26)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	72 (59.5%)	57 (48.7%)
	The number (%) of patients censored [a]	49 (40.5%)	60 (51.3%)
	Median time to event (95% CI) [b]	3.5 (1.9, 5.0)	5.4 (3.3, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.096	
	HR (95% CI) [d]	1.35 (0.95, 1.91)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

Table 7.1.2.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.846	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	12 (21.4%)	19 (36.5%)
	The number (%) of patients censored [a]	44 (78.6%)	33 (63.5%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	4.8 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.027	
	HR (95% CI) [d]	0.45 (0.22, 0.93)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	34 (28.1%)	30 (25.6%)
	The number (%) of patients censored [a]	87 (71.9%)	87 (74.4%)
	Median time to event (95% CI) [b]	NE (18.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.927	
	HR (95% CI) [d]	1.02 (0.62, 1.67)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.069	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	1 (1.8%)	5 (9.6%)
	The number (%) of patients censored [a]	55 (98.2%)	47 (90.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.437	
	HR (95% CI) [d]	0.44 (0.05, 3.77)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	6 (5.0%)	4 (3.4%)
	The number (%) of patients censored [a]	115 (95.0%)	113 (96.6%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.420	
	HR (95% CI) [d]	1.67 (0.47, 5.94)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.271	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	20 (35.7%)	14 (26.9%)
	The number (%) of patients censored [a]	36 (64.3%)	38 (73.1%)
	Median time to event (95% CI) [b]	4.5 (1.5, 8.3)	13.8 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.194	
	HR (95% CI) [d]	1.57 (0.79, 3.12)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	49 (40.5%)	51 (43.6%)
	The number (%) of patients censored [a]	72 (59.5%)	66 (56.4%)
	Median time to event (95% CI) [b]	7.8 (3.8, 12.6)	5.4 (2.8, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.298	
	HR (95% CI) [d]	0.81 (0.54, 1.21)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.119	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	42 (75.0%)	32 (61.5%)
	The number (%) of patients censored [a]	14 (25.0%)	20 (38.5%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.2)	1.7 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.004	
	HR (95% CI) [d]	1.96 (1.23, 3.11)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	89 (73.6%)	75 (64.1%)
	The number (%) of patients censored [a]	32 (26.4%)	42 (35.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.3)	2.7 (1.4, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.66 (1.22, 2.26)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.643	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	14 (25.0%)	13 (25.0%)
	The number (%) of patients censored [a]	42 (75.0%)	39 (75.0%)
	Median time to event (95% CI) [b]	NE (7.2, NE)	9.8 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.374	
	HR (95% CI) [d]	0.71 (0.33, 1.53)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	39 (32.2%)	29 (24.8%)
	The number (%) of patients censored [a]	82 (67.8%)	88 (75.2%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (12.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.350	
	HR (95% CI) [d]	1.26 (0.78, 2.04)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.258	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	27 (48.2%)	24 (46.2%)
	The number (%) of patients censored [a]	29 (51.8%)	28 (53.8%)
	Median time to event (95% CI) [b]	5.0 (2.9, 12.7)	4.2 (2.8, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.568	
	HR (95% CI) [d]	0.85 (0.49, 1.48)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	62 (51.2%)	65 (55.6%)
	The number (%) of patients censored [a]	59 (48.8%)	52 (44.4%)
	Median time to event (95% CI) [b]	6.8 (3.5, 13.3)	3.5 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.138	
	HR (95% CI) [d]	0.77 (0.54, 1.09)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.695	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	5 (8.9%)	2 (3.8%)
	The number (%) of patients censored [a]	51 (91.1%)	50 (96.2%)
	Median time to event (95% CI) [b]	0.9 (0.7, NE)	1.4 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.154	
	HR (95% CI) [d]	3.23 (0.60, 17.45)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	12 (9.9%)	17 (14.5%)
	The number (%) of patients censored [a]	109 (90.1%)	100 (85.5%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	1.4 (1.0, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.207	
	HR (95% CI) [d]	0.62 (0.29, 1.30)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.108	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	21 (37.5%)	16 (30.8%)
	The number (%) of patients censored [a]	35 (62.5%)	36 (69.2%)
	Median time to event (95% CI) [b]	10.2 (3.9, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.930	
	HR (95% CI) [d]	1.04 (0.53, 2.02)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	49 (40.5%)	40 (34.2%)
	The number (%) of patients censored [a]	72 (59.5%)	77 (65.8%)
	Median time to event (95% CI) [b]	9.8 (5.8, NE)	13.0 (10.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.423	
	HR (95% CI) [d]	1.19 (0.78, 1.81)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.2.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.803	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.2.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	26 (46.4%)	12 (23.1%)
	The number (%) of patients censored [a]	30 (53.6%)	40 (76.9%)
	Median time to event (95% CI) [b]	3.6 (1.7, 13.2)	15.9 (15.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.007	
	HR (95% CI) [d]	2.48 (1.25, 4.92)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	49 (40.5%)	51 (43.6%)
	The number (%) of patients censored [a]	72 (59.5%)	66 (56.4%)
	Median time to event (95% CI) [b]	11.8 (4.1, NE)	5.8 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.482	
	HR (95% CI) [d]	0.87 (0.58, 1.28)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.007	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	19 (33.9%)	15 (28.8%)
	The number (%) of patients censored [a]	37 (66.1%)	37 (71.2%)
	Median time to event (95% CI) [b]	6.0 (5.0, NE)	6.4 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.688	
	HR (95% CI) [d]	0.87 (0.44, 1.71)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	21 (17.4%)	27 (23.1%)
	The number (%) of patients censored [a]	100 (82.6%)	90 (76.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.351	
	HR (95% CI) [d]	0.76 (0.43, 1.35)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.789	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
US/Canada/Western Europe	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	56	52
	The number (%) of patients with an event [a]	4 (7.1%)	2 (3.8%)
	The number (%) of patients censored [a]	52 (92.9%)	50 (96.2%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.661	
	HR (95% CI) [d]	1.47 (0.26, 8.24)	
Rest of the World	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	121	117
	The number (%) of patients with an event [a]	13 (10.7%)	9 (7.7%)
	The number (%) of patients censored [a]	108 (89.3%)	108 (92.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.731	
	HR (95% CI) [d]	1.16 (0.50, 2.72)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.2.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Region
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.722	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	82 (61.7%)	72 (55.0%)
	The number (%) of patients censored [a]	51 (38.3%)	59 (45.0%)
	Median time to event (95% CI) [b]	4.1 (2.1, 6.3)	4.2 (2.7, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.910	
	HR (95% CI) [d]	0.99 (0.72, 1.36)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	20 (45.5%)	24 (63.2%)
	The number (%) of patients censored [a]	24 (54.5%)	14 (36.8%)
	Median time to event (95% CI) [b]	2.1 (1.0, 5.1)	3.1 (1.2, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.837	
	HR (95% CI) [d]	0.94 (0.52, 1.71)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.874	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	70 (52.6%)	70 (53.4%)
	The number (%) of patients censored [a]	63 (47.4%)	61 (46.6%)
	Median time to event (95% CI) [b]	7.4 (3.6, 11.6)	4.7 (2.9, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.374	
	HR (95% CI) [d]	0.86 (0.62, 1.20)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	19 (43.2%)	22 (57.9%)
	The number (%) of patients censored [a]	25 (56.8%)	16 (42.1%)
	Median time to event (95% CI) [b]	1.6 (0.9, 7.2)	4.0 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.469	
	HR (95% CI) [d]	1.26 (0.68, 2.33)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.352	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	80 (60.2%)	89 (67.9%)
	The number (%) of patients censored [a]	53 (39.8%)	42 (32.1%)
	Median time to event (95% CI) [b]	1.8 (1.4, 5.1)	2.8 (1.9, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.409	
	HR (95% CI) [d]	0.89 (0.65, 1.20)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	23 (52.3%)	26 (68.4%)
	The number (%) of patients censored [a]	21 (47.7%)	12 (31.6%)
	Median time to event (95% CI) [b]	1.4 (0.9, 1.5)	2.6 (1.0, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.275	
	HR (95% CI) [d]	1.37 (0.77, 2.42)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.182	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	72 (54.1%)	51 (38.9%)
	The number (%) of patients censored [a]	61 (45.9%)	80 (61.1%)
	Median time to event (95% CI) [b]	7.3 (4.3, 9.7)	10.2 (6.9, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.407	
	HR (95% CI) [d]	1.17 (0.81, 1.67)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	10 (22.7%)	17 (44.7%)
	The number (%) of patients censored [a]	34 (77.3%)	21 (55.3%)
	Median time to event (95% CI) [b]	NE (4.3, NE)	7.6 (4.4, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.230	
	HR (95% CI) [d]	0.62 (0.28, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.118	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	82 (61.7%)	85 (64.9%)
	The number (%) of patients censored [a]	51 (38.3%)	46 (35.1%)
	Median time to event (95% CI) [b]	4.2 (2.9, 5.7)	3.0 (2.2, 3.7)
	Nominal p-value for unstratified log-rank test [c]	0.153	
	HR (95% CI) [d]	0.80 (0.59, 1.09)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	15 (34.1%)	19 (50.0%)
	The number (%) of patients censored [a]	29 (65.9%)	19 (50.0%)
	Median time to event (95% CI) [b]	4.2 (2.2, NE)	6.5 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.635	
	HR (95% CI) [d]	0.84 (0.42, 1.69)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.776	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	78 (58.6%)	78 (59.5%)
	The number (%) of patients censored [a]	55 (41.4%)	53 (40.5%)
	Median time to event (95% CI) [b]	3.5 (1.7, 7.2)	3.3 (1.9, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.525	
	HR (95% CI) [d]	0.90 (0.66, 1.24)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	24 (54.5%)	22 (57.9%)
	The number (%) of patients censored [a]	20 (45.5%)	16 (42.1%)
	Median time to event (95% CI) [b]	1.4 (1.0, 2.2)	3.6 (1.0, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.414	
	HR (95% CI) [d]	1.27 (0.71, 2.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.266	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	93 (69.9%)	95 (72.5%)
	The number (%) of patients censored [a]	40 (30.1%)	36 (27.5%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.7)	1.4 (1.1, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.764	
	HR (95% CI) [d]	0.97 (0.72, 1.29)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	26 (59.1%)	29 (76.3%)
	The number (%) of patients censored [a]	18 (40.9%)	9 (23.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 2.1)	1.4 (0.9, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.907	
	HR (95% CI) [d]	0.97 (0.57, 1.66)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.981	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	93 (69.9%)	75 (57.3%)
	The number (%) of patients censored [a]	40 (30.1%)	56 (42.7%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.6)	2.1 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.099	
	HR (95% CI) [d]	1.30 (0.95, 1.76)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	16 (36.4%)	18 (47.4%)
	The number (%) of patients censored [a]	28 (63.6%)	20 (52.6%)
	Median time to event (95% CI) [b]	2.8 (1.7, NE)	4.9 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.908	
	HR (95% CI) [d]	1.04 (0.53, 2.04)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.486	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	70 (52.6%)	76 (58.0%)
	The number (%) of patients censored [a]	63 (47.4%)	55 (42.0%)
	Median time to event (95% CI) [b]	6.5 (2.8, 9.1)	3.0 (2.3, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.166	
	HR (95% CI) [d]	0.80 (0.57, 1.11)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	18 (40.9%)	24 (63.2%)
	The number (%) of patients censored [a]	26 (59.1%)	14 (36.8%)
	Median time to event (95% CI) [b]	2.1 (1.0, NE)	2.6 (1.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.797	
	HR (95% CI) [d]	0.92 (0.50, 1.71)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.655	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	53 (39.8%)	69 (52.7%)
	The number (%) of patients censored [a]	80 (60.2%)	62 (47.3%)
	Median time to event (95% CI) [b]	11.4 (7.7, NE)	4.4 (2.8, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.56 (0.39, 0.80)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	12 (27.3%)	20 (52.6%)
	The number (%) of patients censored [a]	32 (72.7%)	18 (47.4%)
	Median time to event (95% CI) [b]	15.5 (3.1, NE)	4.7 (1.8, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.233	
	HR (95% CI) [d]	0.64 (0.30, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.752	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	67 (50.4%)	68 (51.9%)
	The number (%) of patients censored [a]	66 (49.6%)	63 (48.1%)
	Median time to event (95% CI) [b]	5.5 (3.5, 10.8)	4.2 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.316	
	HR (95% CI) [d]	0.84 (0.60, 1.18)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	13 (29.5%)	19 (50.0%)
	The number (%) of patients censored [a]	31 (70.5%)	19 (50.0%)
	Median time to event (95% CI) [b]	5.4 (2.6, NE)	3.3 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.356	
	HR (95% CI) [d]	0.72 (0.36, 1.46)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.640	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	67 (50.4%)	68 (51.9%)
	The number (%) of patients censored [a]	66 (49.6%)	63 (48.1%)
	Median time to event (95% CI) [b]	4.2 (2.1, NE)	3.5 (1.9, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.353	
	HR (95% CI) [d]	0.86 (0.61, 1.20)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	20 (45.5%)	16 (42.1%)
	The number (%) of patients censored [a]	24 (54.5%)	22 (57.9%)
	Median time to event (95% CI) [b]	2.0 (1.4, 4.0)	5.2 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.058	
	HR (95% CI) [d]	1.89 (0.97, 3.69)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.059	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	78 (58.6%)	70 (53.4%)
	The number (%) of patients censored [a]	55 (41.4%)	61 (46.6%)
	Median time to event (95% CI) [b]	2.4 (1.7, 3.6)	2.8 (1.7, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.915	
	HR (95% CI) [d]	0.98 (0.71, 1.35)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	19 (43.2%)	19 (50.0%)
	The number (%) of patients censored [a]	25 (56.8%)	19 (50.0%)
	Median time to event (95% CI) [b]	2.4 (1.0, NE)	3.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.735	
	HR (95% CI) [d]	1.11 (0.59, 2.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.735	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	99 (74.4%)	58 (44.3%)
	The number (%) of patients censored [a]	34 (25.6%)	73 (55.7%)
	Median time to event (95% CI) [b]	1.7 (1.2, 2.1)	6.2 (4.2, 13.2)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.24 (1.62, 3.11)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	19 (43.2%)	13 (34.2%)
	The number (%) of patients censored [a]	25 (56.8%)	25 (65.8%)
	Median time to event (95% CI) [b]	1.9 (0.8, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.018	
	HR (95% CI) [d]	2.31 (1.13, 4.72)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.731	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	55 (41.4%)	49 (37.4%)
	The number (%) of patients censored [a]	78 (58.6%)	82 (62.6%)
	Median time to event (95% CI) [b]	9.8 (7.2, 21.5)	6.5 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.299	
	HR (95% CI) [d]	0.81 (0.55, 1.20)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	10 (22.7%)	14 (36.8%)
	The number (%) of patients censored [a]	34 (77.3%)	24 (63.2%)
	Median time to event (95% CI) [b]	27.9 (2.9, NE)	10.2 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	0.74 (0.32, 1.72)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.942	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	82 (61.7%)	65 (49.6%)
	The number (%) of patients censored [a]	51 (38.3%)	66 (50.4%)
	Median time to event (95% CI) [b]	3.5 (1.8, 4.6)	4.7 (2.4, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.224	
	HR (95% CI) [d]	1.23 (0.88, 1.70)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	19 (43.2%)	17 (44.7%)
	The number (%) of patients censored [a]	25 (56.8%)	21 (55.3%)
	Median time to event (95% CI) [b]	1.5 (0.9, 3.2)	5.0 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.063	
	HR (95% CI) [d]	1.86 (0.96, 3.60)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.224	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	41 (30.8%)	37 (28.2%)
	The number (%) of patients censored [a]	92 (69.2%)	94 (71.8%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.631	
	HR (95% CI) [d]	0.90 (0.57, 1.40)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	5 (11.4%)	12 (31.6%)
	The number (%) of patients censored [a]	39 (88.6%)	26 (68.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.169	
	HR (95% CI) [d]	0.49 (0.17, 1.39)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.212	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	7 (5.3%)	8 (6.1%)
	The number (%) of patients censored [a]	126 (94.7%)	123 (93.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.763	
	HR (95% CI) [d]	1.17 (0.42, 3.23)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	0 (0.0%)	1 (2.6%)
	The number (%) of patients censored [a]	44 (100.0%)	37 (97.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.994	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	57 (42.9%)	51 (38.9%)
	The number (%) of patients censored [a]	76 (57.1%)	80 (61.1%)
	Median time to event (95% CI) [b]	6.3 (3.6, 11.3)	6.0 (3.1, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.743	
	HR (95% CI) [d]	0.94 (0.64, 1.38)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	12 (27.3%)	14 (36.8%)
	The number (%) of patients censored [a]	32 (72.7%)	24 (63.2%)
	Median time to event (95% CI) [b]	3.8 (1.2, NE)	9.3 (1.4, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.970	
	HR (95% CI) [d]	1.01 (0.46, 2.24)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.605	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	107 (80.5%)	87 (66.4%)
	The number (%) of patients censored [a]	26 (19.5%)	44 (33.6%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.1)	1.9 (1.4, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.66 (1.25, 2.20)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	24 (54.5%)	20 (52.6%)
	The number (%) of patients censored [a]	20 (45.5%)	18 (47.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.6)	4.4 (1.0, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.010	
	HR (95% CI) [d]	2.18 (1.19, 4.00)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.530	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	44 (33.1%)	31 (23.7%)
	The number (%) of patients censored [a]	89 (66.9%)	100 (76.3%)
	Median time to event (95% CI) [b]	24.7 (10.1, NE)	NE (9.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.514	
	HR (95% CI) [d]	1.17 (0.73, 1.85)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	9 (20.5%)	11 (28.9%)
	The number (%) of patients censored [a]	35 (79.5%)	27 (71.1%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.757	
	HR (95% CI) [d]	0.87 (0.36, 2.10)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.421	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	72 (54.1%)	70 (53.4%)
	The number (%) of patients censored [a]	61 (45.9%)	61 (46.6%)
	Median time to event (95% CI) [b]	5.6 (3.6, 9.6)	3.8 (2.8, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.215	
	HR (95% CI) [d]	0.81 (0.58, 1.13)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	17 (38.6%)	19 (50.0%)
	The number (%) of patients censored [a]	27 (61.4%)	19 (50.0%)
	Median time to event (95% CI) [b]	6.8 (2.5, 12.7)	3.7 (1.4, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.392	
	HR (95% CI) [d]	0.75 (0.39, 1.45)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.874	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	13 (9.8%)	15 (11.5%)
	The number (%) of patients censored [a]	120 (90.2%)	116 (88.5%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	1.4 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.220	
	HR (95% CI) [d]	0.62 (0.29, 1.33)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	4 (9.1%)	4 (10.5%)
	The number (%) of patients censored [a]	40 (90.9%)	34 (89.5%)
	Median time to event (95% CI) [b]	2.4 (0.1, NE)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.596	
	HR (95% CI) [d]	1.42 (0.36, 5.70)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.232	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	58 (43.6%)	42 (32.1%)
	The number (%) of patients censored [a]	75 (56.4%)	89 (67.9%)
	Median time to event (95% CI) [b]	10.2 (7.2, NE)	13.0 (10.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.411	
	HR (95% CI) [d]	1.18 (0.79, 1.76)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	12 (27.3%)	14 (36.8%)
	The number (%) of patients censored [a]	32 (72.7%)	24 (63.2%)
	Median time to event (95% CI) [b]	NE (1.5, NE)	NE (2.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.798	
	HR (95% CI) [d]	1.11 (0.51, 2.41)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.3.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.794	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.3.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	53 (39.8%)	50 (38.2%)
	The number (%) of patients censored [a]	80 (60.2%)	81 (61.8%)
	Median time to event (95% CI) [b]	13.2 (5.9, NE)	16.1 (4.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	0.96 (0.65, 1.42)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	22 (50.0%)	13 (34.2%)
	The number (%) of patients censored [a]	22 (50.0%)	25 (65.8%)
	Median time to event (95% CI) [b]	2.3 (1.4, 3.3)	15.9 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.033	
	HR (95% CI) [d]	2.11 (1.05, 4.26)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.048	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	32 (24.1%)	32 (24.4%)
	The number (%) of patients censored [a]	101 (75.9%)	99 (75.6%)
	Median time to event (95% CI) [b]	NE (6.4, NE)	6.5 (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.355	
	HR (95% CI) [d]	0.79 (0.49, 1.30)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	8 (18.2%)	10 (26.3%)
	The number (%) of patients censored [a]	36 (81.8%)	28 (73.7%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	NE (6.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.714	
	HR (95% CI) [d]	1.18 (0.47, 3.00)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.455	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
<65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	133	131
	The number (%) of patients with an event [a]	13 (9.8%)	8 (6.1%)
	The number (%) of patients censored [a]	120 (90.2%)	123 (93.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.722	
	HR (95% CI) [d]	1.17 (0.49, 2.83)	
≥65 Years	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	44	38
	The number (%) of patients with an event [a]	4 (9.1%)	3 (7.9%)
	The number (%) of patients censored [a]	40 (90.9%)	35 (92.1%)
	Median time to event (95% CI) [b]	NE (4.0, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.402	
	HR (95% CI) [d]	1.88 (0.42, 8.47)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.3.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Age Group
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.644	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	67 (58.3%)	63 (60.6%)
	The number (%) of patients censored [a]	48 (41.7%)	41 (39.4%)
	Median time to event (95% CI) [b]	2.1 (1.5, 5.0)	3.3 (1.8, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.645	
	HR (95% CI) [d]	0.93 (0.66, 1.31)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	24 (63.2%)	23 (60.5%)
	The number (%) of patients censored [a]	14 (36.8%)	15 (39.5%)
	Median time to event (95% CI) [b]	4.1 (1.8, 8.4)	4.9 (1.9, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.986	
	HR (95% CI) [d]	1.01 (0.57, 1.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	7 (36.8%)	8 (33.3%)
	The number (%) of patients censored [a]	12 (63.2%)	16 (66.7%)
	Median time to event (95% CI) [b]	15.2 (2.4, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.939	
	HR (95% CI) [d]	0.96 (0.35, 2.67)	
	P-value of subgroup*treatment interaction [e]	0.942	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	56 (48.7%)	56 (53.8%)
	The number (%) of patients censored [a]	59 (51.3%)	48 (46.2%)
	Median time to event (95% CI) [b]	5.3 (2.8, 9.8)	3.7 (2.6, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.618	
	HR (95% CI) [d]	0.91 (0.63, 1.32)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	24 (63.2%)	22 (57.9%)
	The number (%) of patients censored [a]	14 (36.8%)	16 (42.1%)
	Median time to event (95% CI) [b]	3.3 (1.0, 7.9)	4.9 (2.0, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.567	
	HR (95% CI) [d]	1.19 (0.66, 2.13)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	6 (31.6%)	12 (50.0%)
	The number (%) of patients censored [a]	13 (68.4%)	12 (50.0%)
	Median time to event (95% CI) [b]	21.5 (2.4, NE)	5.1 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.102	
	HR (95% CI) [d]	0.45 (0.17, 1.20)	
	P-value of subgroup*treatment interaction [e]	0.233	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	68 (59.1%)	66 (63.5%)
	The number (%) of patients censored [a]	47 (40.9%)	38 (36.5%)
	Median time to event (95% CI) [b]	1.4 (1.1, 1.8)	2.8 (1.7, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.435	
	HR (95% CI) [d]	1.15 (0.82, 1.62)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	23 (60.5%)	28 (73.7%)
	The number (%) of patients censored [a]	15 (39.5%)	10 (26.3%)
	Median time to event (95% CI) [b]	2.5 (1.0, 6.5)	1.9 (1.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.668	
	HR (95% CI) [d]	0.89 (0.51, 1.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	7 (36.8%)	18 (75.0%)
	The number (%) of patients censored [a]	12 (63.2%)	6 (25.0%)
	Median time to event (95% CI) [b]	17.8 (1.0, NE)	2.4 (0.9, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.009	
	HR (95% CI) [d]	0.32 (0.13, 0.79)	
	P-value of subgroup*treatment interaction [e]	0.043	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	51 (44.3%)	43 (41.3%)
	The number (%) of patients censored [a]	64 (55.7%)	61 (58.7%)
	Median time to event (95% CI) [b]	7.8 (4.2, 11.8)	7.3 (4.4, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.891	
	HR (95% CI) [d]	0.97 (0.65, 1.46)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	18 (47.4%)	16 (42.1%)
	The number (%) of patients censored [a]	20 (52.6%)	22 (57.9%)
	Median time to event (95% CI) [b]	11.4 (4.9, NE)	10.0 (7.0, 12.4)
	Nominal p-value for unstratified log-rank test [c]	0.591	
	HR (95% CI) [d]	0.82 (0.41, 1.67)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	9 (47.4%)	8 (33.3%)
	The number (%) of patients censored [a]	10 (52.6%)	16 (66.7%)
	Median time to event (95% CI) [b]	7.3 (3.1, NE)	14.0 (1.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.761	
	HR (95% CI) [d]	1.16 (0.44, 3.03)	
	P-value of subgroup*treatment interaction [e]	0.932	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	58 (50.4%)	62 (59.6%)
	The number (%) of patients censored [a]	57 (49.6%)	42 (40.4%)
	Median time to event (95% CI) [b]	4.3 (2.9, 6.9)	2.8 (1.9, 3.7)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	0.75 (0.52, 1.07)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	22 (57.9%)	24 (63.2%)
	The number (%) of patients censored [a]	16 (42.1%)	14 (36.8%)
	Median time to event (95% CI) [b]	3.6 (2.3, 15.5)	4.4 (3.5, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.784	
	HR (95% CI) [d]	0.92 (0.51, 1.67)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	12 (63.2%)	15 (62.5%)
	The number (%) of patients censored [a]	7 (36.8%)	9 (37.5%)
	Median time to event (95% CI) [b]	4.2 (1.0, 13.1)	2.6 (1.0, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.771	
	HR (95% CI) [d]	0.88 (0.40, 1.93)	
	P-value of subgroup*treatment interaction [e]	0.691	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	61 (53.0%)	59 (56.7%)
	The number (%) of patients censored [a]	54 (47.0%)	45 (43.3%)
	Median time to event (95% CI) [b]	2.2 (1.4, 3.9)	3.3 (1.6, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.910	
	HR (95% CI) [d]	0.98 (0.69, 1.40)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	26 (68.4%)	22 (57.9%)
	The number (%) of patients censored [a]	12 (31.6%)	16 (42.1%)
	Median time to event (95% CI) [b]	2.2 (1.3, 7.5)	4.5 (2.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.500	
	HR (95% CI) [d]	1.22 (0.69, 2.16)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	11 (57.9%)	17 (70.8%)
	The number (%) of patients censored [a]	8 (42.1%)	7 (29.2%)
	Median time to event (95% CI) [b]	3.8 (1.0, NE)	1.4 (0.8, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.115	
	HR (95% CI) [d]	0.53 (0.23, 1.19)	
	P-value of subgroup*treatment interaction [e]	0.233	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	76 (66.1%)	74 (71.2%)
	The number (%) of patients censored [a]	39 (33.9%)	30 (28.8%)
	Median time to event (95% CI) [b]	1.4 (0.9, 1.7)	1.4 (1.0, 1.7)
	Nominal p-value for unstratified log-rank test [c]	0.456	
	HR (95% CI) [d]	0.89 (0.65, 1.23)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	29 (76.3%)	29 (76.3%)
	The number (%) of patients censored [a]	9 (23.7%)	9 (23.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.8)	3.2 (1.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.160	
	HR (95% CI) [d]	1.46 (0.87, 2.45)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	9 (47.4%)	18 (75.0%)
	The number (%) of patients censored [a]	10 (52.6%)	6 (25.0%)
	Median time to event (95% CI) [b]	2.3 (0.8, NE)	1.4 (0.8, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	0.53 (0.24, 1.19)	
	P-value of subgroup*treatment interaction [e]	0.091	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	73 (63.5%)	58 (55.8%)
	The number (%) of patients censored [a]	42 (36.5%)	46 (44.2%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.8)	2.5 (1.6, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.188	
	HR (95% CI) [d]	1.26 (0.89, 1.79)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	21 (55.3%)	19 (50.0%)
	The number (%) of patients censored [a]	17 (44.7%)	19 (50.0%)
	Median time to event (95% CI) [b]	2.2 (1.5, NE)	4.9 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.727	
	HR (95% CI) [d]	1.12 (0.59, 2.10)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	11 (57.9%)	15 (62.5%)
	The number (%) of patients censored [a]	8 (42.1%)	9 (37.5%)
	Median time to event (95% CI) [b]	1.7 (0.8, 3.1)	1.7 (0.8, 3.4)
	Nominal p-value for unstratified log-rank test [c]	0.984	
	HR (95% CI) [d]	0.99 (0.45, 2.19)	
	P-value of subgroup*treatment interaction [e]	0.901	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	56 (48.7%)	61 (58.7%)
	The number (%) of patients censored [a]	59 (51.3%)	43 (41.3%)
	Median time to event (95% CI) [b]	4.4 (1.8, 8.8)	2.8 (1.9, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.340	
	HR (95% CI) [d]	0.84 (0.58, 1.21)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	23 (60.5%)	25 (65.8%)
	The number (%) of patients censored [a]	15 (39.5%)	13 (34.2%)
	Median time to event (95% CI) [b]	5.6 (1.7, 10.8)	3.0 (1.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.503	
	HR (95% CI) [d]	0.82 (0.46, 1.47)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	6 (31.6%)	11 (45.8%)
	The number (%) of patients censored [a]	13 (68.4%)	13 (54.2%)
	Median time to event (95% CI) [b]	17.8 (1.1, NE)	6.5 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.330	
	HR (95% CI) [d]	0.60 (0.22, 1.68)	
	P-value of subgroup*treatment interaction [e]	0.900	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	41 (35.7%)	52 (50.0%)
	The number (%) of patients censored [a]	74 (64.3%)	52 (50.0%)
	Median time to event (95% CI) [b]	15.5 (6.7, NE)	4.9 (2.8, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.012	
	HR (95% CI) [d]	0.60 (0.39, 0.90)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	16 (42.1%)	22 (57.9%)
	The number (%) of patients censored [a]	22 (57.9%)	16 (42.1%)
	Median time to event (95% CI) [b]	11.4 (3.6, NE)	4.9 (2.0, 18.5)
	Nominal p-value for unstratified log-rank test [c]	0.063	
	HR (95% CI) [d]	0.54 (0.28, 1.04)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	6 (31.6%)	12 (50.0%)
	The number (%) of patients censored [a]	13 (68.4%)	12 (50.0%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	4.4 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.265	
	HR (95% CI) [d]	0.58 (0.22, 1.54)	
	P-value of subgroup*treatment interaction [e]	0.982	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	53 (46.1%)	54 (51.9%)
	The number (%) of patients censored [a]	62 (53.9%)	50 (48.1%)
	Median time to event (95% CI) [b]	4.5 (3.2, 9.1)	3.5 (2.2, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.563	
	HR (95% CI) [d]	0.90 (0.61, 1.31)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	16 (42.1%)	20 (52.6%)
	The number (%) of patients censored [a]	22 (57.9%)	18 (47.4%)
	Median time to event (95% CI) [b]	14.4 (3.1, NE)	6.0 (1.9, 13.0)
	Nominal p-value for unstratified log-rank test [c]	0.154	
	HR (95% CI) [d]	0.61 (0.31, 1.21)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	8 (42.1%)	11 (45.8%)
	The number (%) of patients censored [a]	11 (57.9%)	13 (54.2%)
	Median time to event (95% CI) [b]	10.8 (1.2, NE)	4.4 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.684	
	HR (95% CI) [d]	0.83 (0.33, 2.08)	
	P-value of subgroup*treatment interaction [e]	0.737	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	58 (50.4%)	57 (54.8%)
	The number (%) of patients censored [a]	57 (49.6%)	47 (45.2%)
	Median time to event (95% CI) [b]	2.2 (1.6, 11.8)	2.6 (1.7, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.432	
	HR (95% CI) [d]	0.87 (0.60, 1.26)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	17 (44.7%)	17 (44.7%)
	The number (%) of patients censored [a]	21 (55.3%)	21 (55.3%)
	Median time to event (95% CI) [b]	7.9 (2.0, NE)	13.0 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.805	
	HR (95% CI) [d]	1.09 (0.55, 2.14)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	9 (47.4%)	10 (41.7%)
	The number (%) of patients censored [a]	10 (52.6%)	14 (58.3%)
	Median time to event (95% CI) [b]	4.1 (1.0, NE)	3.4 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.800	
	HR (95% CI) [d]	1.12 (0.45, 2.75)	
	P-value of subgroup*treatment interaction [e]	0.847	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	60 (52.2%)	57 (54.8%)
	The number (%) of patients censored [a]	55 (47.8%)	47 (45.2%)
	Median time to event (95% CI) [b]	2.4 (1.7, 4.6)	2.8 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.705	
	HR (95% CI) [d]	0.93 (0.65, 1.34)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	23 (60.5%)	19 (50.0%)
	The number (%) of patients censored [a]	15 (39.5%)	19 (50.0%)
	Median time to event (95% CI) [b]	2.3 (1.0, NE)	6.7 (1.5, 13.3)
	Nominal p-value for unstratified log-rank test [c]	0.504	
	HR (95% CI) [d]	1.23 (0.66, 2.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	10 (52.6%)	12 (50.0%)
	The number (%) of patients censored [a]	9 (47.4%)	12 (50.0%)
	Median time to event (95% CI) [b]	3.5 (1.0, 19.4)	1.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.524	
	HR (95% CI) [d]	0.75 (0.32, 1.76)	
	P-value of subgroup*treatment interaction [e]	0.564	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	72 (62.6%)	37 (35.6%)
	The number (%) of patients censored [a]	43 (37.4%)	67 (64.4%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	10.1 (5.5, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.42 (1.62, 3.60)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	27 (71.1%)	19 (50.0%)
	The number (%) of patients censored [a]	11 (28.9%)	19 (50.0%)
	Median time to event (95% CI) [b]	1.7 (0.8, 4.1)	5.8 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.008	
	HR (95% CI) [d]	2.20 (1.22, 3.98)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	14 (73.7%)	15 (62.5%)
	The number (%) of patients censored [a]	5 (26.3%)	9 (37.5%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	3.1 (1.2, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.043	
	HR (95% CI) [d]	2.17 (1.03, 4.59)	
	P-value of subgroup*treatment interaction [e]	0.891	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	41 (35.7%)	45 (43.3%)
	The number (%) of patients censored [a]	74 (64.3%)	59 (56.7%)
	Median time to event (95% CI) [b]	10.5 (7.0, NE)	4.2 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.036	
	HR (95% CI) [d]	0.63 (0.41, 0.97)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	16 (42.1%)	10 (26.3%)
	The number (%) of patients censored [a]	22 (57.9%)	28 (73.7%)
	Median time to event (95% CI) [b]	9.8 (5.6, NE)	NE (10.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.283	
	HR (95% CI) [d]	1.54 (0.70, 3.40)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	5 (26.3%)	7 (29.2%)
	The number (%) of patients censored [a]	14 (73.7%)	17 (70.8%)
	Median time to event (95% CI) [b]	21.5 (0.7, NE)	6.3 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.583	
	HR (95% CI) [d]	0.69 (0.18, 2.66)	
	P-value of subgroup*treatment interaction [e]	0.136	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	60 (52.2%)	52 (50.0%)
	The number (%) of patients censored [a]	55 (47.8%)	52 (50.0%)
	Median time to event (95% CI) [b]	2.5 (1.7, 4.6)	4.4 (2.6, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	1.22 (0.84, 1.77)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	29 (76.3%)	18 (47.4%)
	The number (%) of patients censored [a]	9 (23.7%)	20 (52.6%)
	Median time to event (95% CI) [b]	2.3 (1.3, 4.6)	7.0 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.014	
	HR (95% CI) [d]	2.07 (1.14, 3.74)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	9 (47.4%)	10 (41.7%)
	The number (%) of patients censored [a]	10 (52.6%)	14 (58.3%)
	Median time to event (95% CI) [b]	3.0 (0.8, NE)	2.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.922	
	HR (95% CI) [d]	0.96 (0.39, 2.36)	
	P-value of subgroup*treatment interaction [e]	0.156	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	34 (29.6%)	37 (35.6%)
	The number (%) of patients censored [a]	81 (70.4%)	67 (64.4%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	6.5 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.141	
	HR (95% CI) [d]	0.70 (0.44, 1.12)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	5 (13.2%)	6 (15.8%)
	The number (%) of patients censored [a]	33 (86.8%)	32 (84.2%)
	Median time to event (95% CI) [b]	NE (18.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	0.67 (0.20, 2.22)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	4 (21.1%)	5 (20.8%)
	The number (%) of patients censored [a]	15 (78.9%)	19 (79.2%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.931	
	HR (95% CI) [d]	0.94 (0.25, 3.52)	
	P-value of subgroup*treatment interaction [e]	0.936	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	6 (5.2%)	7 (6.7%)
	The number (%) of patients censored [a]	109 (94.8%)	97 (93.3%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.621	
	HR (95% CI) [d]	1.32 (0.44, 3.92)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	0 (0.0%)	1 (2.6%)
	The number (%) of patients censored [a]	38 (100.0%)	37 (97.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.264	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	1 (5.3%)	1 (4.2%)
	The number (%) of patients censored [a]	18 (94.7%)	23 (95.8%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.560	
	HR (95% CI) [d]	2.24 (0.14, 35.90)	
	P-value of subgroup*treatment interaction [e]	0.941	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	46 (40.0%)	37 (35.6%)
	The number (%) of patients censored [a]	69 (60.0%)	67 (64.4%)
	Median time to event (95% CI) [b]	3.5 (1.6, 5.6)	5.4 (2.5, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.289	
	HR (95% CI) [d]	1.26 (0.82, 1.95)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	15 (39.5%)	19 (50.0%)
	The number (%) of patients censored [a]	23 (60.5%)	19 (50.0%)
	Median time to event (95% CI) [b]	12.2 (4.2, NE)	6.0 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.196	
	HR (95% CI) [d]	0.62 (0.30, 1.28)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	6 (31.6%)	9 (37.5%)
	The number (%) of patients censored [a]	13 (68.4%)	15 (62.5%)
	Median time to event (95% CI) [b]	13.1 (4.9, NE)	6.3 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.144	
	HR (95% CI) [d]	0.42 (0.13, 1.38)	
	P-value of subgroup*treatment interaction [e]	0.144	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	85 (73.9%)	67 (64.4%)
	The number (%) of patients censored [a]	30 (26.1%)	37 (35.6%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.4)	2.7 (1.5, 4.0)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.76 (1.27, 2.42)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	30 (78.9%)	23 (60.5%)
	The number (%) of patients censored [a]	8 (21.1%)	15 (39.5%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	3.5 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.005	
	HR (95% CI) [d]	2.19 (1.27, 3.80)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	12 (63.2%)	14 (58.3%)
	The number (%) of patients censored [a]	7 (36.8%)	10 (41.7%)
	Median time to event (95% CI) [b]	1.2 (0.8, 5.2)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.831	
	HR (95% CI) [d]	1.08 (0.50, 2.34)	
	P-value of subgroup*treatment interaction [e]	0.375	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.1.4.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	36 (31.3%)	29 (27.9%)
	The number (%) of patients censored [a]	79 (68.7%)	75 (72.1%)
	Median time to event (95% CI) [b]	17.1 (7.5, NE)	9.8 (7.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.669	
	HR (95% CI) [d]	0.90 (0.55, 1.47)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	12 (31.6%)	9 (23.7%)
	The number (%) of patients censored [a]	26 (68.4%)	29 (76.3%)
	Median time to event (95% CI) [b]	17.5 (10.0, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.424	
	HR (95% CI) [d]	1.42 (0.60, 3.41)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	4 (21.1%)	4 (16.7%)
	The number (%) of patients censored [a]	15 (78.9%)	20 (83.3%)
	Median time to event (95% CI) [b]	24.7 (5.6, NE)	NE (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.805	
	HR (95% CI) [d]	1.19 (0.29, 4.86)	
	P-value of subgroup*treatment interaction [e]	0.690	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

Table 7.1.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	58 (50.4%)	54 (51.9%)
	The number (%) of patients censored [a]	57 (49.6%)	50 (48.1%)
	Median time to event (95% CI) [b]	5.6 (3.5, 7.9)	3.6 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.256	
	HR (95% CI) [d]	0.80 (0.55, 1.17)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	23 (60.5%)	23 (60.5%)
	The number (%) of patients censored [a]	15 (39.5%)	15 (39.5%)
	Median time to event (95% CI) [b]	2.9 (1.4, 15.5)	3.9 (1.4, 11.8)
	Nominal p-value for unstratified log-rank test [c]	0.647	
	HR (95% CI) [d]	0.87 (0.48, 1.58)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	6 (31.6%)	10 (41.7%)
	The number (%) of patients censored [a]	13 (68.4%)	14 (58.3%)
	Median time to event (95% CI) [b]	15.9 (1.5, NE)	5.1 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.217	
	HR (95% CI) [d]	0.52 (0.18, 1.49)	
	P-value of subgroup*treatment interaction [e]	0.735	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	12 (10.4%)	12 (11.5%)
	The number (%) of patients censored [a]	103 (89.6%)	92 (88.5%)
	Median time to event (95% CI) [b]	1.0 (0.8, 7.9)	1.4 (0.8, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.772	
	HR (95% CI) [d]	0.86 (0.38, 1.93)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	3 (7.9%)	3 (7.9%)
	The number (%) of patients censored [a]	35 (92.1%)	35 (92.1%)
	Median time to event (95% CI) [b]	2.2 (0.8, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.888	
	HR (95% CI) [d]	1.12 (0.23, 5.58)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

Table 7.1.4.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	2 (10.5%)	4 (16.7%)
	The number (%) of patients censored [a]	17 (89.5%)	20 (83.3%)
	Median time to event (95% CI) [b]	NE (1.0, NE)	3.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.260	
	HR (95% CI) [d]	0.38 (0.07, 2.13)	
	P-value of subgroup*treatment interaction [e]	0.601	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	43 (37.4%)	38 (36.5%)
	The number (%) of patients censored [a]	72 (62.6%)	66 (63.5%)
	Median time to event (95% CI) [b]	9.0 (6.3, NE)	10.5 (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.718	
	HR (95% CI) [d]	0.93 (0.60, 1.44)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	21 (55.3%)	15 (39.5%)
	The number (%) of patients censored [a]	17 (44.7%)	23 (60.5%)
	Median time to event (95% CI) [b]	5.1 (2.3, 15.5)	13.0 (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.228	
	HR (95% CI) [d]	1.51 (0.77, 2.96)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.1.4.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	3 (15.8%)	3 (12.5%)
	The number (%) of patients censored [a]	16 (84.2%)	21 (87.5%)
	Median time to event (95% CI) [b]	NE (1.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.787	
	HR (95% CI) [d]	1.25 (0.25, 6.17)	
	P-value of subgroup*treatment interaction [e]	0.394	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.4.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	52 (45.2%)	40 (38.5%)
	The number (%) of patients censored [a]	63 (54.8%)	64 (61.5%)
	Median time to event (95% CI) [b]	4.3 (3.3, 13.2)	9.7 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.349	
	HR (95% CI) [d]	1.21 (0.80, 1.84)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	13 (34.2%)	15 (39.5%)
	The number (%) of patients censored [a]	25 (65.8%)	23 (60.5%)
	Median time to event (95% CI) [b]	NE (9.6, NE)	16.1 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.566	
	HR (95% CI) [d]	0.80 (0.38, 1.70)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	9 (47.4%)	8 (33.3%)
	The number (%) of patients censored [a]	10 (52.6%)	16 (66.7%)
	Median time to event (95% CI) [b]	4.1 (1.5, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.269	
	HR (95% CI) [d]	1.70 (0.65, 4.44)	
	P-value of subgroup*treatment interaction [e]	0.462	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	30 (26.1%)	28 (26.9%)
	The number (%) of patients censored [a]	85 (73.9%)	76 (73.1%)
	Median time to event (95% CI) [b]	6.4 (6.0, NE)	6.4 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.475	
	HR (95% CI) [d]	0.83 (0.50, 1.39)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	6 (15.8%)	9 (23.7%)
	The number (%) of patients censored [a]	32 (84.2%)	29 (76.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.632	
	HR (95% CI) [d]	0.77 (0.27, 2.17)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	2 (10.5%)	4 (16.7%)
	The number (%) of patients censored [a]	17 (89.5%)	20 (83.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.741	
	HR (95% CI) [d]	0.75 (0.14, 4.13)	
	P-value of subgroup*treatment interaction [e]	0.952	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
White	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	115	104
	The number (%) of patients with an event [a]	10 (8.7%)	6 (5.8%)
	The number (%) of patients censored [a]	105 (91.3%)	98 (94.2%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.831	
	HR (95% CI) [d]	1.12 (0.40, 3.08)	
Asian	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	38	38
	The number (%) of patients with an event [a]	6 (15.8%)	5 (13.2%)
	The number (%) of patients censored [a]	32 (84.2%)	33 (86.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.959	
	HR (95% CI) [d]	1.03 (0.31, 3.40)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.4.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Race
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Other	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	19	24
	The number (%) of patients with an event [a]	1 (5.3%)	0 (0.0%)
	The number (%) of patients censored [a]	18 (94.7%)	24 (100.0%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.197	
	HR (95% CI) [d]	NE (NE, NE)	
	P-value of subgroup*treatment interaction [e]	0.983	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	71 (61.2%)	70 (66.0%)
	The number (%) of patients censored [a]	45 (38.8%)	36 (34.0%)
	Median time to event (95% CI) [b]	3.9 (1.7, 6.0)	2.7 (1.8, 4.5)
	Nominal p-value for unstratified log-rank test [c]	0.367	
	HR (95% CI) [d]	0.86 (0.62, 1.20)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	31 (50.8%)	26 (41.3%)
	The number (%) of patients censored [a]	30 (49.2%)	37 (58.7%)
	Median time to event (95% CI) [b]	3.3 (1.6, 15.2)	7.5 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.465	
	HR (95% CI) [d]	1.22 (0.72, 2.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.279	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	60 (51.7%)	60 (56.6%)
	The number (%) of patients censored [a]	56 (48.3%)	46 (43.4%)
	Median time to event (95% CI) [b]	6.7 (3.3, 9.2)	4.7 (2.8, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.622	
	HR (95% CI) [d]	0.91 (0.64, 1.31)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	29 (47.5%)	32 (50.8%)
	The number (%) of patients censored [a]	32 (52.5%)	31 (49.2%)
	Median time to event (95% CI) [b]	4.2 (1.0, 21.5)	4.4 (1.9, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.707	
	HR (95% CI) [d]	0.91 (0.54, 1.54)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.941	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	70 (60.3%)	76 (71.7%)
	The number (%) of patients censored [a]	46 (39.7%)	30 (28.3%)
	Median time to event (95% CI) [b]	1.9 (1.4, 3.1)	2.8 (1.9, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.567	
	HR (95% CI) [d]	0.91 (0.66, 1.27)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	33 (54.1%)	39 (61.9%)
	The number (%) of patients censored [a]	28 (45.9%)	24 (38.1%)
	Median time to event (95% CI) [b]	1.3 (0.9, 1.7)	2.5 (1.2, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.846	
	HR (95% CI) [d]	1.05 (0.66, 1.68)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.683	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	54 (46.6%)	43 (40.6%)
	The number (%) of patients censored [a]	62 (53.4%)	63 (59.4%)
	Median time to event (95% CI) [b]	9.0 (5.0, 12.2)	10.0 (7.0, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.862	
	HR (95% CI) [d]	1.04 (0.69, 1.56)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	28 (45.9%)	25 (39.7%)
	The number (%) of patients censored [a]	33 (54.1%)	38 (60.3%)
	Median time to event (95% CI) [b]	4.9 (3.2, 12.5)	4.9 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.847	
	HR (95% CI) [d]	1.05 (0.61, 1.82)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.834	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	64 (55.2%)	65 (61.3%)
	The number (%) of patients censored [a]	52 (44.8%)	41 (38.7%)
	Median time to event (95% CI) [b]	5.1 (2.9, 8.4)	3.5 (2.4, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.305	
	HR (95% CI) [d]	0.83 (0.59, 1.18)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	33 (54.1%)	39 (61.9%)
	The number (%) of patients censored [a]	28 (45.9%)	24 (38.1%)
	Median time to event (95% CI) [b]	3.5 (2.3, 4.5)	2.9 (1.7, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.417	
	HR (95% CI) [d]	0.82 (0.52, 1.31)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.986	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	69 (59.5%)	64 (60.4%)
	The number (%) of patients censored [a]	47 (40.5%)	42 (39.6%)
	Median time to event (95% CI) [b]	2.5 (1.5, 7.2)	3.1 (1.6, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.976	
	HR (95% CI) [d]	0.99 (0.71, 1.40)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	33 (54.1%)	36 (57.1%)
	The number (%) of patients censored [a]	28 (45.9%)	27 (42.9%)
	Median time to event (95% CI) [b]	2.4 (1.3, 3.8)	3.6 (2.2, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.883	
	HR (95% CI) [d]	0.97 (0.60, 1.57)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.873	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	84 (72.4%)	81 (76.4%)
	The number (%) of patients censored [a]	32 (27.6%)	25 (23.6%)
	Median time to event (95% CI) [b]	1.5 (1.0, 1.8)	1.4 (1.0, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.940	
	HR (95% CI) [d]	1.02 (0.75, 1.38)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	35 (57.4%)	43 (68.3%)
	The number (%) of patients censored [a]	26 (42.6%)	20 (31.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.7)	1.2 (1.0, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.489	
	HR (95% CI) [d]	0.86 (0.55, 1.36)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.440	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	76 (65.5%)	64 (60.4%)
	The number (%) of patients censored [a]	40 (34.5%)	42 (39.6%)
	Median time to event (95% CI) [b]	2.0 (1.5, 3.1)	2.5 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.358	
	HR (95% CI) [d]	1.17 (0.84, 1.64)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	33 (54.1%)	29 (46.0%)
	The number (%) of patients censored [a]	28 (45.9%)	34 (54.0%)
	Median time to event (95% CI) [b]	1.6 (0.9, 4.2)	3.8 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.134	
	HR (95% CI) [d]	1.47 (0.89, 2.43)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.496	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	64 (55.2%)	66 (62.3%)
	The number (%) of patients censored [a]	52 (44.8%)	40 (37.7%)
	Median time to event (95% CI) [b]	5.6 (2.4, 8.8)	2.8 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.160	
	HR (95% CI) [d]	0.78 (0.55, 1.11)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	24 (39.3%)	34 (54.0%)
	The number (%) of patients censored [a]	37 (60.7%)	29 (46.0%)
	Median time to event (95% CI) [b]	5.0 (1.0, NE)	3.1 (2.1, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.654	
	HR (95% CI) [d]	0.89 (0.53, 1.52)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.799	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	42 (36.2%)	61 (57.5%)
	The number (%) of patients censored [a]	74 (63.8%)	45 (42.5%)
	Median time to event (95% CI) [b]	15.5 (9.7, NE)	4.4 (2.4, 6.2)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	0.49 (0.33, 0.72)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	23 (37.7%)	28 (44.4%)
	The number (%) of patients censored [a]	38 (62.3%)	35 (55.6%)
	Median time to event (95% CI) [b]	6.3 (3.1, NE)	4.9 (3.3, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.402	
	HR (95% CI) [d]	0.79 (0.45, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.194	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	55 (47.4%)	56 (52.8%)
	The number (%) of patients censored [a]	61 (52.6%)	50 (47.2%)
	Median time to event (95% CI) [b]	7.2 (3.5, 14.4)	4.1 (3.1, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.289	
	HR (95% CI) [d]	0.82 (0.56, 1.19)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	25 (41.0%)	31 (49.2%)
	The number (%) of patients censored [a]	36 (59.0%)	32 (50.8%)
	Median time to event (95% CI) [b]	4.5 (1.6, 16.8)	4.2 (2.0, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.478	
	HR (95% CI) [d]	0.83 (0.49, 1.41)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.953	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	54 (46.6%)	59 (55.7%)
	The number (%) of patients censored [a]	62 (53.4%)	47 (44.3%)
	Median time to event (95% CI) [b]	7.9 (2.1, NE)	4.1 (1.9, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	0.80 (0.55, 1.15)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	33 (54.1%)	25 (39.7%)
	The number (%) of patients censored [a]	28 (45.9%)	38 (60.3%)
	Median time to event (95% CI) [b]	2.3 (0.9, 3.6)	5.2 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.097	
	HR (95% CI) [d]	1.55 (0.92, 2.62)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.050	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	63 (54.3%)	61 (57.5%)
	The number (%) of patients censored [a]	53 (45.7%)	45 (42.5%)
	Median time to event (95% CI) [b]	2.5 (1.7, 5.7)	2.7 (1.5, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.538	
	HR (95% CI) [d]	0.89 (0.63, 1.27)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	34 (55.7%)	28 (44.4%)
	The number (%) of patients censored [a]	27 (44.3%)	35 (55.6%)
	Median time to event (95% CI) [b]	2.2 (1.5, 3.6)	6.5 (1.7, 13.3)
	Nominal p-value for unstratified log-rank test [c]	0.418	
	HR (95% CI) [d]	1.23 (0.74, 2.03)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.255	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	80 (69.0%)	44 (41.5%)
	The number (%) of patients censored [a]	36 (31.0%)	62 (58.5%)
	Median time to event (95% CI) [b]	1.7 (1.2, 2.4)	7.4 (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.42 (1.67, 3.50)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	38 (62.3%)	27 (42.9%)
	The number (%) of patients censored [a]	23 (37.7%)	36 (57.1%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.8)	5.1 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	2.12 (1.29, 3.47)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.700	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	41 (35.3%)	38 (35.8%)
	The number (%) of patients censored [a]	75 (64.7%)	68 (64.2%)
	Median time to event (95% CI) [b]	16.1 (8.3, NE)	19.4 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.334	
	HR (95% CI) [d]	0.80 (0.51, 1.25)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	24 (39.3%)	25 (39.7%)
	The number (%) of patients censored [a]	37 (60.7%)	38 (60.3%)
	Median time to event (95% CI) [b]	6.9 (2.4, NE)	4.6 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.756	
	HR (95% CI) [d]	0.92 (0.52, 1.62)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.950	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	71 (61.2%)	52 (49.1%)
	The number (%) of patients censored [a]	45 (38.8%)	54 (50.9%)
	Median time to event (95% CI) [b]	3.5 (1.8, 5.0)	5.0 (2.8, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.106	
	HR (95% CI) [d]	1.34 (0.94, 1.92)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	30 (49.2%)	30 (47.6%)
	The number (%) of patients censored [a]	31 (50.8%)	33 (52.4%)
	Median time to event (95% CI) [b]	2.1 (0.9, 4.6)	4.9 (2.1, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.229	
	HR (95% CI) [d]	1.38 (0.82, 2.30)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.969	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	35 (30.2%)	30 (28.3%)
	The number (%) of patients censored [a]	81 (69.8%)	76 (71.7%)
	Median time to event (95% CI) [b]	NE (13.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.908	
	HR (95% CI) [d]	0.97 (0.59, 1.59)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	11 (18.0%)	19 (30.2%)
	The number (%) of patients censored [a]	50 (82.0%)	44 (69.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.079	
	HR (95% CI) [d]	0.52 (0.25, 1.09)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.128	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	6 (5.2%)	6 (5.7%)
	The number (%) of patients censored [a]	110 (94.8%)	100 (94.3%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.414	
	HR (95% CI) [d]	1.60 (0.51, 4.96)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	1 (1.6%)	3 (4.8%)
	The number (%) of patients censored [a]	60 (98.4%)	60 (95.2%)
	Median time to event (95% CI) [b]	NE (1.4, NE)	3.1 (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.087	
	HR (95% CI) [d]	0.15 (0.01, 1.66)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.136	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	47 (40.5%)	37 (34.9%)
	The number (%) of patients censored [a]	69 (59.5%)	69 (65.1%)
	Median time to event (95% CI) [b]	7.8 (4.3, 12.2)	8.8 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.742	
	HR (95% CI) [d]	1.07 (0.69, 1.66)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	22 (36.1%)	28 (44.4%)
	The number (%) of patients censored [a]	39 (63.9%)	35 (55.6%)
	Median time to event (95% CI) [b]	3.6 (1.4, 13.1)	3.7 (1.9, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.587	
	HR (95% CI) [d]	0.85 (0.48, 1.50)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.393	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	91 (78.4%)	71 (67.0%)
	The number (%) of patients censored [a]	25 (21.6%)	35 (33.0%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	1.7 (1.2, 3.0)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.89 (1.38, 2.59)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	40 (65.6%)	36 (57.1%)
	The number (%) of patients censored [a]	21 (34.4%)	27 (42.9%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.6)	3.3 (1.4, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.093	
	HR (95% CI) [d]	1.48 (0.94, 2.34)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.329	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	38 (32.8%)	28 (26.4%)
	The number (%) of patients censored [a]	78 (67.2%)	78 (73.6%)
	Median time to event (95% CI) [b]	17.5 (10.0, NE)	NE (9.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.581	
	HR (95% CI) [d]	1.15 (0.70, 1.88)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	15 (24.6%)	14 (22.2%)
	The number (%) of patients censored [a]	46 (75.4%)	49 (77.8%)
	Median time to event (95% CI) [b]	24.7 (6.4, NE)	NE (8.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.838	
	HR (95% CI) [d]	0.92 (0.44, 1.94)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.611	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	56 (48.3%)	60 (56.6%)
	The number (%) of patients censored [a]	60 (51.7%)	46 (43.4%)
	Median time to event (95% CI) [b]	6.9 (3.5, 13.3)	3.1 (2.5, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.065	
	HR (95% CI) [d]	0.71 (0.49, 1.02)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	33 (54.1%)	29 (46.0%)
	The number (%) of patients censored [a]	28 (45.9%)	34 (54.0%)
	Median time to event (95% CI) [b]	4.6 (2.1, 9.3)	4.2 (3.1, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.962	
	HR (95% CI) [d]	0.99 (0.60, 1.64)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.229	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	5 (4.3%)	12 (11.3%)
	The number (%) of patients censored [a]	111 (95.7%)	94 (88.7%)
	Median time to event (95% CI) [b]	7.2 (0.7, NE)	1.4 (0.8, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.216	
	HR (95% CI) [d]	0.51 (0.18, 1.46)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	12 (19.7%)	7 (11.1%)
	The number (%) of patients censored [a]	49 (80.3%)	56 (88.9%)
	Median time to event (95% CI) [b]	1.2 (0.8, 7.9)	1.9 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.767	
	HR (95% CI) [d]	1.15 (0.45, 2.93)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.231	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	48 (41.4%)	38 (35.8%)
	The number (%) of patients censored [a]	68 (58.6%)	68 (64.2%)
	Median time to event (95% CI) [b]	10.2 (8.1, 18.7)	12.4 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.547	
	HR (95% CI) [d]	1.14 (0.75, 1.75)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	22 (36.1%)	18 (28.6%)
	The number (%) of patients censored [a]	39 (63.9%)	45 (71.4%)
	Median time to event (95% CI) [b]	7.2 (3.6, NE)	15.4 (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.561	
	HR (95% CI) [d]	1.20 (0.64, 2.25)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.5.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.973	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.5.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	47 (40.5%)	39 (36.8%)
	The number (%) of patients censored [a]	69 (59.5%)	67 (63.2%)
	Median time to event (95% CI) [b]	11.8 (5.9, NE)	19.4 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.595	
	HR (95% CI) [d]	1.12 (0.73, 1.72)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	28 (45.9%)	24 (38.1%)
	The number (%) of patients censored [a]	33 (54.1%)	39 (61.9%)
	Median time to event (95% CI) [b]	3.5 (1.6, 6.4)	15.9 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.425	
	HR (95% CI) [d]	1.25 (0.72, 2.16)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.802	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	31 (26.7%)	28 (26.4%)
	The number (%) of patients censored [a]	85 (73.3%)	78 (73.6%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (6.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.910	
	HR (95% CI) [d]	0.97 (0.58, 1.61)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	9 (14.8%)	14 (22.2%)
	The number (%) of patients censored [a]	52 (85.2%)	49 (77.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.293	
	HR (95% CI) [d]	0.64 (0.27, 1.49)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.378	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
0	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	116	106
	The number (%) of patients with an event [a]	11 (9.5%)	5 (4.7%)
	The number (%) of patients censored [a]	105 (90.5%)	101 (95.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.375	
	HR (95% CI) [d]	1.61 (0.56, 4.65)	
1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	61	63
	The number (%) of patients with an event [a]	6 (9.8%)	6 (9.5%)
	The number (%) of patients censored [a]	55 (90.2%)	57 (90.5%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.978	
	HR (95% CI) [d]	0.99 (0.32, 3.06)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.5.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Baseline ECOG
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.540	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	32 (61.5%)	23 (51.1%)
	The number (%) of patients censored [a]	20 (38.5%)	22 (48.9%)
	Median time to event (95% CI) [b]	3.3 (1.5, 5.6)	4.7 (2.0, 7.3)
	Nominal p-value for unstratified log-rank test [c]	0.530	
	HR (95% CI) [d]	1.20 (0.70, 2.06)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	70 (56.0%)	73 (58.9%)
	The number (%) of patients censored [a]	55 (44.0%)	51 (41.1%)
	Median time to event (95% CI) [b]	4.1 (2.1, 6.3)	3.3 (2.1, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.491	
	HR (95% CI) [d]	0.89 (0.64, 1.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.287	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.2

Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	31 (59.6%)	23 (51.1%)
	The number (%) of patients censored [a]	21 (40.4%)	22 (48.9%)
	Median time to event (95% CI) [b]	3.0 (1.4, 4.3)	4.4 (1.9, 11.1)
	Nominal p-value for unstratified log-rank test [c]	0.300	
	HR (95% CI) [d]	1.33 (0.77, 2.30)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	58 (46.4%)	69 (55.6%)
	The number (%) of patients censored [a]	67 (53.6%)	55 (44.4%)
	Median time to event (95% CI) [b]	7.5 (3.6, 20.1)	4.9 (2.8, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.159	
	HR (95% CI) [d]	0.78 (0.55, 1.11)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.2

Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.087	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.3

Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	31 (59.6%)	31 (68.9%)
	The number (%) of patients censored [a]	21 (40.4%)	14 (31.1%)
	Median time to event (95% CI) [b]	1.5 (1.0, 3.6)	1.9 (1.4, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.777	
	HR (95% CI) [d]	0.93 (0.57, 1.54)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	72 (57.6%)	84 (67.7%)
	The number (%) of patients censored [a]	53 (42.4%)	40 (32.3%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.8)	3.5 (1.7, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.666	
	HR (95% CI) [d]	0.94 (0.68, 1.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.879	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	23 (44.2%)	12 (26.7%)
	The number (%) of patients censored [a]	29 (55.8%)	33 (73.3%)
	Median time to event (95% CI) [b]	8.4 (4.2, NE)	11.1 (6.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.235	
	HR (95% CI) [d]	1.53 (0.75, 3.10)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	59 (47.2%)	56 (45.2%)
	The number (%) of patients censored [a]	66 (52.8%)	68 (54.8%)
	Median time to event (95% CI) [b]	7.8 (4.4, 11.4)	9.1 (4.7, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.813	
	HR (95% CI) [d]	0.96 (0.66, 1.38)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.363	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	28 (53.8%)	25 (55.6%)
	The number (%) of patients censored [a]	24 (46.2%)	20 (44.4%)
	Median time to event (95% CI) [b]	3.5 (1.7, 6.0)	3.8 (2.8, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.974	
	HR (95% CI) [d]	0.99 (0.57, 1.70)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	69 (55.2%)	79 (63.7%)
	The number (%) of patients censored [a]	56 (44.8%)	45 (36.3%)
	Median time to event (95% CI) [b]	4.5 (2.8, 6.9)	2.9 (2.1, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.147	
	HR (95% CI) [d]	0.79 (0.57, 1.09)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.5

Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.570	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	34 (65.4%)	23 (51.1%)
	The number (%) of patients censored [a]	18 (34.6%)	22 (48.9%)
	Median time to event (95% CI) [b]	2.2 (1.5, 3.6)	2.8 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.532	
	HR (95% CI) [d]	1.18 (0.69, 2.03)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	68 (54.4%)	77 (62.1%)
	The number (%) of patients censored [a]	57 (45.6%)	47 (37.9%)
	Median time to event (95% CI) [b]	2.8 (1.4, 7.5)	3.5 (2.2, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.430	
	HR (95% CI) [d]	0.88 (0.63, 1.22)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.6

Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.271	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	36 (69.2%)	32 (71.1%)
	The number (%) of patients censored [a]	16 (30.8%)	13 (28.9%)
	Median time to event (95% CI) [b]	1.2 (0.8, 1.7)	1.4 (1.1, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.299	
	HR (95% CI) [d]	1.29 (0.80, 2.09)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	83 (66.4%)	92 (74.2%)
	The number (%) of patients censored [a]	42 (33.6%)	32 (25.8%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.8)	1.4 (1.0, 2.1)
	Nominal p-value for unstratified log-rank test [c]	0.328	
	HR (95% CI) [d]	0.87 (0.64, 1.17)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.129	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	29 (55.8%)	14 (31.1%)
	The number (%) of patients censored [a]	23 (44.2%)	31 (68.9%)
	Median time to event (95% CI) [b]	2.8 (1.5, 5.7)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.012	
	HR (95% CI) [d]	2.22 (1.17, 4.21)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	80 (64.0%)	79 (63.7%)
	The number (%) of patients censored [a]	45 (36.0%)	45 (36.3%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.6)	1.7 (1.4, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.697	
	HR (95% CI) [d]	1.06 (0.78, 1.46)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.8

Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.054	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.9

Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	30 (57.7%)	24 (53.3%)
	The number (%) of patients censored [a]	22 (42.3%)	21 (46.7%)
	Median time to event (95% CI) [b]	3.5 (1.6, 6.9)	3.1 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.730	
	HR (95% CI) [d]	1.10 (0.64, 1.90)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	58 (46.4%)	76 (61.3%)
	The number (%) of patients censored [a]	67 (53.6%)	48 (38.7%)
	Median time to event (95% CI) [b]	7.7 (2.5, 11.8)	2.8 (2.1, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.044	
	HR (95% CI) [d]	0.71 (0.50, 1.00)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.9

Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.128	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.10

Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	22 (42.3%)	24 (53.3%)
	The number (%) of patients censored [a]	30 (57.7%)	21 (46.7%)
	Median time to event (95% CI) [b]	7.2 (2.4, NE)	2.8 (1.5, 5.7)
	Nominal p-value for unstratified log-rank test [c]	0.077	
	HR (95% CI) [d]	0.59 (0.32, 1.07)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	43 (34.4%)	65 (52.4%)
	The number (%) of patients censored [a]	82 (65.6%)	59 (47.6%)
	Median time to event (95% CI) [b]	15.5 (9.6, NE)	4.9 (3.3, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	0.55 (0.37, 0.81)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.10

Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.830	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.11

Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	21 (40.4%)	20 (44.4%)
	The number (%) of patients censored [a]	31 (59.6%)	25 (55.6%)
	Median time to event (95% CI) [b]	5.5 (2.8, NE)	4.1 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.548	
	HR (95% CI) [d]	0.82 (0.44, 1.53)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	59 (47.2%)	67 (54.0%)
	The number (%) of patients censored [a]	66 (52.8%)	57 (46.0%)
	Median time to event (95% CI) [b]	5.3 (3.5, 10.8)	4.2 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	0.82 (0.58, 1.17)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.834	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.12

Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	23 (44.2%)	16 (35.6%)
	The number (%) of patients censored [a]	29 (55.8%)	29 (64.4%)
	Median time to event (95% CI) [b]	4.2 (1.7, NE)	7.3 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.410	
	HR (95% CI) [d]	1.31 (0.69, 2.49)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	64 (51.2%)	68 (54.8%)
	The number (%) of patients censored [a]	61 (48.8%)	56 (45.2%)
	Median time to event (95% CI) [b]	3.4 (1.8, 11.8)	3.5 (2.1, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.610	
	HR (95% CI) [d]	0.92 (0.65, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.12

Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.393	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.13

Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	30 (57.7%)	17 (37.8%)
	The number (%) of patients censored [a]	22 (42.3%)	28 (62.2%)
	Median time to event (95% CI) [b]	2.1 (1.4, 3.5)	6.7 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.041	
	HR (95% CI) [d]	1.84 (1.01, 3.36)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	67 (53.6%)	72 (58.1%)
	The number (%) of patients censored [a]	58 (46.4%)	52 (41.9%)
	Median time to event (95% CI) [b]	2.5 (1.8, 6.9)	2.3 (1.5, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.308	
	HR (95% CI) [d]	0.84 (0.60, 1.17)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.13

Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.030	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.14

Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	34 (65.4%)	24 (53.3%)
	The number (%) of patients censored [a]	18 (34.6%)	21 (46.7%)
	Median time to event (95% CI) [b]	1.7 (0.9, 2.2)	2.9 (1.9, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.045	
	HR (95% CI) [d]	1.70 (1.01, 2.88)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	84 (67.2%)	47 (37.9%)
	The number (%) of patients censored [a]	41 (32.8%)	77 (62.1%)
	Median time to event (95% CI) [b]	1.6 (1.0, 2.8)	10.1 (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.58 (1.80, 3.69)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.141	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	23 (44.2%)	18 (40.0%)
	The number (%) of patients censored [a]	29 (55.8%)	27 (60.0%)
	Median time to event (95% CI) [b]	7.9 (5.0, NE)	4.7 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.390	
	HR (95% CI) [d]	0.76 (0.40, 1.43)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	42 (33.6%)	45 (36.3%)
	The number (%) of patients censored [a]	83 (66.4%)	79 (63.7%)
	Median time to event (95% CI) [b]	19.0 (7.9, 27.9)	19.4 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.319	
	HR (95% CI) [d]	0.80 (0.52, 1.23)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.905	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.1

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	31 (59.6%)	24 (53.3%)
	The number (%) of patients censored [a]	21 (40.4%)	21 (46.7%)
	Median time to event (95% CI) [b]	1.7 (1.0, 4.2)	2.8 (1.5, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.301	
	HR (95% CI) [d]	1.33 (0.78, 2.28)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	70 (56.0%)	58 (46.8%)
	The number (%) of patients censored [a]	55 (44.0%)	66 (53.2%)
	Median time to event (95% CI) [b]	3.0 (1.8, 4.6)	5.2 (3.3, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.104	
	HR (95% CI) [d]	1.33 (0.94, 1.89)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.1

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.966	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.2

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	11 (21.2%)	12 (26.7%)
	The number (%) of patients censored [a]	41 (78.8%)	33 (73.3%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.224	
	HR (95% CI) [d]	0.59 (0.26, 1.38)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	35 (28.0%)	37 (29.8%)
	The number (%) of patients censored [a]	90 (72.0%)	87 (70.2%)
	Median time to event (95% CI) [b]	NE (13.3, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.579	
	HR (95% CI) [d]	0.88 (0.55, 1.39)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.465	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.3

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	1 (1.9%)	4 (8.9%)
	The number (%) of patients censored [a]	51 (98.1%)	41 (91.1%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.259	
	HR (95% CI) [d]	0.30 (0.03, 2.69)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	6 (4.8%)	5 (4.0%)
	The number (%) of patients censored [a]	119 (95.2%)	119 (96.0%)
	Median time to event (95% CI) [b]	NE (2.7, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.451	
	HR (95% CI) [d]	1.58 (0.48, 5.17)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.3

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.184	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.4

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	19 (36.5%)	10 (22.2%)
	The number (%) of patients censored [a]	33 (63.5%)	35 (77.8%)
	Median time to event (95% CI) [b]	5.5 (1.6, NE)	9.3 (3.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.308	
	HR (95% CI) [d]	1.50 (0.69, 3.24)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	50 (40.0%)	55 (44.4%)
	The number (%) of patients censored [a]	75 (60.0%)	69 (55.6%)
	Median time to event (95% CI) [b]	6.3 (2.4, 12.2)	4.9 (2.5, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.490	
	HR (95% CI) [d]	0.87 (0.59, 1.28)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.4

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.259	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - TPC of Chemotherapy Prior to Randomization (mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	40 (76.9%)	33 (73.3%)
	The number (%) of patients censored [a]	12 (23.1%)	12 (26.7%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.5)	1.1 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.226	
	HR (95% CI) [d]	1.33 (0.83, 2.12)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	91 (72.8%)	74 (59.7%)
	The number (%) of patients censored [a]	34 (27.2%)	50 (40.3%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.1)	3.1 (1.7, 5.1)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.87 (1.37, 2.54)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.166	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.6

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	17 (32.7%)	7 (15.6%)
	The number (%) of patients censored [a]	35 (67.3%)	38 (84.4%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	NE (9.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.200	
	HR (95% CI) [d]	1.78 (0.73, 4.33)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	36 (28.8%)	35 (28.2%)
	The number (%) of patients censored [a]	89 (71.2%)	89 (71.8%)
	Median time to event (95% CI) [b]	24.7 (17.1, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.768	
	HR (95% CI) [d]	0.93 (0.58, 1.49)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.6

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.202	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.7

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	27 (51.9%)	20 (44.4%)
	The number (%) of patients censored [a]	25 (48.1%)	25 (55.6%)
	Median time to event (95% CI) [b]	4.8 (1.7, 12.7)	3.8 (2.8, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.872	
	HR (95% CI) [d]	0.95 (0.53, 1.72)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	62 (49.6%)	69 (55.6%)
	The number (%) of patients censored [a]	63 (50.4%)	55 (44.4%)
	Median time to event (95% CI) [b]	6.8 (3.6, 10.8)	3.7 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.098	
	HR (95% CI) [d]	0.75 (0.53, 1.06)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.7

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.484	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.8

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	4 (7.7%)	6 (13.3%)
	The number (%) of patients censored [a]	48 (92.3%)	39 (86.7%)
	Median time to event (95% CI) [b]	7.9 (0.7, NE)	1.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.132	
	HR (95% CI) [d]	0.34 (0.08, 1.43)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	13 (10.4%)	13 (10.5%)
	The number (%) of patients censored [a]	112 (89.6%)	111 (89.5%)
	Median time to event (95% CI) [b]	1.2 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.894	
	HR (95% CI) [d]	1.03 (0.48, 2.22)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.2.8

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.218	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	27 (51.9%)	12 (26.7%)
	The number (%) of patients censored [a]	25 (48.1%)	33 (73.3%)
	Median time to event (95% CI) [b]	6.3 (3.2, 10.2)	11.1 (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.130	
	HR (95% CI) [d]	1.69 (0.85, 3.37)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	43 (34.4%)	44 (35.5%)
	The number (%) of patients censored [a]	82 (65.6%)	80 (64.5%)
	Median time to event (95% CI) [b]	18.7 (9.0, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.813	
	HR (95% CI) [d]	0.95 (0.62, 1.45)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.6.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.121	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.6.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	25 (48.1%)	15 (33.3%)
	The number (%) of patients censored [a]	27 (51.9%)	30 (66.7%)
	Median time to event (95% CI) [b]	3.6 (1.4, NE)	5.6 (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.307	
	HR (95% CI) [d]	1.40 (0.74, 2.66)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	50 (40.0%)	48 (38.7%)
	The number (%) of patients censored [a]	75 (60.0%)	76 (61.3%)
	Median time to event (95% CI) [b]	11.4 (4.1, 22.4)	15.9 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.669	
	HR (95% CI) [d]	1.09 (0.73, 1.61)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.642	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.5
Time to First Meaningful Deterioration for PGIC by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	15 (28.8%)	13 (28.9%)
	The number (%) of patients censored [a]	37 (71.2%)	32 (71.1%)
	Median time to event (95% CI) [b]	6.4 (5.0, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.378	
	HR (95% CI) [d]	0.71 (0.33, 1.51)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	25 (20.0%)	29 (23.4%)
	The number (%) of patients censored [a]	100 (80.0%)	95 (76.6%)
	Median time to event (95% CI) [b]	NE (NE, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.728	
	HR (95% CI) [d]	0.91 (0.53, 1.56)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.5
Time to First Meaningful Deterioration for PGIC by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.505	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.6
Time to First Meaningful Deterioration for PGIS by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Paclitaxel	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	52	45
	The number (%) of patients with an event [a]	6 (11.5%)	3 (6.7%)
	The number (%) of patients censored [a]	46 (88.5%)	42 (93.3%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.631	
	HR (95% CI) [d]	1.40 (0.35, 5.62)	
Gemcitabine/Carboplatin	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	125	124
	The number (%) of patients with an event [a]	11 (8.8%)	8 (6.5%)
	The number (%) of patients censored [a]	114 (91.2%)	116 (93.5%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.674	
	HR (95% CI) [d]	1.22 (0.49, 3.03)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.6.6
Time to First Meaningful Deterioration for PGIS by Subgroup - TPC of Chemotherapy Prior to Randomization
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.928	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	26 (55.3%)	14 (35.9%)
	The number (%) of patients censored [a]	21 (44.7%)	25 (64.1%)
	Median time to event (95% CI) [b]	5.0 (1.7, 8.4)	5.7 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.515	
	HR (95% CI) [d]	1.25 (0.65, 2.41)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	76 (58.5%)	82 (63.1%)
	The number (%) of patients censored [a]	54 (41.5%)	48 (36.9%)
	Median time to event (95% CI) [b]	3.2 (1.7, 5.6)	3.3 (2.1, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.614	
	HR (95% CI) [d]	0.93 (0.68, 1.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.342	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	21 (44.7%)	16 (41.0%)
	The number (%) of patients censored [a]	26 (55.3%)	23 (59.0%)
	Median time to event (95% CI) [b]	7.2 (3.5, 15.9)	4.6 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.537	
	HR (95% CI) [d]	0.81 (0.41, 1.59)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	68 (52.3%)	76 (58.5%)
	The number (%) of patients censored [a]	62 (47.7%)	54 (41.5%)
	Median time to event (95% CI) [b]	4.2 (2.3, 9.2)	4.9 (2.8, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.758	
	HR (95% CI) [d]	0.95 (0.69, 1.32)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.692	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	24 (51.1%)	20 (51.3%)
	The number (%) of patients censored [a]	23 (48.9%)	19 (48.7%)
	Median time to event (95% CI) [b]	2.5 (1.1, NE)	2.8 (1.0, 9.1)
	Nominal p-value for unstratified log-rank test [c]	0.841	
	HR (95% CI) [d]	0.94 (0.51, 1.71)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	79 (60.8%)	95 (73.1%)
	The number (%) of patients censored [a]	51 (39.2%)	35 (26.9%)
	Median time to event (95% CI) [b]	1.5 (1.4, 2.2)	2.6 (1.9, 3.8)
	Nominal p-value for unstratified log-rank test [c]	0.856	
	HR (95% CI) [d]	0.98 (0.72, 1.32)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.867	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	22 (46.8%)	6 (15.4%)
	The number (%) of patients censored [a]	25 (53.2%)	33 (84.6%)
	Median time to event (95% CI) [b]	7.7 (3.6, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.118	
	HR (95% CI) [d]	2.03 (0.82, 5.04)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	60 (46.2%)	62 (47.7%)
	The number (%) of patients censored [a]	70 (53.8%)	68 (52.3%)
	Median time to event (95% CI) [b]	8.4 (4.6, 12.2)	8.3 (5.7, 10.8)
	Nominal p-value for unstratified log-rank test [c]	0.700	
	HR (95% CI) [d]	0.93 (0.65, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.147	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	23 (48.9%)	18 (46.2%)
	The number (%) of patients censored [a]	24 (51.1%)	21 (53.8%)
	Median time to event (95% CI) [b]	4.3 (2.6, 13.1)	3.5 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.453	
	HR (95% CI) [d]	0.78 (0.42, 1.46)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	74 (56.9%)	86 (66.2%)
	The number (%) of patients censored [a]	56 (43.1%)	44 (33.8%)
	Median time to event (95% CI) [b]	4.2 (2.8, 5.7)	3.3 (2.2, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.260	
	HR (95% CI) [d]	0.84 (0.61, 1.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.948	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	25 (53.2%)	13 (33.3%)
	The number (%) of patients censored [a]	22 (46.8%)	26 (66.7%)
	Median time to event (95% CI) [b]	3.6 (1.6, 7.2)	NE (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.190	
	HR (95% CI) [d]	1.55 (0.79, 3.04)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	77 (59.2%)	87 (66.9%)
	The number (%) of patients censored [a]	53 (40.8%)	43 (33.1%)
	Median time to event (95% CI) [b]	2.2 (1.4, 3.5)	3.1 (1.9, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.513	
	HR (95% CI) [d]	0.90 (0.66, 1.23)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.181	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	32 (68.1%)	20 (51.3%)
	The number (%) of patients censored [a]	15 (31.9%)	19 (48.7%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.7)	1.9 (1.1, 5.4)
	Nominal p-value for unstratified log-rank test [c]	0.120	
	HR (95% CI) [d]	1.57 (0.90, 2.75)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	87 (66.9%)	104 (80.0%)
	The number (%) of patients censored [a]	43 (33.1%)	26 (20.0%)
	Median time to event (95% CI) [b]	1.5 (1.0, 1.8)	1.2 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.250	
	HR (95% CI) [d]	0.85 (0.64, 1.13)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.074	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	30 (63.8%)	19 (48.7%)
	The number (%) of patients censored [a]	17 (36.2%)	20 (51.3%)
	Median time to event (95% CI) [b]	1.8 (0.9, 3.1)	3.8 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.265	
	HR (95% CI) [d]	1.39 (0.78, 2.49)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	79 (60.8%)	74 (56.9%)
	The number (%) of patients censored [a]	51 (39.2%)	56 (43.1%)
	Median time to event (95% CI) [b]	2.0 (1.4, 2.9)	2.5 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.257	
	HR (95% CI) [d]	1.20 (0.87, 1.66)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.678	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	22 (46.8%)	17 (43.6%)
	The number (%) of patients censored [a]	25 (53.2%)	22 (56.4%)
	Median time to event (95% CI) [b]	5.0 (2.2, 16.0)	3.7 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.702	
	HR (95% CI) [d]	0.88 (0.45, 1.70)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	66 (50.8%)	83 (63.8%)
	The number (%) of patients censored [a]	64 (49.2%)	47 (36.2%)
	Median time to event (95% CI) [b]	5.6 (1.8, 7.8)	2.8 (2.2, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.196	
	HR (95% CI) [d]	0.81 (0.59, 1.12)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.793	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	15 (31.9%)	12 (30.8%)
	The number (%) of patients censored [a]	32 (68.1%)	27 (69.2%)
	Median time to event (95% CI) [b]	NE (3.8, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.438	
	HR (95% CI) [d]	0.74 (0.34, 1.59)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	50 (38.5%)	77 (59.2%)
	The number (%) of patients censored [a]	80 (61.5%)	53 (40.8%)
	Median time to event (95% CI) [b]	12.2 (7.2, NE)	4.4 (2.4, 5.5)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.55 (0.39, 0.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.563	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	23 (48.9%)	16 (41.0%)
	The number (%) of patients censored [a]	24 (51.1%)	23 (59.0%)
	Median time to event (95% CI) [b]	5.3 (2.3, NE)	3.1 (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.595	
	HR (95% CI) [d]	0.84 (0.44, 1.60)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	57 (43.8%)	71 (54.6%)
	The number (%) of patients censored [a]	73 (56.2%)	59 (45.4%)
	Median time to event (95% CI) [b]	5.5 (3.6, 14.4)	4.4 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.203	
	HR (95% CI) [d]	0.80 (0.56, 1.13)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.911	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	24 (51.1%)	12 (30.8%)
	The number (%) of patients censored [a]	23 (48.9%)	27 (69.2%)
	Median time to event (95% CI) [b]	3.1 (1.5, NE)	9.2 (1.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.252	
	HR (95% CI) [d]	1.51 (0.75, 3.03)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	63 (48.5%)	72 (55.4%)
	The number (%) of patients censored [a]	67 (51.5%)	58 (44.6%)
	Median time to event (95% CI) [b]	4.0 (2.0, 13.6)	3.5 (1.9, 7.3)
	Nominal p-value for unstratified log-rank test [c]	0.481	
	HR (95% CI) [d]	0.89 (0.63, 1.25)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.175	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	26 (55.3%)	19 (48.7%)
	The number (%) of patients censored [a]	21 (44.7%)	20 (51.3%)
	Median time to event (95% CI) [b]	2.3 (1.6, 12.4)	1.6 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.459	
	HR (95% CI) [d]	0.79 (0.43, 1.45)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	71 (54.6%)	70 (53.8%)
	The number (%) of patients censored [a]	59 (45.4%)	60 (46.2%)
	Median time to event (95% CI) [b]	2.4 (1.7, 4.2)	4.0 (2.2, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.799	
	HR (95% CI) [d]	1.04 (0.75, 1.45)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.558	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	35 (74.5%)	10 (25.6%)
	The number (%) of patients censored [a]	12 (25.5%)	29 (74.4%)
	Median time to event (95% CI) [b]	1.0 (0.9, 2.2)	10.1 (3.9, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	3.68 (1.81, 7.48)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	83 (63.8%)	61 (46.9%)
	The number (%) of patients censored [a]	47 (36.2%)	69 (53.1%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.9)	6.0 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.05 (1.47, 2.86)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.111	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	17 (36.2%)	6 (15.4%)
	The number (%) of patients censored [a]	30 (63.8%)	33 (84.6%)
	Median time to event (95% CI) [b]	10.5 (4.3, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.480	
	HR (95% CI) [d]	1.41 (0.54, 3.66)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	48 (36.9%)	57 (43.8%)
	The number (%) of patients censored [a]	82 (63.1%)	73 (56.2%)
	Median time to event (95% CI) [b]	9.8 (7.4, NE)	6.3 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.161	
	HR (95% CI) [d]	0.76 (0.51, 1.12)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.156	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	28 (59.6%)	13 (33.3%)
	The number (%) of patients censored [a]	19 (40.4%)	26 (66.7%)
	Median time to event (95% CI) [b]	2.1 (1.4, 5.8)	5.0 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.099	
	HR (95% CI) [d]	1.74 (0.89, 3.39)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	73 (56.2%)	69 (53.1%)
	The number (%) of patients censored [a]	57 (43.8%)	61 (46.9%)
	Median time to event (95% CI) [b]	2.5 (1.7, 4.2)	3.8 (2.1, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.198	
	HR (95% CI) [d]	1.24 (0.89, 1.73)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.341	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	11 (23.4%)	11 (28.2%)
	The number (%) of patients censored [a]	36 (76.6%)	28 (71.8%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (2.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.158	
	HR (95% CI) [d]	0.55 (0.23, 1.28)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	35 (26.9%)	38 (29.2%)
	The number (%) of patients censored [a]	95 (73.1%)	92 (70.8%)
	Median time to event (95% CI) [b]	NE (15.8, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.590	
	HR (95% CI) [d]	0.88 (0.56, 1.40)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.350	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	3 (6.4%)	0 (0.0%)
	The number (%) of patients censored [a]	44 (93.6%)	39 (100.0%)
	Median time to event (95% CI) [b]	NE (1.1, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.198	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	4 (3.1%)	9 (6.9%)
	The number (%) of patients censored [a]	126 (96.9%)	121 (93.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.687	
	HR (95% CI) [d]	0.79 (0.24, 2.56)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.992	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	20 (42.6%)	8 (20.5%)
	The number (%) of patients censored [a]	27 (57.4%)	31 (79.5%)
	Median time to event (95% CI) [b]	4.2 (2.2, 12.6)	13.8 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.320	
	HR (95% CI) [d]	1.51 (0.66, 3.46)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	49 (37.7%)	57 (43.8%)
	The number (%) of patients censored [a]	81 (62.3%)	73 (56.2%)
	Median time to event (95% CI) [b]	6.3 (2.2, 12.2)	5.4 (3.0, 8.8)
	Nominal p-value for unstratified log-rank test [c]	0.529	
	HR (95% CI) [d]	0.88 (0.60, 1.30)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.200	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	35 (74.5%)	19 (48.7%)
	The number (%) of patients censored [a]	12 (25.5%)	20 (51.3%)
	Median time to event (95% CI) [b]	1.1 (0.8, 1.6)	2.7 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.032	
	HR (95% CI) [d]	1.83 (1.05, 3.20)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	96 (73.8%)	88 (67.7%)
	The number (%) of patients censored [a]	34 (26.2%)	42 (32.3%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.1)	1.9 (1.4, 3.8)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.78 (1.33, 2.39)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.965	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	12 (25.5%)	4 (10.3%)
	The number (%) of patients censored [a]	35 (74.5%)	35 (89.7%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.179	
	HR (95% CI) [d]	2.13 (0.69, 6.62)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	41 (31.5%)	38 (29.2%)
	The number (%) of patients censored [a]	89 (68.5%)	92 (70.8%)
	Median time to event (95% CI) [b]	17.5 (10.0, NE)	NE (9.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.906	
	HR (95% CI) [d]	1.03 (0.66, 1.60)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.416	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	20 (42.6%)	14 (35.9%)
	The number (%) of patients censored [a]	27 (57.4%)	25 (64.1%)
	Median time to event (95% CI) [b]	9.6 (3.2, NE)	5.0 (3.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.574	
	HR (95% CI) [d]	0.82 (0.40, 1.65)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	69 (53.1%)	75 (57.7%)
	The number (%) of patients censored [a]	61 (46.9%)	55 (42.3%)
	Median time to event (95% CI) [b]	4.8 (3.3, 9.3)	3.1 (2.2, 5.1)
	Nominal p-value for unstratified log-rank test [c]	0.200	
	HR (95% CI) [d]	0.81 (0.58, 1.12)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.828	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	3 (6.4%)	1 (2.6%)
	The number (%) of patients censored [a]	44 (93.6%)	38 (97.4%)
	Median time to event (95% CI) [b]	3.5 (0.9, NE)	NE (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.514	
	HR (95% CI) [d]	2.10 (0.22, 20.49)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	14 (10.8%)	18 (13.8%)
	The number (%) of patients censored [a]	116 (89.2%)	112 (86.2%)
	Median time to event (95% CI) [b]	2.2 (0.8, NE)	1.4 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.441	
	HR (95% CI) [d]	0.75 (0.37, 1.52)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.471	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	21 (44.7%)	10 (25.6%)
	The number (%) of patients censored [a]	26 (55.3%)	29 (74.4%)
	Median time to event (95% CI) [b]	8.8 (3.6, 18.7)	NE (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.424	
	HR (95% CI) [d]	1.36 (0.63, 2.92)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	49 (37.7%)	46 (35.4%)
	The number (%) of patients censored [a]	81 (62.3%)	84 (64.6%)
	Median time to event (95% CI) [b]	12.0 (7.2, NE)	13.0 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.695	
	HR (95% CI) [d]	1.09 (0.73, 1.63)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.7.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.591	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.7.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	23 (48.9%)	14 (35.9%)
	The number (%) of patients censored [a]	24 (51.1%)	25 (64.1%)
	Median time to event (95% CI) [b]	9.6 (3.5, 18.6)	15.9 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.885	
	HR (95% CI) [d]	0.95 (0.47, 1.89)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	52 (40.0%)	49 (37.7%)
	The number (%) of patients censored [a]	78 (60.0%)	81 (62.3%)
	Median time to event (95% CI) [b]	9.1 (3.5, NE)	16.1 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.421	
	HR (95% CI) [d]	1.17 (0.79, 1.73)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.775	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	8 (17.0%)	5 (12.8%)
	The number (%) of patients censored [a]	39 (83.0%)	34 (87.2%)
	Median time to event (95% CI) [b]	6.4 (6.4, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	0.90 (0.29, 2.76)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	32 (24.6%)	37 (28.5%)
	The number (%) of patients censored [a]	98 (75.4%)	93 (71.5%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.621	
	HR (95% CI) [d]	0.89 (0.55, 1.42)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.936	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	47	39
	The number (%) of patients with an event [a]	4 (8.5%)	2 (5.1%)
	The number (%) of patients censored [a]	43 (91.5%)	37 (94.9%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.982	
	HR (95% CI) [d]	0.98 (0.18, 5.35)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	130	130
	The number (%) of patients with an event [a]	13 (10.0%)	9 (6.9%)
	The number (%) of patients censored [a]	117 (90.0%)	121 (93.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.539	
	HR (95% CI) [d]	1.30 (0.56, 3.05)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.7.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Liver Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.687	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	3 (37.5%)	4 (44.4%)
	The number (%) of patients censored [a]	5 (62.5%)	5 (55.6%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	2.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.942	
	HR (95% CI) [d]	0.99 (0.22, 4.43)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	99 (58.6%)	92 (57.5%)
	The number (%) of patients censored [a]	70 (41.4%)	68 (42.5%)
	Median time to event (95% CI) [b]	3.6 (2.1, 5.7)	4.1 (2.6, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.808	
	HR (95% CI) [d]	0.97 (0.73, 1.29)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.938	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	2 (25.0%)	5 (55.6%)
	The number (%) of patients censored [a]	6 (75.0%)	4 (44.4%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.206	
	HR (95% CI) [d]	0.38 (0.07, 1.98)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	87 (51.5%)	87 (54.4%)
	The number (%) of patients censored [a]	82 (48.5%)	73 (45.6%)
	Median time to event (95% CI) [b]	5.3 (3.1, 8.8)	4.7 (3.1, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.729	
	HR (95% CI) [d]	0.95 (0.71, 1.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.185	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	3 (37.5%)	5 (55.6%)
	The number (%) of patients censored [a]	5 (62.5%)	4 (44.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	4.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.549	
	HR (95% CI) [d]	0.67 (0.16, 2.82)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	100 (59.2%)	110 (68.8%)
	The number (%) of patients censored [a]	69 (40.8%)	50 (31.3%)
	Median time to event (95% CI) [b]	1.5 (1.4, 2.3)	2.8 (1.9, 3.7)
	Nominal p-value for unstratified log-rank test [c]	0.791	
	HR (95% CI) [d]	0.97 (0.74, 1.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.518	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	5 (62.5%)	3 (33.3%)
	The number (%) of patients censored [a]	3 (37.5%)	6 (66.7%)
	Median time to event (95% CI) [b]	3.1 (0.8, NE)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.423	
	HR (95% CI) [d]	1.78 (0.42, 7.51)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	77 (45.6%)	65 (40.6%)
	The number (%) of patients censored [a]	92 (54.4%)	95 (59.4%)
	Median time to event (95% CI) [b]	8.8 (4.9, 11.8)	9.1 (6.5, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.988	
	HR (95% CI) [d]	1.00 (0.72, 1.40)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.367	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	5 (55.6%)
	The number (%) of patients censored [a]	4 (50.0%)	4 (44.4%)
	Median time to event (95% CI) [b]	1.7 (0.7, NE)	2.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.805	
	HR (95% CI) [d]	0.87 (0.23, 3.27)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	93 (55.0%)	99 (61.9%)
	The number (%) of patients censored [a]	76 (45.0%)	61 (38.1%)
	Median time to event (95% CI) [b]	4.2 (2.9, 5.7)	3.5 (2.4, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.184	
	HR (95% CI) [d]	0.83 (0.62, 1.10)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.931	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	5 (55.6%)
	The number (%) of patients censored [a]	4 (50.0%)	4 (44.4%)
	Median time to event (95% CI) [b]	1.2 (0.7, NE)	2.9 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.985	
	HR (95% CI) [d]	1.03 (0.27, 3.85)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	98 (58.0%)	95 (59.4%)
	The number (%) of patients censored [a]	71 (42.0%)	65 (40.6%)
	Median time to event (95% CI) [b]	2.5 (1.6, 3.8)	3.3 (2.2, 4.8)
	Nominal p-value for unstratified log-rank test [c]	0.871	
	HR (95% CI) [d]	0.98 (0.74, 1.30)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.994	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	5 (62.5%)	5 (55.6%)
	The number (%) of patients censored [a]	3 (37.5%)	4 (44.4%)
	Median time to event (95% CI) [b]	0.8 (0.7, NE)	4.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.239	
	HR (95% CI) [d]	2.13 (0.60, 7.53)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	114 (67.5%)	119 (74.4%)
	The number (%) of patients censored [a]	55 (32.5%)	41 (25.6%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.7)	1.4 (1.1, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.543	
	HR (95% CI) [d]	0.93 (0.72, 1.20)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.159	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	4 (44.4%)
	The number (%) of patients censored [a]	4 (50.0%)	5 (55.6%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	8.1 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.779	
	HR (95% CI) [d]	0.82 (0.20, 3.29)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	105 (62.1%)	89 (55.6%)
	The number (%) of patients censored [a]	64 (37.9%)	71 (44.4%)
	Median time to event (95% CI) [b]	1.8 (1.4, 2.8)	2.6 (1.7, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.102	
	HR (95% CI) [d]	1.27 (0.95, 1.68)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.617	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	5 (55.6%)
	The number (%) of patients censored [a]	4 (50.0%)	4 (44.4%)
	Median time to event (95% CI) [b]	1.7 (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.914	
	HR (95% CI) [d]	1.08 (0.27, 4.32)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	84 (49.7%)	95 (59.4%)
	The number (%) of patients censored [a]	85 (50.3%)	65 (40.6%)
	Median time to event (95% CI) [b]	5.6 (2.4, 8.8)	3.0 (2.4, 4.4)
	Nominal p-value for unstratified log-rank test [c]	0.140	
	HR (95% CI) [d]	0.80 (0.60, 1.08)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.576	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	2 (25.0%)	4 (44.4%)
	The number (%) of patients censored [a]	6 (75.0%)	5 (55.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	2.8 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.462	
	HR (95% CI) [d]	0.53 (0.10, 2.92)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	63 (37.3%)	85 (53.1%)
	The number (%) of patients censored [a]	106 (62.7%)	75 (46.9%)
	Median time to event (95% CI) [b]	12.2 (7.7, NE)	4.9 (3.1, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	0.57 (0.41, 0.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.978	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	5 (55.6%)
	The number (%) of patients censored [a]	7 (87.5%)	4 (44.4%)
	Median time to event (95% CI) [b]	NE (5.3, NE)	1.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.024	
	HR (95% CI) [d]	0.12 (0.01, 1.05)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	79 (46.7%)	82 (51.3%)
	The number (%) of patients censored [a]	90 (53.3%)	78 (48.8%)
	Median time to event (95% CI) [b]	5.1 (3.5, 9.1)	4.2 (3.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.375	
	HR (95% CI) [d]	0.87 (0.64, 1.19)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.071	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	3 (37.5%)	4 (44.4%)
	The number (%) of patients censored [a]	5 (62.5%)	5 (55.6%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.491	
	HR (95% CI) [d]	0.62 (0.14, 2.80)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	84 (49.7%)	80 (50.0%)
	The number (%) of patients censored [a]	85 (50.3%)	80 (50.0%)
	Median time to event (95% CI) [b]	3.6 (2.0, 8.8)	5.0 (2.6, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.961	
	HR (95% CI) [d]	1.01 (0.74, 1.38)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.349	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	4 (44.4%)
	The number (%) of patients censored [a]	4 (50.0%)	5 (55.6%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	6.5 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.663	
	HR (95% CI) [d]	1.44 (0.32, 6.46)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	93 (55.0%)	85 (53.1%)
	The number (%) of patients censored [a]	76 (45.0%)	75 (46.9%)
	Median time to event (95% CI) [b]	2.4 (1.7, 3.7)	3.3 (1.9, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.993	
	HR (95% CI) [d]	1.00 (0.74, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.718	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	7 (87.5%)	3 (33.3%)
	The number (%) of patients censored [a]	1 (12.5%)	6 (66.7%)
	Median time to event (95% CI) [b]	1.5 (0.7, 1.8)	NE (1.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	14.73 (1.73, 125.55)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	111 (65.7%)	68 (42.5%)
	The number (%) of patients censored [a]	58 (34.3%)	92 (57.5%)
	Median time to event (95% CI) [b]	1.7 (1.2, 2.4)	6.9 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.20 (1.62, 2.98)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.109	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	2 (22.2%)
	The number (%) of patients censored [a]	4 (50.0%)	7 (77.8%)
	Median time to event (95% CI) [b]	2.1 (0.7, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.180	
	HR (95% CI) [d]	2.99 (0.55, 16.40)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	61 (36.1%)	61 (38.1%)
	The number (%) of patients censored [a]	108 (63.9%)	99 (61.9%)
	Median time to event (95% CI) [b]	10.5 (7.9, 27.9)	8.7 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.154	
	HR (95% CI) [d]	0.77 (0.54, 1.10)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.089	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	5 (62.5%)	3 (33.3%)
	The number (%) of patients censored [a]	3 (37.5%)	6 (66.7%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	NE (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.523	
	HR (95% CI) [d]	1.55 (0.36, 6.61)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	96 (56.8%)	79 (49.4%)
	The number (%) of patients censored [a]	73 (43.2%)	81 (50.6%)
	Median time to event (95% CI) [b]	2.5 (1.7, 3.7)	5.0 (2.8, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.073	
	HR (95% CI) [d]	1.32 (0.98, 1.77)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.683	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	3 (33.3%)
	The number (%) of patients censored [a]	7 (87.5%)	6 (66.7%)
	Median time to event (95% CI) [b]	NE (3.1, NE)	8.7 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.463	
	HR (95% CI) [d]	0.43 (0.04, 4.30)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	45 (26.6%)	46 (28.8%)
	The number (%) of patients censored [a]	124 (73.4%)	114 (71.3%)
	Median time to event (95% CI) [b]	NE (18.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.394	
	HR (95% CI) [d]	0.84 (0.55, 1.26)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.425	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	8 (100.0%)	9 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	7 (4.1%)	9 (5.6%)
	The number (%) of patients censored [a]	162 (95.9%)	151 (94.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.942	
	HR (95% CI) [d]	1.04 (0.39, 2.79)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	2 (25.0%)	3 (33.3%)
	The number (%) of patients censored [a]	6 (75.0%)	6 (66.7%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.521	
	HR (95% CI) [d]	0.55 (0.09, 3.31)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	67 (39.6%)	62 (38.8%)
	The number (%) of patients censored [a]	102 (60.4%)	98 (61.3%)
	Median time to event (95% CI) [b]	5.6 (3.6, 9.8)	6.3 (3.3, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.886	
	HR (95% CI) [d]	0.97 (0.69, 1.38)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.707	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	4 (50.0%)	3 (33.3%)
	The number (%) of patients censored [a]	4 (50.0%)	6 (66.7%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	8.1 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.630	
	HR (95% CI) [d]	1.45 (0.32, 6.59)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	127 (75.1%)	104 (65.0%)
	The number (%) of patients censored [a]	42 (24.9%)	56 (35.0%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.1)	2.0 (1.4, 3.3)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	1.77 (1.36, 2.30)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.831	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	2 (22.2%)
	The number (%) of patients censored [a]	7 (87.5%)	7 (77.8%)
	Median time to event (95% CI) [b]	NE (3.9, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.712	
	HR (95% CI) [d]	0.63 (0.05, 7.48)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	52 (30.8%)	40 (25.0%)
	The number (%) of patients censored [a]	117 (69.2%)	120 (75.0%)
	Median time to event (95% CI) [b]	24.7 (10.1, NE)	NE (12.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.617	
	HR (95% CI) [d]	1.11 (0.73, 1.68)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.555	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	2 (25.0%)	5 (55.6%)
	The number (%) of patients censored [a]	6 (75.0%)	4 (44.4%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	3.2 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.162	
	HR (95% CI) [d]	0.33 (0.06, 1.72)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	87 (51.5%)	84 (52.5%)
	The number (%) of patients censored [a]	82 (48.5%)	76 (47.5%)
	Median time to event (95% CI) [b]	5.6 (3.6, 9.3)	3.8 (2.8, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.214	
	HR (95% CI) [d]	0.83 (0.61, 1.12)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.255	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	2 (22.2%)
	The number (%) of patients censored [a]	7 (87.5%)	7 (77.8%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	0.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.302	
	HR (95% CI) [d]	0.29 (0.03, 3.42)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	16 (9.5%)	17 (10.6%)
	The number (%) of patients censored [a]	153 (90.5%)	143 (89.4%)
	Median time to event (95% CI) [b]	2.8 (0.9, 7.9)	1.4 (1.0, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.779	
	HR (95% CI) [d]	0.89 (0.45, 1.77)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.087	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	1 (11.1%)
	The number (%) of patients censored [a]	7 (87.5%)	8 (88.9%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.992	
	HR (95% CI) [d]	1.01 (0.06, 16.37)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	69 (40.8%)	55 (34.4%)
	The number (%) of patients censored [a]	100 (59.2%)	105 (65.6%)
	Median time to event (95% CI) [b]	9.8 (6.3, 18.7)	12.4 (10.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.441	
	HR (95% CI) [d]	1.15 (0.81, 1.65)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.8.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.990	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.8.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	3 (33.3%)
	The number (%) of patients censored [a]	7 (87.5%)	6 (66.7%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	2.8 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.459	
	HR (95% CI) [d]	0.43 (0.04, 4.21)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	74 (43.8%)	60 (37.5%)
	The number (%) of patients censored [a]	95 (56.2%)	100 (62.5%)
	Median time to event (95% CI) [b]	9.1 (3.7, 18.6)	15.9 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.311	
	HR (95% CI) [d]	1.19 (0.85, 1.67)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.309	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	0 (0.0%)	2 (22.2%)
	The number (%) of patients censored [a]	8 (100.0%)	7 (77.8%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.200	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	40 (23.7%)	40 (25.0%)
	The number (%) of patients censored [a]	129 (76.3%)	120 (75.0%)
	Median time to event (95% CI) [b]	NE (6.4, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.645	
	HR (95% CI) [d]	0.90 (0.58, 1.40)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.979	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Yes	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	8	9
	The number (%) of patients with an event [a]	1 (12.5%)	0 (0.0%)
	The number (%) of patients censored [a]	7 (87.5%)	9 (100.0%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.221	
	HR (95% CI) [d]	NE (NE, NE)	
No	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	169	160
	The number (%) of patients with an event [a]	16 (9.5%)	11 (6.9%)
	The number (%) of patients censored [a]	153 (90.5%)	149 (93.1%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.708	
	HR (95% CI) [d]	1.16 (0.54, 2.50)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.8.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Brain Metastasis
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.988	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	42 (63.6%)	40 (61.5%)
	The number (%) of patients censored [a]	24 (36.4%)	25 (38.5%)
	Median time to event (95% CI) [b]	3.6 (1.4, 5.1)	2.7 (1.6, 4.7)
	Nominal p-value for unstratified log-rank test [c]	0.616	
	HR (95% CI) [d]	0.90 (0.58, 1.39)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	6 (50.0%)	4 (40.0%)
	The number (%) of patients censored [a]	6 (50.0%)	6 (60.0%)
	Median time to event (95% CI) [b]	2.3 (0.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	1.54 (0.43, 5.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.370	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	34 (51.5%)	36 (55.4%)
	The number (%) of patients censored [a]	32 (48.5%)	29 (44.6%)
	Median time to event (95% CI) [b]	5.6 (1.7, NE)	3.7 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.421	
	HR (95% CI) [d]	0.83 (0.51, 1.34)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	6 (50.0%)	4 (40.0%)
	The number (%) of patients censored [a]	6 (50.0%)	6 (60.0%)
	Median time to event (95% CI) [b]	6.3 (0.8, NE)	19.4 (2.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.262	
	HR (95% CI) [d]	2.17 (0.54, 8.72)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.213	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	40 (60.6%)	44 (67.7%)
	The number (%) of patients censored [a]	26 (39.4%)	21 (32.3%)
	Median time to event (95% CI) [b]	1.5 (1.0, 3.2)	1.9 (1.0, 3.1)
	Nominal p-value for unstratified log-rank test [c]	0.574	
	HR (95% CI) [d]	0.89 (0.58, 1.37)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	7 (58.3%)	4 (40.0%)
	The number (%) of patients censored [a]	5 (41.7%)	6 (60.0%)
	Median time to event (95% CI) [b]	1.1 (0.8, NE)	10.6 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.109	
	HR (95% CI) [d]	2.98 (0.74, 11.91)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.104	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	38 (57.6%)	23 (35.4%)
	The number (%) of patients censored [a]	28 (42.4%)	42 (64.6%)
	Median time to event (95% CI) [b]	6.0 (4.2, 9.0)	10.0 (6.9, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.183	
	HR (95% CI) [d]	1.43 (0.85, 2.41)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	4 (33.3%)	3 (30.0%)
	The number (%) of patients censored [a]	8 (66.7%)	7 (70.0%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.725	
	HR (95% CI) [d]	1.32 (0.29, 5.97)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.922	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	44 (66.7%)	37 (56.9%)
	The number (%) of patients censored [a]	22 (33.3%)	28 (43.1%)
	Median time to event (95% CI) [b]	3.6 (2.8, 4.9)	3.5 (2.1, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.896	
	HR (95% CI) [d]	1.03 (0.66, 1.60)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	6 (50.0%)	7 (70.0%)
	The number (%) of patients censored [a]	6 (50.0%)	3 (30.0%)
	Median time to event (95% CI) [b]	7.9 (0.8, NE)	3.0 (0.7, 7.3)
	Nominal p-value for unstratified log-rank test [c]	0.349	
	HR (95% CI) [d]	0.60 (0.20, 1.79)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.379	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	40 (60.6%)	34 (52.3%)
	The number (%) of patients censored [a]	26 (39.4%)	31 (47.7%)
	Median time to event (95% CI) [b]	2.2 (1.5, 3.6)	3.6 (1.6, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.507	
	HR (95% CI) [d]	1.17 (0.74, 1.85)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	7 (58.3%)	7 (70.0%)
	The number (%) of patients censored [a]	5 (41.7%)	3 (30.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.598	
	HR (95% CI) [d]	0.75 (0.25, 2.27)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.484	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	44 (66.7%)	49 (75.4%)
	The number (%) of patients censored [a]	22 (33.3%)	16 (24.6%)
	Median time to event (95% CI) [b]	1.4 (0.8, 2.4)	1.9 (1.1, 3.0)
	Nominal p-value for unstratified log-rank test [c]	0.641	
	HR (95% CI) [d]	0.92 (0.61, 1.38)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	8 (66.7%)	6 (60.0%)
	The number (%) of patients censored [a]	4 (33.3%)	4 (40.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, NE)	1.2 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.890	
	HR (95% CI) [d]	1.09 (0.38, 3.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.837	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	40 (60.6%)	34 (52.3%)
	The number (%) of patients censored [a]	26 (39.4%)	31 (47.7%)
	Median time to event (95% CI) [b]	2.1 (1.5, 5.7)	2.5 (1.7, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.361	
	HR (95% CI) [d]	1.24 (0.79, 1.96)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	5 (41.7%)	4 (40.0%)
	The number (%) of patients censored [a]	7 (58.3%)	6 (60.0%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	9.5 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.901	
	HR (95% CI) [d]	1.10 (0.29, 4.12)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.942	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	35 (53.0%)	40 (61.5%)
	The number (%) of patients censored [a]	31 (47.0%)	25 (38.5%)
	Median time to event (95% CI) [b]	5.6 (2.4, 10.0)	2.8 (1.5, 3.7)
	Nominal p-value for unstratified log-rank test [c]	0.188	
	HR (95% CI) [d]	0.74 (0.46, 1.17)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	8 (66.7%)	5 (50.0%)
	The number (%) of patients censored [a]	4 (33.3%)	5 (50.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, 6.9)	4.1 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.291	
	HR (95% CI) [d]	1.83 (0.59, 5.67)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.081	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	23 (34.8%)	35 (53.8%)
	The number (%) of patients censored [a]	43 (65.2%)	30 (46.2%)
	Median time to event (95% CI) [b]	12.2 (6.3, NE)	3.1 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	0.48 (0.28, 0.82)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	3 (25.0%)	5 (50.0%)
	The number (%) of patients censored [a]	9 (75.0%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (1.9, NE)	6.3 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.238	
	HR (95% CI) [d]	0.43 (0.10, 1.82)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.918	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	31 (47.0%)	31 (47.7%)
	The number (%) of patients censored [a]	35 (53.0%)	34 (52.3%)
	Median time to event (95% CI) [b]	5.4 (3.5, 14.4)	4.2 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.541	
	HR (95% CI) [d]	0.85 (0.52, 1.40)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	7 (58.3%)	4 (40.0%)
	The number (%) of patients censored [a]	5 (41.7%)	6 (60.0%)
	Median time to event (95% CI) [b]	1.9 (0.8, NE)	9.0 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.113	
	HR (95% CI) [d]	2.70 (0.76, 9.60)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.070	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	31 (47.0%)	30 (46.2%)
	The number (%) of patients censored [a]	35 (53.0%)	35 (53.8%)
	Median time to event (95% CI) [b]	4.1 (2.1, NE)	5.2 (2.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.928	
	HR (95% CI) [d]	0.98 (0.59, 1.62)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	6 (50.0%)	5 (50.0%)
	The number (%) of patients censored [a]	6 (50.0%)	5 (50.0%)
	Median time to event (95% CI) [b]	4.2 (0.8, NE)	3.5 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.708	
	HR (95% CI) [d]	0.79 (0.24, 2.61)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.752	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	38 (57.6%)	30 (46.2%)
	The number (%) of patients censored [a]	28 (42.4%)	35 (53.8%)
	Median time to event (95% CI) [b]	2.8 (1.7, 6.9)	4.7 (1.9, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.631	
	HR (95% CI) [d]	1.12 (0.70, 1.82)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	7 (58.3%)	6 (60.0%)
	The number (%) of patients censored [a]	5 (41.7%)	4 (40.0%)
	Median time to event (95% CI) [b]	1.0 (0.7, NE)	6.7 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.934	
	HR (95% CI) [d]	1.02 (0.34, 3.06)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.833	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	47 (71.2%)	27 (41.5%)
	The number (%) of patients censored [a]	19 (28.8%)	38 (58.5%)
	Median time to event (95% CI) [b]	1.5 (0.9, 2.1)	5.8 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.70 (1.67, 4.35)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	10 (83.3%)	5 (50.0%)
	The number (%) of patients censored [a]	2 (16.7%)	5 (50.0%)
	Median time to event (95% CI) [b]	2.6 (0.8, 5.8)	4.9 (1.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.086	
	HR (95% CI) [d]	2.50 (0.85, 7.40)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.828	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	24 (36.4%)	25 (38.5%)
	The number (%) of patients censored [a]	42 (63.6%)	40 (61.5%)
	Median time to event (95% CI) [b]	10.5 (5.5, NE)	5.2 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.364	
	HR (95% CI) [d]	0.77 (0.44, 1.36)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	3 (25.0%)	5 (50.0%)
	The number (%) of patients censored [a]	9 (75.0%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (0.8, NE)	19.4 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.720	
	HR (95% CI) [d]	0.76 (0.17, 3.42)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.809	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	42 (63.6%)	34 (52.3%)
	The number (%) of patients censored [a]	24 (36.4%)	31 (47.7%)
	Median time to event (95% CI) [b]	1.6 (1.0, 3.5)	2.1 (1.4, 5.0)
	Nominal p-value for unstratified log-rank test [c]	0.189	
	HR (95% CI) [d]	1.36 (0.86, 2.13)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	7 (58.3%)	4 (40.0%)
	The number (%) of patients censored [a]	5 (41.7%)	6 (60.0%)
	Median time to event (95% CI) [b]	1.5 (0.7, NE)	NE (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.166	
	HR (95% CI) [d]	2.34 (0.68, 8.04)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.376	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	13 (19.7%)	16 (24.6%)
	The number (%) of patients censored [a]	53 (80.3%)	49 (75.4%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.436	
	HR (95% CI) [d]	0.75 (0.36, 1.56)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	1 (8.3%)	5 (50.0%)
	The number (%) of patients censored [a]	11 (91.7%)	5 (50.0%)
	Median time to event (95% CI) [b]	NE (3.6, NE)	3.8 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.036	
	HR (95% CI) [d]	0.14 (0.02, 1.20)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.138	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	2 (3.0%)	3 (4.6%)
	The number (%) of patients censored [a]	64 (97.0%)	62 (95.4%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.944	
	HR (95% CI) [d]	0.94 (0.16, 5.62)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	0 (0.0%)	0 (0.0%)
	The number (%) of patients censored [a]	12 (100.0%)	10 (100.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	1.000	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	24 (36.4%)	22 (33.8%)
	The number (%) of patients censored [a]	42 (63.6%)	43 (66.2%)
	Median time to event (95% CI) [b]	8.3 (2.2, 12.6)	5.4 (2.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.838	
	HR (95% CI) [d]	0.94 (0.52, 1.68)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	5 (41.7%)	4 (40.0%)
	The number (%) of patients censored [a]	7 (58.3%)	6 (60.0%)
	Median time to event (95% CI) [b]	1.2 (1.0, NE)	6.3 (1.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.201	
	HR (95% CI) [d]	2.38 (0.62, 9.05)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.250	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	49 (74.2%)	39 (60.0%)
	The number (%) of patients censored [a]	17 (25.8%)	26 (40.0%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.4)	1.7 (1.2, 4.0)
	Nominal p-value for unstratified log-rank test [c]	0.002	
	HR (95% CI) [d]	1.94 (1.27, 2.97)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	9 (75.0%)	6 (60.0%)
	The number (%) of patients censored [a]	3 (25.0%)	4 (40.0%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.2)	1.9 (0.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.130	
	HR (95% CI) [d]	2.24 (0.77, 6.46)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.599	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	20 (30.3%)	19 (29.2%)
	The number (%) of patients censored [a]	46 (69.7%)	46 (70.8%)
	Median time to event (95% CI) [b]	NE (5.4, NE)	9.8 (7.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.673	
	HR (95% CI) [d]	0.87 (0.47, 1.64)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	3 (25.0%)	2 (20.0%)
	The number (%) of patients censored [a]	9 (75.0%)	8 (80.0%)
	Median time to event (95% CI) [b]	NE (2.8, NE)	NE (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.947	
	HR (95% CI) [d]	1.06 (0.17, 6.52)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.815	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	37 (56.1%)	31 (47.7%)
	The number (%) of patients censored [a]	29 (43.9%)	34 (52.3%)
	Median time to event (95% CI) [b]	5.0 (3.1, 9.6)	4.2 (1.9, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.880	
	HR (95% CI) [d]	0.96 (0.60, 1.56)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	7 (58.3%)	6 (60.0%)
	The number (%) of patients censored [a]	5 (41.7%)	4 (40.0%)
	Median time to event (95% CI) [b]	4.8 (1.0, NE)	3.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.551	
	HR (95% CI) [d]	0.71 (0.24, 2.13)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.693	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	8 (12.1%)	7 (10.8%)
	The number (%) of patients censored [a]	58 (87.9%)	58 (89.2%)
	Median time to event (95% CI) [b]	0.8 (0.7, 0.9)	1.4 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	5.19 (1.58, 17.07)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	1 (8.3%)	0 (0.0%)
	The number (%) of patients censored [a]	11 (91.7%)	10 (100.0%)
	Median time to event (95% CI) [b]	NE (1.2, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	NE	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	NE	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	33 (50.0%)	25 (38.5%)
	The number (%) of patients censored [a]	33 (50.0%)	40 (61.5%)
	Median time to event (95% CI) [b]	8.8 (4.1, 12.0)	12.4 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.552	
	HR (95% CI) [d]	1.17 (0.70, 1.98)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	5 (41.7%)	0 (0.0%)
	The number (%) of patients censored [a]	7 (58.3%)	10 (100.0%)
	Median time to event (95% CI) [b]	7.2 (1.0, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.024	
	HR (95% CI) [d]	NE (NE, NE)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.9.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.983	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.9.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	25 (37.9%)	23 (35.4%)
	The number (%) of patients censored [a]	41 (62.1%)	42 (64.6%)
	Median time to event (95% CI) [b]	9.6 (4.2, NE)	15.9 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.892	
	HR (95% CI) [d]	1.04 (0.59, 1.83)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	8 (66.7%)	3 (30.0%)
	The number (%) of patients censored [a]	4 (33.3%)	7 (70.0%)
	Median time to event (95% CI) [b]	1.0 (0.2, 3.5)	19.4 (0.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.014	
	HR (95% CI) [d]	5.72 (1.18, 27.72)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.023	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.5
Time to First Meaningful Deterioration for PGIC by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	21 (31.8%)	16 (24.6%)
	The number (%) of patients censored [a]	45 (68.2%)	49 (75.4%)
	Median time to event (95% CI) [b]	NE (4.4, NE)	6.4 (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.848	
	HR (95% CI) [d]	1.07 (0.56, 2.05)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	3 (25.0%)	2 (20.0%)
	The number (%) of patients censored [a]	9 (75.0%)	8 (80.0%)
	Median time to event (95% CI) [b]	NE (3.5, NE)	NE (3.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.586	
	HR (95% CI) [d]	1.64 (0.27, 9.81)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.5
Time to First Meaningful Deterioration for PGIC by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.571	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.6
Time to First Meaningful Deterioration for PGIS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Wild-type	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	66	65
	The number (%) of patients with an event [a]	10 (15.2%)	5 (7.7%)
	The number (%) of patients censored [a]	56 (84.8%)	60 (92.3%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.445	
	HR (95% CI) [d]	1.52 (0.52, 4.44)	
Mutant	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	12	10
	The number (%) of patients with an event [a]	1 (8.3%)	0 (0.0%)
	The number (%) of patients censored [a]	11 (91.7%)	10 (100.0%)
	Median time to event (95% CI) [b]	NE (4.5, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.414	
	HR (95% CI) [d]	NE (NE, NE)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.9.6
Time to First Meaningful Deterioration for PGIS by Subgroup - BRCA1/2 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.993	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	20 (54.1%)	25 (51.0%)
	The number (%) of patients censored [a]	17 (45.9%)	24 (49.0%)
	Median time to event (95% CI) [b]	3.9 (1.7, NE)	5.6 (3.0, 14.0)
	Nominal p-value for unstratified log-rank test [c]	0.656	
	HR (95% CI) [d]	1.15 (0.63, 2.07)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	82 (58.6%)	71 (59.7%)
	The number (%) of patients censored [a]	58 (41.4%)	48 (40.3%)
	Median time to event (95% CI) [b]	3.6 (1.7, 5.8)	3.1 (1.7, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.364	
	HR (95% CI) [d]	0.86 (0.63, 1.19)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.1

Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.448	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	14 (37.8%)	25 (51.0%)
	The number (%) of patients censored [a]	23 (62.2%)	24 (49.0%)
	Median time to event (95% CI) [b]	11.6 (5.6, NE)	5.8 (2.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.165	
	HR (95% CI) [d]	0.63 (0.33, 1.22)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	75 (53.6%)	66 (55.5%)
	The number (%) of patients censored [a]	65 (46.4%)	53 (44.5%)
	Median time to event (95% CI) [b]	4.2 (2.2, 7.9)	4.4 (2.8, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.852	
	HR (95% CI) [d]	0.97 (0.70, 1.36)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.323	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	15 (40.5%)	34 (69.4%)
	The number (%) of patients censored [a]	22 (59.5%)	15 (30.6%)
	Median time to event (95% CI) [b]	11.2 (2.7, NE)	2.8 (1.4, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	0.44 (0.24, 0.80)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	88 (62.9%)	80 (67.2%)
	The number (%) of patients censored [a]	52 (37.1%)	39 (32.8%)
	Median time to event (95% CI) [b]	1.4 (1.0, 1.6)	2.5 (1.7, 4.1)
	Nominal p-value for unstratified log-rank test [c]	0.369	
	HR (95% CI) [d]	1.16 (0.85, 1.57)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.008	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	19 (51.4%)	15 (30.6%)
	The number (%) of patients censored [a]	18 (48.6%)	34 (69.4%)
	Median time to event (95% CI) [b]	7.3 (4.2, 16.2)	14.0 (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.206	
	HR (95% CI) [d]	1.55 (0.78, 3.08)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	63 (45.0%)	52 (43.7%)
	The number (%) of patients censored [a]	77 (55.0%)	67 (56.3%)
	Median time to event (95% CI) [b]	8.4 (4.3, 11.4)	7.6 (4.6, 10.8)
	Nominal p-value for unstratified log-rank test [c]	0.680	
	HR (95% CI) [d]	0.93 (0.64, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.176	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	16 (43.2%)	34 (69.4%)
	The number (%) of patients censored [a]	21 (56.8%)	15 (30.6%)
	Median time to event (95% CI) [b]	6.4 (3.5, NE)	2.8 (1.6, 4.7)
	Nominal p-value for unstratified log-rank test [c]	0.017	
	HR (95% CI) [d]	0.49 (0.27, 0.89)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	81 (57.9%)	69 (58.0%)
	The number (%) of patients censored [a]	59 (42.1%)	50 (42.0%)
	Median time to event (95% CI) [b]	3.5 (2.6, 5.1)	3.5 (2.6, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.944	
	HR (95% CI) [d]	0.99 (0.72, 1.37)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.035	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	22 (59.5%)	33 (67.3%)
	The number (%) of patients censored [a]	15 (40.5%)	16 (32.7%)
	Median time to event (95% CI) [b]	3.8 (1.6, 12.2)	3.1 (1.4, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.218	
	HR (95% CI) [d]	0.70 (0.40, 1.24)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	80 (57.1%)	66 (55.5%)
	The number (%) of patients censored [a]	60 (42.9%)	53 (44.5%)
	Median time to event (95% CI) [b]	2.2 (1.4, 3.6)	3.3 (1.9, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.722	
	HR (95% CI) [d]	1.06 (0.77, 1.47)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.446	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	21 (56.8%)	35 (71.4%)
	The number (%) of patients censored [a]	16 (43.2%)	14 (28.6%)
	Median time to event (95% CI) [b]	2.1 (0.8, NE)	1.6 (1.1, 3.2)
	Nominal p-value for unstratified log-rank test [c]	0.336	
	HR (95% CI) [d]	0.77 (0.45, 1.33)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	98 (70.0%)	88 (73.9%)
	The number (%) of patients censored [a]	42 (30.0%)	31 (26.1%)
	Median time to event (95% CI) [b]	1.1 (0.8, 1.5)	1.2 (1.0, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	0.98 (0.74, 1.31)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.457	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	23 (62.2%)	29 (59.2%)
	The number (%) of patients censored [a]	14 (37.8%)	20 (40.8%)
	Median time to event (95% CI) [b]	2.9 (1.7, 11.7)	1.9 (1.4, 8.1)
	Nominal p-value for unstratified log-rank test [c]	0.849	
	HR (95% CI) [d]	0.95 (0.54, 1.66)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	86 (61.4%)	63 (52.9%)
	The number (%) of patients censored [a]	54 (38.6%)	56 (47.1%)
	Median time to event (95% CI) [b]	1.7 (1.4, 2.6)	3.4 (1.7, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.049	
	HR (95% CI) [d]	1.39 (1.00, 1.92)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.290	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
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Table 7.1.10.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	14 (37.8%)	26 (53.1%)
	The number (%) of patients censored [a]	23 (62.2%)	23 (46.9%)
	Median time to event (95% CI) [b]	10.0 (3.2, NE)	4.4 (1.9, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.094	
	HR (95% CI) [d]	0.57 (0.29, 1.11)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	74 (52.9%)	74 (62.2%)
	The number (%) of patients censored [a]	66 (47.1%)	45 (37.8%)
	Median time to event (95% CI) [b]	3.5 (1.7, 7.7)	2.8 (2.1, 3.7)
	Nominal p-value for unstratified log-rank test [c]	0.323	
	HR (95% CI) [d]	0.85 (0.62, 1.18)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.264	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	12 (32.4%)	28 (57.1%)
	The number (%) of patients censored [a]	25 (67.6%)	21 (42.9%)
	Median time to event (95% CI) [b]	NE (7.2, NE)	4.9 (1.9, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.011	
	HR (95% CI) [d]	0.42 (0.21, 0.84)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	53 (37.9%)	60 (50.4%)
	The number (%) of patients censored [a]	87 (62.1%)	59 (49.6%)
	Median time to event (95% CI) [b]	11.4 (6.7, NE)	4.9 (3.1, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.012	
	HR (95% CI) [d]	0.63 (0.43, 0.91)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.262	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	17 (45.9%)	27 (55.1%)
	The number (%) of patients censored [a]	20 (54.1%)	22 (44.9%)
	Median time to event (95% CI) [b]	5.5 (3.1, NE)	4.4 (2.8, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.344	
	HR (95% CI) [d]	0.74 (0.40, 1.38)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	63 (45.0%)	59 (49.6%)
	The number (%) of patients censored [a]	77 (55.0%)	60 (50.4%)
	Median time to event (95% CI) [b]	5.4 (3.2, 9.1)	4.1 (2.3, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.369	
	HR (95% CI) [d]	0.85 (0.60, 1.21)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.683	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	18 (48.6%)	21 (42.9%)
	The number (%) of patients censored [a]	19 (51.4%)	28 (57.1%)
	Median time to event (95% CI) [b]	7.9 (1.4, NE)	7.3 (2.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.775	
	HR (95% CI) [d]	1.10 (0.58, 2.07)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	69 (49.3%)	62 (52.1%)
	The number (%) of patients censored [a]	71 (50.7%)	57 (47.9%)
	Median time to event (95% CI) [b]	3.1 (1.9, 11.8)	4.1 (1.9, 7.9)
	Nominal p-value for unstratified log-rank test [c]	0.734	
	HR (95% CI) [d]	0.95 (0.67, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.675	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	15 (40.5%)	22 (44.9%)
	The number (%) of patients censored [a]	22 (59.5%)	27 (55.1%)
	Median time to event (95% CI) [b]	12.4 (1.4, NE)	6.9 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.590	
	HR (95% CI) [d]	0.84 (0.43, 1.62)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	82 (58.6%)	66 (55.5%)
	The number (%) of patients censored [a]	58 (41.4%)	53 (44.5%)
	Median time to event (95% CI) [b]	2.2 (1.7, 3.0)	2.7 (1.6, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.914	
	HR (95% CI) [d]	1.01 (0.73, 1.40)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.662	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	26 (70.3%)	21 (42.9%)
	The number (%) of patients censored [a]	11 (29.7%)	28 (57.1%)
	Median time to event (95% CI) [b]	1.7 (0.8, 2.9)	7.4 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.006	
	HR (95% CI) [d]	2.24 (1.25, 4.01)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	92 (65.7%)	49 (41.2%)
	The number (%) of patients censored [a]	48 (34.3%)	70 (58.8%)
	Median time to event (95% CI) [b]	1.7 (1.1, 2.6)	6.5 (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.32 (1.64, 3.28)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.880	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.15
Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	14 (37.8%)	22 (44.9%)
	The number (%) of patients censored [a]	23 (62.2%)	27 (55.1%)
	Median time to event (95% CI) [b]	16.1 (5.5, NE)	5.1 (1.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.044	
	HR (95% CI) [d]	0.49 (0.24, 0.99)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	51 (36.4%)	41 (34.5%)
	The number (%) of patients censored [a]	89 (63.6%)	78 (65.5%)
	Median time to event (95% CI) [b]	9.8 (7.9, NE)	19.4 (4.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.819	
	HR (95% CI) [d]	0.95 (0.63, 1.45)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.214	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	20 (54.1%)	26 (53.1%)
	The number (%) of patients censored [a]	17 (45.9%)	23 (46.9%)
	Median time to event (95% CI) [b]	2.1 (1.4, 13.3)	3.7 (1.4, 7.0)
	Nominal p-value for unstratified log-rank test [c]	0.838	
	HR (95% CI) [d]	1.07 (0.59, 1.93)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	81 (57.9%)	56 (47.1%)
	The number (%) of patients censored [a]	59 (42.1%)	63 (52.9%)
	Median time to event (95% CI) [b]	2.5 (1.7, 3.8)	5.0 (2.8, 12.7)
	Nominal p-value for unstratified log-rank test [c]	0.040	
	HR (95% CI) [d]	1.43 (1.02, 2.01)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.430	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	11 (29.7%)	17 (34.7%)
	The number (%) of patients censored [a]	26 (70.3%)	32 (65.3%)
	Median time to event (95% CI) [b]	NE (11.7, NE)	NE (3.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.359	
	HR (95% CI) [d]	0.70 (0.32, 1.51)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	35 (25.0%)	32 (26.9%)
	The number (%) of patients censored [a]	105 (75.0%)	87 (73.1%)
	Median time to event (95% CI) [b]	NE (18.5, NE)	NE (8.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.469	
	HR (95% CI) [d]	0.84 (0.52, 1.36)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.795	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	4 (10.8%)	5 (10.2%)
	The number (%) of patients censored [a]	33 (89.2%)	44 (89.8%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (1.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.543	
	HR (95% CI) [d]	1.52 (0.41, 5.65)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	3 (2.1%)	4 (3.4%)
	The number (%) of patients censored [a]	137 (97.9%)	115 (96.6%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.750	
	HR (95% CI) [d]	0.78 (0.17, 3.48)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.521	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	16 (43.2%)	21 (42.9%)
	The number (%) of patients censored [a]	21 (56.8%)	28 (57.1%)
	Median time to event (95% CI) [b]	5.5 (1.7, NE)	4.6 (1.6, 8.4)
	Nominal p-value for unstratified log-rank test [c]	0.443	
	HR (95% CI) [d]	0.77 (0.39, 1.51)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	53 (37.9%)	43 (36.1%)
	The number (%) of patients censored [a]	87 (62.1%)	76 (63.9%)
	Median time to event (95% CI) [b]	7.0 (3.5, 12.6)	8.8 (3.3, 15.2)
	Nominal p-value for unstratified log-rank test [c]	0.740	
	HR (95% CI) [d]	1.07 (0.71, 1.61)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.387	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	31 (83.8%)	34 (69.4%)
	The number (%) of patients censored [a]	6 (16.2%)	15 (30.6%)
	Median time to event (95% CI) [b]	0.8 (0.8, 1.0)	1.4 (1.0, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.003	
	HR (95% CI) [d]	2.11 (1.29, 3.45)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	100 (71.4%)	72 (60.5%)
	The number (%) of patients censored [a]	40 (28.6%)	47 (39.5%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.4)	2.7 (1.4, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.69 (1.25, 2.29)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.5

Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.403	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	8 (21.6%)	12 (24.5%)
	The number (%) of patients censored [a]	29 (78.4%)	37 (75.5%)
	Median time to event (95% CI) [b]	NE (10.0, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.682	
	HR (95% CI) [d]	0.83 (0.34, 2.04)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	45 (32.1%)	30 (25.2%)
	The number (%) of patients censored [a]	95 (67.9%)	89 (74.8%)
	Median time to event (95% CI) [b]	24.7 (9.3, NE)	NE (12.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.725	
	HR (95% CI) [d]	1.09 (0.68, 1.73)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.723	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	16 (43.2%)	33 (67.3%)
	The number (%) of patients censored [a]	21 (56.8%)	16 (32.7%)
	Median time to event (95% CI) [b]	13.3 (3.2, NE)	2.8 (1.9, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.024	
	HR (95% CI) [d]	0.50 (0.27, 0.92)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	73 (52.1%)	55 (46.2%)
	The number (%) of patients censored [a]	67 (47.9%)	64 (53.8%)
	Median time to event (95% CI) [b]	5.6 (3.5, 7.9)	4.2 (3.1, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.787	
	HR (95% CI) [d]	0.95 (0.67, 1.35)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.076	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	3 (8.1%)	8 (16.3%)
	The number (%) of patients censored [a]	34 (91.9%)	41 (83.7%)
	Median time to event (95% CI) [b]	3.5 (0.7, NE)	1.4 (0.8, 3.3)
	Nominal p-value for unstratified log-rank test [c]	0.906	
	HR (95% CI) [d]	0.89 (0.23, 3.45)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	14 (10.0%)	11 (9.2%)
	The number (%) of patients censored [a]	126 (90.0%)	108 (90.8%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	1.0 (0.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.616	
	HR (95% CI) [d]	0.81 (0.37, 1.79)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.877	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	13 (35.1%)	15 (30.6%)
	The number (%) of patients censored [a]	24 (64.9%)	34 (69.4%)
	Median time to event (95% CI) [b]	10.2 (6.3, NE)	15.4 (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.830	
	HR (95% CI) [d]	1.09 (0.51, 2.30)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	57 (40.7%)	41 (34.5%)
	The number (%) of patients censored [a]	83 (59.3%)	78 (65.5%)
	Median time to event (95% CI) [b]	9.8 (5.8, NE)	12.4 (5.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.571	
	HR (95% CI) [d]	1.13 (0.75, 1.68)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
Program Path: ...03-Team_Folder\06-Programing\A-Primary\Programs\t_tte.sas
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Table 7.1.10.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.957	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.10.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	9 (24.3%)	21 (42.9%)
	The number (%) of patients censored [a]	28 (75.7%)	28 (57.1%)
	Median time to event (95% CI) [b]	NE (6.4, NE)	16.1 (1.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.119	
	HR (95% CI) [d]	0.54 (0.25, 1.18)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	66 (47.1%)	42 (35.3%)
	The number (%) of patients censored [a]	74 (52.9%)	77 (64.7%)
	Median time to event (95% CI) [b]	5.9 (3.5, 13.2)	15.9 (5.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.102	
	HR (95% CI) [d]	1.38 (0.94, 2.03)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.033	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	5 (13.5%)	16 (32.7%)
	The number (%) of patients censored [a]	32 (86.5%)	33 (67.3%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.054	
	HR (95% CI) [d]	0.38 (0.14, 1.05)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	35 (25.0%)	26 (21.8%)
	The number (%) of patients censored [a]	105 (75.0%)	93 (78.2%)
	Median time to event (95% CI) [b]	NE (6.4, NE)	6.5 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.741	
	HR (95% CI) [d]	1.09 (0.65, 1.81)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.5
Time to First Meaningful Deterioration for PGIC by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.066	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
Pre-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	37	49
	The number (%) of patients with an event [a]	3 (8.1%)	5 (10.2%)
	The number (%) of patients censored [a]	34 (91.9%)	44 (89.8%)
	Median time to event (95% CI) [b]	NE (5.6, NE)	NE (5.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.963	
	HR (95% CI) [d]	0.97 (0.23, 4.06)	
Post-menopausal	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	140	119
	The number (%) of patients with an event [a]	14 (10.0%)	6 (5.0%)
	The number (%) of patients censored [a]	126 (90.0%)	113 (95.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.411	
	HR (95% CI) [d]	1.49 (0.57, 3.88)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.10.6
Time to First Meaningful Deterioration for PGIS by Subgroup - Menopausal Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.610	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	40 (59.7%)	37 (62.7%)
	The number (%) of patients censored [a]	27 (40.3%)	22 (37.3%)
	Median time to event (95% CI) [b]	3.6 (1.6, 6.0)	2.7 (1.6, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.376	
	HR (95% CI) [d]	0.82 (0.52, 1.28)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	62 (56.9%)	59 (53.6%)
	The number (%) of patients censored [a]	47 (43.1%)	51 (46.4%)
	Median time to event (95% CI) [b]	4.1 (1.7, 6.3)	4.7 (2.7, 6.9)
	Nominal p-value for unstratified log-rank test [c]	0.774	
	HR (95% CI) [d]	1.06 (0.74, 1.52)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.1
Time to First Meaningful Deterioration for EORTC QLQ-C30 Global Health Status/QoL by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.316	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	31 (46.3%)	33 (55.9%)
	The number (%) of patients censored [a]	36 (53.7%)	26 (44.1%)
	Median time to event (95% CI) [b]	6.4 (3.6, NE)	4.4 (2.9, 8.3)
	Nominal p-value for unstratified log-rank test [c]	0.203	
	HR (95% CI) [d]	0.73 (0.44, 1.19)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	58 (53.2%)	59 (53.6%)
	The number (%) of patients censored [a]	51 (46.8%)	51 (46.4%)
	Median time to event (95% CI) [b]	4.2 (2.1, 9.2)	4.6 (2.6, 9.0)
	Nominal p-value for unstratified log-rank test [c]	0.898	
	HR (95% CI) [d]	1.03 (0.71, 1.48)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.2
Time to First Meaningful Deterioration for EORTC QLQ-C30 Physical Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.255	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	36 (53.7%)	37 (62.7%)
	The number (%) of patients censored [a]	31 (46.3%)	22 (37.3%)
	Median time to event (95% CI) [b]	2.5 (1.3, 11.2)	3.3 (1.1, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.449	
	HR (95% CI) [d]	0.84 (0.53, 1.33)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	67 (61.5%)	78 (70.9%)
	The number (%) of patients censored [a]	42 (38.5%)	32 (29.1%)
	Median time to event (95% CI) [b]	1.5 (1.2, 1.9)	2.5 (1.7, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.824	
	HR (95% CI) [d]	1.05 (0.75, 1.46)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.3
Time to First Meaningful Deterioration for EORTC QLQ-C30 Role Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.438	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.4

Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	36 (53.7%)	28 (47.5%)
	The number (%) of patients censored [a]	31 (46.3%)	31 (52.5%)
	Median time to event (95% CI) [b]	6.0 (4.2, 11.4)	5.6 (3.8, 12.3)
	Nominal p-value for unstratified log-rank test [c]	0.667	
	HR (95% CI) [d]	0.90 (0.54, 1.47)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	46 (42.2%)	40 (36.4%)
	The number (%) of patients censored [a]	63 (57.8%)	70 (63.6%)
	Median time to event (95% CI) [b]	9.0 (5.5, 15.5)	10.2 (7.6, 14.0)
	Nominal p-value for unstratified log-rank test [c]	0.691	
	HR (95% CI) [d]	1.09 (0.71, 1.68)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.4
Time to First Meaningful Deterioration for EORTC QLQ-C30 Emotional Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.484	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	38 (56.7%)	34 (57.6%)
	The number (%) of patients censored [a]	29 (43.3%)	25 (42.4%)
	Median time to event (95% CI) [b]	4.6 (3.4, 6.9)	3.0 (1.8, 4.9)
	Nominal p-value for unstratified log-rank test [c]	0.445	
	HR (95% CI) [d]	0.83 (0.52, 1.33)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	59 (54.1%)	70 (63.6%)
	The number (%) of patients censored [a]	50 (45.9%)	40 (36.4%)
	Median time to event (95% CI) [b]	3.6 (2.8, 7.6)	3.7 (2.4, 4.2)
	Nominal p-value for unstratified log-rank test [c]	0.234	
	HR (95% CI) [d]	0.81 (0.57, 1.15)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.5
Time to First Meaningful Deterioration for EORTC QLQ-C30 Cognitive Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.992	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	41 (61.2%)	38 (64.4%)
	The number (%) of patients censored [a]	26 (38.8%)	21 (35.6%)
	Median time to event (95% CI) [b]	1.7 (1.1, 7.2)	2.9 (0.9, 3.6)
	Nominal p-value for unstratified log-rank test [c]	0.542	
	HR (95% CI) [d]	0.87 (0.56, 1.36)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	61 (56.0%)	62 (56.4%)
	The number (%) of patients censored [a]	48 (44.0%)	48 (43.6%)
	Median time to event (95% CI) [b]	3.1 (1.6, 4.2)	4.0 (2.8, 5.8)
	Nominal p-value for unstratified log-rank test [c]	0.807	
	HR (95% CI) [d]	1.05 (0.73, 1.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.6
Time to First Meaningful Deterioration for EORTC QLQ-C30 Social Functioning by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.450	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	41 (61.2%)	44 (74.6%)
	The number (%) of patients censored [a]	26 (38.8%)	15 (25.4%)
	Median time to event (95% CI) [b]	1.5 (0.8, 3.9)	1.2 (0.9, 2.7)
	Nominal p-value for unstratified log-rank test [c]	0.222	
	HR (95% CI) [d]	0.77 (0.51, 1.19)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	78 (71.6%)	80 (72.7%)
	The number (%) of patients censored [a]	31 (28.4%)	30 (27.3%)
	Median time to event (95% CI) [b]	1.4 (0.8, 1.7)	1.4 (1.1, 1.9)
	Nominal p-value for unstratified log-rank test [c]	0.625	
	HR (95% CI) [d]	1.09 (0.80, 1.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.7
Time to First Meaningful Deterioration for EORTC QLQ-C30 Fatigue by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.187	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	43 (64.2%)	34 (57.6%)
	The number (%) of patients censored [a]	24 (35.8%)	25 (42.4%)
	Median time to event (95% CI) [b]	1.7 (1.0, 4.2)	3.8 (2.1, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.285	
	HR (95% CI) [d]	1.28 (0.81, 2.03)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	66 (60.6%)	59 (53.6%)
	The number (%) of patients censored [a]	43 (39.4%)	51 (46.4%)
	Median time to event (95% CI) [b]	2.4 (1.5, 2.9)	1.9 (1.5, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.318	
	HR (95% CI) [d]	1.20 (0.84, 1.70)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.8
Time to First Meaningful Deterioration for EORTC QLQ-C30 Nausea and Vomiting by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.685	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	37 (55.2%)	36 (61.0%)
	The number (%) of patients censored [a]	30 (44.8%)	23 (39.0%)
	Median time to event (95% CI) [b]	6.5 (2.8, 9.8)	2.4 (1.6, 3.6)
	Nominal p-value for unstratified log-rank test [c]	0.055	
	HR (95% CI) [d]	0.64 (0.40, 1.02)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	51 (46.8%)	64 (58.2%)
	The number (%) of patients censored [a]	58 (53.2%)	46 (41.8%)
	Median time to event (95% CI) [b]	3.5 (1.6, 15.5)	3.7 (2.8, 6.1)
	Nominal p-value for unstratified log-rank test [c]	0.645	
	HR (95% CI) [d]	0.92 (0.64, 1.34)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.9
Time to First Meaningful Deterioration for EORTC QLQ-C30 Pain by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.314	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	24 (35.8%)	28 (47.5%)
	The number (%) of patients censored [a]	43 (64.2%)	31 (52.5%)
	Median time to event (95% CI) [b]	11.4 (7.2, NE)	5.0 (3.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.034	
	HR (95% CI) [d]	0.56 (0.32, 0.96)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	41 (37.6%)	61 (55.5%)
	The number (%) of patients censored [a]	68 (62.4%)	49 (44.5%)
	Median time to event (95% CI) [b]	12.2 (5.3, NE)	4.4 (2.4, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.007	
	HR (95% CI) [d]	0.59 (0.39, 0.87)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.10
Time to First Meaningful Deterioration for EORTC QLQ-C30 Dyspnoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.908	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	31 (46.3%)	30 (50.8%)
	The number (%) of patients censored [a]	36 (53.7%)	29 (49.2%)
	Median time to event (95% CI) [b]	7.2 (3.5, NE)	4.2 (3.1, 6.0)
	Nominal p-value for unstratified log-rank test [c]	0.382	
	HR (95% CI) [d]	0.80 (0.48, 1.32)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	49 (45.0%)	57 (51.8%)
	The number (%) of patients censored [a]	60 (55.0%)	53 (48.2%)
	Median time to event (95% CI) [b]	5.4 (3.1, 14.4)	4.1 (2.1, 6.5)
	Nominal p-value for unstratified log-rank test [c]	0.322	
	HR (95% CI) [d]	0.82 (0.56, 1.21)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.11
Time to First Meaningful Deterioration for EORTC QLQ-C30 Insomnia by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.897	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	35 (52.2%)	31 (52.5%)
	The number (%) of patients censored [a]	32 (47.8%)	28 (47.5%)
	Median time to event (95% CI) [b]	2.2 (1.5, NE)	5.0 (1.8, 9.2)
	Nominal p-value for unstratified log-rank test [c]	0.988	
	HR (95% CI) [d]	1.00 (0.62, 1.63)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	52 (47.7%)	53 (48.2%)
	The number (%) of patients censored [a]	57 (52.3%)	57 (51.8%)
	Median time to event (95% CI) [b]	4.1 (2.0, NE)	4.1 (2.1, 14.5)
	Nominal p-value for unstratified log-rank test [c]	0.889	
	HR (95% CI) [d]	0.98 (0.67, 1.43)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.12
Time to First Meaningful Deterioration for EORTC QLQ-C30 Appetite Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.897	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	38 (56.7%)	30 (50.8%)
	The number (%) of patients censored [a]	29 (43.3%)	29 (49.2%)
	Median time to event (95% CI) [b]	2.1 (1.4, 4.6)	2.7 (1.1, 6.6)
	Nominal p-value for unstratified log-rank test [c]	0.945	
	HR (95% CI) [d]	1.01 (0.63, 1.64)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	59 (54.1%)	59 (53.6%)
	The number (%) of patients censored [a]	50 (45.9%)	51 (46.4%)
	Median time to event (95% CI) [b]	2.7 (1.9, 5.7)	3.5 (1.9, 6.7)
	Nominal p-value for unstratified log-rank test [c]	0.989	
	HR (95% CI) [d]	1.00 (0.70, 1.44)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.13
Time to First Meaningful Deterioration for EORTC QLQ-C30 Constipation by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.979	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	42 (62.7%)	22 (37.3%)
	The number (%) of patients censored [a]	25 (37.3%)	37 (62.7%)
	Median time to event (95% CI) [b]	1.8 (1.1, 3.6)	10.1 (3.3, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.46 (1.47, 4.14)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	76 (69.7%)	49 (44.5%)
	The number (%) of patients censored [a]	33 (30.3%)	61 (55.5%)
	Median time to event (95% CI) [b]	1.6 (1.0, 2.1)	6.2 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	<.001	
	HR (95% CI) [d]	2.26 (1.57, 3.24)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.14
Time to First Meaningful Deterioration for EORTC QLQ-C30 Diarrhoea by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.818	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	29 (43.3%)	26 (44.1%)
	The number (%) of patients censored [a]	38 (56.7%)	33 (55.9%)
	Median time to event (95% CI) [b]	9.8 (6.9, 19.0)	5.2 (2.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.144	
	HR (95% CI) [d]	0.67 (0.39, 1.15)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	36 (33.0%)	37 (33.6%)
	The number (%) of patients censored [a]	73 (67.0%)	73 (66.4%)
	Median time to event (95% CI) [b]	21.5 (5.5, NE)	10.2 (4.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.788	
	HR (95% CI) [d]	0.94 (0.59, 1.49)	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.1.15

Time to First Meaningful Deterioration for EORTC QLQ-C30 Financial Difficulties by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.428	

Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	41 (61.2%)	28 (47.5%)
	The number (%) of patients censored [a]	26 (38.8%)	31 (52.5%)
	Median time to event (95% CI) [b]	2.1 (1.4, 4.2)	4.9 (1.8, NE)
	Nominal p-value for unstratified log-rank test [c]	0.137	
	HR (95% CI) [d]	1.44 (0.89, 2.33)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	60 (55.0%)	54 (49.1%)
	The number (%) of patients censored [a]	49 (45.0%)	56 (50.9%)
	Median time to event (95% CI) [b]	3.2 (1.7, 5.0)	5.1 (2.8, 9.3)
	Nominal p-value for unstratified log-rank test [c]	0.187	
	HR (95% CI) [d]	1.28 (0.89, 1.85)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.1
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Body Image by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.753	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	21 (31.3%)	14 (23.7%)
	The number (%) of patients censored [a]	46 (68.7%)	45 (76.3%)
	Median time to event (95% CI) [b]	18.5 (11.7, NE)	NE (6.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.916	
	HR (95% CI) [d]	1.04 (0.52, 2.05)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	25 (22.9%)	35 (31.8%)
	The number (%) of patients censored [a]	84 (77.1%)	75 (68.2%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (7.0, NE)
	Nominal p-value for unstratified log-rank test [c]	0.170	
	HR (95% CI) [d]	0.70 (0.42, 1.17)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.2
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Function by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.244	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	4 (6.0%)	2 (3.4%)
	The number (%) of patients censored [a]	63 (94.0%)	57 (96.6%)
	Median time to event (95% CI) [b]	NE (0.7, NE)	NE (0.9, NE)
	Nominal p-value for unstratified log-rank test [c]	0.347	
	HR (95% CI) [d]	2.22 (0.40, 12.21)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	3 (2.8%)	7 (6.4%)
	The number (%) of patients censored [a]	106 (97.2%)	103 (93.6%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.437	
	HR (95% CI) [d]	0.59 (0.15, 2.27)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.3
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Sexual Enjoyment by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.234	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	28 (41.8%)	27 (45.8%)
	The number (%) of patients censored [a]	39 (58.2%)	32 (54.2%)
	Median time to event (95% CI) [b]	5.6 (2.1, 18.5)	3.9 (1.5, 13.8)
	Nominal p-value for unstratified log-rank test [c]	0.427	
	HR (95% CI) [d]	0.80 (0.47, 1.37)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	41 (37.6%)	38 (34.5%)
	The number (%) of patients censored [a]	68 (62.4%)	72 (65.5%)
	Median time to event (95% CI) [b]	6.3 (3.5, 9.8)	7.0 (3.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.645	
	HR (95% CI) [d]	1.11 (0.71, 1.74)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.4
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Future Perspective by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.271	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	49 (73.1%)	34 (57.6%)
	The number (%) of patients censored [a]	18 (26.9%)	25 (42.4%)
	Median time to event (95% CI) [b]	1.0 (0.8, 1.3)	3.1 (1.7, 5.6)
	Nominal p-value for unstratified log-rank test [c]	0.005	
	HR (95% CI) [d]	1.87 (1.21, 2.91)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	82 (75.2%)	73 (66.4%)
	The number (%) of patients censored [a]	27 (24.8%)	37 (33.6%)
	Median time to event (95% CI) [b]	0.9 (0.8, 1.2)	1.5 (1.1, 3.5)
	Nominal p-value for unstratified log-rank test [c]	0.001	
	HR (95% CI) [d]	1.68 (1.23, 2.31)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.5
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Systemic Therapy Side Effects by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.716	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	23 (34.3%)	20 (33.9%)
	The number (%) of patients censored [a]	44 (65.7%)	39 (66.1%)
	Median time to event (95% CI) [b]	17.1 (8.5, NE)	8.1 (5.1, NE)
	Nominal p-value for unstratified log-rank test [c]	0.518	
	HR (95% CI) [d]	0.82 (0.45, 1.50)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	30 (27.5%)	22 (20.0%)
	The number (%) of patients censored [a]	79 (72.5%)	88 (80.0%)
	Median time to event (95% CI) [b]	24.7 (10.2, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.299	
	HR (95% CI) [d]	1.34 (0.77, 2.32)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.6
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Breast Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.253	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	35 (52.2%)	31 (52.5%)
	The number (%) of patients censored [a]	32 (47.8%)	28 (47.5%)
	Median time to event (95% CI) [b]	4.5 (2.2, 13.3)	4.2 (2.9, 6.3)
	Nominal p-value for unstratified log-rank test [c]	0.512	
	HR (95% CI) [d]	0.85 (0.52, 1.38)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	54 (49.5%)	58 (52.7%)
	The number (%) of patients censored [a]	55 (50.5%)	52 (47.3%)
	Median time to event (95% CI) [b]	6.8 (4.1, 12.7)	3.5 (2.8, 6.2)
	Nominal p-value for unstratified log-rank test [c]	0.130	
	HR (95% CI) [d]	0.75 (0.51, 1.09)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.7
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Arm Symptoms by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.745	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	8 (11.9%)	6 (10.2%)
	The number (%) of patients censored [a]	59 (88.1%)	53 (89.8%)
	Median time to event (95% CI) [b]	1.2 (0.8, NE)	0.8 (0.7, 1.5)
	Nominal p-value for unstratified log-rank test [c]	0.281	
	HR (95% CI) [d]	0.54 (0.18, 1.64)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	9 (8.3%)	13 (11.8%)
	The number (%) of patients censored [a]	100 (91.7%)	97 (88.2%)
	Median time to event (95% CI) [b]	3.5 (0.8, NE)	1.9 (1.0, 4.6)
	Nominal p-value for unstratified log-rank test [c]	0.706	
	HR (95% CI) [d]	0.84 (0.36, 1.98)	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.2.8
Time to First Meaningful Deterioration for EORTC QLQ-BR23 Upset by Hair Loss by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.477	

Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	23 (34.3%)	20 (33.9%)
	The number (%) of patients censored [a]	44 (65.7%)	39 (66.1%)
	Median time to event (95% CI) [b]	18.7 (8.1, NE)	NE (4.4, NE)
	Nominal p-value for unstratified log-rank test [c]	0.521	
	HR (95% CI) [d]	0.82 (0.45, 1.50)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	47 (43.1%)	36 (32.7%)
	The number (%) of patients censored [a]	62 (56.9%)	74 (67.3%)
	Median time to event (95% CI) [b]	8.8 (4.9, 15.5)	12.4 (10.5, NE)
	Nominal p-value for unstratified log-rank test [c]	0.129	
	HR (95% CI) [d]	1.40 (0.91, 2.17)	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.11.3
Time to First Meaningful Deterioration for EQ-VAS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.141	

Note: The response threshold for EQ-VAS is ≥15 points.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Table 7.1.11.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	23 (34.3%)	19 (32.2%)
	The number (%) of patients censored [a]	44 (65.7%)	40 (67.8%)
	Median time to event (95% CI) [b]	13.6 (9.1, NE)	15.9 (9.7, NE)
	Nominal p-value for unstratified log-rank test [c]	0.740	
	HR (95% CI) [d]	0.90 (0.49, 1.65)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	52 (47.7%)	44 (40.0%)
	The number (%) of patients censored [a]	57 (52.3%)	66 (60.0%)
	Median time to event (95% CI) [b]	4.1 (2.4, 9.6)	16.1 (4.2, NE)
	Nominal p-value for unstratified log-rank test [c]	0.128	
	HR (95% CI) [d]	1.36 (0.91, 2.04)	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.4
Time to First Meaningful Deterioration for FACT-GP5 by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.317	

Note: 'Quite a bit' and 'very much' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; FACT-GP5 = Functional Assessment of Cancer Therapy – General Population item 5; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.5
Time to First Meaningful Deterioration for PGIC by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	13 (19.4%)	13 (22.0%)
	The number (%) of patients censored [a]	54 (80.6%)	46 (78.0%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (5.6, NE)
	Nominal p-value for unstratified log-rank test [c]	0.414	
	HR (95% CI) [d]	0.73 (0.34, 1.57)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	27 (24.8%)	29 (26.4%)
	The number (%) of patients censored [a]	82 (75.2%)	81 (73.6%)
	Median time to event (95% CI) [b]	NE (6.0, NE)	6.4 (6.3, NE)
	Nominal p-value for unstratified log-rank test [c]	0.714	
	HR (95% CI) [d]	0.91 (0.54, 1.53)	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.5
Time to First Meaningful Deterioration for PGIC by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.787	

Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 7.1.11.6
Time to First Meaningful Deterioration for PGIS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
CPS <1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	67	59
	The number (%) of patients with an event [a]	9 (13.4%)	3 (5.1%)
	The number (%) of patients censored [a]	58 (86.6%)	56 (94.9%)
	Median time to event (95% CI) [b]	NE (6.3, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.395	
	HR (95% CI) [d]	1.75 (0.47, 6.48)	
CPS ≥1	The number of patients in the mITT excluding patients preselected to receive nab-paclitaxel	109	110
	The number (%) of patients with an event [a]	8 (7.3%)	8 (7.3%)
	The number (%) of patients censored [a]	101 (92.7%)	102 (92.7%)
	Median time to event (95% CI) [b]	NE (NE, NE)	NE (NE, NE)
	Nominal p-value for unstratified log-rank test [c]	0.930	
	HR (95% CI) [d]	0.96 (0.36, 2.56)	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX

Run Date: 03JUN2026

Table 7.1.11.6
Time to First Meaningful Deterioration for PGIS by Subgroup - PD-L1 Status
(mITT excluding patients preselected to receive nab-paclitaxel)

Subgroup	Parameter	SG (N=177)	TPC (N=169)
	P-value of subgroup*treatment interaction [e]	0.436	

Note: 'Very poor' and 'poor' are classified as responders.
[a] Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel per subgroup.
[b] Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
[c] P-value was estimated from the unstratified log-rank test.
[d] HR (95% CI) of SG vs. TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
[e] P-value of subgroup*treatment interaction from a Cox model with treatment, subgroup and treatment*subgroup interaction.
CI = Confidence Interval; HR = hazard ratio; NE = Not Estimable; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Data Source: ADSL ADQS ADRBC ADEX
Run Date: 03JUN2026

Figure 1.1.1.1
Observed Mean Change from Baseline in EORTC QLQ-C30 Global Health Status/QoL by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

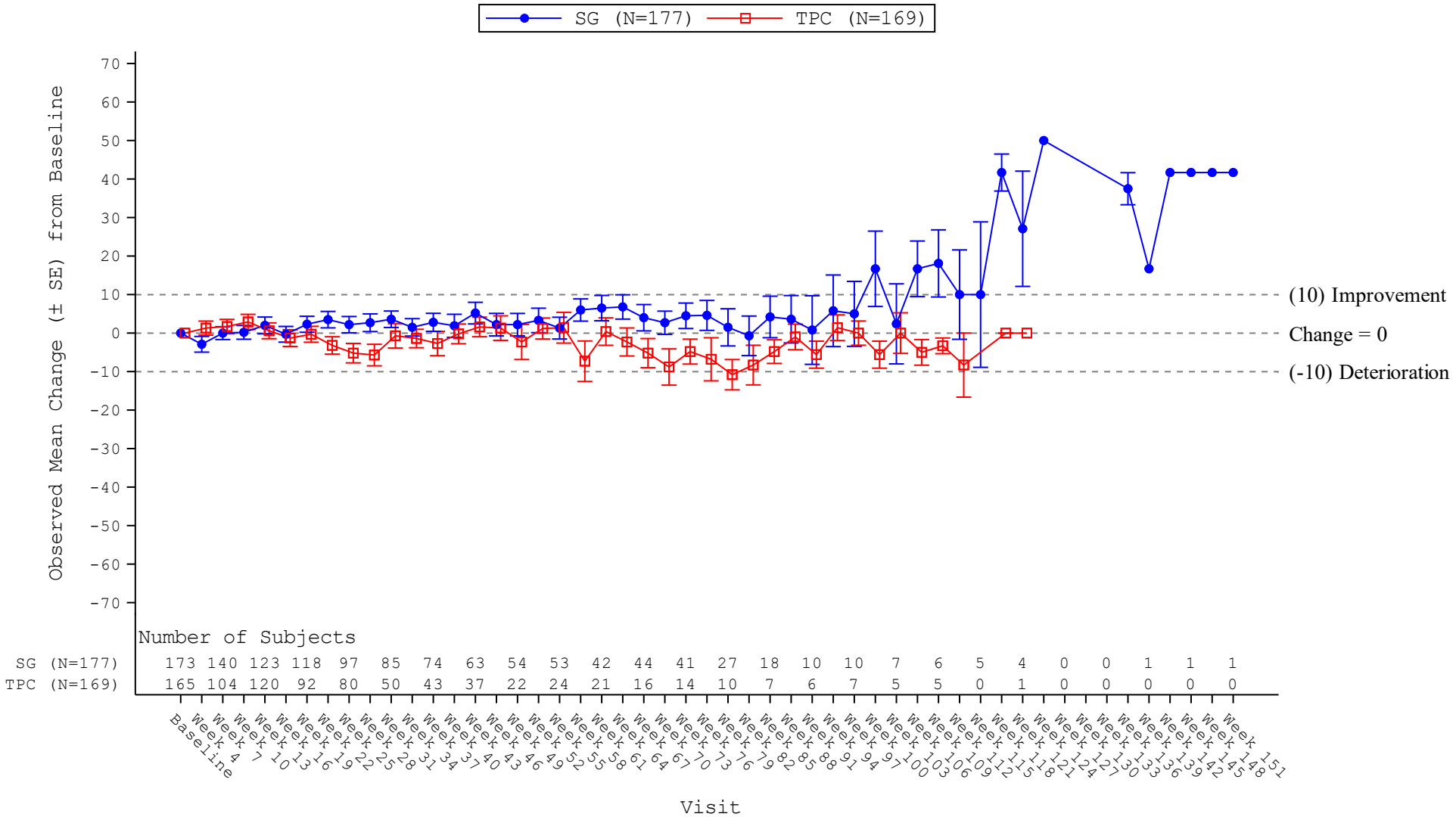


Figure 1.1.1.2
Observed Mean Change from Baseline in EORTC QLQ-C30 Physical Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

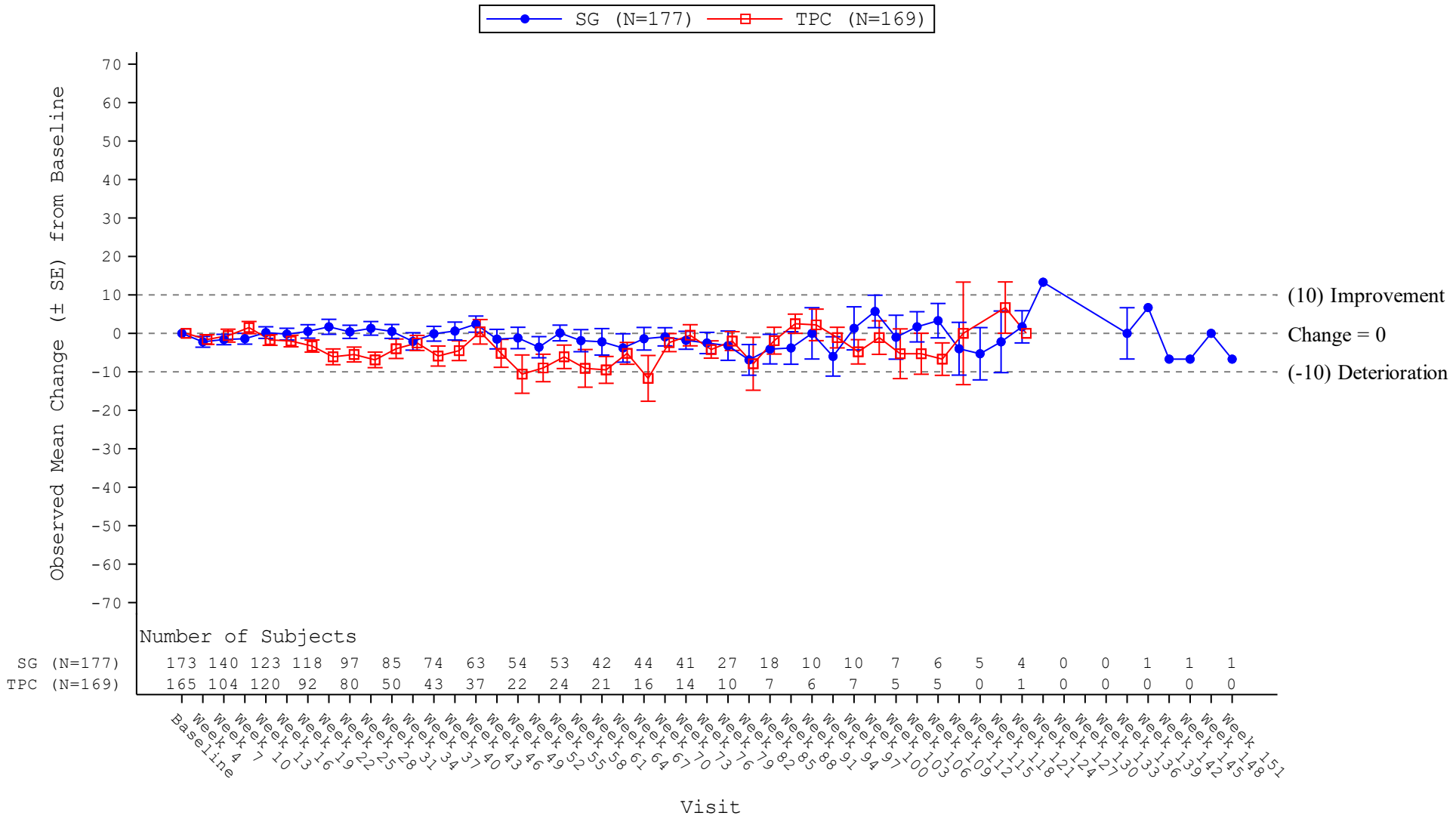


Figure 1.1.1.3
Observed Mean Change from Baseline in EORTC QLQ-C30 Role Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

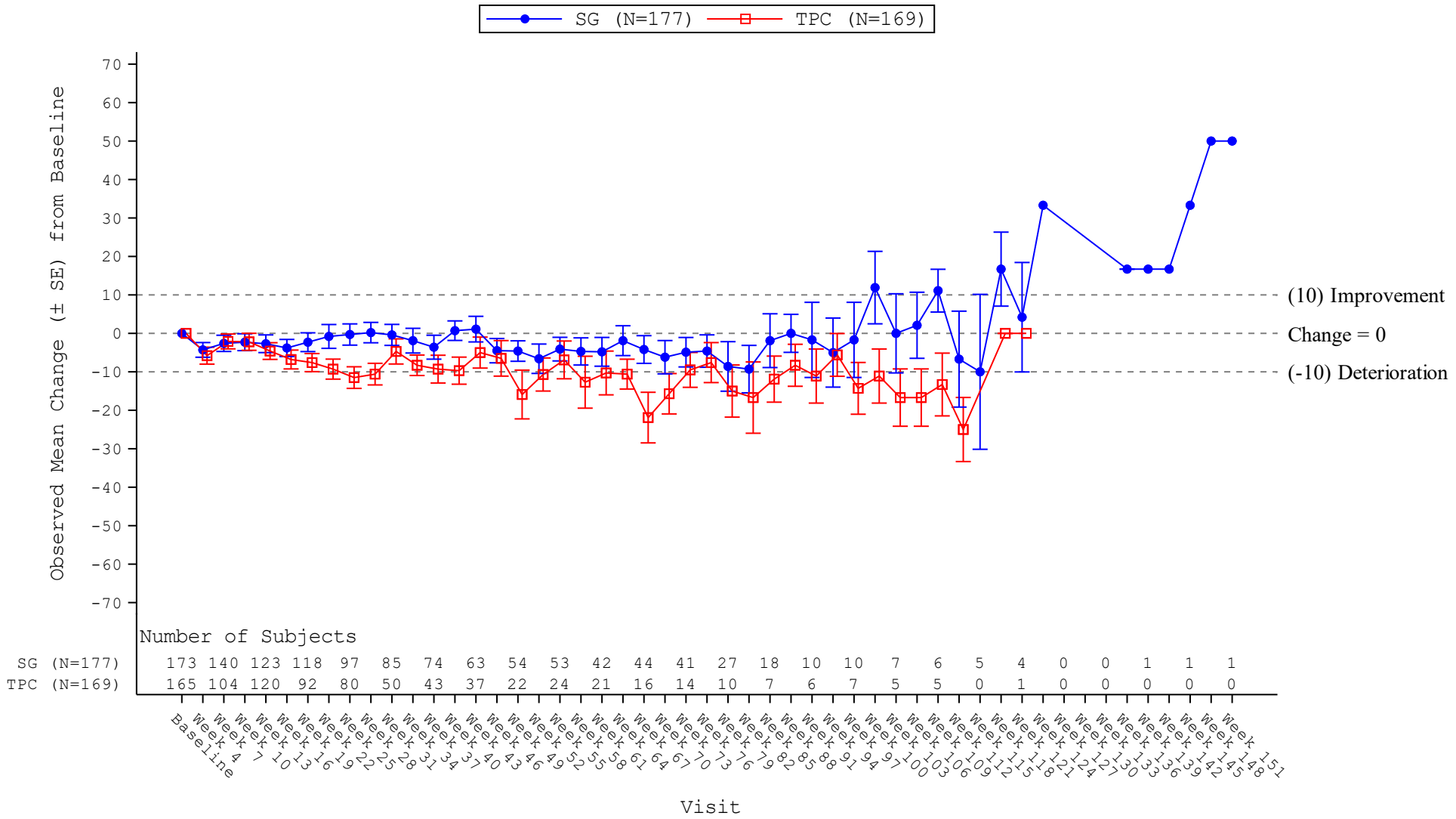


Figure 1.1.1.4
Observed Mean Change from Baseline in EORTC QLQ-C30 Emotional Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

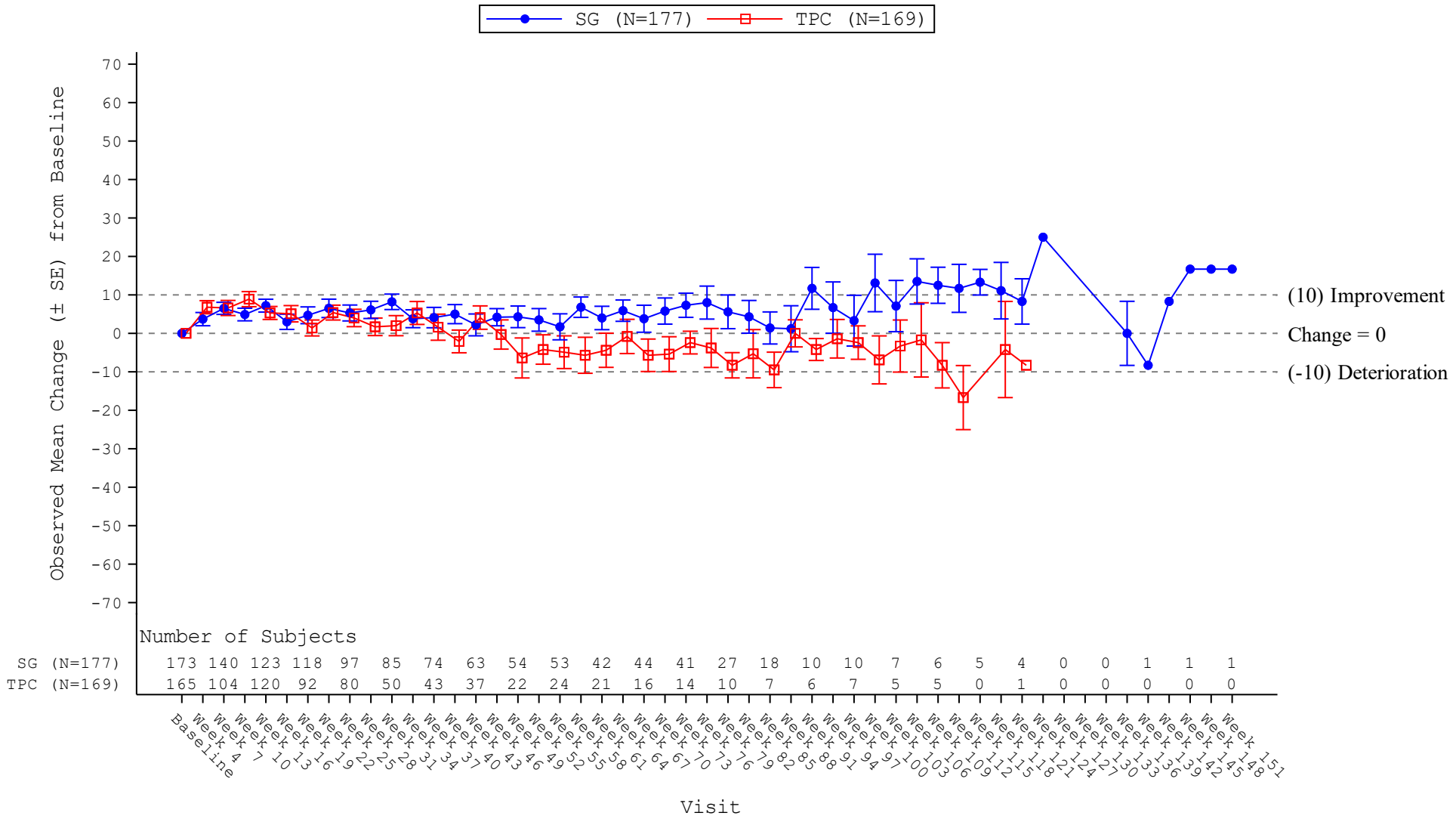


Figure 1.1.1.5
Observed Mean Change from Baseline in EORTC QLQ-C30 Cognitive Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

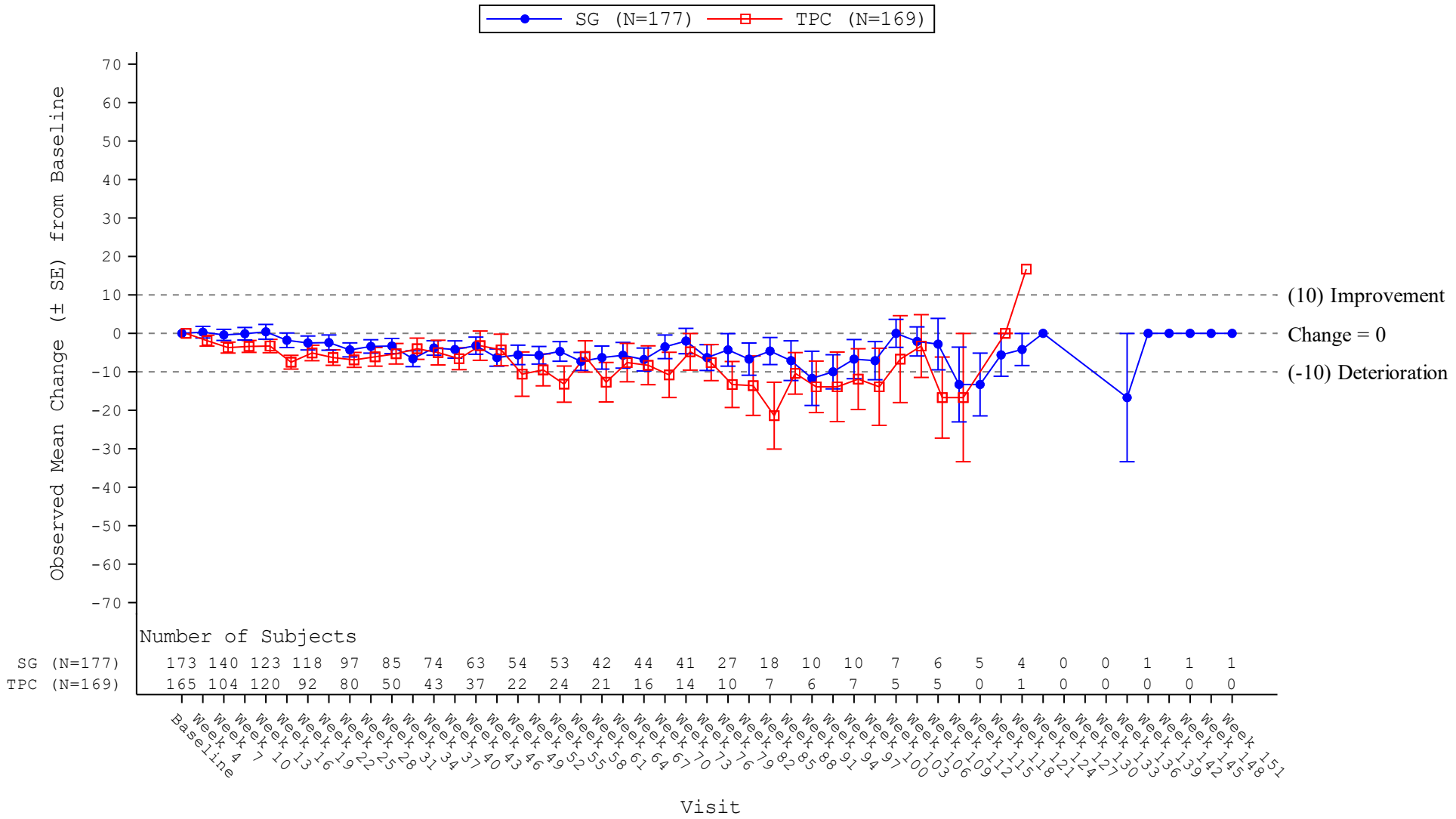


Figure 1.1.1.6
Observed Mean Change from Baseline in EORTC QLQ-C30 Social Functioning by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

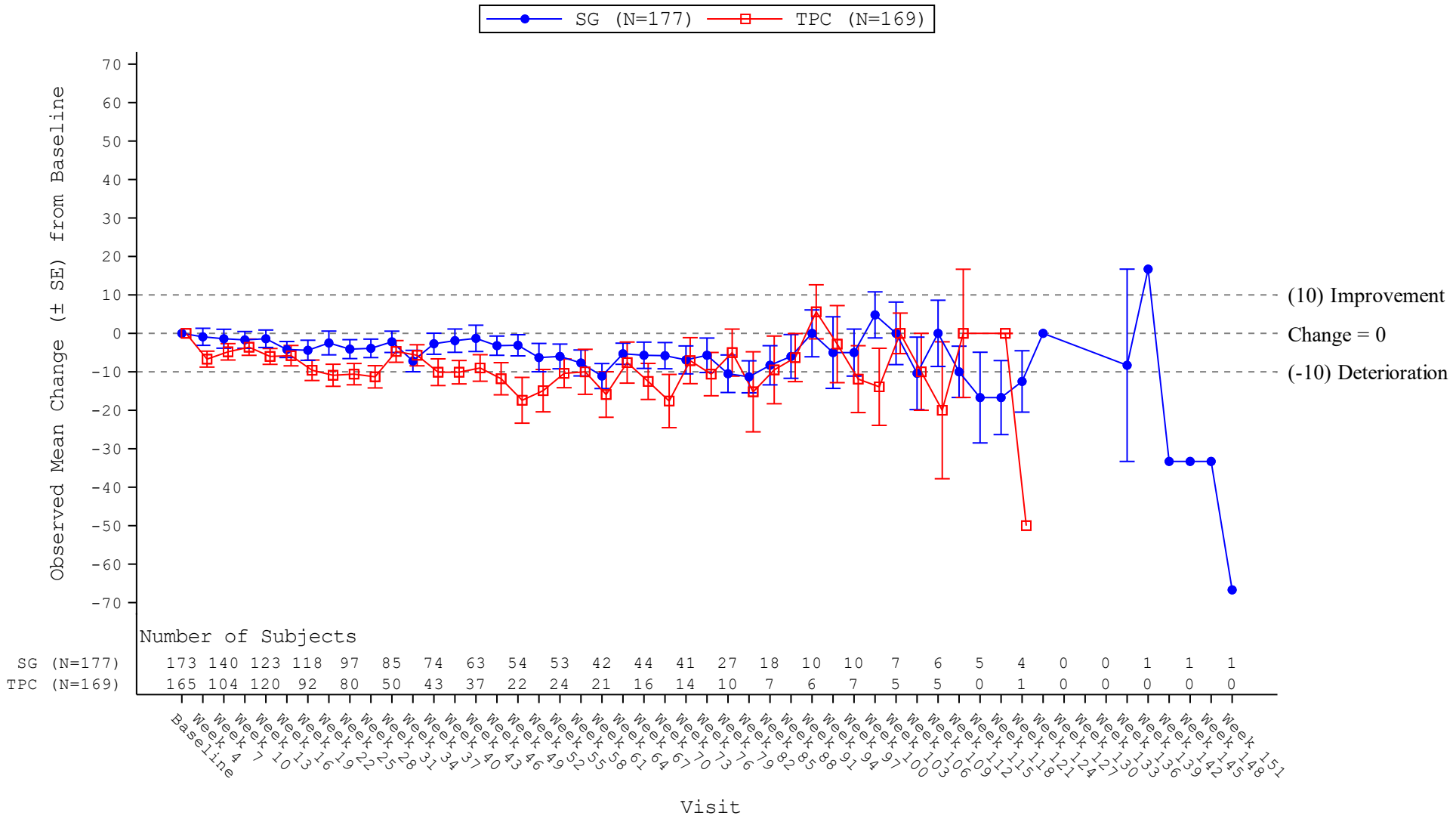


Figure 1.1.1.7
Observed Mean Change from Baseline in EORTC QLQ-C30 Fatigue by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

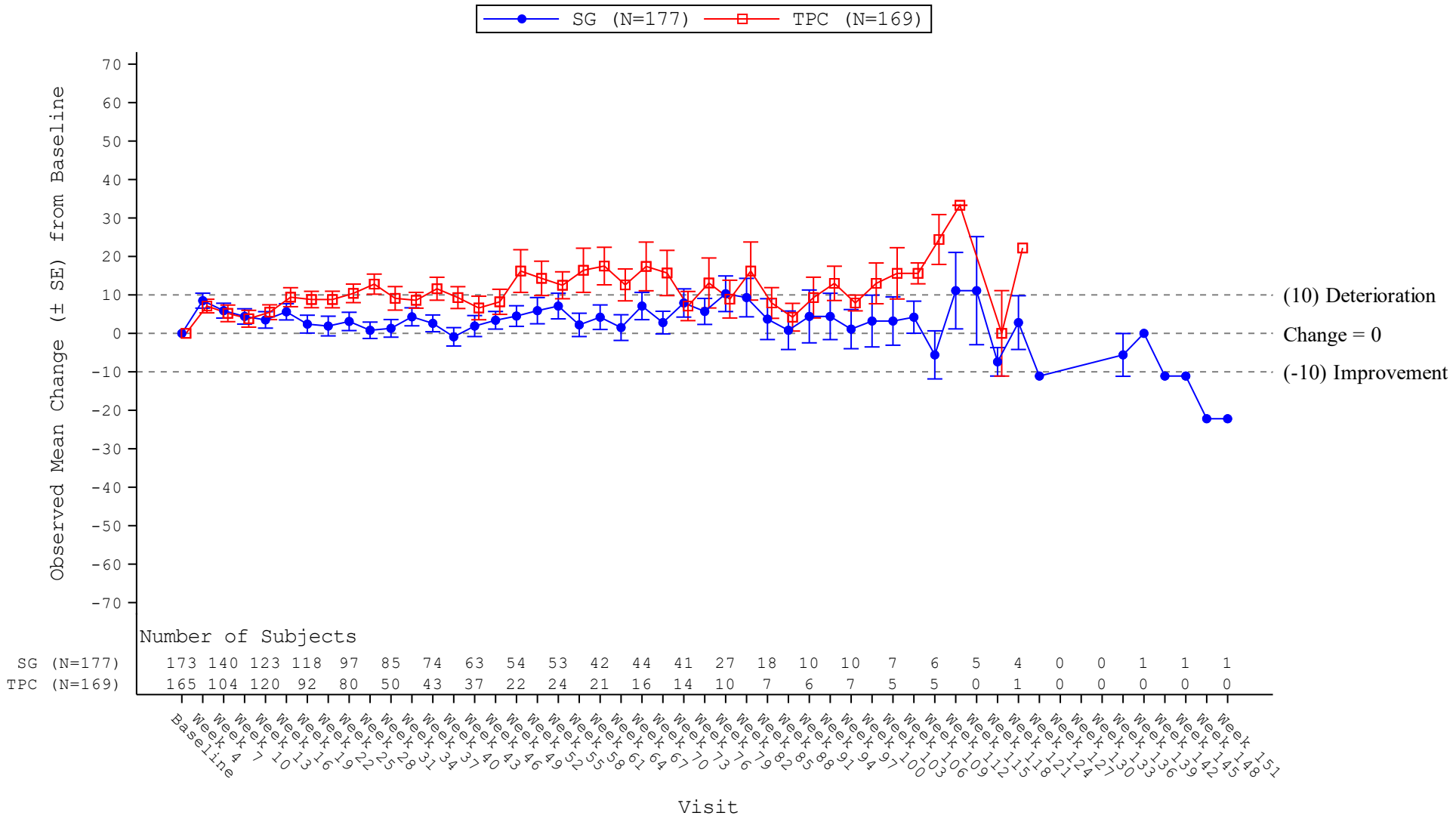


Figure 1.1.1.8
Observed Mean Change from Baseline in EORTC QLQ-C30 Nausea and Vomiting by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

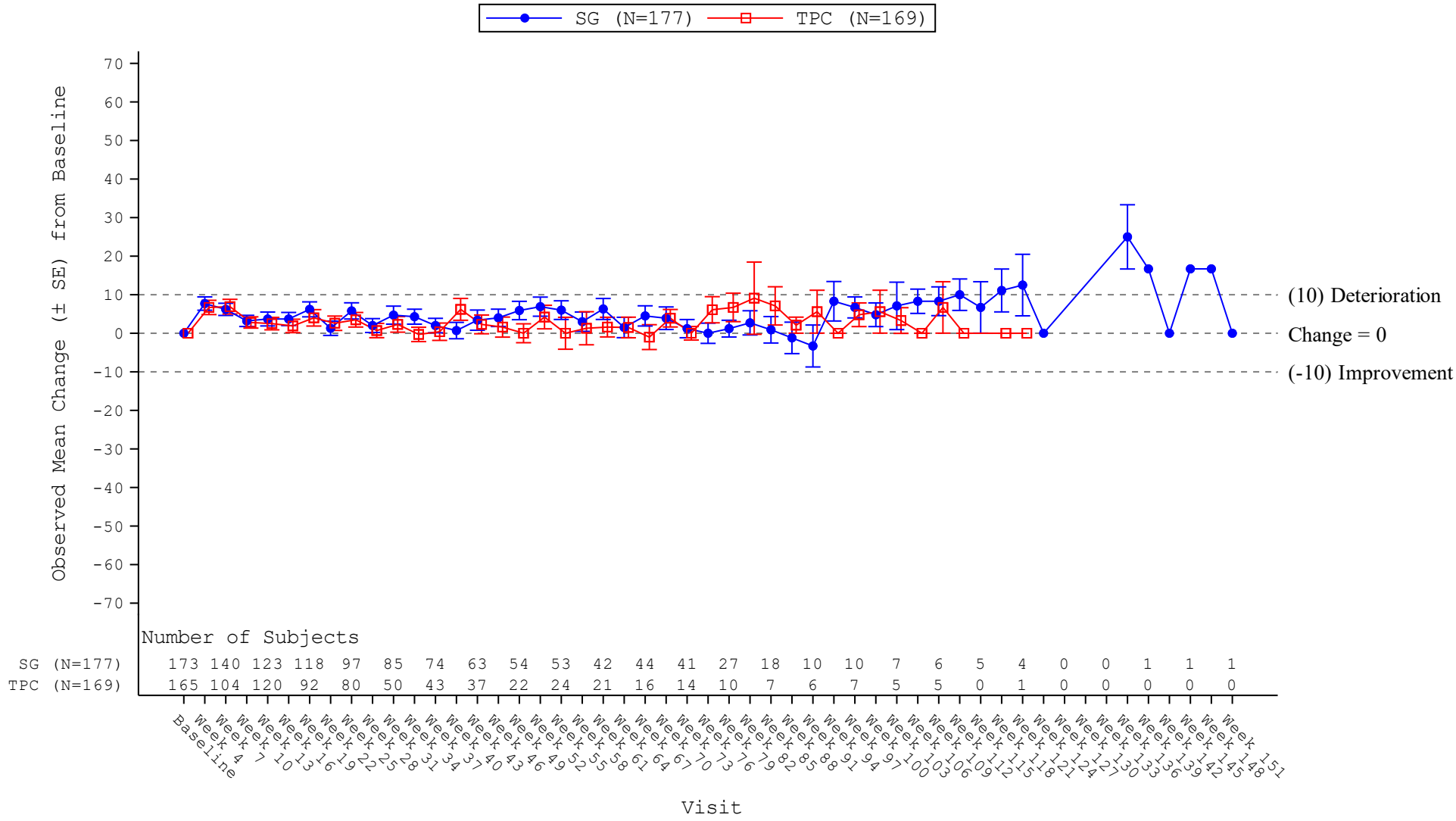

SG (N=177)
TPC (N=169)
Observed Mean Change (± SE) from Baseline
70
60
50
40
30
20
10
0
-10
-20
-30
-40
-50
-60
-70
(10) Deterioration
Change = 0
(-10) Improvement
Number of Subjects
SG (N=177) 173 140 123 118 97 85 74 63 54 53 42 44 41 27 18 10 10 7 6 5 4 0 0 1 1 1
TPC (N=169) 165 104 120 92 80 50 43 37 22 24 21 16 14 10 7 6 7 5 5 0 1 0 0 0 0 0
Baseline
Week 1
Week 4
Week 7
Week 10
Week 13
Week 16
Week 19
Week 22
Week 25
Week 28
Week 31
Week 34
Week 37
Week 40
Week 43
Week 46
Week 49
Week 52
Week 55
Week 58
Week 61
Week 64
Week 67
Week 70
Week 73
Week 76
Week 79
Week 82
Week 85
Week 88
Week 91
Week 94
Week 97
Week 100
Week 103
Week 106
Week 109
Week 112
Week 115
Week 118
Week 121
Week 124
Week 127
Week 130
Week 133
Week 136
Week 139
Week 142
Week 145
Week 148
Week 151
Visit

Figure 1.1.1.9
Observed Mean Change from Baseline in EORTC QLQ-C30 Pain by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

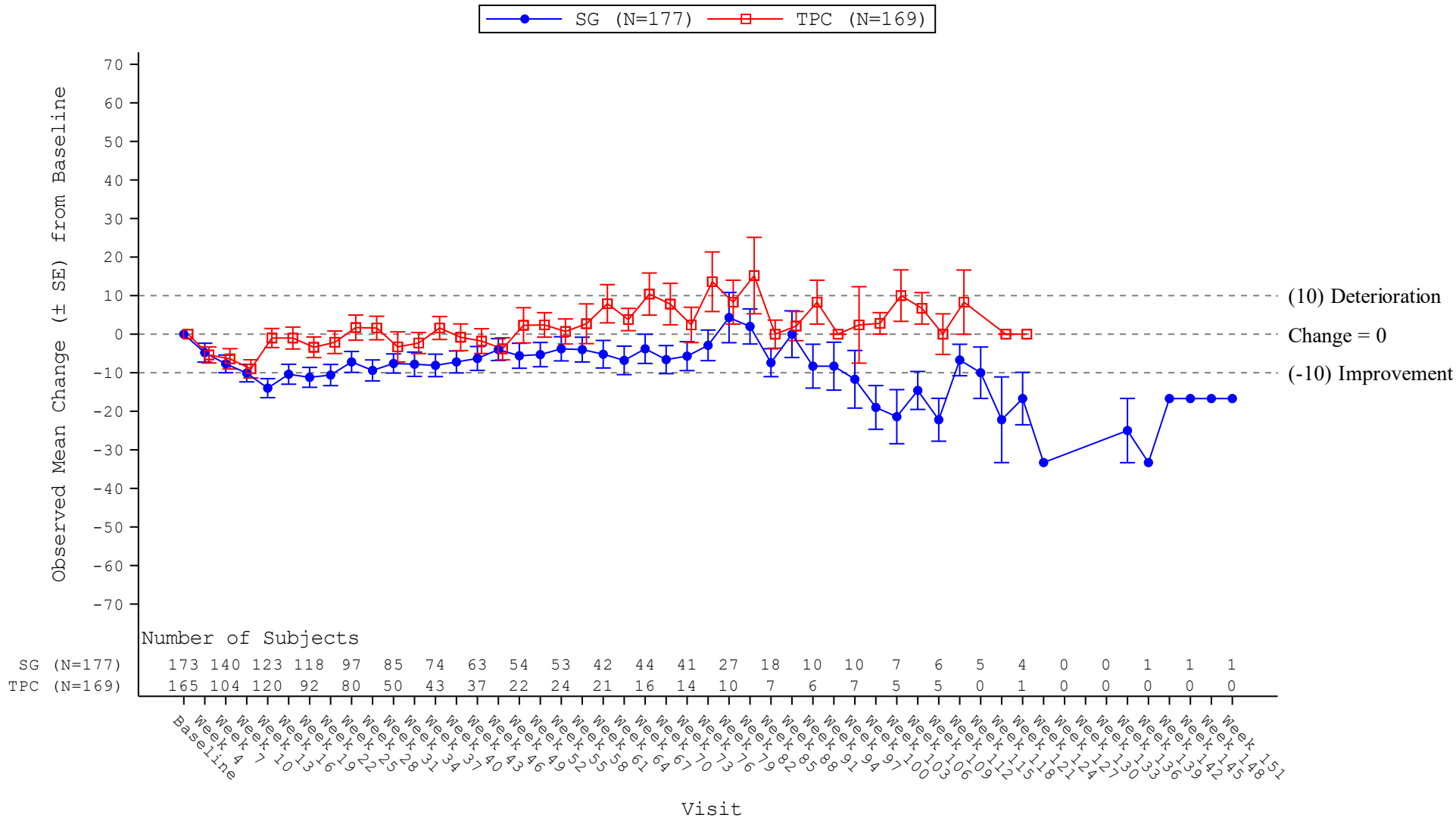


Figure 1.1.1.10
Observed Mean Change from Baseline in EORTC QLQ-C30 Dyspnea by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

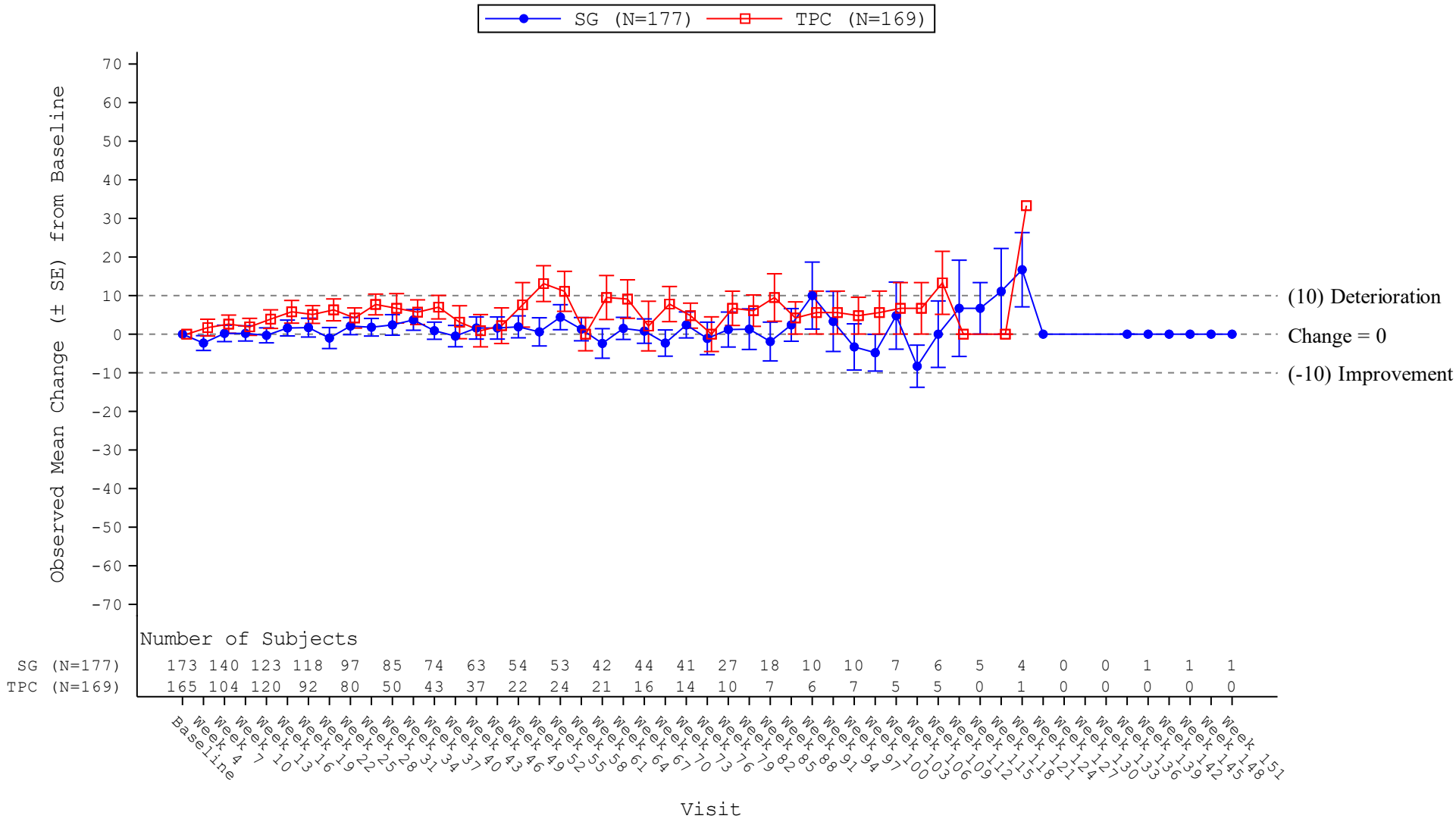


Figure 1.1.1.11
Observed Mean Change from Baseline in EORTC QLQ-C30 Insomnia by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

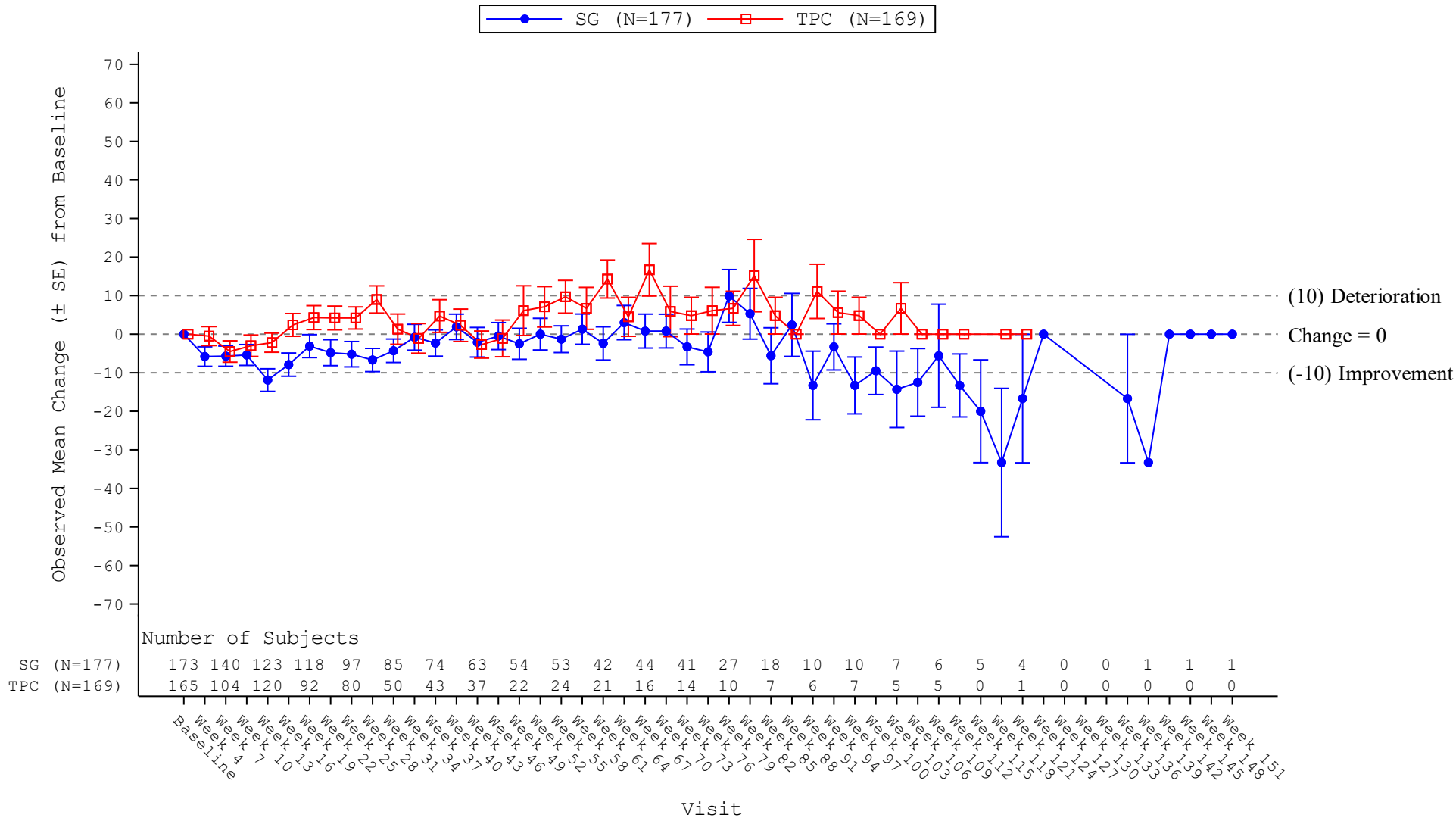


Figure 1.1.1.12
Observed Mean Change from Baseline in EORTC QLQ-C30 Appetite Loss by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

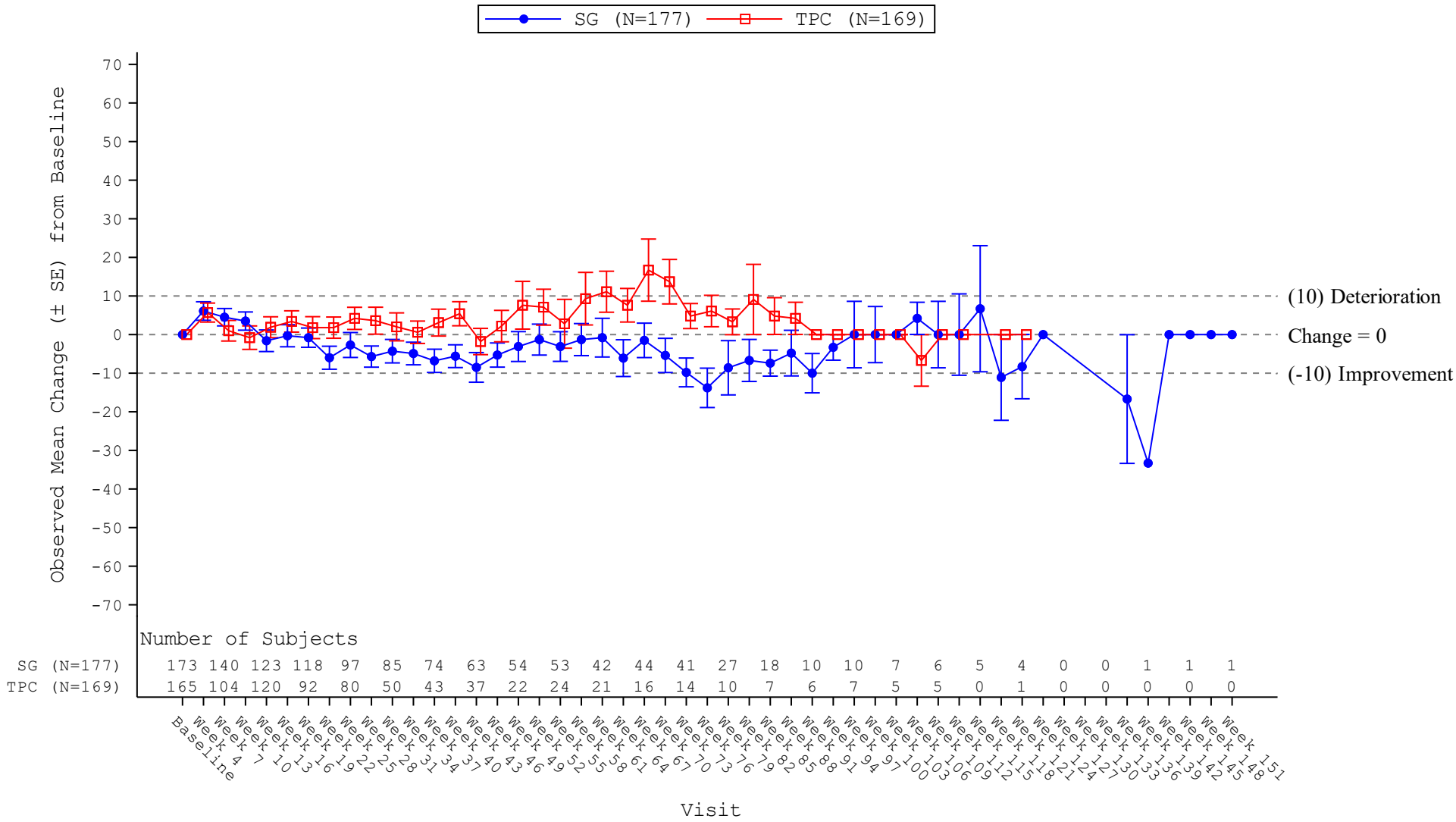


Figure 1.1.1.13
Observed Mean Change from Baseline in EORTC QLQ-C30 Constipation by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

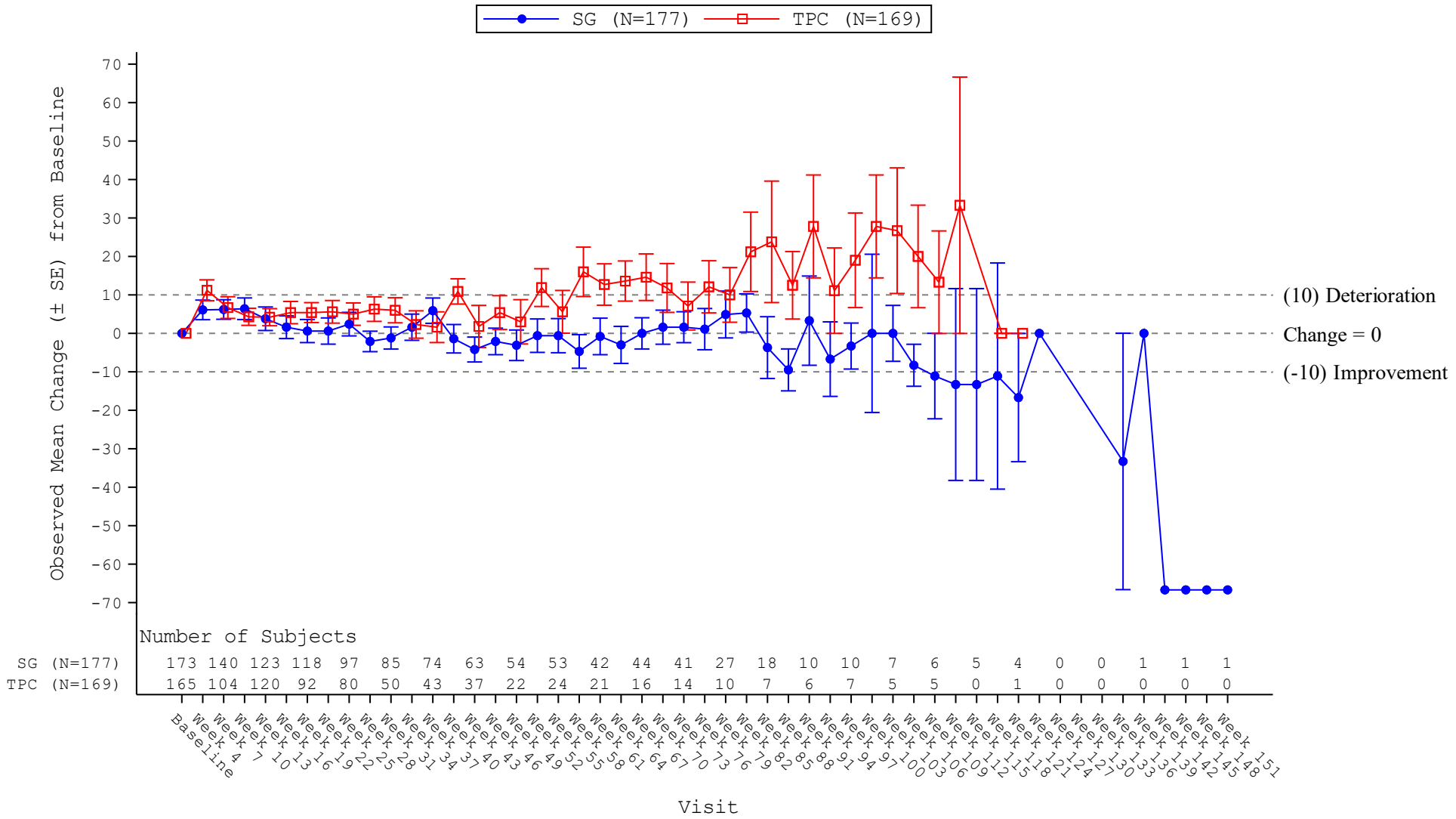


Figure 1.1.1.14
Observed Mean Change from Baseline in EORTC QLQ-C30 Diarrhea by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

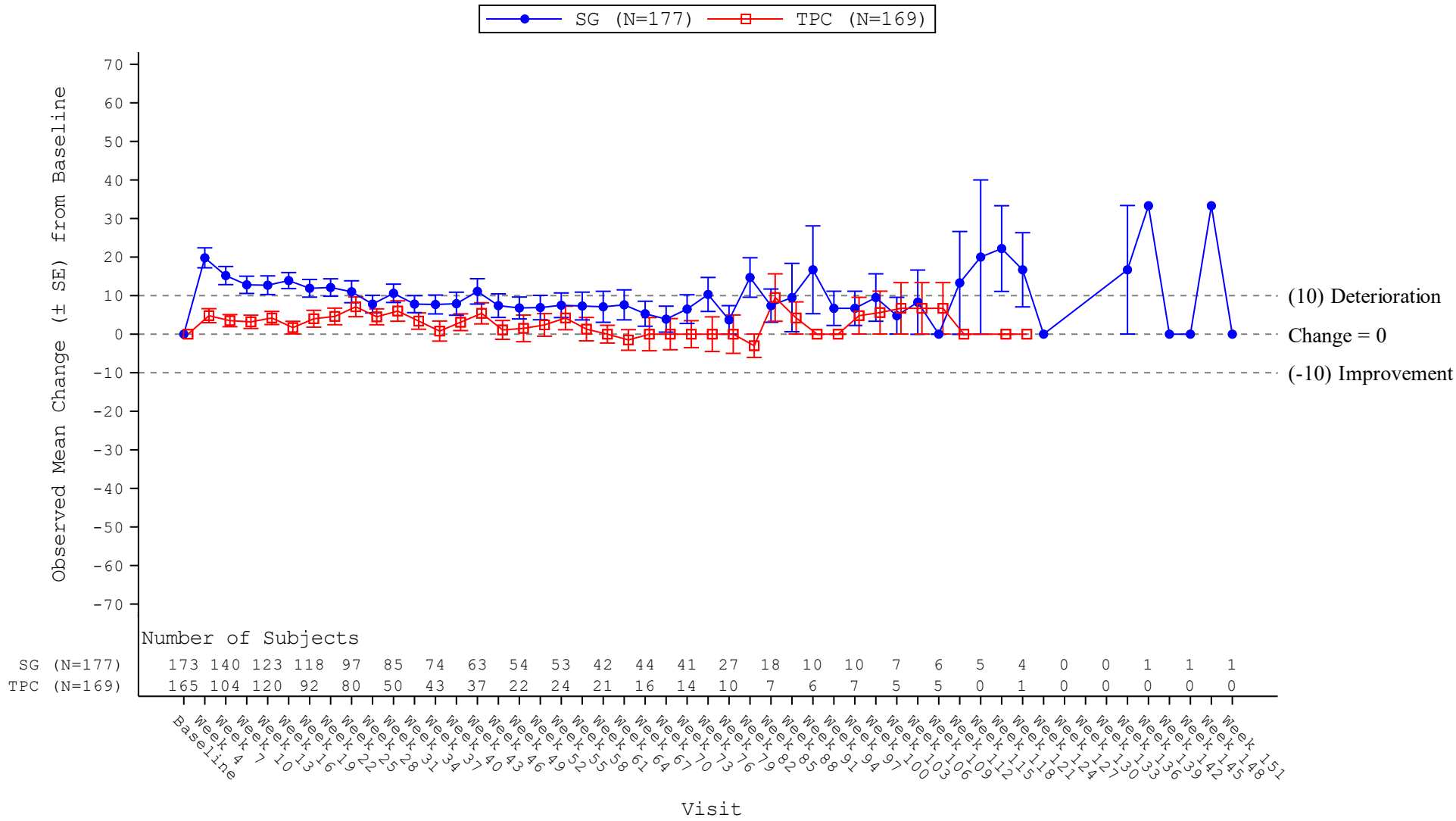


Figure 1.1.1.15
Observed Mean Change from Baseline in EORTC QLQ-C30 Financial Difficulties by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

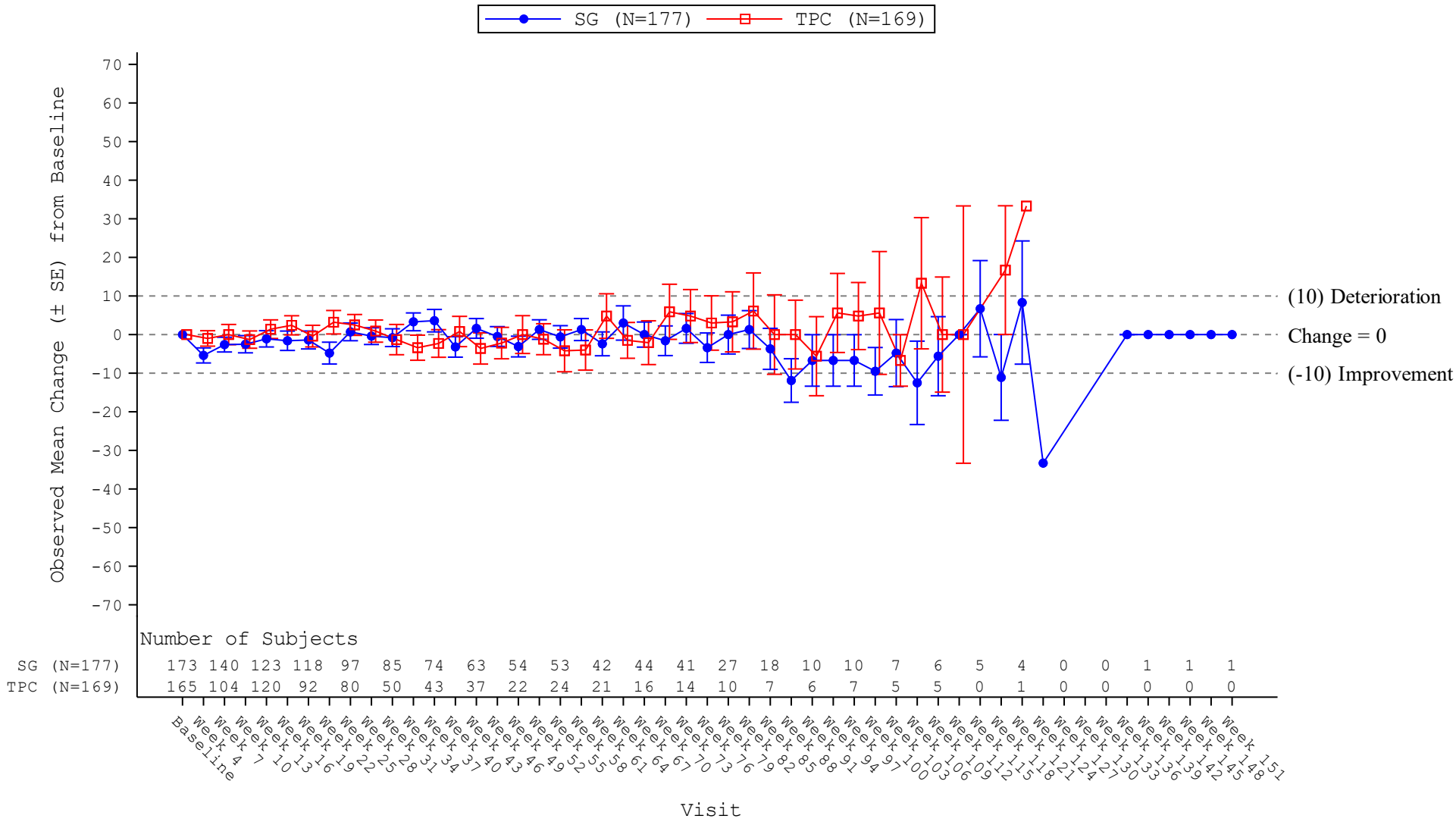


Figure 1.1.2.1
Observed Mean Change from Baseline in EORTC QLQ-BR23 Body Image by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

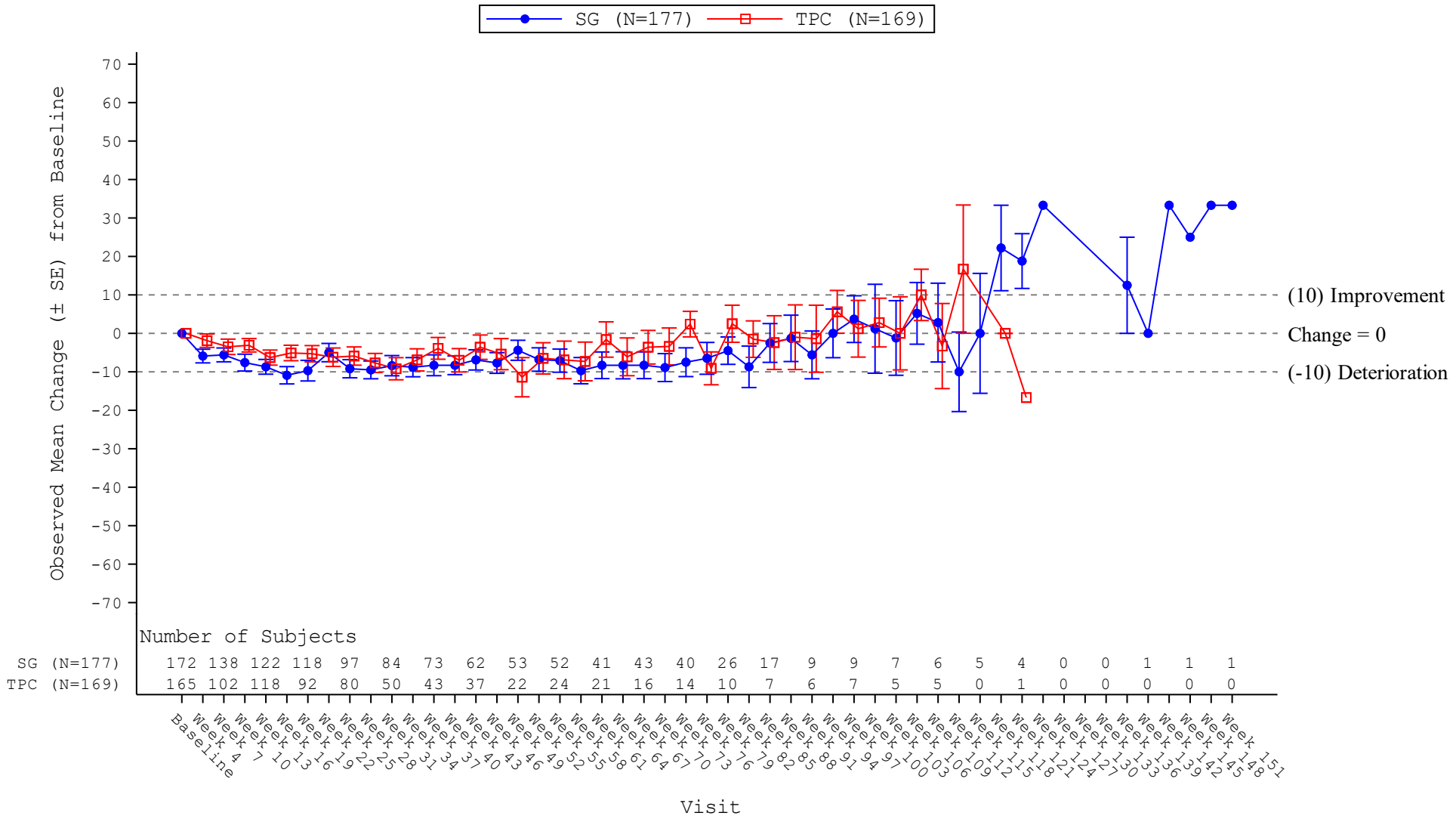


Figure 1.1.2.2
Observed Mean Change from Baseline in EORTC QLQ-BR23 Sexual Function by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

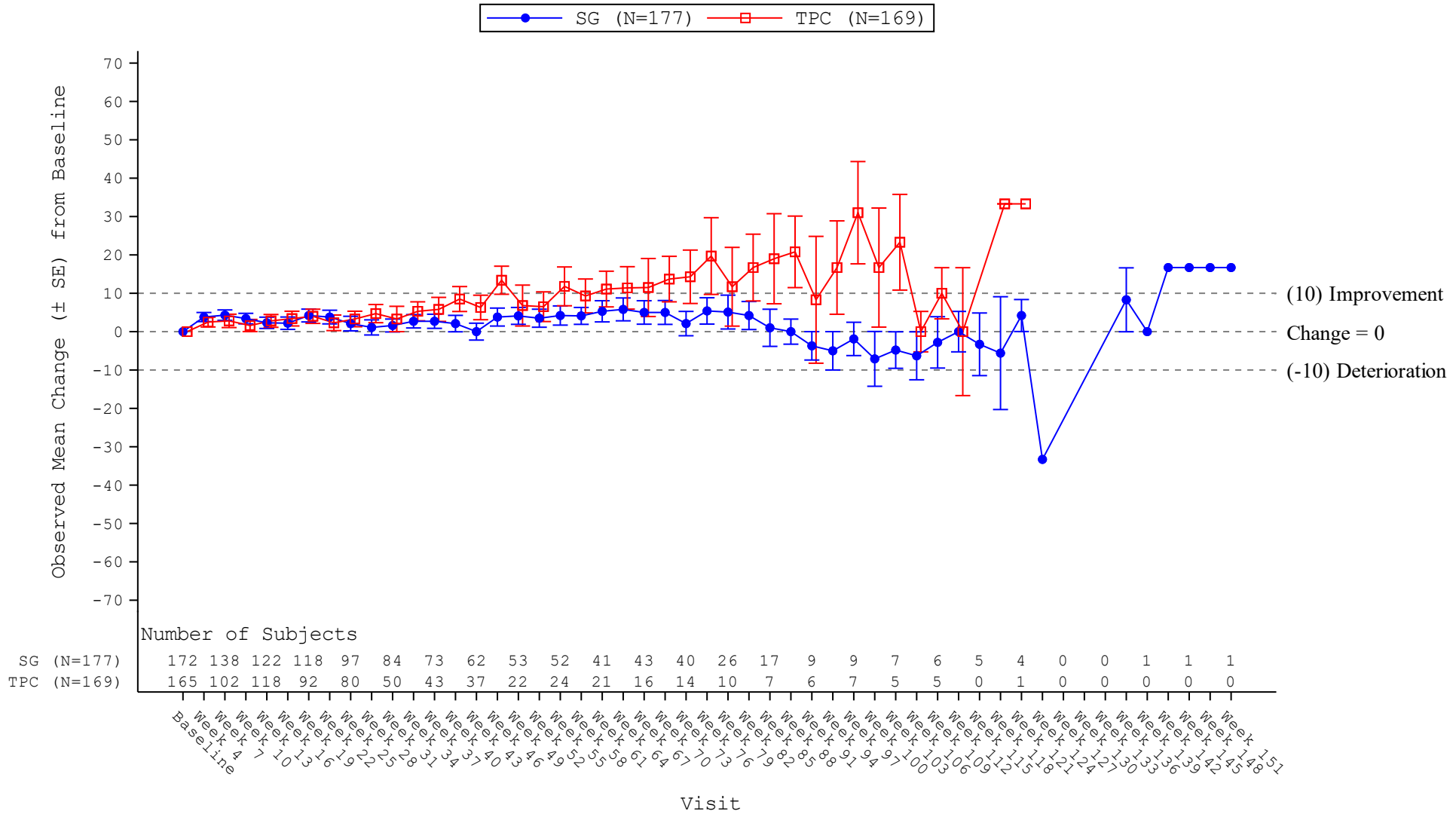

SG (N=177)
TPC (N=169)
Observed Mean Change (± SE) from Baseline
70
60
50
40
30
20
10
0
-10
-20
-30
-40
-50
-60
-70
(10) Improvement
Change = 0
(-10) Deterioration
Number of Subjects
SG (N=177) 172 138 122 118 97 84 73 62 53 52 41 43 40 26 17 9 9 7 6 5 4 0 0 1 1 1
TPC (N=169) 165 102 118 92 80 50 43 37 22 24 21 16 14 10 7 6 7 5 5 0 1 0 0 0 0 0
Baseline
week 4
week 7
week 10
week 13
week 16
week 19
week 22
week 25
week 28
week 31
week 34
week 37
week 40
week 43
week 46
week 49
week 52
week 55
week 58
week 61
week 64
week 67
week 70
week 73
week 76
week 79
week 82
week 85
week 88
week 91
week 94
week 97
week 100
week 103
week 106
week 109
week 112
week 115
week 118
week 121
week 124
week 127
week 130
week 133
week 136
week 139
week 142
week 145
week 148
week 151
Visit

Figure 1.1.2.3
Observed Mean Change from Baseline in EORTC QLQ-BR23 Sexual Enjoyment by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

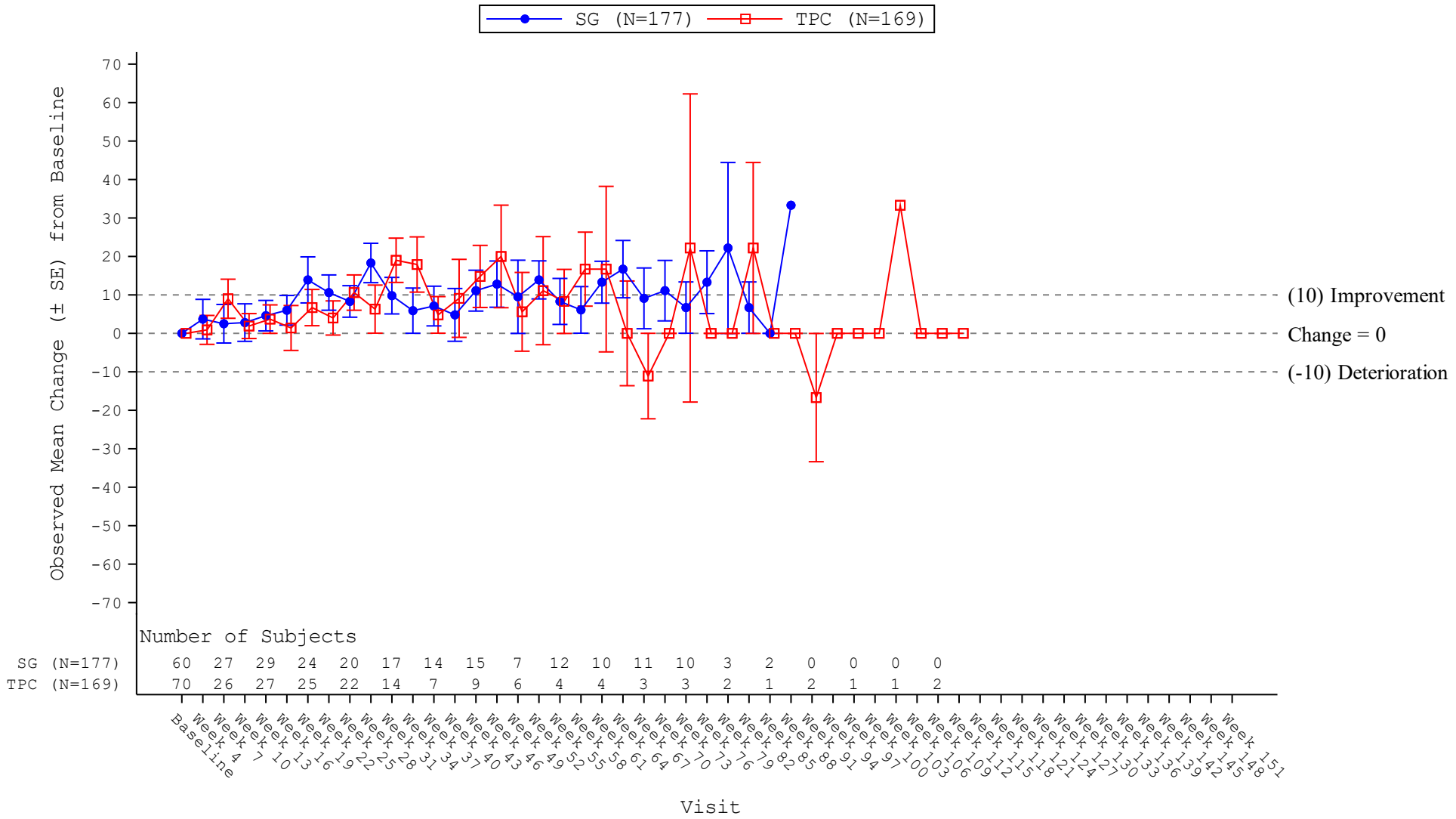


Figure 1.1.2.4
Observed Mean Change from Baseline in EORTC QLQ-BR23 Future Perspective by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

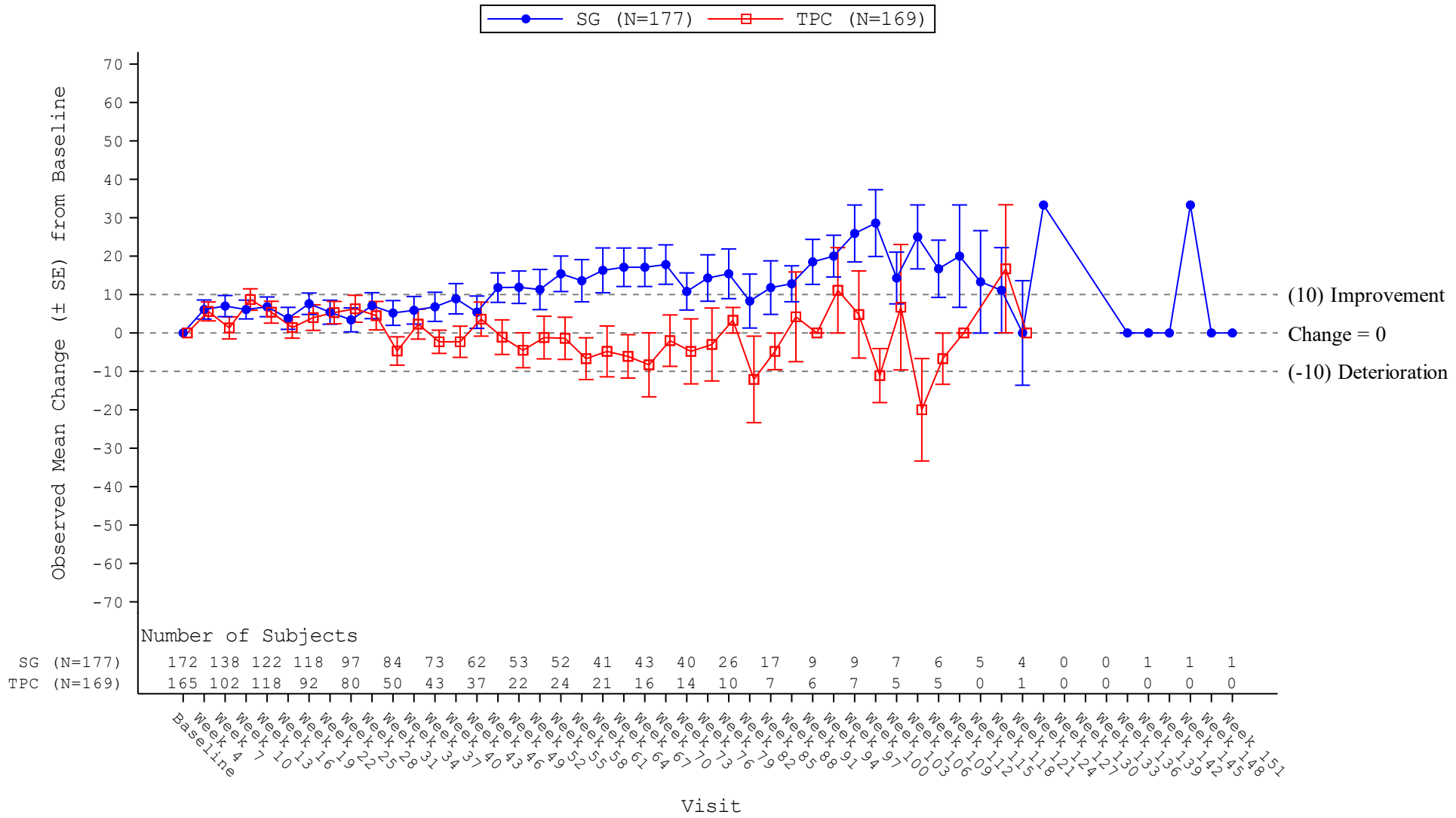


Figure 1.1.2.5
Observed Mean Change from Baseline in EORTC QLQ-BR23 Systemic Therapy Side Effects by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

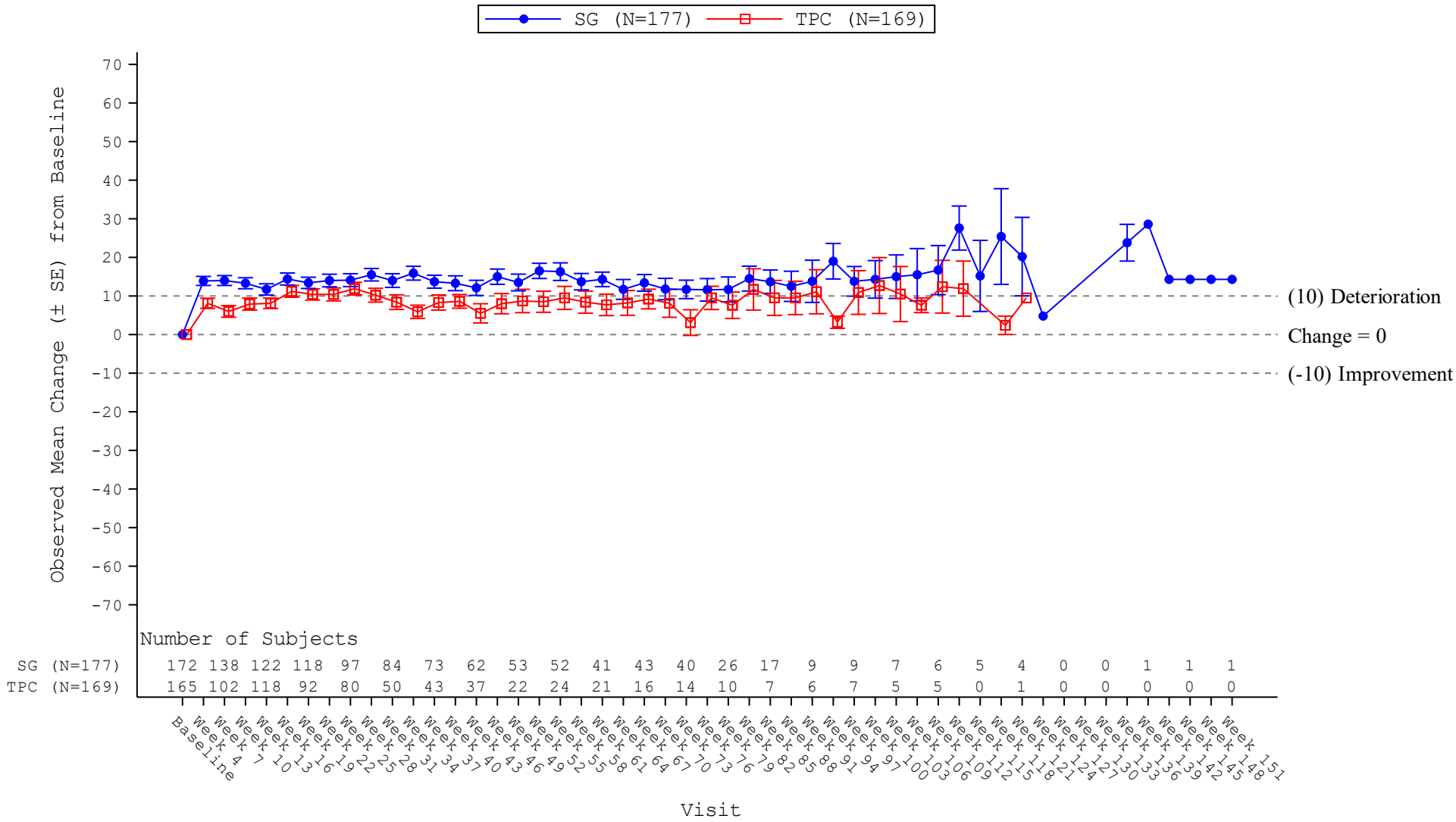


Figure 1.1.2.6
Observed Mean Change from Baseline in EORTC QLQ-BR23 Breast Symptoms by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

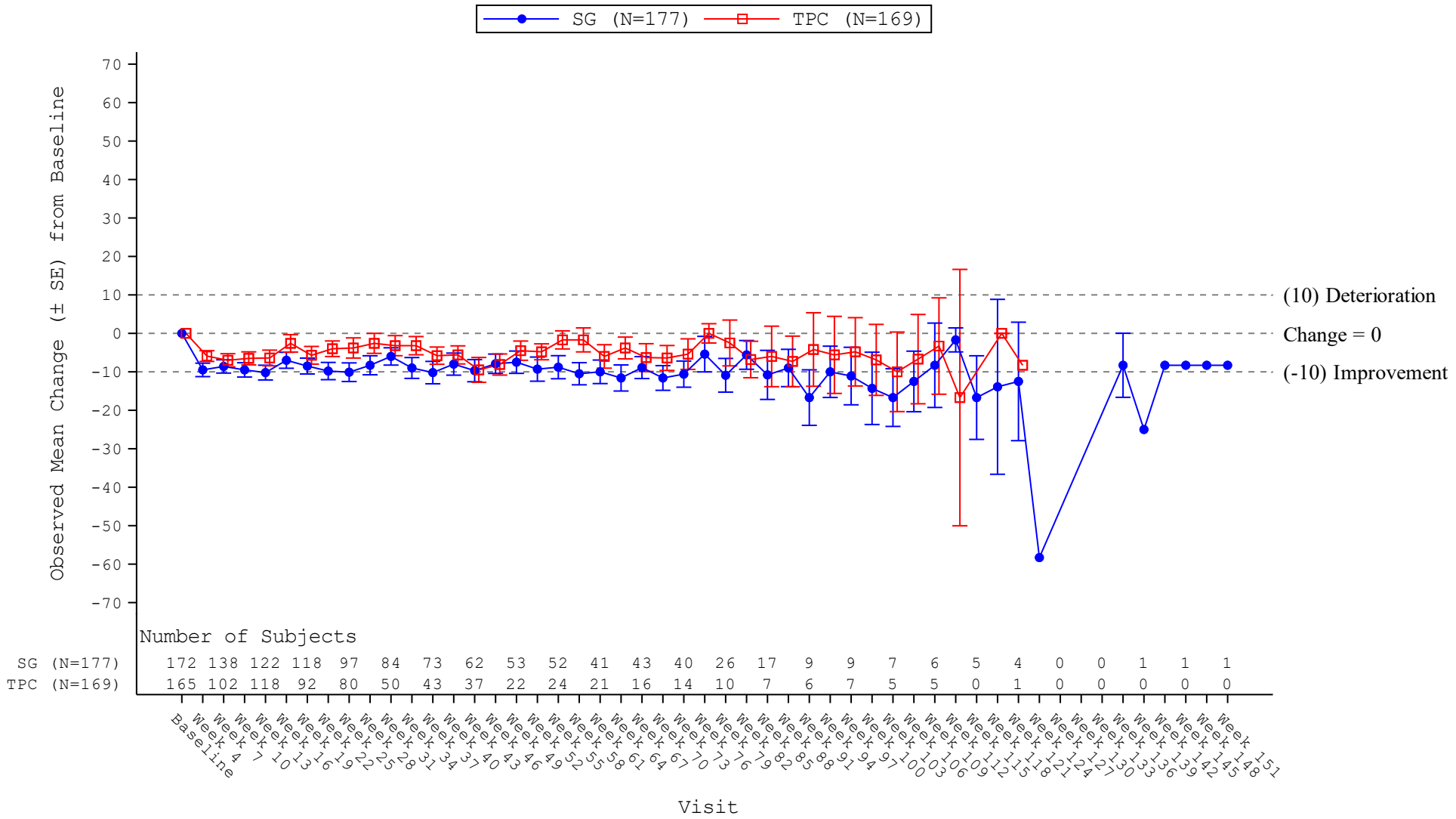


Figure 1.1.2.7
Observed Mean Change from Baseline in EORTC QLQ-BR23 Arm Symptoms by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

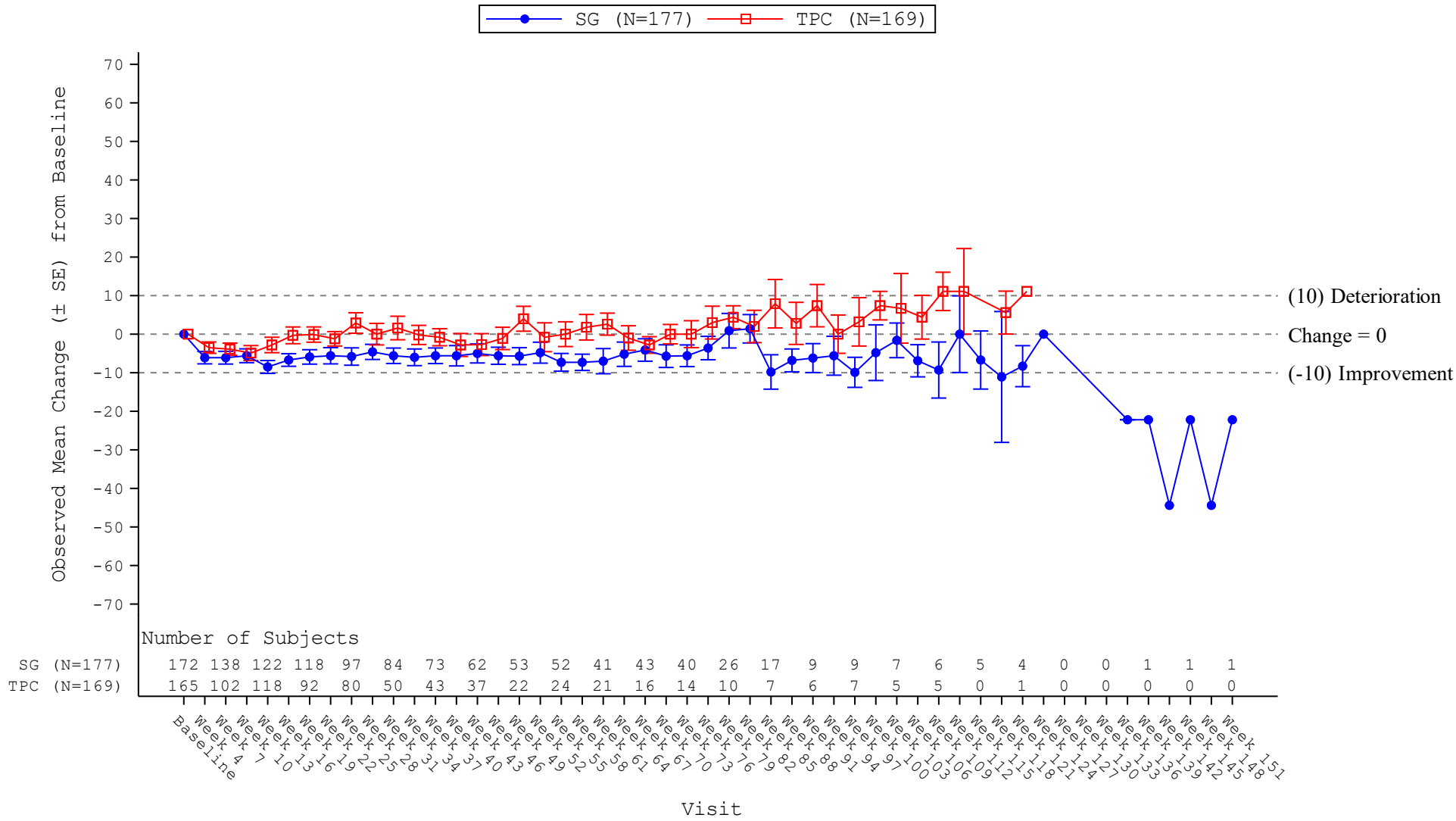


Figure 1.1.2.8
Observed Mean Change from Baseline in EORTC QLQ-BR23 Upset by Hair Loss by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

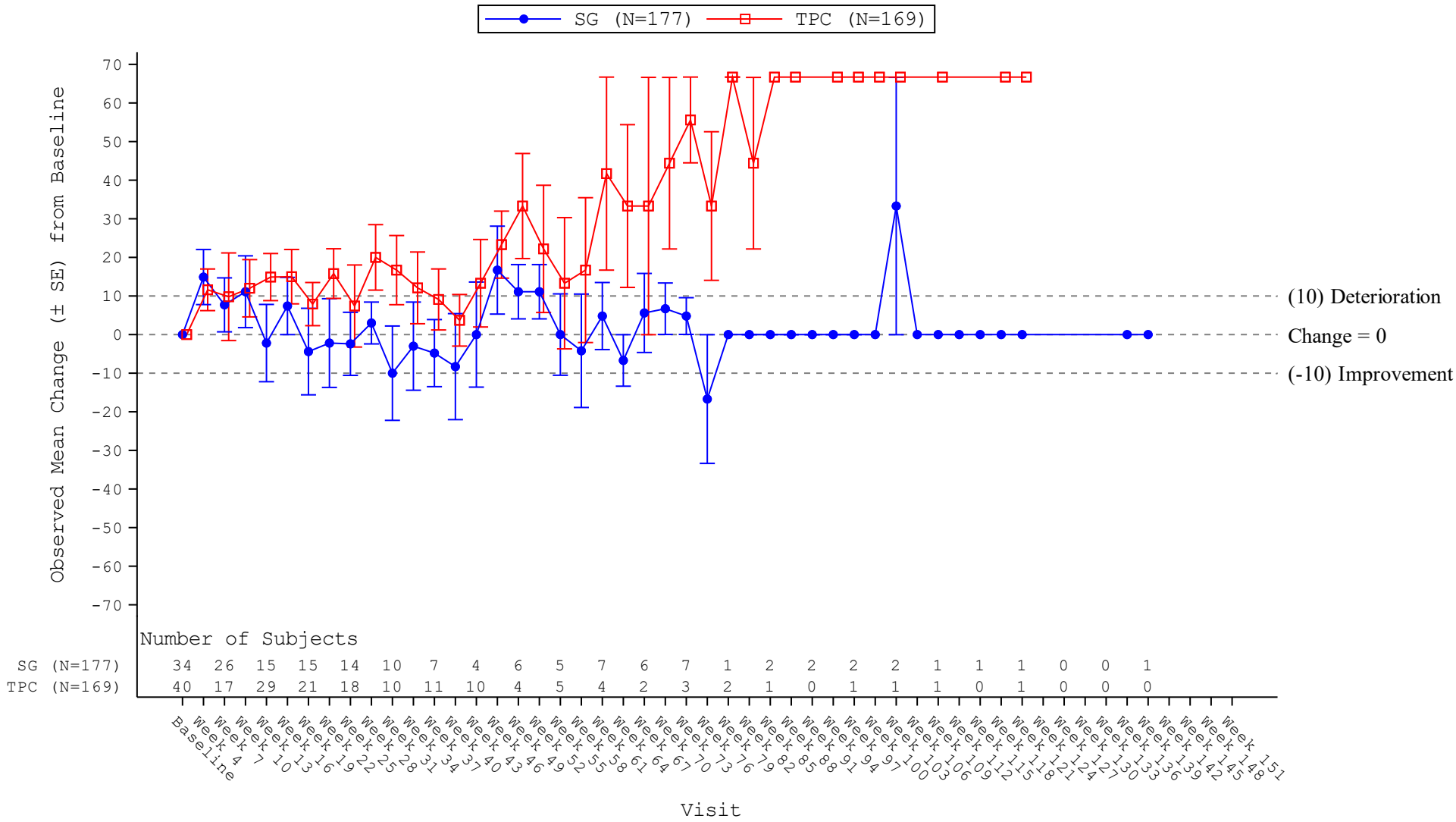


Figure 1.1.3
Observed Mean Change from Baseline in EQ-VAS by Visit and Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)

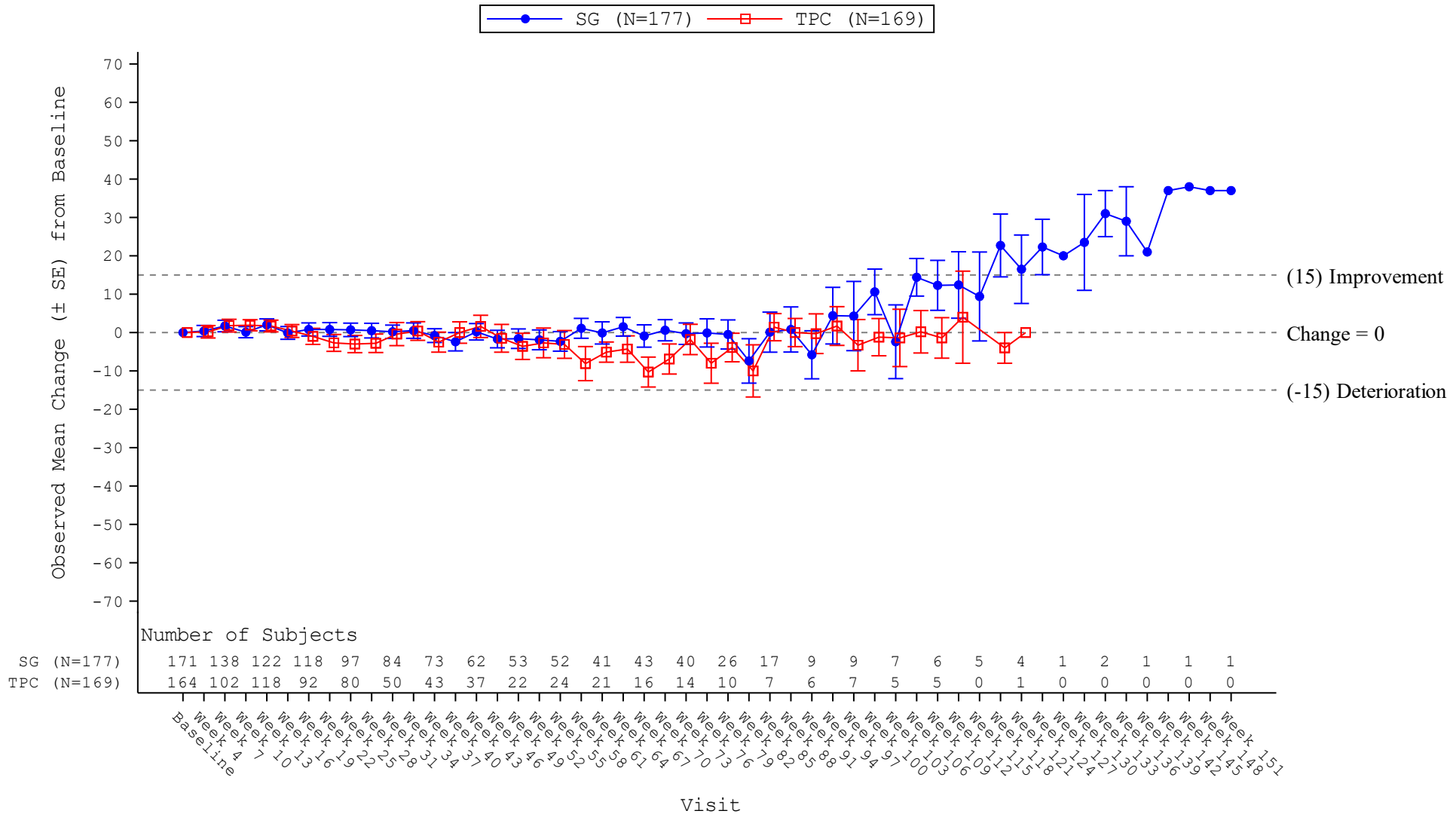
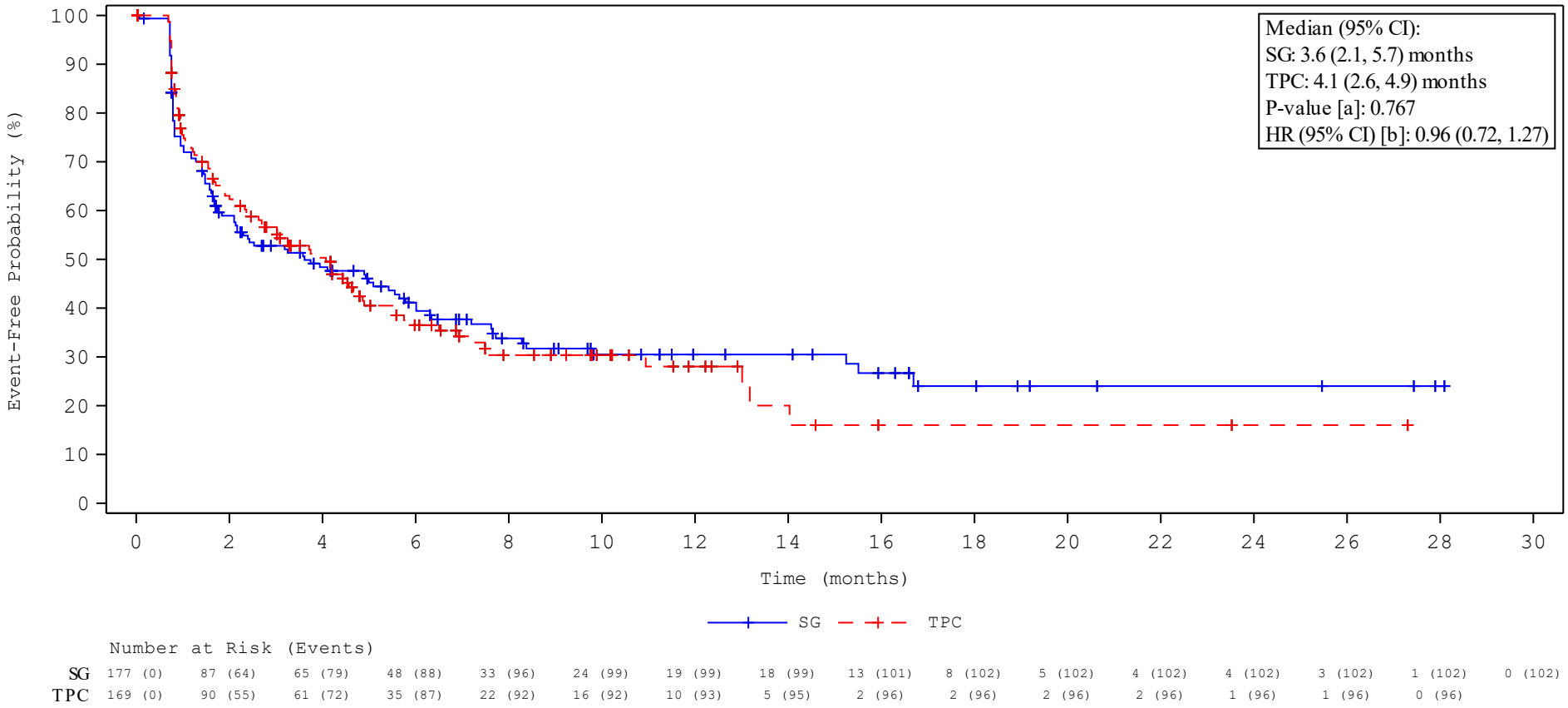


Figure 2.1.1.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



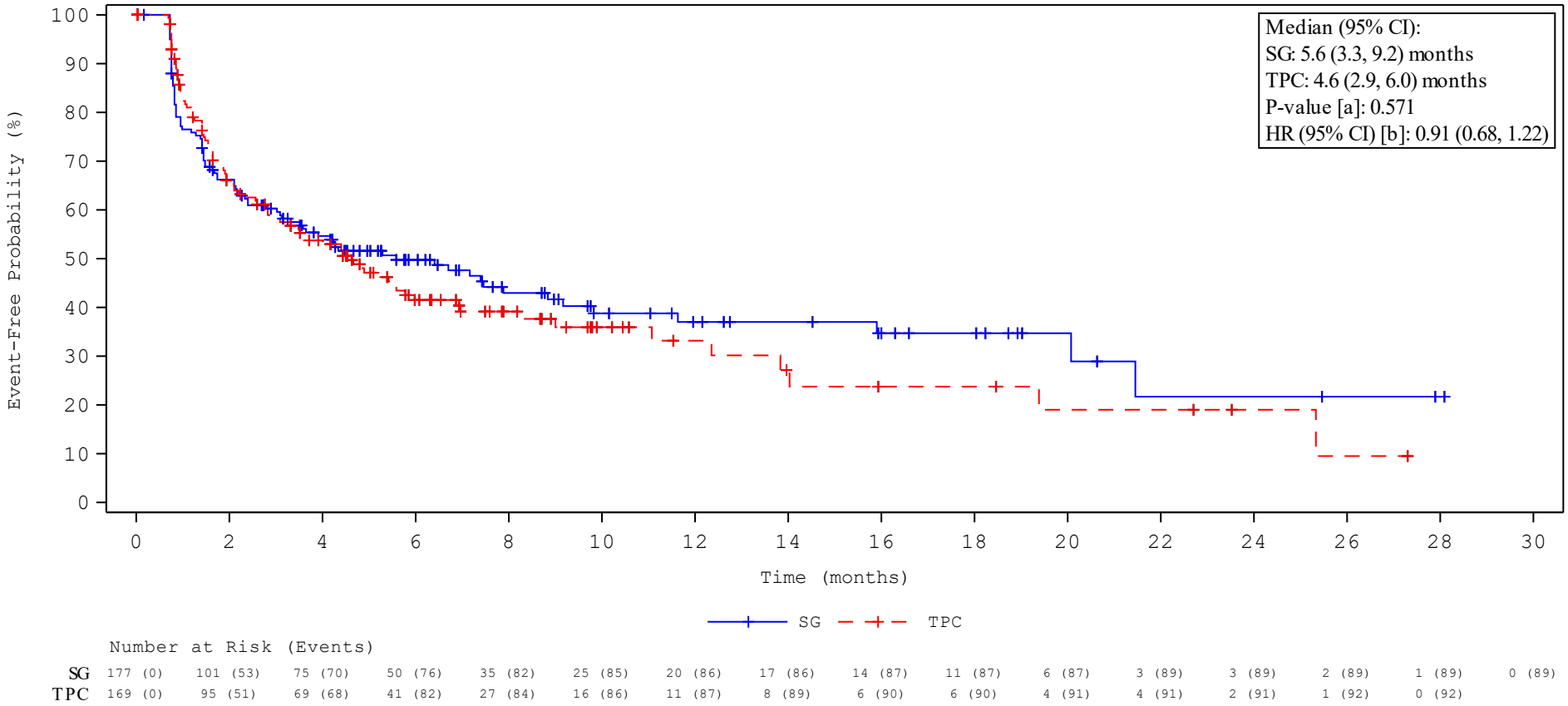
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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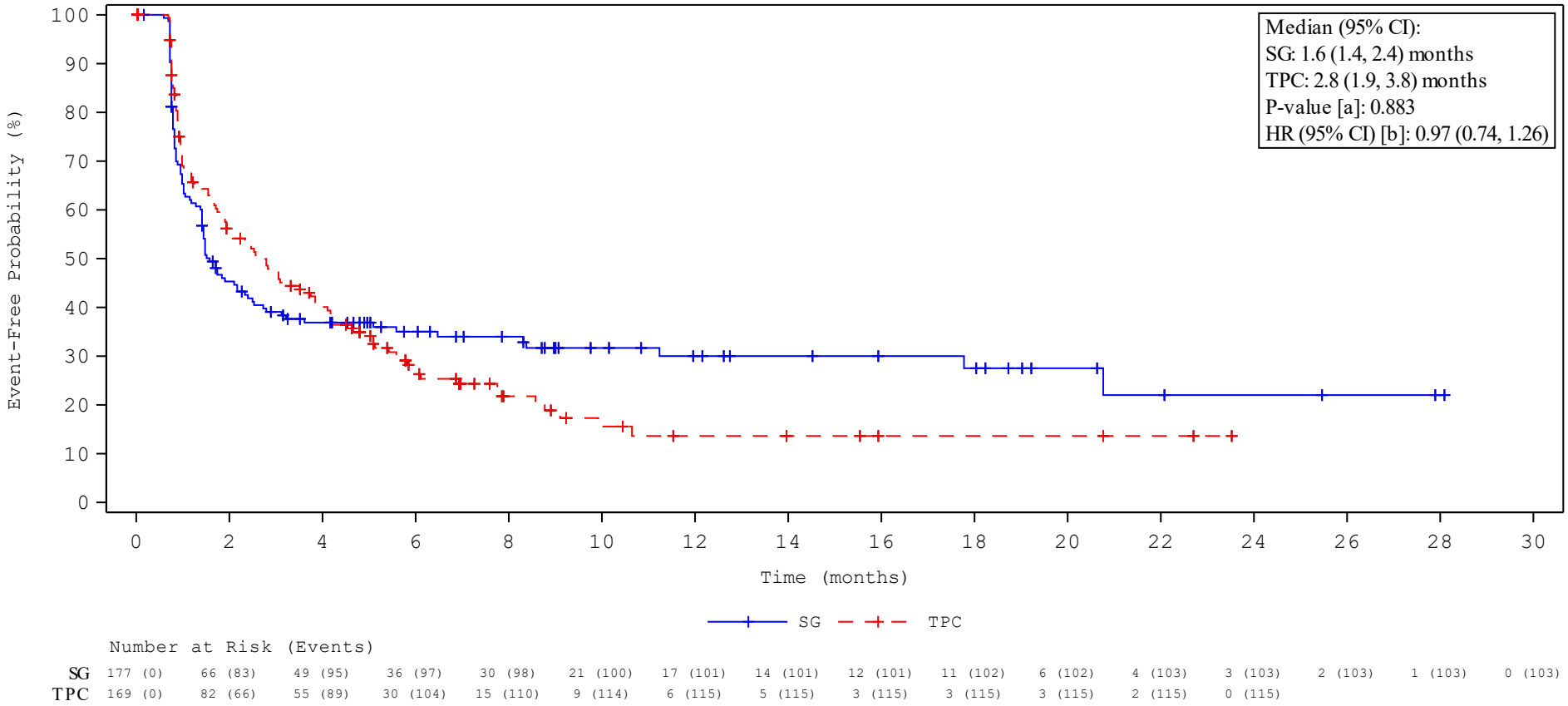
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Figure 2.1.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Physical Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



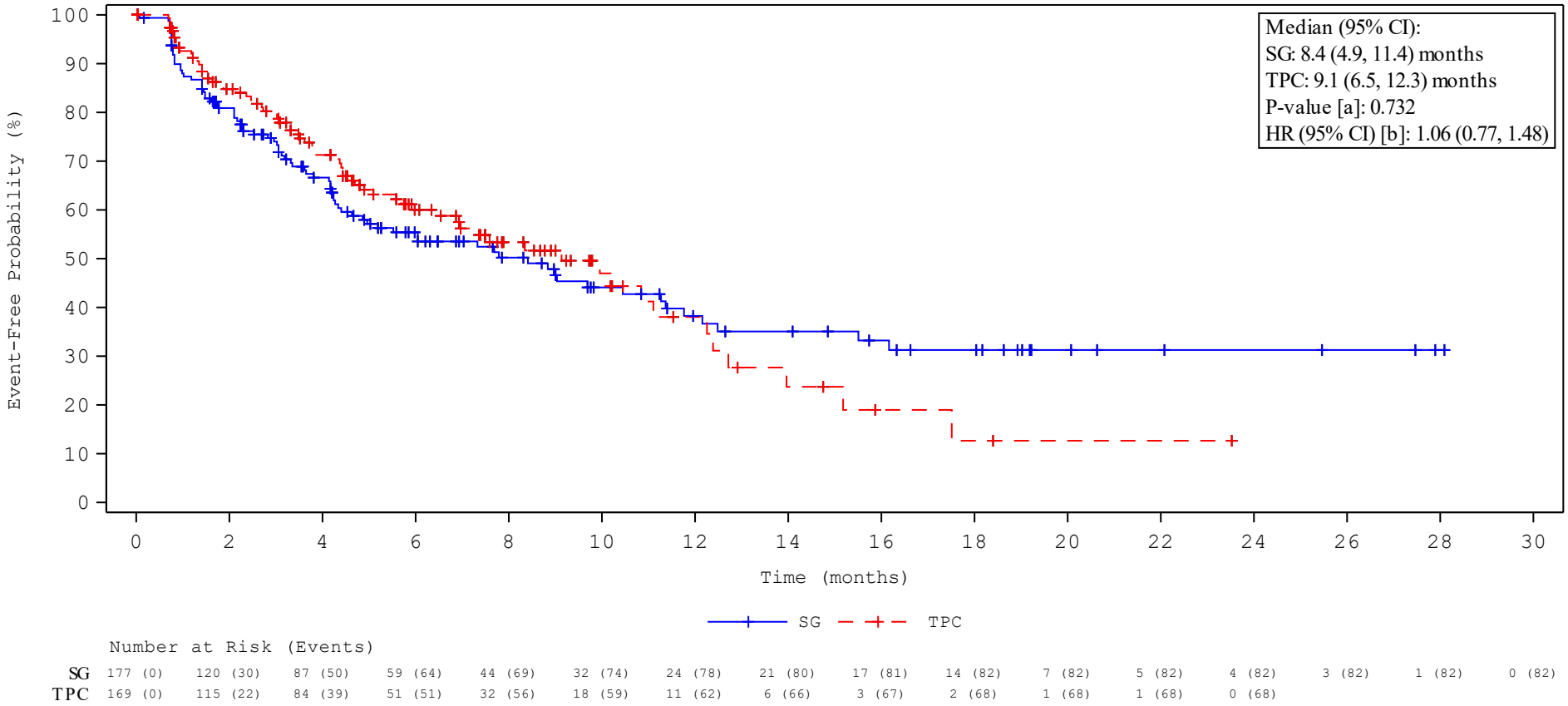
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



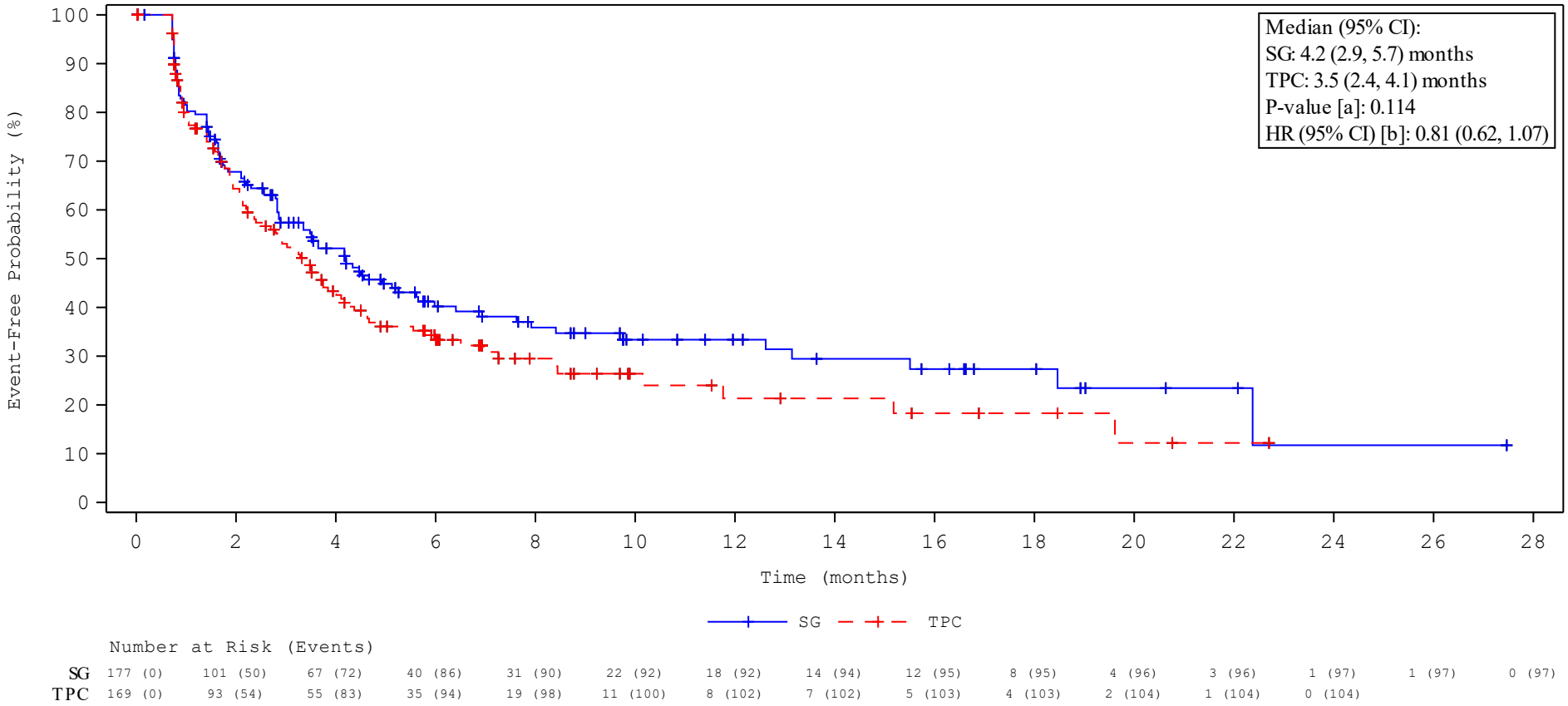
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Emotional Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



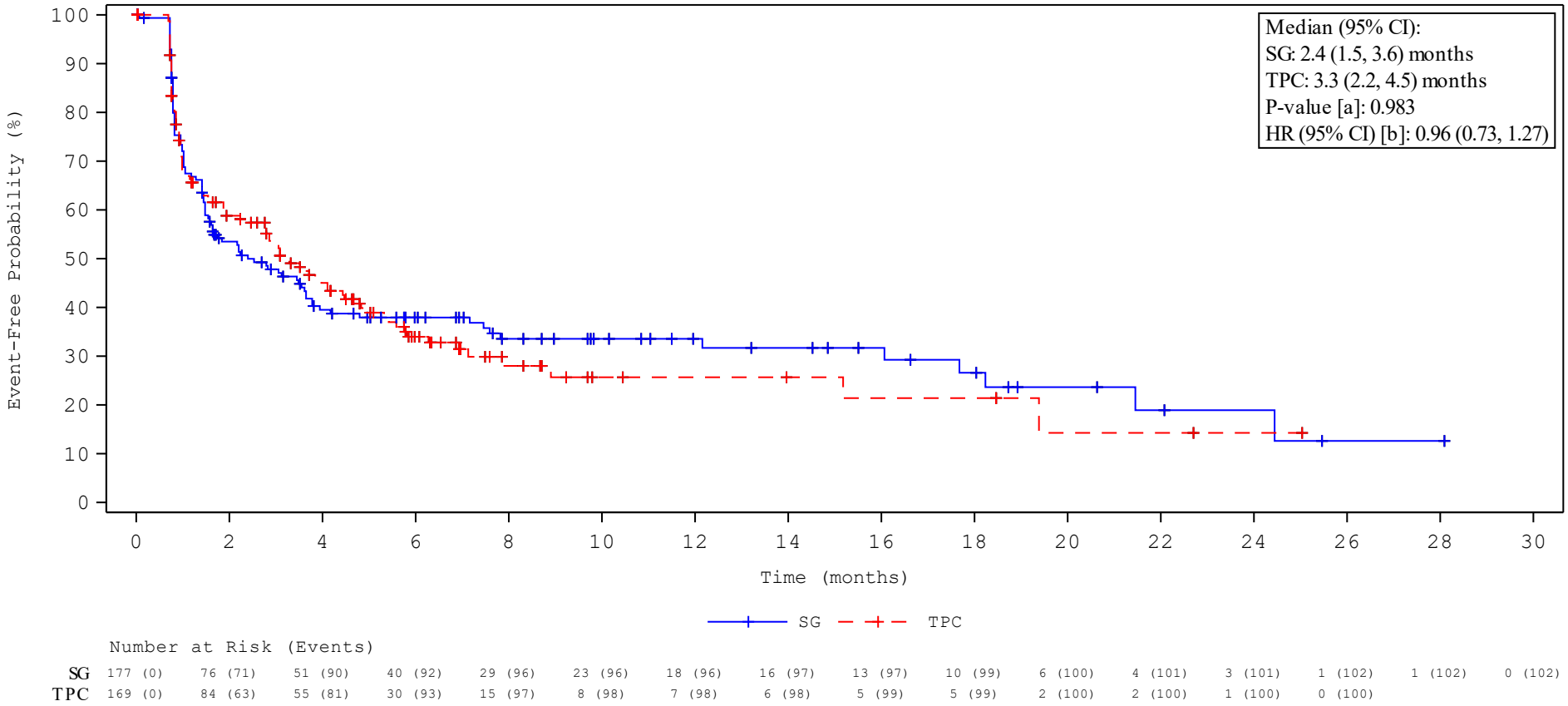
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Cognitive Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



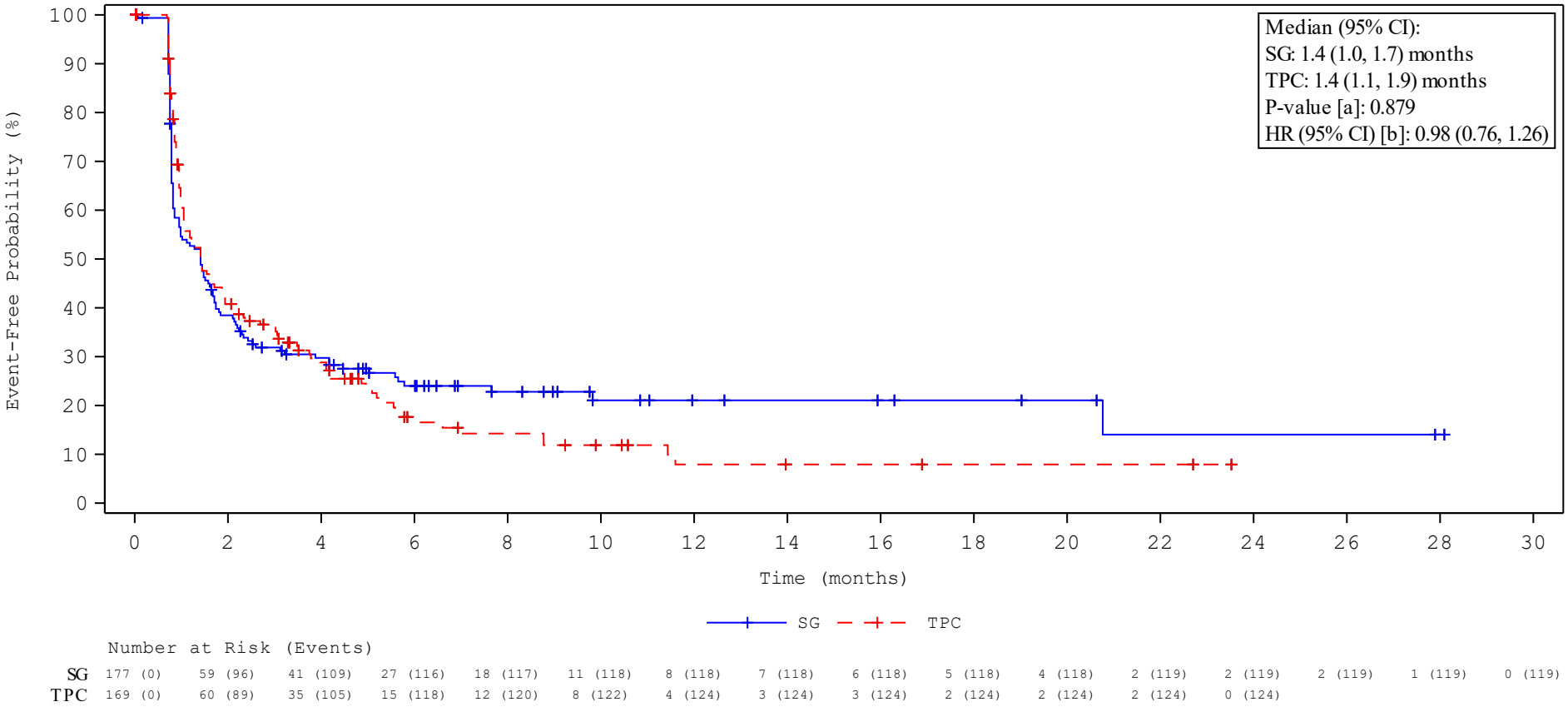
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.6
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Social Functioning by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



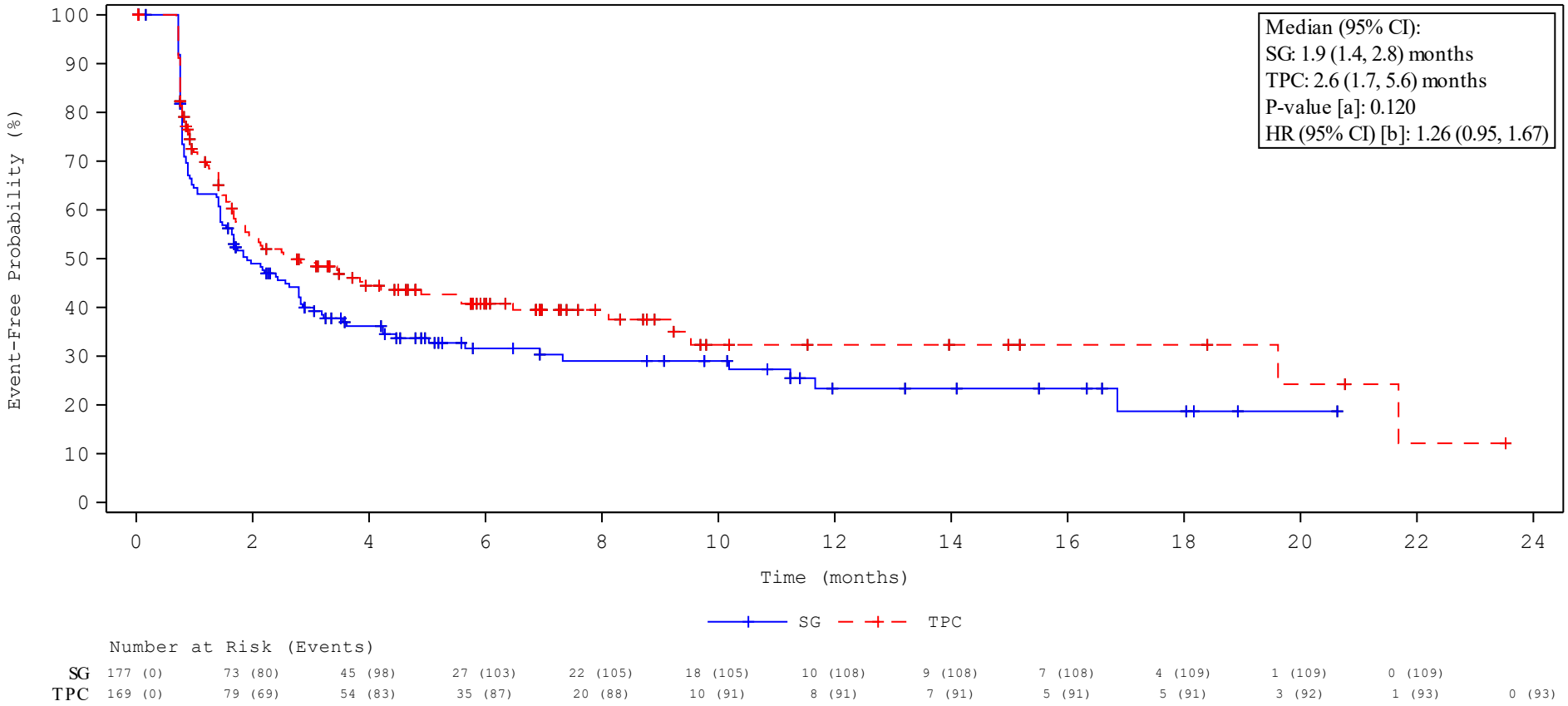
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.7
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Fatigue by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



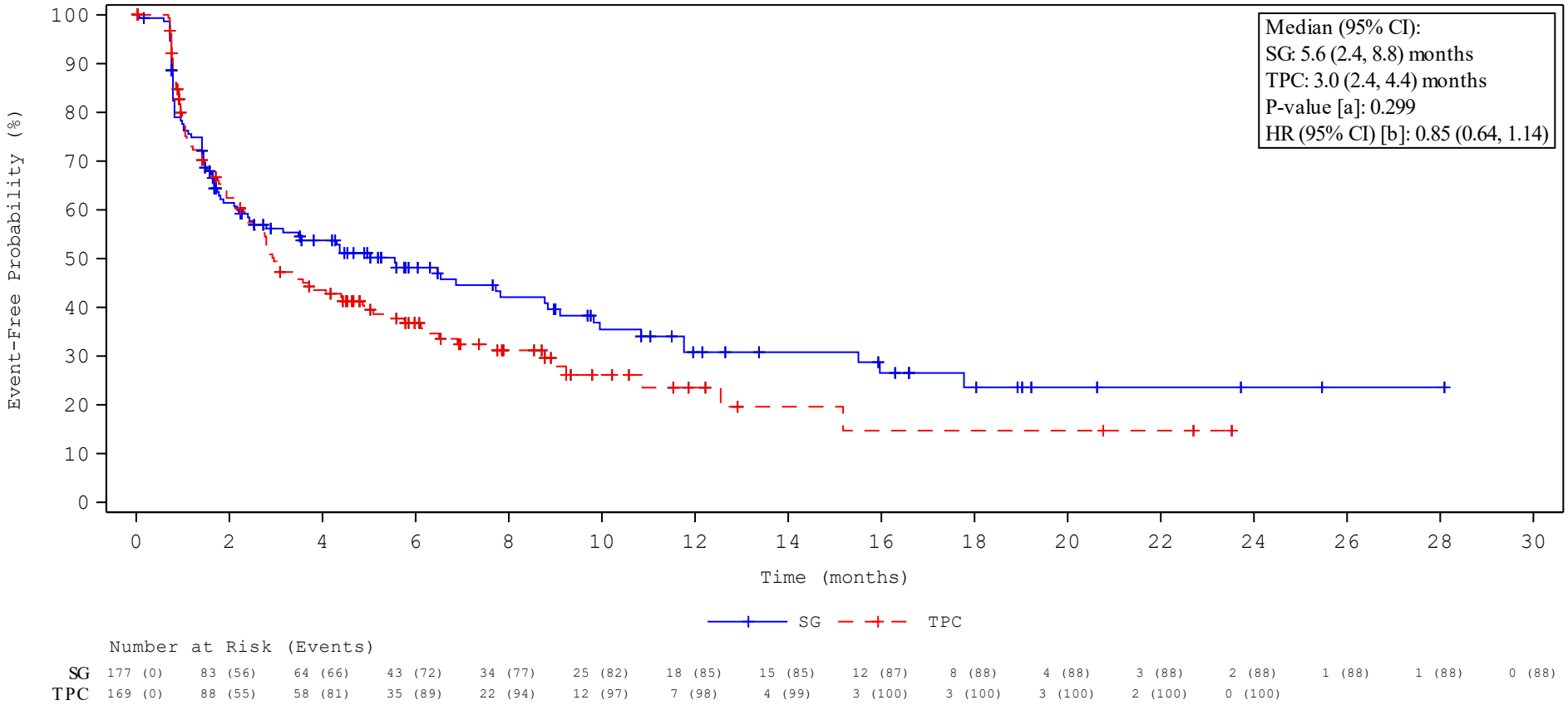
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.8
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



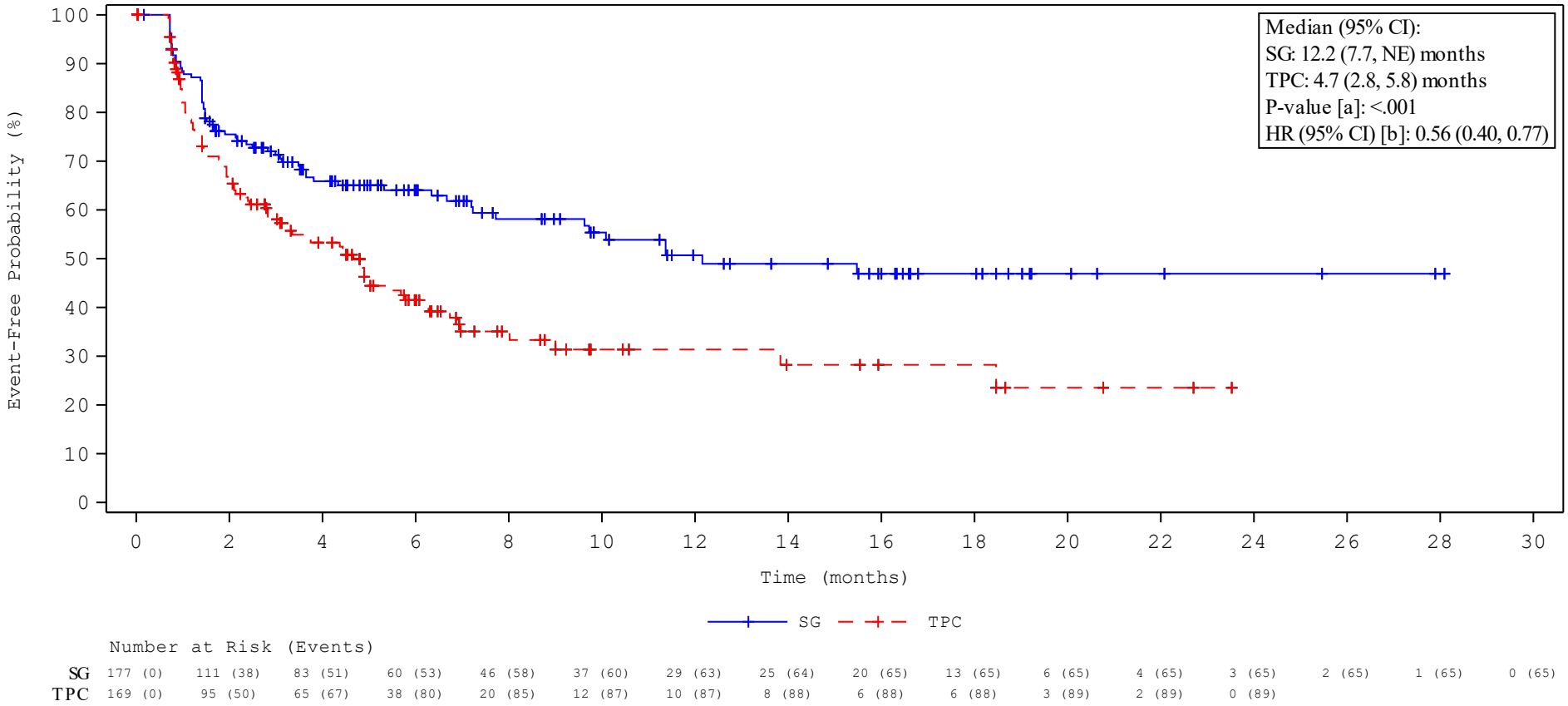
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.9
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Pain by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



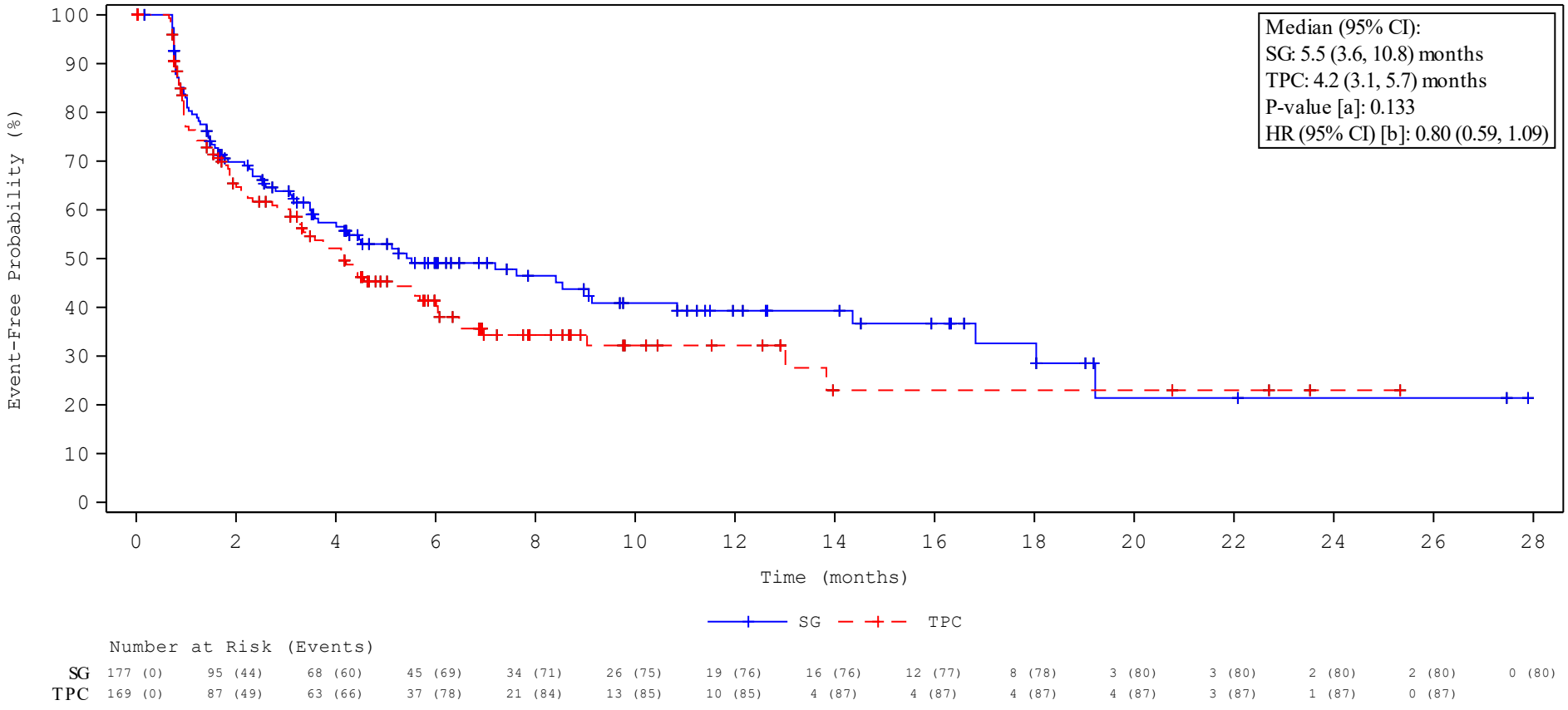
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.10
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Dyspnea by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



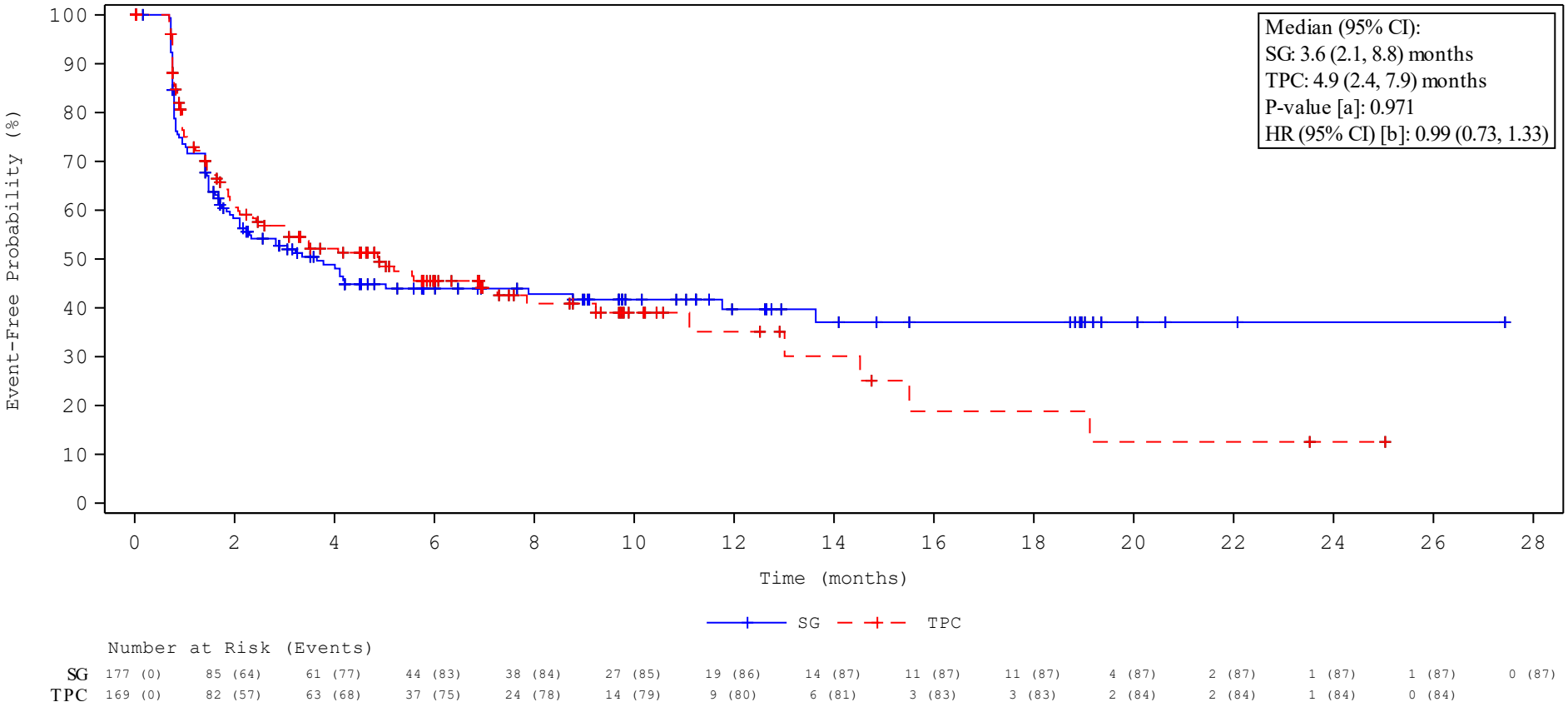
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.11
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Insomnia by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



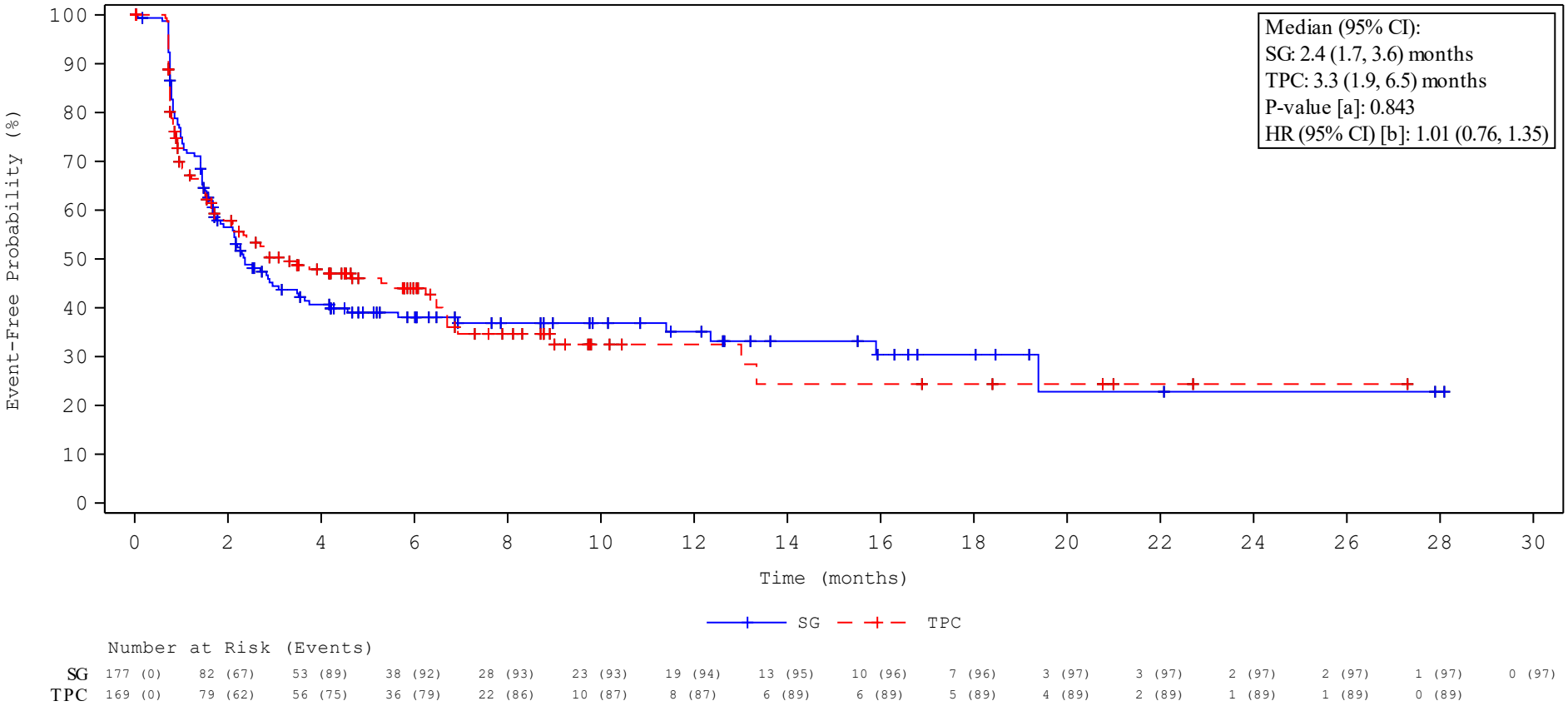
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.12
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Appetite Loss by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



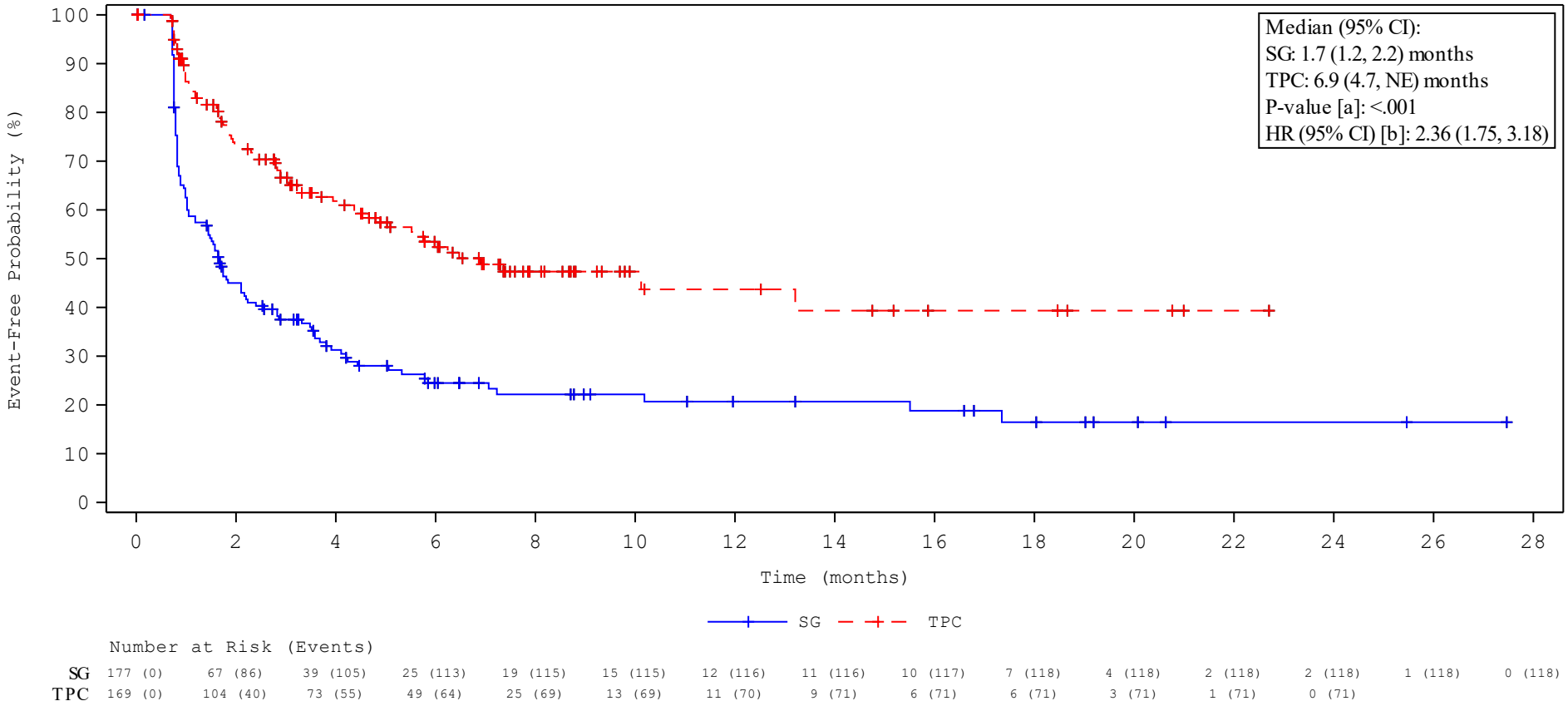
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.13
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Constipation by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



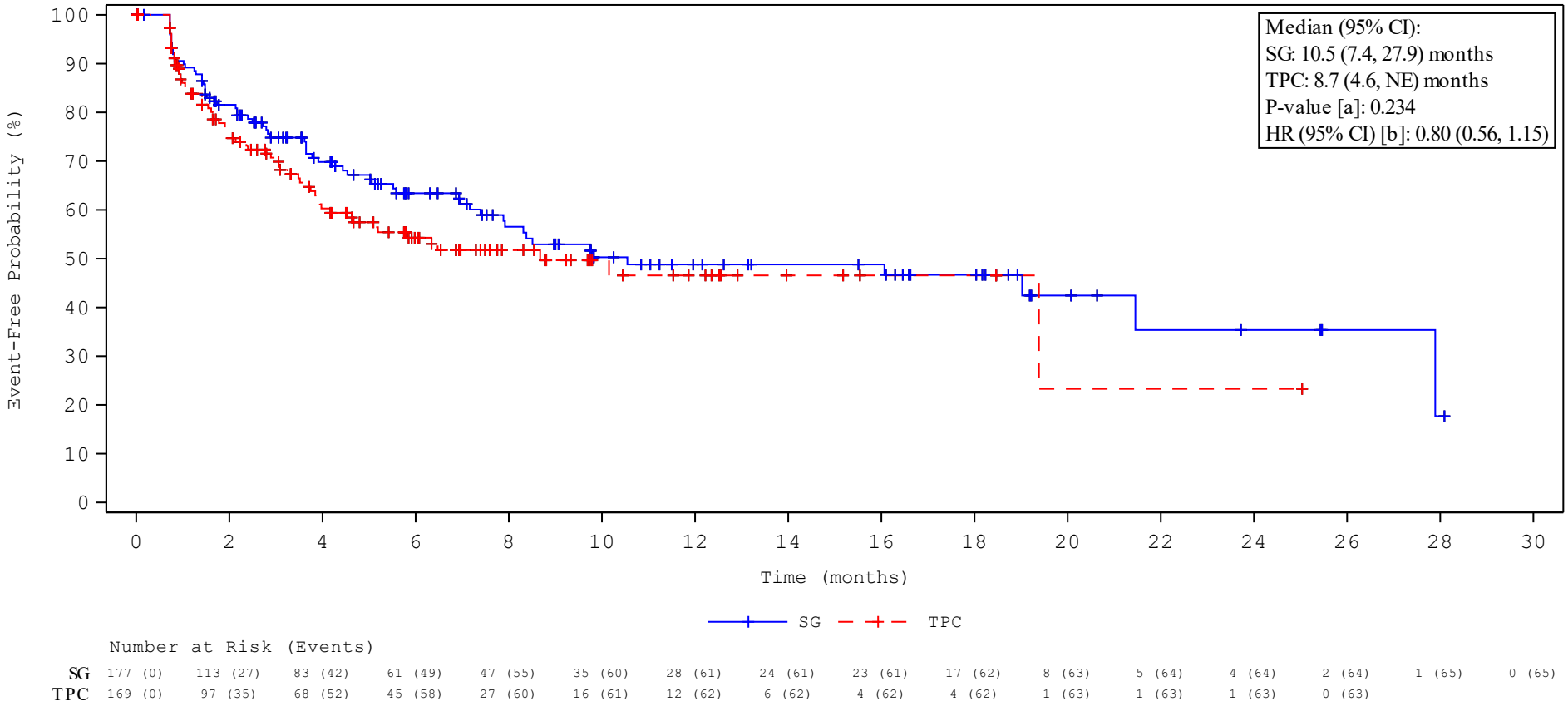
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.14
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



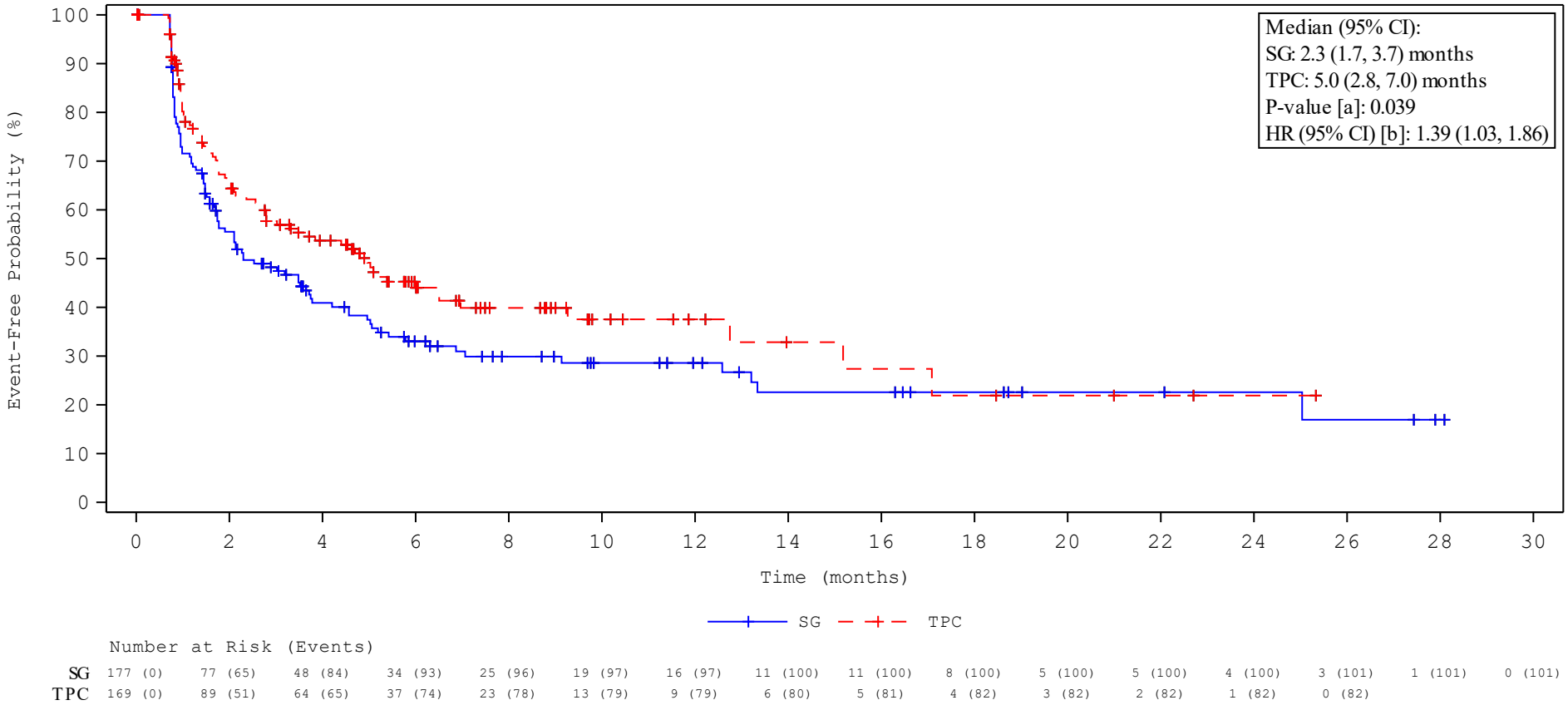
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.1.15
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Financial Difficulties by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



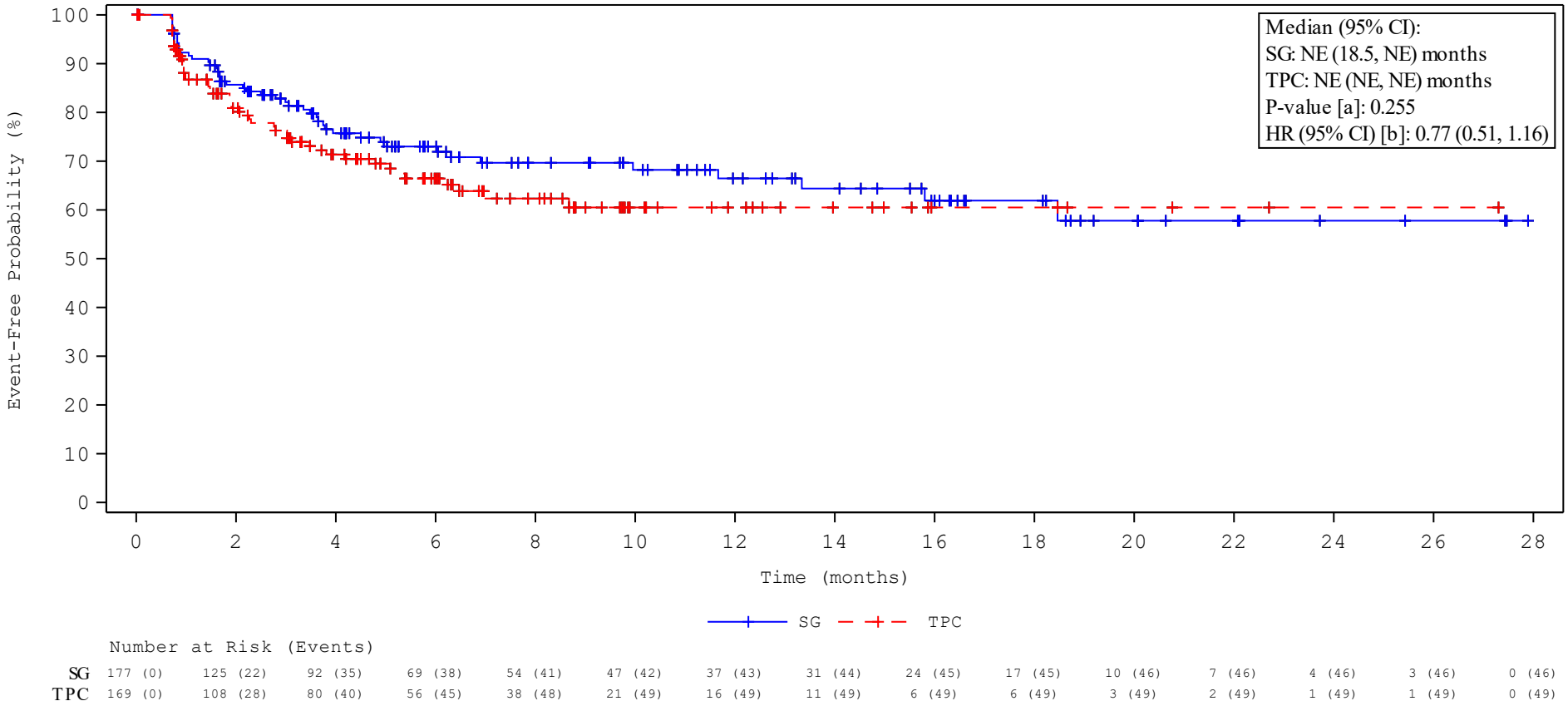
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Body Image by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



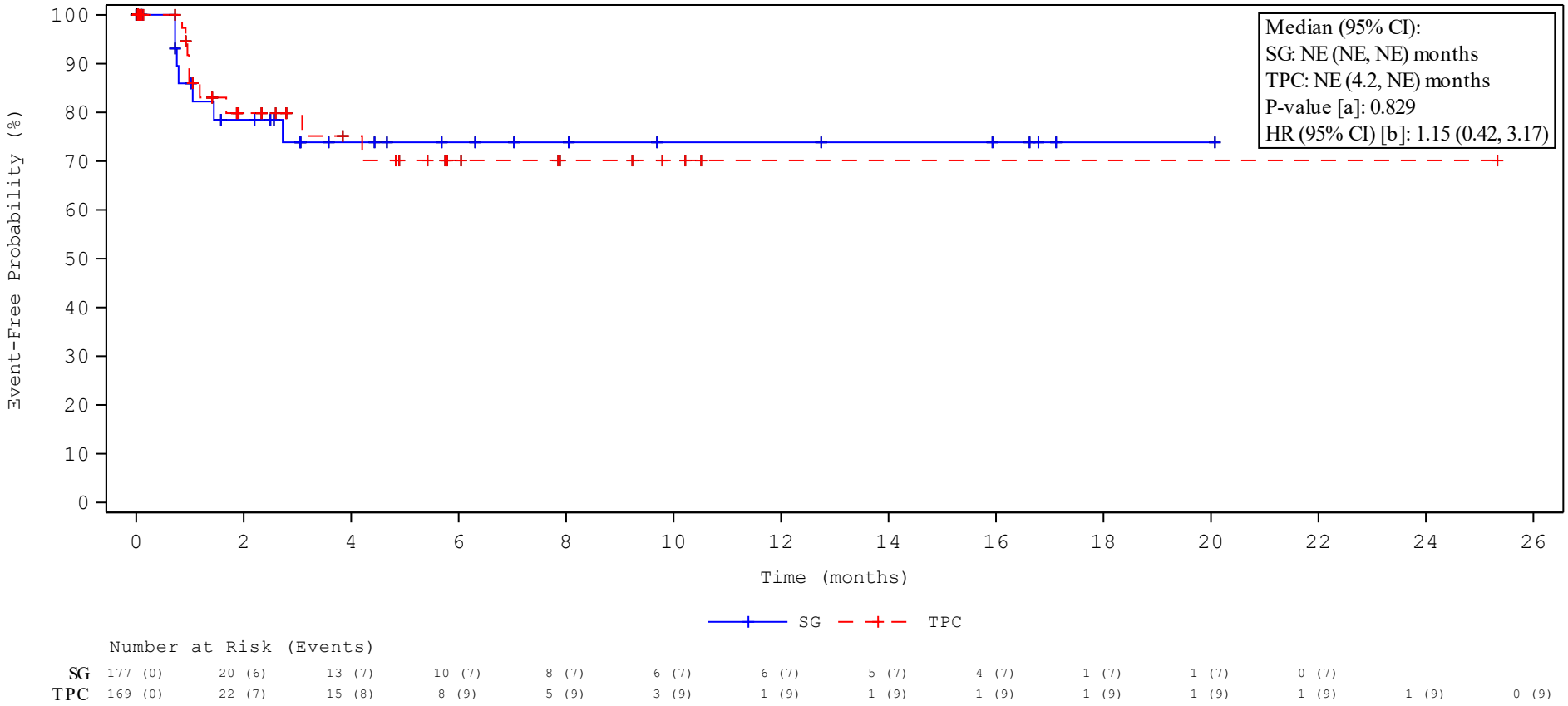
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Function by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



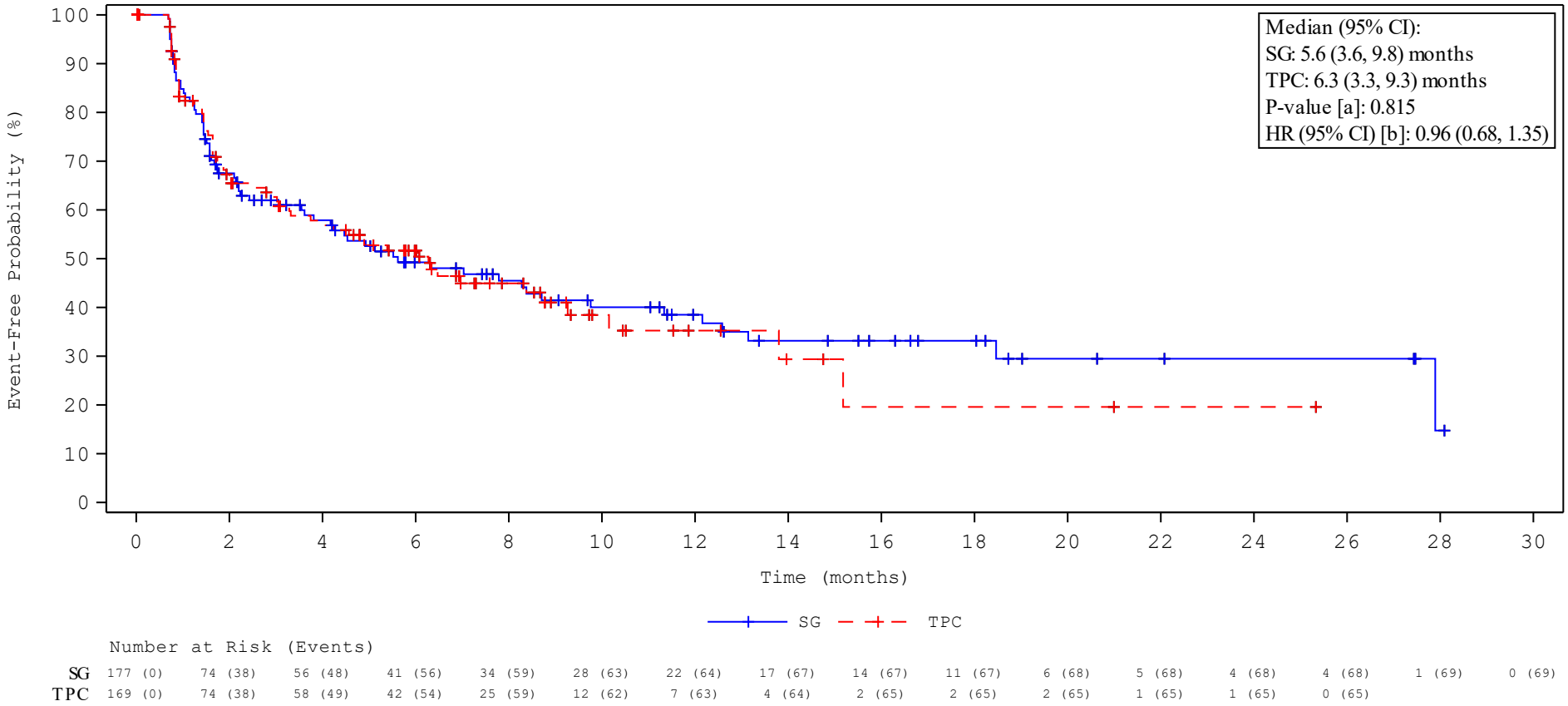
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Sexual Enjoyment by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



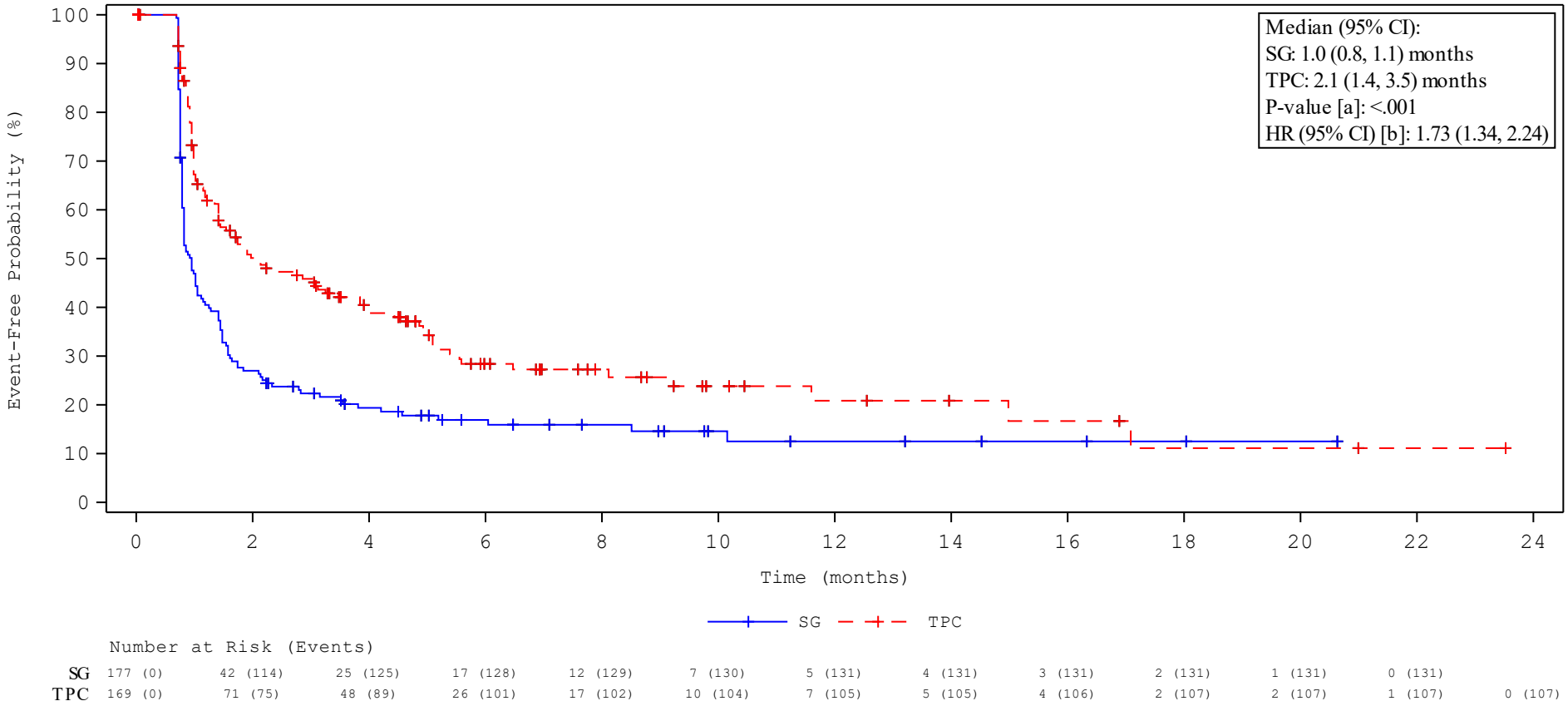
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Future Perspective by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



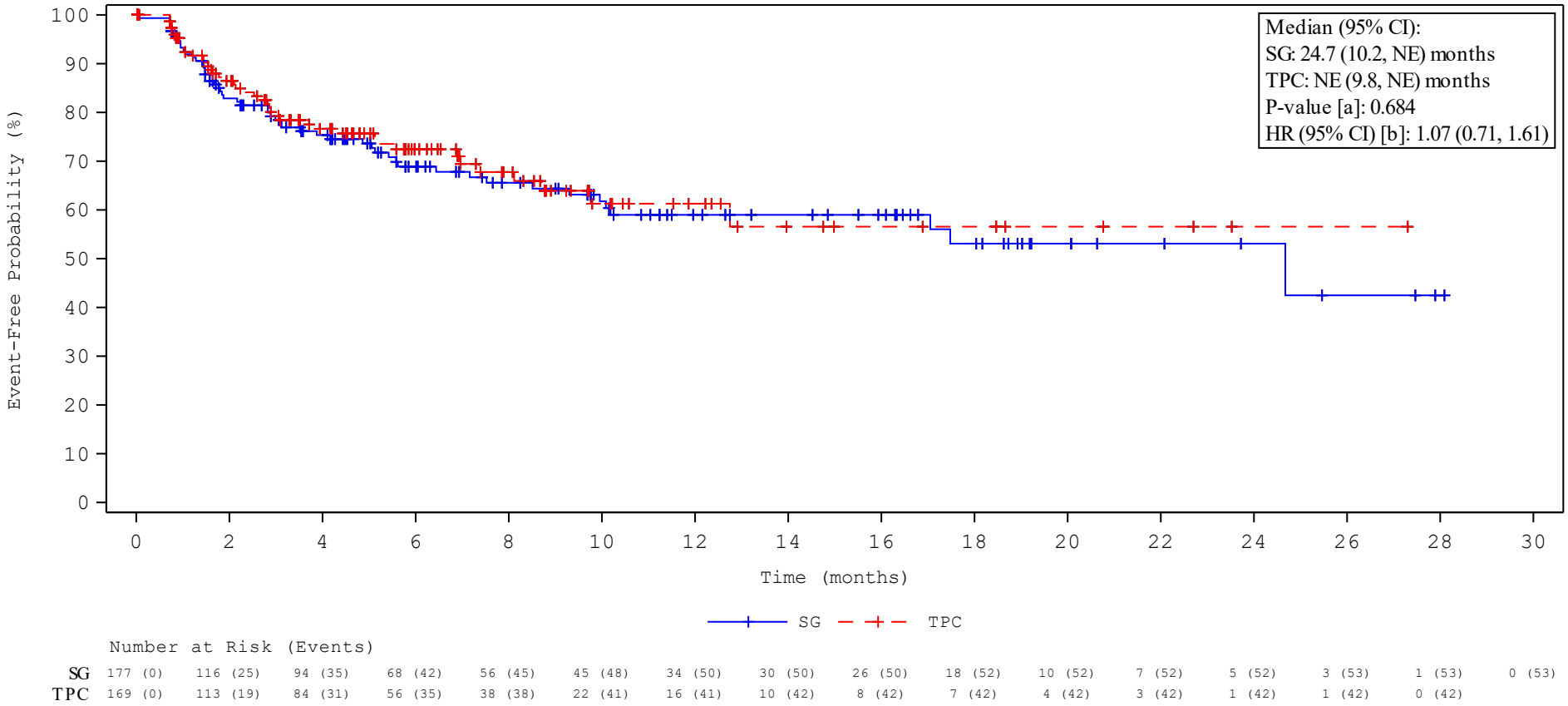
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Systemic Therapy Side Effects by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



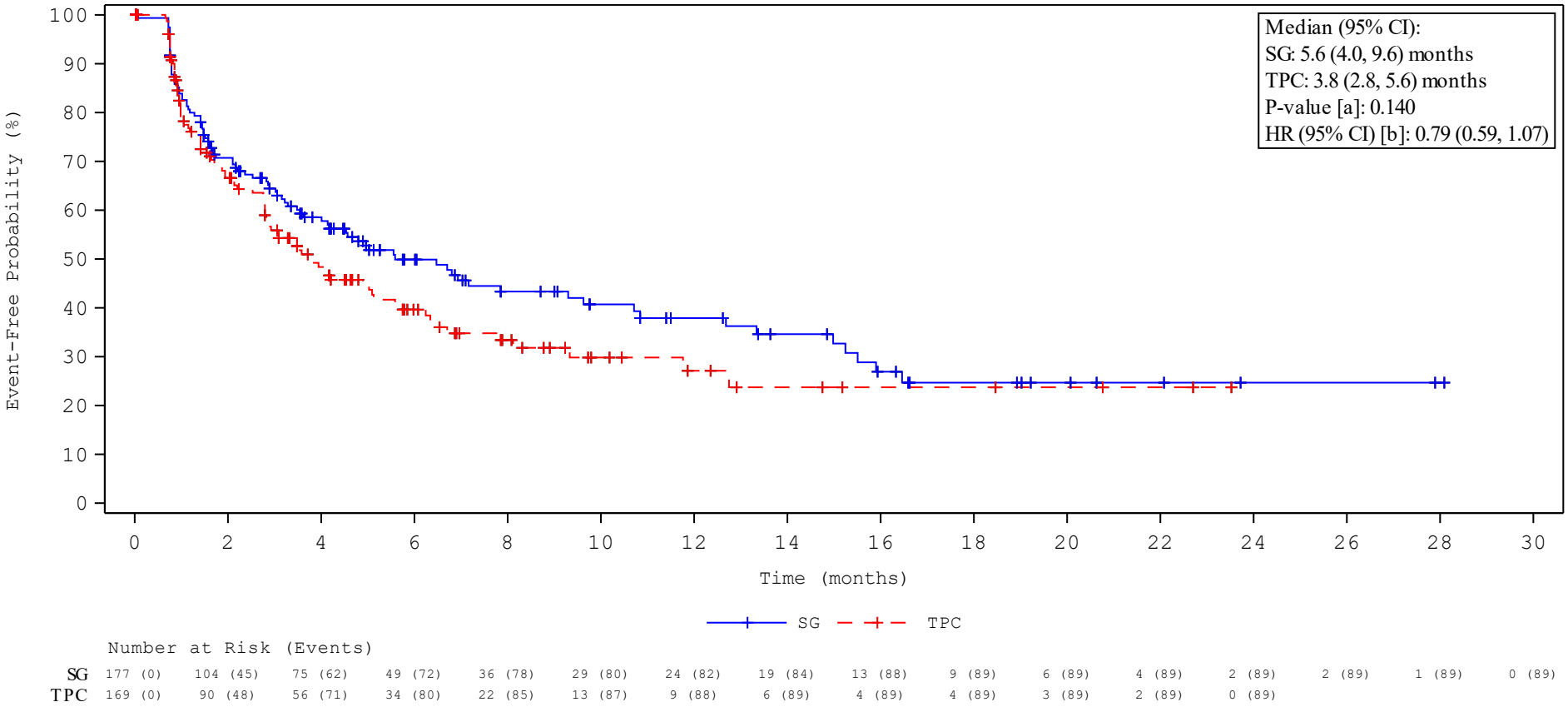
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.6
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Breast Symptoms by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



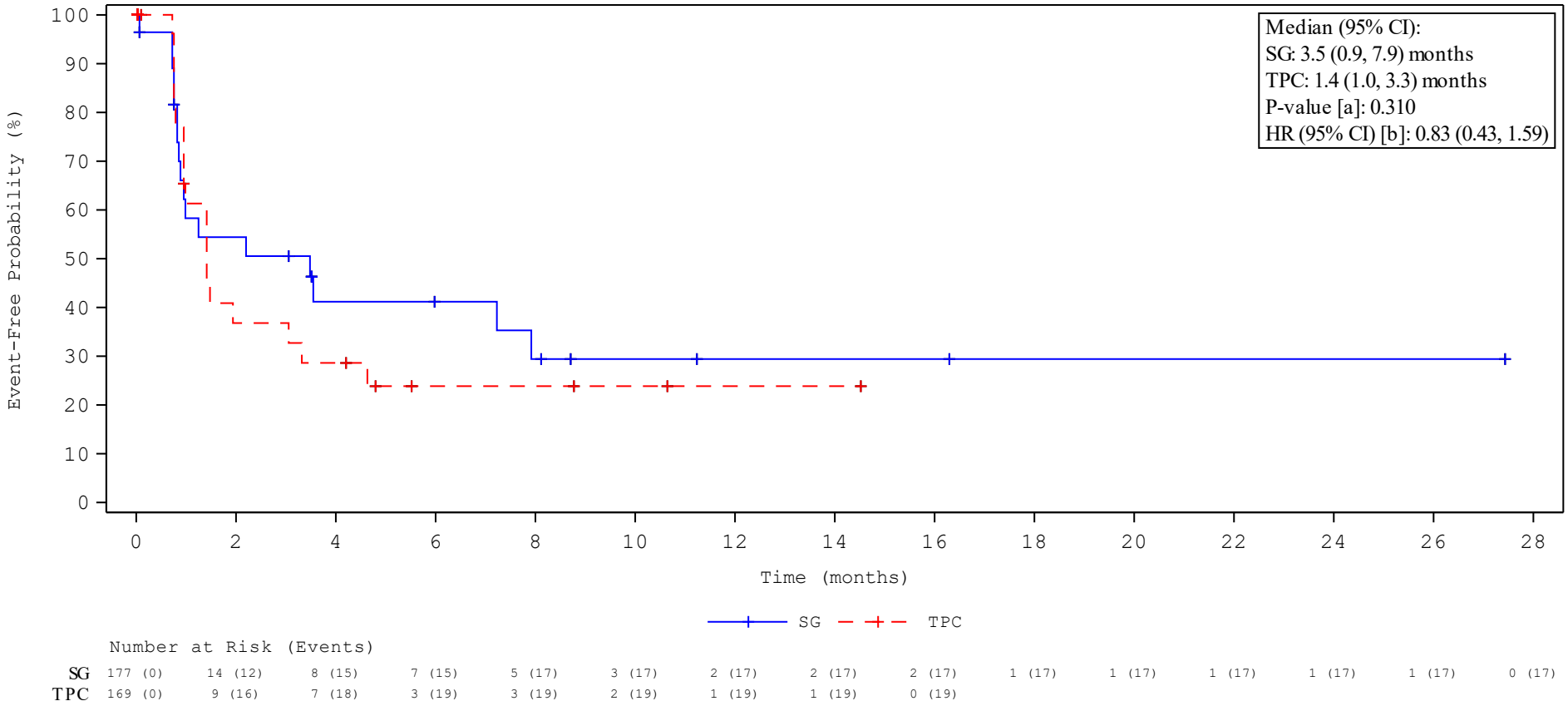
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.7
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Arm Symptoms by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



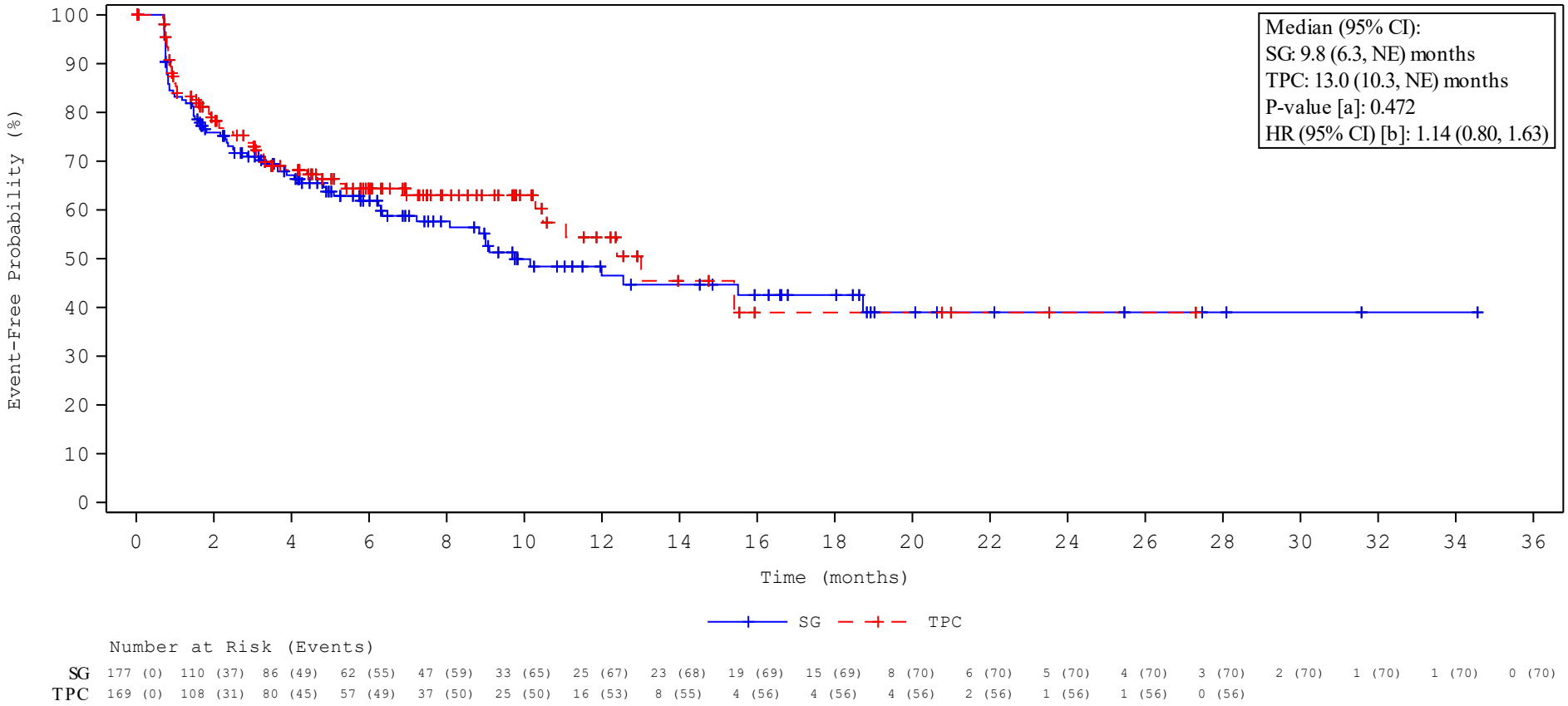
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.2.8
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-BR23 Upset by Hair Loss by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



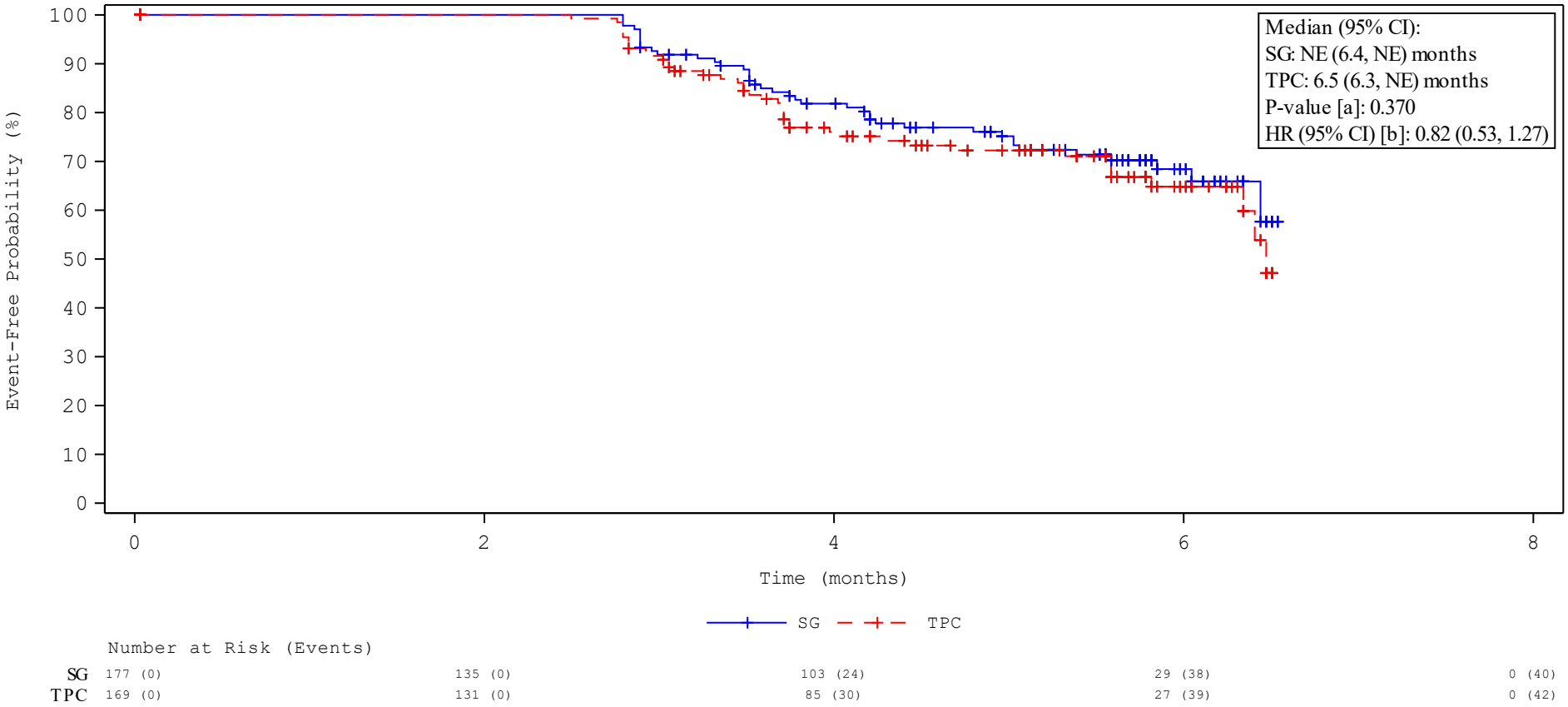
Note: The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EQ-VAS by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



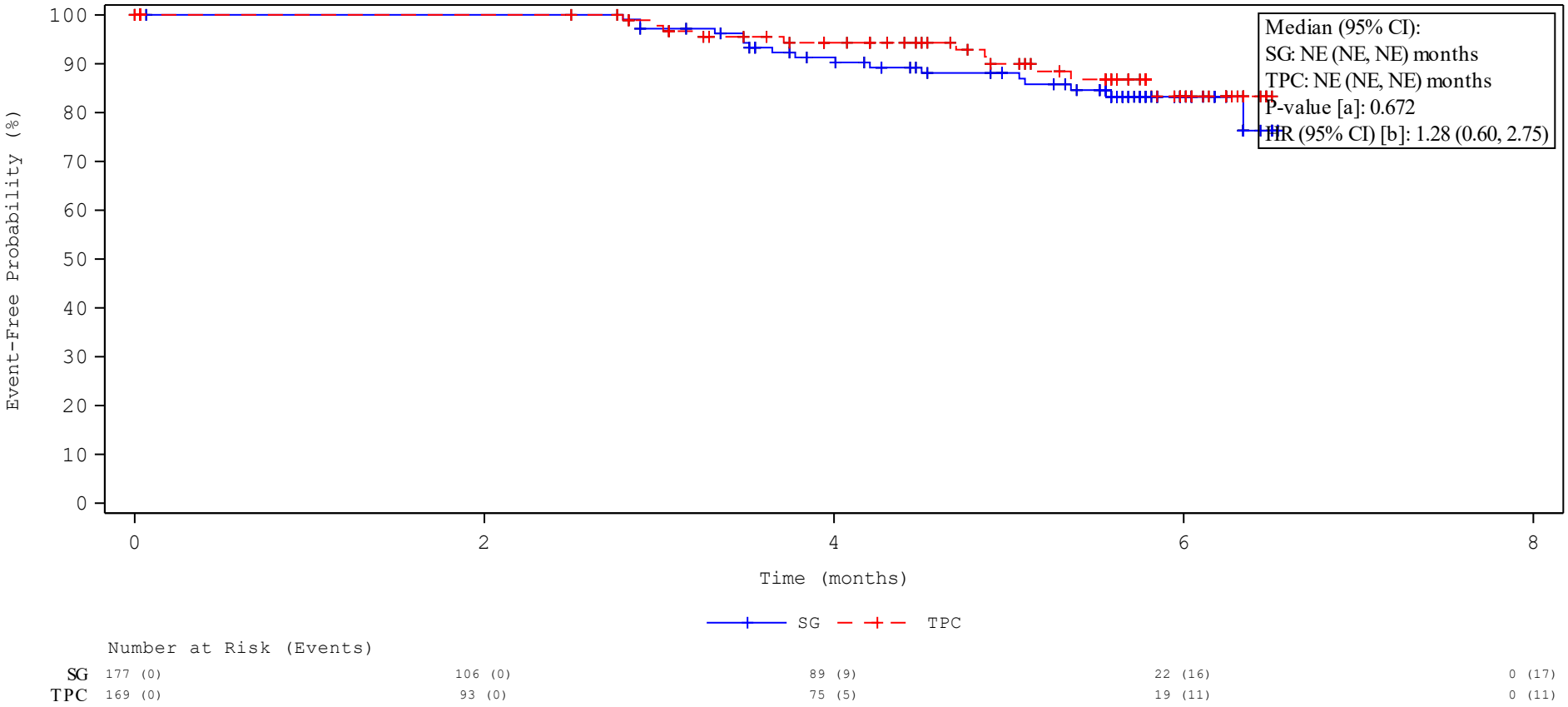
Note: The response threshold for EQ-VAS is ≥15 points.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = Visual analogue scale.
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Figure 2.1.4
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIC by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



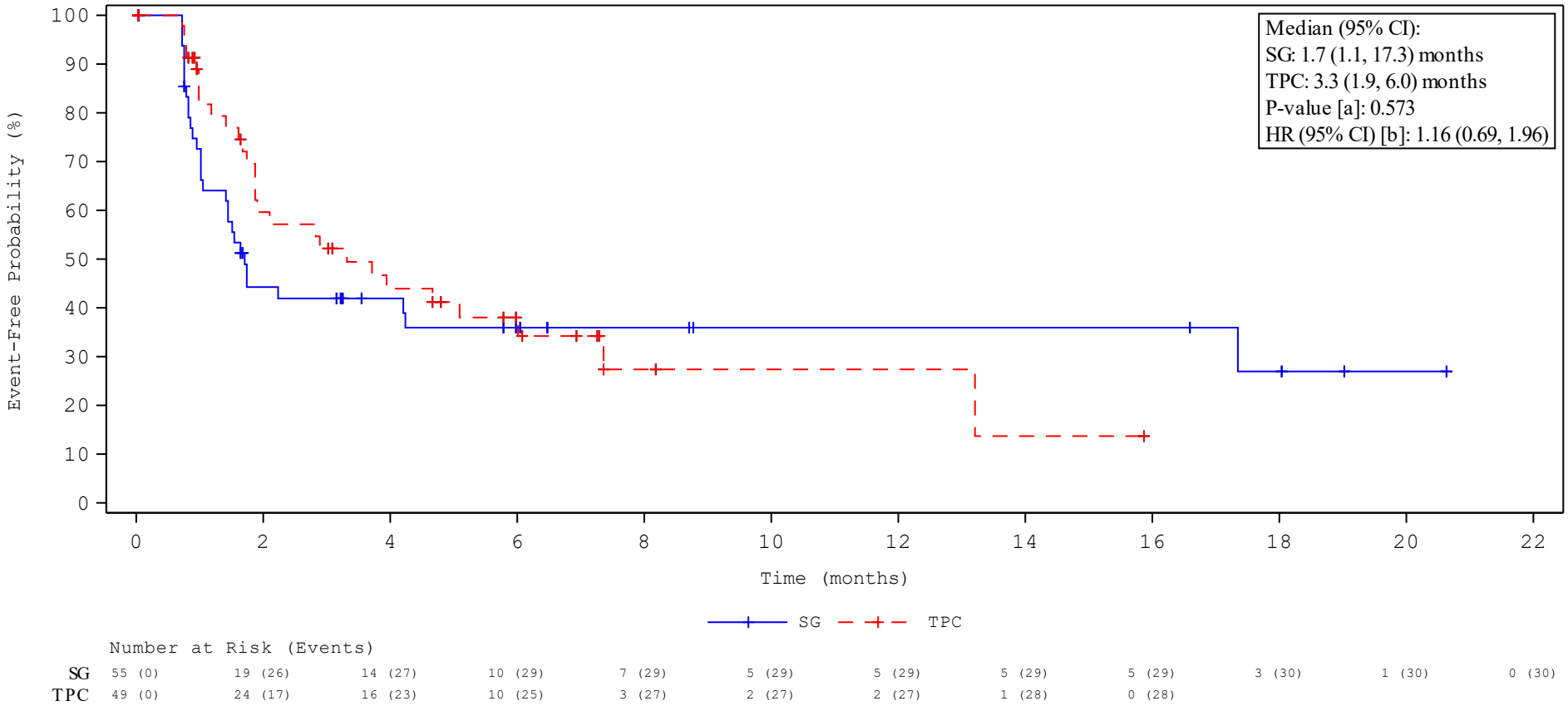
Note: 'Minimally worsened', 'much worsened', and 'very much worsened' are classified as responders.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; PGIC = Patient Global Impression of Change; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 2.1.5
Kaplan-Meier Plot of Time to First Meaningful Deterioration in PGIS by Treatment Group
(mITT excluding patients preselected to receive nab-paclitaxel)



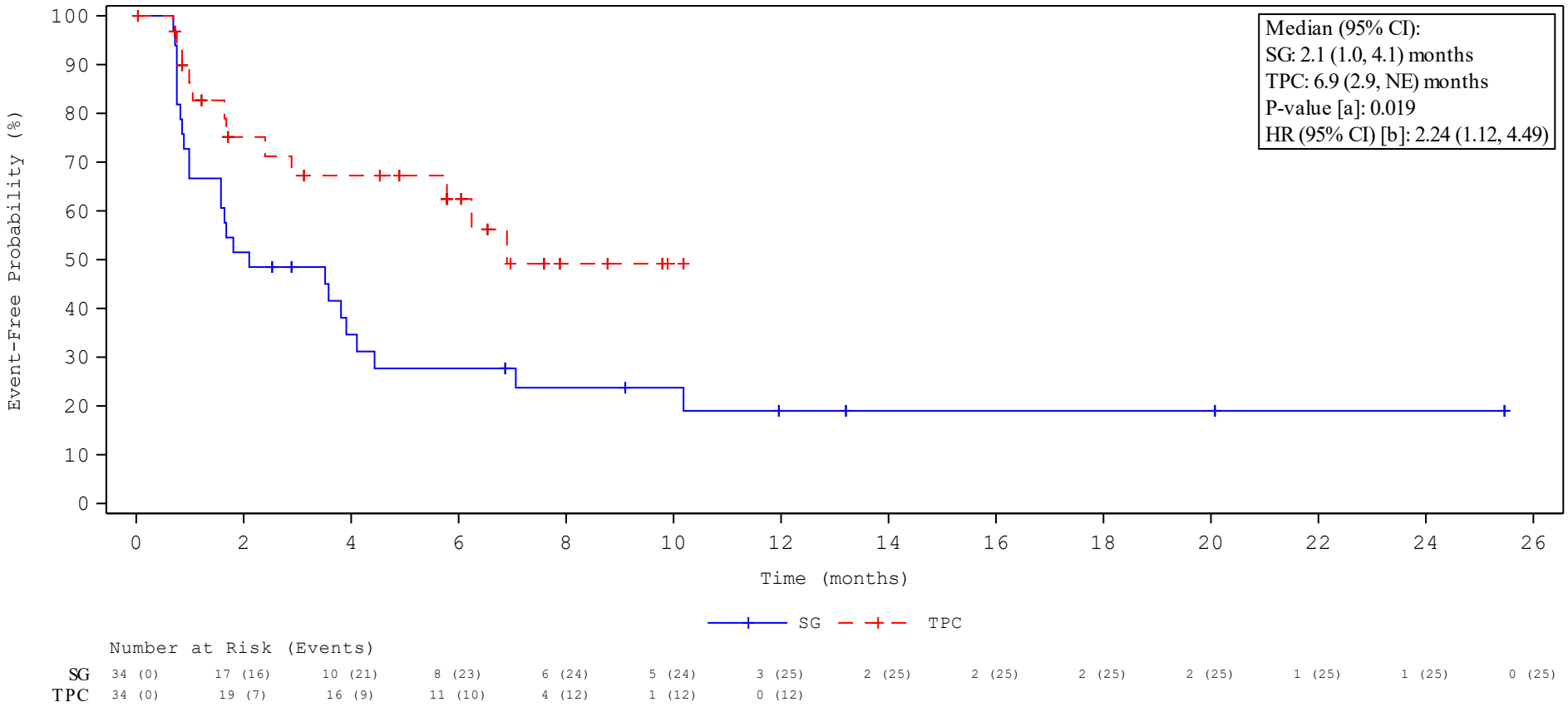
Note: 'Very poor' and 'poor' are classified as responders.
[a] P-value was estimated from the stratified log-rank test by randomization stratification factors.
[b] HR (95% CI) of SG versus TPC was estimated using a Cox proportional hazards regression model stratified by the randomization stratification factors.
CI = Confidence Interval; HR = hazard ratio; PGIS = Patient Global Impression of Severity; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.1.1.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group (Disease-free Interval = De novo)
(mITT excluding patients preselected to receive nab-paclitaxel)



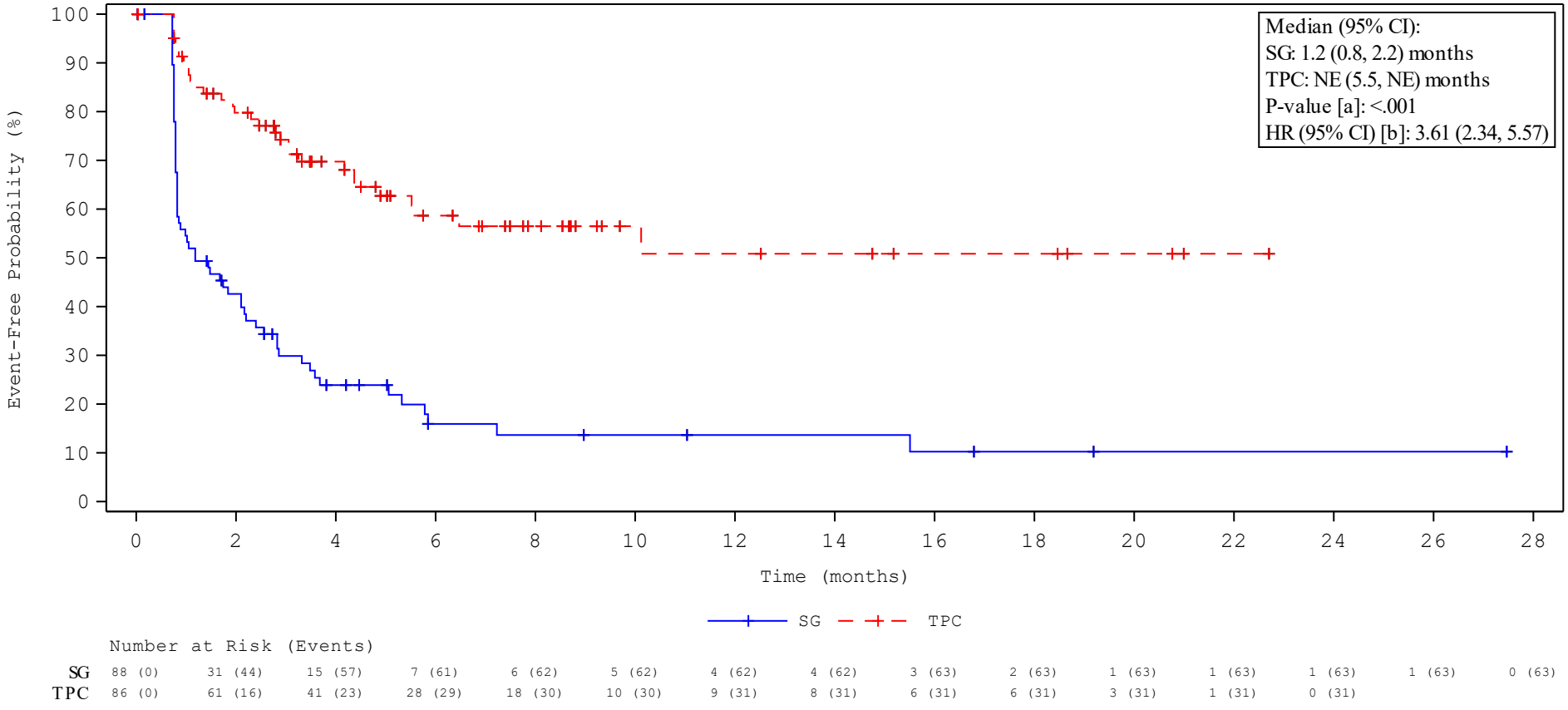
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.1.1.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group (Disease-free Interval = Recurrent Disease within 6 to 12 Months)
(mITT excluding patients preselected to receive nab-paclitaxel)



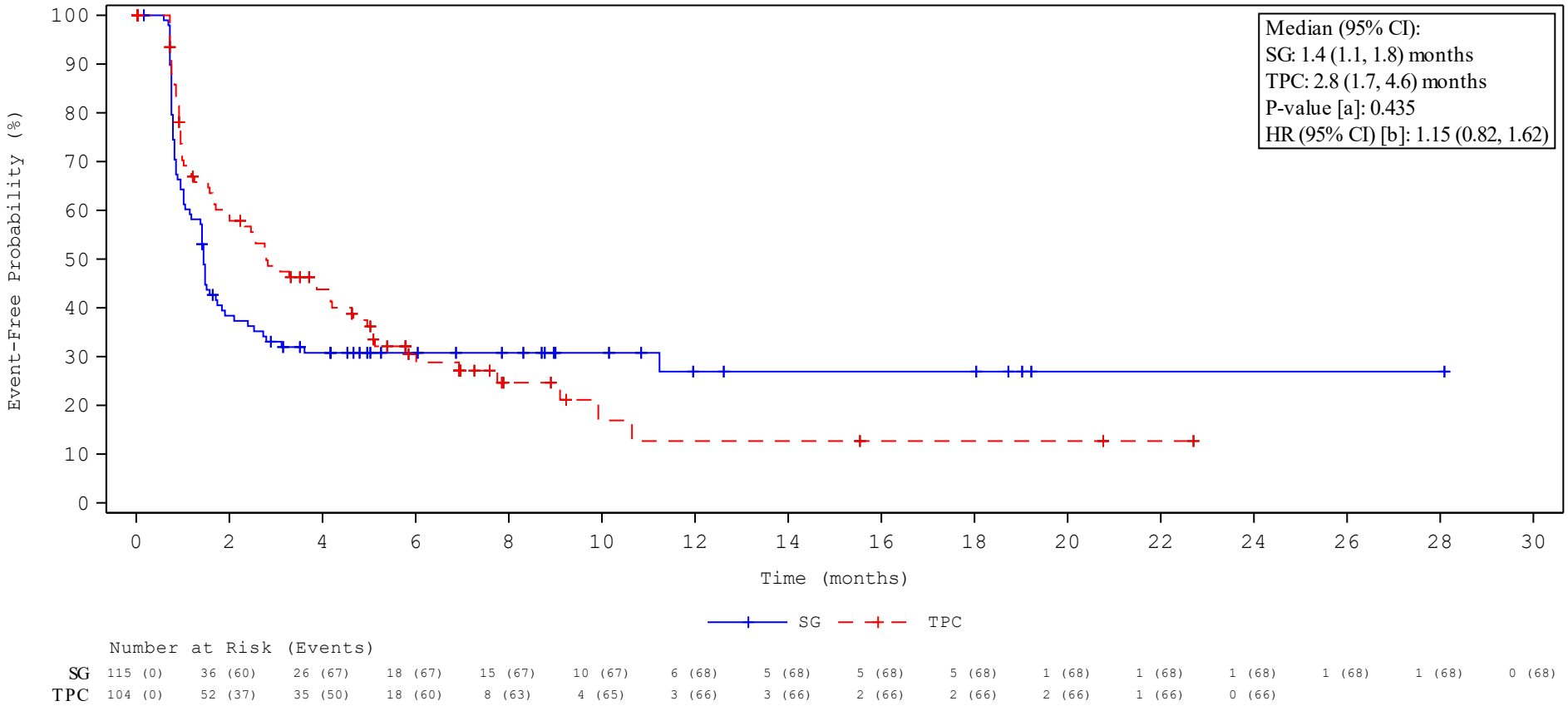
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.1.1.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Diarrhoea by Treatment Group (Disease-free Interval = Recurrent Disease Occurring > 12 Months)
(mITT excluding patients preselected to receive nab-paclitaxel)



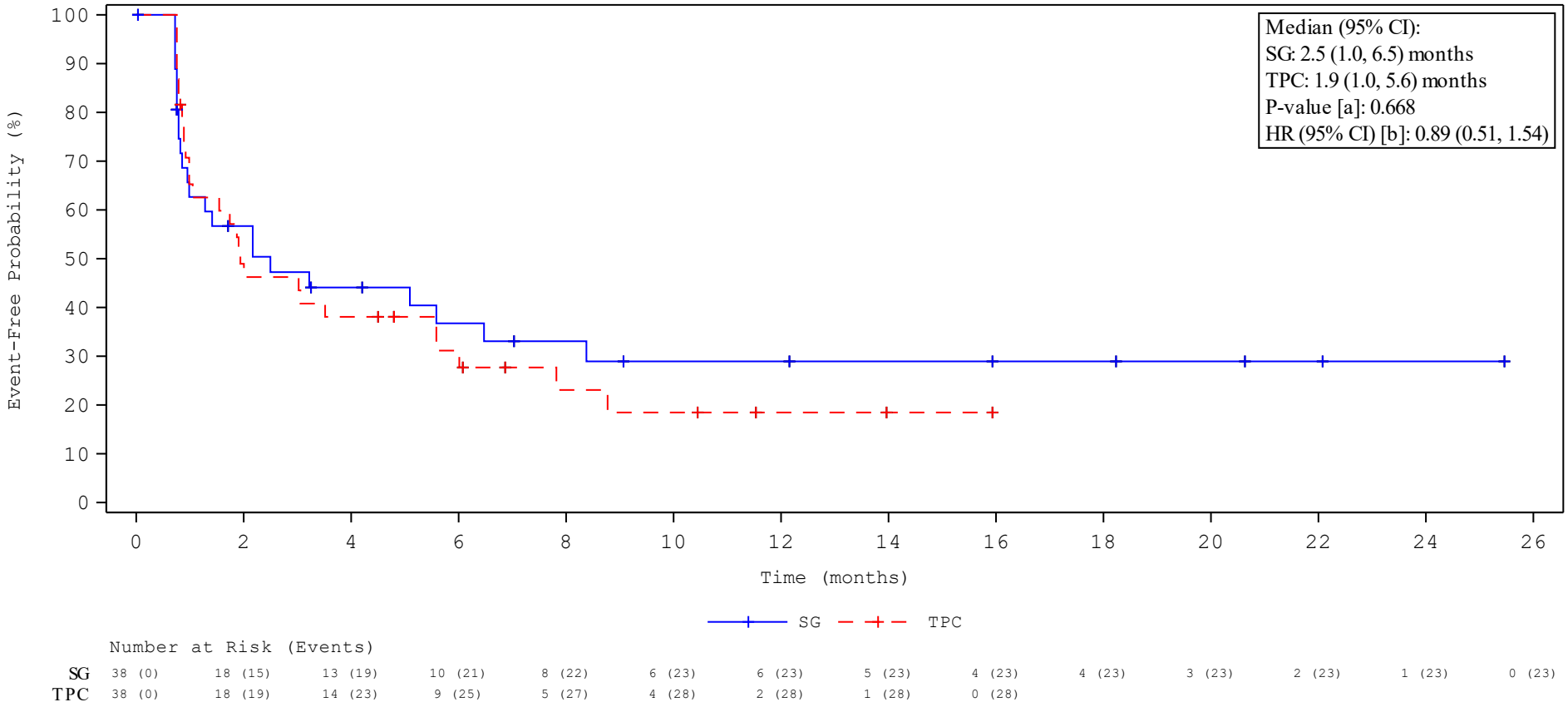
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.1.4.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Race = White)
(mITT excluding patients preselected to receive nab-paclitaxel)



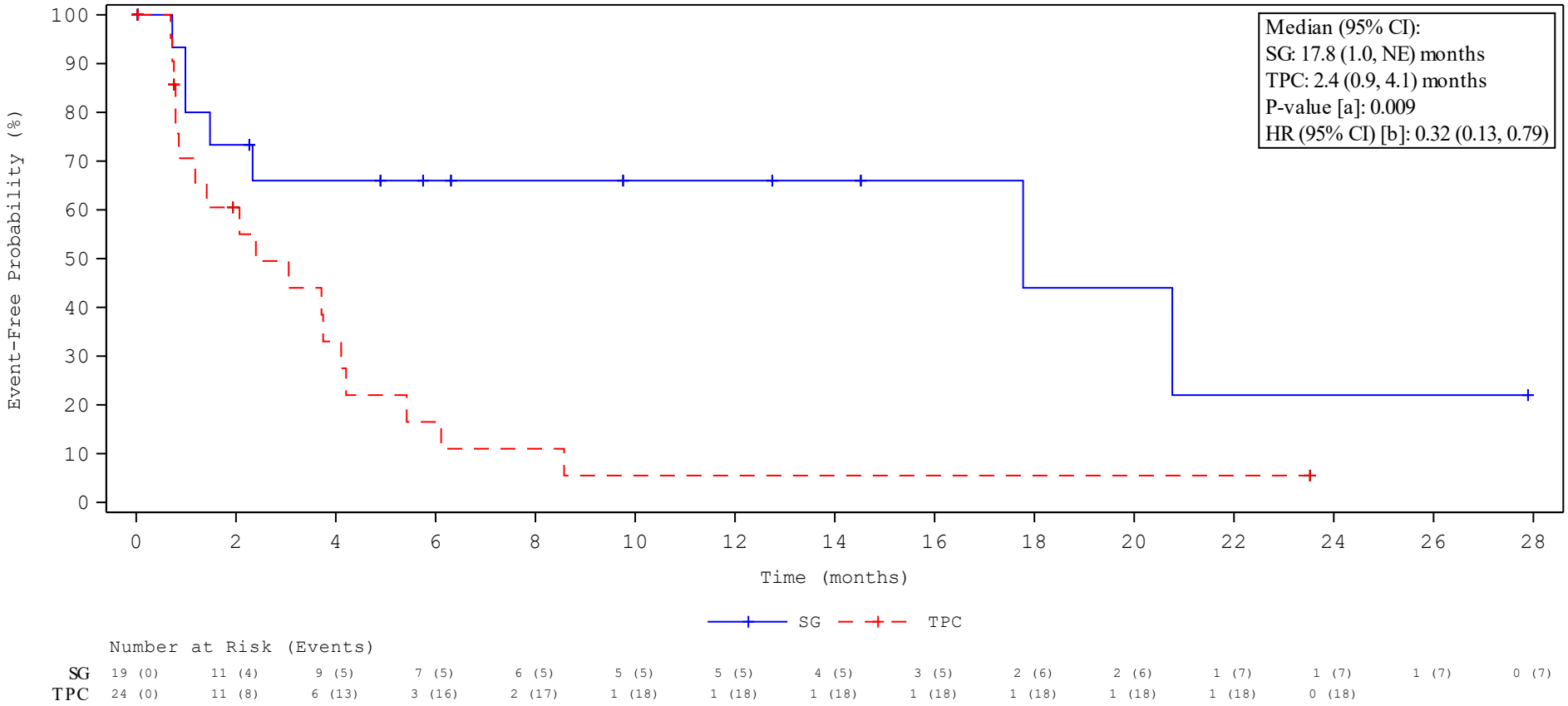
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.1.4.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Race = Asian)
(mITT excluding patients preselected to receive nab-paclitaxel)



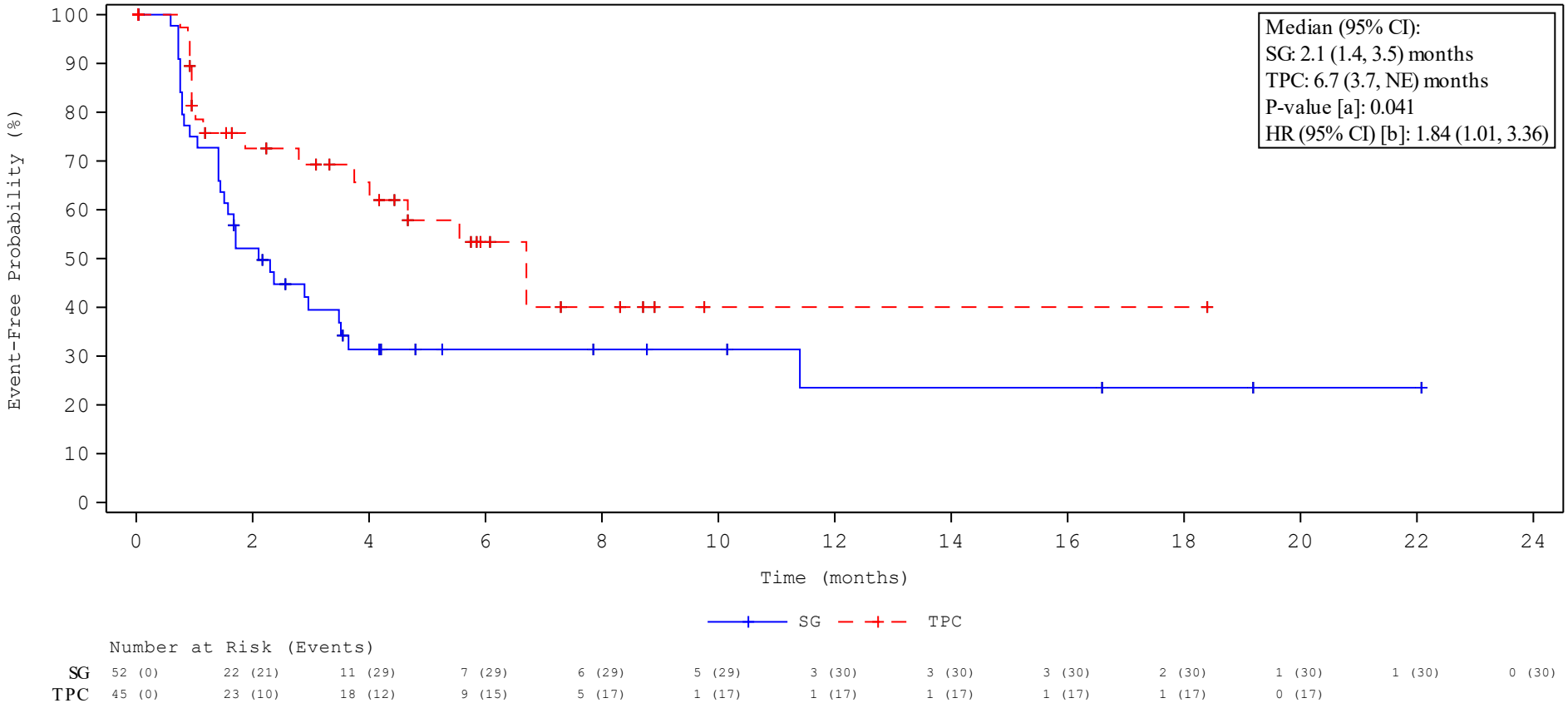
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.1.4.3
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Race = Other)
(mITT excluding patients preselected to receive nab-paclitaxel)



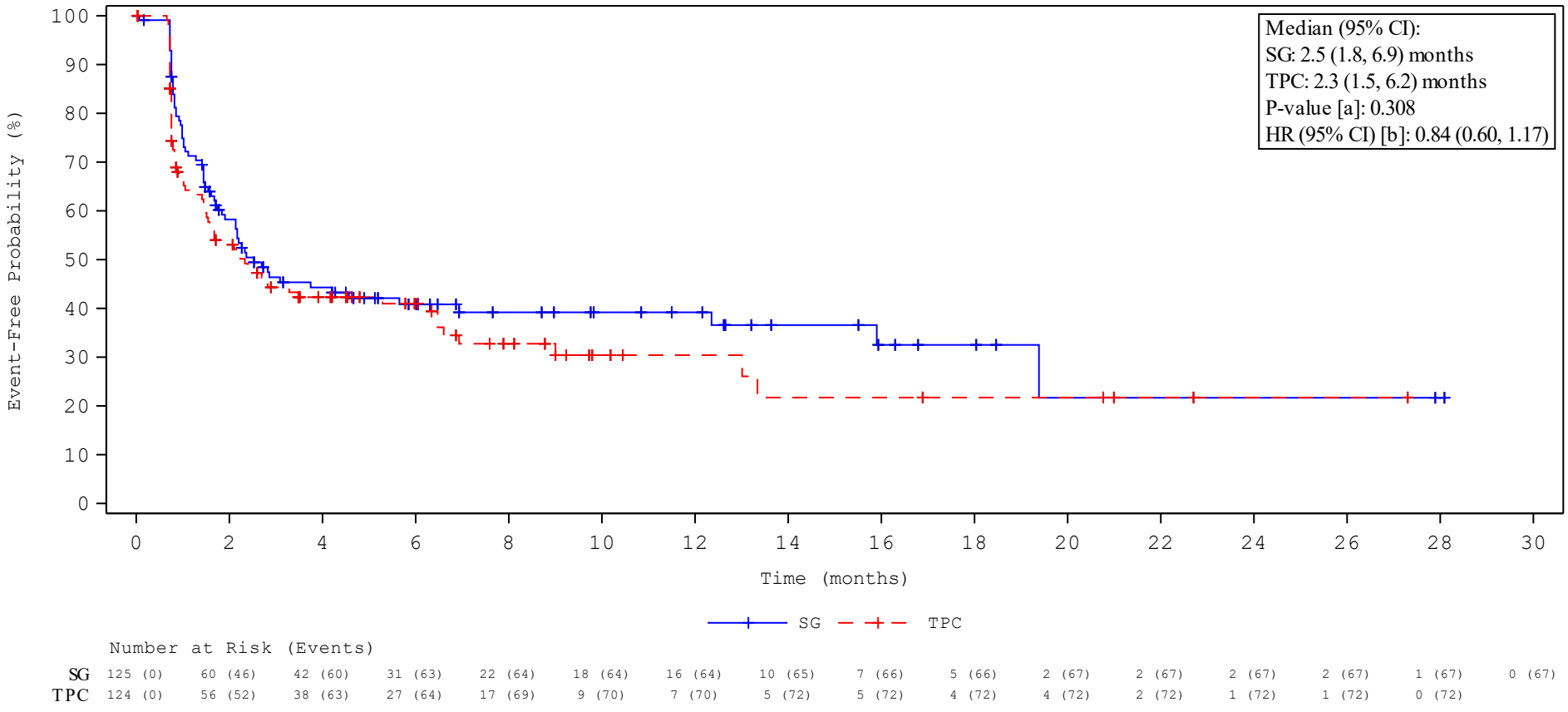
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Figure 4.1.5.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Constipation by Treatment Group (TPC of Chemotherapy Prior to Randomization = Paclitaxel)
(mITT excluding patients preselected to receive nab-paclitaxel)



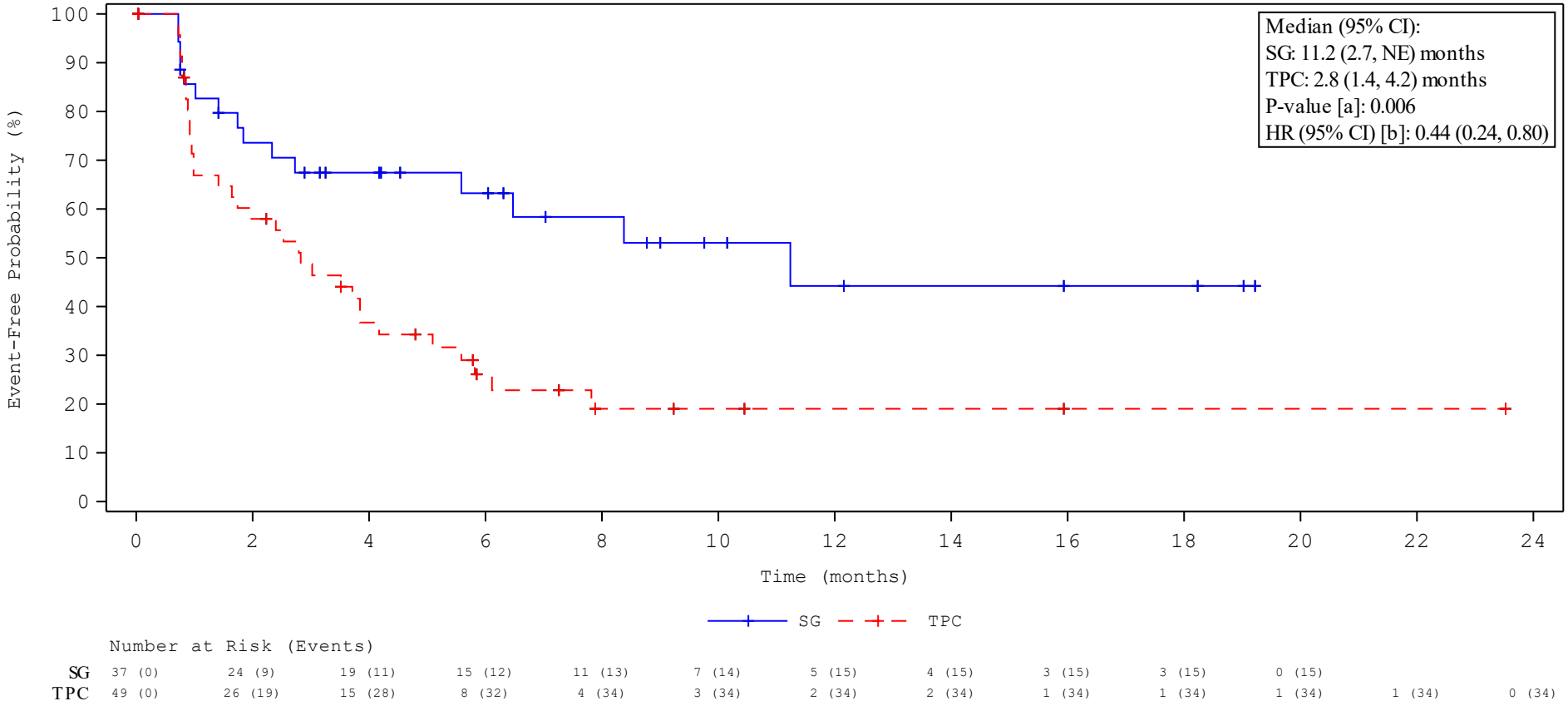
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.1.5.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Constipation by Treatment Group (TPC of Chemotherapy Prior to Randomization = Gemcitabine/Carboplatin)
(mITT excluding patients preselected to receive nab-paclitaxel)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Figure 4.1.7.1
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Menopausal Status = Pre-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel)



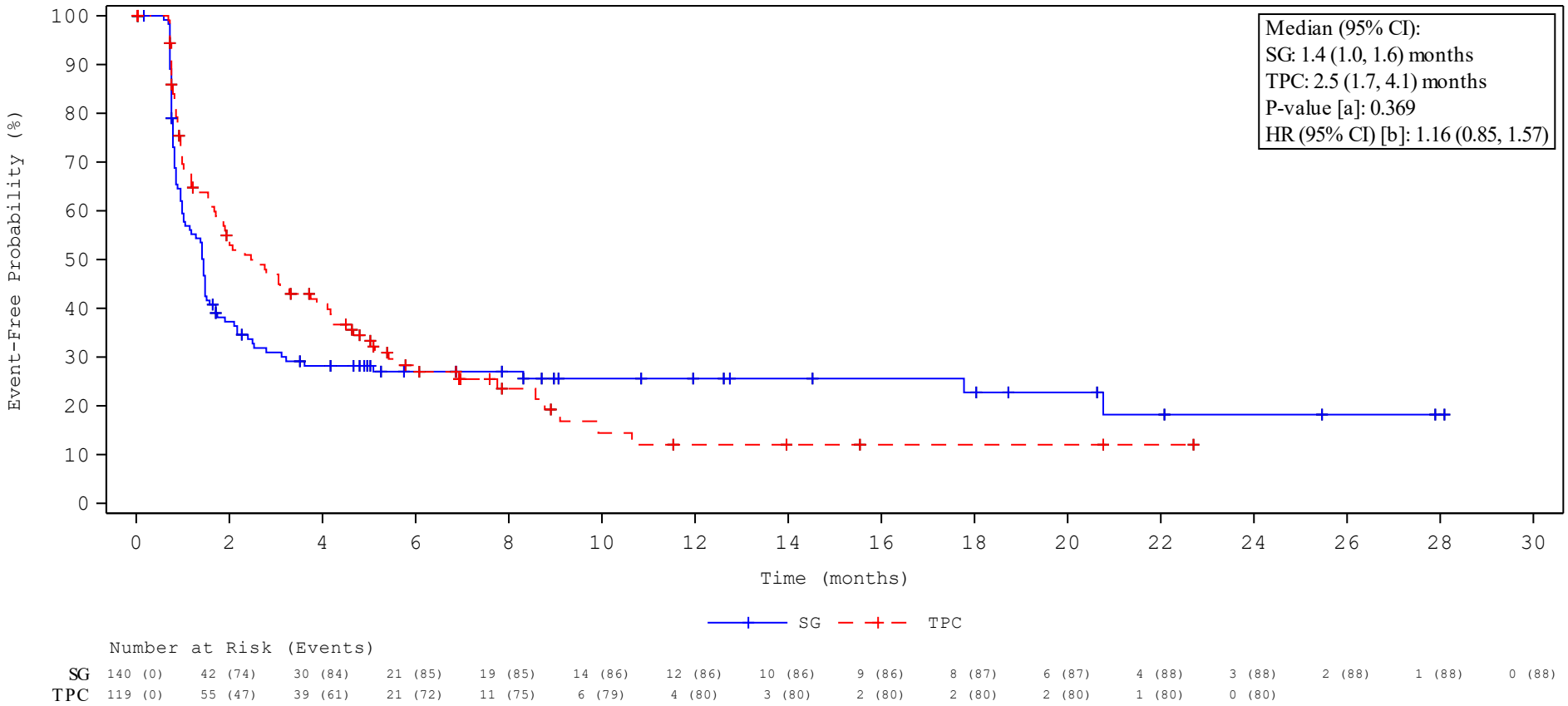
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.

CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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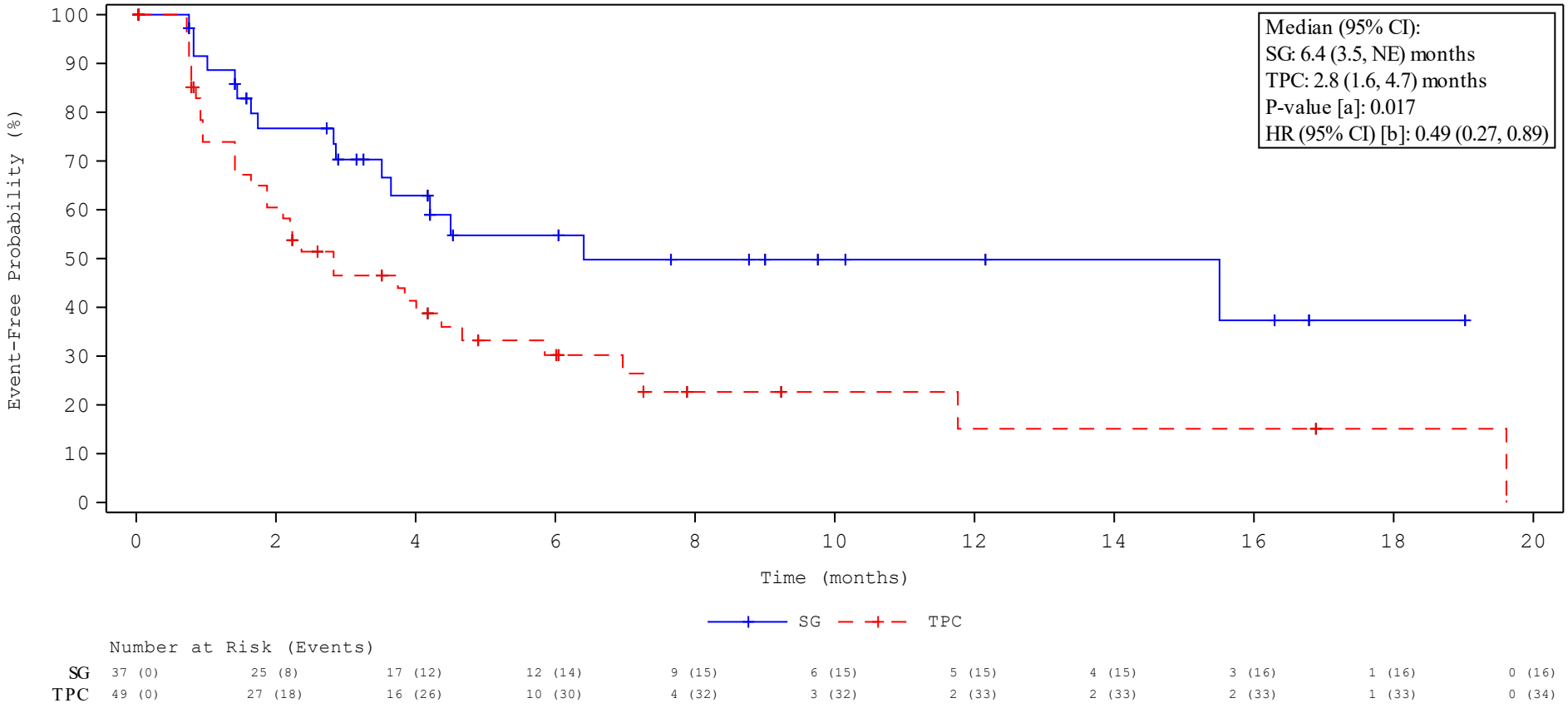
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Figure 4.1.7.2
Kaplan-Meier Plot of Time to First Meaningful Deterioration in EORTC QLQ-C30 Role Functioning by Treatment Group (Menopausal Status = Post-menopausal)
(mITT excluding patients preselected to receive nab-paclitaxel)



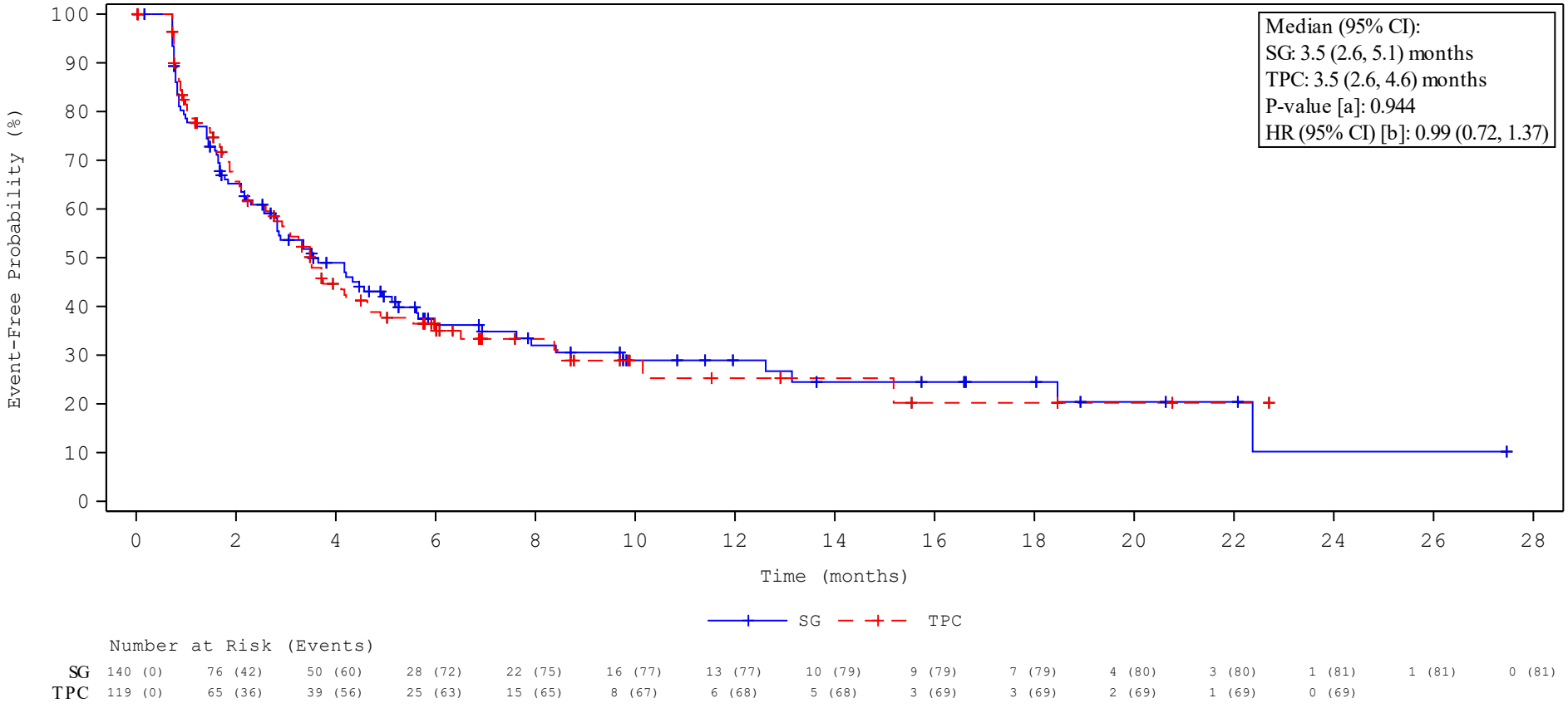
Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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(mITT excluding patients preselected to receive nab-paclitaxel)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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(mITT excluding patients preselected to receive nab-paclitaxel)



Note: The response threshold for EORTC QLQ-C30 domains is ≥10 points.
[a] P-value was estimated from the unstratified log-rank test .
[b] HR (95% CI) of SG versus TPC was estimated using an unadjusted/unstratified Cox proportional hazards regression model.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR = hazard ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

1. Statistical Analysis for German Submission of ASCENT-03

2. TFLs

Population: Triple-negative breast cancer (mTNBC)

Sub-Populations:
— Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Data Cut Date: 22 APR 2026

Version 1.0

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4. PRO - mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

4.1. Table 1.1.1.1: — Observation Period (Months) — EORTC QLQ-C30 — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
N	51	44	95
Mean (SD)	11.7 (9.09)	5.9 (4.41)	9.0 (7.84)
95% CI	9.2, 14.3	4.5, 7.2	7.4, 10.6
Median	10.0	5.7	6.9
Q1, Q3	4.2, 18.4	2.6, 8.3	3.2, 12.8
Min, Max	0.0, 32.5	0.0, 18.4	0.0, 32.5

SG = Sacituzumab Govitecan, TPC = treatment of physician's choice
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occurred earlier.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; SD = standard deviation.
Data Cut off : 22 APR 2026

4.2. Table 1.1.1.2: — Observation Period (Months) — EORTC QLQ-BR23 — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
N	51	44	95
Mean (SD)	11.8 (9.08)	5.8 (4.48)	9.0 (7.86)
95% CI	9.2, 14.3	4.5, 7.2	7.4, 10.6
Median	10.0	5.7	6.9
Q1, Q3	4.4, 18.4	2.5, 8.5	3.2, 12.8
Min, Max	0.0, 32.5	0.0, 18.4	0.0, 32.5

SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occurred earlier.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; SD = standard deviation;.
Data Cut off :22 APR 2026

4.3. Table 1.1.1.3: — Observation Period (Months) — EQ-5D-5L-VAS — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
N	50	44	94
Mean (SD)	12.0 (9.01)	5.8 (4.48)	9.1 (7.85)
95% CI	9.4, 14.6	4.5, 7.2	7.5, 10.7
Median	10.1	5.7	7.0
Q1, Q3	4.4, 18.4	2.5, 8.5	3.3, 13.4
Min, Max	0.0, 32.5	0.0, 18.4	0.0, 32.5

SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occurred earlier.
CI = Confidence Interval; VAS = Visual analogue scale; SD = standard deviation.
Data Cut off : 22 APR 2026

4.4. Table 1.1.1.5: — Observation Period (Months) — PGI-Change — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
N	40	32	72
Mean (SD)	6.5 (3.45)	5.0 (0.99)	5.8 (2.74)
95% CI	5.4, 7.6	4.6, 5.4	5.2, 6.5
Median	5.8	5.5	5.6
Q1, Q3	5.5, 6.3	4.4, 5.6	4.8, 6.0
Min, Max	3.0, 22.6	2.8, 6.2	2.8, 22.6

SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occurred earlier.
PGIC = Patient Global Impression of Change;
CI = Confidence Interval; SD = standard deviation.
Data Cut off : 22 APR 2026

4.5. Table 1.1.1.6: — Observation Period (Months) — PGI-Severity — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Statistic	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
N	49	43	92
Mean (SD)	5.3 (4.01)	3.7 (2.36)	4.5 (3.42)
95% CI	4.1, 6.4	3.0, 4.4	3.8, 5.3
Median	5.7	4.6	5.5
Q1, Q3	4.2, 6.2	1.4, 5.6	3.0, 5.8
Min, Max	0.0, 22.6	0.0, 6.2	0.0, 22.6

SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
PGIS = Patient Global Impression of Severity;
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; SD = standard deviation.
Data Cut off : 22 APR 2026

4.6. Table 1.1.3.1: — Summary of Available Data Rates of EORTC QLQ-C30 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	38/52 (73.1%)	30/45 (66.7%)	68/97 (70.1%)
Week 7	40/52 (76.9%)	9/45 (20.0%)	49/97 (50.5%)
Week 10	36/52 (69.2%)	31/45 (68.9%)	67/97 (69.1%)
Week 13	34/52 (65.4%)	31/45 (68.9%)	65/97 (67.0%)
Week 16	36/52 (69.2%)	20/45 (44.4%)	56/97 (57.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	22/45 (48.9%)	52/97 (53.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	27/52 (51.9%)	13/45 (28.9%)	40/97 (41.2%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 31	25/52 (48.1%)	5/45 (11.1%)	30/97 (30.9%)
Week 34	22/52 (42.3%)	9/45 (20.0%)	31/97 (32.0%)
Week 37	26/52 (50.0%)	8/45 (17.8%)	34/97 (35.1%)
Week 40	21/52 (40.4%)	5/45 (11.1%)	26/97 (26.8%)
Week 43	22/52 (42.3%)	4/45 (8.9%)	26/97 (26.8%)
Week 46	23/52 (44.2%)	4/45 (8.9%)	27/97 (27.8%)
Week 49	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 52	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 55	18/52 (34.6%)	2/45 (4.4%)	20/97 (20.6%)
Week 58	17/52 (32.7%)	3/45 (6.7%)	20/97 (20.6%)
Week 61	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)
Week 64	14/52 (26.9%)	2/45 (4.4%)	16/97 (16.5%)
Week 67	15/52 (28.8%)	1/45 (2.2%)	16/97 (16.5%)
Week 70	17/52 (32.7%)	1/45 (2.2%)	18/97 (18.6%)
Week 73	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 76	12/52 (23.1%)	2/45 (4.4%)	14/97 (14.4%)
Week 79	12/52 (23.1%)	0/45 (0.0%)	12/97 (12.4%)
Week 82	9/52 (17.3%)	0/45 (0.0%)	9/97 (9.3%)
Week 85	10/52 (19.2%)	0/45 (0.0%)	10/97 (10.3%)
Week 88	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 91	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 94	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 97	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 100	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 103	5/52 (9.6%)	0/45 (0.0%)	5/97 (5.2%)
Week 106	5/52 (9.6%)	0/45 (0.0%)	5/97 (5.2%)
Week 109	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 112	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 115	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 118	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 121	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 124	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 127	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 130	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 133	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 136	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 139	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 142	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
End of Treatment	33/52 (63.5%)	32/45 (71.1%)	65/97 (67.0%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.7. Table 1.1.3.2: — Summary of Available Data Rates of EORTC QLQ-BR23 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	37/52 (71.2%)	30/45 (66.7%)	67/97 (69.1%)
Week 7	40/52 (76.9%)	8/45 (17.8%)	48/97 (49.5%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 10	36/52 (69.2%)	31/45 (68.9%)	67/97 (69.1%)
Week 13	34/52 (65.4%)	30/45 (66.7%)	64/97 (66.0%)
Week 16	36/52 (69.2%)	19/45 (42.2%)	55/97 (56.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	27/52 (51.9%)	13/45 (28.9%)	40/97 (41.2%)
Week 31	25/52 (48.1%)	5/45 (11.1%)	30/97 (30.9%)
Week 34	22/52 (42.3%)	9/45 (20.0%)	31/97 (32.0%)
Week 37	26/52 (50.0%)	8/45 (17.8%)	34/97 (35.1%)
Week 40	21/52 (40.4%)	5/45 (11.1%)	26/97 (26.8%)
Week 43	22/52 (42.3%)	4/45 (8.9%)	26/97 (26.8%)
Week 46	23/52 (44.2%)	4/45 (8.9%)	27/97 (27.8%)
Week 49	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 52	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 55	18/52 (34.6%)	2/45 (4.4%)	20/97 (20.6%)
Week 58	17/52 (32.7%)	3/45 (6.7%)	20/97 (20.6%)
Week 61	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)
Week 64	14/52 (26.9%)	2/45 (4.4%)	16/97 (16.5%)
Week 67	15/52 (28.8%)	1/45 (2.2%)	16/97 (16.5%)
Week 70	17/52 (32.7%)	1/45 (2.2%)	18/97 (18.6%)
Week 73	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 76	12/52 (23.1%)	2/45 (4.4%)	14/97 (14.4%)
Week 79	12/52 (23.1%)	0/45 (0.0%)	12/97 (12.4%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 82	9/52 (17.3%)	0/45 (0.0%)	9/97 (9.3%)
Week 85	10/52 (19.2%)	0/45 (0.0%)	10/97 (10.3%)
Week 88	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 91	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 94	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 97	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 100	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 103	5/52 (9.6%)	0/45 (0.0%)	5/97 (5.2%)
Week 106	5/52 (9.6%)	0/45 (0.0%)	5/97 (5.2%)
Week 109	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 112	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 115	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 118	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 121	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 124	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 127	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 130	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 133	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 136	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 139	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 142	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
End of Treatment	33/52 (63.5%)	31/45 (68.9%)	64/97 (66.0%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.8. Table 1.1.3.3: — Summary of Available Data Rates of EQ-5D-VAS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	49/52 (94.2%)	43/45 (95.6%)	92/97 (94.8%)
Week 4	37/52 (71.2%)	30/45 (66.7%)	67/97 (69.1%)
Week 7	40/52 (76.9%)	8/45 (17.8%)	48/97 (49.5%)
Week 10	36/52 (69.2%)	31/45 (68.9%)	67/97 (69.1%)
Week 13	34/52 (65.4%)	30/45 (66.7%)	64/97 (66.0%)
Week 16	36/52 (69.2%)	19/45 (42.2%)	55/97 (56.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	27/52 (51.9%)	13/45 (28.9%)	40/97 (41.2%)
Week 31	25/52 (48.1%)	5/45 (11.1%)	30/97 (30.9%)
Week 34	22/52 (42.3%)	9/45 (20.0%)	31/97 (32.0%)
Week 37	26/52 (50.0%)	8/45 (17.8%)	34/97 (35.1%)
Week 40	21/52 (40.4%)	5/45 (11.1%)	26/97 (26.8%)
Week 43	22/52 (42.3%)	4/45 (8.9%)	26/97 (26.8%)
Week 46	23/52 (44.2%)	4/45 (8.9%)	27/97 (27.8%)
Week 49	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 52	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 55	18/52 (34.6%)	2/45 (4.4%)	20/97 (20.6%)
Week 58	17/52 (32.7%)	3/45 (6.7%)	20/97 (20.6%)
Week 61	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)
Week 64	14/52 (26.9%)	2/45 (4.4%)	16/97 (16.5%)
Week 67	15/52 (28.8%)	1/45 (2.2%)	16/97 (16.5%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 70	17/52 (32.7%)	1/45 (2.2%)	18/97 (18.6%)
Week 73	16/52 (30.8%)	2/45 (4.4%)	18/97 (18.6%)
Week 76	12/52 (23.1%)	2/45 (4.4%)	14/97 (14.4%)
Week 79	12/52 (23.1%)	0/45 (0.0%)	12/97 (12.4%)
Week 82	9/52 (17.3%)	0/45 (0.0%)	9/97 (9.3%)
Week 85	10/52 (19.2%)	0/45 (0.0%)	10/97 (10.3%)
Week 88	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 91	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 94	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 97	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 100	7/52 (13.5%)	0/45 (0.0%)	7/97 (7.2%)
Week 103	5/52 (9.6%)	0/45 (0.0%)	5/97 (5.2%)
Week 106	5/52 (9.6%)	0/45 (0.0%)	5/97 (5.2%)
Week 109	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 112	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 115	4/52 (7.7%)	0/45 (0.0%)	4/97 (4.1%)
Week 118	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 121	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 124	3/52 (5.8%)	0/45 (0.0%)	3/97 (3.1%)
Week 127	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 130	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
Week 133	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 136	2/52 (3.8%)	0/45 (0.0%)	2/97 (2.1%)
Week 139	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 142	1/52 (1.9%)	0/45 (0.0%)	1/97 (1.0%)
End of Treatment	33/52 (63.5%)	31/45 (68.9%)	64/97 (66.0%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.9. Table 1.1.3.5: — Summary of Available Data Rates of PGIS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	48/52 (92.3%)	43/45 (95.6%)	91/97 (93.8%)
Week 13	23/52 (44.2%)	29/45 (64.4%)	52/97 (53.6%)
Week 16	35/52 (67.3%)	19/45 (42.2%)	54/97 (55.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.10. Table 1.1.3.6: — Summary of Available Data Rates of PGIC by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 13	23/52 (44.2%)	29/45 (64.4%)	52/97 (53.6%)
Week 16	35/52 (67.3%)	19/45 (42.2%)	54/97 (55.7%)
Week 19	31/52 (59.6%)	11/45 (24.4%)	42/97 (43.3%)
Week 22	30/52 (57.7%)	21/45 (46.7%)	51/97 (52.6%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 25	30/52 (57.7%)	17/45 (37.8%)	47/97 (48.5%)
Week 28	15/52 (28.8%)	3/45 (6.7%)	18/97 (18.6%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.11. Table 1.1.4.1: — Summary of Modified Available Data Rates of EORTC QLQ-C30 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	38/51 (74.5%)	30/44 (68.2%)	68/95 (71.6%)
Week 7	40/51 (78.4%)	9/44 (20.5%)	49/95 (51.6%)
Week 10	36/51 (70.6%)	31/44 (70.5%)	67/95 (70.5%)
Week 13	34/51 (66.7%)	31/43 (72.1%)	65/94 (69.1%)
Week 16	36/51 (70.6%)	20/43 (46.5%)	56/94 (59.6%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	22/41 (53.7%)	52/92 (56.5%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	27/49 (55.1%)	13/40 (32.5%)	40/89 (44.9%)
Week 31	25/49 (51.0%)	5/40 (12.5%)	30/89 (33.7%)
Week 34	22/49 (44.9%)	9/39 (23.1%)	31/88 (35.2%)
Week 37	26/48 (54.2%)	8/39 (20.5%)	34/87 (39.1%)
Week 40	21/47 (44.7%)	5/39 (12.8%)	26/86 (30.2%)
Week 43	22/47 (46.8%)	4/38 (10.5%)	26/85 (30.6%)
Week 46	23/47 (48.9%)	4/38 (10.5%)	27/85 (31.8%)
Week 49	16/46 (34.8%)	2/36 (5.6%)	18/82 (22.0%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 52	16/46 (34.8%)	2/35 (5.7%)	18/81 (22.2%)
Week 55	18/44 (40.9%)	2/34 (5.9%)	20/78 (25.6%)
Week 58	17/43 (39.5%)	3/32 (9.4%)	20/75 (26.7%)
Week 61	15/41 (36.6%)	3/30 (10.0%)	18/71 (25.4%)
Week 64	14/41 (34.1%)	2/28 (7.1%)	16/69 (23.2%)
Week 67	15/41 (36.6%)	1/28 (3.6%)	16/69 (23.2%)
Week 70	17/39 (43.6%)	1/26 (3.8%)	18/65 (27.7%)
Week 73	16/38 (42.1%)	2/24 (8.3%)	18/62 (29.0%)
Week 76	12/38 (31.6%)	2/24 (8.3%)	14/62 (22.6%)
Week 79	12/36 (33.3%)	0/23 (0.0%)	12/59 (20.3%)
Week 82	9/35 (25.7%)	0/22 (0.0%)	9/57 (15.8%)
Week 85	10/34 (29.4%)	0/22 (0.0%)	10/56 (17.9%)
Week 88	7/34 (20.6%)	0/21 (0.0%)	7/55 (12.7%)
Week 91	7/33 (21.2%)	0/20 (0.0%)	7/53 (13.2%)
Week 94	7/32 (21.9%)	0/19 (0.0%)	7/51 (13.7%)
Week 97	7/32 (21.9%)	0/18 (0.0%)	7/50 (14.0%)
Week 100	7/32 (21.9%)	0/18 (0.0%)	7/50 (14.0%)
Week 103	5/31 (16.1%)	0/17 (0.0%)	5/48 (10.4%)
Week 106	5/30 (16.7%)	0/17 (0.0%)	5/47 (10.6%)
Week 109	4/30 (13.3%)	0/15 (0.0%)	4/45 (8.9%)
Week 112	3/28 (10.7%)	0/14 (0.0%)	3/42 (7.1%)
Week 115	4/28 (14.3%)	0/14 (0.0%)	4/42 (9.5%)
Week 118	2/28 (7.1%)	0/13 (0.0%)	2/41 (4.9%)
Week 121	2/28 (7.1%)	0/13 (0.0%)	2/41 (4.9%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 124	3/28 (10.7%)	0/13 (0.0%)	3/41 (7.3%)
Week 127	2/27 (7.4%)	0/11 (0.0%)	2/38 (5.3%)
Week 130	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
Week 133	2/27 (7.4%)	0/10 (0.0%)	2/37 (5.4%)
Week 136	2/27 (7.4%)	0/10 (0.0%)	2/37 (5.4%)
Week 139	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
Week 142	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
End of Treatment	33/43 (76.7%)	32/42 (76.2%)	65/85 (76.5%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.12. Table 1.1.4.2: — Summary of Modified Available Data Rates of EORTC QLQ-BR23 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	50/52 (96.2%)	44/45 (97.8%)	94/97 (96.9%)
Week 4	37/51 (72.5%)	30/44 (68.2%)	67/95 (70.5%)
Week 7	40/51 (78.4%)	8/44 (18.2%)	48/95 (50.5%)
Week 10	36/51 (70.6%)	31/44 (70.5%)	67/95 (70.5%)
Week 13	34/51 (66.7%)	30/43 (69.8%)	64/94 (68.1%)
Week 16	36/51 (70.6%)	19/43 (44.2%)	55/94 (58.5%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	27/49 (55.1%)	13/40 (32.5%)	40/89 (44.9%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 31	25/49 (51.0%)	5/40 (12.5%)	30/89 (33.7%)
Week 34	22/49 (44.9%)	9/39 (23.1%)	31/88 (35.2%)
Week 37	26/48 (54.2%)	8/39 (20.5%)	34/87 (39.1%)
Week 40	21/47 (44.7%)	5/39 (12.8%)	26/86 (30.2%)
Week 43	22/47 (46.8%)	4/38 (10.5%)	26/85 (30.6%)
Week 46	23/47 (48.9%)	4/38 (10.5%)	27/85 (31.8%)
Week 49	16/46 (34.8%)	2/36 (5.6%)	18/82 (22.0%)
Week 52	16/46 (34.8%)	2/35 (5.7%)	18/81 (22.2%)
Week 55	18/44 (40.9%)	2/34 (5.9%)	20/78 (25.6%)
Week 58	17/43 (39.5%)	3/32 (9.4%)	20/75 (26.7%)
Week 61	15/41 (36.6%)	3/30 (10.0%)	18/71 (25.4%)
Week 64	14/41 (34.1%)	2/28 (7.1%)	16/69 (23.2%)
Week 67	15/41 (36.6%)	1/28 (3.6%)	16/69 (23.2%)
Week 70	17/39 (43.6%)	1/26 (3.8%)	18/65 (27.7%)
Week 73	16/38 (42.1%)	2/24 (8.3%)	18/62 (29.0%)
Week 76	12/38 (31.6%)	2/24 (8.3%)	14/62 (22.6%)
Week 79	12/36 (33.3%)	0/23 (0.0%)	12/59 (20.3%)
Week 82	9/35 (25.7%)	0/22 (0.0%)	9/57 (15.8%)
Week 85	10/34 (29.4%)	0/22 (0.0%)	10/56 (17.9%)
Week 88	7/34 (20.6%)	0/21 (0.0%)	7/55 (12.7%)
Week 91	7/33 (21.2%)	0/20 (0.0%)	7/53 (13.2%)
Week 94	7/32 (21.9%)	0/19 (0.0%)	7/51 (13.7%)
Week 97	7/32 (21.9%)	0/18 (0.0%)	7/50 (14.0%)
Week 100	7/32 (21.9%)	0/18 (0.0%)	7/50 (14.0%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 103	5/31 (16.1%)	0/17 (0.0%)	5/48 (10.4%)
Week 106	5/30 (16.7%)	0/17 (0.0%)	5/47 (10.6%)
Week 109	4/30 (13.3%)	0/15 (0.0%)	4/45 (8.9%)
Week 112	3/28 (10.7%)	0/14 (0.0%)	3/42 (7.1%)
Week 115	4/28 (14.3%)	0/14 (0.0%)	4/42 (9.5%)
Week 118	2/28 (7.1%)	0/13 (0.0%)	2/41 (4.9%)
Week 121	2/28 (7.1%)	0/13 (0.0%)	2/41 (4.9%)
Week 124	3/28 (10.7%)	0/13 (0.0%)	3/41 (7.3%)
Week 127	2/27 (7.4%)	0/11 (0.0%)	2/38 (5.3%)
Week 130	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
Week 133	2/27 (7.4%)	0/10 (0.0%)	2/37 (5.4%)
Week 136	2/27 (7.4%)	0/10 (0.0%)	2/37 (5.4%)
Week 139	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
Week 142	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
End of Treatment	33/43 (76.7%)	31/42 (73.8%)	64/85 (75.3%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.13. Table 1.1.4.3: — Summary of Modified Available Data Rates of EQ-5D-VAS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	49/52 (94.2%)	43/45 (95.6%)	92/97 (94.8%)
Week 4	37/51 (72.5%)	30/44 (68.2%)	67/95 (70.5%)
Week 7	40/51 (78.4%)	8/44 (18.2%)	48/95 (50.5%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 10	36/51 (70.6%)	31/44 (70.5%)	67/95 (70.5%)
Week 13	34/51 (66.7%)	30/43 (69.8%)	64/94 (68.1%)
Week 16	36/51 (70.6%)	19/43 (44.2%)	55/94 (58.5%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	27/49 (55.1%)	13/40 (32.5%)	40/89 (44.9%)
Week 31	25/49 (51.0%)	5/40 (12.5%)	30/89 (33.7%)
Week 34	22/49 (44.9%)	9/39 (23.1%)	31/88 (35.2%)
Week 37	26/48 (54.2%)	8/39 (20.5%)	34/87 (39.1%)
Week 40	21/47 (44.7%)	5/39 (12.8%)	26/86 (30.2%)
Week 43	22/47 (46.8%)	4/38 (10.5%)	26/85 (30.6%)
Week 46	23/47 (48.9%)	4/38 (10.5%)	27/85 (31.8%)
Week 49	16/46 (34.8%)	2/36 (5.6%)	18/82 (22.0%)
Week 52	16/46 (34.8%)	2/35 (5.7%)	18/81 (22.2%)
Week 55	18/44 (40.9%)	2/34 (5.9%)	20/78 (25.6%)
Week 58	17/43 (39.5%)	3/32 (9.4%)	20/75 (26.7%)
Week 61	15/41 (36.6%)	3/30 (10.0%)	18/71 (25.4%)
Week 64	14/41 (34.1%)	2/28 (7.1%)	16/69 (23.2%)
Week 67	15/41 (36.6%)	1/28 (3.6%)	16/69 (23.2%)
Week 70	17/39 (43.6%)	1/26 (3.8%)	18/65 (27.7%)
Week 73	16/38 (42.1%)	2/24 (8.3%)	18/62 (29.0%)
Week 76	12/38 (31.6%)	2/24 (8.3%)	14/62 (22.6%)
Week 79	12/36 (33.3%)	0/23 (0.0%)	12/59 (20.3%)

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 82	9/35 (25.7%)	0/22 (0.0%)	9/57 (15.8%)
Week 85	10/34 (29.4%)	0/22 (0.0%)	10/56 (17.9%)
Week 88	7/34 (20.6%)	0/21 (0.0%)	7/55 (12.7%)
Week 91	7/33 (21.2%)	0/20 (0.0%)	7/53 (13.2%)
Week 94	7/32 (21.9%)	0/19 (0.0%)	7/51 (13.7%)
Week 97	7/32 (21.9%)	0/18 (0.0%)	7/50 (14.0%)
Week 100	7/32 (21.9%)	0/18 (0.0%)	7/50 (14.0%)
Week 103	5/31 (16.1%)	0/17 (0.0%)	5/48 (10.4%)
Week 106	5/30 (16.7%)	0/17 (0.0%)	5/47 (10.6%)
Week 109	4/30 (13.3%)	0/15 (0.0%)	4/45 (8.9%)
Week 112	3/28 (10.7%)	0/14 (0.0%)	3/42 (7.1%)
Week 115	4/28 (14.3%)	0/14 (0.0%)	4/42 (9.5%)
Week 118	2/28 (7.1%)	0/13 (0.0%)	2/41 (4.9%)
Week 121	2/28 (7.1%)	0/13 (0.0%)	2/41 (4.9%)
Week 124	3/28 (10.7%)	0/13 (0.0%)	3/41 (7.3%)
Week 127	2/27 (7.4%)	0/11 (0.0%)	2/38 (5.3%)
Week 130	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
Week 133	2/27 (7.4%)	0/10 (0.0%)	2/37 (5.4%)
Week 136	2/27 (7.4%)	0/10 (0.0%)	2/37 (5.4%)
Week 139	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
Week 142	1/27 (3.7%)	0/10 (0.0%)	1/37 (2.7%)
End of Treatment	33/43 (76.7%)	31/42 (73.8%)	64/85 (75.3%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.14. Table 1.1.4.5: — Summary of Modified Available Data Rates of PGIS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Baseline (Week 1)	48/52 (92.3%)	43/45 (95.6%)	91/97 (93.8%)
Week 13	23/51 (45.1%)	29/43 (67.4%)	52/94 (55.3%)
Week 16	35/51 (68.6%)	19/43 (44.2%)	54/94 (57.4%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	15/49 (30.6%)	3/40 (7.5%)	18/89 (20.2%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.15. Table 1.1.4.6: — Summary of Modified Available Data Rates of PGIC by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Visit	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
Week 13	23/51 (45.1%)	29/43 (67.4%)	52/94 (55.3%)
Week 16	35/51 (68.6%)	19/43 (44.2%)	54/94 (57.4%)
Week 19	31/51 (60.8%)	11/41 (26.8%)	42/92 (45.7%)
Week 22	30/51 (58.8%)	21/41 (51.2%)	51/92 (55.4%)
Week 25	30/50 (60.0%)	17/41 (41.5%)	47/91 (51.6%)
Week 28	15/49 (30.6%)	3/40 (7.5%)	18/89 (20.2%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.16. Table 1.1.9: PGI-Change | Observed Scores and Change from Baseline by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Item	Visit	Response Level	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
PGIC	Week 13		N=23	N=29	N=52
		Very much improved	1 (4.3%)	3 (10.3%)	4 (7.7%)
		Much improved	4 (17.4%)	5 (17.2%)	9 (17.3%)
		Minimally improved	10 (43.5%)	9 (31.0%)	19 (36.5%)
		No change	4 (17.4%)	4 (13.8%)	8 (15.4%)
		Minimally worsened	3 (13.0%)	7 (24.1%)	10 (19.2%)
		Much worsened	1 (4.3%)	1 (3.4%)	2 (3.8%)
	Week 16		N=35	N=19	N=54
		Very much improved	4 (11.4%)	1 (5.3%)	5 (9.3%)
		Much improved	7 (20.0%)	6 (31.6%)	13 (24.1%)
		Minimally improved	13 (37.1%)	5 (26.3%)	18 (33.3%)
		No change	5 (14.3%)	3 (15.8%)	8 (14.8%)
		Minimally worsened	4 (11.4%)	3 (15.8%)	7 (13.0%)
		Much worsened	2 (5.7%)	1 (5.3%)	3 (5.6%)
	Week 19		N=31	N=11	N=42
		Very much improved	2 (6.5%)	0 (0.0%)	2 (4.8%)
		Much improved	10 (32.3%)	2 (18.2%)	12 (28.6%)
		Minimally improved	6 (19.4%)	2 (18.2%)	8 (19.0%)
		No change	5 (16.1%)	4 (36.4%)	9 (21.4%)
		Minimally worsened	7 (22.6%)	2 (18.2%)	9 (21.4%)
		Much worsened	1 (3.2%)	1 (9.1%)	2 (4.8%)
	Week 22		N=30	N=21	N=51
		Very much improved	2 (6.7%)	2 (9.5%)	4 (7.8%)

Item	Visit	Response Level	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
		Much improved	12 (40.0%)	6 (28.6%)	18 (35.3%)
		Minimally improved	4 (13.3%)	3 (14.3%)	7 (13.7%)
		No change	6 (20.0%)	4 (19.0%)	10 (19.6%)
		Minimally worsened	5 (16.7%)	4 (19.0%)	9 (17.6%)
		Much worsened	1 (3.3%)	2 (9.5%)	3 (5.9%)
	Week 25		N=30	N=17	N=47
		Very much improved	3 (10.0%)	1 (5.9%)	4 (8.5%)
		Much improved	12 (40.0%)	6 (35.3%)	18 (38.3%)
		Minimally improved	7 (23.3%)	2 (11.8%)	9 (19.1%)
		No change	5 (16.7%)	2 (11.8%)	7 (14.9%)
		Minimally worsened	2 (6.7%)	5 (29.4%)	7 (14.9%)
		Much worsened	1 (3.3%)	1 (5.9%)	2 (4.3%)
	Week 28		N=15	N=3	N=18
		Very much improved	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Much improved	3 (20.0%)	2 (66.7%)	5 (27.8%)
		Minimally improved	7 (46.7%)	1 (33.3%)	8 (44.4%)
		No change	2 (13.3%)	0 (0.0%)	2 (11.1%)
		Minimally worsened	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Much worsened	1 (6.7%)	0 (0.0%)	1 (5.6%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Data cut off: 22 APR 2026

4.17. Table 1.1.10: PGI-Severity | Observed Scores and Change from Baseline by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

Item	Visit	Response Level	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
PGIS	Baseline (Week 1)		N=48	N=43	N=91
		Very Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Poor	8 (16.7%)	8 (18.6%)	16 (17.6%)
		Fair	14 (29.2%)	13 (30.2%)	27 (29.7%)
		Good	22 (45.8%)	15 (34.9%)	37 (40.7%)
		Excellent	4 (8.3%)	7 (16.3%)	11 (12.1%)
	Week 13		N=23	N=29	N=52
		Very Poor	1 (4.3%)	0 (0.0%)	1 (1.9%)
		Poor	3 (13.0%)	2 (6.9%)	5 (9.6%)
		Fair	10 (43.5%)	14 (48.3%)	24 (46.2%)
		Good	8 (34.8%)	12 (41.4%)	20 (38.5%)
		Excellent	1 (4.3%)	1 (3.4%)	2 (3.8%)
	Week 16		N=35	N=19	N=54
		Very Poor	1 (2.9%)	0 (0.0%)	1 (1.9%)
		Poor	4 (11.4%)	4 (21.1%)	8 (14.8%)
		Fair	21 (60.0%)	6 (31.6%)	27 (50.0%)
		Good	7 (20.0%)	9 (47.4%)	16 (29.6%)
		Excellent	2 (5.7%)	0 (0.0%)	2 (3.7%)
	Week 19		N=31	N=11	N=42
		Very Poor	0 (0.0%)	2 (18.2%)	2 (4.8%)
		Poor	4 (12.9%)	0 (0.0%)	4 (9.5%)
		Fair	12 (38.7%)	5 (45.5%)	17 (40.5%)

Item	Visit	Response Level	Sacituzumab Govitecan (N=52)	Treatment Physician Choice (N=45)	Overall (N=97)
		Good	14 (45.2%)	4 (36.4%)	18 (42.9%)
		Excellent	1 (3.2%)	0 (0.0%)	1 (2.4%)
	Week 22		N=30	N=21	N=51
		Very Poor	1 (3.3%)	0 (0.0%)	1 (2.0%)
		Poor	2 (6.7%)	6 (28.6%)	8 (15.7%)
		Fair	16 (53.3%)	6 (28.6%)	22 (43.1%)
		Good	11 (36.7%)	9 (42.9%)	20 (39.2%)
		Excellent	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 25		N=30	N=17	N=47
		Very Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Poor	6 (20.0%)	4 (23.5%)	10 (21.3%)
		Fair	10 (33.3%)	5 (29.4%)	15 (31.9%)
		Good	14 (46.7%)	8 (47.1%)	22 (46.8%)
		Excellent	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 28		N=15	N=3	N=18
		Very Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Poor	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Fair	10 (66.7%)	0 (0.0%)	10 (55.6%)
		Good	4 (26.7%)	2 (66.7%)	6 (33.3%)
		Excellent	0 (0.0%)	1 (33.3%)	1 (5.6%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Data cut off: 22 APR 2026

4.18. Table 1.1.14.1: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Global Health Status/QoL | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	32 (61.5%)	23 (51.1%)
A meaningful deterioration	32 (61.5%)	23 (51.1%)
Censored, n (%)	20 (38.5%)	22 (48.9%)
Not at risk at baseline	0 (0.0%)	1 (2.2%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	2 (4.4%)
Premature treatment discontinuation	10 (19.2%)	15 (33.3%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	3.3 (1.5, 5.6)	4.7 (2.0, 7.3)
Q1	1.1 (0.7, 1.6)	1.9 (1.0, 3.7)
Q3	8.3 (5.4, NE)	7.6 (5.6, NE)
Event-free rate, % (95% CI)		
At 3 months	52.1 (36.5, 65.6)	66.3 (48.2, 79.4)
At 6 months	30.6 (17.0, 45.3)	39.7 (22.1, 56.8)
At 12 months	24.5 (12.2, 39.1)	20.2 (6.9, 38.3)
At 18 months	12.2 (1.4, 35.7)	20.2 (6.9, 38.3)
At 24 months	12.2 (1.4, 35.7)	20.2 (6.9, 38.3)
p-value (two-sided, stratified log-rank)	0.6087	
Adjusted HR (95% CI), SG vs TPC	1.1811 (0.6842, 2.0389)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; QoL = Quality of life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.19. Table 1.1.14.2: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Physical Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	31 (59.6%)	23 (51.1%)
A meaningful deterioration	31 (59.6%)	23 (51.1%)
Censored, n (%)	21 (40.4%)	22 (48.9%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation	11 (21.2%)	17 (37.8%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	3.0 (1.4, 4.3)	4.4 (1.9, 11.1)
Q1	0.9 (0.8, 1.6)	1.9 (1.0, 2.8)
Q3	9.2 (4.2, NE)	11.1 (4.7, NE)
Event-free rate, % (95% CI)		
At 3 months	50.0 (34.6, 63.6)	56.6 (39.0, 70.9)
At 6 months	30.4 (16.5, 45.6)	34.0 (17.8, 51.0)
At 12 months	16.2 (4.0, 35.8)	17.0 (1.7, 46.3)
At 18 months	16.2 (4.0, 35.8)	17.0 (1.7, 46.3)
At 24 months	16.2 (4.0, 35.8)	17.0 (1.7, 46.3)
p-value (two-sided, stratified log-rank)	0.4904	

	SG (N=52)	TPC (N=45)
Adjusted HR (95% CI), SG vs TPC	1.3139 (0.7595, 2.2728)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.20. Table 1.1.14.3: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Role Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	31 (59.6%)	31 (68.9%)
A meaningful deterioration	31 (59.6%)	31 (68.9%)
Censored, n (%)	21 (40.4%)	14 (31.1%)
Not at risk at baseline	0 (0.0%)	1 (2.2%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	0 (0.0%)	1 (2.2%)
Premature treatment discontinuation	12 (23.1%)	8 (17.8%)
Others	1 (1.9%)	0 (0.0%)
Median TTD, months (95% CI)	1.5 (1.0, 3.6)	1.9 (1.4, 3.0)
Q1	0.8 (0.7, 1.2)	1.0 (0.9, 1.7)
Q3	NE	3.8 (2.8, NE)
Event-free rate, % (95% CI)		
At 3 months	36.4 (22.6, 50.3)	35.8 (20.8, 51.0)

	SG (N=52)	TPC (N=45)
At 6 months	30.5 (17.4, 44.8)	14.9 (5.5, 28.6)
At 12 months	27.2 (14.4, 41.6)	14.9 (5.5, 28.6)
At 18 months	27.2 (14.4, 41.6)	14.9 (5.5, 28.6)
At 24 months	27.2 (14.4, 41.6)	14.9 (5.5, 28.6)
p-value (two-sided, stratified log-rank)	0.7942	
Adjusted HR (95% CI), SG vs TPC	0.9402 (0.5677, 1.5572)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.21. Table 1.1.14.4: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Emotional Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	24 (46.2%)	12 (26.7%)
A meaningful deterioration	24 (46.2%)	12 (26.7%)
Censored, n (%)	28 (53.8%)	33 (73.3%)
Not at risk at baseline	1 (1.9%)	2 (4.4%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation	13 (25.0%)	25 (55.6%)
Others	3 (5.8%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Median TTD, months (95% CI)	8.4 (4.2, 18.7)	11.1 (6.5, NE)
Q1	3.0 (1.4, 4.3)	6.5 (1.9, 7.6)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	76.3 (60.4, 86.5)	91.1 (75.0, 97.1)
At 6 months	55.1 (38.3, 69.0)	76.0 (55.6, 87.9)
At 12 months	41.9 (25.5, 57.4)	39.2 (13.6, 64.4)
At 18 months	37.2 (20.9, 53.6)	39.2 (13.6, 64.4)
At 24 months	31.0 (14.7, 48.9)	39.2 (13.6, 64.4)
p-value (two-sided, stratified log-rank)	0.2201	
Adjusted HR (95% CI), SG vs TPC	1.4850 (0.7287, 3.0261)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.22. Table 1.1.14.5: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Cognitive Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	29 (55.8%)	25 (55.6%)
A meaningful deterioration	29 (55.8%)	25 (55.6%)
Censored, n (%)	23 (44.2%)	20 (44.4%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Missing baseline only	1 (1.9%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation	11 (21.2%)	15 (33.3%)
Others	2 (3.8%)	0 (0.0%)
Median TTD, months (95% CI)	3.5 (1.7, 6.0)	3.8 (2.8, 5.8)
Q1	1.4 (0.8, 1.7)	1.9 (1.0, 3.7)
Q3	18.7 (5.3, NE)	6.5 (4.6, NE)
Event-free rate, % (95% CI)		
At 3 months	56.3 (40.3, 69.5)	64.4 (46.5, 77.7)
At 6 months	34.1 (19.7, 49.1)	29.9 (14.9, 46.6)
At 12 months	30.7 (16.7, 45.9)	12.5 (1.3, 36.9)
At 18 months	30.7 (16.7, 45.9)	12.5 (1.3, 36.9)
At 24 months	20.5 (5.7, 41.6)	12.5 (1.3, 36.9)
p-value (two-sided, stratified log-rank)	0.9314	
Adjusted HR (95% CI), SG vs TPC	1.0262 (0.5842, 1.8024)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.23. Table 1.1.14.6: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Social Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	34 (65.4%)	23 (51.1%)
A meaningful deterioration	34 (65.4%)	23 (51.1%)
Censored, n (%)	18 (34.6%)	22 (48.9%)
Not at risk at baseline	0 (0.0%)	1 (2.2%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	1 (2.2%)
Premature treatment discontinuation	7 (13.5%)	16 (35.6%)
Others	1 (1.9%)	0 (0.0%)
Median TTD, months (95% CI)	2.2 (1.5, 3.6)	2.8 (1.5, NE)
Q1	1.1 (0.8, 1.6)	1.1 (0.9, 1.9)
Q3	7.6 (3.5, NE)	8.9 (3.7, NE)
Event-free rate, % (95% CI)		
At 3 months	44.6 (29.5, 58.7)	47.6 (30.4, 62.9)
At 6 months	29.8 (16.8, 43.8)	35.7 (19.3, 52.4)
At 12 months	22.3 (10.4, 37.0)	0.0 (NA, NA)
At 18 months	14.9 (3.9, 32.6)	0.0 (NA, NA)
At 24 months	7.4 (0.7, 26.1)	0.0 (NA, NA)
p-value (two-sided, stratified log-rank)	0.4316	
Adjusted HR (95% CI), SG vs TPC	1.1731 (0.6796, 2.0250)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.24. Table 1.1.14.7: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Fatigue | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	36 (69.2%)	32 (71.1%)
A meaningful deterioration	36 (69.2%)	32 (71.1%)
Censored, n (%)	16 (30.8%)	13 (28.9%)
Not at risk at baseline	1 (1.9%)	1 (2.2%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	1 (1.9%)	2 (4.4%)
Premature treatment discontinuation	6 (11.5%)	6 (13.3%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	1.2 (0.8, 1.7)	1.4 (1.1, 1.9)
Q1	0.8 (0.7, 0.8)	1.0 (1.0, 1.1)
Q3	2.4 (1.6, 5.8)	3.8 (1.9, 8.8)
Event-free rate, % (95% CI)		
At 3 months	23.3 (12.0, 36.6)	32.5 (18.3, 47.6)
At 6 months	9.3 (1.9, 23.9)	10.3 (2.3, 25.5)
At 12 months	9.3 (1.9, 23.9)	5.2 (0.4, 19.9)
At 18 months	9.3 (1.9, 23.9)	5.2 (0.4, 19.9)
At 24 months	9.3 (1.9, 23.9)	5.2 (0.4, 19.9)
p-value (two-sided, stratified log-rank)	0.1834	

	SG (N=52)	TPC (N=45)
Adjusted HR (95% CI), SG vs TPC	1.2942 (0.7993, 2.0957)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.25. Table 1.1.14.8: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Nausea and Vomiting | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	29 (55.8%)	14 (31.1%)
A meaningful deterioration	29 (55.8%)	14 (31.1%)
Censored, n (%)	23 (44.2%)	31 (68.9%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation	11 (21.2%)	25 (55.6%)
Others	1 (1.9%)	0 (0.0%)
Median TTD, months (95% CI)	2.8 (1.5, 5.7)	NE
Q1	0.9 (0.7, 1.7)	1.9 (1.1, 6.5)
Q3	16.9 (5.0, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	46.5 (31.1, 60.5)	72.8 (55.1, 84.4)

	SG (N=52)	TPC (N=45)
At 6 months	34.7 (20.2, 49.6)	60.6 (41.0, 75.5)
At 12 months	31.2 (17.2, 46.4)	53.9 (32.5, 71.2)
At 18 months	20.8 (5.8, 42.1)	53.9 (32.5, 71.2)
At 24 months	20.8 (5.8, 42.1)	53.9 (32.5, 71.2)
p-value (two-sided, stratified log-rank)	0.0316	
Adjusted HR (95% CI), SG vs TPC	2.0166 (1.0551, 3.8542)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.26. Table 1.1.14.9: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Pain | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	30 (57.7%)	24 (53.3%)
A meaningful deterioration	30 (57.7%)	24 (53.3%)
Censored, n (%)	22 (42.3%)	21 (46.7%)
Not at risk at baseline	3 (5.8%)	0 (0.0%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	4 (7.7%)	2 (4.4%)
Premature treatment discontinuation	7 (13.5%)	15 (33.3%)
Others	0 (0.0%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Median TTD, months (95% CI)	3.5 (1.6, 6.9)	3.1 (1.9, 6.9)
Q1	1.2 (0.8, 1.7)	1.1 (1.0, 2.8)
Q3	10.0 (5.6, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	50.4 (34.1, 64.6)	53.3 (35.8, 67.9)
At 6 months	34.8 (19.7, 50.2)	34.1 (18.7, 50.1)
At 12 months	13.5 (3.8, 29.4)	28.4 (13.2, 45.7)
At 18 months	13.5 (3.8, 29.4)	28.4 (13.2, 45.7)
At 24 months	13.5 (3.8, 29.4)	28.4 (13.2, 45.7)
p-value (two-sided, stratified log-rank)	0.6921	
Adjusted HR (95% CI), SG vs TPC	1.0919 (0.6289, 1.8958)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.27. Table 1.1.14.10: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Dyspnoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	22 (42.3%)	24 (53.3%)
A meaningful deterioration	22 (42.3%)	24 (53.3%)
Censored, n (%)	30 (57.7%)	21 (46.7%)
Not at risk at baseline	1 (1.9%)	1 (2.2%)
Missing baseline only	1 (1.9%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	2 (4.4%)
Premature treatment discontinuation	17 (32.7%)	14 (31.1%)
Others	2 (3.8%)	0 (0.0%)
Median TTD, months (95% CI)	7.2 (2.4, NE)	2.8 (1.5, 5.7)
Q1	1.5 (1.0, 3.5)	1.1 (1.0, 1.9)
Q3	NE	6.9 (4.7, NE)
Event-free rate, % (95% CI)		
At 3 months	64.9 (48.6, 77.1)	46.9 (29.8, 62.2)
At 6 months	56.8 (40.3, 70.3)	32.4 (17.1, 48.8)
At 12 months	40.1 (22.8, 56.9)	24.3 (8.9, 43.8)
At 18 months	40.1 (22.8, 56.9)	24.3 (8.9, 43.8)
At 24 months	40.1 (22.8, 56.9)	24.3 (8.9, 43.8)
p-value (two-sided, stratified log-rank)	0.1178	
Adjusted HR (95% CI), SG vs TPC	0.5794 (0.3181, 1.0552)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.28. Table 1.1.14.11: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Insomnia | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	21 (40.4%)	20 (44.4%)
A meaningful deterioration	21 (40.4%)	20 (44.4%)
Censored, n (%)	31 (59.6%)	25 (55.6%)
Not at risk at baseline	4 (7.7%)	3 (6.7%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	5 (9.6%)	2 (4.4%)
Premature treatment discontinuation	12 (23.1%)	16 (35.6%)
Others	2 (3.8%)	0 (0.0%)
Median TTD, months (95% CI)	5.5 (2.8, NE)	4.1 (1.9, NE)
Q1	1.6 (0.9, 3.5)	1.4 (1.0, 2.0)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	64.3 (47.2, 77.1)	53.8 (35.9, 68.8)
At 6 months	47.4 (29.9, 63.0)	42.4 (24.9, 58.9)
At 12 months	43.1 (25.7, 59.4)	37.1 (19.7, 54.6)
At 18 months	43.1 (25.7, 59.4)	37.1 (19.7, 54.6)
At 24 months	32.3 (12.4, 54.3)	37.1 (19.7, 54.6)
p-value (two-sided, stratified log-rank)	0.3834	
Adjusted HR (95% CI), SG vs TPC	0.8330 (0.4448, 1.5598)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.29. Table 1.1.14.12: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Appetite Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	23 (44.2%)	16 (35.6%)
A meaningful deterioration	23 (44.2%)	16 (35.6%)
Censored, n (%)	29 (55.8%)	29 (64.4%)
Not at risk at baseline	2 (3.8%)	3 (6.7%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	4 (7.7%)	2 (4.4%)
Premature treatment discontinuation	14 (26.9%)	20 (44.4%)
Others	1 (1.9%)	0 (0.0%)
Median TTD, months (95% CI)	4.2 (1.7, NE)	7.3 (1.9, NE)
Q1	1.4 (0.7, 1.7)	1.9 (1.0, 4.9)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	51.6 (35.5, 65.6)	61.1 (42.4, 75.4)
At 6 months	45.3 (29.2, 60.0)	53.0 (33.9, 68.8)
At 12 months	41.5 (25.5, 56.8)	46.3 (26.2, 64.3)
At 18 months	41.5 (25.5, 56.8)	46.3 (26.2, 64.3)
At 24 months	41.5 (25.5, 56.8)	46.3 (26.2, 64.3)
p-value (two-sided, stratified log-rank)	0.4171	

	SG (N=52)	TPC (N=45)
Adjusted HR (95% CI), SG vs TPC	1.3446 (0.7059, 2.5613)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.30. Table 1.1.14.13: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Constipation | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	30 (57.7%)	17 (37.8%)
A meaningful deterioration	30 (57.7%)	17 (37.8%)
Censored, n (%)	22 (42.3%)	28 (62.2%)
Not at risk at baseline	0 (0.0%)	2 (4.4%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	3 (5.8%)	1 (2.2%)
Premature treatment discontinuation	10 (19.2%)	21 (46.7%)
Others	1 (1.9%)	0 (0.0%)
Median TTD, months (95% CI)	2.1 (1.4, 3.5)	6.7 (3.7, NE)
Q1	1.0 (0.8, 1.5)	1.9 (0.9, 4.7)
Q3	11.4 (3.0, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	39.5 (24.9, 53.8)	69.3 (51.2, 81.8)

	SG (N=52)	TPC (N=45)
At 6 months	31.4 (17.9, 45.8)	53.4 (34.0, 69.4)
At 12 months	23.5 (9.1, 41.7)	40.1 (19.7, 59.7)
At 18 months	23.5 (9.1, 41.7)	40.1 (19.7, 59.7)
At 24 months	23.5 (9.1, 41.7)	40.1 (19.7, 59.7)
p-value (two-sided, stratified log-rank)	0.0761	
Adjusted HR (95% CI), SG vs TPC	1.8640 (1.0140, 3.4265)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.31. Table 1.1.14.14: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Diarrhoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	35 (67.3%)	24 (53.3%)
A meaningful deterioration	35 (67.3%)	24 (53.3%)
Censored, n (%)	17 (32.7%)	21 (46.7%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Missing baseline only	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation	6 (11.5%)	15 (33.3%)
Others	0 (0.0%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Median TTD, months (95% CI)	1.7 (0.9, 2.2)	2.9 (1.9, 6.5)
Q1	0.8 (0.7, 1.2)	1.4 (1.0, 1.9)
Q3	4.2 (2.2, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	35.7 (21.9, 49.8)	48.8 (31.4, 64.2)
At 6 months	18.1 (7.7, 32.1)	35.5 (19.7, 51.7)
At 12 months	18.1 (7.7, 32.1)	27.1 (12.6, 43.8)
At 18 months	18.1 (7.7, 32.1)	27.1 (12.6, 43.8)
At 24 months	18.1 (7.7, 32.1)	27.1 (12.6, 43.8)
p-value (two-sided, stratified log-rank)	0.0793	
Adjusted HR (95% CI), SG vs TPC	1.6604 (0.9793, 2.8154)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.32. Table 1.1.14.15: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Financial Difficulties | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	23 (44.2%)	18 (40.0%)
A meaningful deterioration	23 (44.2%)	18 (40.0%)
Censored, n (%)	29 (55.8%)	27 (60.0%)
Not at risk at baseline	0 (0.0%)	1 (2.2%)
Missing baseline only	1 (1.9%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Having baseline but no postbaseline visit	6 (11.5%)	3 (6.7%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	4 (7.7%)	2 (4.4%)
Premature treatment discontinuation	15 (28.8%)	20 (44.4%)
Others	2 (3.8%)	0 (0.0%)
Median TTD, months (95% CI)	7.9 (5.0, NE)	4.7 (2.8, NE)
Q1	2.9 (1.0, 5.6)	1.9 (1.0, 3.7)
Q3	NE	10.2 (10.2, NE)
Event-free rate, % (95% CI)		
At 3 months	74.4 (58.5, 85.0)	65.4 (47.0, 78.8)
At 6 months	59.4 (42.1, 73.2)	46.7 (28.3, 63.2)
At 12 months	34.2 (18.1, 51.0)	23.4 (2.0, 58.2)
At 18 months	34.2 (18.1, 51.0)	23.4 (2.0, 58.2)
At 24 months	34.2 (18.1, 51.0)	23.4 (2.0, 58.2)
p-value (two-sided, stratified log-rank)	0.4523	
Adjusted HR (95% CI), SG vs TPC	0.7084 (0.3753, 1.3370)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.33. Table 1.1.15.1: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Body Image | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	31 (59.6%)	21 (46.7%)
A meaningful deterioration	31 (59.6%)	21 (46.7%)
Censored, n (%)	21 (40.4%)	24 (53.3%)
Not at risk at baseline	2 (3.8%)	1 (2.2%)
Having baseline but no postbaseline visit	6 (11.5%)	5 (11.1%)
Missing baseline only	1 (1.9%)	0 (0.0%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	3 (6.7%)
Premature treatment discontinuation	5 (9.6%)	13 (28.9%)
Others	4 (7.7%)	1 (2.2%)
Median TTFD, months (95% CI)	1.6 (0.9, 4.2)	3.7 (1.9, 6.5)
Q1	0.8 (0.8, 1.2)	1.2 (1.0, 2.8)
Q3	5.8 (3.2, NE)	9.3 (4.6, NE)
Event-free rate, % (95% CI)		
At 3 months	41.2 (26.1, 55.6)	50.8 (32.5, 66.5)
At 6 months	23.0 (10.8, 38.0)	37.2 (19.4, 55.0)
At 12 months	23.0 (10.8, 38.0)	14.9 (1.4, 42.7)
At 18 months	23.0 (10.8, 38.0)	14.9 (1.4, 42.7)
At 24 months	23.0 (10.8, 38.0)	14.9 (1.4, 42.7)
p-value (two-sided, stratified log-rank)	0.1874	
Adjusted HR (95% CI), SG vs TPC	1.4043 (0.7892, 2.4988)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.

Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.34. Table 1.1.15.2: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Sexual Functioning | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	11 (21.2%)	10 (22.2%)
A meaningful deterioration	11 (21.2%)	10 (22.2%)
Censored, n (%)	41 (78.8%)	35 (77.8%)
Not at risk at baseline	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	5 (11.1%)
Missing baseline only	1 (1.9%)	0 (0.0%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	3 (6.7%)
Premature treatment discontinuation	13 (25.0%)	20 (44.4%)
Others	17 (32.7%)	6 (13.3%)
Median TTFD, months (95% CI)	NE	NE
Q1	5.0 (2.8, NE)	2.8 (1.0, NE)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	85.0 (69.6, 93.0)	72.7 (53.9, 84.9)
At 6 months	72.8 (54.9, 84.5)	67.9 (47.7, 81.6)
At 12 months	72.8 (54.9, 84.5)	67.9 (47.7, 81.6)
At 18 months	65.5 (43.3, 80.7)	67.9 (47.7, 81.6)

	SG (N=52)	TPC (N=45)
At 24 months	65.5 (43.3, 80.7)	67.9 (47.7, 81.6)
p-value (two-sided, stratified log-rank)	0.4815	
Adjusted HR (95% CI), SG vs TPC	0.7058 (0.2845, 1.7509)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.35. Table 1.1.15.3: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Sexual Enjoyment | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	1 (1.9%)	4 (8.9%)
A meaningful deterioration	1 (1.9%)	4 (8.9%)
Censored, n (%)	51 (98.1%)	41 (91.1%)
Not at risk at baseline	1 (1.9%)	1 (2.2%)
Having baseline but no postbaseline visit	5 (9.6%)	3 (6.7%)
Missing baseline only	8 (15.4%)	5 (11.1%)
No baseline or any postbaseline	31 (59.6%)	26 (57.8%)
Missing PRO for two consecutive visits	5 (9.6%)	3 (6.7%)
Premature treatment discontinuation	0 (0.0%)	3 (6.7%)
Others	1 (1.9%)	0 (0.0%)
Median TTFD, months (95% CI)	NE	NE
Q1	NE	1.0 (0.9, NE)
Q3	NE	NE

	SG (N=52)	TPC (N=45)
Event-free rate, % (95% CI)		
At 3 months	80.0 (20.4, 96.9)	51.4 (16.0, 78.6)
At 6 months	80.0 (20.4, 96.9)	51.4 (16.0, 78.6)
At 12 months	80.0 (20.4, 96.9)	51.4 (16.0, 78.6)
At 18 months	80.0 (20.4, 96.9)	51.4 (16.0, 78.6)
At 24 months	80.0 (20.4, 96.9)	51.4 (16.0, 78.6)
p-value (two-sided, stratified log-rank)	0.3889	
Adjusted HR (95% CI), SG vs TPC	0.3068 (0.0336, 2.8047)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.36. Table 1.1.15.4: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Future Perspective | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	20 (38.5%)	8 (17.8%)
A meaningful deterioration	20 (38.5%)	8 (17.8%)
Censored, n (%)	32 (61.5%)	37 (82.2%)
Not at risk at baseline	11 (21.2%)	12 (26.7%)
Having baseline but no postbaseline visit	6 (11.5%)	5 (11.1%)
Missing baseline only	1 (1.9%)	0 (0.0%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	2 (3.8%)	3 (6.7%)

	SG (N=52)	TPC (N=45)
Premature treatment discontinuation	6 (11.5%)	13 (28.9%)
Others	5 (9.6%)	3 (6.7%)
Median TTFD, months (95% CI)	5.5 (1.6, 17.8)	9.3 (2.8, NE)
Q1	1.5 (0.7, 3.6)	2.8 (1.0, NE)
Q3	17.8 (8.3, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	62.6 (43.6, 76.8)	73.3 (49.7, 87.1)
At 6 months	44.6 (26.4, 61.2)	68.4 (44.7, 83.6)
At 12 months	34.4 (16.9, 52.7)	45.6 (9.9, 76.6)
At 18 months	22.9 (5.8, 46.6)	45.6 (9.9, 76.6)
At 24 months	22.9 (5.8, 46.6)	45.6 (9.9, 76.6)
p-value (two-sided, stratified log-rank)	0.3587	
Adjusted HR (95% CI), SG vs TPC	1.5436 (0.6525, 3.6515)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.37. Table 1.1.15.5: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Systemic Therapy Side Effects | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	39 (75.0%)	32 (71.1%)
A meaningful deterioration	39 (75.0%)	32 (71.1%)
Censored, n (%)	13 (25.0%)	13 (28.9%)

	SG (N=52)	TPC (N=45)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (11.5%)	5 (11.1%)
Missing baseline only	1 (1.9%)	0 (0.0%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	1 (1.9%)	1 (2.2%)
Premature treatment discontinuation	1 (1.9%)	6 (13.3%)
Others	3 (5.8%)	0 (0.0%)
Median TTFD, months (95% CI)	1.0 (0.8, 1.5)	1.1 (1.0, 1.9)
Q1	0.8 (0.7, 0.8)	1.0 (0.9, 1.0)
Q3	1.7 (1.4, 4.2)	3.8 (1.2, 4.9)
Event-free rate, % (95% CI)		
At 3 months	17.5 (7.9, 30.2)	25.4 (12.5, 40.6)
At 6 months	12.5 (4.7, 24.3)	7.3 (1.3, 20.3)
At 12 months	9.4 (2.8, 21.0)	7.3 (1.3, 20.3)
At 18 months	9.4 (2.8, 21.0)	7.3 (1.3, 20.3)
At 24 months	9.4 (2.8, 21.0)	7.3 (1.3, 20.3)
p-value (two-sided, stratified log-rank)	0.1587	
Adjusted HR (95% CI), SG vs TPC	1.2395 (0.7611, 2.0186)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.38. Table 1.1.15.6: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Breast Symptoms | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	17 (32.7%)	7 (15.6%)
A meaningful deterioration	17 (32.7%)	7 (15.6%)
Censored, n (%)	35 (67.3%)	38 (84.4%)
Not at risk at baseline	3 (5.8%)	2 (4.4%)
Having baseline but no postbaseline visit	6 (11.5%)	5 (11.1%)
Missing baseline only	1 (1.9%)	0 (0.0%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	3 (5.8%)	3 (6.7%)
Premature treatment discontinuation	12 (23.1%)	22 (48.9%)
Others	9 (17.3%)	5 (11.1%)
Median TTFD, months (95% CI)	NE	NE
Q1	3.5 (0.8, 7.2)	6.9 (1.9, NE)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	75.1 (58.6, 85.8)	86.6 (67.8, 94.8)
At 6 months	66.7 (49.4, 79.2)	82.6 (62.9, 92.4)
At 12 months	51.4 (32.9, 67.2)	59.5 (24.8, 82.4)
At 18 months	51.4 (32.9, 67.2)	59.5 (24.8, 82.4)
At 24 months	51.4 (32.9, 67.2)	59.5 (24.8, 82.4)
p-value (two-sided, stratified log-rank)	0.1019	
Adjusted HR (95% CI), SG vs TPC	1.7036 (0.6839, 4.2437)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.39. Table 1.1.15.7: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Arm Symptoms | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	27 (51.9%)	17 (37.8%)
A meaningful deterioration	27 (51.9%)	17 (37.8%)
Censored, n (%)	25 (48.1%)	28 (62.2%)
Not at risk at baseline	0 (0.0%)	1 (2.2%)
Having baseline but no postbaseline visit	6 (11.5%)	5 (11.1%)
Missing baseline only	1 (1.9%)	0 (0.0%)
No baseline or any postbaseline	1 (1.9%)	1 (2.2%)
Missing PRO for two consecutive visits	3 (5.8%)	2 (4.4%)
Premature treatment discontinuation	9 (17.3%)	17 (37.8%)
Others	5 (9.6%)	2 (4.4%)
Median TTFD, months (95% CI)	4.8 (1.7, 12.7)	3.9 (2.8, NE)
Q1	1.4 (0.8, 2.1)	1.9 (1.0, 2.8)
Q3	15.0 (10.7, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	57.9 (41.7, 71.0)	56.2 (37.0, 71.5)
At 6 months	40.8 (25.2, 55.8)	47.5 (28.5, 64.4)
At 12 months	36.2 (20.6, 52.1)	38.0 (17.0, 59.0)
At 18 months	24.8 (10.1, 43.0)	38.0 (17.0, 59.0)
At 24 months	24.8 (10.1, 43.0)	38.0 (17.0, 59.0)
p-value (two-sided, stratified log-rank)	0.9506	

	SG (N=52)	TPC (N=45)
Adjusted HR (95% CI), SG vs TPC	1.0969 (0.5773, 2.0844)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.40. Table 1.1.15.8: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Upset By Hair Loss | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	3 (5.8%)	7 (15.6%)
A meaningful deterioration	3 (5.8%)	7 (15.6%)
Censored, n (%)	49 (94.2%)	38 (84.4%)
Not at risk at baseline	1 (1.9%)	0 (0.0%)
Having baseline but no postbaseline visit	2 (3.8%)	3 (6.7%)
Missing baseline only	36 (69.2%)	31 (68.9%)
No baseline or any postbaseline	5 (9.6%)	3 (6.7%)
Missing PRO for two consecutive visits	2 (3.8%)	0 (0.0%)
Premature treatment discontinuation	2 (3.8%)	1 (2.2%)
Others	1 (1.9%)	0 (0.0%)
Median TTFD, months (95% CI)	NE	1.4 (0.8, NE)
Q1	0.8 (0.7, NE)	1.0 (0.8, 1.9)
Q3	NE	4.6 (1.0, NE)
Event-free rate, % (95% CI)		
At 3 months	71.4 (25.8, 92.0)	33.3 (5.6, 65.8)

	SG (N=52)	TPC (N=45)
At 6 months	53.6 (13.2, 82.5)	0.0 (NA, NA)
At 12 months	53.6 (13.2, 82.5)	0.0 (NA, NA)
At 18 months	53.6 (13.2, 82.5)	0.0 (NA, NA)
At 24 months	53.6 (13.2, 82.5)	0.0 (NA, NA)
p-value (two-sided, stratified log-rank)	0.2268	
Adjusted HR (95% CI), SG vs TPC	0.3672 (0.0856, 1.5762)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.41. Table 1.1.16: Time to First Deterioration of EQ-5D VAS — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	27 (51.9%)	12 (26.7%)
A meaningful deterioration	27 (51.9%)	12 (26.7%)
Censored, n (%)	25 (48.1%)	33 (73.3%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	5 (9.6%)	4 (8.9%)
Missing baseline only	1 (1.9%)	1 (2.2%)
No baseline or any postbaseline	2 (3.8%)	1 (2.2%)
Missing PRO for two consecutive visits	4 (7.7%)	3 (6.7%)
Premature treatment discontinuation	12 (23.1%)	24 (53.3%)
Others	1 (1.9%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Median TTD, months (95% CI)	6.3 (3.2, 10.2)	11.1 (4.7, NE)
Q1	1.8 (0.8, 3.6)	2.8 (1.0, 11.1)
Q3	12.6 (8.1, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	68.0 (52.0, 79.6)	73.1 (54.4, 85.1)
At 6 months	54.7 (38.3, 68.5)	65.1 (45.2, 79.3)
At 12 months	29.0 (14.1, 45.8)	43.4 (10.1, 73.8)
At 18 months	23.2 (9.2, 40.9)	43.4 (10.1, 73.8)
At 24 months	23.2 (9.2, 40.9)	43.4 (10.1, 73.8)
p-value (two-sided, stratified log-rank)	0.0483	
Adjusted HR (95% CI), SG vs TPC	1.7784 (0.8865, 3.5678)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EQ-5D VAS is ≥15 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; VAS = Visual analogue scale; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.42. Table 1.1.18: Time to First Deterioration of PGI-Change — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	15 (28.8%)	13 (28.9%)
A meaningful deterioration	15 (28.8%)	13 (28.9%)
Censored, n (%)	37 (71.2%)	32 (71.1%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	0 (0.0%)	0 (0.0%)

	SG (N=52)	TPC (N=45)
Missing baseline only	0 (0.0%)	0 (0.0%)
No baseline or any postbaseline	12 (23.1%)	13 (28.9%)
Missing PRO for two consecutive visits	3 (5.8%)	1 (2.2%)
Premature treatment discontinuation	22 (42.3%)	18 (40.0%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	6.4 (5.0, NE)	NE
Q1	4.2 (3.0, 5.9)	3.4 (2.8, 4.7)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	89.7 (74.9, 96.0)	78.1 (59.5, 88.9)
At 6 months	59.2 (39.7, 74.2)	55.5 (35.4, 71.7)
At 12 months	49.3 (25.6, 69.3)	55.5 (35.4, 71.7)
At 18 months	49.3 (25.6, 69.3)	55.5 (35.4, 71.7)
At 24 months	49.3 (25.6, 69.3)	55.5 (35.4, 71.7)
p-value (two-sided, stratified log-rank)	0.1873	
Adjusted HR (95% CI), SG vs TPC	0.5983 (0.2744, 1.3045)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
For PGIC, "minimally worsened", "much worsened," and "very much worsened" are classified as responders.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.43. Table 1.1.19: Time to First Deterioration of PGI-Severity — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)
Events, n (%)	6 (11.5%)	3 (6.7%)

	SG (N=52)	TPC (N=45)
A meaningful deterioration	6 (11.5%)	3 (6.7%)
Censored, n (%)	46 (88.5%)	42 (93.3%)
Not at risk at baseline	7 (13.5%)	6 (13.3%)
Having baseline but no postbaseline visit	9 (17.3%)	11 (24.4%)
Missing baseline only	0 (0.0%)	0 (0.0%)
No baseline or any postbaseline	3 (5.8%)	2 (4.4%)
Missing PRO for two consecutive visits	4 (7.7%)	1 (2.2%)
Premature treatment discontinuation	23 (44.2%)	22 (48.9%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	NE	NE
Q1	NE	NE
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	93.8 (77.3, 98.4)	100.0 (NA, NA)
At 6 months	78.4 (57.4, 89.9)	82.7 (54.9, 94.2)
At 12 months	78.4 (57.4, 89.9)	82.7 (54.9, 94.2)
At 18 months	78.4 (57.4, 89.9)	82.7 (54.9, 94.2)
At 24 months	78.4 (57.4, 89.9)	82.7 (54.9, 94.2)
p-value (two-sided, stratified log-rank)	0.7276	
Adjusted HR (95% CI), SG vs TPC	1.4217 (0.3534, 5.7199)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
For PGIS, "very poor" and "poor" were classified as responders.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.44. Table 1.1.20.1: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Global Health Status/QoL | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.9608
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	8 (47.1%)	
Number (%) of Participants Censored	10 (38.5%)	9 (52.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.64 (1.18, 7.62)	4.80 (1.02, 7.56)	
Log-Rank Test p-value (unstratified)	0.9611		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.030 (0.433, 2.452)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	15 (53.6%)	
Number (%) of Participants Censored	10 (38.5%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.50 (1.02, 5.55)	4.67 (1.91, 7.49)	
Log-Rank Test p-value (unstratified)	0.5313		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.255 (0.619, 2.541)		
Age group			
< 65	35	35	0.8466
Number (%) of Participants with Events (Deterioration)	24 (68.6%)	17 (48.6%)	
Number (%) of Participants Censored	11 (31.4%)	18 (51.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.75 (1.58, 7.62)	4.67 (2.00, 7.49)	
Log-Rank Test p-value (unstratified)	0.5710		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.202 (0.640, 2.256)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	6 (60.0%)	
Number (%) of Participants Censored	9 (52.9%)	4 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.72, NR)	4.44 (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.7674		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.198 (0.412, 3.485)		
Baseline ECOG status			
0	35	26	0.6547
Number (%) of Participants with Events (Deterioration)	23 (65.7%)	16 (61.5%)	
Number (%) of Participants Censored	12 (34.3%)	10 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, 5.55)	4.47 (1.54, 6.51)	
Log-Rank Test p-value (unstratified)	0.9749		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.000 (0.521, 1.919)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	9 (52.9%)	7 (36.8%)	
Number (%) of Participants Censored	8 (47.1%)	12 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.61 (0.79, NR)	7.49 (2.00, NR)	
Log-Rank Test p-value (unstratified)	0.4135		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.508 (0.560, 4.063)		
History of liver metastasis			
Yes	11	13	0.3105

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	8 (72.7%)	5 (38.5%)	
Number (%) of Participants Censored	3 (27.3%)	8 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.66 (0.72, 3.61)	4.67 (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.1750		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.154 (0.698, 6.648)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	24 (58.5%)	18 (56.2%)	
Number (%) of Participants Censored	17 (41.5%)	14 (43.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.94 (1.48, 7.62)	4.80 (2.00, 7.49)	
Log-Rank Test p-value (unstratified)	0.9354		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.031 (0.555, 1.914)		
PD-L1 Status			
CPS < 1	23	7	0.3255
Number (%) of Participants with Events (Deterioration)	14 (60.9%)	4 (57.1%)	
Number (%) of Participants Censored	9 (39.1%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.75 (0.79, NR)	2.00 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.6055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.756 (0.243, 2.357)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	18 (64.3%)	19 (50.0%)	
Number (%) of Participants Censored	10 (35.7%)	19 (50.0%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, 7.62)	4.67 (3.02, 7.49)	
Log-Rank Test p-value (unstratified)	0.3274		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.387 (0.726, 2.648)		
Menopausal status			
Pre-menopausal	8	14	0.3810
Number (%) of Participants with Events (Deterioration)	6 (75.0%)	7 (50.0%)	
Number (%) of Participants Censored	2 (25.0%)	7 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.50 (0.79, NR)	4.80 (3.02, 7.49)	
Log-Rank Test p-value (unstratified)	0.1726		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.146 (0.699, 6.584)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	16 (51.6%)	
Number (%) of Participants Censored	18 (40.9%)	15 (48.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, 5.65)	3.75 (1.18, 6.51)	
Log-Rank Test p-value (unstratified)	0.9047		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.049 (0.558, 1.971)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.45. Table 1.1.20.2: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Physical Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.5882
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	7 (41.2%)	
Number (%) of Participants Censored	11 (42.3%)	10 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.22 (0.95, 4.34)	3.71 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.2650		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.664 (0.674, 4.112)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	16 (57.1%)	
Number (%) of Participants Censored	10 (38.5%)	12 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.32 (0.82, 9.17)	4.63 (1.94, 11.07)	
Log-Rank Test p-value (unstratified)	0.7130		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.139 (0.562, 2.307)		
Age group			
< 65	35	35	0.8780
Number (%) of Participants with Events (Deterioration)	23 (65.7%)	16 (45.7%)	
Number (%) of Participants Censored	12 (34.3%)	19 (54.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.91 (2.10, 5.59)	5.55 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.3357		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.370 (0.718, 2.612)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	7 (70.0%)	
Number (%) of Participants Censored	9 (52.9%)	3 (30.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.38 (0.72, NR)	2.35 (0.92, 4.44)	
Log-Rank Test p-value (unstratified)	0.7088		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.203 (0.434, 3.337)		
Baseline ECOG status			
0	35	26	0.4893
Number (%) of Participants with Events (Deterioration)	22 (62.9%)	16 (61.5%)	
Number (%) of Participants Censored	13 (37.1%)	10 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.48, 5.59)	3.71 (1.87, 5.98)	
Log-Rank Test p-value (unstratified)	0.7489		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.108 (0.578, 2.127)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	9 (52.9%)	7 (36.8%)	
Number (%) of Participants Censored	8 (47.1%)	12 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.24 (0.76, NR)	4.44 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.2181		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.854 (0.688, 4.996)		
History of liver metastasis			
Yes	11	13	0.9709

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	7 (63.6%)	5 (38.5%)	
Number (%) of Participants Censored	4 (36.4%)	8 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.83 (0.72, NR)	4.67 (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.5765		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.405 (0.424, 4.653)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	24 (58.5%)	18 (56.2%)	
Number (%) of Participants Censored	17 (41.5%)	14 (43.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.46 (1.38, 5.59)	3.71 (1.94, 11.07)	
Log-Rank Test p-value (unstratified)	0.3219		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.359 (0.737, 2.507)		
PD-L1 Status			
CPS < 1	23	7	0.0758
Number (%) of Participants with Events (Deterioration)	11 (47.8%)	4 (57.1%)	
Number (%) of Participants Censored	12 (52.2%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.34 (1.74, NR)	2.00 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.3371		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.569 (0.178, 1.824)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	20 (71.4%)	19 (50.0%)	
Number (%) of Participants Censored	8 (28.6%)	19 (50.0%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.64 (0.82, 4.17)	4.63 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.0485		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.876 (0.991, 3.551)		
Menopausal status			
Pre-menopausal	8	14	0.1690
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	6 (42.9%)	
Number (%) of Participants Censored	5 (62.5%)	8 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.63 (0.79, NR)	5.98 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.2705		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.413 (0.082, 2.088)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	28 (63.6%)	17 (54.8%)	
Number (%) of Participants Censored	16 (36.4%)	14 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.12 (1.18, 3.91)	3.71 (1.91, 5.55)	
Log-Rank Test p-value (unstratified)	0.1735		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.518 (0.827, 2.785)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.46. Table 1.1.20.3: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Role Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.9374
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	11 (64.7%)	
Number (%) of Participants Censored	12 (46.2%)	6 (35.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.82, 8.31)	1.94 (1.18, 3.84)	
Log-Rank Test p-value (unstratified)	0.9175		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.967 (0.430, 2.175)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	17 (65.4%)	20 (71.4%)	
Number (%) of Participants Censored	9 (34.6%)	8 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.76, 5.59)	1.94 (0.99, 3.02)	
Log-Rank Test p-value (unstratified)	0.8025		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.928 (0.485, 1.777)		
Age group			
< 65	35	35	0.2992
Number (%) of Participants with Events (Deterioration)	21 (60.0%)	24 (68.6%)	
Number (%) of Participants Censored	14 (40.0%)	11 (31.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, NR)	2.00 (1.54, 3.06)	
Log-Rank Test p-value (unstratified)	0.4686		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.806 (0.446, 1.457)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	7 (70.0%)	
Number (%) of Participants Censored	7 (41.2%)	3 (30.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.72, 1.48)	1.18 (0.92, 3.09)	
Log-Rank Test p-value (unstratified)	0.5625		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.331 (0.502, 3.526)		
Baseline ECOG status			
0	35	26	0.5636
Number (%) of Participants with Events (Deterioration)	21 (60.0%)	19 (73.1%)	
Number (%) of Participants Censored	14 (40.0%)	7 (26.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.18, 5.59)	1.91 (0.99, 3.09)	
Log-Rank Test p-value (unstratified)	0.5297		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.818 (0.434, 1.539)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	12 (63.2%)	
Number (%) of Participants Censored	7 (41.2%)	7 (36.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.76, NR)	2.00 (1.18, 3.06)	
Log-Rank Test p-value (unstratified)	0.6939		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.195 (0.514, 2.778)		
History of liver metastasis			
Yes	11	13	0.0865

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (45.5%)	8 (61.5%)	
Number (%) of Participants Censored	6 (54.5%)	5 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.86 (0.72, NR)	1.54 (0.92, 2.76)	
Log-Rank Test p-value (unstratified)	0.1755		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.457 (0.145, 1.433)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	26 (63.4%)	23 (71.9%)	
Number (%) of Participants Censored	15 (36.6%)	9 (28.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.82, 2.17)	2.00 (1.71, 3.09)	
Log-Rank Test p-value (unstratified)	0.6276		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.159 (0.658, 2.041)		
PD-L1 Status			
CPS < 1	23	7	0.8193
Number (%) of Participants with Events (Deterioration)	12 (52.2%)	3 (42.9%)	
Number (%) of Participants Censored	11 (47.8%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.50 (0.89, NR)	2.00 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.9475		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.052 (0.293, 3.779)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	19 (67.9%)	28 (73.7%)	
Number (%) of Participants Censored	9 (32.1%)	10 (26.3%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.76, 2.17)	1.94 (1.41, 3.02)	
Log-Rank Test p-value (unstratified)	0.7262		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.112 (0.619, 1.998)		
Menopausal status			
Pre-menopausal	8	14	<0.001
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	11 (78.6%)	
Number (%) of Participants Censored	7 (87.5%)	3 (21.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (5.59, NR)	1.68 (0.92, 3.84)	
Log-Rank Test p-value (unstratified)	0.0017		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.073 (0.009, 0.582)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	30 (68.2%)	20 (64.5%)	
Number (%) of Participants Censored	14 (31.8%)	11 (35.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.40 (0.82, 1.71)	2.00 (1.54, 3.09)	
Log-Rank Test p-value (unstratified)	0.2090		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.453 (0.823, 2.565)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.47. Table 1.1.20.4: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Emotional Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3891
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	4 (23.5%)	
Number (%) of Participants Censored	14 (53.8%)	13 (76.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (2.10, 9.69)	7.56 (5.68, NR)	
Log-Rank Test p-value (unstratified)	0.1718		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.163 (0.694, 6.747)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	8 (28.6%)	
Number (%) of Participants Censored	14 (53.8%)	20 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.16 (4.17, NR)	11.10 (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.6991		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.201 (0.474, 3.043)		
Age group			
< 65	35	35	0.0396
Number (%) of Participants with Events (Deterioration)	20 (57.1%)	7 (20.0%)	
Number (%) of Participants Censored	15 (42.9%)	28 (80.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (4.17, 18.73)	NR (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.0503		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.337 (0.973, 5.613)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	4 (23.5%)	5 (50.0%)	
Number (%) of Participants Censored	13 (76.5%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.02, NR)	7.56 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.3457		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.534 (0.142, 2.010)		
Baseline ECOG status			
0	35	26	0.7319
Number (%) of Participants with Events (Deterioration)	14 (40.0%)	7 (26.9%)	
Number (%) of Participants Censored	21 (60.0%)	19 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.16 (4.63, NR)	11.10 (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.5436		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.334 (0.525, 3.389)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	5 (26.3%)	
Number (%) of Participants Censored	7 (41.2%)	14 (73.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.24 (2.30, 9.69)	NR (3.81, NR)	
Log-Rank Test p-value (unstratified)	0.1911		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.037 (0.686, 6.048)		
History of liver metastasis			
Yes	11	13	0.8937

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (45.5%)	2 (15.4%)	
Number (%) of Participants Censored	6 (54.5%)	11 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.34 (1.18, NR)	NR (1.84, NR)	
Log-Rank Test p-value (unstratified)	0.5304		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.684 (0.325, 8.741)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	19 (46.3%)	10 (31.2%)	
Number (%) of Participants Censored	22 (53.7%)	22 (68.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (3.81, 18.73)	11.10 (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.3047		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.501 (0.687, 3.282)		
PD-L1 Status			
CPS < 1	23	7	0.1170
Number (%) of Participants with Events (Deterioration)	11 (47.8%)	3 (42.9%)	
Number (%) of Participants Censored	12 (52.2%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (4.24, NR)	7.26 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.2682		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.473 (0.124, 1.803)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	13 (46.4%)	9 (23.7%)	
Number (%) of Participants Censored	15 (53.6%)	29 (76.3%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.00 (2.17, NR)	11.10 (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.1122		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.999 (0.837, 4.774)		
Menopausal status			
Pre-menopausal	8	14	0.3436
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	2 (14.3%)	
Number (%) of Participants Censored	3 (37.5%)	12 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.84 (2.30, NR)	NR (5.68, NR)	
Log-Rank Test p-value (unstratified)	0.2348		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.696 (0.491, 14.796)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	10 (32.3%)	
Number (%) of Participants Censored	25 (56.8%)	21 (67.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (3.61, NR)	7.56 (4.63, NR)	
Log-Rank Test p-value (unstratified)	0.5819		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.242 (0.571, 2.703)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.48. Table 1.1.20.5: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Cognitive Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3706
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	9 (52.9%)	
Number (%) of Participants Censored	11 (42.3%)	8 (47.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (0.85, 4.34)	3.75 (1.02, NR)	
Log-Rank Test p-value (unstratified)	0.6018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.252 (0.546, 2.870)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	16 (57.1%)	
Number (%) of Participants Censored	12 (46.2%)	12 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (1.74, NR)	4.01 (2.79, 6.51)	
Log-Rank Test p-value (unstratified)	0.5502		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.795 (0.380, 1.664)		
Age group			
< 65	35	35	0.7467
Number (%) of Participants with Events (Deterioration)	21 (60.0%)	21 (60.0%)	
Number (%) of Participants Censored	14 (40.0%)	14 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.68, 18.73)	3.84 (2.83, 5.55)	
Log-Rank Test p-value (unstratified)	0.8326		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.935 (0.503, 1.738)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	4 (40.0%)	
Number (%) of Participants Censored	9 (52.9%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (0.82, NR)	6.51 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.7660		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.202 (0.351, 4.123)		
Baseline ECOG status			
0	35	26	0.6427
Number (%) of Participants with Events (Deterioration)	20 (57.1%)	17 (65.4%)	
Number (%) of Participants Censored	15 (42.9%)	9 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.58, 7.62)	3.75 (2.79, 6.51)	
Log-Rank Test p-value (unstratified)	0.7578		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.899 (0.464, 1.742)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	9 (52.9%)	8 (42.1%)	
Number (%) of Participants Censored	8 (47.1%)	11 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (0.82, NR)	4.63 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.6081		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.281 (0.491, 3.338)		
History of liver metastasis			
Yes	11	13	0.9245

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (54.5%)	5 (38.5%)	
Number (%) of Participants Censored	5 (45.5%)	8 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (0.85, NR)	4.67 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.8150		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.139 (0.343, 3.785)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	23 (56.1%)	20 (62.5%)	
Number (%) of Participants Censored	18 (43.9%)	12 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.64, 7.62)	3.84 (2.79, 5.85)	
Log-Rank Test p-value (unstratified)	0.9165		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.973 (0.529, 1.789)		
PD-L1 Status			
CPS < 1	23	7	0.3801
Number (%) of Participants with Events (Deterioration)	11 (47.8%)	1 (14.3%)	
Number (%) of Participants Censored	12 (52.2%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (1.58, NR)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.3024		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.816 (0.362, 21.882)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	18 (64.3%)	24 (63.2%)	
Number (%) of Participants Censored	10 (35.7%)	14 (36.8%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (1.41, 7.62)	3.75 (2.79, 5.55)	
Log-Rank Test p-value (unstratified)	0.9938		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.992 (0.530, 1.855)		
Menopausal status			
Pre-menopausal	8	14	0.0336
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	11 (78.6%)	
Number (%) of Participants Censored	5 (62.5%)	3 (21.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.74, NR)	3.75 (1.41, 4.67)	
Log-Rank Test p-value (unstratified)	0.0714		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.324 (0.089, 1.170)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	14 (45.2%)	
Number (%) of Participants Censored	18 (40.9%)	17 (54.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (1.41, 5.26)	4.63 (2.79, 10.15)	
Log-Rank Test p-value (unstratified)	0.3298		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.387 (0.719, 2.674)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.49. Table 1.1.20.6: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Social Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.6237
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	7 (41.2%)	
Number (%) of Participants Censored	12 (46.2%)	10 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.22 (1.18, 3.61)	3.71 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.4056		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.463 (0.590, 3.630)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	20 (76.9%)	16 (57.1%)	
Number (%) of Participants Censored	6 (23.1%)	12 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.18 (1.02, 7.16)	2.79 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.8003		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.087 (0.550, 2.150)		
Age group			
< 65	35	35	0.8433
Number (%) of Participants with Events (Deterioration)	25 (71.4%)	19 (54.3%)	
Number (%) of Participants Censored	10 (28.6%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.58, 7.16)	2.79 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.7233		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.115 (0.602, 2.063)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	9 (52.9%)	4 (40.0%)	
Number (%) of Participants Censored	8 (47.1%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.64 (0.76, 3.45)	1.87 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.8003		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.162 (0.355, 3.799)		
Baseline ECOG status			
0	35	26	0.5247
Number (%) of Participants with Events (Deterioration)	23 (65.7%)	15 (57.7%)	
Number (%) of Participants Censored	12 (34.3%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, 7.16)	1.91 (1.15, 4.80)	
Log-Rank Test p-value (unstratified)	0.8473		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.065 (0.546, 2.075)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	11 (64.7%)	8 (42.1%)	
Number (%) of Participants Censored	6 (35.3%)	11 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.82, 4.17)	3.02 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.4422		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.429 (0.572, 3.573)		
History of liver metastasis			
Yes	11	13	0.0149

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	10 (90.9%)	3 (23.1%)	
Number (%) of Participants Censored	1 (9.1%)	10 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.95 (0.72, 3.61)	NR (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.0192		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	4.158 (1.140, 15.166)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	24 (58.5%)	20 (62.5%)	
Number (%) of Participants Censored	17 (41.5%)	12 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.41, 7.59)	1.91 (1.05, 4.80)	
Log-Rank Test p-value (unstratified)	0.5487		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.828 (0.449, 1.527)		
PD-L1 Status			
CPS < 1	23	7	0.7360
Number (%) of Participants with Events (Deterioration)	15 (65.2%)	2 (28.6%)	
Number (%) of Participants Censored	8 (34.8%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.61 (0.79, 17.68)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.4540		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.779 (0.395, 8.016)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	19 (67.9%)	21 (55.3%)	
Number (%) of Participants Censored	9 (32.1%)	17 (44.7%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.64, 3.61)	2.79 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.7156		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.115 (0.598, 2.079)		
Menopausal status			
Pre-menopausal	8	14	0.9635
Number (%) of Participants with Events (Deterioration)	7 (87.5%)	8 (57.1%)	
Number (%) of Participants Censored	1 (12.5%)	6 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.84 (0.76, NR)	3.02 (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.6453		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.283 (0.443, 3.713)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	27 (61.4%)	15 (48.4%)	
Number (%) of Participants Censored	17 (38.6%)	16 (51.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, 3.55)	2.79 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.5919		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.186 (0.626, 2.245)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.50. Table 1.1.20.7: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Fatigue | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.4561
Number (%) of Participants with Events (Deterioration)	17 (65.4%)	11 (64.7%)	
Number (%) of Participants Censored	9 (34.6%)	6 (35.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.79, 1.71)	1.87 (1.08, 5.55)	
Log-Rank Test p-value (unstratified)	0.1888		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.679 (0.780, 3.610)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	19 (73.1%)	21 (75.0%)	
Number (%) of Participants Censored	7 (26.9%)	7 (25.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.80 (0.76, 2.23)	1.08 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.6218		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.171 (0.626, 2.192)		
Age group			
< 65	35	35	0.8106
Number (%) of Participants with Events (Deterioration)	26 (74.3%)	26 (74.3%)	
Number (%) of Participants Censored	9 (25.7%)	9 (25.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.30 (0.79, 2.14)	1.41 (1.05, 3.02)	
Log-Rank Test p-value (unstratified)	0.4618		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.232 (0.713, 2.128)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	6 (60.0%)	
Number (%) of Participants Censored	7 (41.2%)	4 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.72, 2.23)	1.71 (0.92, 3.02)	
Log-Rank Test p-value (unstratified)	0.5308		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.424 (0.504, 4.028)		
Baseline ECOG status			
0	35	26	0.4583
Number (%) of Participants with Events (Deterioration)	26 (74.3%)	19 (73.1%)	
Number (%) of Participants Censored	9 (25.7%)	7 (26.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.76, 1.74)	1.87 (0.99, 5.55)	
Log-Rank Test p-value (unstratified)	0.2163		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.466 (0.809, 2.657)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	13 (68.4%)	
Number (%) of Participants Censored	7 (41.2%)	6 (31.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.76, NR)	1.18 (1.05, 1.71)	
Log-Rank Test p-value (unstratified)	0.9475		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.028 (0.444, 2.383)		
History of liver metastasis			
Yes	11	13	0.8114

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	8 (72.7%)	8 (61.5%)	
Number (%) of Participants Censored	3 (27.3%)	5 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.46 (0.72, NR)	1.87 (0.92, 3.78)	
Log-Rank Test p-value (unstratified)	0.9694		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.021 (0.367, 2.840)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	28 (68.3%)	24 (75.0%)	
Number (%) of Participants Censored	13 (31.7%)	8 (25.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.76, 1.64)	1.22 (1.02, 3.02)	
Log-Rank Test p-value (unstratified)	0.3187		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.328 (0.768, 2.297)		
PD-L1 Status			
CPS < 1	23	7	0.2893
Number (%) of Participants with Events (Deterioration)	14 (60.9%)	5 (71.4%)	
Number (%) of Participants Censored	9 (39.1%)	2 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.76, 5.03)	1.08 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.9703		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.995 (0.353, 2.800)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	22 (78.6%)	27 (71.1%)	
Number (%) of Participants Censored	6 (21.4%)	11 (28.9%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.76, 1.71)	1.71 (1.02, 3.02)	
Log-Rank Test p-value (unstratified)	0.0969		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.606 (0.906, 2.846)		
Menopausal status			
Pre-menopausal	8	14	0.3130
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	11 (78.6%)	
Number (%) of Participants Censored	3 (37.5%)	3 (21.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.86 (0.76, NR)	1.87 (1.05, 5.98)	
Log-Rank Test p-value (unstratified)	0.5633		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.737 (0.254, 2.137)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	31 (70.5%)	21 (67.7%)	
Number (%) of Participants Censored	13 (29.5%)	10 (32.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.76, 1.48)	1.22 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.2787		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.378 (0.789, 2.406)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.51. Table 1.1.20.8: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Nausea and Vomiting | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3570
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	7 (41.2%)	
Number (%) of Participants Censored	12 (46.2%)	10 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (0.89, 5.65)	5.55 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.2930		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.629 (0.656, 4.049)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	7 (25.0%)	
Number (%) of Participants Censored	11 (42.3%)	21 (75.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.20 (0.79, NR)	NR (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.0219		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.744 (1.117, 6.738)		
Age group			
< 65	35	35	0.5420
Number (%) of Participants with Events (Deterioration)	22 (62.9%)	11 (31.4%)	
Number (%) of Participants Censored	13 (37.1%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.61 (1.41, 6.93)	NR (5.55, NR)	
Log-Rank Test p-value (unstratified)	0.0145		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.410 (1.165, 4.986)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	3 (30.0%)	
Number (%) of Participants Censored	10 (58.8%)	7 (70.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (0.76, NR)	NR (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.6026		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.446 (0.371, 5.638)		
Baseline ECOG status			
0	35	26	0.9966
Number (%) of Participants with Events (Deterioration)	19 (54.3%)	8 (30.8%)	
Number (%) of Participants Censored	16 (45.7%)	18 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.41, 16.85)	NR (5.55, NR)	
Log-Rank Test p-value (unstratified)	0.0449		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.281 (0.996, 5.221)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	6 (31.6%)	
Number (%) of Participants Censored	7 (41.2%)	13 (68.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (0.76, NR)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.1038		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.296 (0.824, 6.392)		
History of liver metastasis			
Yes	11	13	0.6361

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	7 (63.6%)	4 (30.8%)	
Number (%) of Participants Censored	4 (36.4%)	9 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (0.79, NR)	NR (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.3618		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.761 (0.512, 6.056)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	22 (53.7%)	10 (31.2%)	
Number (%) of Participants Censored	19 (46.3%)	22 (68.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (0.92, 6.93)	NR (5.55, NR)	
Log-Rank Test p-value (unstratified)	0.0190		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.393 (1.131, 5.061)		
PD-L1 Status			
CPS < 1	23	7	0.1464
Number (%) of Participants with Events (Deterioration)	10 (43.5%)	0	
Number (%) of Participants Censored	13 (56.5%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.65 (0.89, NR)	NR (NR, NR)	
Log-Rank Test p-value (unstratified)	0.0910		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	19 (67.9%)	14 (36.8%)	
Number (%) of Participants Censored	9 (32.1%)	24 (63.2%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.56 (0.92, 3.61)	6.47 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.0065		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.542 (1.271, 5.085)		
Menopausal status			
Pre-menopausal	8	14	0.4412
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	4 (28.6%)	
Number (%) of Participants Censored	4 (50.0%)	10 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.85 (0.79, NR)	NR (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.9714		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.012 (0.224, 4.565)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	25 (56.8%)	10 (32.3%)	
Number (%) of Participants Censored	19 (43.2%)	21 (67.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.92, 5.03)	NR (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.0148		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.433 (1.165, 5.080)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.52. Table 1.1.20.9: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Pain | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.2792
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	9 (52.9%)	
Number (%) of Participants Censored	14 (53.8%)	8 (47.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.37 (0.82, 11.76)	2.79 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.5267		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.751 (0.307, 1.839)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	18 (69.2%)	15 (53.6%)	
Number (%) of Participants Censored	8 (30.8%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.32 (1.41, 6.87)	3.75 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.3735		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.372 (0.686, 2.742)		
Age group			
< 65	35	35	0.8452
Number (%) of Participants with Events (Deterioration)	22 (62.9%)	19 (54.3%)	
Number (%) of Participants Censored	13 (37.1%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.64, 8.77)	3.06 (1.94, 6.90)	
Log-Rank Test p-value (unstratified)	0.9225		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.029 (0.548, 1.932)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	5 (50.0%)	
Number (%) of Participants Censored	9 (52.9%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (0.72, NR)	1.18 (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.8200		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.122 (0.363, 3.466)		
Baseline ECOG status			
0	35	26	0.5237
Number (%) of Participants with Events (Deterioration)	22 (62.9%)	15 (57.7%)	
Number (%) of Participants Censored	13 (37.1%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.68, 6.87)	3.71 (0.99, 6.90)	
Log-Rank Test p-value (unstratified)	0.7945		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.909 (0.463, 1.787)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	9 (47.4%)	
Number (%) of Participants Censored	9 (52.9%)	10 (52.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.92 (0.76, 11.76)	3.02 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.4757		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.451 (0.537, 3.922)		
History of liver metastasis			
Yes	11	13	0.5996

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (54.5%)	6 (46.2%)	
Number (%) of Participants Censored	5 (45.5%)	7 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.61 (0.72, NR)	2.76 (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.9059		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.923 (0.278, 3.060)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	24 (58.5%)	18 (56.2%)	
Number (%) of Participants Censored	17 (41.5%)	14 (43.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.45, 6.87)	3.06 (1.18, 6.90)	
Log-Rank Test p-value (unstratified)	0.5984		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.181 (0.636, 2.193)		
PD-L1 Status			
CPS < 1	23	7	0.3091
Number (%) of Participants with Events (Deterioration)	14 (60.9%)	4 (57.1%)	
Number (%) of Participants Censored	9 (39.1%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.64, 9.95)	1.18 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.1805		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.457 (0.141, 1.478)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	16 (57.1%)	20 (52.6%)	
Number (%) of Participants Censored	12 (42.9%)	18 (47.4%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (0.79, 6.87)	3.06 (2.76, NR)	
Log-Rank Test p-value (unstratified)	0.3144		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.397 (0.723, 2.701)		
Menopausal status			
Pre-menopausal	8	14	0.7667
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	6 (42.9%)	
Number (%) of Participants Censored	4 (50.0%)	8 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.36 (4.37, NR)	6.90 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.3062		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.474 (0.111, 2.032)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	18 (58.1%)	
Number (%) of Participants Censored	18 (40.9%)	13 (41.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.41, 5.55)	2.79 (1.02, 4.44)	
Log-Rank Test p-value (unstratified)	0.9015		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.040 (0.565, 1.914)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.53. Table 1.1.20.10: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Dyspnoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.0942
Number (%) of Participants with Events (Deterioration)	13 (50.0%)	9 (52.9%)	
Number (%) of Participants Censored	13 (50.0%)	8 (47.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.41, 10.09)	4.67 (1.18, 6.90)	
Log-Rank Test p-value (unstratified)	0.8968		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.950 (0.400, 2.260)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	9 (34.6%)	15 (53.6%)	
Number (%) of Participants Censored	17 (65.4%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (3.09, NR)	2.83 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.0258		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.380 (0.159, 0.910)		
Age group			
< 65	35	35	0.7003
Number (%) of Participants with Events (Deterioration)	17 (48.6%)	19 (54.3%)	
Number (%) of Participants Censored	18 (51.4%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.20 (2.37, NR)	2.83 (1.54, 6.90)	
Log-Rank Test p-value (unstratified)	0.1271		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.594 (0.302, 1.168)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	5 (29.4%)	5 (50.0%)	
Number (%) of Participants Censored	12 (70.6%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.37 (0.72, NR)	4.44 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.3863		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.578 (0.164, 2.029)		
Baseline ECOG status			
0	35	26	0.5971
Number (%) of Participants with Events (Deterioration)	14 (40.0%)	15 (57.7%)	
Number (%) of Participants Censored	21 (60.0%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.09 (2.17, NR)	2.83 (1.12, 6.90)	
Log-Rank Test p-value (unstratified)	0.0790		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.507 (0.235, 1.094)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	9 (47.4%)	
Number (%) of Participants Censored	9 (52.9%)	10 (52.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.34 (0.95, NR)	4.44 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.6423		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.798 (0.306, 2.084)		
History of liver metastasis			
Yes	11	13	0.4134

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	3 (27.3%)	5 (38.5%)	
Number (%) of Participants Censored	8 (72.7%)	8 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.18, NR)	2.83 (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.1456		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.350 (0.080, 1.523)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	19 (46.3%)	19 (59.4%)	
Number (%) of Participants Censored	22 (53.7%)	13 (40.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (1.64, NR)	2.83 (1.18, 5.68)	
Log-Rank Test p-value (unstratified)	0.1826		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.646 (0.336, 1.242)		
PD-L1 Status			
CPS < 1	23	7	0.8747
Number (%) of Participants with Events (Deterioration)	12 (52.2%)	3 (42.9%)	
Number (%) of Participants Censored	11 (47.8%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (2.37, 11.37)	1.18 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.2995		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.504 (0.135, 1.883)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	10 (35.7%)	21 (55.3%)	
Number (%) of Participants Censored	18 (64.3%)	17 (44.7%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.41, NR)	2.83 (1.54, 5.68)	
Log-Rank Test p-value (unstratified)	0.1687		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.592 (0.278, 1.263)		
Menopausal status			
Pre-menopausal	8	14	0.7584
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	7 (50.0%)	
Number (%) of Participants Censored	5 (62.5%)	7 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (2.37, NR)	5.68 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.2172		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.432 (0.110, 1.700)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	17 (54.8%)	
Number (%) of Participants Censored	25 (56.8%)	14 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (1.64, NR)	2.38 (1.12, 4.86)	
Log-Rank Test p-value (unstratified)	0.1126		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.586 (0.299, 1.148)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.54. Table 1.1.20.11: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Insomnia | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.0617
Number (%) of Participants with Events (Deterioration)	11 (42.3%)	5 (29.4%)	
Number (%) of Participants Censored	15 (57.7%)	12 (70.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.51, NR)	NR (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.2929		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.760 (0.606, 5.117)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	10 (38.5%)	15 (53.6%)	
Number (%) of Participants Censored	16 (61.5%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.22 (2.17, NR)	2.83 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.1134		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.512 (0.222, 1.177)		
Age group			
< 65	35	35	0.5328
Number (%) of Participants with Events (Deterioration)	16 (45.7%)	16 (45.7%)	
Number (%) of Participants Censored	19 (54.3%)	19 (54.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (1.64, NR)	4.14 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.8105		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.905 (0.446, 1.836)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	5 (29.4%)	4 (40.0%)	
Number (%) of Participants Censored	12 (70.6%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.42 (1.64, NR)	1.91 (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.4461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.601 (0.160, 2.260)		
Baseline ECOG status			
0	35	26	0.5963
Number (%) of Participants with Events (Deterioration)	13 (37.1%)	12 (46.2%)	
Number (%) of Participants Censored	22 (62.9%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.22 (2.33, NR)	5.68 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.4192		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.711 (0.318, 1.591)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	8 (42.1%)	
Number (%) of Participants Censored	9 (52.9%)	11 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.24 (0.89, NR)	2.23 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.9153		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.055 (0.393, 2.829)		
History of liver metastasis			
Yes	11	13	0.6858

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (45.5%)	4 (30.8%)	
Number (%) of Participants Censored	6 (54.5%)	9 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.22 (0.79, NR)	NR (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.8382		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.136 (0.280, 4.604)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	16 (39.0%)	16 (50.0%)	
Number (%) of Participants Censored	25 (61.0%)	16 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (2.79, NR)	4.14 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.5080		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.790 (0.394, 1.582)		
PD-L1 Status			
CPS < 1	23	7	0.0682
Number (%) of Participants with Events (Deterioration)	8 (34.8%)	5 (71.4%)	
Number (%) of Participants Censored	15 (65.2%)	2 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.58, NR)	2.23 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.0287		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.283 (0.085, 0.944)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	13 (46.4%)	15 (39.5%)	
Number (%) of Participants Censored	15 (53.6%)	23 (60.5%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (1.64, 19.22)	6.51 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.7182		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.134 (0.530, 2.429)		
Menopausal status			
Pre-menopausal	8	14	0.5429
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	8 (57.1%)	
Number (%) of Participants Censored	3 (37.5%)	6 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (0.79, NR)	4.14 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.9045		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.077 (0.320, 3.622)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	16 (36.4%)	12 (38.7%)	
Number (%) of Participants Censored	28 (63.6%)	19 (61.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.62 (2.79, NR)	3.81 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.6100		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.817 (0.385, 1.732)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.55. Table 1.1.20.12: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Appetite Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.5076
Number (%) of Participants with Events (Deterioration)	9 (34.6%)	4 (23.5%)	
Number (%) of Participants Censored	17 (65.4%)	13 (76.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.41, NR)	NR (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.3460		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.768 (0.543, 5.757)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	12 (42.9%)	
Number (%) of Participants Censored	12 (46.2%)	16 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.41, NR)	5.55 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.7490		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.129 (0.519, 2.455)		
Age group			
< 65	35	35	0.4872
Number (%) of Participants with Events (Deterioration)	16 (45.7%)	11 (31.4%)	
Number (%) of Participants Censored	19 (54.3%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (1.74, NR)	NR (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.3828		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.405 (0.650, 3.040)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	5 (50.0%)	
Number (%) of Participants Censored	10 (58.8%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.59 (0.72, NR)	1.87 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.7935		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.271, 2.766)		
Baseline ECOG status			
0	35	26	0.2921
Number (%) of Participants with Events (Deterioration)	13 (37.1%)	10 (38.5%)	
Number (%) of Participants Censored	22 (62.9%)	16 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (2.10, NR)	7.26 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.9824		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.013 (0.443, 2.317)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	6 (31.6%)	
Number (%) of Participants Censored	7 (41.2%)	13 (68.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.72, NR)	NR (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.1294		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.167 (0.785, 5.983)		
History of liver metastasis			
Yes	11	13	0.6210

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (45.5%)	5 (38.5%)	
Number (%) of Participants Censored	6 (54.5%)	8 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.49 (0.72, NR)	5.55 (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.8670		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.132 (0.325, 3.944)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	18 (43.9%)	11 (34.4%)	
Number (%) of Participants Censored	23 (56.1%)	21 (65.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.48, NR)	NR (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.3490		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.428 (0.673, 3.027)		
PD-L1 Status			
CPS < 1	23	7	0.8002
Number (%) of Participants with Events (Deterioration)	9 (39.1%)	2 (28.6%)	
Number (%) of Participants Censored	14 (60.9%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (1.48, NR)	7.26 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.9468		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.072 (0.226, 5.077)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	14 (50.0%)	14 (36.8%)	
Number (%) of Participants Censored	14 (50.0%)	24 (63.2%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.33 (1.41, NR)	5.55 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.2310		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.561 (0.743, 3.281)		
Menopausal status			
Pre-menopausal	8	14	0.4625
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	2 (14.3%)	
Number (%) of Participants Censored	5 (62.5%)	12 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.76, NR)	NR (7.26, NR)	
Log-Rank Test p-value (unstratified)	0.5796		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.674 (0.266, 10.531)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	14 (45.2%)	
Number (%) of Participants Censored	24 (54.5%)	17 (54.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.41, NR)	1.94 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.8658		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.067 (0.538, 2.116)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.56. Table 1.1.20.13: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Constipation | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3314
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	4 (23.5%)	
Number (%) of Participants Censored	12 (46.2%)	13 (76.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.41, 3.65)	NR (1.02, NR)	
Log-Rank Test p-value (unstratified)	0.0412		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.087 (0.995, 9.579)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	13 (46.4%)	
Number (%) of Participants Censored	10 (38.5%)	15 (53.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.00 (0.79, 11.40)	6.70 (1.15, NR)	
Log-Rank Test p-value (unstratified)	0.2984		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.467 (0.700, 3.071)		
Age group			
< 65	35	35	0.3520
Number (%) of Participants with Events (Deterioration)	23 (65.7%)	13 (37.1%)	
Number (%) of Participants Censored	12 (34.3%)	22 (62.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.41, 3.52)	6.70 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.0220		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.172 (1.093, 4.316)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	4 (40.0%)	
Number (%) of Participants Censored	10 (58.8%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (0.72, NR)	4.21 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.9637		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.028 (0.289, 3.662)		
Baseline ECOG status			
0	35	26	0.4449
Number (%) of Participants with Events (Deterioration)	20 (57.1%)	10 (38.5%)	
Number (%) of Participants Censored	15 (42.9%)	16 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.92, 3.48)	5.55 (1.15, NR)	
Log-Rank Test p-value (unstratified)	0.0465		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.141 (0.996, 4.606)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	7 (36.8%)	
Number (%) of Participants Censored	7 (41.2%)	12 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.41, NR)	6.70 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.5777		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.293 (0.480, 3.483)		
History of liver metastasis			
Yes	11	13	0.8667

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (54.5%)	4 (30.8%)	
Number (%) of Participants Censored	5 (45.5%)	9 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.61 (0.72, NR)	NR (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.5331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.471 (0.414, 5.225)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	24 (58.5%)	13 (40.6%)	
Number (%) of Participants Censored	17 (41.5%)	19 (59.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.41, 3.52)	6.70 (3.75, NR)	
Log-Rank Test p-value (unstratified)	0.0590		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.903 (0.963, 3.761)		
PD-L1 Status			
CPS < 1	23	7	0.2586
Number (%) of Participants with Events (Deterioration)	14 (60.9%)	1 (14.3%)	
Number (%) of Participants Censored	9 (39.1%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (0.79, 3.65)	NR (1.15, NR)	
Log-Rank Test p-value (unstratified)	0.1271		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	4.266 (0.560, 32.494)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	16 (57.1%)	16 (42.1%)	
Number (%) of Participants Censored	12 (42.9%)	22 (57.9%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.41, NR)	6.70 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.2692		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.471 (0.730, 2.964)		
Menopausal status			
Pre-menopausal	8	14	0.9788
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	5 (35.7%)	
Number (%) of Participants Censored	3 (37.5%)	9 (64.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.99 (0.76, NR)	NR (1.15, NR)	
Log-Rank Test p-value (unstratified)	0.3352		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.825 (0.527, 6.319)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	25 (56.8%)	12 (38.7%)	
Number (%) of Participants Censored	19 (43.2%)	19 (61.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.41, 3.52)	6.70 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.0847		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.814 (0.905, 3.638)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.57. Table 1.1.20.14: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Diarrhoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3517
Number (%) of Participants with Events (Deterioration)	17 (65.4%)	8 (47.1%)	
Number (%) of Participants Censored	9 (34.6%)	9 (52.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.82, 2.10)	1.91 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.0660		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.253 (0.930, 5.459)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	18 (69.2%)	16 (57.1%)	
Number (%) of Participants Censored	8 (30.8%)	12 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.95 (0.79, 5.78)	3.32 (1.87, 6.47)	
Log-Rank Test p-value (unstratified)	0.3461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.393 (0.703, 2.759)		
Age group			
< 65	35	35	0.0697
Number (%) of Participants with Events (Deterioration)	29 (82.9%)	19 (54.3%)	
Number (%) of Participants Censored	6 (17.1%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.85, 2.10)	3.94 (1.87, 6.90)	
Log-Rank Test p-value (unstratified)	0.0047		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.290 (1.270, 4.128)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	6 (35.3%)	5 (50.0%)	
Number (%) of Participants Censored	11 (64.7%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (0.72, NR)	1.87 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.4987		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.667 (0.198, 2.246)		
Baseline ECOG status			
0	35	26	0.5555
Number (%) of Participants with Events (Deterioration)	24 (68.6%)	13 (50.0%)	
Number (%) of Participants Censored	11 (31.4%)	13 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.18, 3.58)	4.67 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.0389		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.033 (1.021, 4.048)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	11 (64.7%)	11 (57.9%)	
Number (%) of Participants Censored	6 (35.3%)	8 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.76, 4.24)	1.87 (1.05, 4.86)	
Log-Rank Test p-value (unstratified)	0.4205		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.419 (0.612, 3.293)		
History of liver metastasis			
Yes	11	13	0.0394

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	10 (90.9%)	3 (23.1%)	
Number (%) of Participants Censored	1 (9.1%)	10 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.46 (0.72, 3.58)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.0062		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	5.074 (1.392, 18.496)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	25 (61.0%)	21 (65.6%)	
Number (%) of Participants Censored	16 (39.0%)	11 (34.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.69 (0.82, 3.91)	2.83 (1.18, 4.86)	
Log-Rank Test p-value (unstratified)	0.4662		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.245 (0.690, 2.246)		
PD-L1 Status			
CPS < 1	23	7	0.1931
Number (%) of Participants with Events (Deterioration)	15 (65.2%)	4 (57.1%)	
Number (%) of Participants Censored	8 (34.8%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (0.89, 4.24)	1.18 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.7286		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.824 (0.269, 2.523)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	20 (71.4%)	20 (52.6%)	
Number (%) of Participants Censored	8 (28.6%)	18 (47.4%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.82, 2.17)	3.32 (1.87, 6.90)	
Log-Rank Test p-value (unstratified)	0.0127		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.167 (1.157, 4.060)		
Menopausal status			
Pre-menopausal	8	14	0.3936
Number (%) of Participants with Events (Deterioration)	6 (75.0%)	6 (42.9%)	
Number (%) of Participants Censored	2 (25.0%)	8 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.46 (0.76, NR)	NR (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.1787		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.173 (0.699, 6.763)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	29 (65.9%)	18 (58.1%)	
Number (%) of Participants Censored	15 (34.1%)	13 (41.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.69 (0.89, 3.48)	2.89 (1.87, 4.86)	
Log-Rank Test p-value (unstratified)	0.2078		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.465 (0.808, 2.655)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.58. Table 1.1.20.15: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Financial Difficulties | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.8605
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	7 (41.2%)	
Number (%) of Participants Censored	14 (53.8%)	10 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (2.79, 10.55)	3.88 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.5183		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.727 (0.280, 1.886)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	11 (42.3%)	11 (39.3%)	
Number (%) of Participants Censored	15 (57.7%)	17 (60.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.79 (5.59, NR)	10.15 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.3964		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.691 (0.290, 1.645)		
Age group			
< 65	35	35	0.4659
Number (%) of Participants with Events (Deterioration)	18 (51.4%)	13 (37.1%)	
Number (%) of Participants Censored	17 (48.6%)	22 (62.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (5.03, 10.55)	NR (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.6498		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.841 (0.404, 1.751)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	5 (29.4%)	5 (50.0%)	
Number (%) of Participants Censored	12 (70.6%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.02, NR)	3.88 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.3331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.554 (0.159, 1.930)		
Baseline ECOG status			
0	35	26	0.6811
Number (%) of Participants with Events (Deterioration)	17 (48.6%)	12 (46.2%)	
Number (%) of Participants Censored	18 (51.4%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.16 (4.53, 9.79)	4.67 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.5931		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.814 (0.385, 1.717)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	6 (35.3%)	6 (31.6%)	
Number (%) of Participants Censored	11 (64.7%)	13 (68.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.55 (1.41, NR)	4.63 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.5139		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.673 (0.206, 2.198)		
History of liver metastasis			
Yes	11	13	0.0799

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (45.5%)	1 (7.7%)	
Number (%) of Participants Censored	6 (54.5%)	12 (92.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.85 (0.72, NR)	NR (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.3179		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.951 (0.320, 27.219)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	18 (43.9%)	17 (53.1%)	
Number (%) of Participants Censored	23 (56.1%)	15 (46.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (5.03, NR)	3.88 (1.91, 10.15)	
Log-Rank Test p-value (unstratified)	0.1497		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.612 (0.312, 1.201)		
PD-L1 Status			
CPS < 1	23	7	0.9301
Number (%) of Participants with Events (Deterioration)	12 (52.2%)	2 (28.6%)	
Number (%) of Participants Censored	11 (47.8%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (4.53, 10.55)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.6236		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.688 (0.135, 3.511)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	11 (39.3%)	16 (42.1%)	
Number (%) of Participants Censored	17 (60.7%)	22 (57.9%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.31 (2.86, NR)	4.67 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.4409		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.737 (0.339, 1.601)		
Menopausal status			
Pre-menopausal	8	14	0.9056
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	4 (28.6%)	
Number (%) of Participants Censored	5 (62.5%)	10 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.31 (5.52, NR)	NR (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.7672		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.795 (0.173, 3.646)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	14 (45.2%)	
Number (%) of Participants Censored	24 (54.5%)	17 (54.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (3.61, 10.55)	3.88 (1.94, 10.15)	
Log-Rank Test p-value (unstratified)	0.2882		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.689 (0.343, 1.383)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.59. Table 1.1.21.1: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Body Image | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.5553
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	6 (35.3%)	
Number (%) of Participants Censored	11 (42.3%)	11 (64.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.82, 3.19)	2.79 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.2418		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.770 (0.682, 4.598)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	15 (53.6%)	
Number (%) of Participants Censored	10 (38.5%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.79, 25.03)	4.63 (1.91, 9.26)	
Log-Rank Test p-value (unstratified)	0.6351		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.204 (0.586, 2.474)		
Age group			
< 65	35	35	0.4887
Number (%) of Participants with Events (Deterioration)	24 (68.6%)	16 (45.7%)	
Number (%) of Participants Censored	11 (31.4%)	19 (54.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (0.95, 4.21)	3.71 (1.54, NE)	
Log-Rank Test p-value (unstratified)	0.1293		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.637 (0.864, 3.104)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	5 (50.0%)	
Number (%) of Participants Censored	10 (58.8%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.76, NE)	2.76 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.9248		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.067 (0.332, 3.430)		
Baseline ECOG status			
0	35	26	0.2661
Number (%) of Participants with Events (Deterioration)	22 (62.9%)	14 (53.8%)	
Number (%) of Participants Censored	13 (37.1%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.18, 5.03)	3.71 (1.54, NE)	
Log-Rank Test p-value (unstratified)	0.6589		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.168 (0.591, 2.311)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	9 (52.9%)	7 (36.8%)	
Number (%) of Participants Censored	8 (47.1%)	12 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.72, NE)	2.76 (1.05, NE)	
Log-Rank Test p-value (unstratified)	0.0607		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.564 (0.944, 6.961)		
History of liver metastasis			

	SG (N=52)	TPC (N=45)	Interaction
Yes	11	13	0.5630
Number (%) of Participants with Events (Deterioration)	6 (54.5%)	5 (38.5%)	
Number (%) of Participants Censored	5 (45.5%)	8 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.42 (0.72, NE)	4.70 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.8797		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.910 (0.267, 3.102)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	25 (61.0%)	16 (50.0%)	
Number (%) of Participants Censored	16 (39.0%)	16 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.82, 3.48)	2.79 (1.22, NE)	
Log-Rank Test p-value (unstratified)	0.1361		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.618 (0.858, 3.052)		
PD-L1 Status			
CPS < 1	23	7	0.5680
Number (%) of Participants with Events (Deterioration)	13 (56.5%)	2 (28.6%)	
Number (%) of Participants Censored	10 (43.5%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (0.82, 25.03)	1.15 (1.05, NE)	
Log-Rank Test p-value (unstratified)	0.8382		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.185 (0.258, 5.437)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	18 (64.3%)	19 (50.0%)	

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants Censored	10 (35.7%)	19 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.82, 3.48)	3.71 (1.94, 6.51)	
Log-Rank Test p-value (unstratified)	0.0913		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.729 (0.906, 3.301)		
Menopausal status			
Pre-menopausal	8	14	0.2325
Number (%) of Participants with Events (Deterioration)	7 (87.5%)	6 (42.9%)	
Number (%) of Participants Censored	1 (12.5%)	8 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.76, 2.14)	3.71 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.0869		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.557 (0.837, 7.814)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	15 (48.4%)	
Number (%) of Participants Censored	20 (45.5%)	16 (51.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (0.82, 5.03)	4.63 (1.91, 9.26)	
Log-Rank Test p-value (unstratified)	0.4927		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.266 (0.658, 2.435)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.

4.60. Table 1.1.21.2: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Sexual Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3402
Number (%) of Participants with Events (Deterioration)	5 (19.2%)	5 (29.4%)	
Number (%) of Participants Censored	21 (80.8%)	12 (70.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.80 (5.03, NE)	4.80 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.1986		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.424 (0.113, 1.597)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	6 (23.1%)	5 (17.9%)	
Number (%) of Participants Censored	20 (76.9%)	23 (82.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8685		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.105 (0.337, 3.624)		
Age group			
< 65	35	35	0.0496
Number (%) of Participants with Events (Deterioration)	10 (28.6%)	7 (20.0%)	
Number (%) of Participants Censored	25 (71.4%)	28 (80.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.03, NE)	NE (4.80, NE)	

	SG (N=52)	TPC (N=45)	Interaction
Log-Rank Test p-value (unstratified)	0.7751		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.155 (0.430, 3.105)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	1 (5.9%)	3 (30.0%)	
Number (%) of Participants Censored	16 (94.1%)	7 (70.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	2.76 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.0262		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.113 (0.011, 1.116)		
Baseline ECOG status			
0	35	26	0.7830
Number (%) of Participants with Events (Deterioration)	8 (22.9%)	6 (23.1%)	
Number (%) of Participants Censored	27 (77.1%)	20 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.03, NE)	NE (2.07, NE)	
Log-Rank Test p-value (unstratified)	0.6677		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.785 (0.268, 2.298)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	3 (17.6%)	4 (21.1%)	
Number (%) of Participants Censored	14 (82.4%)	15 (78.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	NE (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.6762		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.727 (0.162, 3.260)		

	SG (N=52)	TPC (N=45)	Interaction
History of liver metastasis			
Yes	11	13	0.8429
Number (%) of Participants with Events (Deterioration)	3 (27.3%)	3 (23.1%)	
Number (%) of Participants Censored	8 (72.7%)	10 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.85, NE)	NE (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.9777		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.977 (0.196, 4.865)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	8 (19.5%)	7 (21.9%)	
Number (%) of Participants Censored	33 (80.5%)	25 (78.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.80, NE)	NE (4.80, NE)	
Log-Rank Test p-value (unstratified)	0.4966		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.696 (0.248, 1.956)		
PD-L1 Status			
CPS < 1	23	7	0.9541
Number (%) of Participants with Events (Deterioration)	5 (21.7%)	1 (14.3%)	
Number (%) of Participants Censored	18 (78.3%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	NE (2.07, NE)	
Log-Rank Test p-value (unstratified)	0.6304		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.587 (0.065, 5.272)		
CPS ≥ 1	28	38	

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (21.4%)	9 (23.7%)	
Number (%) of Participants Censored	22 (78.6%)	29 (76.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.65, NE)	NE (4.80, NE)	
Log-Rank Test p-value (unstratified)	0.7903		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.307, 2.434)		
Menopausal status			
Pre-menopausal	8	14	0.4181
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	3 (21.4%)	
Number (%) of Participants Censored	5 (62.5%)	11 (78.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.45, NE)	NE (1.91, NE)	
Log-Rank Test p-value (unstratified)	0.6671		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.419 (0.286, 7.047)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	8 (18.2%)	7 (22.6%)	
Number (%) of Participants Censored	36 (81.8%)	24 (77.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.80, NE)	NE (2.76, NE)	
Log-Rank Test p-value (unstratified)	0.3920		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.637 (0.227, 1.791)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.

Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.61. Table 1.1.21.3: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Sexual Enjoyment | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.2362
Number (%) of Participants with Events (Deterioration)	0	2 (11.8%)	
Number (%) of Participants Censored	26 (100.0%)	15 (88.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	1.89 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.1869		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	1 (3.8%)	2 (7.1%)	
Number (%) of Participants Censored	25 (96.2%)	26 (92.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.72 (1.05, NE)	1.43 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.7822		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.712 (0.063, 8.022)		
Age group			
< 65	35	35	1.0000
Number (%) of Participants with Events (Deterioration)	1 (2.9%)	3 (8.6%)	
Number (%) of Participants Censored	34 (97.1%)	32 (91.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	NE (1.05, NE)	NE (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.3796		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.374 (0.038, 3.657)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	0	1 (10.0%)	
Number (%) of Participants Censored	17 (100.0%)	9 (90.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	0.99 (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.000 (1.000, 1.000)		
Baseline ECOG status			
0	35	26	1.0000
Number (%) of Participants with Events (Deterioration)	1 (2.9%)	4 (15.4%)	
Number (%) of Participants Censored	34 (97.1%)	22 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	0.99 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.2787		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.303 (0.033, 2.805)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	17 (100.0%)	19 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
History of liver metastasis			
Yes	11	13	0.0998
Number (%) of Participants with Events (Deterioration)	1 (9.1%)	0	
Number (%) of Participants Censored	10 (90.9%)	13 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.5637		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	41	32	
Number (%) of Participants with Events (Deterioration)	0	4 (12.5%)	
Number (%) of Participants Censored	41 (100.0%)	28 (87.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	0.99 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.2124		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
PD-L1 Status			
CPS < 1	23	7	1.0000
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	23 (100.0%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		

	SG (N=52)	TPC (N=45)	Interaction
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	1 (3.6%)	4 (10.5%)	
Number (%) of Participants Censored	27 (96.4%)	34 (89.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	0.99 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.2719		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.302 (0.033, 2.766)		
Menopausal status			
Pre-menopausal	8	14	0.1285
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	2 (14.3%)	
Number (%) of Participants Censored	7 (87.5%)	12 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.05 (NE, NE)	NE (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.7357		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.517 (0.133, 17.350)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	0	2 (6.5%)	
Number (%) of Participants Censored	44 (100.0%)	29 (93.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	1.89 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.1266		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.

Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.62. Table 1.1.21.4: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Future Perspective | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.0102
Number (%) of Participants with Events (Deterioration)	10 (38.5%)	0	
Number (%) of Participants Censored	16 (61.5%)	17 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.53 (0.82, 8.28)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.0339		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	10 (38.5%)	8 (28.6%)	
Number (%) of Participants Censored	16 (61.5%)	20 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.33 (1.58, NE)	9.26 (2.00, NE)	
Log-Rank Test p-value (unstratified)	0.9461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.974 (0.361, 2.623)		
Age group			
< 65	35	35	0.9353
Number (%) of Participants with Events (Deterioration)	14 (40.0%)	6 (17.1%)	
Number (%) of Participants Censored	21 (60.0%)	29 (82.9%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.28 (3.61, NE)	NE (2.83, NE)	
Log-Rank Test p-value (unstratified)	0.2866		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.706 (0.640, 4.547)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	6 (35.3%)	2 (20.0%)	
Number (%) of Participants Censored	11 (64.7%)	8 (80.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.72, NE)	9.26 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.6855		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.396 (0.276, 7.057)		
Baseline ECOG status			
0	35	26	0.5181
Number (%) of Participants with Events (Deterioration)	12 (34.3%)	3 (11.5%)	
Number (%) of Participants Censored	23 (65.7%)	23 (88.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.28 (1.58, NE)	9.26 (9.26, NE)	
Log-Rank Test p-value (unstratified)	0.1901		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.334 (0.643, 8.481)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	8 (47.1%)	5 (26.3%)	
Number (%) of Participants Censored	9 (52.9%)	14 (73.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.76, 5.62)	3.02 (0.92, NE)	

	SG (N=52)	TPC (N=45)	Interaction
Log-Rank Test p-value (unstratified)	0.4325		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.564 (0.507, 4.823)		
History of liver metastasis			
Yes	11	13	0.9087
Number (%) of Participants with Events (Deterioration)	4 (36.4%)	2 (15.4%)	
Number (%) of Participants Censored	7 (63.6%)	11 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (0.72, NE)	NE (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.5274		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.722 (0.313, 9.488)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	16 (39.0%)	6 (18.8%)	
Number (%) of Participants Censored	25 (61.0%)	26 (81.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (1.58, 17.81)	9.26 (2.83, NE)	
Log-Rank Test p-value (unstratified)	0.2058		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.848 (0.710, 4.807)		
PD-L1 Status			
CPS < 1	23	7	0.1210
Number (%) of Participants with Events (Deterioration)	8 (34.8%)	2 (28.6%)	
Number (%) of Participants Censored	15 (65.2%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.33 (1.58, NE)	2.00 (1.94, NE)	
Log-Rank Test p-value (unstratified)	0.6134		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.665 (0.135, 3.269)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	12 (42.9%)	6 (15.8%)	
Number (%) of Participants Censored	16 (57.1%)	32 (84.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.76, NE)	9.26 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.0293		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.910 (1.071, 7.903)		
Menopausal status			
Pre-menopausal	8	14	0.2887
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	1 (7.1%)	
Number (%) of Participants Censored	4 (50.0%)	13 (92.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (1.58, NE)	NE (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.2786		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.286 (0.337, 32.015)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	16 (36.4%)	7 (22.6%)	
Number (%) of Participants Censored	28 (63.6%)	24 (77.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (1.41, NE)	9.26 (1.94, NE)	
Log-Rank Test p-value (unstratified)	0.4038		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.475 (0.600, 3.628)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.63. Table 1.1.21.5: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Systemic Therapy Side Effects | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.5949
Number (%) of Participants with Events (Deterioration)	19 (73.1%)	12 (70.6%)	
Number (%) of Participants Censored	7 (26.9%)	5 (29.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.07 (0.79, 1.48)	1.00 (0.92, 1.87)	
Log-Rank Test p-value (unstratified)	0.8388		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.104 (0.528, 2.307)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	20 (76.9%)	20 (71.4%)	
Number (%) of Participants Censored	6 (23.1%)	8 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.92 (0.76, 2.10)	1.15 (0.99, 4.01)	
Log-Rank Test p-value (unstratified)	0.2751		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.404 (0.753, 2.619)		
Age group			
< 65	35	35	0.6064
Number (%) of Participants with Events (Deterioration)	28 (80.0%)	26 (74.3%)	

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants Censored	7 (20.0%)	9 (25.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.05 (0.79, 1.58)	1.15 (0.99, 1.91)	
Log-Rank Test p-value (unstratified)	0.5414		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.184 (0.688, 2.036)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	11 (64.7%)	6 (60.0%)	
Number (%) of Participants Censored	6 (35.3%)	4 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.92 (0.72, 1.48)	0.99 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.3790		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.533 (0.522, 4.499)		
Baseline ECOG status			
0	35	26	0.1256
Number (%) of Participants with Events (Deterioration)	25 (71.4%)	21 (80.8%)	
Number (%) of Participants Censored	10 (28.6%)	5 (19.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.18 (0.79, 1.64)	0.99 (0.99, 1.54)	
Log-Rank Test p-value (unstratified)	0.9398		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.963 (0.533, 1.740)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	14 (82.4%)	11 (57.9%)	
Number (%) of Participants Censored	3 (17.6%)	8 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	0.82 (0.76, 1.41)	1.87 (0.95, 4.44)	
Log-Rank Test p-value (unstratified)	0.0500		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.210 (0.993, 4.916)		
History of liver metastasis			
Yes	11	13	0.5872
Number (%) of Participants with Events (Deterioration)	8 (72.7%)	7 (53.8%)	
Number (%) of Participants Censored	3 (27.3%)	6 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.72, 3.55)	0.99 (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.9988		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.983 (0.352, 2.748)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	31 (75.6%)	25 (78.1%)	
Number (%) of Participants Censored	10 (24.4%)	7 (21.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.76, 1.41)	1.12 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.2637		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.353 (0.793, 2.310)		
PD-L1 Status			
CPS < 1	23	7	0.6235
Number (%) of Participants with Events (Deterioration)	16 (69.6%)	2 (28.6%)	
Number (%) of Participants Censored	7 (30.4%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 2.10)	1.15 (1.05, NE)	

	SG (N=52)	TPC (N=45)	Interaction
Log-Rank Test p-value (unstratified)	0.3027		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.136 (0.487, 9.366)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	23 (82.1%)	30 (78.9%)	
Number (%) of Participants Censored	5 (17.9%)	8 (21.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.92 (0.76, 1.48)	0.99 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.2109		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.396 (0.800, 2.434)		
Menopausal status			
Pre-menopausal	8	14	0.9124
Number (%) of Participants with Events (Deterioration)	8 (100.0%)	11 (78.6%)	
Number (%) of Participants Censored	0	3 (21.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.20 (0.76, 3.55)	1.15 (0.92, 3.84)	
Log-Rank Test p-value (unstratified)	0.6332		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.255 (0.482, 3.271)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	31 (70.5%)	21 (67.7%)	
Number (%) of Participants Censored	13 (29.5%)	10 (32.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.79, 1.41)	1.05 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.3560		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.299 (0.744, 2.268)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.

Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.64. Table 1.1.21.6: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Breast Symptoms | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.9336
Number (%) of Participants with Events (Deterioration)	7 (26.9%)	2 (11.8%)	
Number (%) of Participants Censored	19 (73.1%)	15 (88.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.09 (3.55, NE)	9.49 (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.6728		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.396 (0.286, 6.808)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	10 (38.5%)	5 (17.9%)	
Number (%) of Participants Censored	16 (61.5%)	23 (82.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.83, NE)	NE (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.2297		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.930 (0.651, 5.726)		
Age group			
< 65	35	35	0.5809

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	14 (40.0%)	6 (17.1%)	
Number (%) of Participants Censored	21 (60.0%)	29 (82.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.09 (2.99, NE)	NE (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.1652		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.976 (0.745, 5.239)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	3 (17.6%)	1 (10.0%)	
Number (%) of Participants Censored	14 (82.4%)	9 (90.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	NE (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.9894		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.984 (0.098, 9.841)		
Baseline ECOG status			
0	35	26	0.4013
Number (%) of Participants with Events (Deterioration)	13 (37.1%)	4 (15.4%)	
Number (%) of Participants Censored	22 (62.9%)	22 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.09 (3.55, NE)	NE (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.1785		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.144 (0.688, 6.678)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	4 (23.5%)	3 (15.8%)	
Number (%) of Participants Censored	13 (76.5%)	16 (84.2%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.99, NE)	NE (2.89, NE)	
Log-Rank Test p-value (unstratified)	0.9917		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.008 (0.223, 4.560)		
History of liver metastasis			
Yes	11	13	0.1623
Number (%) of Participants with Events (Deterioration)	3 (27.3%)	0	
Number (%) of Participants Censored	8 (72.7%)	13 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.95, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.1299		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	41	32	
Number (%) of Participants with Events (Deterioration)	14 (34.1%)	7 (21.9%)	
Number (%) of Participants Censored	27 (65.9%)	25 (78.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.09 (5.42, NE)	NE (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.4420		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.434 (0.574, 3.582)		
PD-L1 Status			
CPS < 1	23	7	0.0509
Number (%) of Participants with Events (Deterioration)	5 (21.7%)	2 (28.6%)	
Number (%) of Participants Censored	18 (78.3%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	NE (9.95, NE)	6.90 (2.89, NE)	
Log-Rank Test p-value (unstratified)	0.1279		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.269 (0.044, 1.645)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	12 (42.9%)	5 (13.2%)	
Number (%) of Participants Censored	16 (57.1%)	33 (86.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.44 (2.99, NE)	NE (9.49, NE)	
Log-Rank Test p-value (unstratified)	0.0230		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.159 (1.110, 8.991)		
Menopausal status			
Pre-menopausal	8	14	0.6653
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	3 (21.4%)	
Number (%) of Participants Censored	5 (62.5%)	11 (78.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.95 (1.58, NE)	9.49 (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.6584		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.658 (0.102, 4.243)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	14 (31.8%)	4 (12.9%)	
Number (%) of Participants Censored	30 (68.2%)	27 (87.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	NE (3.06, NE)	
Log-Rank Test p-value (unstratified)	0.1877		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.088 (0.683, 6.383)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.65. Table 1.1.21.7: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Arm Symptoms | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.2380
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	4 (23.5%)	
Number (%) of Participants Censored	12 (46.2%)	13 (76.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.41, 12.68)	NE (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.3791		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.642 (0.535, 5.035)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	13 (50.0%)	13 (46.4%)	
Number (%) of Participants Censored	13 (50.0%)	15 (53.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.71 (1.58, NE)	3.94 (1.15, NE)	
Log-Rank Test p-value (unstratified)	0.6886		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.850 (0.379, 1.909)		
Age group			
< 65	35	35	0.5954
Number (%) of Participants with Events (Deterioration)	20 (57.1%)	14 (40.0%)	
Number (%) of Participants Censored	15 (42.9%)	21 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.53 (1.61, 14.98)	6.70 (2.79, NE)	
Log-Rank Test p-value (unstratified)	0.6074		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.196 (0.598, 2.390)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	3 (30.0%)	
Number (%) of Participants Censored	10 (58.8%)	7 (70.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.71 (0.76, NE)	2.76 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.7952		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.838 (0.198, 3.551)		
Baseline ECOG status			
0	35	26	0.6206
Number (%) of Participants with Events (Deterioration)	17 (48.6%)	11 (42.3%)	
Number (%) of Participants Censored	18 (51.4%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.80 (1.48, NE)	2.92 (1.15, NE)	
Log-Rank Test p-value (unstratified)	0.8161		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.086 (0.504, 2.336)		

	SG (N=52)	TPC (N=45)	Interaction
1	17	19	
Number (%) of Participants with Events (Deterioration)	10 (58.8%)	6 (31.6%)	
Number (%) of Participants Censored	7 (41.2%)	13 (68.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.60 (0.95, 14.98)	3.94 (1.94, NE)	
Log-Rank Test p-value (unstratified)	0.8899		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.078 (0.371, 3.134)		
History of liver metastasis			
Yes	11	13	0.4623
Number (%) of Participants with Events (Deterioration)	3 (27.3%)	3 (23.1%)	
Number (%) of Participants Censored	8 (72.7%)	10 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.18, NE)	NE (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.7312		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.151, 3.774)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	24 (58.5%)	14 (43.8%)	
Number (%) of Participants Censored	17 (41.5%)	18 (56.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.29 (1.48, 10.71)	3.81 (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.6099		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.189 (0.606, 2.332)		
PD-L1 Status			
CPS < 1	23	7	0.1280

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	11 (47.8%)	3 (42.9%)	
Number (%) of Participants Censored	12 (52.2%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.53 (1.61, NE)	1.15 (1.08, NE)	
Log-Rank Test p-value (unstratified)	0.0877		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.323 (0.083, 1.261)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	16 (57.1%)	14 (36.8%)	
Number (%) of Participants Censored	12 (42.9%)	24 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.80 (1.18, 12.68)	6.70 (2.76, NE)	
Log-Rank Test p-value (unstratified)	0.4787		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.303 (0.617, 2.750)		
Menopausal status			
Pre-menopausal	8	14	0.7021
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	7 (50.0%)	
Number (%) of Participants Censored	3 (37.5%)	7 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.48 (0.76, NE)	2.92 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.8716		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.092 (0.345, 3.453)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	22 (50.0%)	10 (32.3%)	
Number (%) of Participants Censored	22 (50.0%)	21 (67.7%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.80 (2.10, 12.68)	6.70 (2.76, NE)	
Log-Rank Test p-value (unstratified)	0.6545		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.193 (0.556, 2.560)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.66. Table 1.1.21.8: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Upset By Hair Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	1.0000
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	26 (100.0%)	17 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	3 (11.5%)	7 (25.0%)	
Number (%) of Participants Censored	23 (88.5%)	21 (75.0%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	1.45 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.1336		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.356 (0.089, 1.424)		
Age group			
< 65	35	35	0.4300
Number (%) of Participants with Events (Deterioration)	3 (8.6%)	6 (17.1%)	
Number (%) of Participants Censored	32 (91.4%)	29 (82.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.39 (0.72, NE)	1.45 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.2124		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.403 (0.097, 1.666)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	0	1 (10.0%)	
Number (%) of Participants Censored	17 (100.0%)	9 (90.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	0.85 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.4795		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
Baseline ECOG status			
0	35	26	0.2916
Number (%) of Participants with Events (Deterioration)	1 (2.9%)	2 (7.7%)	
Number (%) of Participants Censored	34 (97.1%)	24 (92.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

		SG (N=52)	TPC (N=45)	Interaction
	Median	NE (0.76, NE)	0.95 (NE, NE)	
	Log-Rank Test p-value (unstratified)	0.4281		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.342 (0.030, 3.851)		
1		17	19	
	Number (%) of Participants with Events (Deterioration)	2 (11.8%)	5 (26.3%)	
	Number (%) of Participants Censored	15 (88.2%)	14 (73.7%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	3.55 (0.72, NE)	1.94 (0.76, NE)	
	Log-Rank Test p-value (unstratified)	0.4660		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.545 (0.104, 2.852)		
History of liver metastasis				
Yes		11	13	0.7837
	Number (%) of Participants with Events (Deterioration)	1 (9.1%)	1 (7.7%)	
	Number (%) of Participants Censored	10 (90.9%)	12 (92.3%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	3.55 (NE, NE)	0.95 (NE, NE)	
	Log-Rank Test p-value (unstratified)	0.3173		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
No		41	32	
	Number (%) of Participants with Events (Deterioration)	2 (4.9%)	6 (18.8%)	
	Number (%) of Participants Censored	39 (95.1%)	26 (81.2%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	NE (0.72, NE)	1.94 (0.76, NE)	
	Log-Rank Test p-value (unstratified)	0.1317		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.304 (0.059, 1.572)		
PD-L1 Status			
CPS < 1	23	7	1.0000
Number (%) of Participants with Events (Deterioration)	1 (4.3%)	0	
Number (%) of Participants Censored	22 (95.7%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.53 (0.76, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	2 (7.1%)	7 (18.4%)	
Number (%) of Participants Censored	26 (92.9%)	31 (81.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	1.45 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.1262		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.301 (0.061, 1.491)		
Menopausal status			
Pre-menopausal	8	14	0.6439
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	2 (14.3%)	
Number (%) of Participants Censored	7 (87.5%)	12 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (NE, NE)	1.45 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.2253		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		

	SG (N=52)	TPC (N=45)	Interaction
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	2 (4.5%)	5 (16.1%)	
Number (%) of Participants Censored	42 (95.5%)	26 (83.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	2.79 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.1864		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.339 (0.063, 1.820)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
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4.67. Table 1.1.22: Subgroup Analysis of Time to First Deterioration by response threshold in EQ-5D-VAS — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.4765
Number (%) of Participants with Events (Deterioration)	11 (42.3%)	2 (11.8%)	
Number (%) of Participants Censored	15 (57.7%)	15 (88.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.00 (1.48, NE)	NE (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.1965		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.642 (0.578, 12.066)		

	SG (N=52)	TPC (N=45)	Interaction
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	10 (35.7%)	
Number (%) of Participants Censored	10 (38.5%)	18 (64.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.78 (2.17, 12.55)	11.07 (2.79, NE)	
Log-Rank Test p-value (unstratified)	0.2897		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.544 (0.691, 3.450)		
Age group			
< 65	35	35	0.1366
Number (%) of Participants with Events (Deterioration)	20 (57.1%)	8 (22.9%)	
Number (%) of Participants Censored	15 (42.9%)	27 (77.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (3.65, 11.30)	11.07 (4.67, NE)	
Log-Rank Test p-value (unstratified)	0.1198		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.906 (0.833, 4.359)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	4 (40.0%)	
Number (%) of Participants Censored	10 (58.8%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.72, NE)	0.99 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.9453		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.034 (0.288, 3.711)		
Baseline ECOG status			
0	35	26	0.7516

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	20 (57.1%)	8 (30.8%)	
Number (%) of Participants Censored	15 (42.9%)	18 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.24 (2.17, 10.15)	11.07 (2.79, NE)	
Log-Rank Test p-value (unstratified)	0.2097		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.689 (0.738, 3.864)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	4 (21.1%)	
Number (%) of Participants Censored	10 (58.8%)	15 (78.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (0.82, NE)	NE (1.05, NE)	
Log-Rank Test p-value (unstratified)	0.4369		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.622 (0.472, 5.577)		
History of liver metastasis			
Yes	11	13	0.6924
Number (%) of Participants with Events (Deterioration)	7 (63.6%)	3 (23.1%)	
Number (%) of Participants Censored	4 (36.4%)	10 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.99 (0.72, NE)	NE (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.4200		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.762 (0.437, 7.110)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	20 (48.8%)	9 (28.1%)	
Number (%) of Participants Censored	21 (51.2%)	23 (71.9%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (3.19, 12.55)	11.07 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.2543		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.587 (0.717, 3.515)		
PD-L1 Status			
CPS < 1	23	7	0.6240
Number (%) of Participants with Events (Deterioration)	10 (43.5%)	1 (14.3%)	
Number (%) of Participants Censored	13 (56.5%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.00 (3.25, NE)	NE (1.05, NE)	
Log-Rank Test p-value (unstratified)	0.8990		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.146 (0.140, 9.402)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	17 (60.7%)	11 (28.9%)	
Number (%) of Participants Censored	11 (39.3%)	27 (71.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.78 (1.48, 10.15)	11.07 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.0366		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.210 (1.032, 4.732)		
Menopausal status			
Pre-menopausal	8	14	0.0516
Number (%) of Participants with Events (Deterioration)	7 (87.5%)	2 (14.3%)	
Number (%) of Participants Censored	1 (12.5%)	12 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	6.34 (0.76, 9.00)	NE (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.0577		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	4.229 (0.842, 21.234)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	10 (32.3%)	
Number (%) of Participants Censored	24 (54.5%)	21 (67.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.24 (2.50, NE)	11.07 (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.7230		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.152 (0.536, 2.478)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.68. Table 1.1.24: Subgroup Analysis of Time to First Deterioration by response threshold in PGIC — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.3209
Number (%) of Participants with Events (Deterioration)	10 (38.5%)	4 (23.5%)	
Number (%) of Participants Censored	16 (61.5%)	13 (76.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	5.03 (2.99, NE)	NE (2.79, NE)	
Log-Rank Test p-value (unstratified)	0.9275		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.946 (0.290, 3.086)		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	5 (19.2%)	9 (32.1%)	
Number (%) of Participants Censored	21 (80.8%)	19 (67.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.88, NE)	NE (4.30, NE)	
Log-Rank Test p-value (unstratified)	0.1059		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.410 (0.135, 1.245)		
Age group			
< 65	35	35	0.1962
Number (%) of Participants with Events (Deterioration)	10 (28.6%)	8 (22.9%)	
Number (%) of Participants Censored	25 (71.4%)	27 (77.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.03, NE)	NE (4.30, NE)	
Log-Rank Test p-value (unstratified)	0.7390		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.849 (0.326, 2.207)		
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	5 (29.4%)	5 (50.0%)	
Number (%) of Participants Censored	12 (70.6%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.88 (2.79, NE)	2.83 (2.76, NE)	
Log-Rank Test p-value (unstratified)	0.0885		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.315 (0.083, 1.188)		
Baseline ECOG status			
0	35	26	0.0806
Number (%) of Participants with Events (Deterioration)	8 (22.9%)	9 (34.6%)	
Number (%) of Participants Censored	27 (77.1%)	17 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.44, NE)	NE (2.92, NE)	
Log-Rank Test p-value (unstratified)	0.1298		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.467 (0.172, 1.268)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	7 (41.2%)	4 (21.1%)	
Number (%) of Participants Censored	10 (58.8%)	15 (78.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (3.35, NE)	NE (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.4007		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.687 (0.492, 5.785)		
History of liver metastasis			
Yes	11	13	0.8748
Number (%) of Participants with Events (Deterioration)	4 (36.4%)	2 (15.4%)	
Number (%) of Participants Censored	7 (63.6%)	11 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.44 (2.99, NE)	NE (2.76, NE)	
Log-Rank Test p-value (unstratified)	0.6909		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.693 (0.112, 4.272)		

	SG (N=52)	TPC (N=45)	Interaction
No	41	32	
Number (%) of Participants with Events (Deterioration)	11 (26.8%)	11 (34.4%)	
Number (%) of Participants Censored	30 (73.2%)	21 (65.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.80, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.4171		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.704 (0.303, 1.634)		
PD-L1 Status			
CPS < 1	23	7	0.9056
Number (%) of Participants with Events (Deterioration)	5 (21.7%)	1 (14.3%)	
Number (%) of Participants Censored	18 (78.3%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.03, NE)	NE (4.70, NE)	
Log-Rank Test p-value (unstratified)	0.9241		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.901 (0.105, 7.755)		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	10 (35.7%)	12 (31.6%)	
Number (%) of Participants Censored	18 (64.3%)	26 (68.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.44 (3.55, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.7450		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.861 (0.362, 2.047)		
Menopausal status			
Pre-menopausal	8	14	0.1283

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	5 (35.7%)	
Number (%) of Participants Censored	7 (87.5%)	9 (64.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.21, NE)	NE (2.92, NE)	
Log-Rank Test p-value (unstratified)	0.1492		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.233 (0.027, 2.010)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	14 (31.8%)	8 (25.8%)	
Number (%) of Participants Censored	30 (68.2%)	23 (74.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.44 (4.80, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.7116		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.842 (0.344, 2.061)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.69. Table 1.1.25: Subgroup Analysis of Time to First Deterioration by response threshold in PGIS — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

	SG (N=52)	TPC (N=45)	Interaction
Geographic region			
US/Canada/Western Europe	26	17	0.1998

	SG (N=52)	TPC (N=45)	Interaction
Number (%) of Participants with Events (Deterioration)	2 (7.7%)	0	
Number (%) of Participants Censored	24 (92.3%)	17 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.2945		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Rest of the world	26	28	
Number (%) of Participants with Events (Deterioration)	4 (15.4%)	3 (10.7%)	
Number (%) of Participants Censored	22 (84.6%)	25 (89.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.59, NE)	NE (4.86, NE)	
Log-Rank Test p-value (unstratified)	0.9349		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.939 (0.207, 4.254)		
Age group			
< 65	35	35	0.3065
Number (%) of Participants with Events (Deterioration)	4 (11.4%)	3 (8.6%)	
Number (%) of Participants Censored	31 (88.6%)	32 (91.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.16, NE)	
Log-Rank Test p-value (unstratified)	0.9869		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.013 (0.225, 4.551)		

	SG (N=52)	TPC (N=45)	Interaction
>= 65	17	10	
Number (%) of Participants with Events (Deterioration)	2 (11.8%)	0	
Number (%) of Participants Censored	15 (88.2%)	10 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.79, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4452		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Baseline ECOG status			
0	35	26	0.6000
Number (%) of Participants with Events (Deterioration)	5 (14.3%)	2 (7.7%)	
Number (%) of Participants Censored	30 (85.7%)	24 (92.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.59, NE)	NE (4.86, NE)	
Log-Rank Test p-value (unstratified)	0.4960		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.757 (0.340, 9.092)		
1	17	19	
Number (%) of Participants with Events (Deterioration)	1 (5.9%)	1 (5.3%)	
Number (%) of Participants Censored	16 (94.1%)	18 (94.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.89, NE)	NE (5.16, NE)	
Log-Rank Test p-value (unstratified)	0.8779		

	SG (N=52)	TPC (N=45)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.805 (0.050, 12.876)		
History of liver metastasis			
Yes	11	13	0.9095
Number (%) of Participants with Events (Deterioration)	2 (18.2%)	1 (7.7%)	
Number (%) of Participants Censored	9 (81.8%)	12 (92.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.32, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.8061		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.350 (0.122, 14.965)		
No	41	32	
Number (%) of Participants with Events (Deterioration)	4 (9.8%)	2 (6.2%)	
Number (%) of Participants Censored	37 (90.2%)	30 (93.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7145		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.372 (0.250, 7.521)		
PD-L1 Status			
CPS < 1	23	7	0.2735
Number (%) of Participants with Events (Deterioration)	4 (17.4%)	0	
Number (%) of Participants Censored	19 (82.6%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=52)	TPC (N=45)	Interaction
Median	NE (5.36, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4174		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
CPS ≥ 1	28	38	
Number (%) of Participants with Events (Deterioration)	2 (7.1%)	3 (7.9%)	
Number (%) of Participants Censored	26 (92.9%)	35 (92.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.16, NE)	
Log-Rank Test p-value (unstratified)	0.8743		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.866 (0.144, 5.190)		
Menopausal status			
Pre-menopausal	8	14	0.5861
Number (%) of Participants with Events (Deterioration)	2 (25.0%)	1 (7.1%)	
Number (%) of Participants Censored	6 (75.0%)	13 (92.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.52, NE)	NE (5.16, NE)	
Log-Rank Test p-value (unstratified)	0.5375		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.108 (0.187, 23.757)		
Post-menopausal	44	31	
Number (%) of Participants with Events (Deterioration)	4 (9.1%)	2 (6.5%)	
Number (%) of Participants Censored	40 (90.9%)	29 (93.5%)	

	SG (N=52)	TPC (N=45)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.86, NE)	
Log-Rank Test p-value (unstratified)	0.8781		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.142 (0.209, 6.241)		

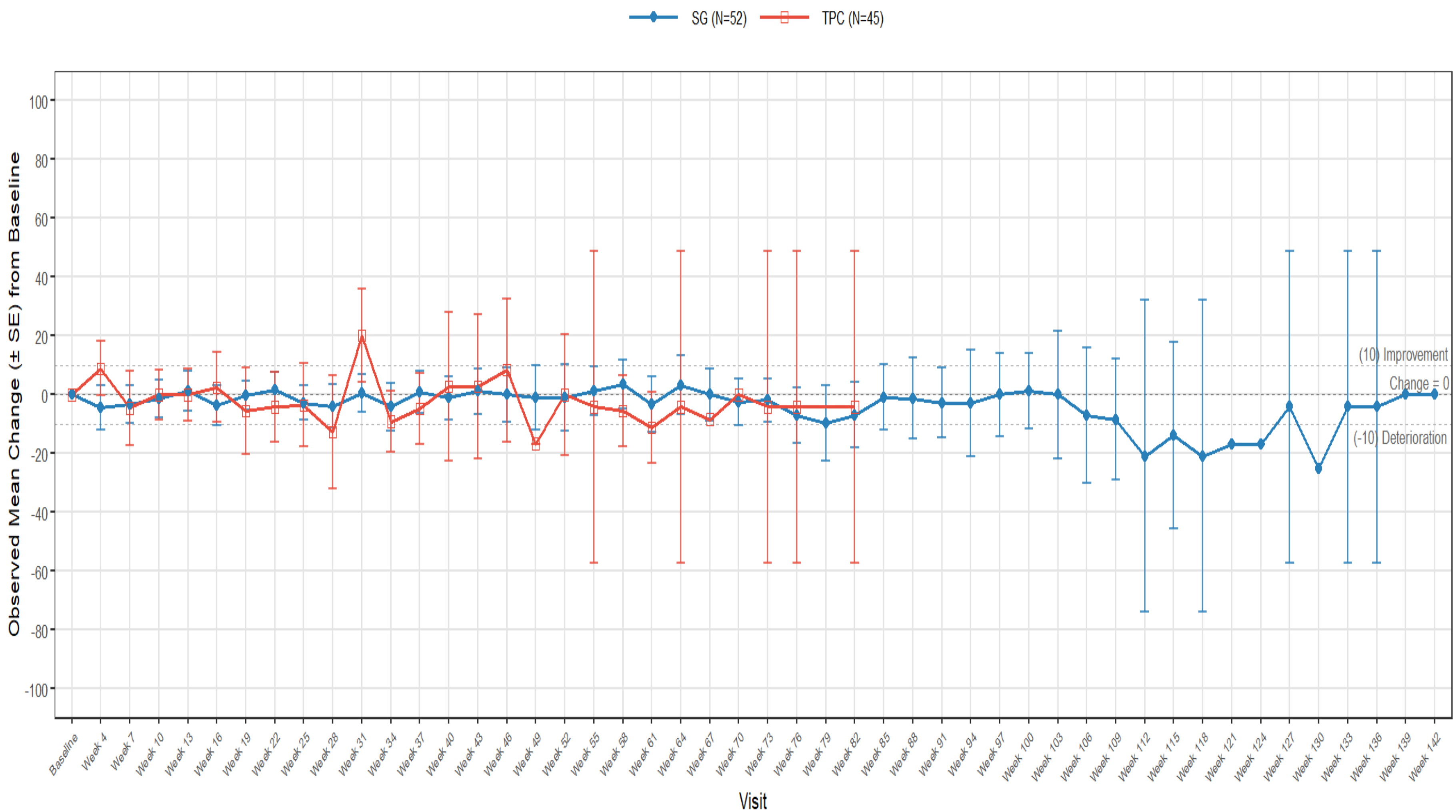
SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5. KM FIGURES — PRO

5.1. Figure 1.1.1: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 GLOBAL HEALTH STATUS QOL — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

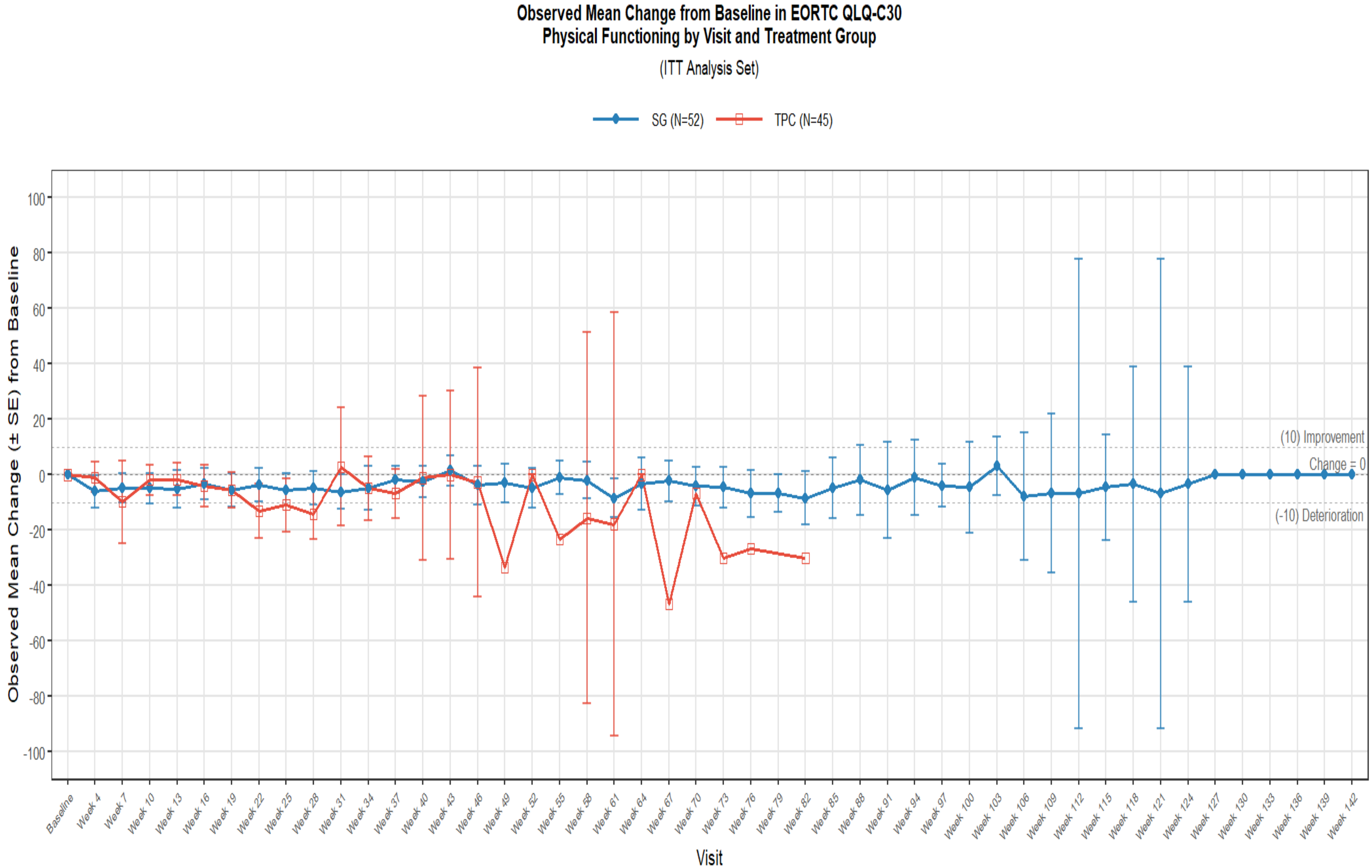
Observed Mean Change from Baseline in EORTC QLQ-C30
Global Health Status/Qol by Visit and Treatment Group

(ITT Analysis Set)



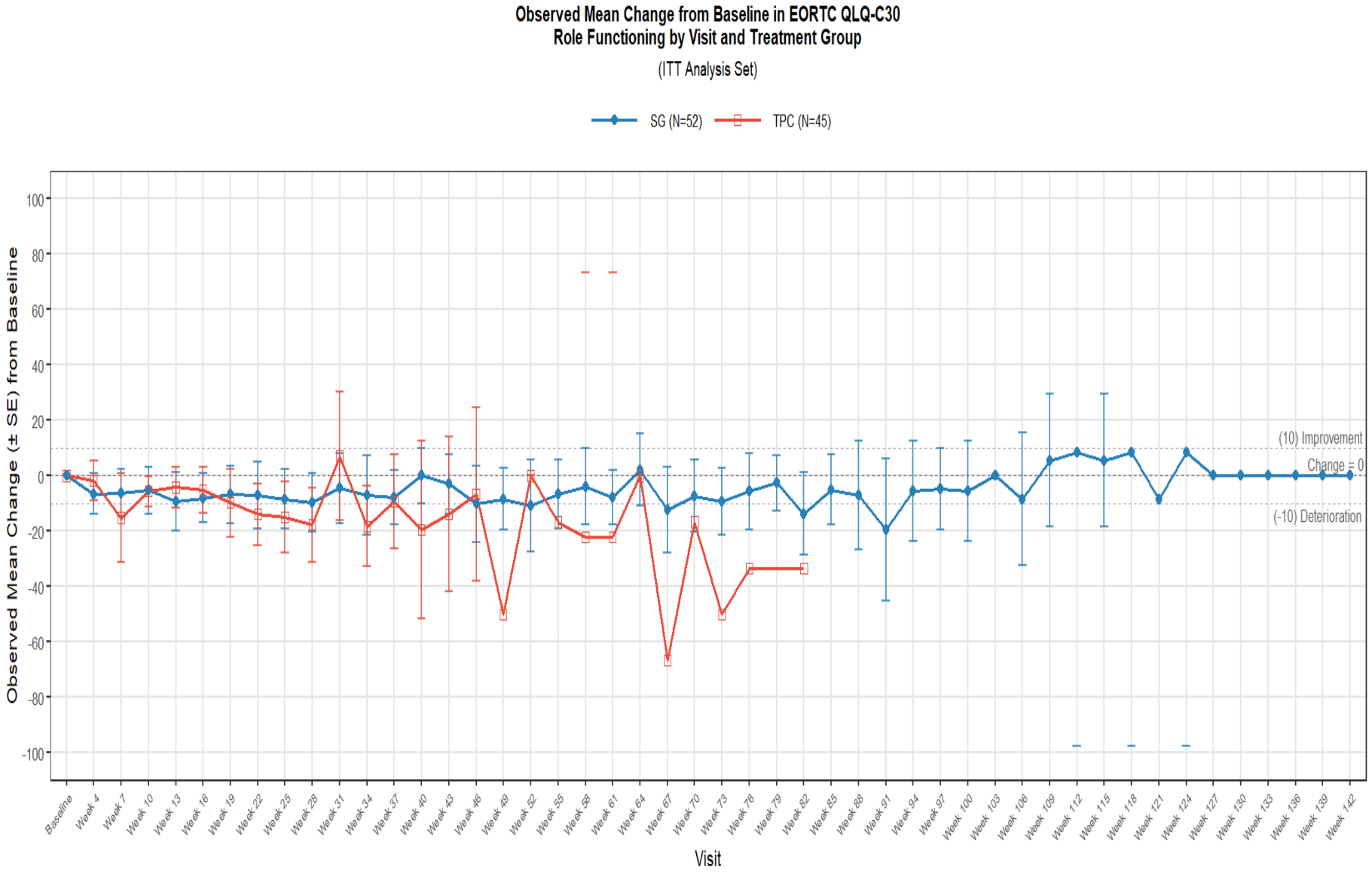
Number of Subjects
SG (N=52): 50 38 41 38 34 37 32 31 30 28 26 24 26 24 22 23 18 17 18 17 15 15 15 16 18 12 13 11 10 7 6 6 7 6 4 6 3 2 3 2 2 2 2 1 2 2 1 1
TPC (N=45): 44 30 11 33 32 23 12 24 19 17 7 11 9 6 6 5 2 3 2 3 3 2 1 1 2 2 0 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

5.2. Figure 1.1.2: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 PHYSICAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

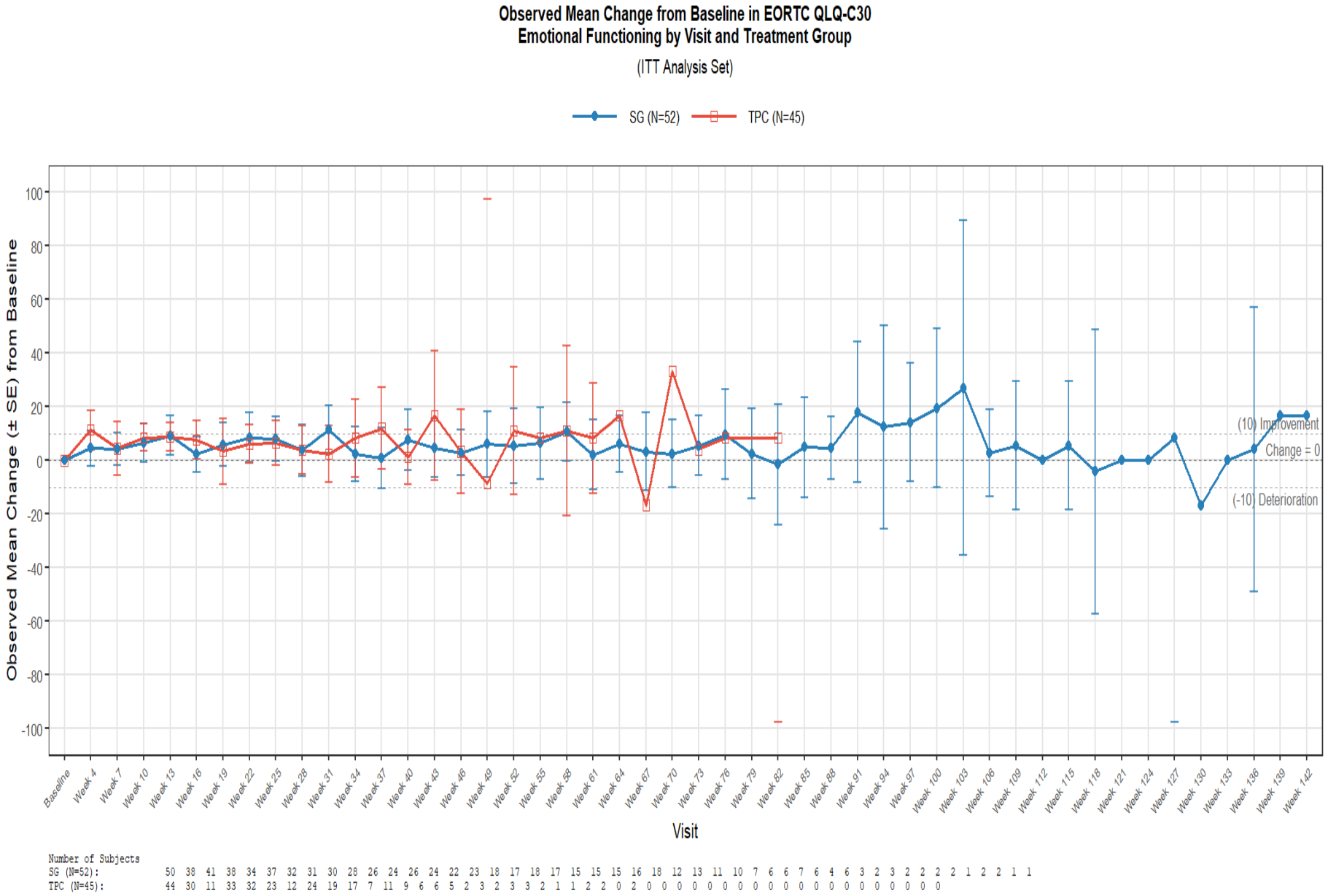


Number of Subjects
SG (N=52): 50 38 41 38 34 37 32 31 30 28 26 24 26 24 22 23 18 17 18 17 15 15 15 16 18 12 13 11 10 7 6 6 7 6 4 6 3 2 3 2 2 2 2 1 2 2 1 1
TPC (N=45): 44 30 11 33 32 23 12 24 19 17 7 11 9 6 6 5 2 3 2 3 3 2 1 1 2 2 0 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

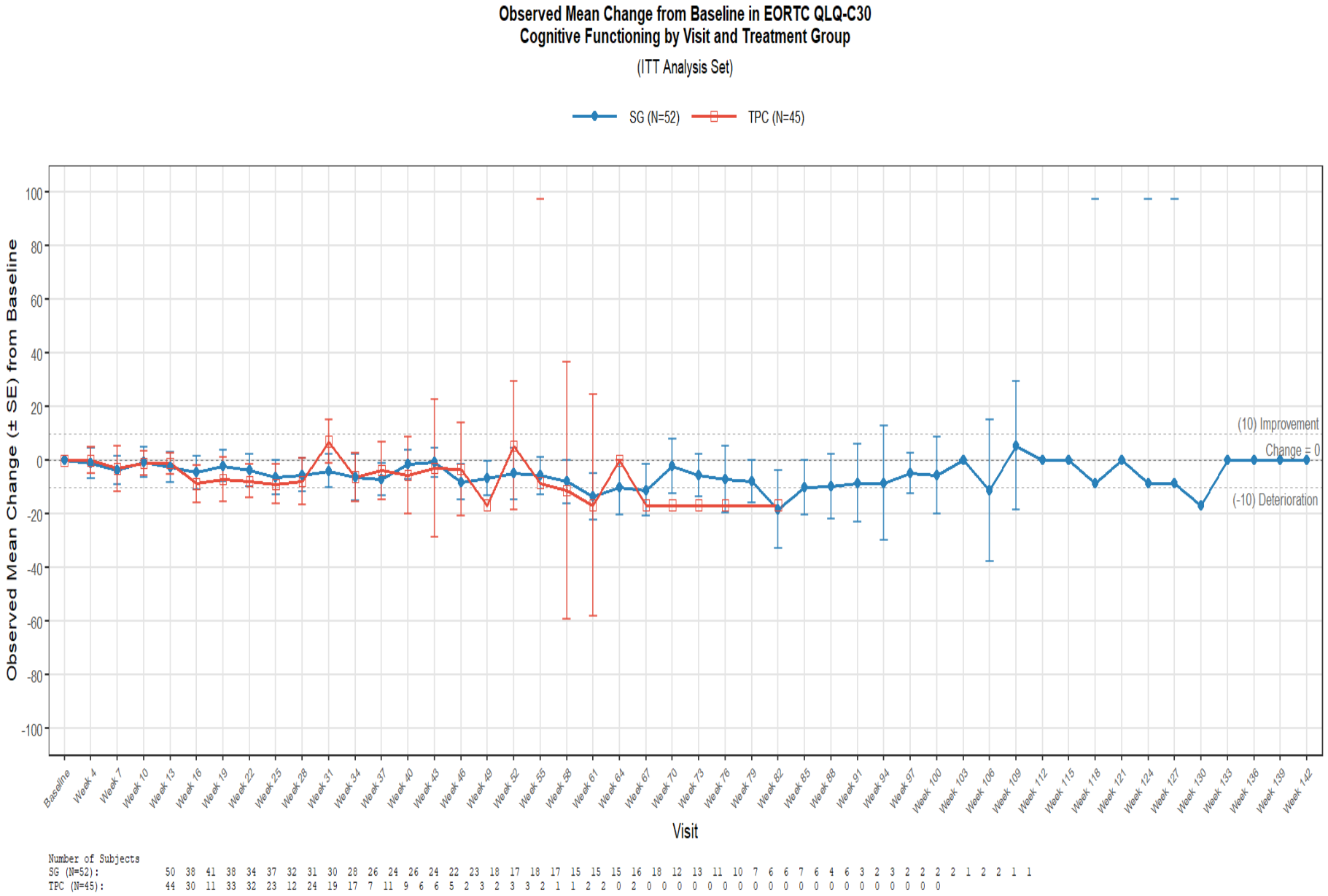
5.3. Figure 1.1.3: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 ROLE FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



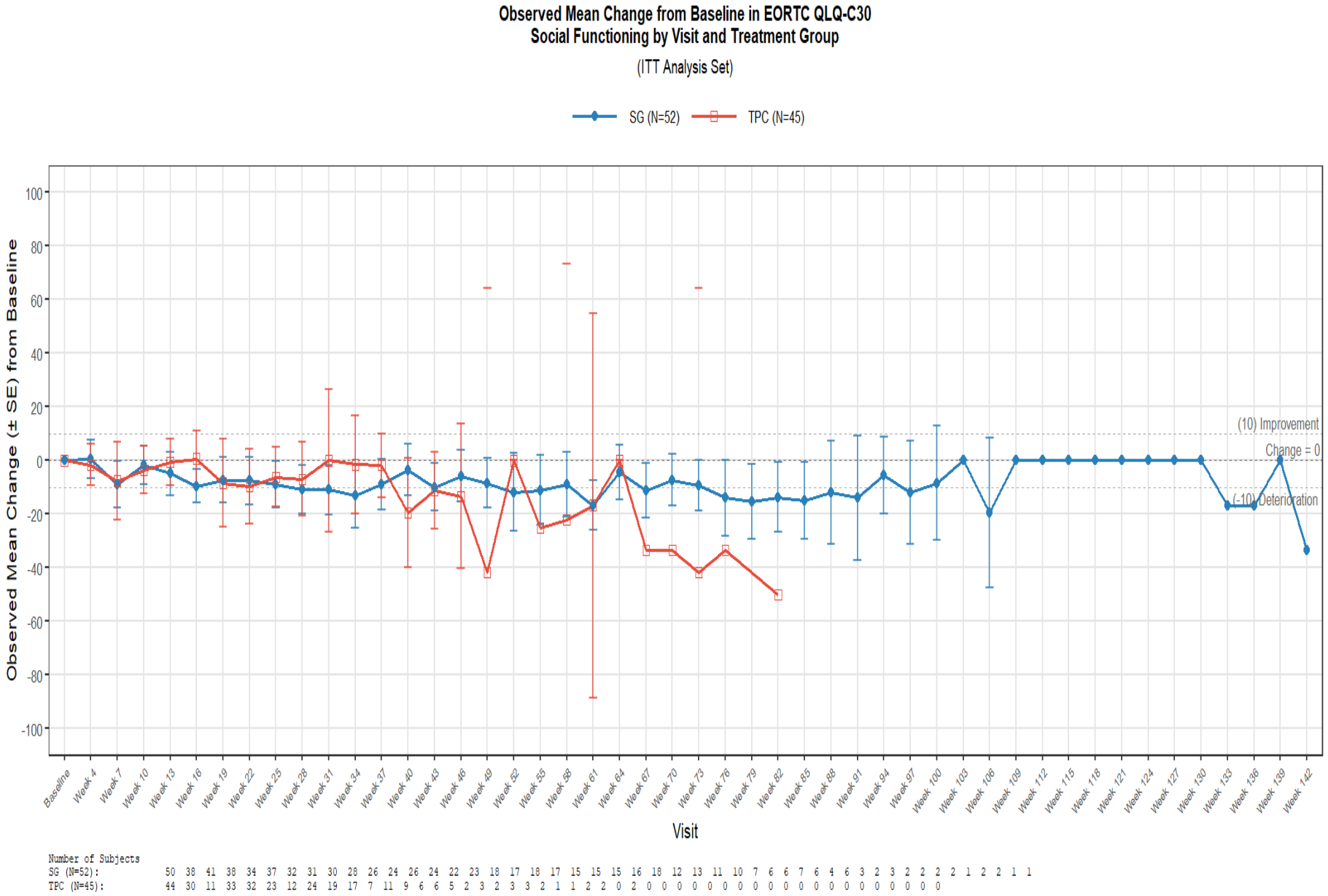
5.4. Figure 1.1.4: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 EMOTIONAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin



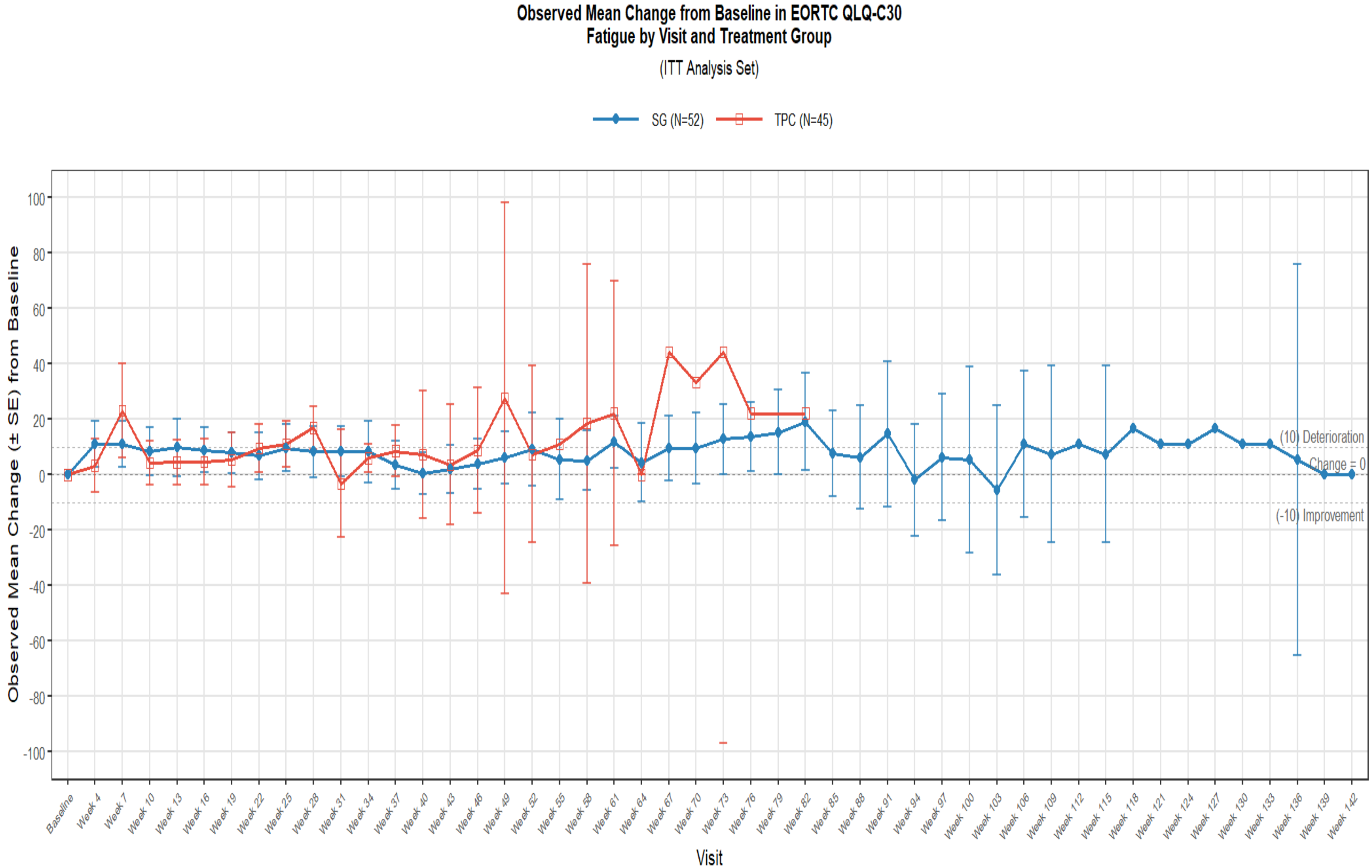
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5.6. Figure 1.1.6: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 SOCIAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

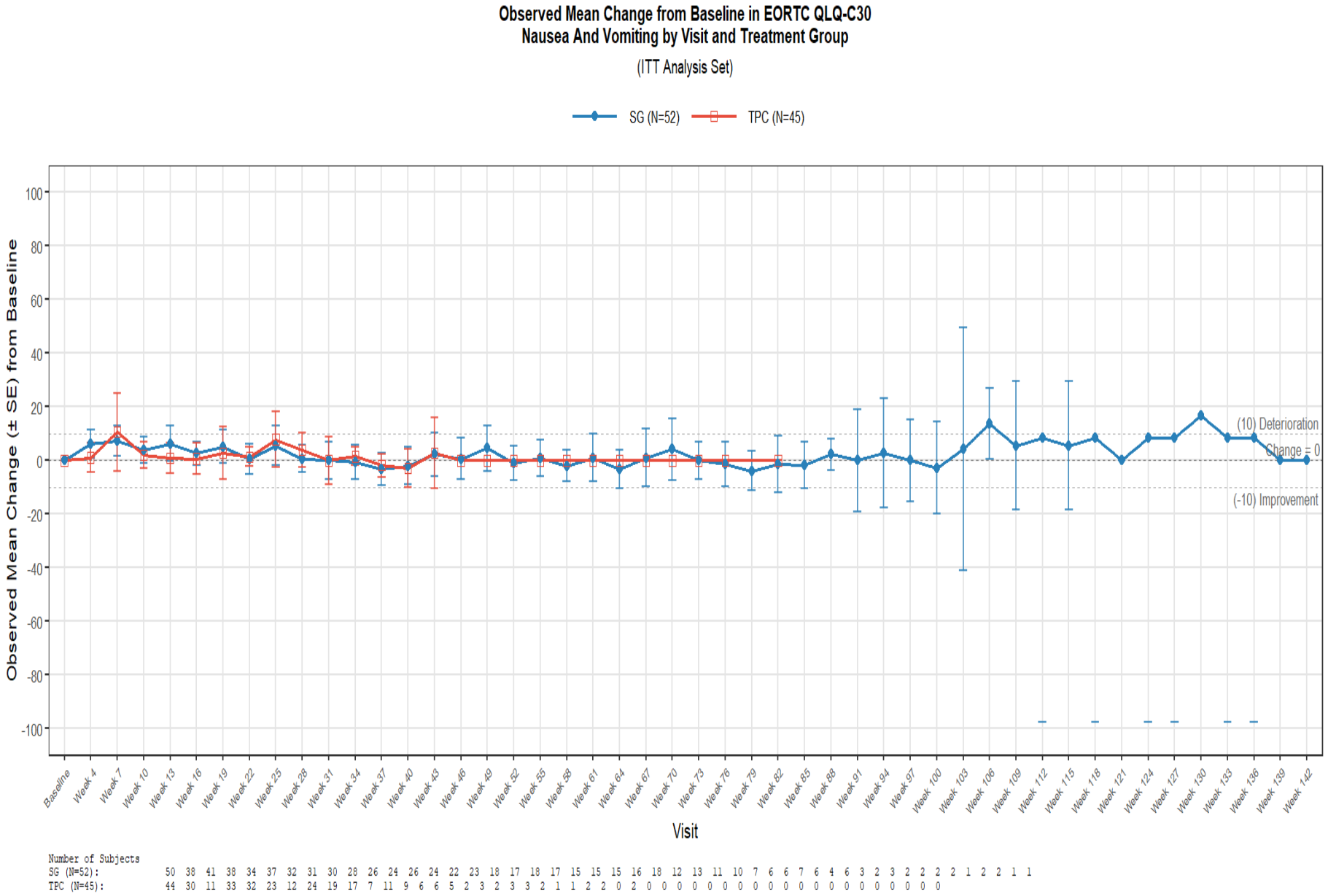


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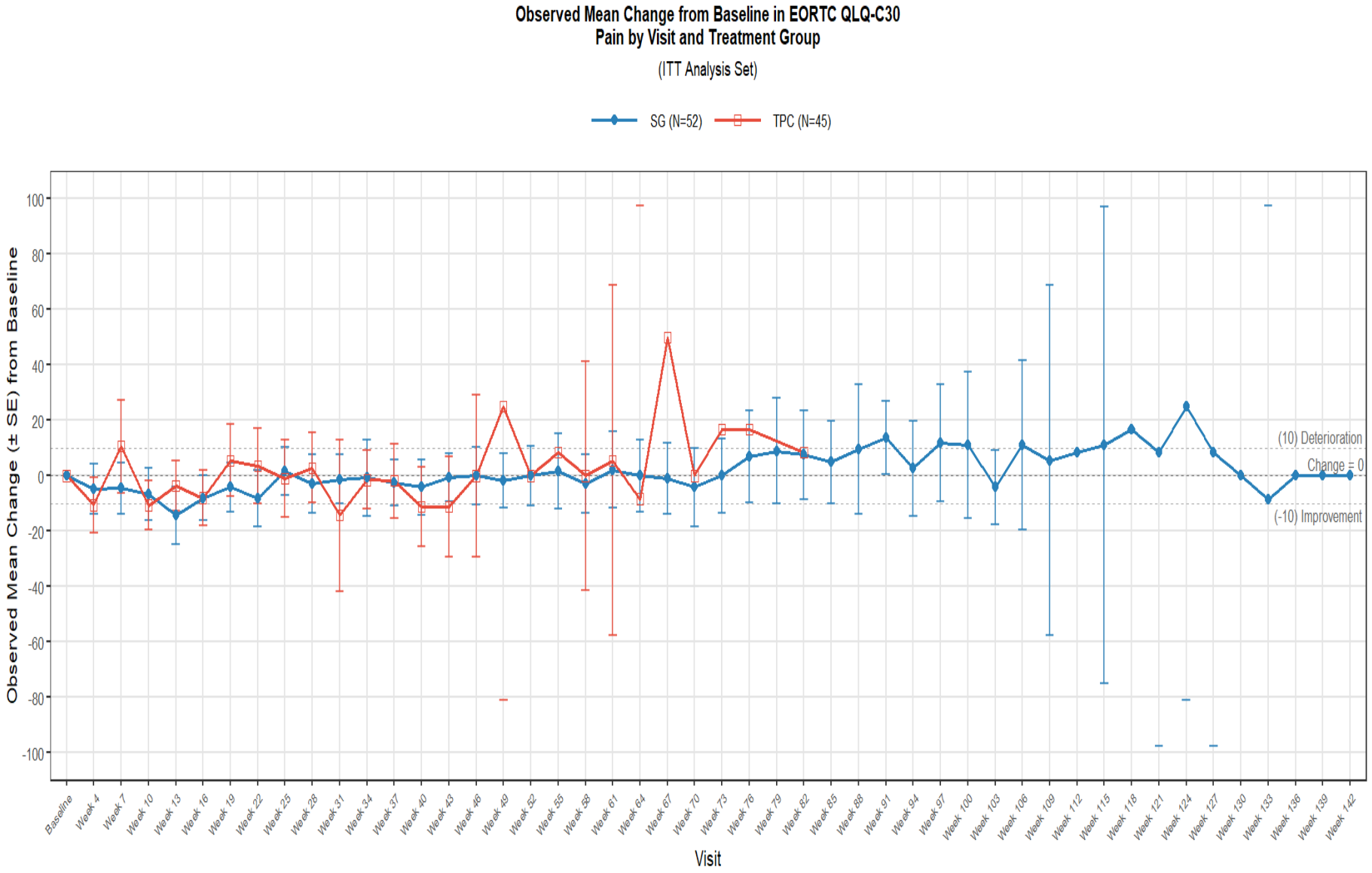



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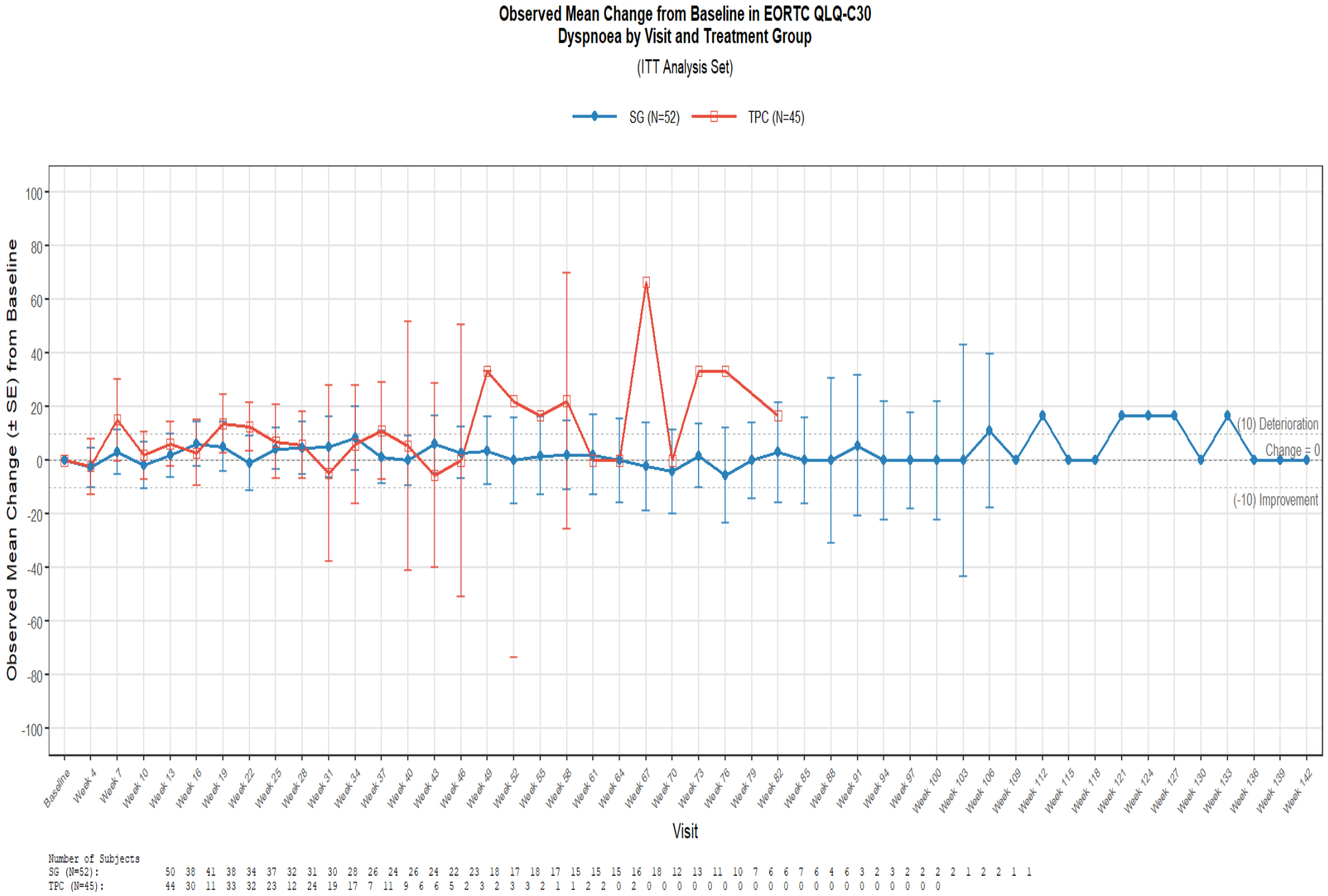
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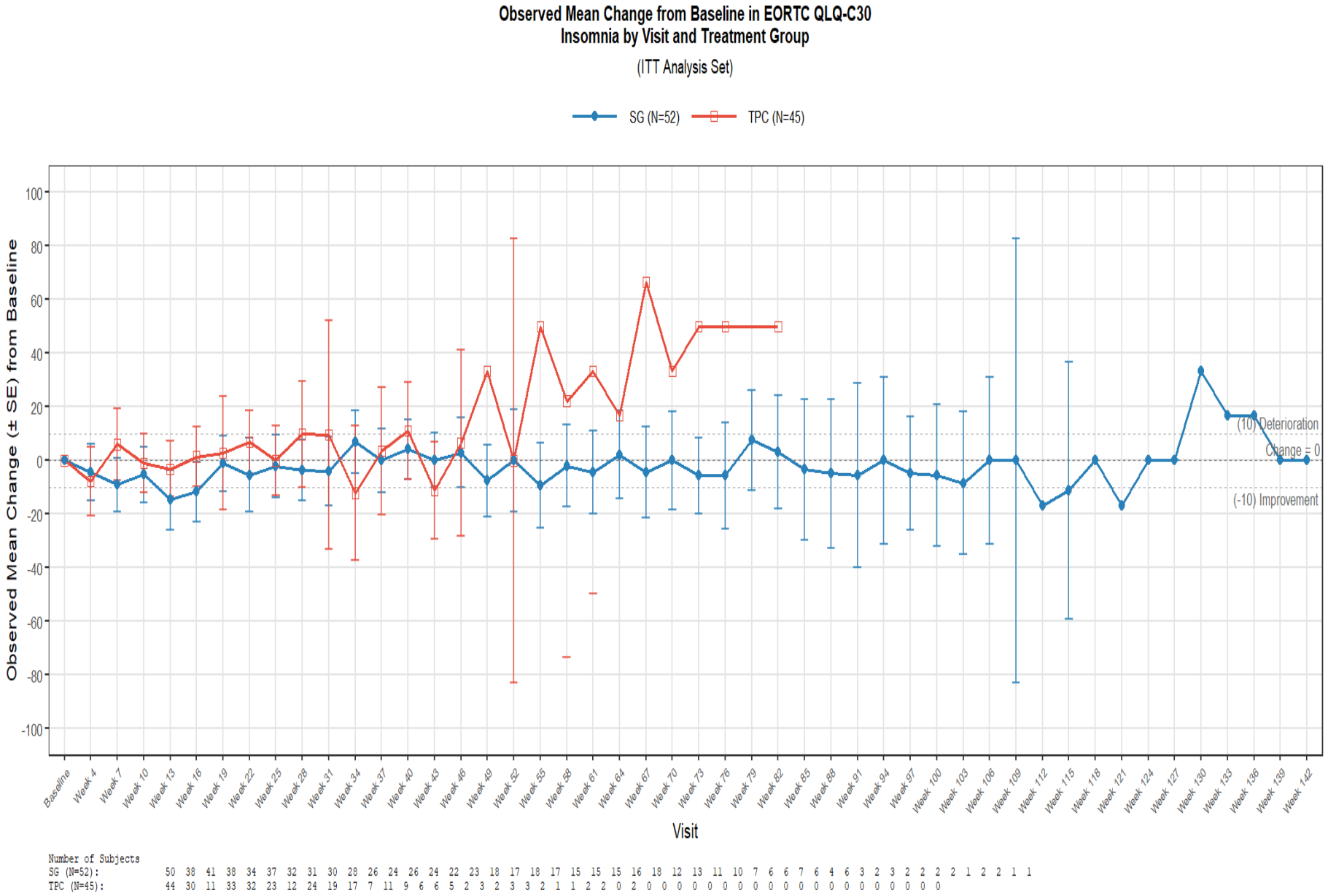
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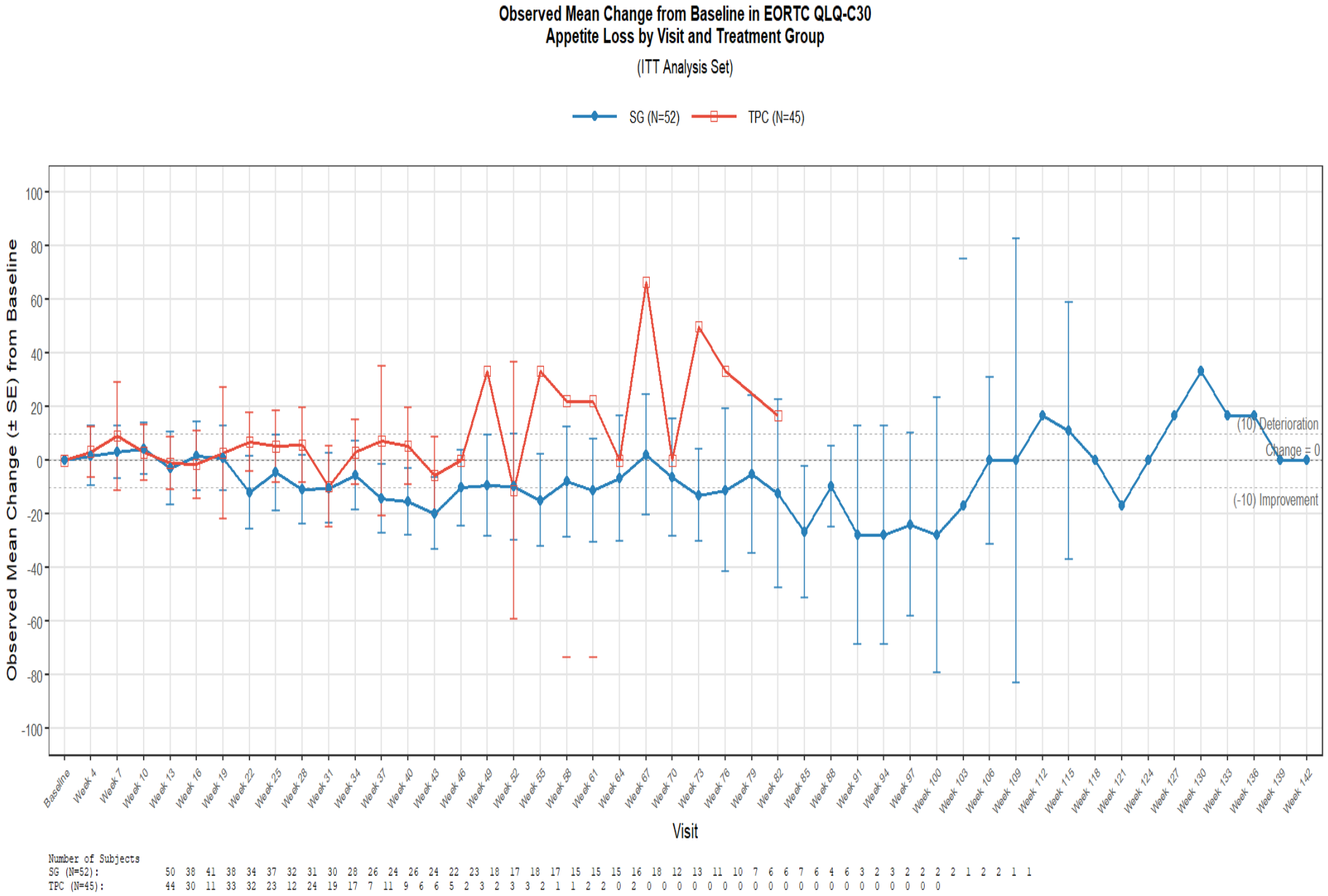
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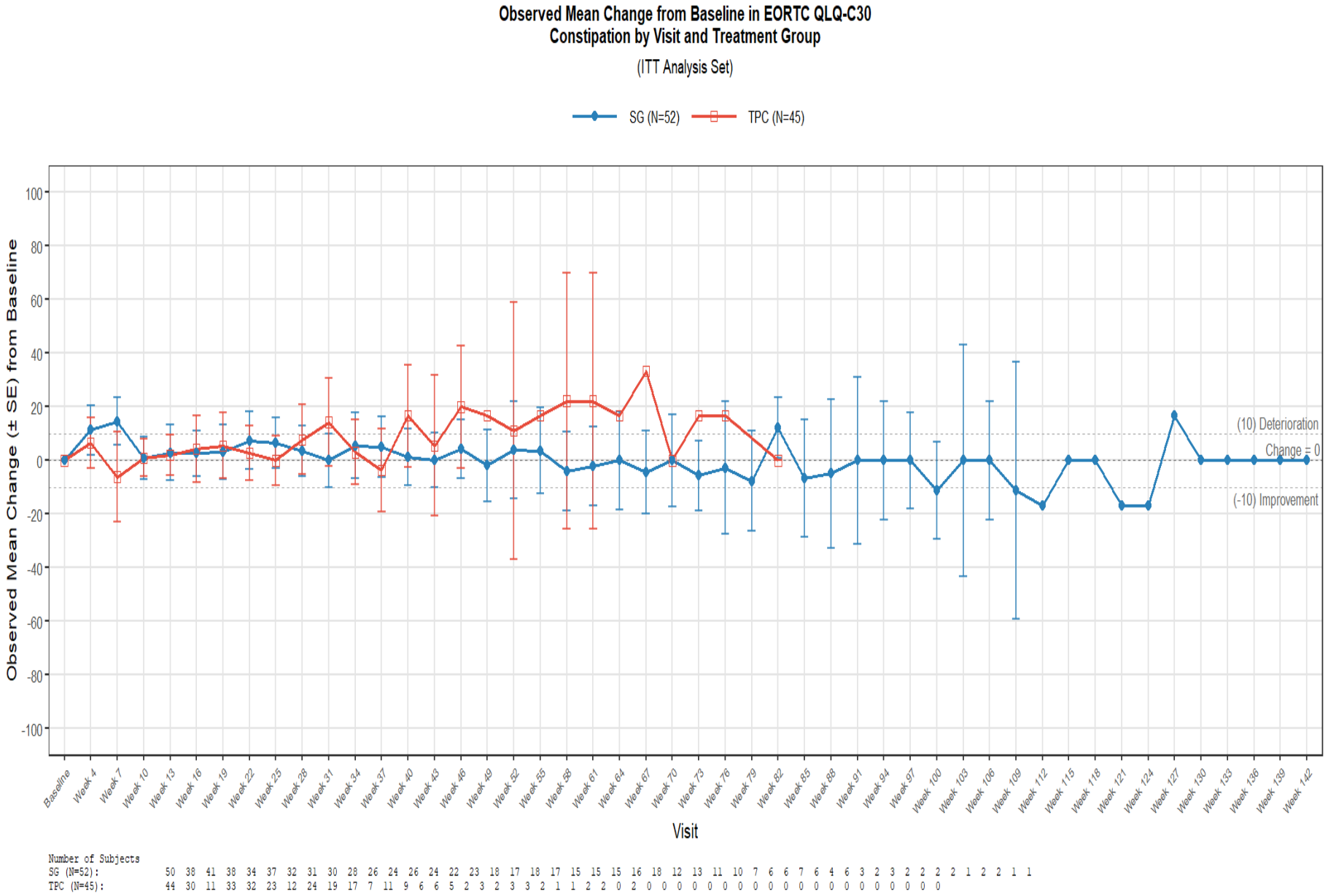
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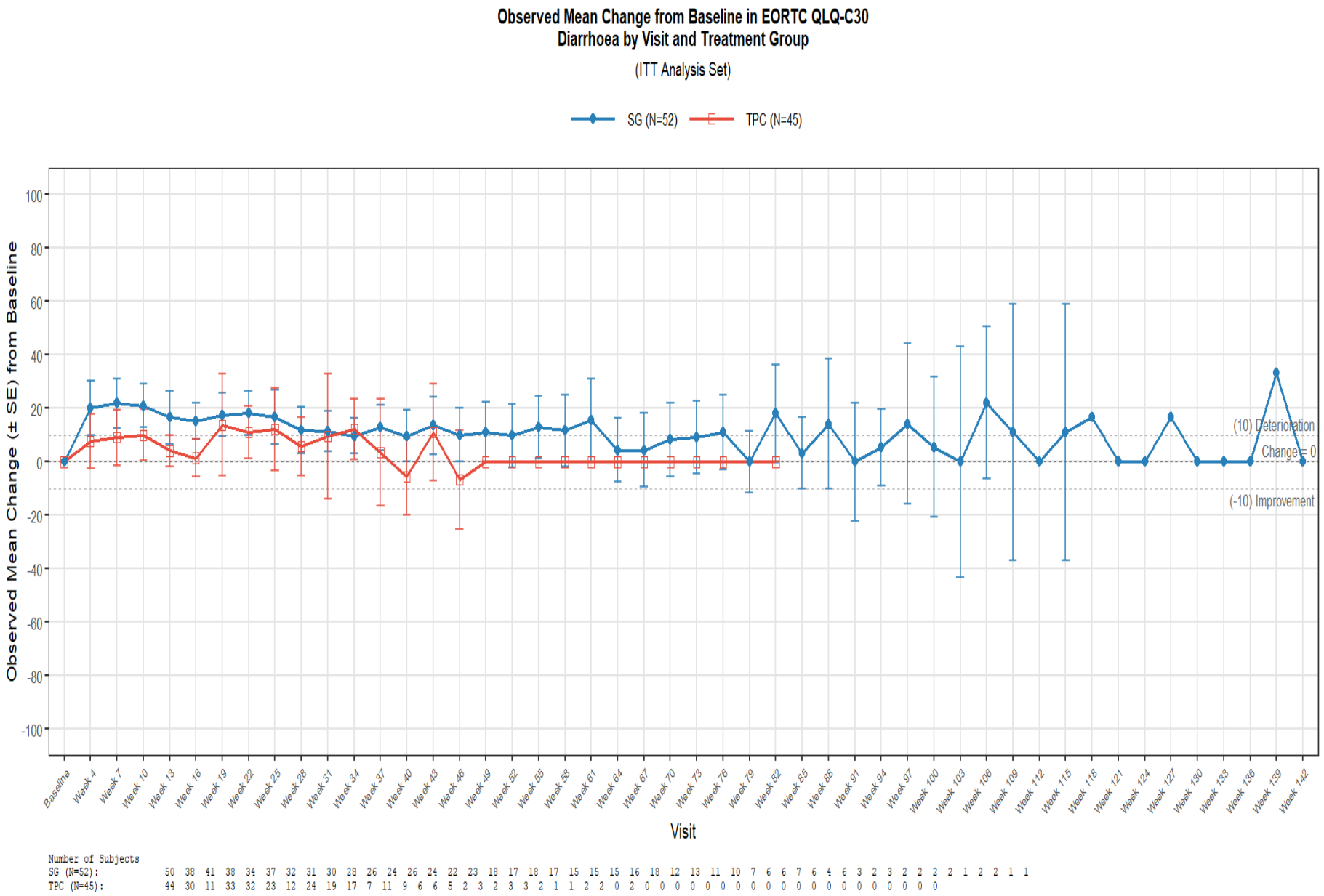
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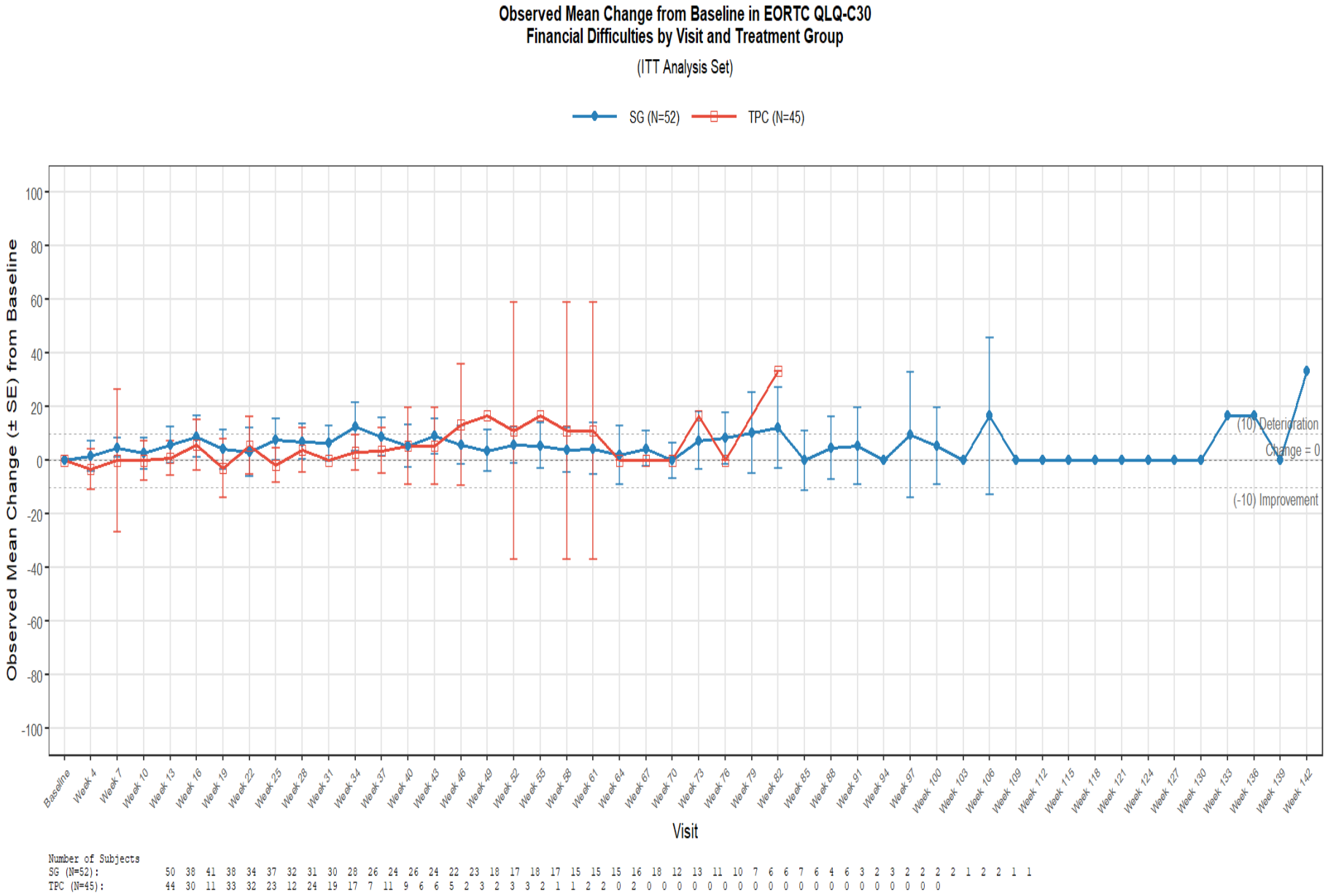
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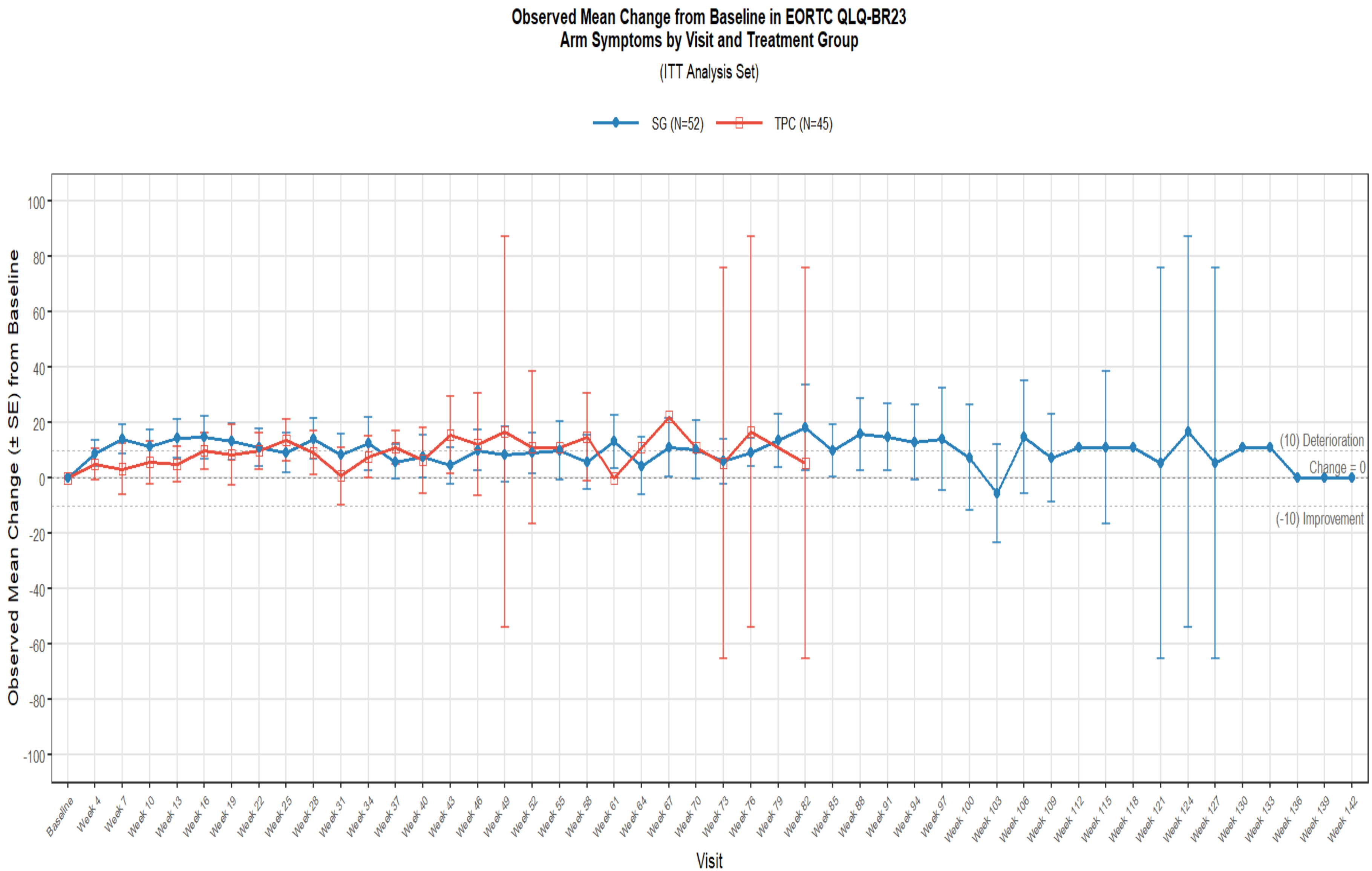
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5.15. Figure 1.1.15: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 FINANCIAL DIFFICULTIES — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

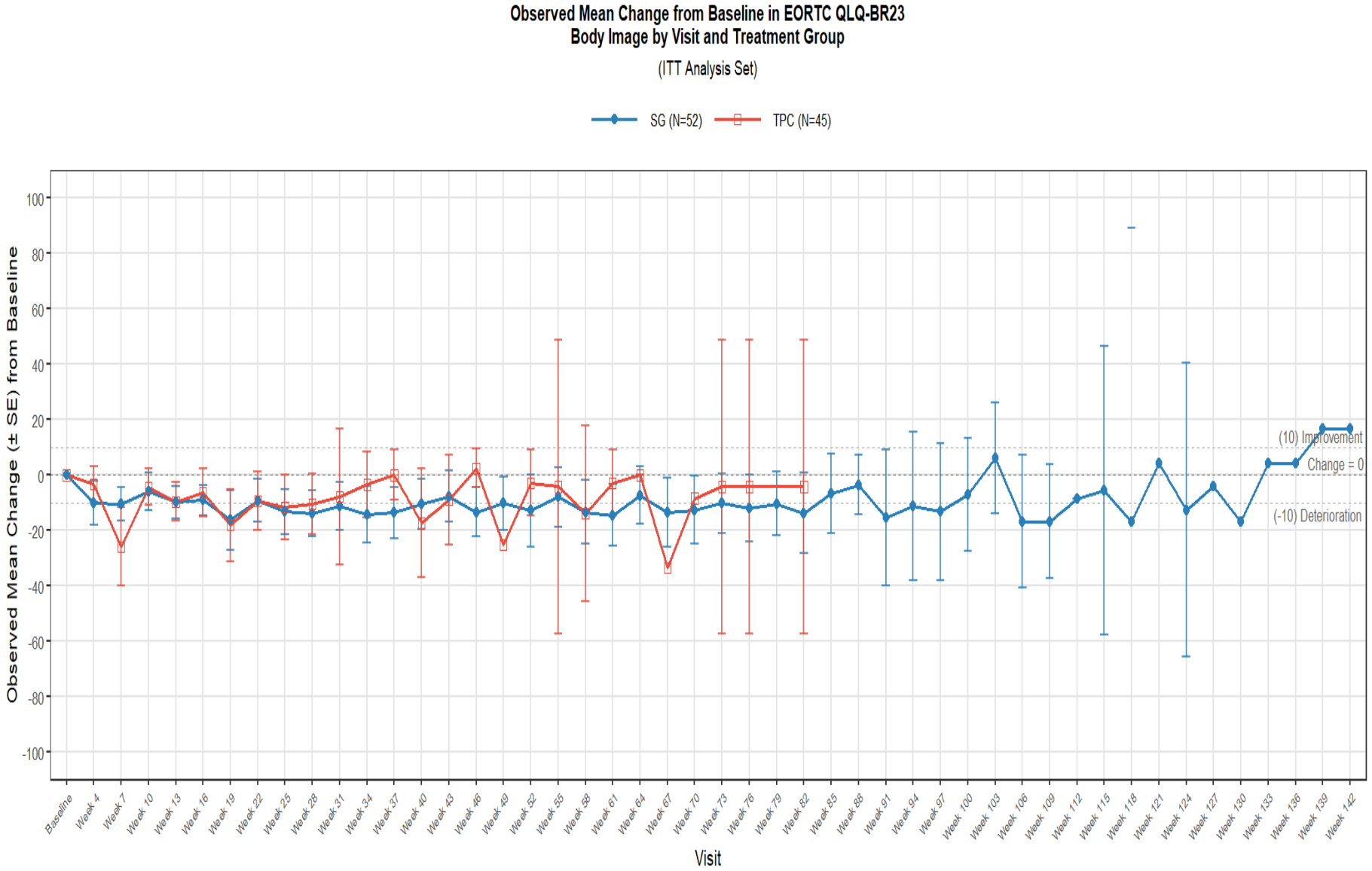


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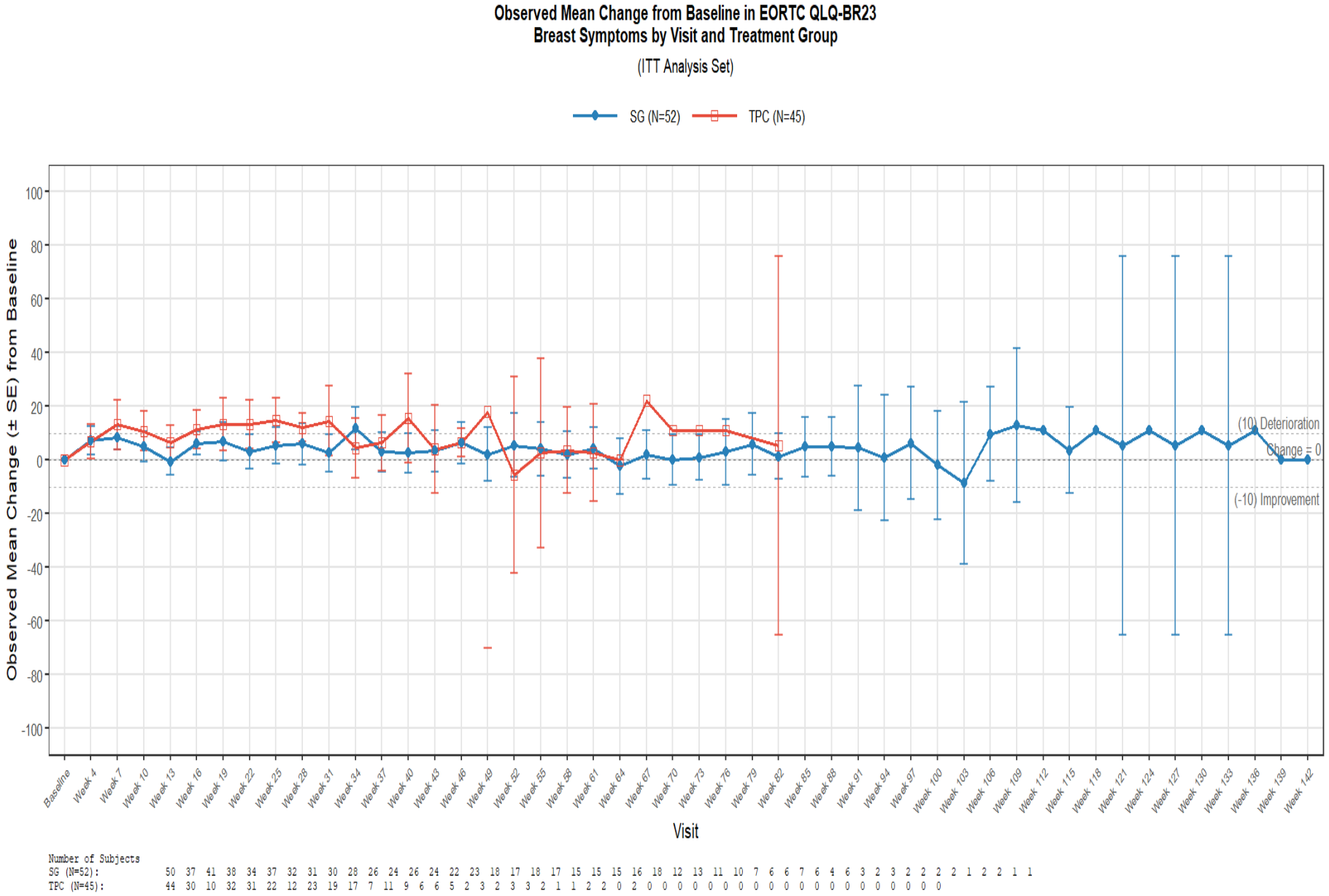


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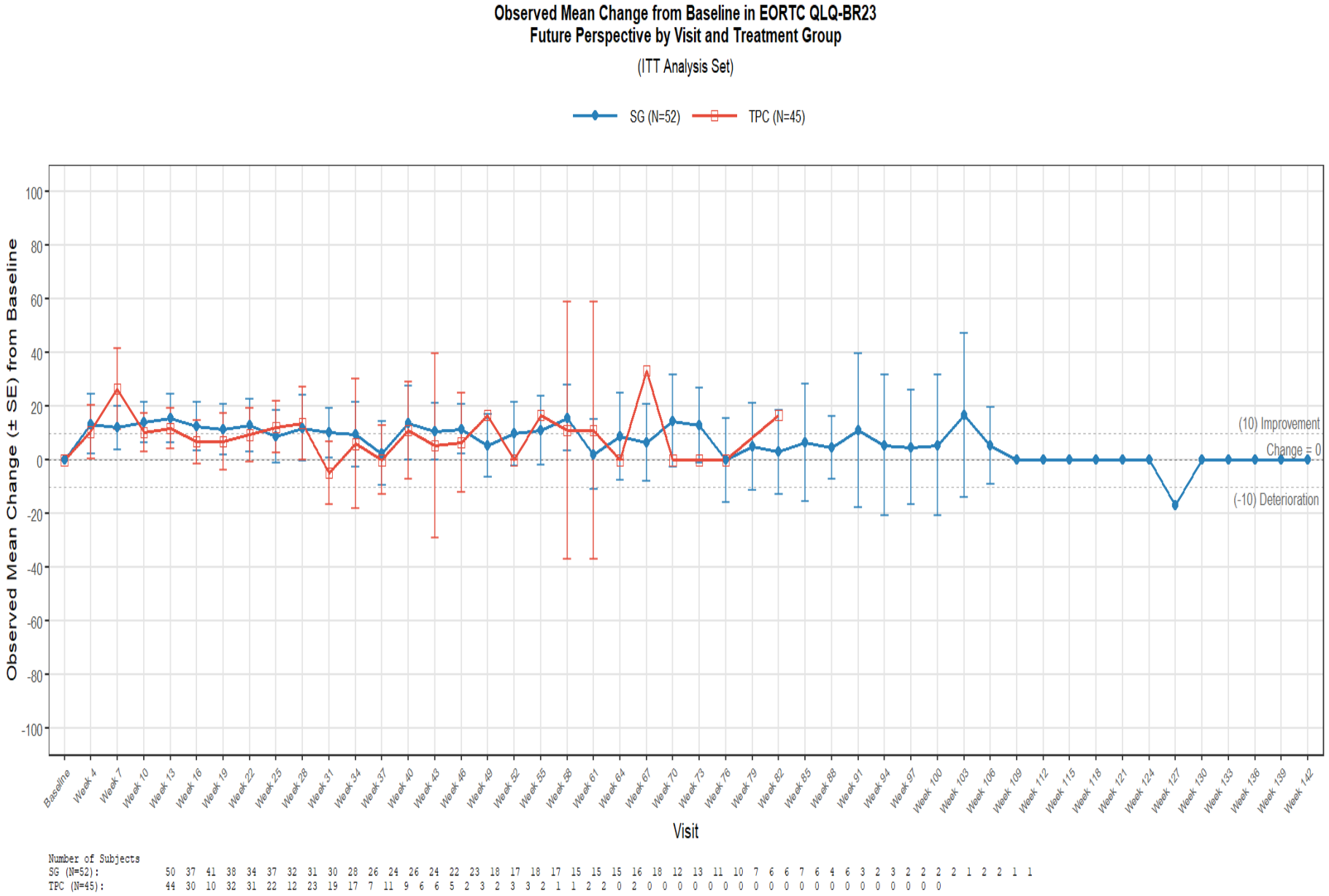
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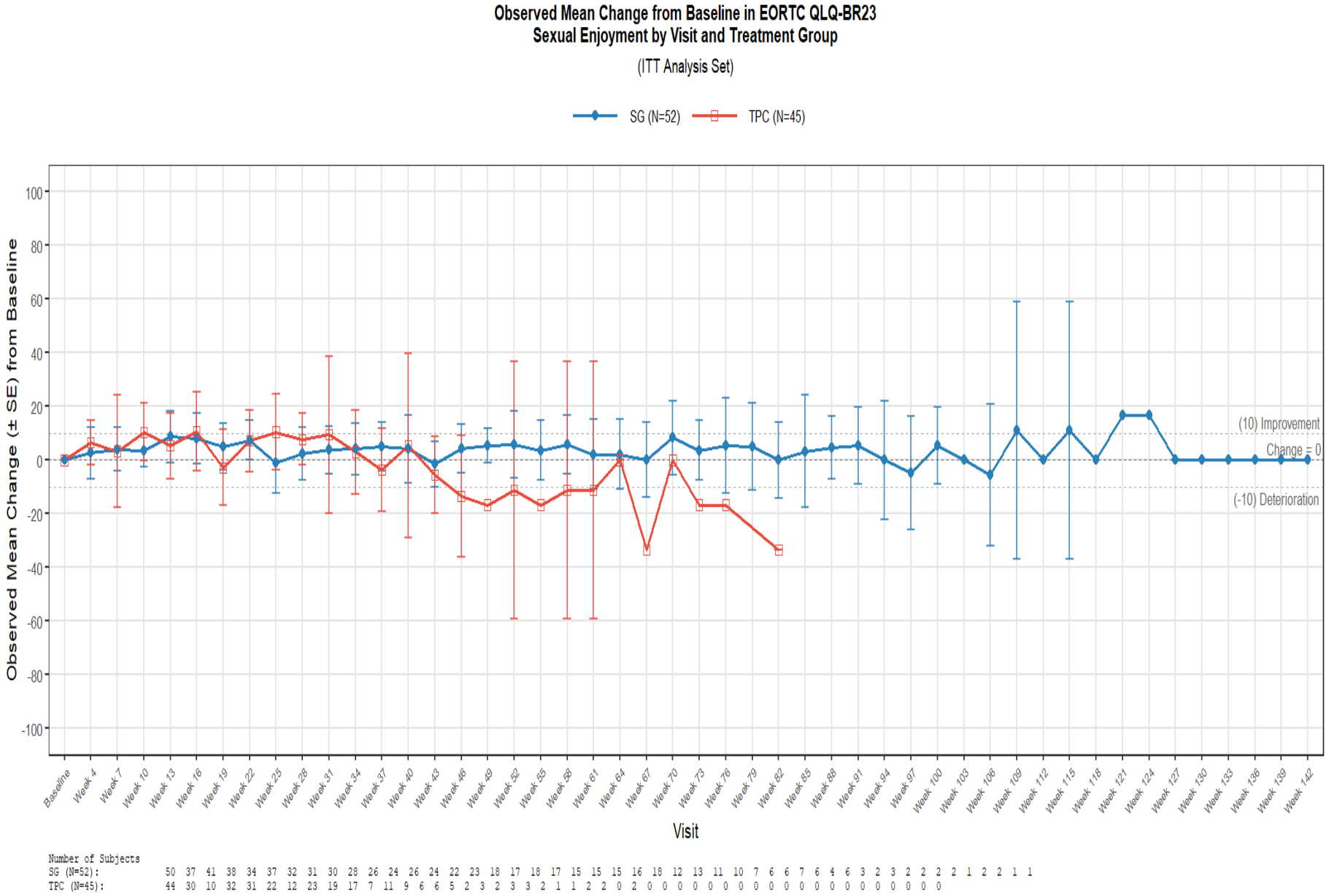
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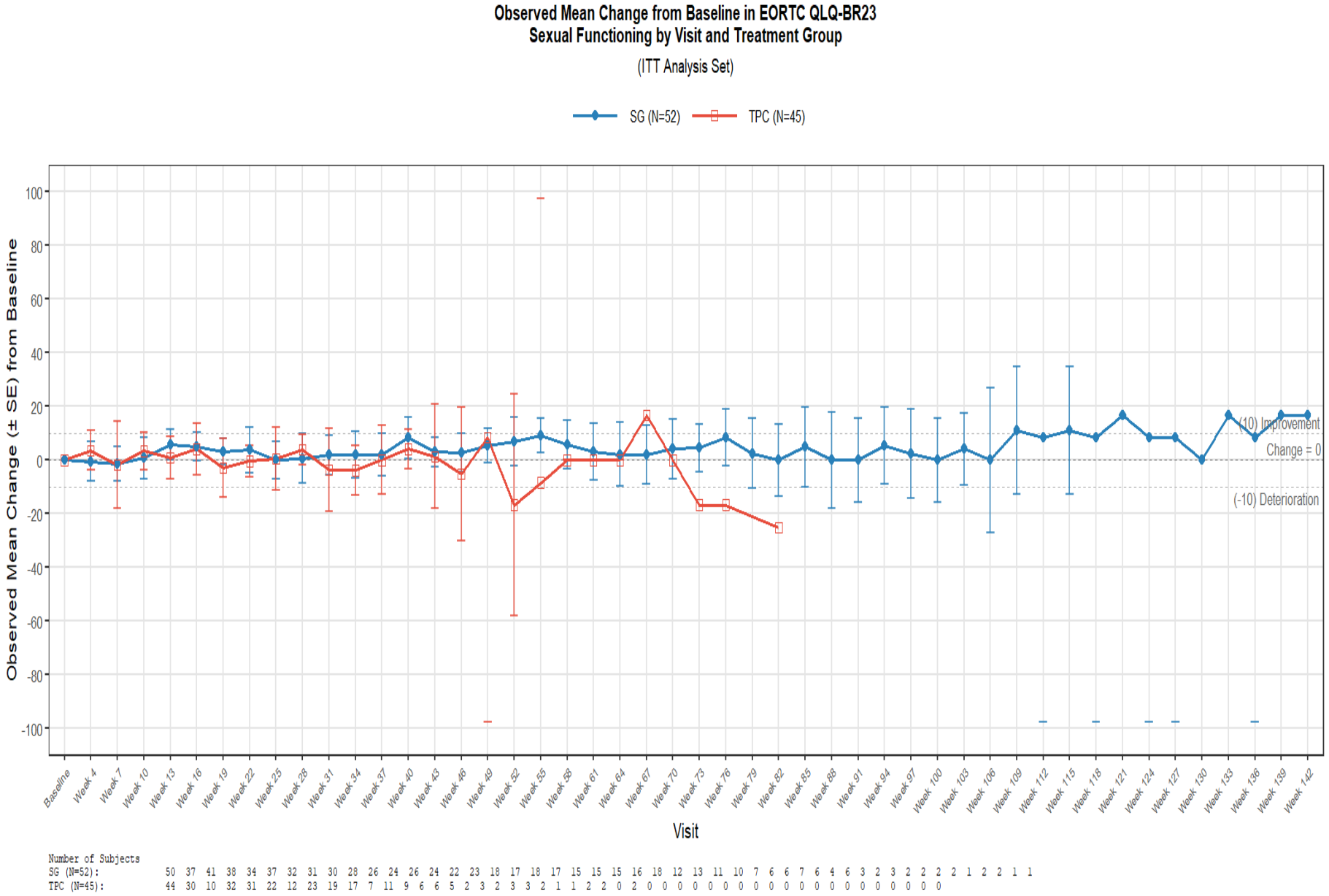
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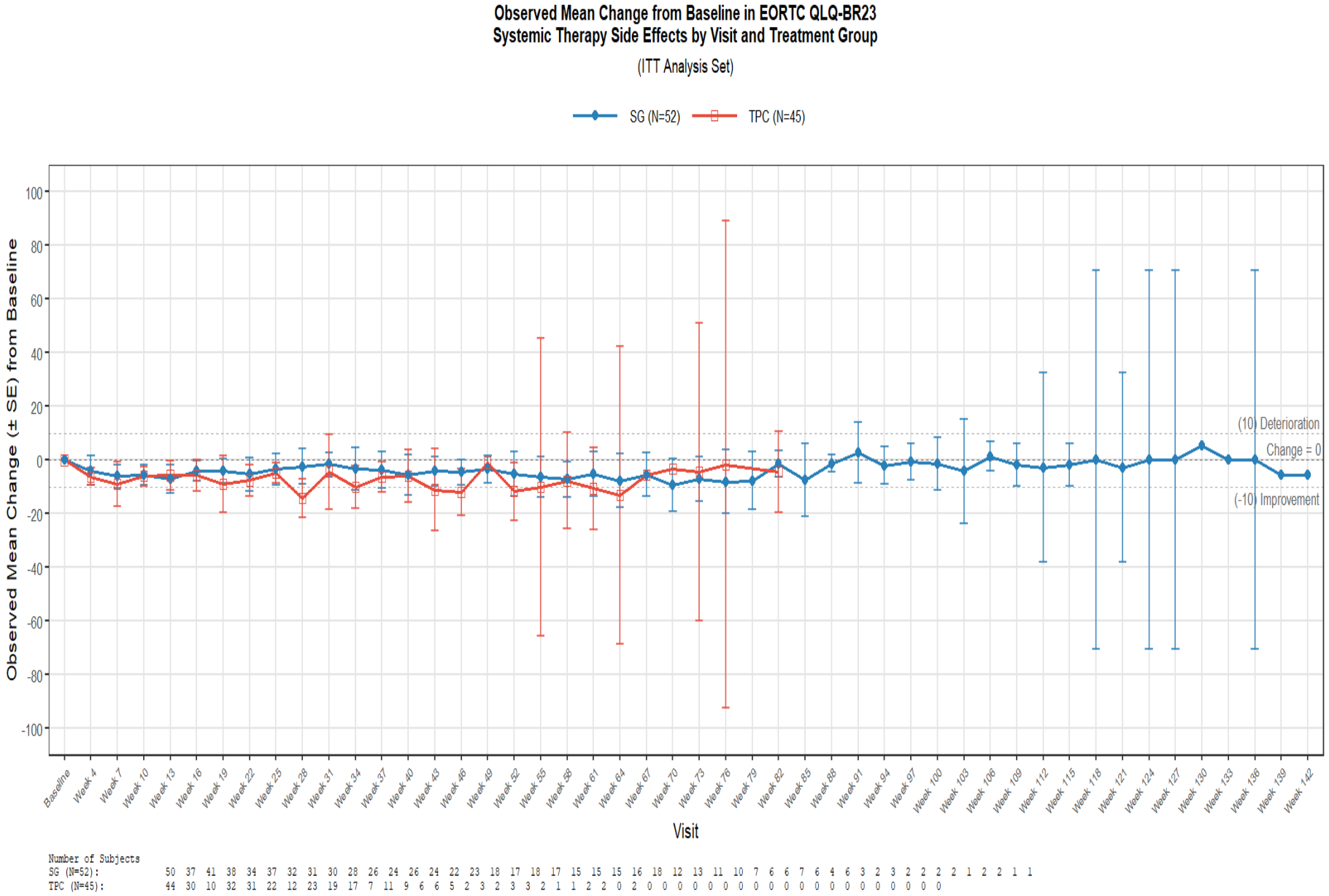
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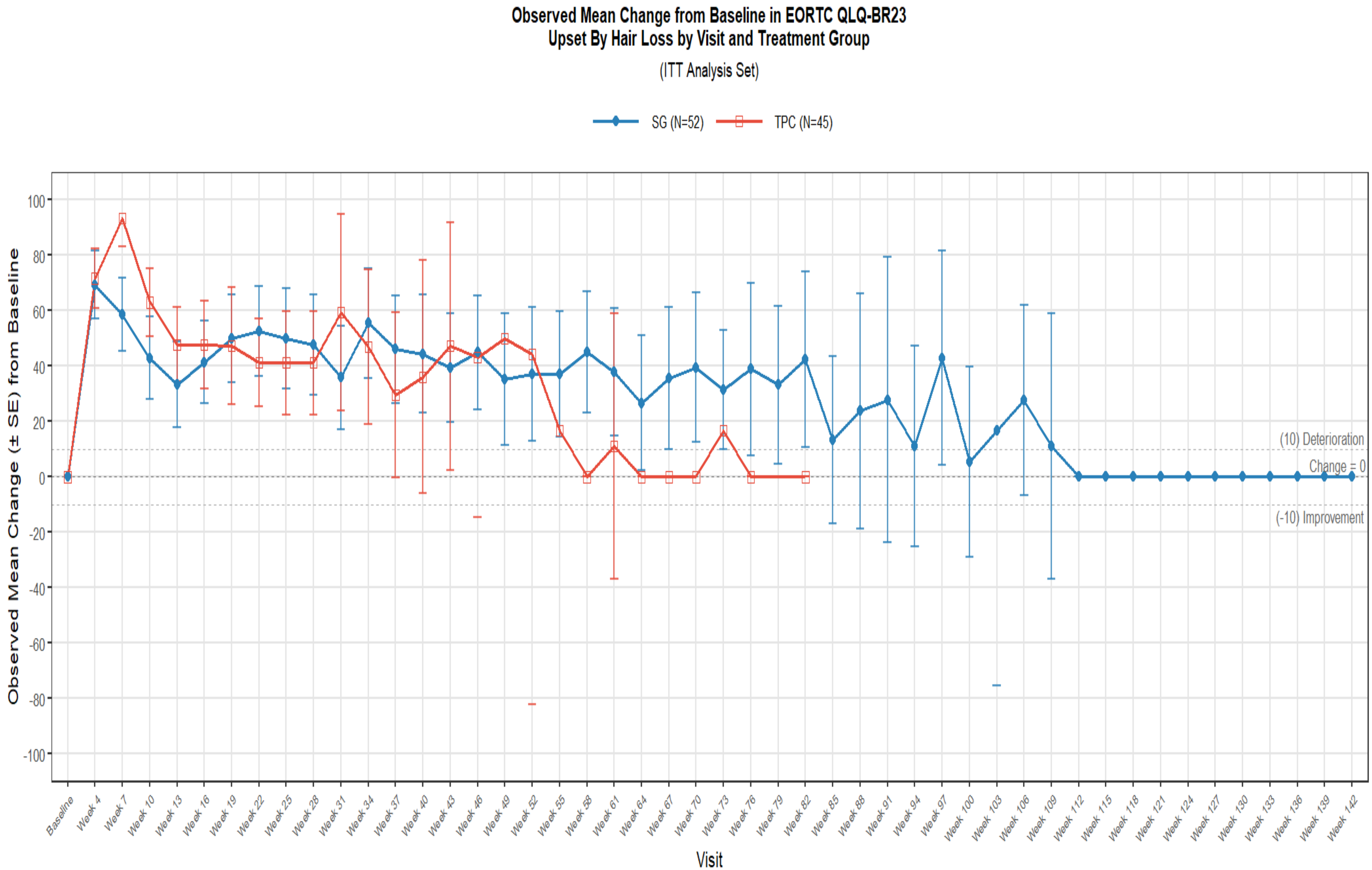
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5.22. Figure 1.1.22: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SYSTEMIC THERAPY SIDE EFFECTS — mITT — Excluding patients preselected to receive nab-paclitaxel or gemcitabine+carboplatin

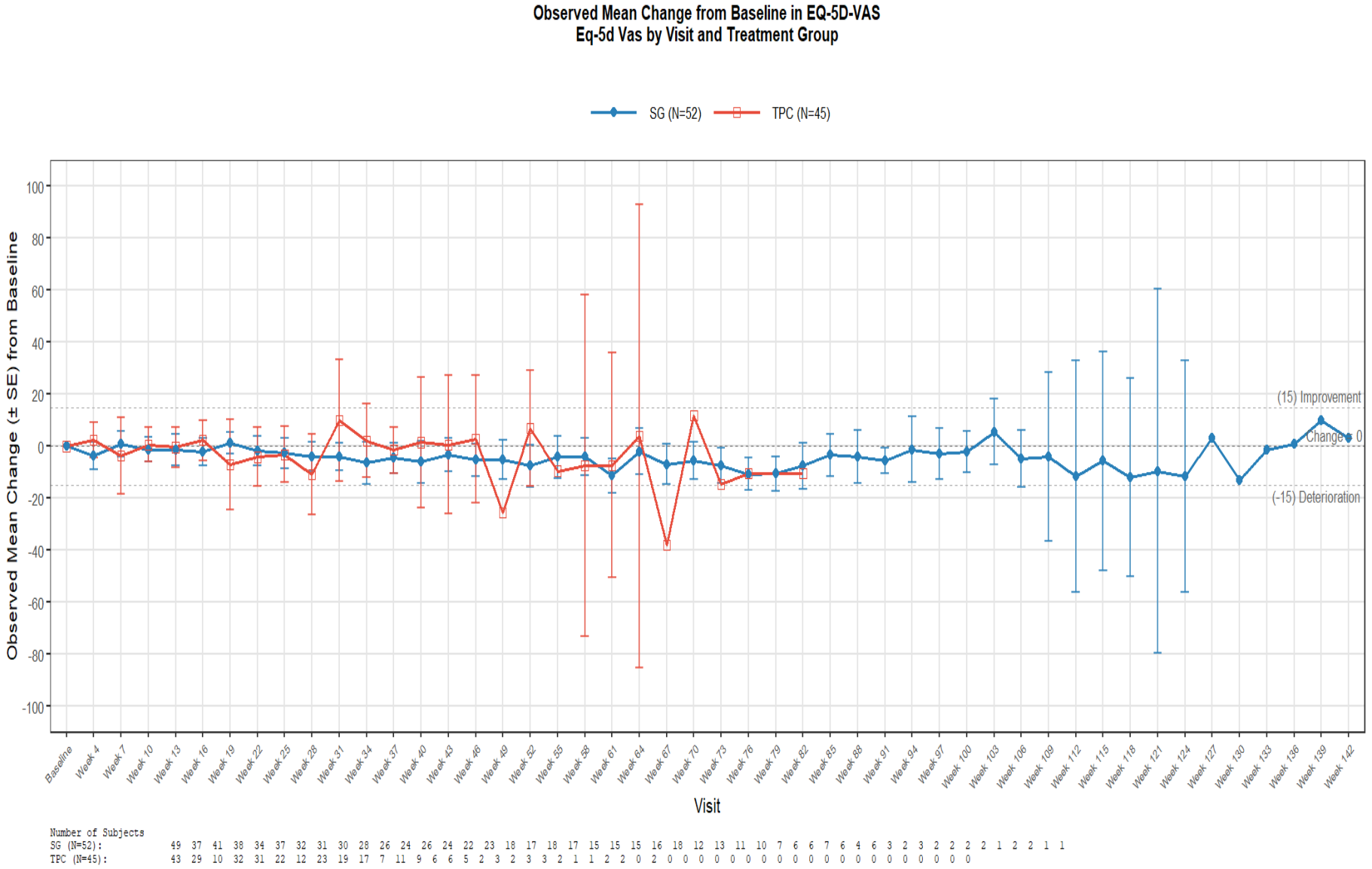


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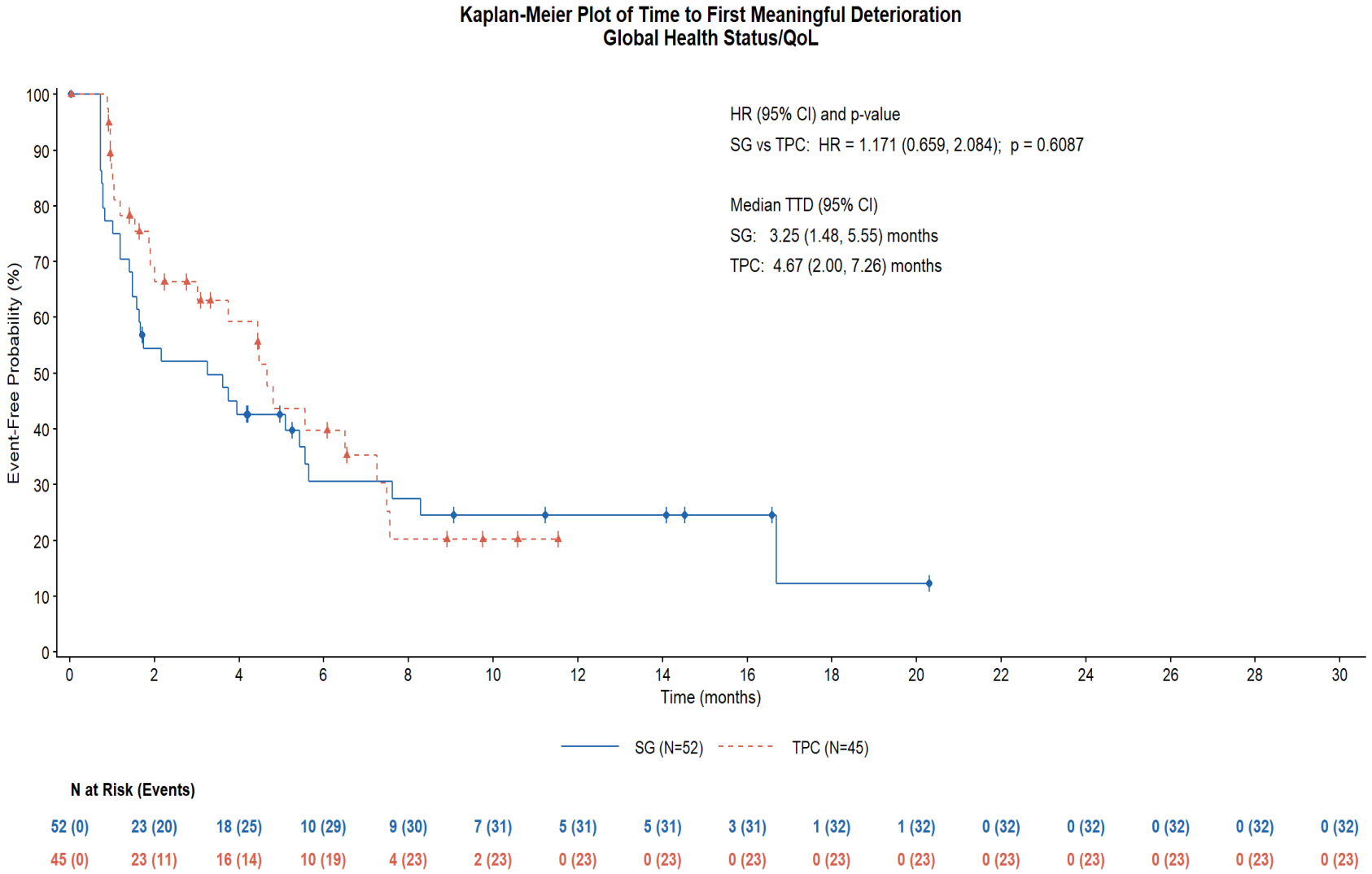


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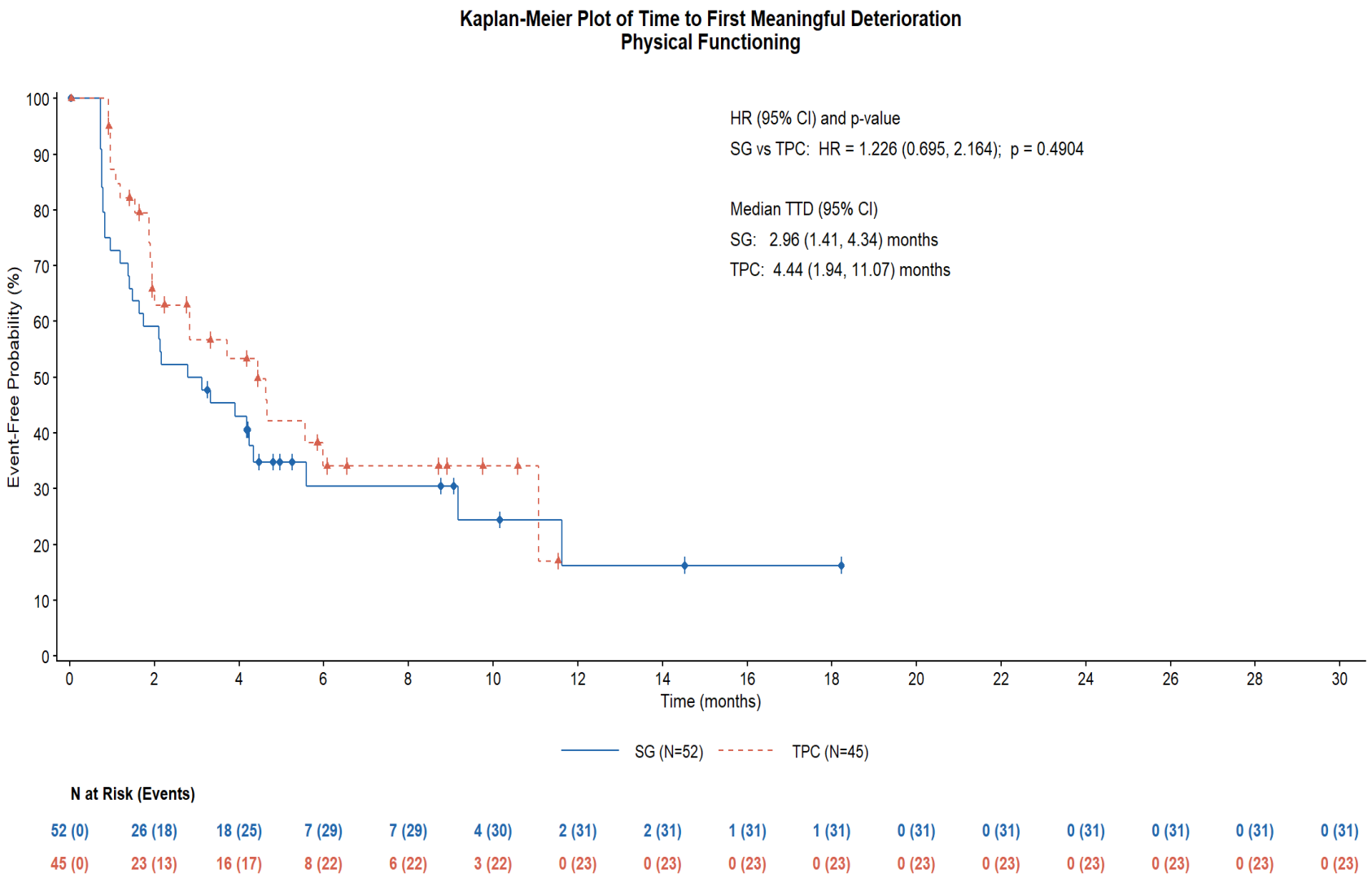
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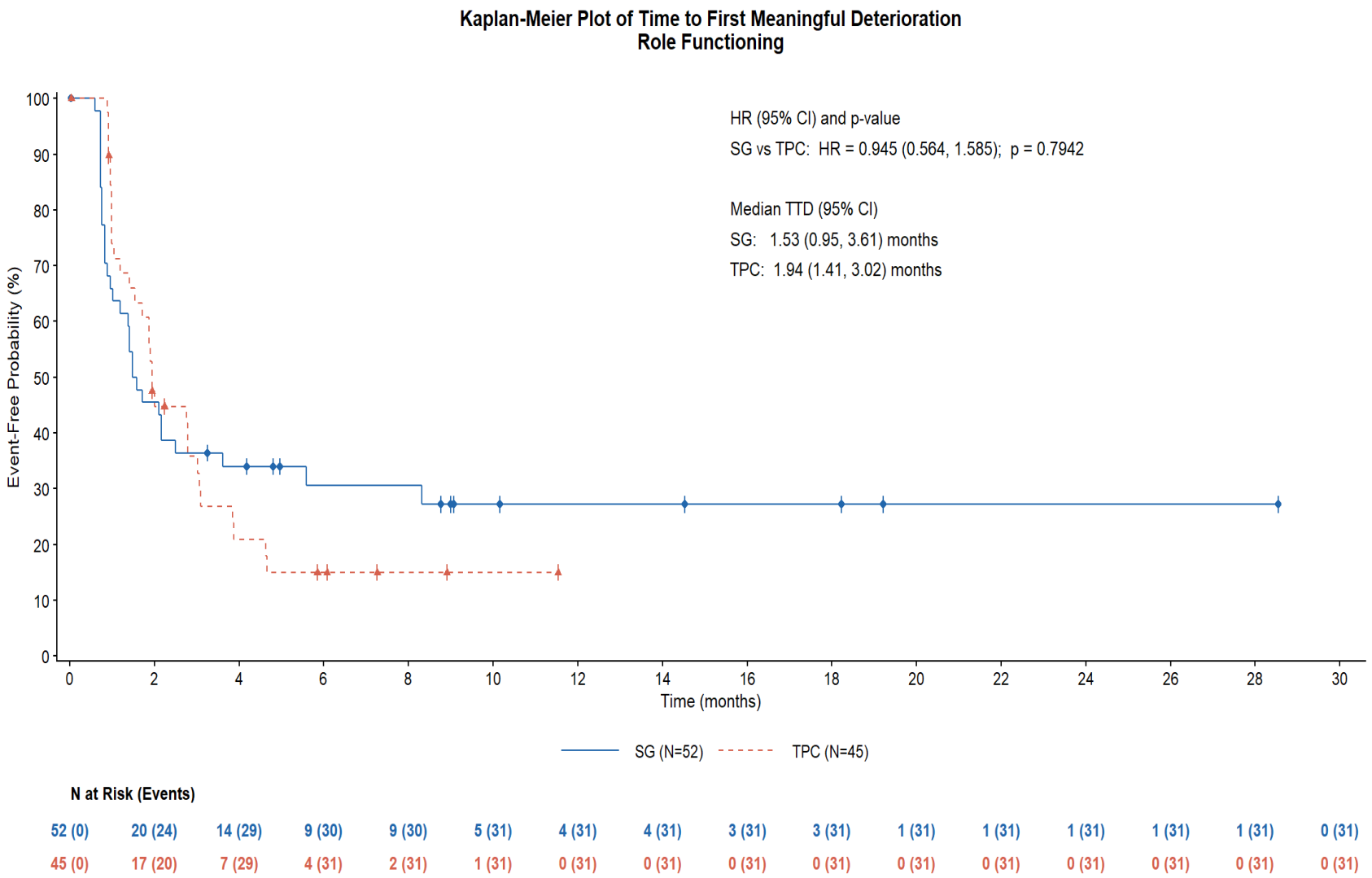
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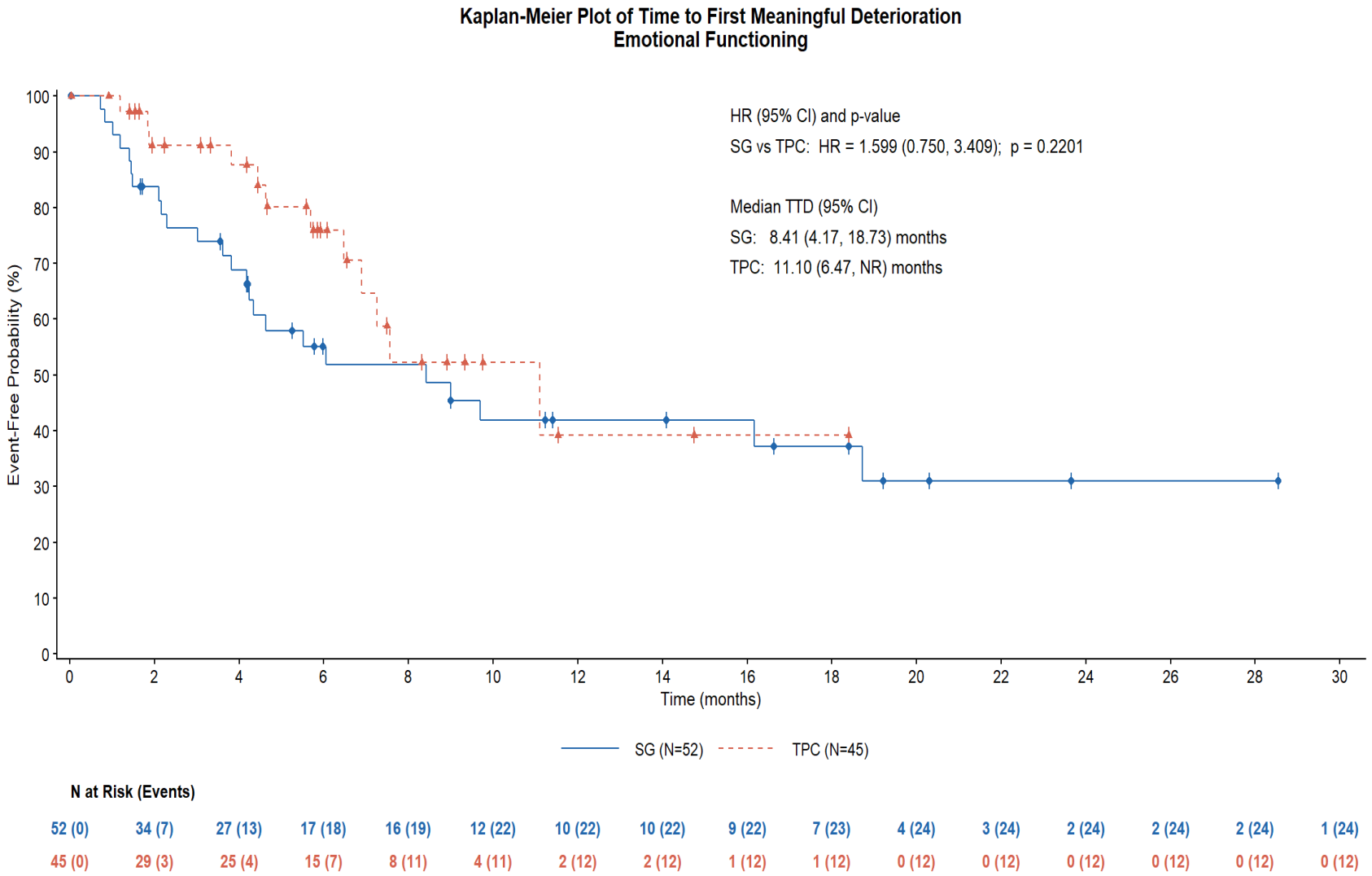
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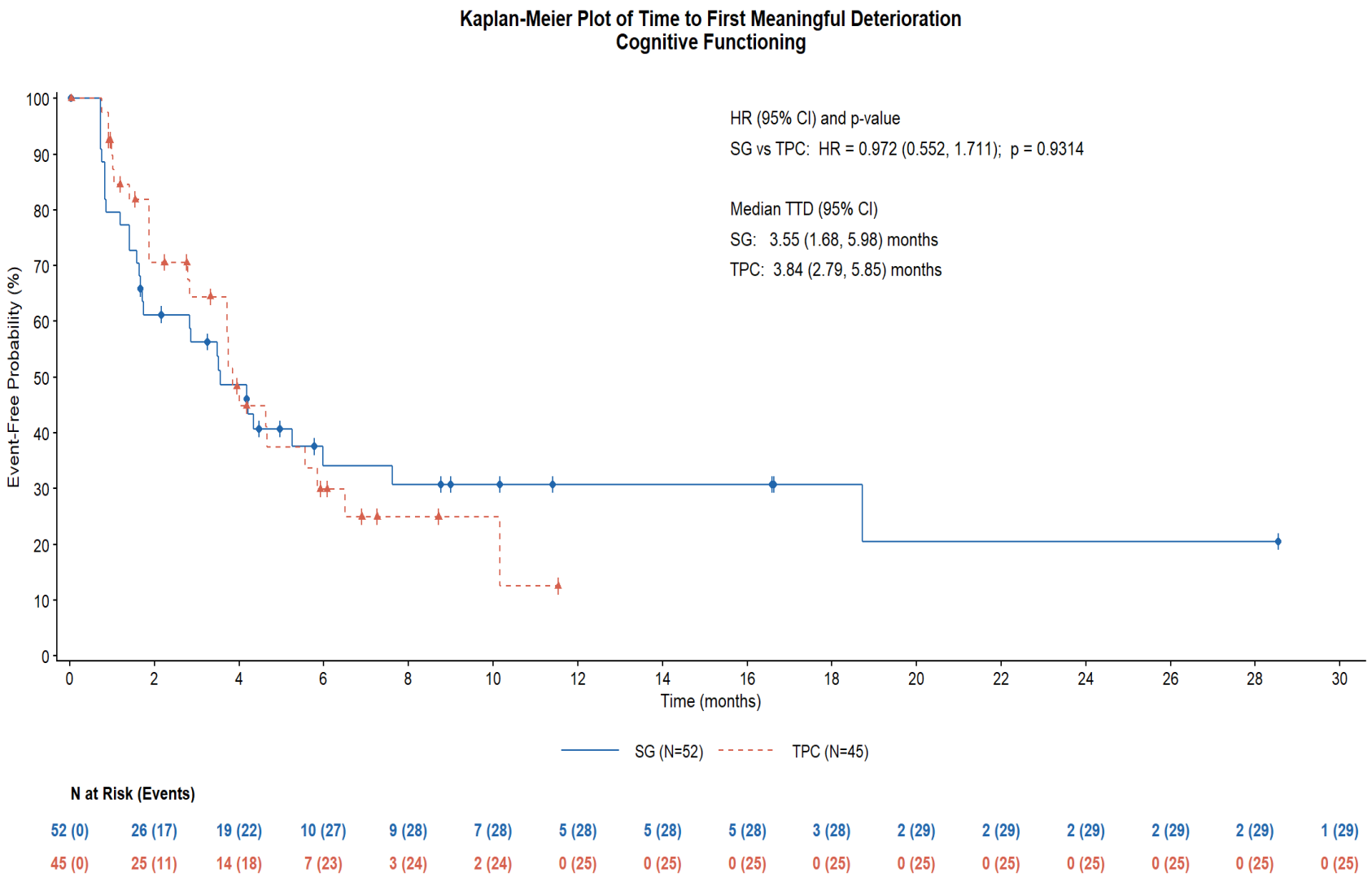
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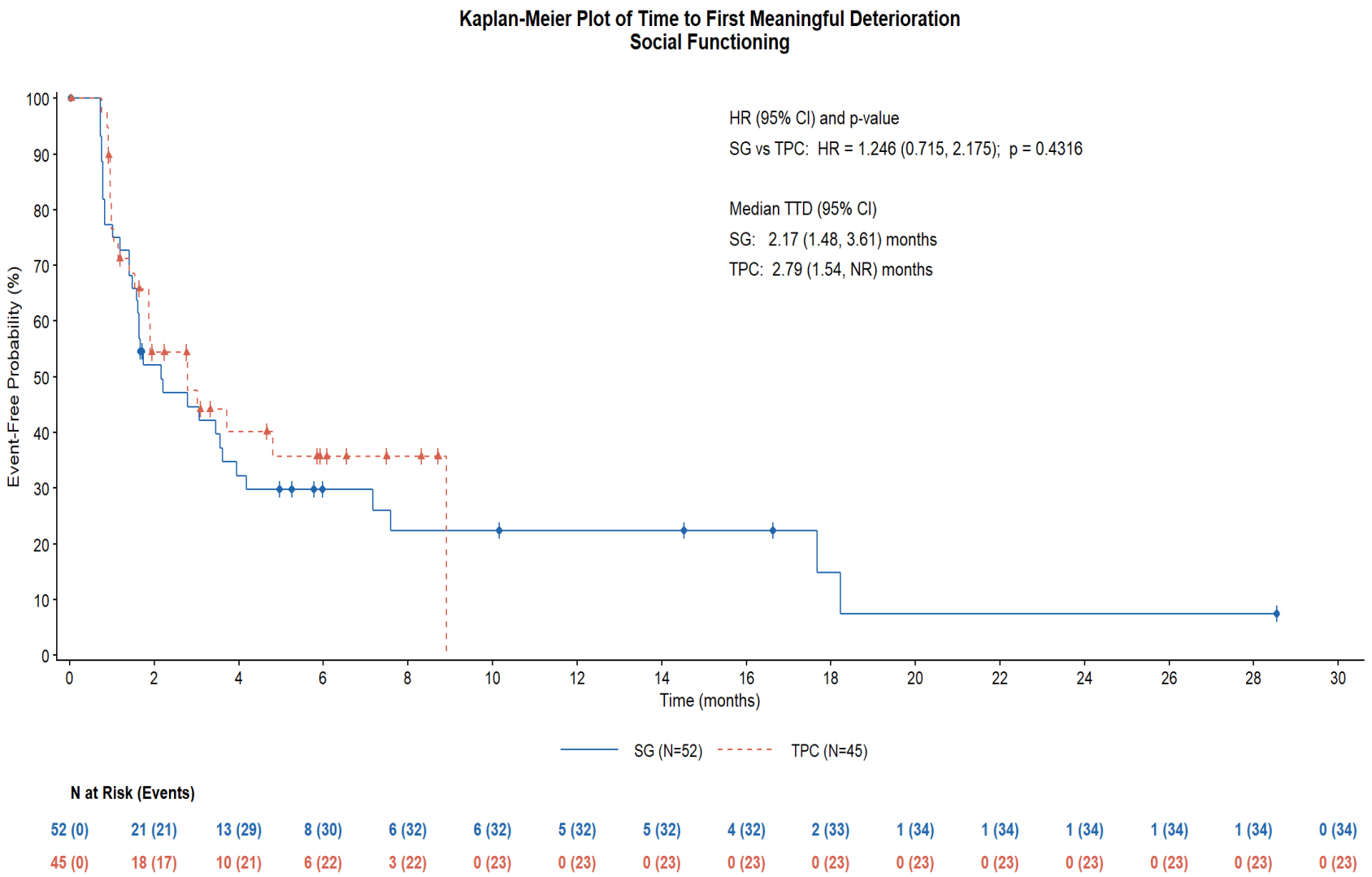
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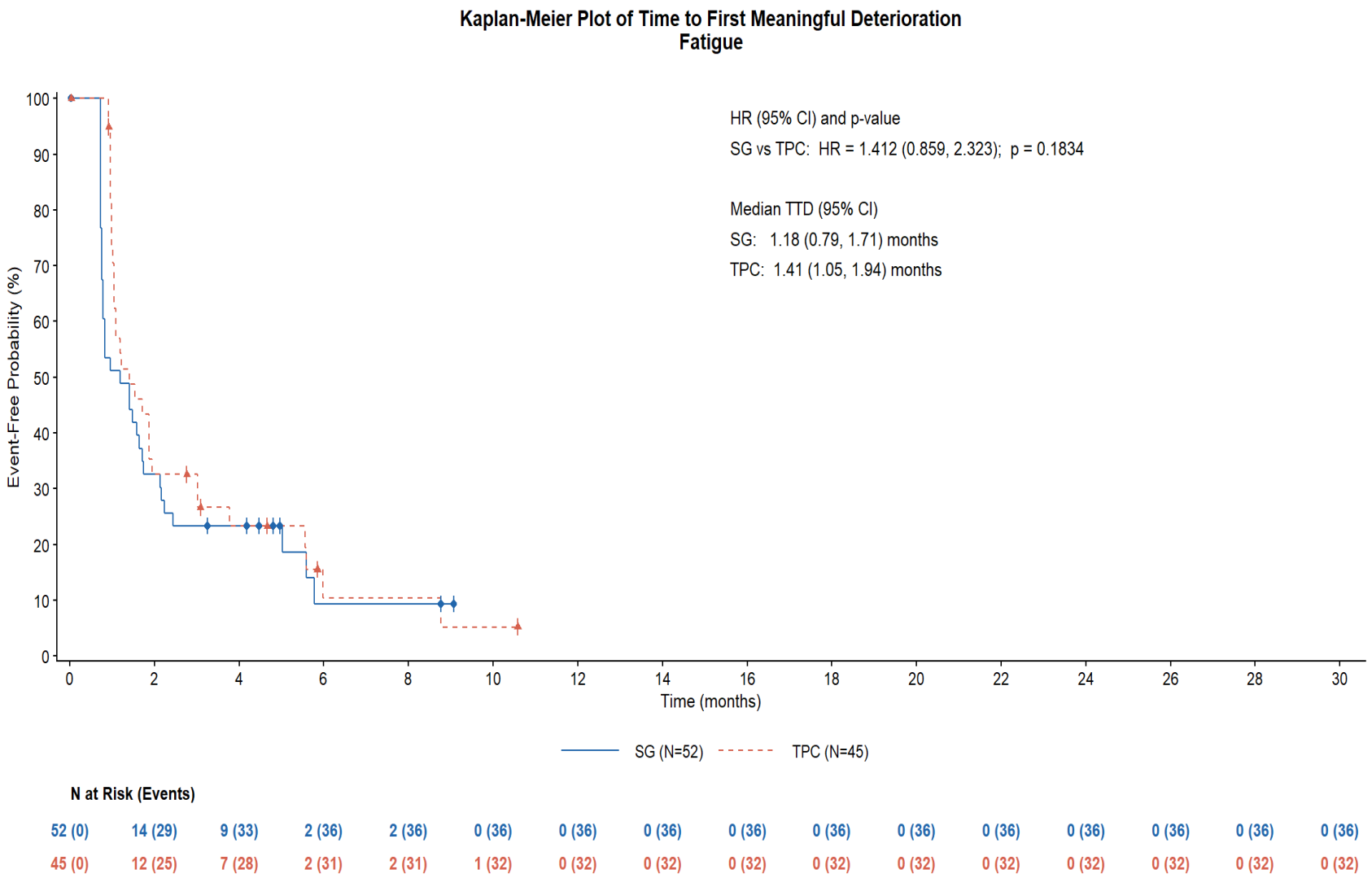
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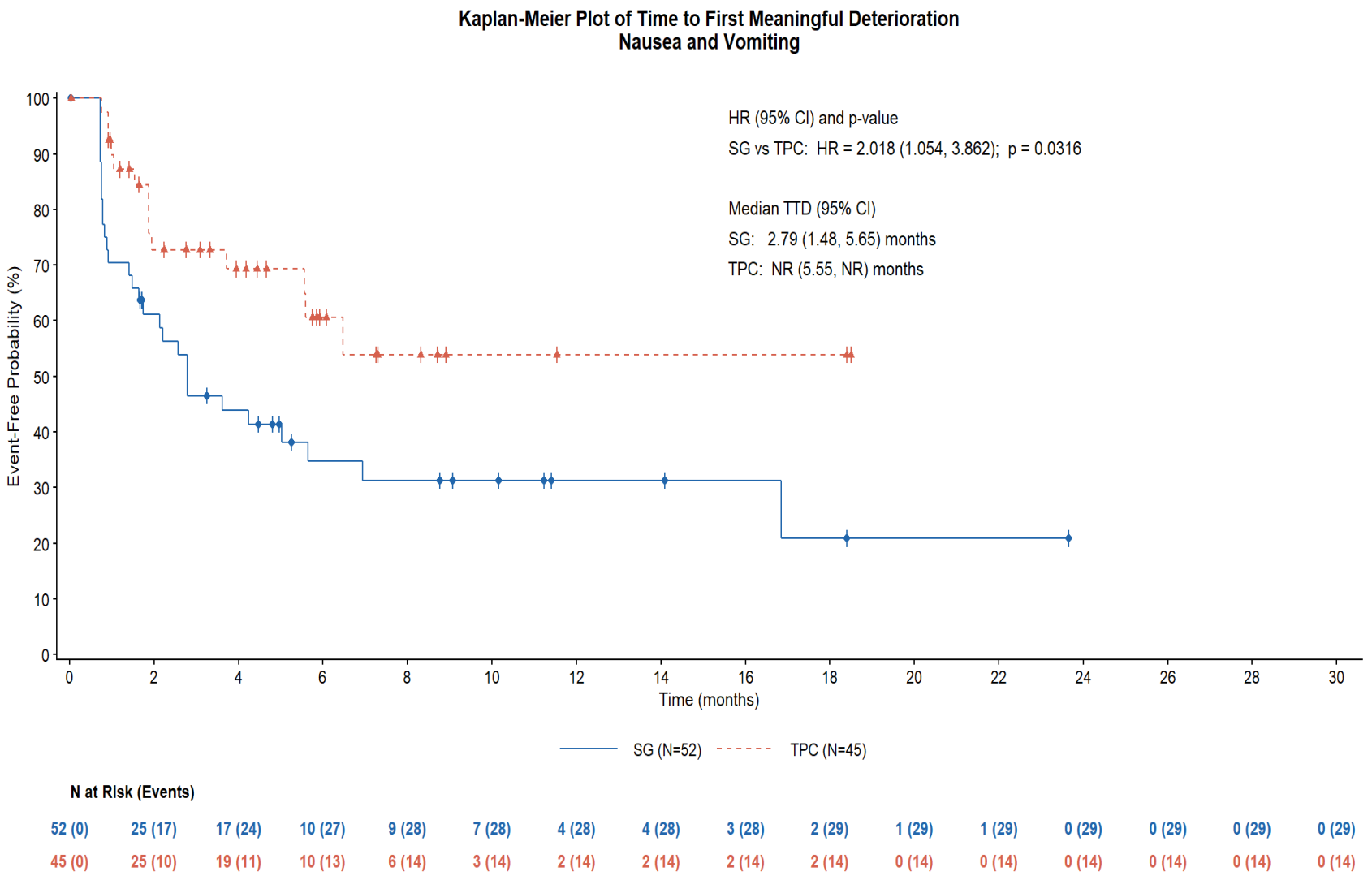
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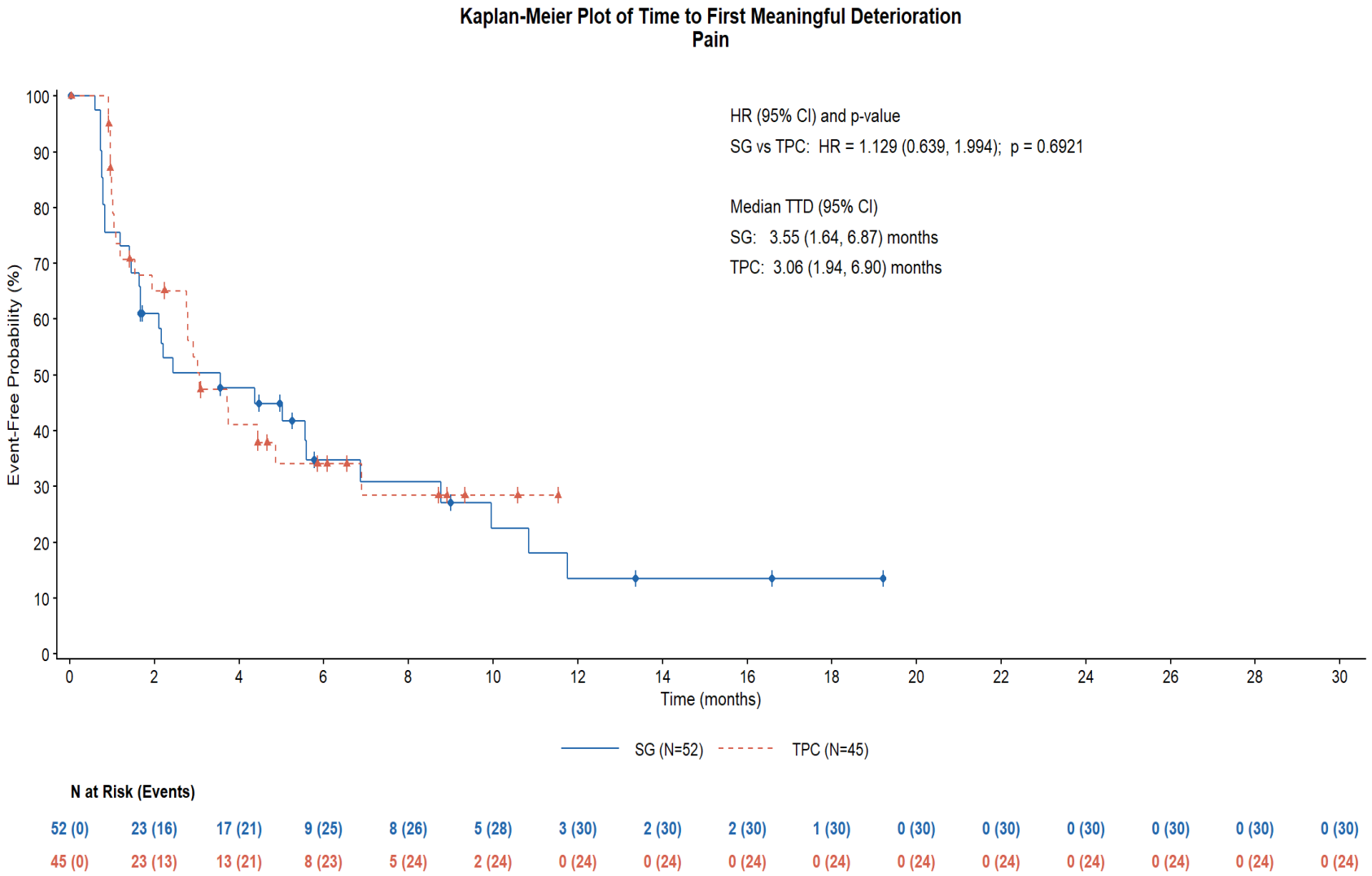
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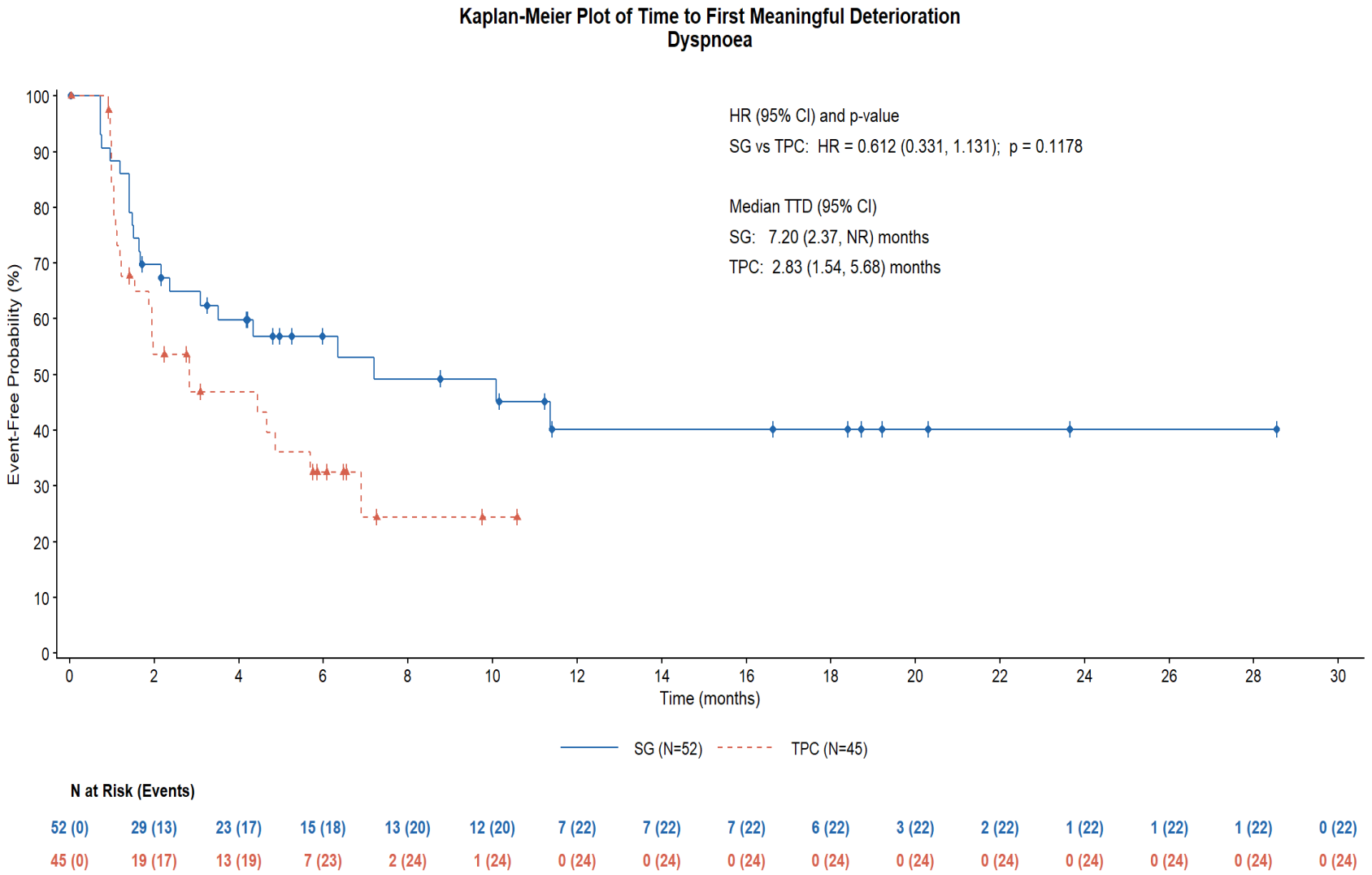
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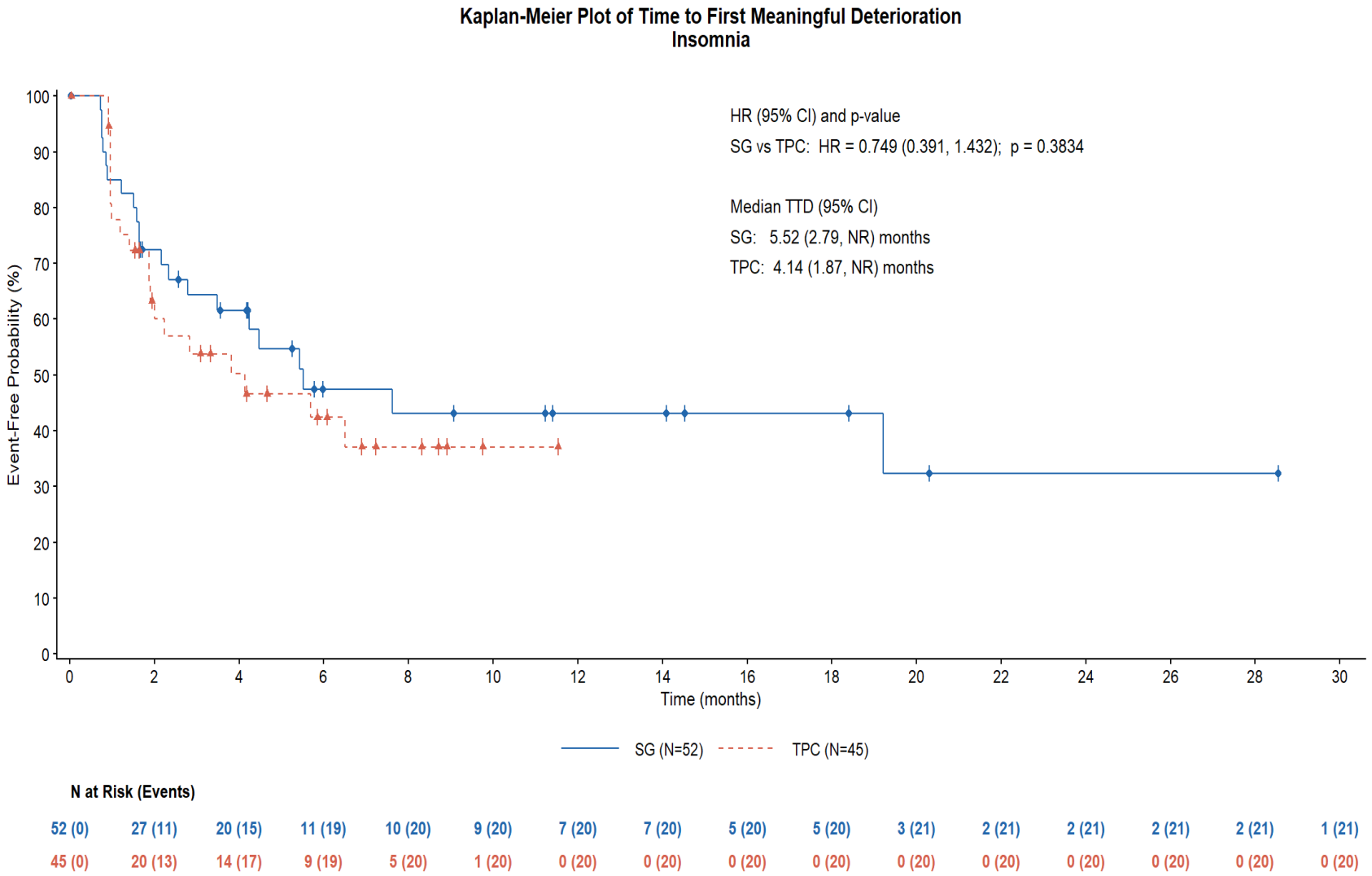
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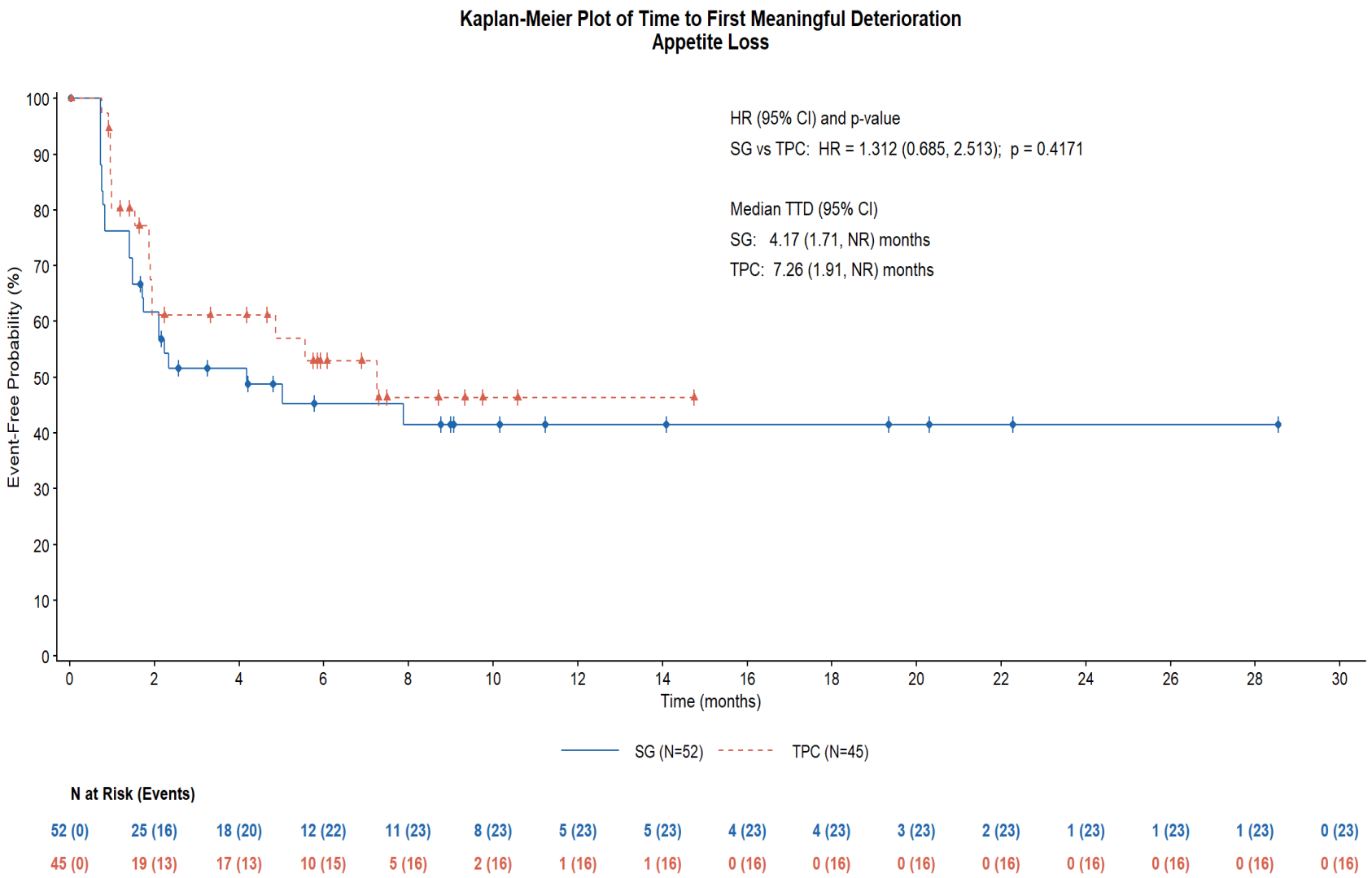
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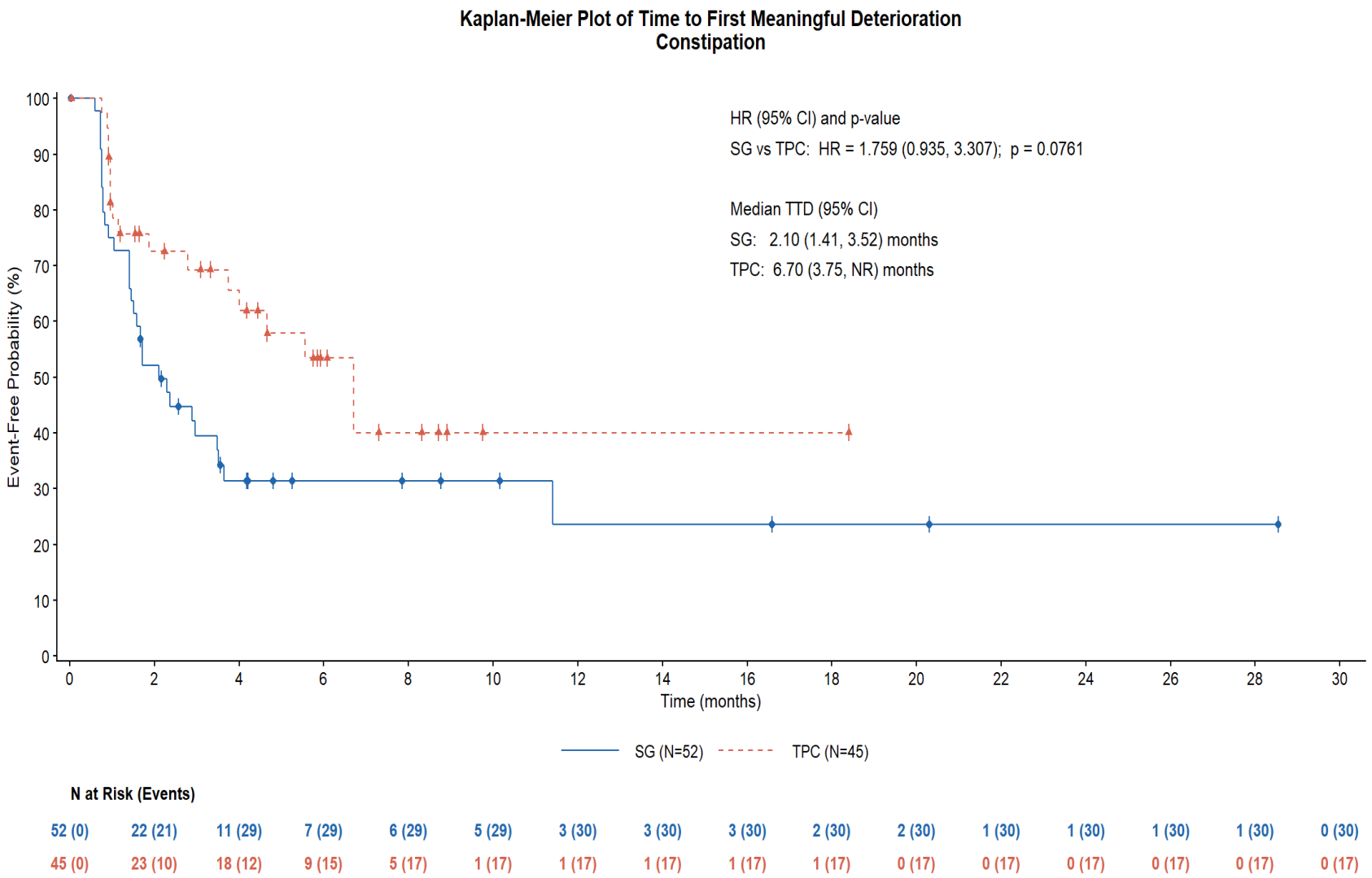
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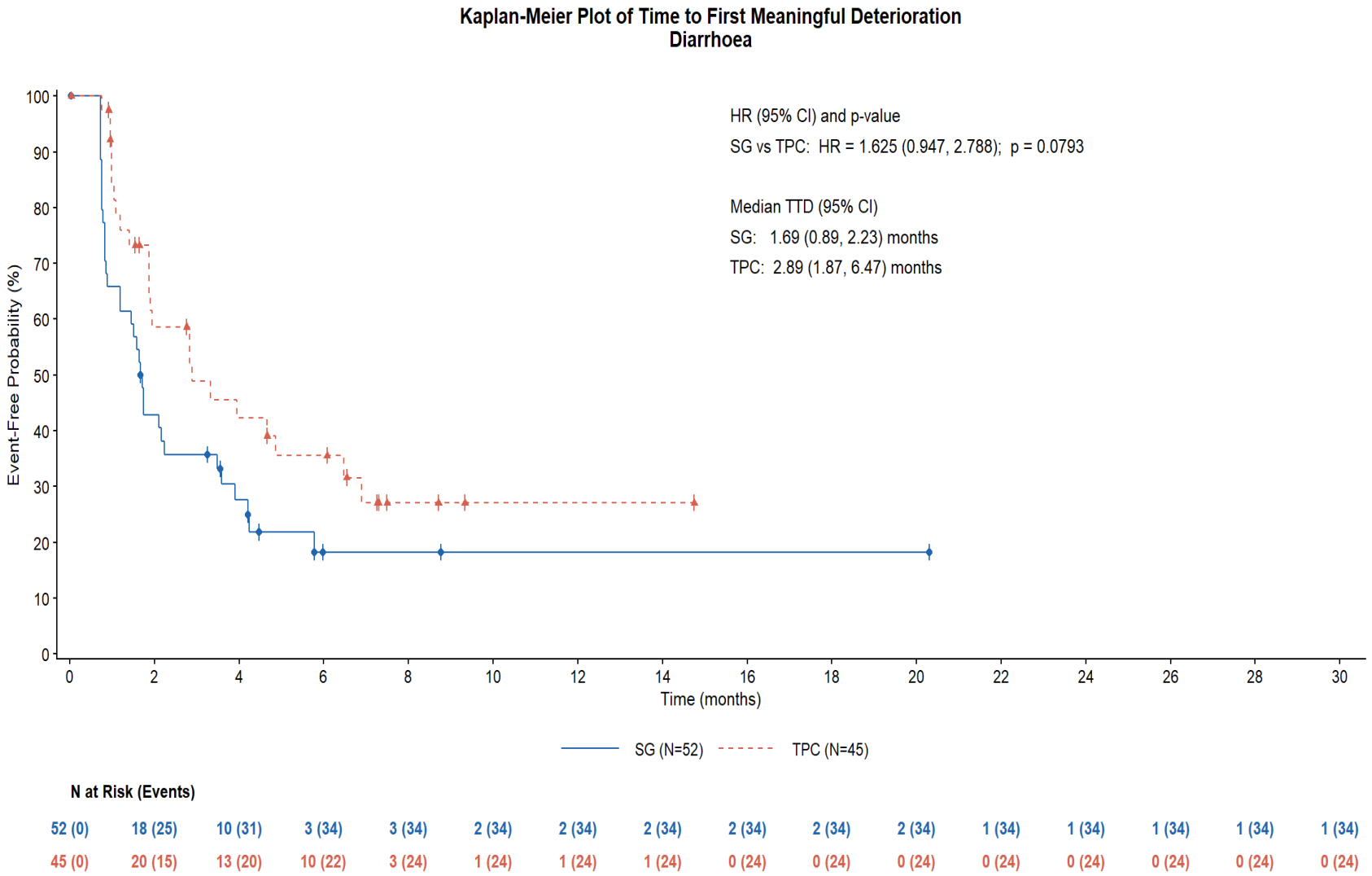
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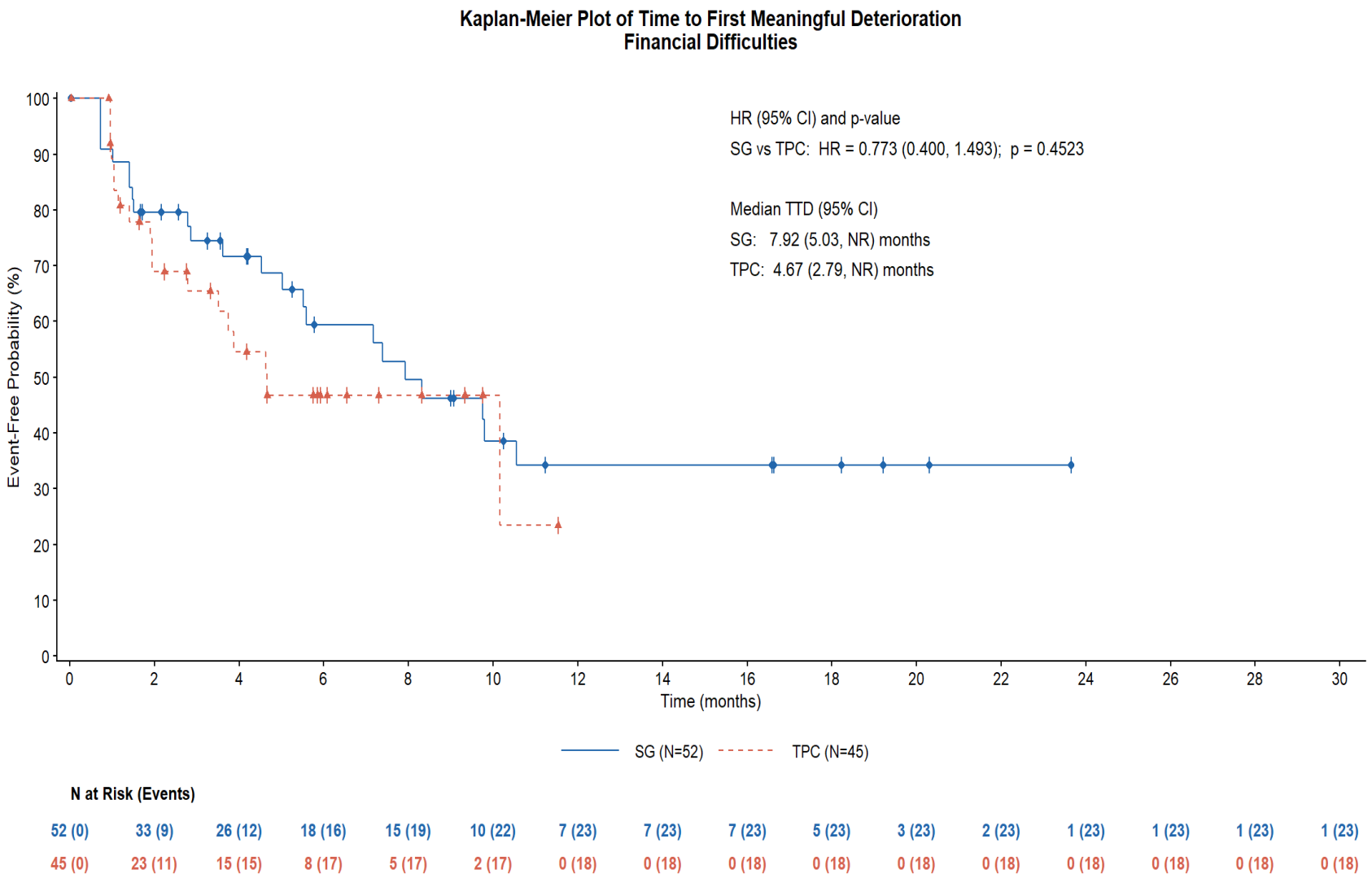
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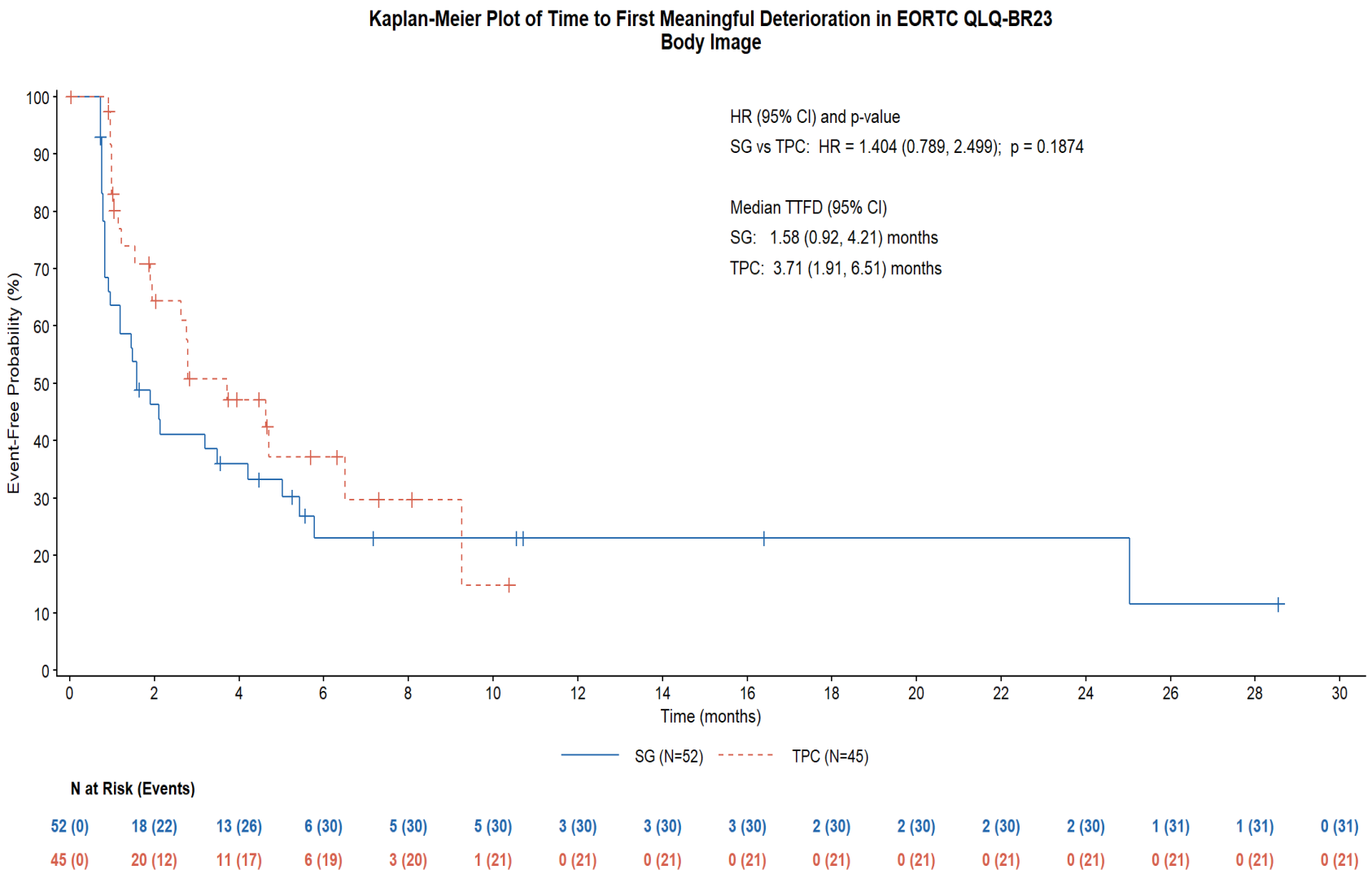
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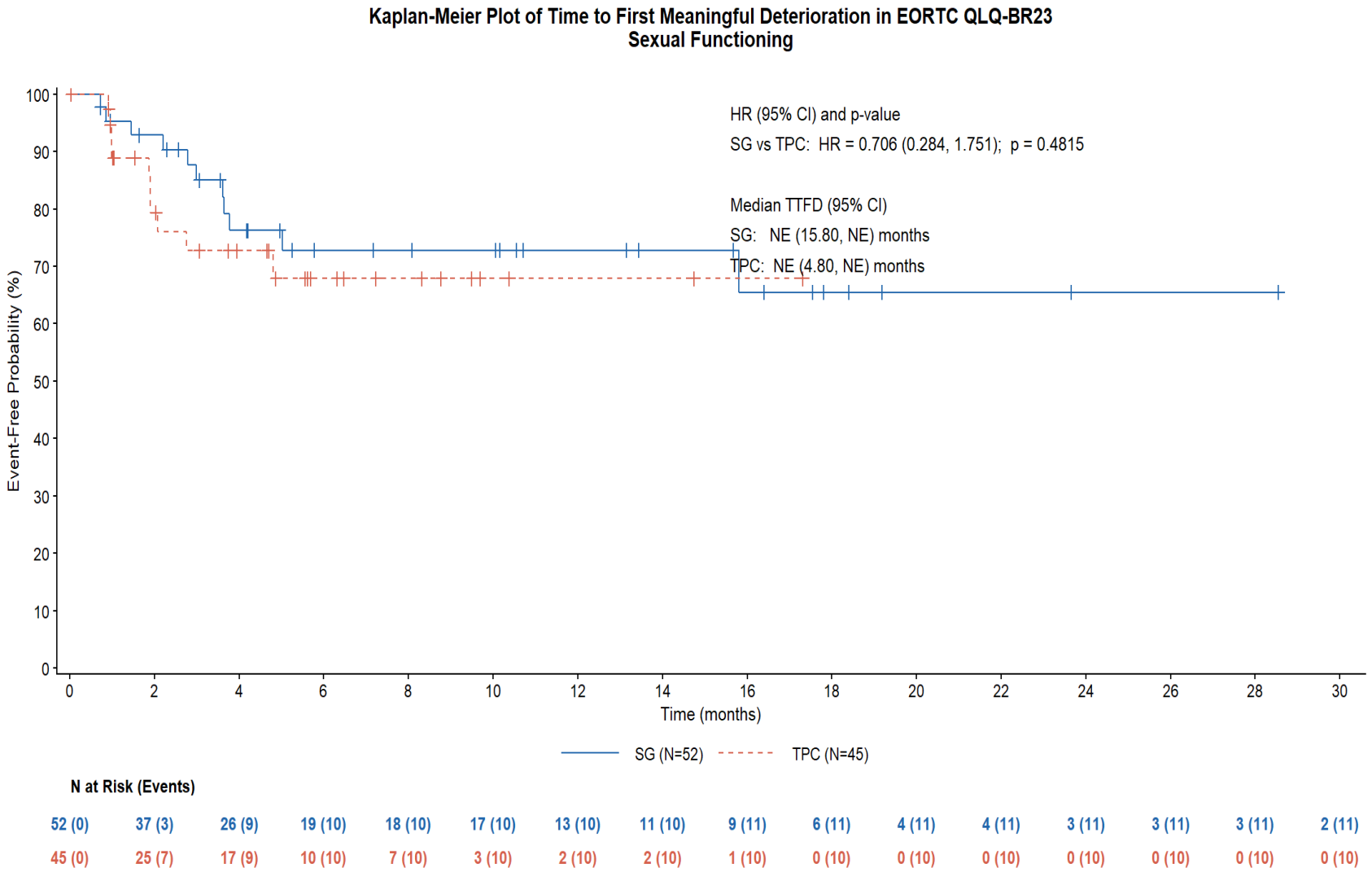
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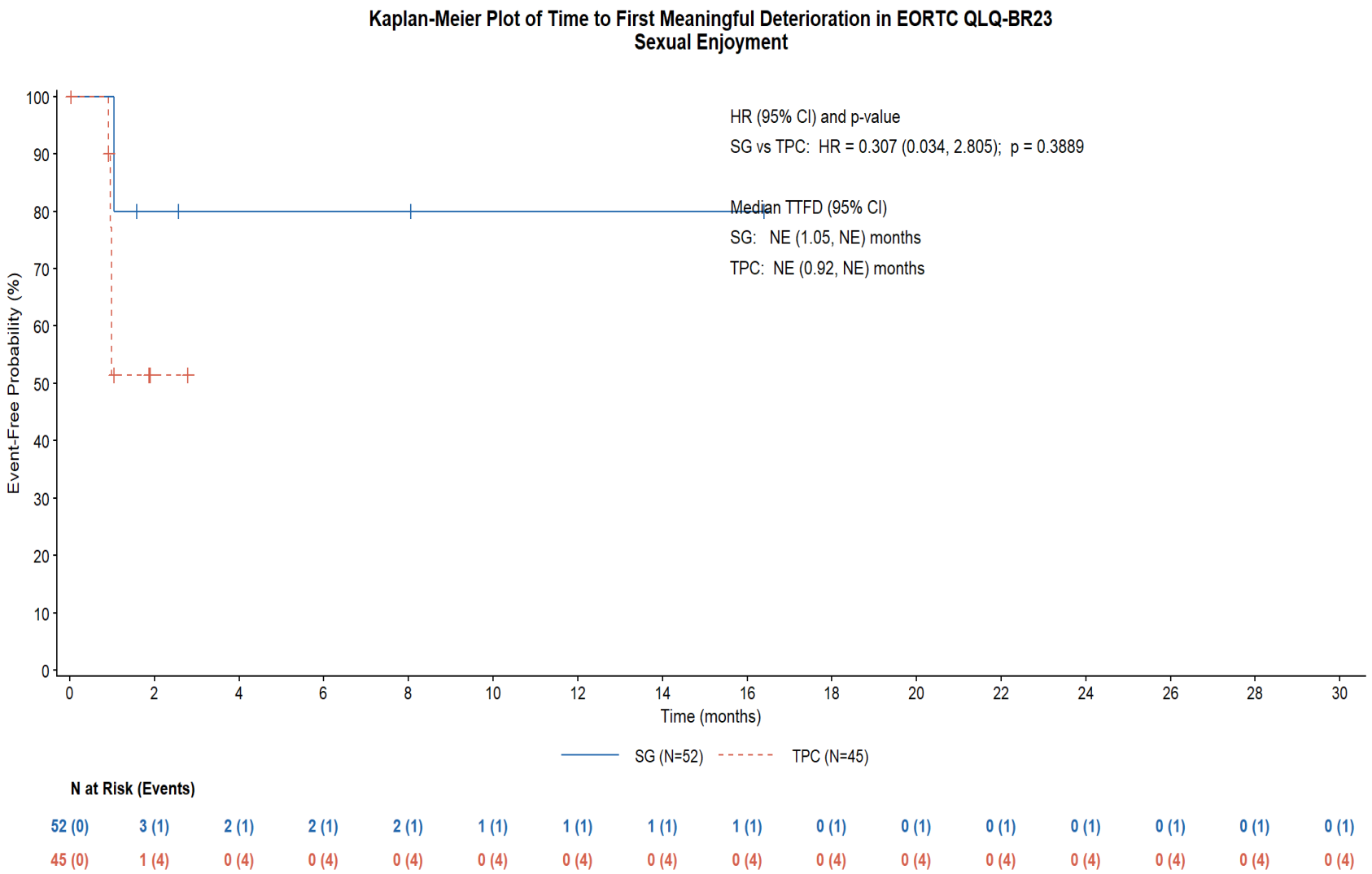
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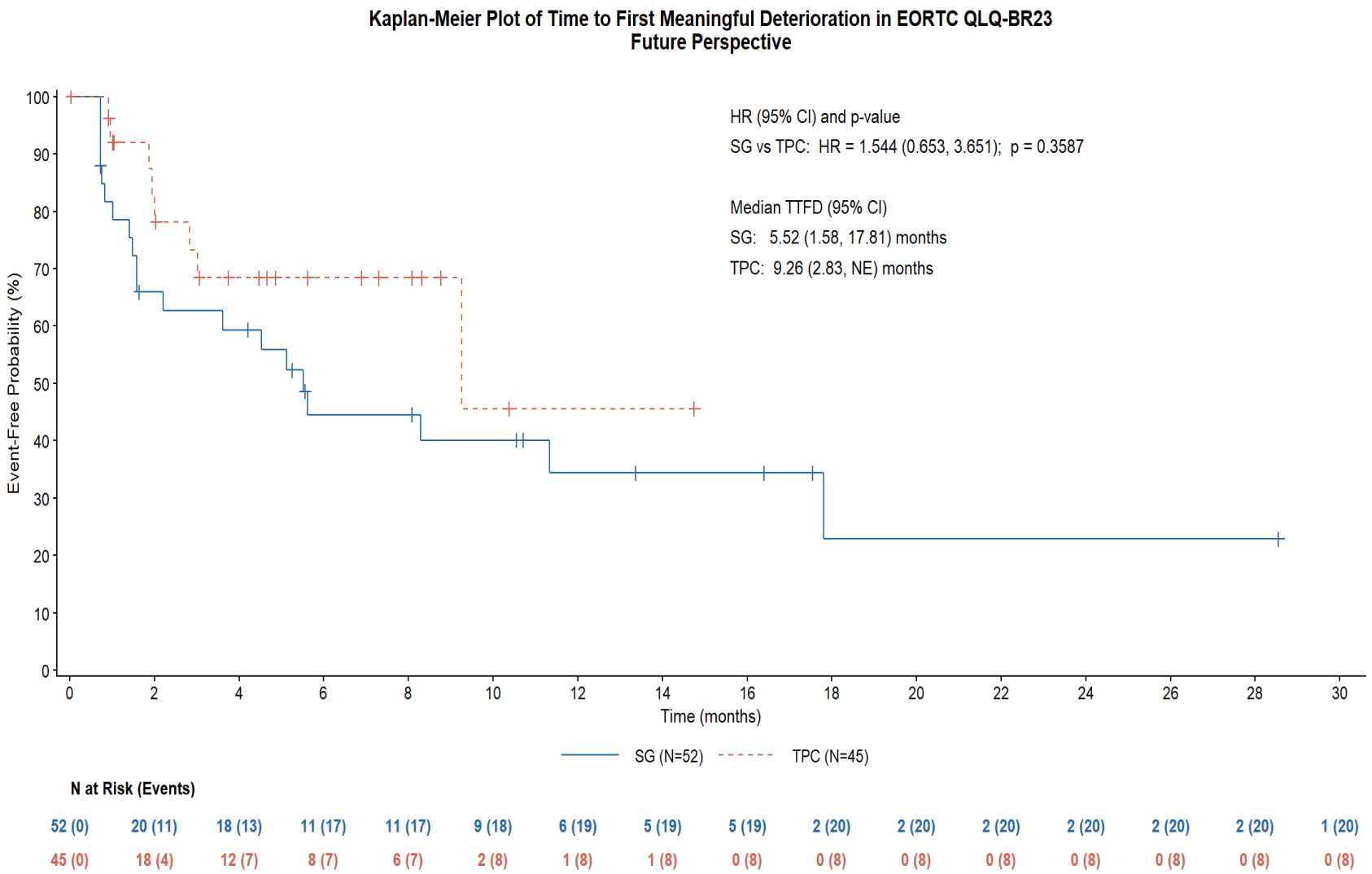
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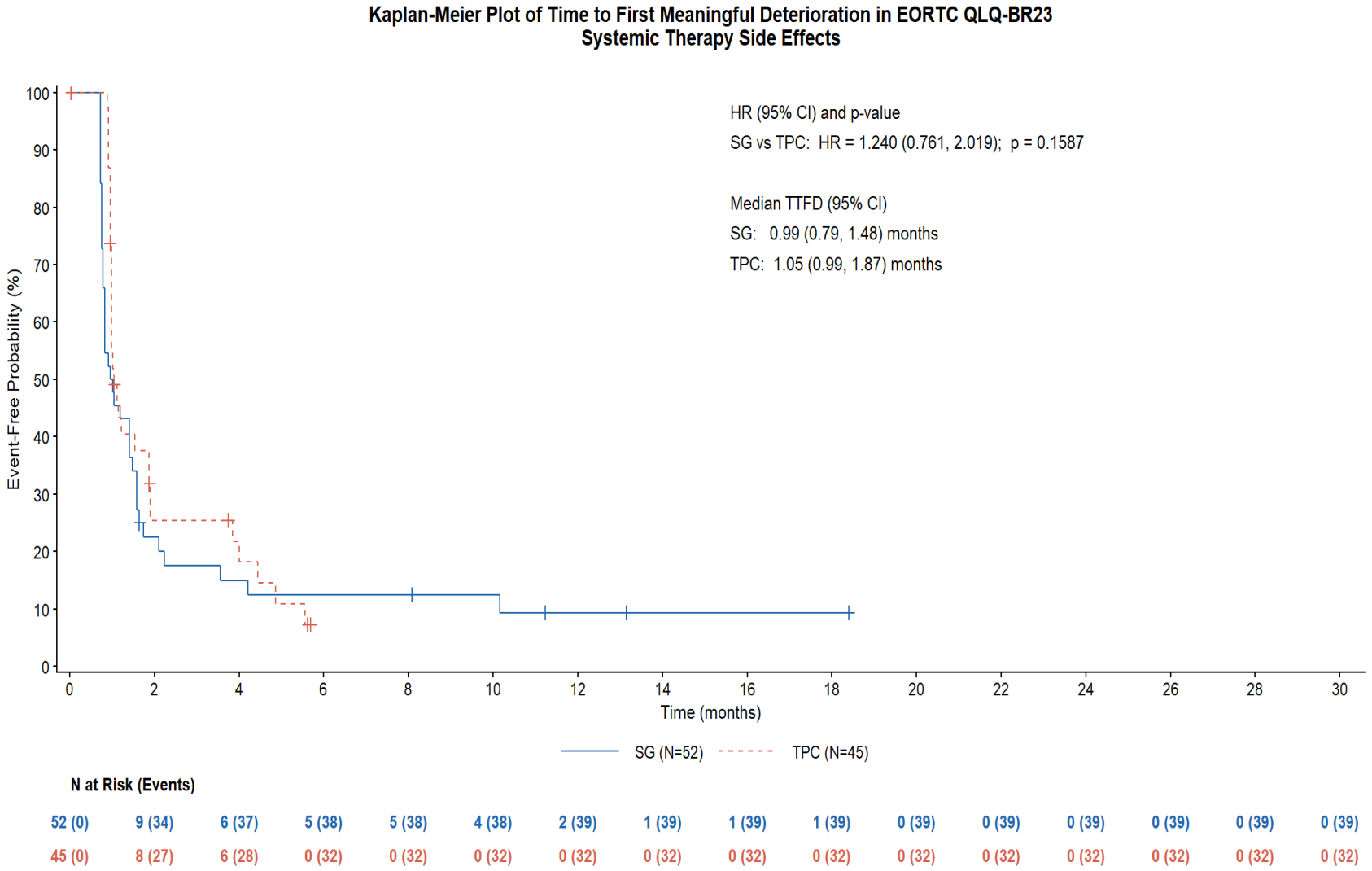
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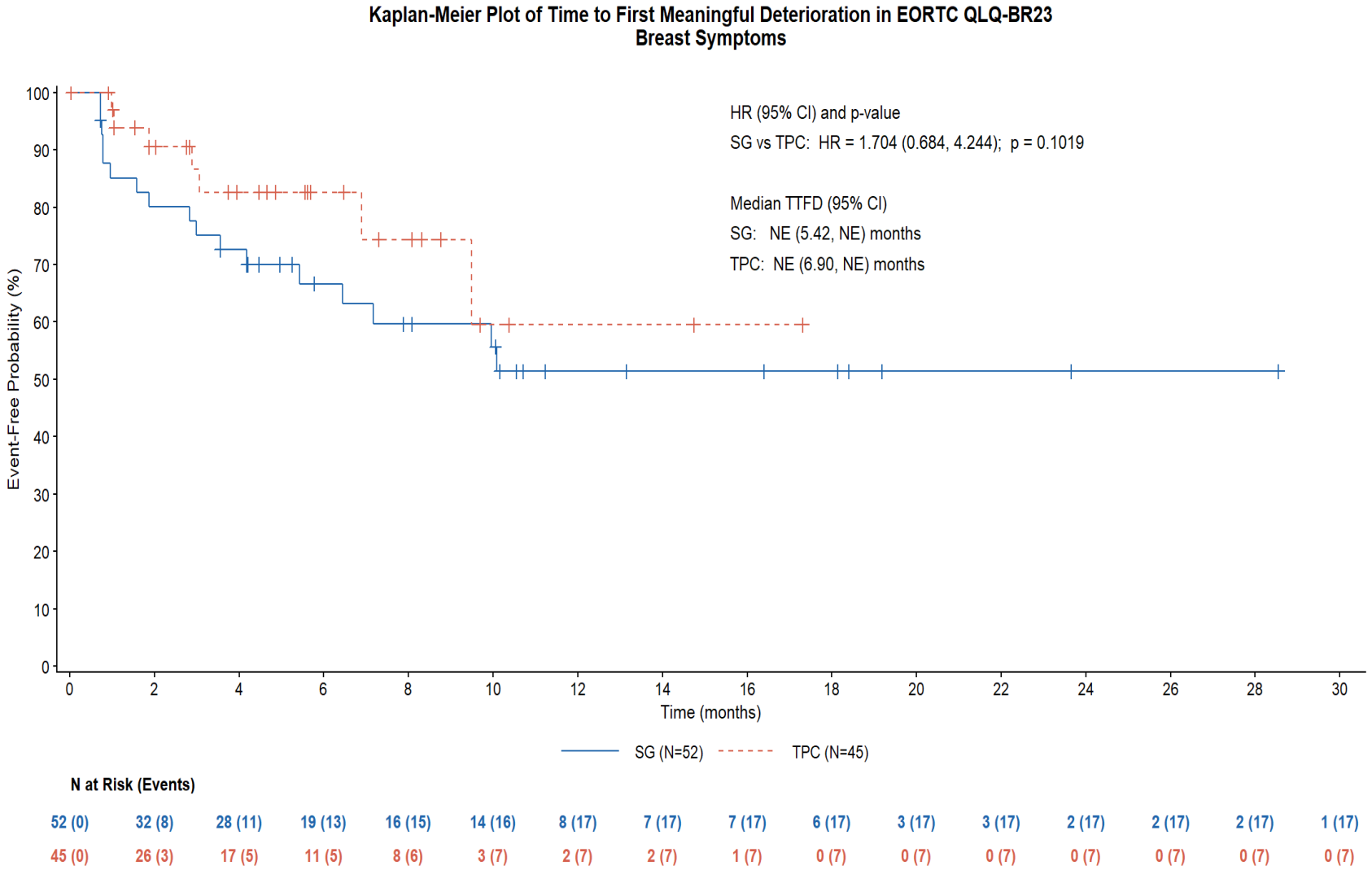
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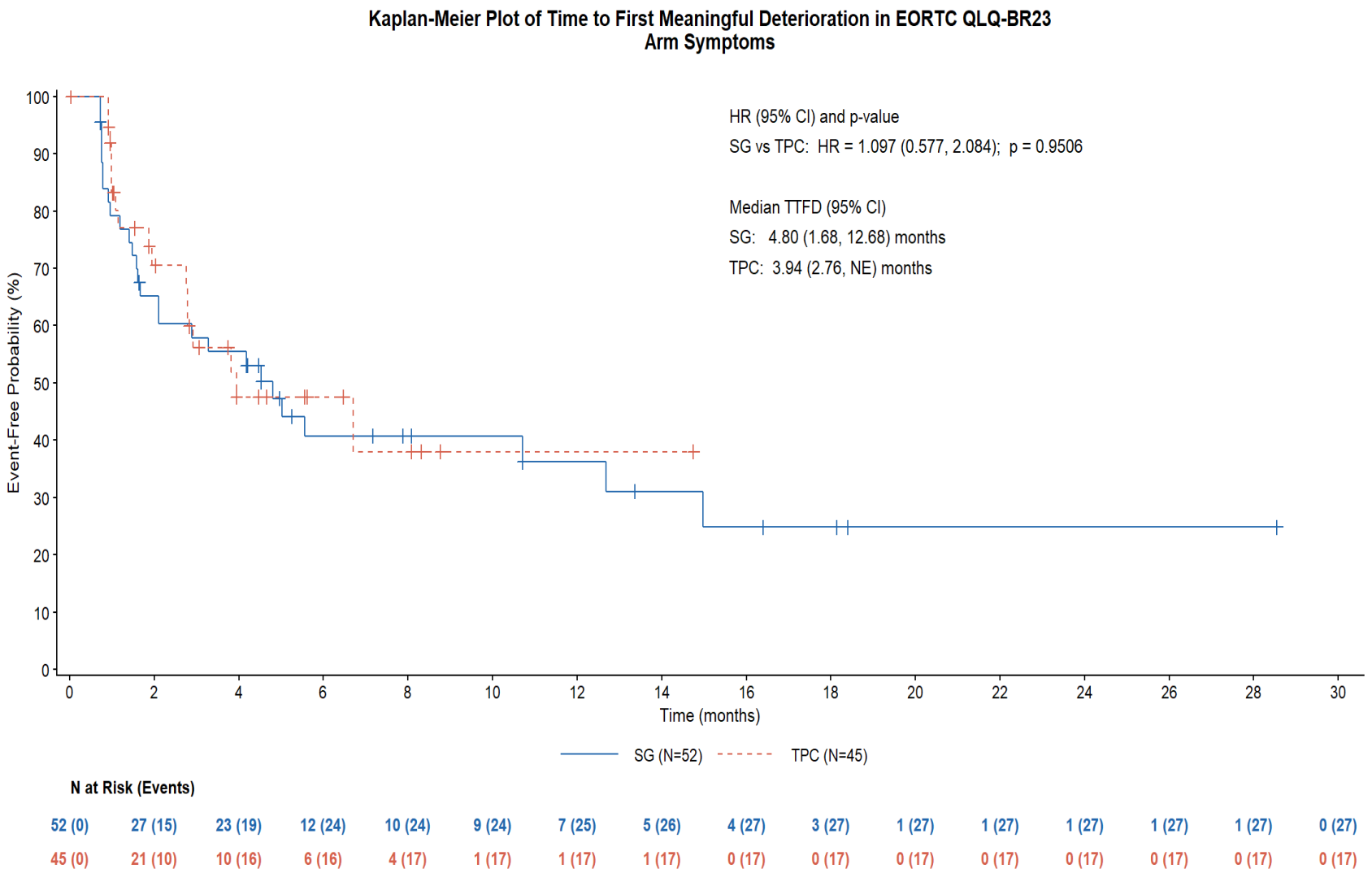
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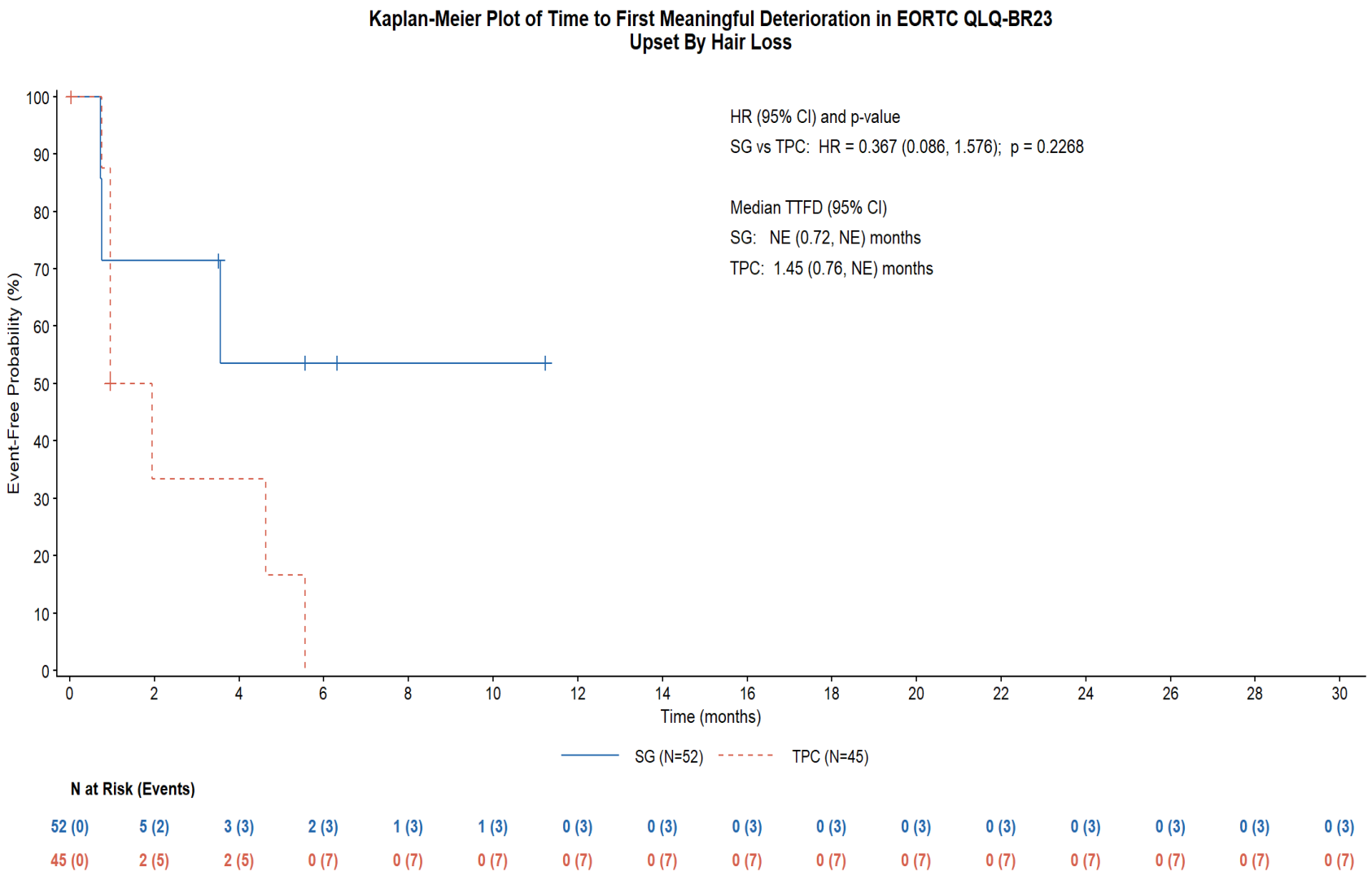
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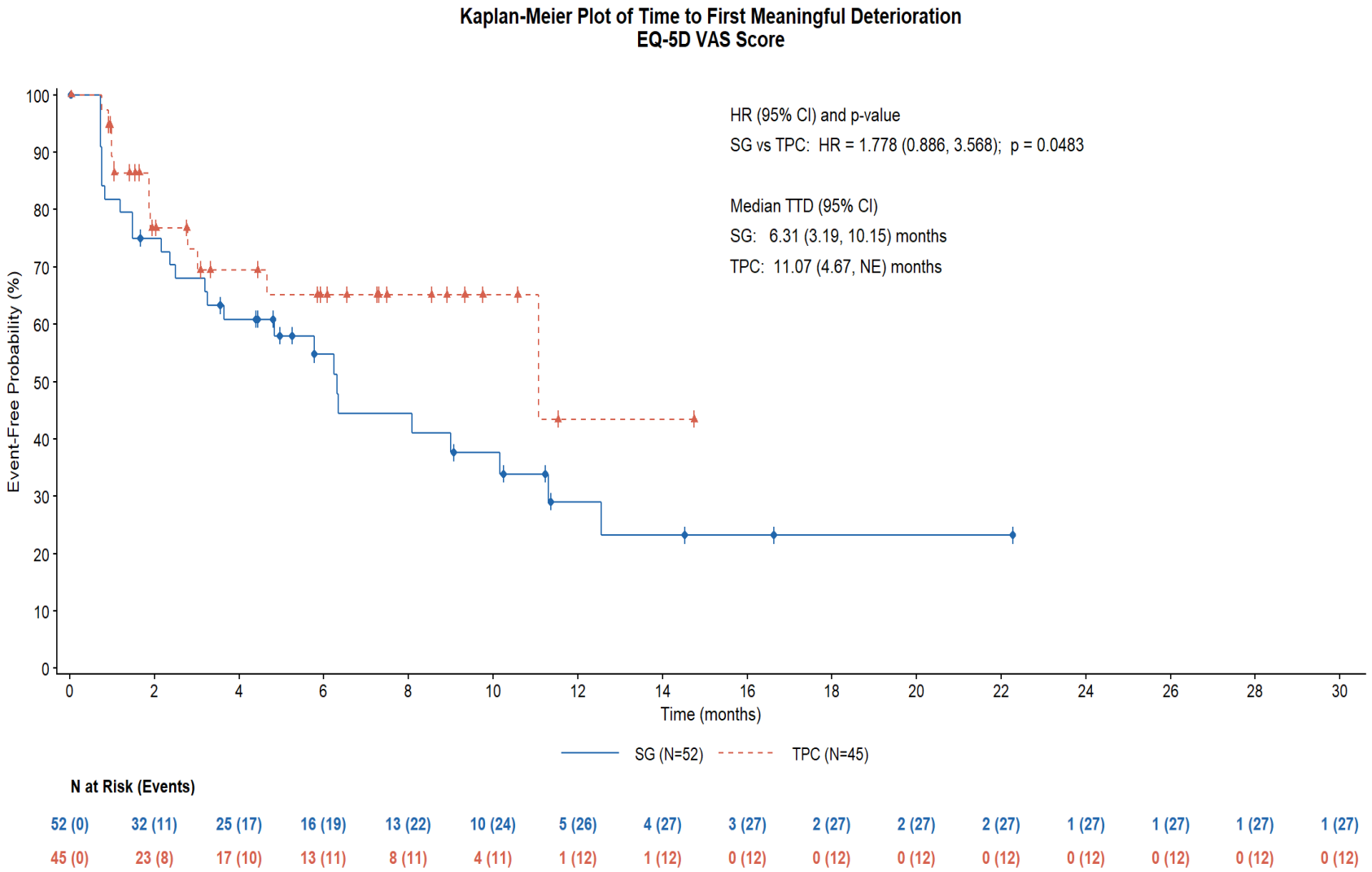
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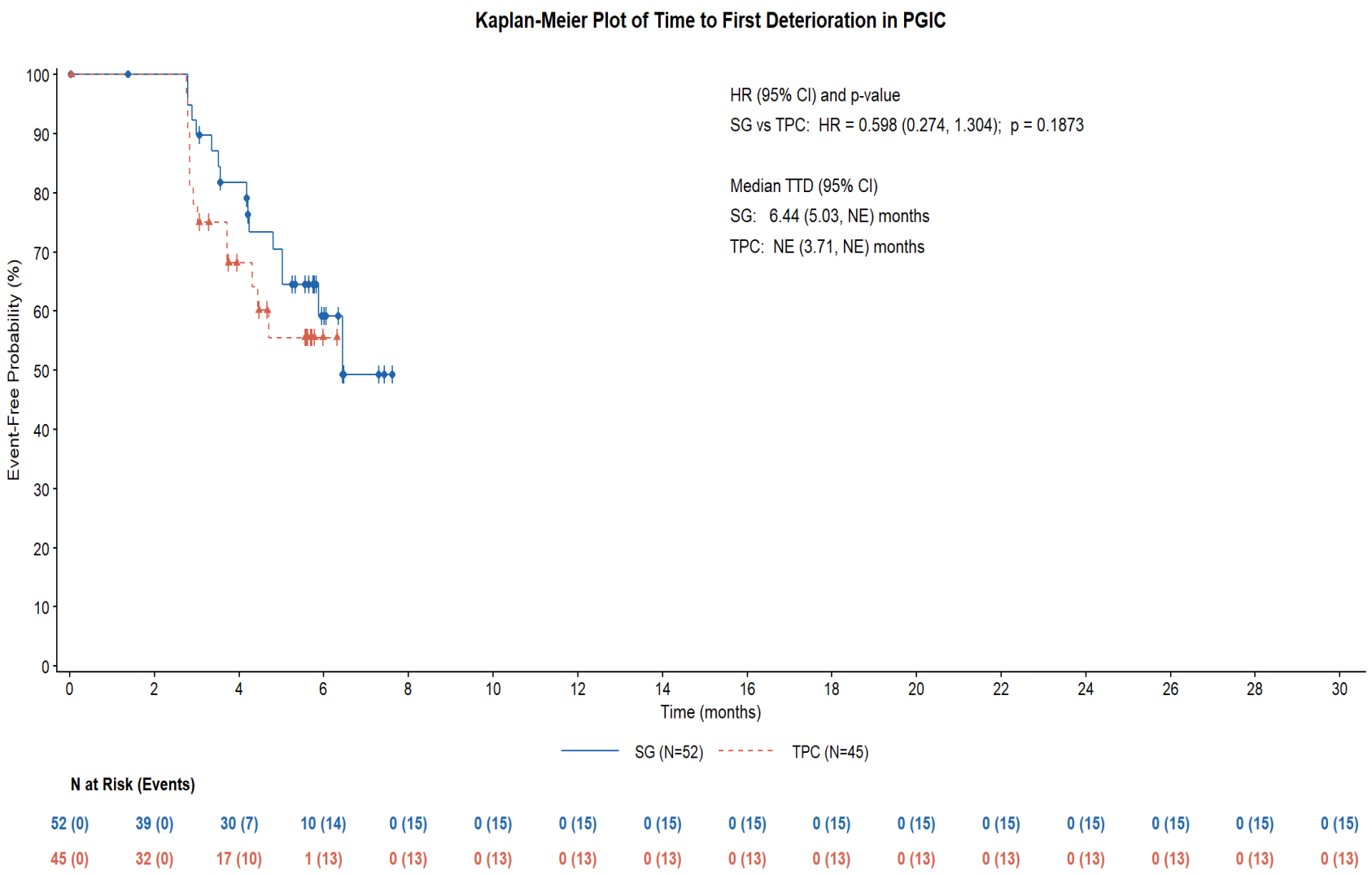
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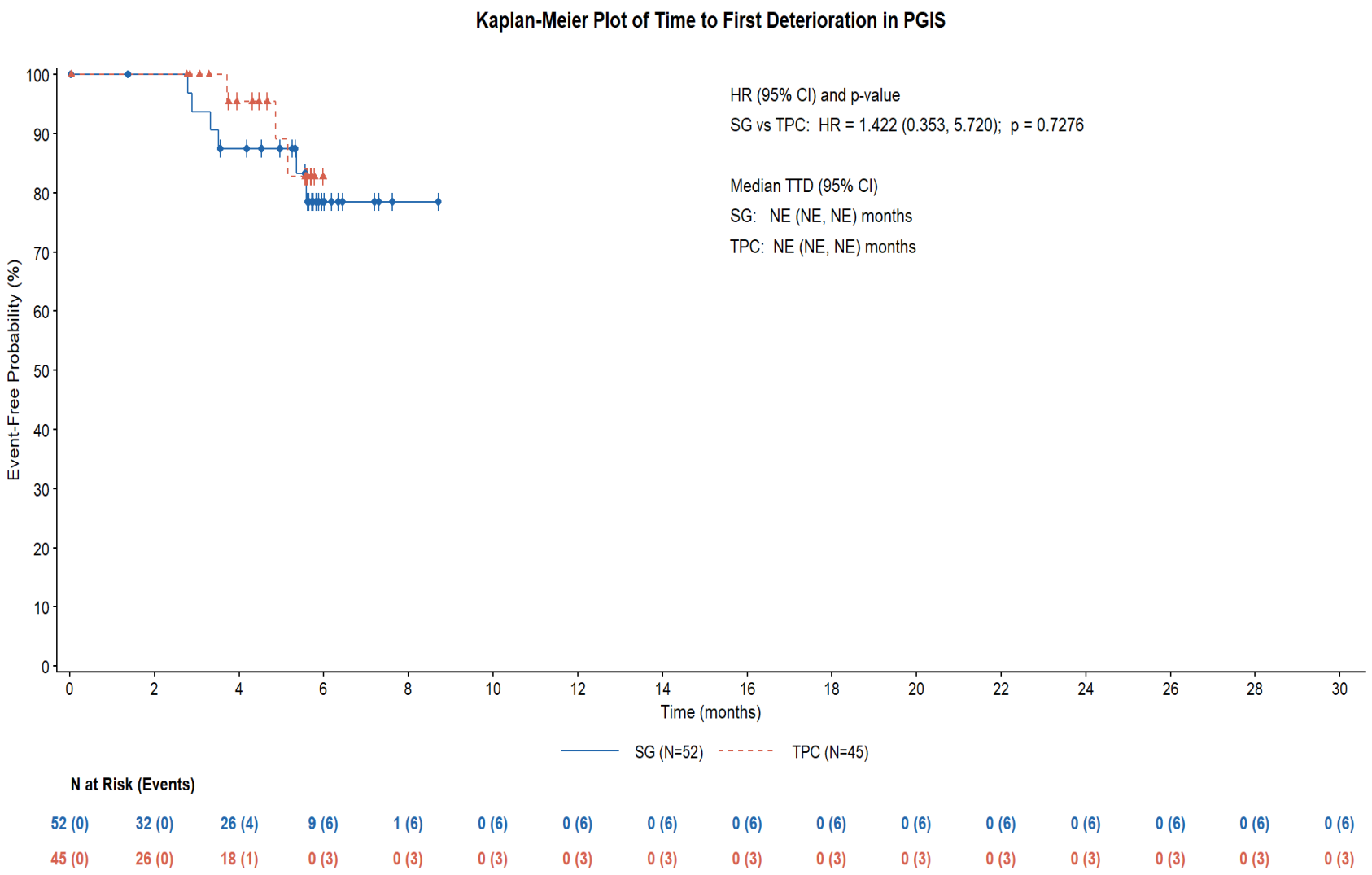
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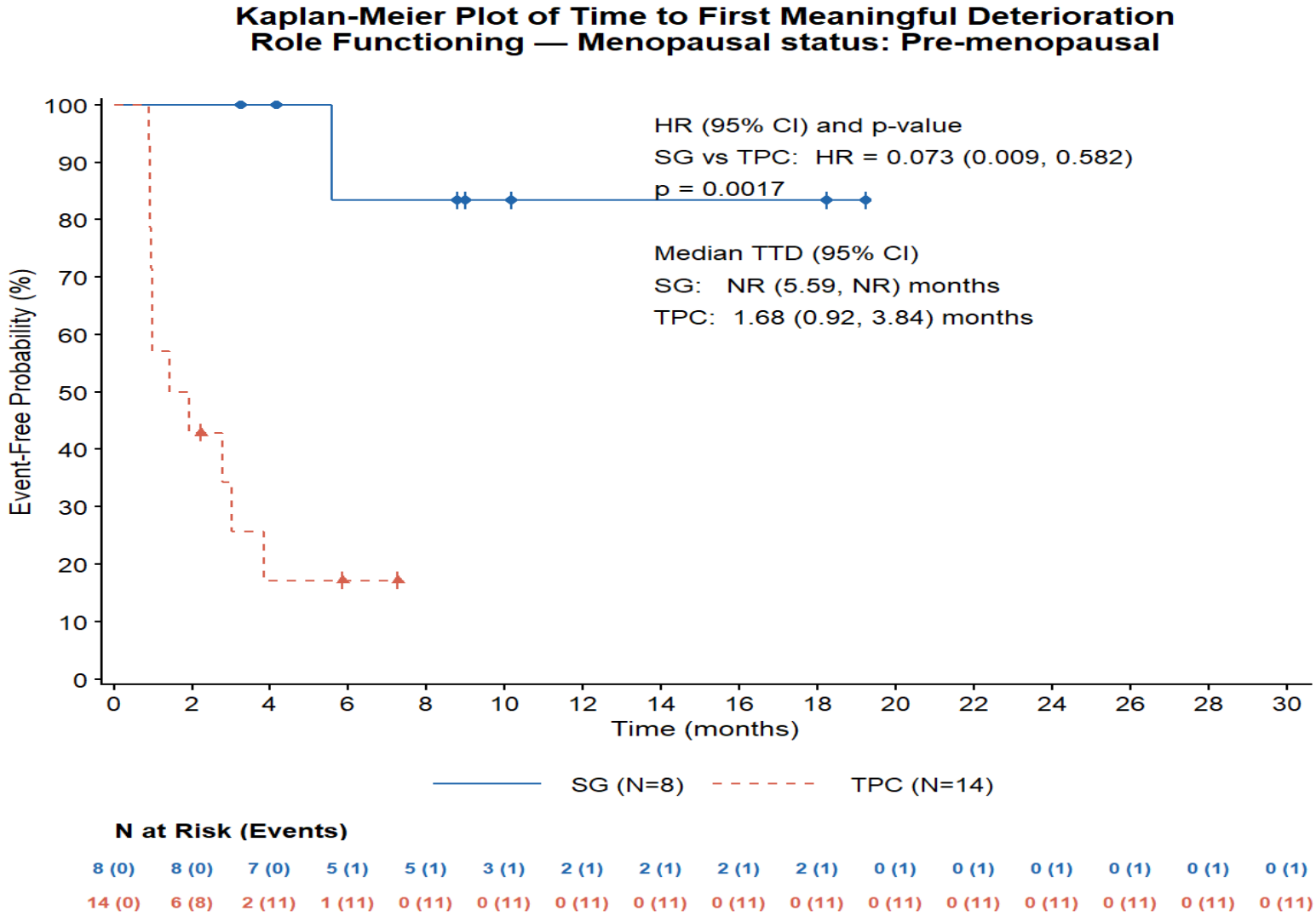
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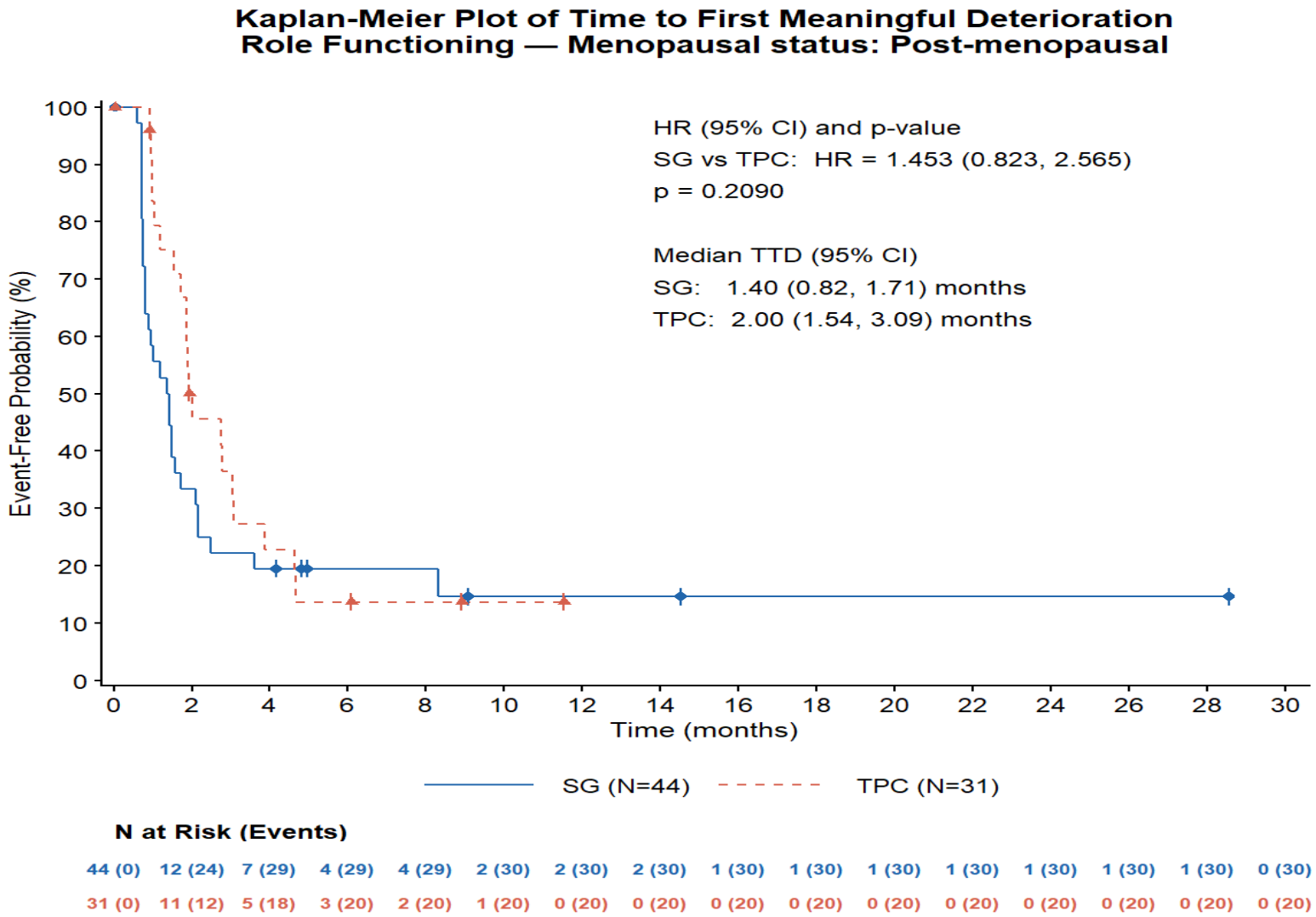
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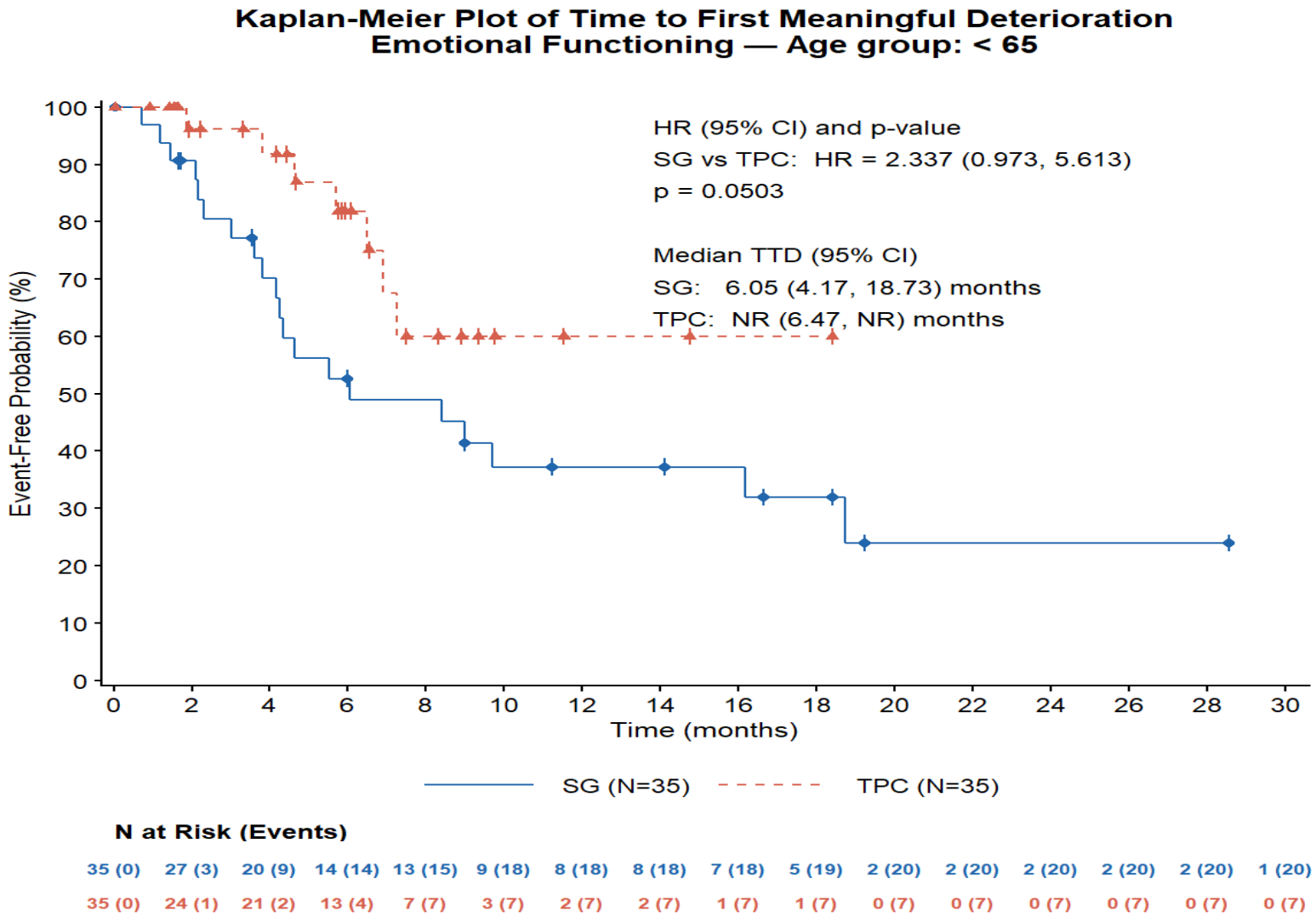
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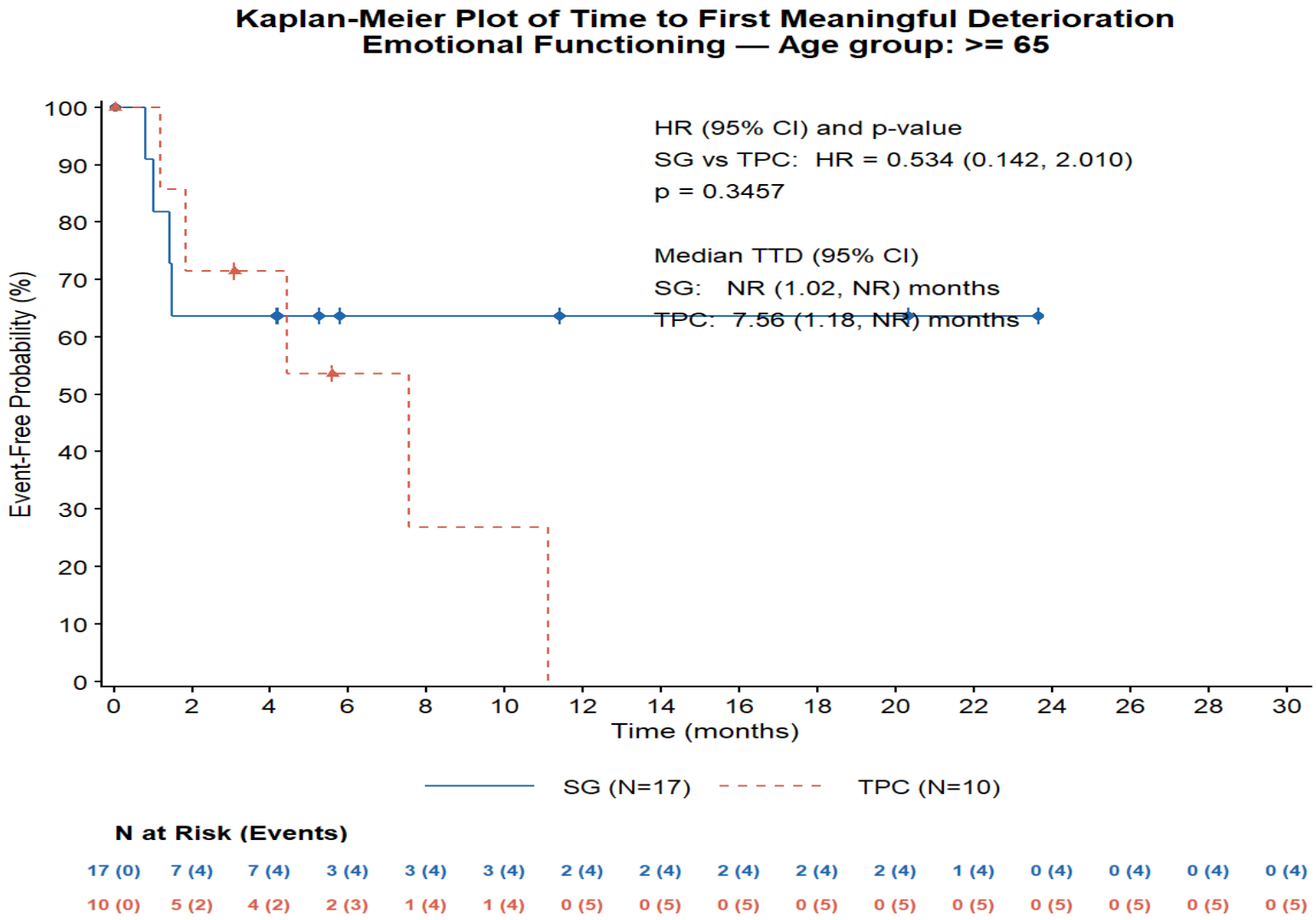
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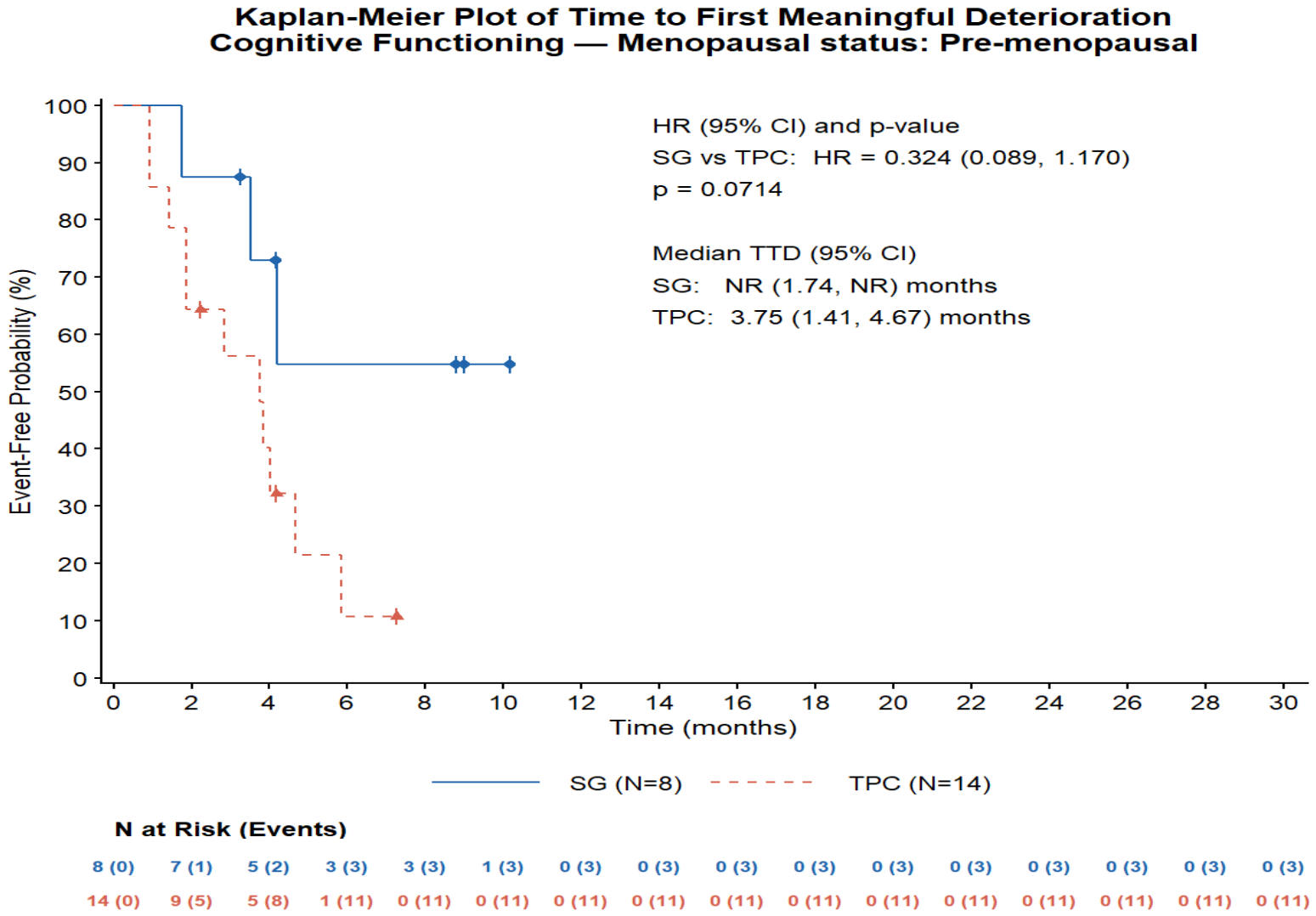
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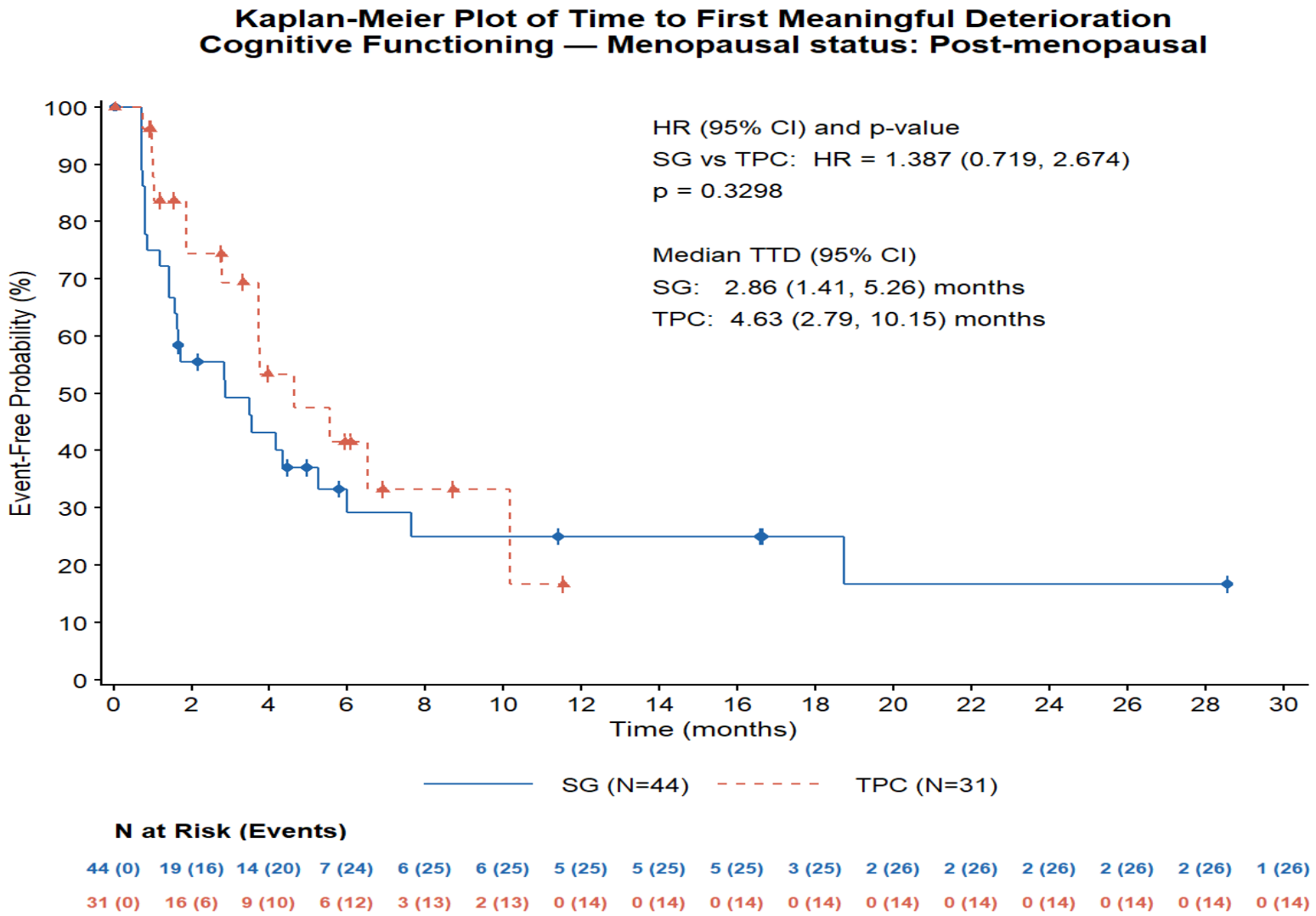
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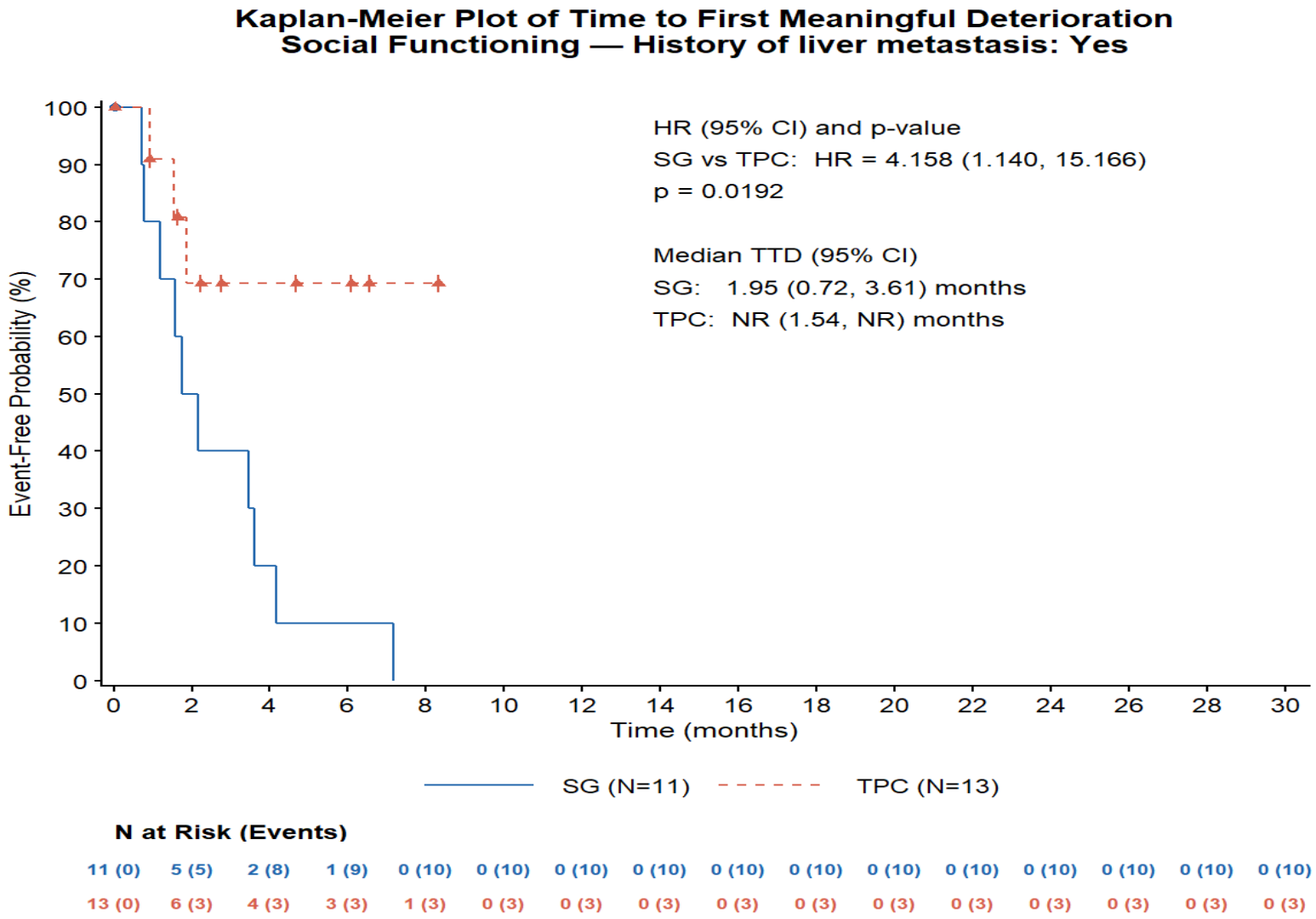
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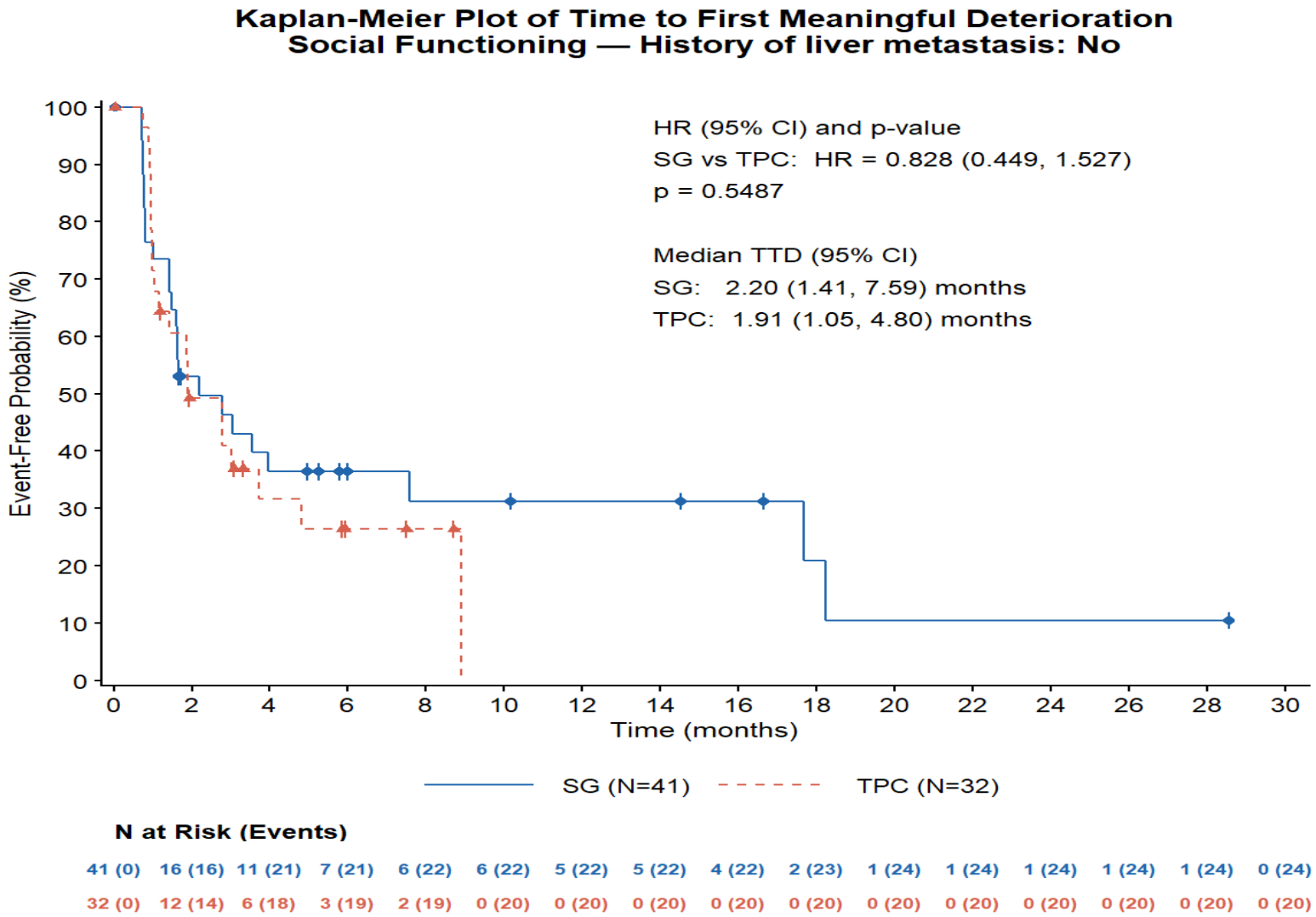
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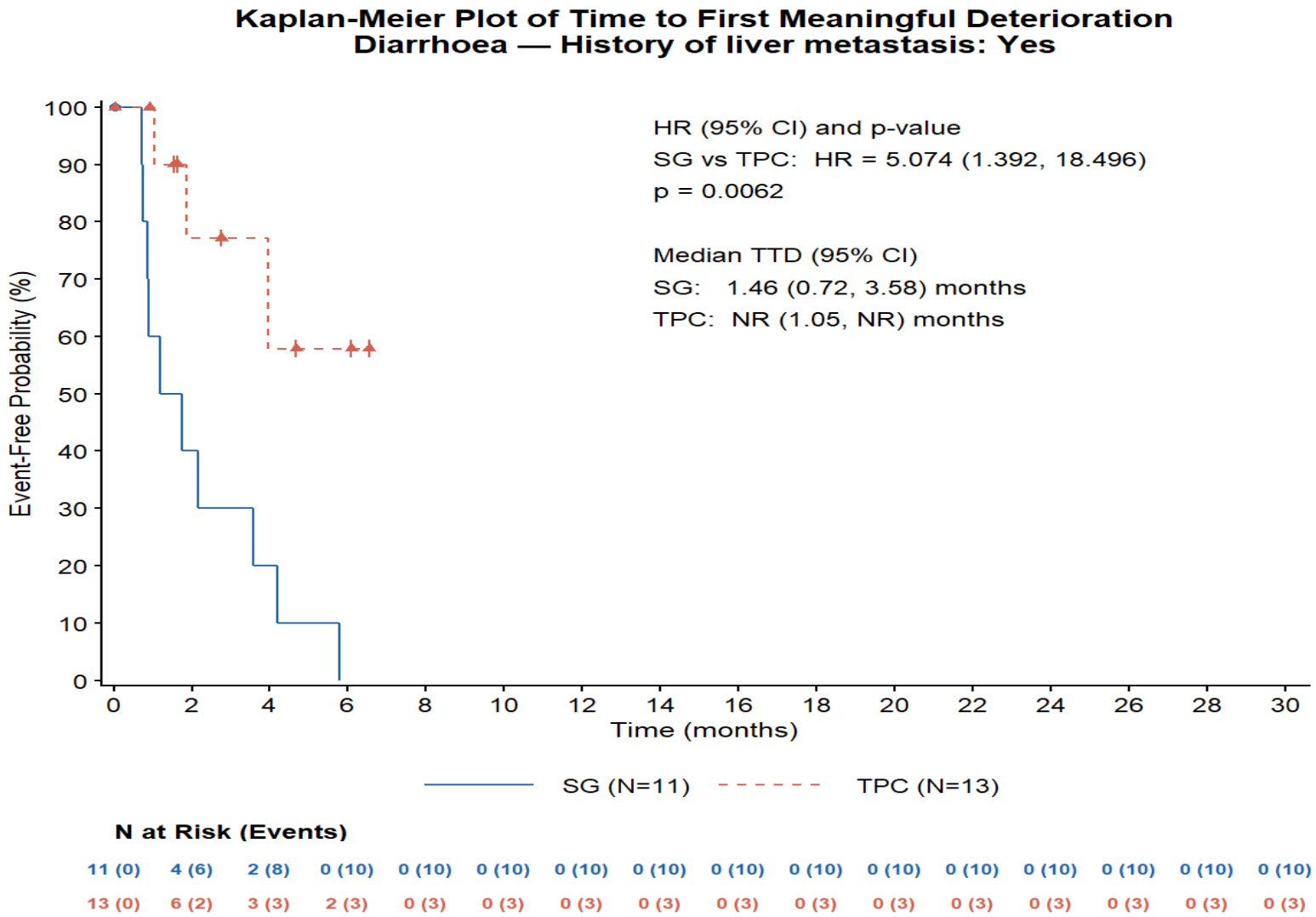
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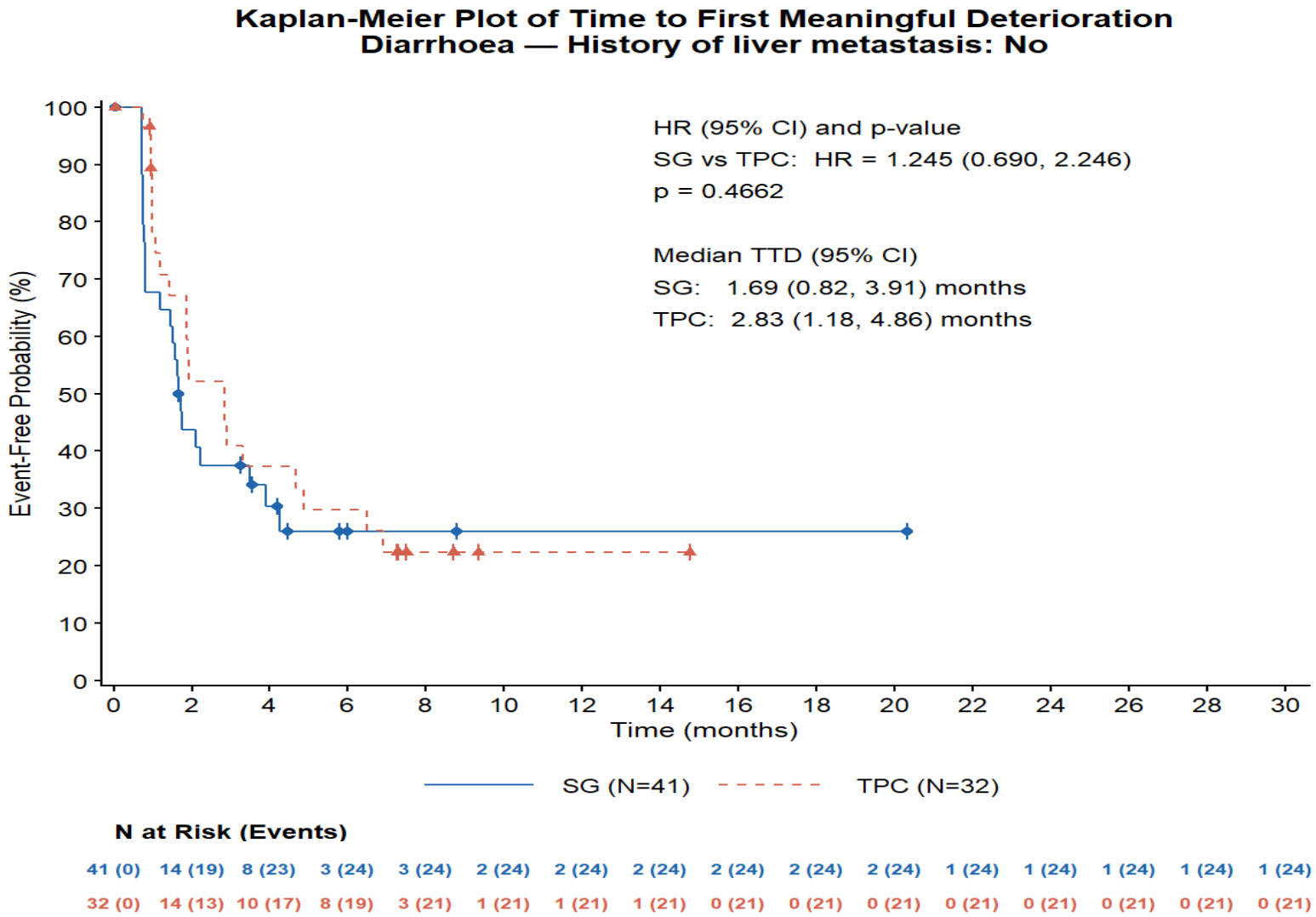
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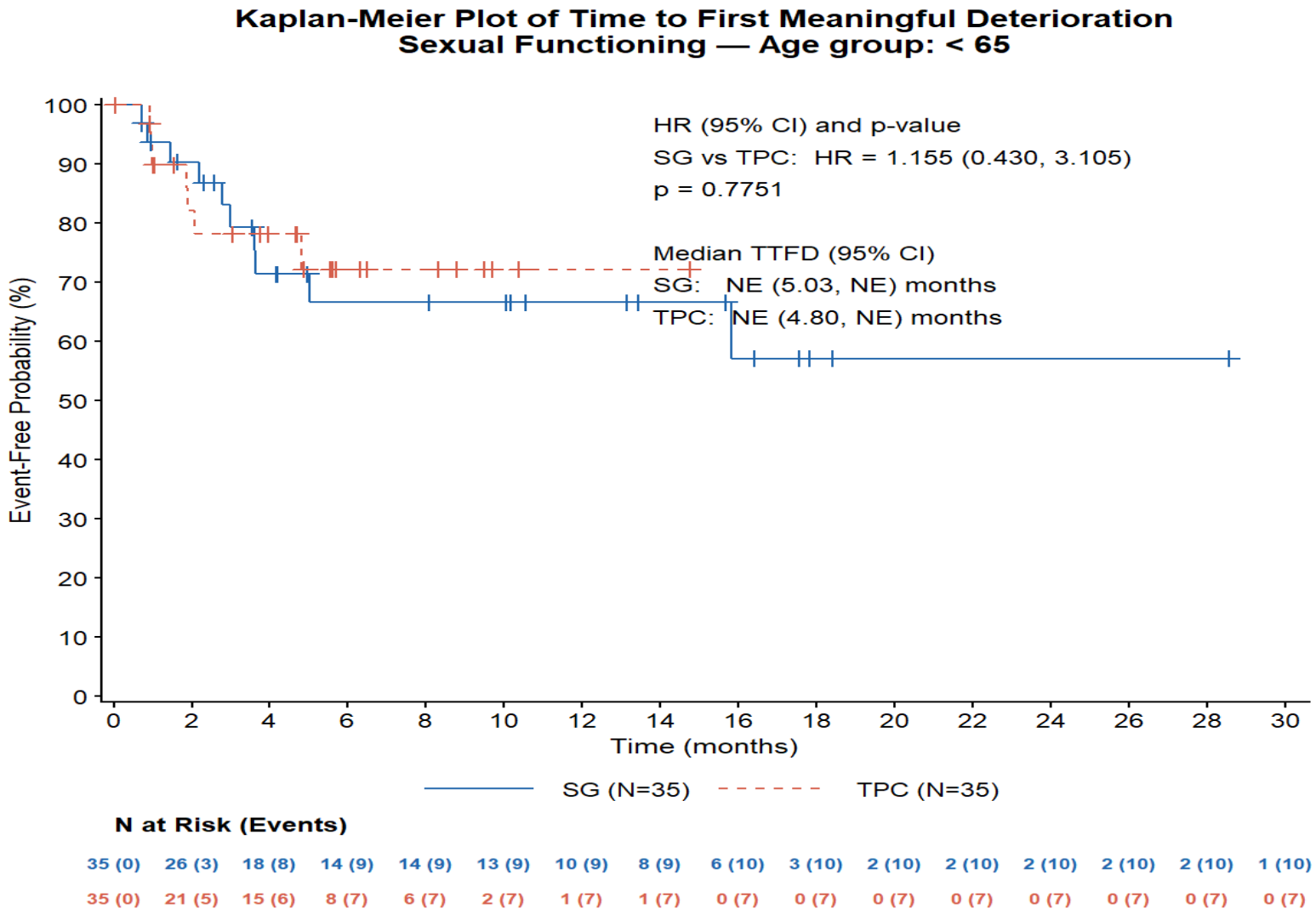
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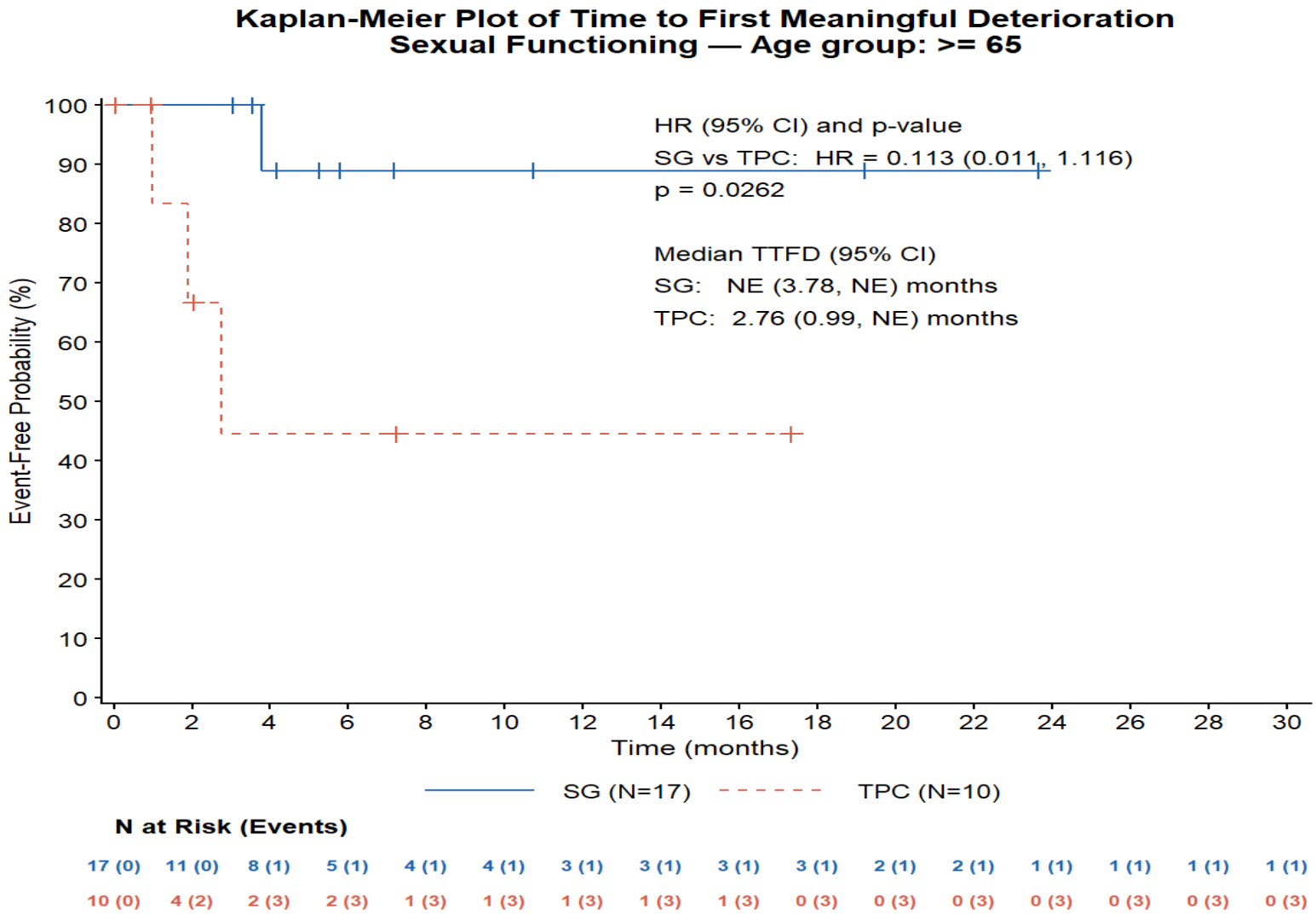
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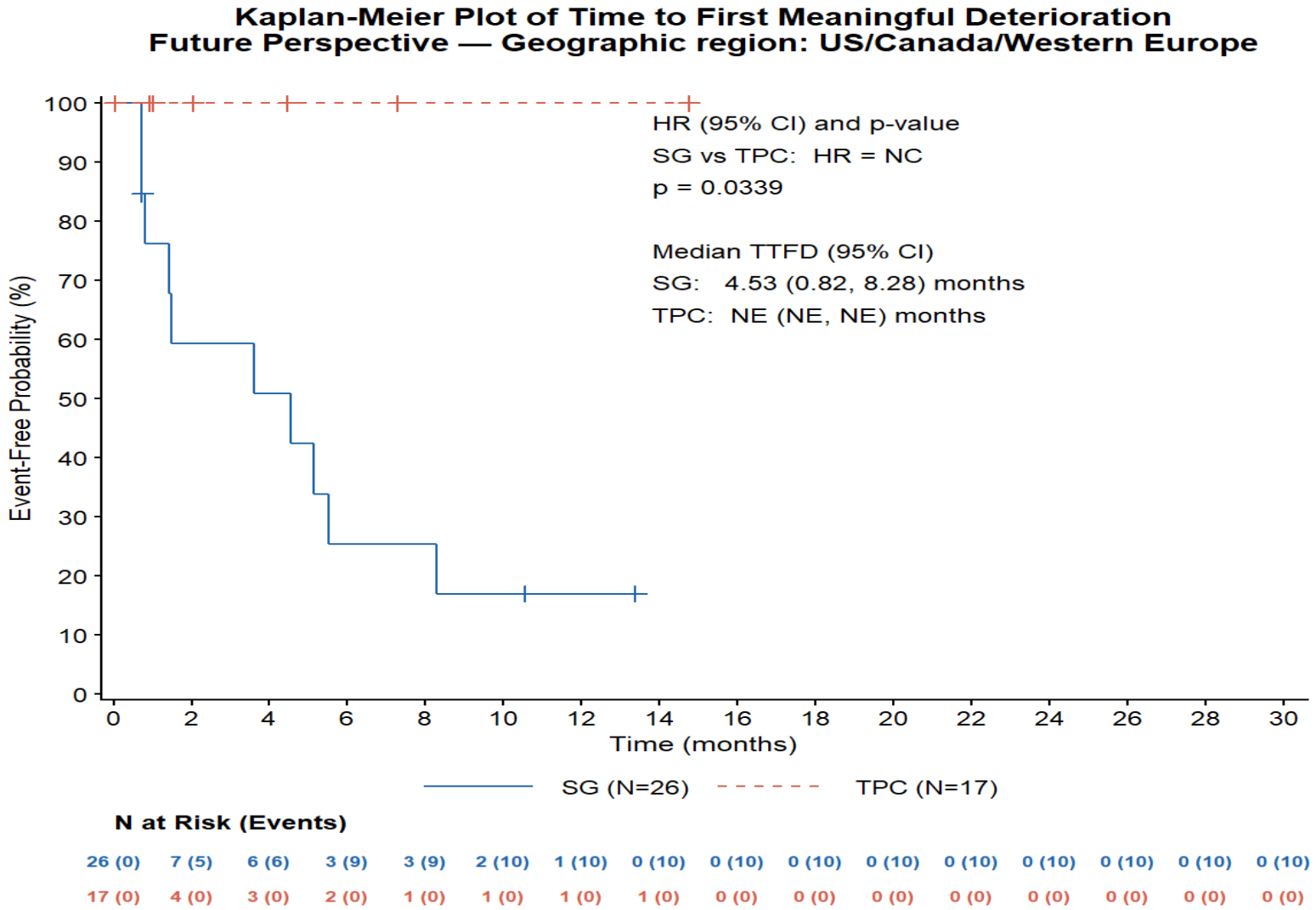
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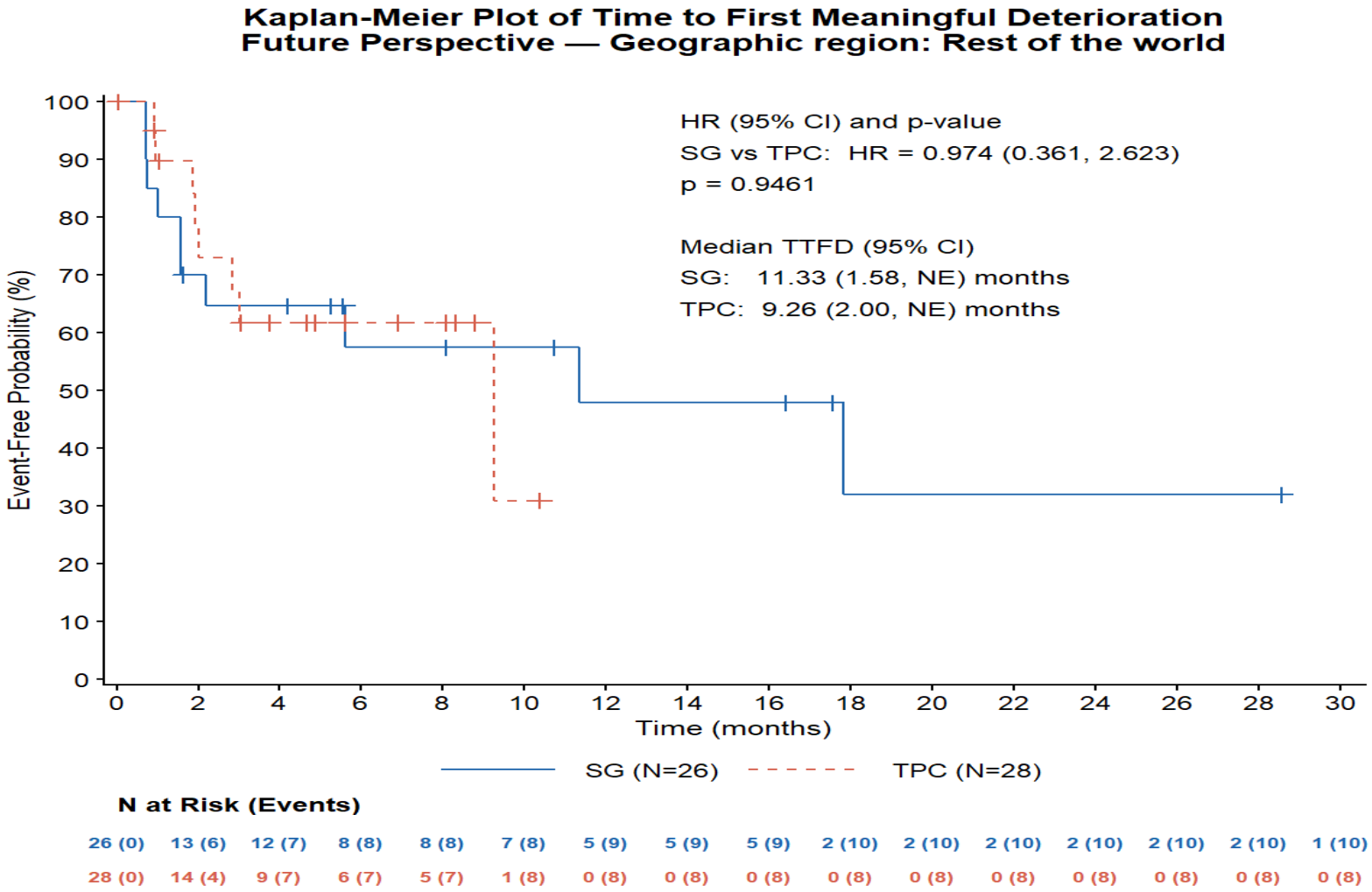
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1. Statistical Analysis for German Submission of ASCENT-03

2. TFLs

Population: Triple-negative breast cancer (mTNBC)

Sub-Populations:
— Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Data Cut Date: 22 APR 2026

Version 1.0

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4. PRO - mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

4.1. Table 1.1.1.1: — Observation Period (Months) — EORTC QLQ-C30 — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
N	125	123	248
Mean (SD)	10.3 (8.71)	8.8 (7.36)	9.6 (8.09)
95% CI	8.8, 11.8	7.5, 10.1	8.6, 10.6
Median	7.4	6.8	6.9
Q1, Q3	4.2, 15.9	4.2, 10.5	4.2, 12.9
Min, Max	0.0, 40.7	0.0, 33.4	0.0, 40.7

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.2. Table 1.1.1.2: — Observation Period (Months) — EORTC QLQ-BR23 — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
N	124	123	247
Mean (SD)	10.2 (8.67)	8.8 (7.38)	9.5 (8.07)
95% CI	8.7, 11.8	7.5, 10.1	8.5, 10.5
Median	7.3	6.8	6.9
Q1, Q3	4.2, 15.6	4.2, 10.5	4.2, 12.8
Min, Max	0.0, 40.7	0.0, 33.4	0.0, 40.7

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.3. Table 1.1.1.3: — Observation Period (Months) — EQ-5D-5L-VAS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
N	125	123	248
Mean (SD)	10.3 (8.70)	8.8 (7.38)	9.6 (8.09)
95% CI	8.8, 11.9	7.5, 10.1	8.6, 10.6
Median	7.4	6.8	6.9
Q1, Q3	4.1, 15.9	4.2, 10.5	4.2, 12.9
Min, Max	0.0, 40.7	0.0, 33.4	0.0, 40.7

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; VAS = Visual analogue scale; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.4. Table 1.1.1.5: — Observation Period (Months) — PGI-Change — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
N	96	101	197
Mean (SD)	7.1 (5.92)	6.5 (4.00)	6.8 (5.02)
95% CI	5.9, 8.3	5.7, 7.3	6.1, 7.5
Median	5.7	5.9	5.8
Q1, Q3	5.1, 6.2	5.1, 6.5	5.1, 6.4
Min, Max	1.2, 37.3	0.0, 30.9	0.0, 37.3

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.5. Table 1.1.1.6: — Observation Period (Months) — PGI-Severity — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Statistic	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
N	122	123	245
Mean (SD)	5.6 (6.00)	5.3 (4.40)	5.5 (5.25)
95% CI	4.5, 6.7	4.6, 6.1	4.8, 6.1
Median	5.6	5.6	5.6
Q1, Q3	3.6, 6.0	3.5, 6.4	3.6, 6.2
Min, Max	0.0, 37.3	0.0, 30.9	0.0, 37.3

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.6. Table 1.1.3.1: — Summary of Available Data Rates of EORTC QLQ-C30 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	123/125 (98.4%)	121/124 (97.6%)	244/249 (98.0%)
Week 4	106/125 (84.8%)	110/124 (88.7%)	216/249 (86.7%)
Week 7	99/125 (79.2%)	94/124 (75.8%)	193/249 (77.5%)
Week 10	94/125 (75.2%)	91/124 (73.4%)	185/249 (74.3%)
Week 13	85/125 (68.0%)	87/124 (70.2%)	172/249 (69.1%)
Week 16	82/125 (65.6%)	72/124 (58.1%)	154/249 (61.8%)
Week 19	85/125 (68.0%)	79/124 (63.7%)	164/249 (65.9%)
Week 22	72/125 (57.6%)	66/124 (53.2%)	138/249 (55.4%)
Week 25	63/125 (50.4%)	58/124 (46.8%)	121/249 (48.6%)
Week 28	63/125 (50.4%)	49/124 (39.5%)	112/249 (45.0%)
Week 31	61/125 (48.8%)	38/124 (30.6%)	99/249 (39.8%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 34	56/125 (44.8%)	45/124 (36.3%)	101/249 (40.6%)
Week 37	49/125 (39.2%)	33/124 (26.6%)	82/249 (32.9%)
Week 40	47/125 (37.6%)	31/124 (25.0%)	78/249 (31.3%)
Week 43	35/125 (28.0%)	28/124 (22.6%)	63/249 (25.3%)
Week 46	40/125 (32.0%)	24/124 (19.4%)	64/249 (25.7%)
Week 49	35/125 (28.0%)	20/124 (16.1%)	55/249 (22.1%)
Week 52	34/125 (27.2%)	24/124 (19.4%)	58/249 (23.3%)
Week 55	33/125 (26.4%)	20/124 (16.1%)	53/249 (21.3%)
Week 58	32/125 (25.6%)	18/124 (14.5%)	50/249 (20.1%)
Week 61	27/125 (21.6%)	17/124 (13.7%)	44/249 (17.7%)
Week 64	28/125 (22.4%)	18/124 (14.5%)	46/249 (18.5%)
Week 67	28/125 (22.4%)	14/124 (11.3%)	42/249 (16.9%)
Week 70	27/125 (21.6%)	13/124 (10.5%)	40/249 (16.1%)
Week 73	26/125 (20.8%)	13/124 (10.5%)	39/249 (15.7%)
Week 76	25/125 (20.0%)	11/124 (8.9%)	36/249 (14.5%)
Week 79	22/125 (17.6%)	10/124 (8.1%)	32/249 (12.9%)
Week 82	23/125 (18.4%)	9/124 (7.3%)	32/249 (12.9%)
Week 85	16/125 (12.8%)	8/124 (6.5%)	24/249 (9.6%)
Week 88	17/125 (13.6%)	9/124 (7.3%)	26/249 (10.4%)
Week 91	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 94	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 97	15/125 (12.0%)	9/124 (7.3%)	24/249 (9.6%)
Week 100	13/125 (10.4%)	7/124 (5.6%)	20/249 (8.0%)
Week 103	11/125 (8.8%)	6/124 (4.8%)	17/249 (6.8%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 106	10/125 (8.0%)	6/124 (4.8%)	16/249 (6.4%)
Week 109	8/125 (6.4%)	6/124 (4.8%)	14/249 (5.6%)
Week 112	6/125 (4.8%)	6/124 (4.8%)	12/249 (4.8%)
Week 115	8/125 (6.4%)	5/124 (4.0%)	13/249 (5.2%)
Week 118	4/125 (3.2%)	6/124 (4.8%)	10/249 (4.0%)
Week 121	4/125 (3.2%)	4/124 (3.2%)	8/249 (3.2%)
Week 124	2/125 (1.6%)	5/124 (4.0%)	7/249 (2.8%)
Week 127	0/125 (0.0%)	3/124 (2.4%)	3/249 (1.2%)
Week 130	0/125 (0.0%)	2/124 (1.6%)	2/249 (0.8%)
Week 133	0/125 (0.0%)	2/124 (1.6%)	2/249 (0.8%)
Week 136	3/125 (2.4%)	1/124 (0.8%)	4/249 (1.6%)
Week 139	1/125 (0.8%)	2/124 (1.6%)	3/249 (1.2%)
Week 142	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 145	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 148	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 151	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 154	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 157	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 160	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 163	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 166	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 169	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 172	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 175	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 178	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
End of Treatment	71/125 (56.8%)	84/124 (67.7%)	155/249 (62.2%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.7. Table 1.1.3.2: — Summary of Available Data Rates of EORTC QLQ-BR23 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/125 (84.0%)	108/124 (87.1%)	213/249 (85.5%)
Week 7	97/125 (77.6%)	93/124 (75.0%)	190/249 (76.3%)
Week 10	91/125 (72.8%)	90/124 (72.6%)	181/249 (72.7%)
Week 13	84/125 (67.2%)	87/124 (70.2%)	171/249 (68.7%)
Week 16	82/125 (65.6%)	72/124 (58.1%)	154/249 (61.8%)
Week 19	85/125 (68.0%)	79/124 (63.7%)	164/249 (65.9%)
Week 22	71/125 (56.8%)	66/124 (53.2%)	137/249 (55.0%)
Week 25	63/125 (50.4%)	58/124 (46.8%)	121/249 (48.6%)
Week 28	63/125 (50.4%)	49/124 (39.5%)	112/249 (45.0%)
Week 31	60/125 (48.0%)	38/124 (30.6%)	98/249 (39.4%)
Week 34	54/125 (43.2%)	44/124 (35.5%)	98/249 (39.4%)
Week 37	48/125 (38.4%)	33/124 (26.6%)	81/249 (32.5%)
Week 40	46/125 (36.8%)	31/124 (25.0%)	77/249 (30.9%)
Week 43	34/125 (27.2%)	28/124 (22.6%)	62/249 (24.9%)
Week 46	39/125 (31.2%)	24/124 (19.4%)	63/249 (25.3%)
Week 49	34/125 (27.2%)	20/124 (16.1%)	54/249 (21.7%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 52	34/125 (27.2%)	24/124 (19.4%)	58/249 (23.3%)
Week 55	32/125 (25.6%)	20/124 (16.1%)	52/249 (20.9%)
Week 58	31/125 (24.8%)	18/124 (14.5%)	49/249 (19.7%)
Week 61	26/125 (20.8%)	17/124 (13.7%)	43/249 (17.3%)
Week 64	27/125 (21.6%)	18/124 (14.5%)	45/249 (18.1%)
Week 67	27/125 (21.6%)	14/124 (11.3%)	41/249 (16.5%)
Week 70	27/125 (21.6%)	13/124 (10.5%)	40/249 (16.1%)
Week 73	25/125 (20.0%)	13/124 (10.5%)	38/249 (15.3%)
Week 76	24/125 (19.2%)	11/124 (8.9%)	35/249 (14.1%)
Week 79	21/125 (16.8%)	10/124 (8.1%)	31/249 (12.4%)
Week 82	22/125 (17.6%)	9/124 (7.3%)	31/249 (12.4%)
Week 85	15/125 (12.0%)	8/124 (6.5%)	23/249 (9.2%)
Week 88	16/125 (12.8%)	9/124 (7.3%)	25/249 (10.0%)
Week 91	15/125 (12.0%)	7/124 (5.6%)	22/249 (8.8%)
Week 94	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 97	14/125 (11.2%)	9/124 (7.3%)	23/249 (9.2%)
Week 100	13/125 (10.4%)	7/124 (5.6%)	20/249 (8.0%)
Week 103	11/125 (8.8%)	6/124 (4.8%)	17/249 (6.8%)
Week 106	10/125 (8.0%)	6/124 (4.8%)	16/249 (6.4%)
Week 109	8/125 (6.4%)	6/124 (4.8%)	14/249 (5.6%)
Week 112	6/125 (4.8%)	6/124 (4.8%)	12/249 (4.8%)
Week 115	8/125 (6.4%)	5/124 (4.0%)	13/249 (5.2%)
Week 118	4/125 (3.2%)	6/124 (4.8%)	10/249 (4.0%)
Week 121	4/125 (3.2%)	4/124 (3.2%)	8/249 (3.2%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 124	2/125 (1.6%)	5/124 (4.0%)	7/249 (2.8%)
Week 127	0/125 (0.0%)	3/124 (2.4%)	3/249 (1.2%)
Week 130	0/125 (0.0%)	2/124 (1.6%)	2/249 (0.8%)
Week 133	0/125 (0.0%)	2/124 (1.6%)	2/249 (0.8%)
Week 136	3/125 (2.4%)	1/124 (0.8%)	4/249 (1.6%)
Week 139	1/125 (0.8%)	2/124 (1.6%)	3/249 (1.2%)
Week 142	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 145	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 148	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 151	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 154	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 157	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 160	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 163	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 166	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 169	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 172	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 175	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 178	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
End of Treatment	71/125 (56.8%)	83/124 (66.9%)	154/249 (61.8%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.8. Table 1.1.3.3: — Summary of Available Data Rates of EQ-5D-VAS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/125 (84.0%)	106/124 (85.5%)	211/249 (84.7%)
Week 7	97/125 (77.6%)	93/124 (75.0%)	190/249 (76.3%)
Week 10	91/125 (72.8%)	90/124 (72.6%)	181/249 (72.7%)
Week 13	84/125 (67.2%)	87/124 (70.2%)	171/249 (68.7%)
Week 16	82/125 (65.6%)	72/124 (58.1%)	154/249 (61.8%)
Week 19	85/125 (68.0%)	79/124 (63.7%)	164/249 (65.9%)
Week 22	71/125 (56.8%)	66/124 (53.2%)	137/249 (55.0%)
Week 25	63/125 (50.4%)	58/124 (46.8%)	121/249 (48.6%)
Week 28	63/125 (50.4%)	49/124 (39.5%)	112/249 (45.0%)
Week 31	61/125 (48.8%)	38/124 (30.6%)	99/249 (39.8%)
Week 34	55/125 (44.0%)	44/124 (35.5%)	99/249 (39.8%)
Week 37	49/125 (39.2%)	33/124 (26.6%)	82/249 (32.9%)
Week 40	47/125 (37.6%)	31/124 (25.0%)	78/249 (31.3%)
Week 43	35/125 (28.0%)	28/124 (22.6%)	63/249 (25.3%)
Week 46	40/125 (32.0%)	24/124 (19.4%)	64/249 (25.7%)
Week 49	35/125 (28.0%)	20/124 (16.1%)	55/249 (22.1%)
Week 52	34/125 (27.2%)	24/124 (19.4%)	58/249 (23.3%)
Week 55	33/125 (26.4%)	20/124 (16.1%)	53/249 (21.3%)
Week 58	32/125 (25.6%)	18/124 (14.5%)	50/249 (20.1%)
Week 61	27/125 (21.6%)	17/124 (13.7%)	44/249 (17.7%)
Week 64	28/125 (22.4%)	18/124 (14.5%)	46/249 (18.5%)
Week 67	28/125 (22.4%)	14/124 (11.3%)	42/249 (16.9%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 70	27/125 (21.6%)	13/124 (10.5%)	40/249 (16.1%)
Week 73	26/125 (20.8%)	13/124 (10.5%)	39/249 (15.7%)
Week 76	25/125 (20.0%)	11/124 (8.9%)	36/249 (14.5%)
Week 79	22/125 (17.6%)	10/124 (8.1%)	32/249 (12.9%)
Week 82	23/125 (18.4%)	9/124 (7.3%)	32/249 (12.9%)
Week 85	16/125 (12.8%)	8/124 (6.5%)	24/249 (9.6%)
Week 88	17/125 (13.6%)	9/124 (7.3%)	26/249 (10.4%)
Week 91	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 94	16/125 (12.8%)	7/124 (5.6%)	23/249 (9.2%)
Week 97	15/125 (12.0%)	9/124 (7.3%)	24/249 (9.6%)
Week 100	13/125 (10.4%)	7/124 (5.6%)	20/249 (8.0%)
Week 103	11/125 (8.8%)	6/124 (4.8%)	17/249 (6.8%)
Week 106	10/125 (8.0%)	6/124 (4.8%)	16/249 (6.4%)
Week 109	8/125 (6.4%)	6/124 (4.8%)	14/249 (5.6%)
Week 112	6/125 (4.8%)	6/124 (4.8%)	12/249 (4.8%)
Week 115	8/125 (6.4%)	5/124 (4.0%)	13/249 (5.2%)
Week 118	4/125 (3.2%)	6/124 (4.8%)	10/249 (4.0%)
Week 121	4/125 (3.2%)	4/124 (3.2%)	8/249 (3.2%)
Week 124	2/125 (1.6%)	5/124 (4.0%)	7/249 (2.8%)
Week 127	0/125 (0.0%)	3/124 (2.4%)	3/249 (1.2%)
Week 130	0/125 (0.0%)	2/124 (1.6%)	2/249 (0.8%)
Week 133	0/125 (0.0%)	2/124 (1.6%)	2/249 (0.8%)
Week 136	3/125 (2.4%)	1/124 (0.8%)	4/249 (1.6%)
Week 139	1/125 (0.8%)	2/124 (1.6%)	3/249 (1.2%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 142	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 145	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 148	2/125 (1.6%)	1/124 (0.8%)	3/249 (1.2%)
Week 151	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 154	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 157	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 160	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 163	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 166	2/125 (1.6%)	0/124 (0.0%)	2/249 (0.8%)
Week 169	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 172	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 175	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
Week 178	1/125 (0.8%)	0/124 (0.0%)	1/249 (0.4%)
End of Treatment	70/125 (56.0%)	83/124 (66.9%)	153/249 (61.4%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.9. Table 1.1.3.5: — Summary of Available Data Rates of PGIS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	118/125 (94.4%)	119/124 (96.0%)	237/249 (95.2%)
Week 13	61/125 (48.8%)	56/124 (45.2%)	117/249 (47.0%)
Week 16	79/125 (63.2%)	68/124 (54.8%)	147/249 (59.0%)
Week 19	84/125 (67.2%)	75/124 (60.5%)	159/249 (63.9%)
Week 22	71/125 (56.8%)	65/124 (52.4%)	136/249 (54.6%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 25	63/125 (50.4%)	57/124 (46.0%)	120/249 (48.2%)
Week 28	32/125 (25.6%)	40/124 (32.3%)	72/249 (28.9%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.10. Table 1.1.3.6: — Summary of Available Data Rates of PGIC by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 13	61/125 (48.8%)	56/124 (45.2%)	117/249 (47.0%)
Week 16	79/125 (63.2%)	68/124 (54.8%)	147/249 (59.0%)
Week 19	84/125 (67.2%)	75/124 (60.5%)	159/249 (63.9%)
Week 22	71/125 (56.8%)	65/124 (52.4%)	136/249 (54.6%)
Week 25	63/125 (50.4%)	57/124 (46.0%)	120/249 (48.2%)
Week 28	32/125 (25.6%)	40/124 (32.3%)	72/249 (28.9%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.11. Table 1.1.4.2: — Summary of Modified Available Data Rates of EORTC QLQ-BR23 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/123 (85.4%)	108/124 (87.1%)	213/247 (86.2%)
Week 7	97/120 (80.8%)	93/123 (75.6%)	190/243 (78.2%)
Week 10	91/119 (76.5%)	90/122 (73.8%)	181/241 (75.1%)
Week 13	84/119 (70.6%)	87/121 (71.9%)	171/240 (71.2%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 16	82/116 (70.7%)	72/120 (60.0%)	154/236 (65.3%)
Week 19	85/112 (75.9%)	79/117 (67.5%)	164/229 (71.6%)
Week 22	71/107 (66.4%)	66/115 (57.4%)	137/222 (61.7%)
Week 25	63/107 (58.9%)	58/111 (52.3%)	121/218 (55.5%)
Week 28	63/105 (60.0%)	49/111 (44.1%)	112/216 (51.9%)
Week 31	60/104 (57.7%)	38/107 (35.5%)	98/211 (46.4%)
Week 34	54/102 (52.9%)	44/105 (41.9%)	98/207 (47.3%)
Week 37	48/102 (47.1%)	33/104 (31.7%)	81/206 (39.3%)
Week 40	46/101 (45.5%)	31/103 (30.1%)	77/204 (37.7%)
Week 43	34/100 (34.0%)	28/100 (28.0%)	62/200 (31.0%)
Week 46	39/97 (40.2%)	24/99 (24.2%)	63/196 (32.1%)
Week 49	34/95 (35.8%)	20/96 (20.8%)	54/191 (28.3%)
Week 52	34/89 (38.2%)	24/92 (26.1%)	58/181 (32.0%)
Week 55	32/89 (36.0%)	20/90 (22.2%)	52/179 (29.1%)
Week 58	31/86 (36.0%)	18/89 (20.2%)	49/175 (28.0%)
Week 61	26/84 (31.0%)	17/87 (19.5%)	43/171 (25.1%)
Week 64	27/84 (32.1%)	18/86 (20.9%)	45/170 (26.5%)
Week 67	27/81 (33.3%)	14/81 (17.3%)	41/162 (25.3%)
Week 70	27/78 (34.6%)	13/79 (16.5%)	40/157 (25.5%)
Week 73	25/74 (33.8%)	13/78 (16.7%)	38/152 (25.0%)
Week 76	24/72 (33.3%)	11/76 (14.5%)	35/148 (23.6%)
Week 79	21/67 (31.3%)	10/74 (13.5%)	31/141 (22.0%)
Week 82	22/64 (34.4%)	9/71 (12.7%)	31/135 (23.0%)
Week 85	15/60 (25.0%)	8/69 (11.6%)	23/129 (17.8%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 88	16/60 (26.7%)	9/63 (14.3%)	25/123 (20.3%)
Week 91	15/58 (25.9%)	7/62 (11.3%)	22/120 (18.3%)
Week 94	16/55 (29.1%)	7/58 (12.1%)	23/113 (20.4%)
Week 97	14/53 (26.4%)	9/57 (15.8%)	23/110 (20.9%)
Week 100	13/52 (25.0%)	7/54 (13.0%)	20/106 (18.9%)
Week 103	11/50 (22.0%)	6/52 (11.5%)	17/102 (16.7%)
Week 106	10/49 (20.4%)	6/52 (11.5%)	16/101 (15.8%)
Week 109	8/49 (16.3%)	6/51 (11.8%)	14/100 (14.0%)
Week 112	6/48 (12.5%)	6/50 (12.0%)	12/98 (12.2%)
Week 115	8/47 (17.0%)	5/50 (10.0%)	13/97 (13.4%)
Week 118	4/45 (8.9%)	6/49 (12.2%)	10/94 (10.6%)
Week 121	4/45 (8.9%)	4/47 (8.5%)	8/92 (8.7%)
Week 124	2/44 (4.5%)	5/46 (10.9%)	7/90 (7.8%)
Week 127	0/43 (0.0%)	3/45 (6.7%)	3/88 (3.4%)
Week 130	0/42 (0.0%)	2/44 (4.5%)	2/86 (2.3%)
Week 133	0/42 (0.0%)	2/44 (4.5%)	2/86 (2.3%)
Week 136	3/42 (7.1%)	1/44 (2.3%)	4/86 (4.7%)
Week 139	1/42 (2.4%)	2/44 (4.5%)	3/86 (3.5%)
Week 142	2/42 (4.8%)	1/44 (2.3%)	3/86 (3.5%)
Week 145	2/41 (4.9%)	1/44 (2.3%)	3/85 (3.5%)
Week 148	2/41 (4.9%)	1/43 (2.3%)	3/84 (3.6%)
Week 151	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 154	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 157	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 160	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 163	2/40 (5.0%)	0/43 (0.0%)	2/83 (2.4%)
Week 166	2/40 (5.0%)	0/43 (0.0%)	2/83 (2.4%)
Week 169	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 172	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 175	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 178	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
End of Treatment	71/104 (68.3%)	83/115 (72.2%)	154/219 (70.3%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.12. Table 1.1.4.1: — Summary of Modified Available Data Rates of EORTC QLQ-C30 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	123/125 (98.4%)	121/124 (97.6%)	244/249 (98.0%)
Week 4	106/123 (86.2%)	110/124 (88.7%)	216/247 (87.4%)
Week 7	99/120 (82.5%)	94/123 (76.4%)	193/243 (79.4%)
Week 10	94/119 (79.0%)	91/122 (74.6%)	185/241 (76.8%)
Week 13	85/119 (71.4%)	87/121 (71.9%)	172/240 (71.7%)
Week 16	82/116 (70.7%)	72/120 (60.0%)	154/236 (65.3%)
Week 19	85/112 (75.9%)	79/117 (67.5%)	164/229 (71.6%)
Week 22	72/107 (67.3%)	66/115 (57.4%)	138/222 (62.2%)
Week 25	63/107 (58.9%)	58/111 (52.3%)	121/218 (55.5%)
Week 28	63/105 (60.0%)	49/111 (44.1%)	112/216 (51.9%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 31	61/104 (58.7%)	38/107 (35.5%)	99/211 (46.9%)
Week 34	56/102 (54.9%)	45/105 (42.9%)	101/207 (48.8%)
Week 37	49/102 (48.0%)	33/104 (31.7%)	82/206 (39.8%)
Week 40	47/101 (46.5%)	31/103 (30.1%)	78/204 (38.2%)
Week 43	35/100 (35.0%)	28/100 (28.0%)	63/200 (31.5%)
Week 46	40/97 (41.2%)	24/99 (24.2%)	64/196 (32.7%)
Week 49	35/95 (36.8%)	20/96 (20.8%)	55/191 (28.8%)
Week 52	34/89 (38.2%)	24/92 (26.1%)	58/181 (32.0%)
Week 55	33/89 (37.1%)	20/90 (22.2%)	53/179 (29.6%)
Week 58	32/86 (37.2%)	18/89 (20.2%)	50/175 (28.6%)
Week 61	27/84 (32.1%)	17/87 (19.5%)	44/171 (25.7%)
Week 64	28/84 (33.3%)	18/86 (20.9%)	46/170 (27.1%)
Week 67	28/81 (34.6%)	14/81 (17.3%)	42/162 (25.9%)
Week 70	27/78 (34.6%)	13/79 (16.5%)	40/157 (25.5%)
Week 73	26/74 (35.1%)	13/78 (16.7%)	39/152 (25.7%)
Week 76	25/72 (34.7%)	11/76 (14.5%)	36/148 (24.3%)
Week 79	22/67 (32.8%)	10/74 (13.5%)	32/141 (22.7%)
Week 82	23/64 (35.9%)	9/71 (12.7%)	32/135 (23.7%)
Week 85	16/60 (26.7%)	8/69 (11.6%)	24/129 (18.6%)
Week 88	17/60 (28.3%)	9/63 (14.3%)	26/123 (21.1%)
Week 91	16/58 (27.6%)	7/62 (11.3%)	23/120 (19.2%)
Week 94	16/55 (29.1%)	7/58 (12.1%)	23/113 (20.4%)
Week 97	15/53 (28.3%)	9/57 (15.8%)	24/110 (21.8%)
Week 100	13/52 (25.0%)	7/54 (13.0%)	20/106 (18.9%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 103	11/50 (22.0%)	6/52 (11.5%)	17/102 (16.7%)
Week 106	10/49 (20.4%)	6/52 (11.5%)	16/101 (15.8%)
Week 109	8/49 (16.3%)	6/51 (11.8%)	14/100 (14.0%)
Week 112	6/48 (12.5%)	6/50 (12.0%)	12/98 (12.2%)
Week 115	8/47 (17.0%)	5/50 (10.0%)	13/97 (13.4%)
Week 118	4/45 (8.9%)	6/49 (12.2%)	10/94 (10.6%)
Week 121	4/45 (8.9%)	4/47 (8.5%)	8/92 (8.7%)
Week 124	2/44 (4.5%)	5/46 (10.9%)	7/90 (7.8%)
Week 127	0/43 (0.0%)	3/45 (6.7%)	3/88 (3.4%)
Week 130	0/42 (0.0%)	2/44 (4.5%)	2/86 (2.3%)
Week 133	0/42 (0.0%)	2/44 (4.5%)	2/86 (2.3%)
Week 136	3/42 (7.1%)	1/44 (2.3%)	4/86 (4.7%)
Week 139	1/42 (2.4%)	2/44 (4.5%)	3/86 (3.5%)
Week 142	2/42 (4.8%)	1/44 (2.3%)	3/86 (3.5%)
Week 145	2/41 (4.9%)	1/44 (2.3%)	3/85 (3.5%)
Week 148	2/41 (4.9%)	1/43 (2.3%)	3/84 (3.6%)
Week 151	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 154	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 157	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 160	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 163	2/40 (5.0%)	0/43 (0.0%)	2/83 (2.4%)
Week 166	2/40 (5.0%)	0/43 (0.0%)	2/83 (2.4%)
Week 169	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 172	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 175	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 178	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
End of Treatment	71/104 (68.3%)	84/115 (73.0%)	155/219 (70.8%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.13. Table 1.1.4.3: — Summary of Modified Available Data Rates of EQ-5D-VAS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	122/125 (97.6%)	121/124 (97.6%)	243/249 (97.6%)
Week 4	105/123 (85.4%)	106/124 (85.5%)	211/247 (85.4%)
Week 7	97/120 (80.8%)	93/123 (75.6%)	190/243 (78.2%)
Week 10	91/119 (76.5%)	90/122 (73.8%)	181/241 (75.1%)
Week 13	84/119 (70.6%)	87/121 (71.9%)	171/240 (71.2%)
Week 16	82/116 (70.7%)	72/120 (60.0%)	154/236 (65.3%)
Week 19	85/112 (75.9%)	79/117 (67.5%)	164/229 (71.6%)
Week 22	71/107 (66.4%)	66/115 (57.4%)	137/222 (61.7%)
Week 25	63/107 (58.9%)	58/111 (52.3%)	121/218 (55.5%)
Week 28	63/105 (60.0%)	49/111 (44.1%)	112/216 (51.9%)
Week 31	61/104 (58.7%)	38/107 (35.5%)	99/211 (46.9%)
Week 34	55/102 (53.9%)	44/105 (41.9%)	99/207 (47.8%)
Week 37	49/102 (48.0%)	33/104 (31.7%)	82/206 (39.8%)
Week 40	47/101 (46.5%)	31/103 (30.1%)	78/204 (38.2%)
Week 43	35/100 (35.0%)	28/100 (28.0%)	63/200 (31.5%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 46	40/97 (41.2%)	24/99 (24.2%)	64/196 (32.7%)
Week 49	35/95 (36.8%)	20/96 (20.8%)	55/191 (28.8%)
Week 52	34/89 (38.2%)	24/92 (26.1%)	58/181 (32.0%)
Week 55	33/89 (37.1%)	20/90 (22.2%)	53/179 (29.6%)
Week 58	32/86 (37.2%)	18/89 (20.2%)	50/175 (28.6%)
Week 61	27/84 (32.1%)	17/87 (19.5%)	44/171 (25.7%)
Week 64	28/84 (33.3%)	18/86 (20.9%)	46/170 (27.1%)
Week 67	28/81 (34.6%)	14/81 (17.3%)	42/162 (25.9%)
Week 70	27/78 (34.6%)	13/79 (16.5%)	40/157 (25.5%)
Week 73	26/74 (35.1%)	13/78 (16.7%)	39/152 (25.7%)
Week 76	25/72 (34.7%)	11/76 (14.5%)	36/148 (24.3%)
Week 79	22/67 (32.8%)	10/74 (13.5%)	32/141 (22.7%)
Week 82	23/64 (35.9%)	9/71 (12.7%)	32/135 (23.7%)
Week 85	16/60 (26.7%)	8/69 (11.6%)	24/129 (18.6%)
Week 88	17/60 (28.3%)	9/63 (14.3%)	26/123 (21.1%)
Week 91	16/58 (27.6%)	7/62 (11.3%)	23/120 (19.2%)
Week 94	16/55 (29.1%)	7/58 (12.1%)	23/113 (20.4%)
Week 97	15/53 (28.3%)	9/57 (15.8%)	24/110 (21.8%)
Week 100	13/52 (25.0%)	7/54 (13.0%)	20/106 (18.9%)
Week 103	11/50 (22.0%)	6/52 (11.5%)	17/102 (16.7%)
Week 106	10/49 (20.4%)	6/52 (11.5%)	16/101 (15.8%)
Week 109	8/49 (16.3%)	6/51 (11.8%)	14/100 (14.0%)
Week 112	6/48 (12.5%)	6/50 (12.0%)	12/98 (12.2%)
Week 115	8/47 (17.0%)	5/50 (10.0%)	13/97 (13.4%)

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 118	4/45 (8.9%)	6/49 (12.2%)	10/94 (10.6%)
Week 121	4/45 (8.9%)	4/47 (8.5%)	8/92 (8.7%)
Week 124	2/44 (4.5%)	5/46 (10.9%)	7/90 (7.8%)
Week 127	0/43 (0.0%)	3/45 (6.7%)	3/88 (3.4%)
Week 130	0/42 (0.0%)	2/44 (4.5%)	2/86 (2.3%)
Week 133	0/42 (0.0%)	2/44 (4.5%)	2/86 (2.3%)
Week 136	3/42 (7.1%)	1/44 (2.3%)	4/86 (4.7%)
Week 139	1/42 (2.4%)	2/44 (4.5%)	3/86 (3.5%)
Week 142	2/42 (4.8%)	1/44 (2.3%)	3/86 (3.5%)
Week 145	2/41 (4.9%)	1/44 (2.3%)	3/85 (3.5%)
Week 148	2/41 (4.9%)	1/43 (2.3%)	3/84 (3.6%)
Week 151	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 154	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 157	2/41 (4.9%)	0/43 (0.0%)	2/84 (2.4%)
Week 160	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 163	2/40 (5.0%)	0/43 (0.0%)	2/83 (2.4%)
Week 166	2/40 (5.0%)	0/43 (0.0%)	2/83 (2.4%)
Week 169	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 172	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 175	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
Week 178	1/40 (2.5%)	0/43 (0.0%)	1/83 (1.2%)
End of Treatment	70/104 (67.3%)	83/115 (72.2%)	153/219 (69.9%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.14. Table 1.1.4.5: — Summary of Modified Available Data Rates of PGIS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Baseline (Week 1)	118/125 (94.4%)	119/124 (96.0%)	237/249 (95.2%)
Week 13	61/119 (51.3%)	56/121 (46.3%)	117/240 (48.8%)
Week 16	79/116 (68.1%)	68/120 (56.7%)	147/236 (62.3%)
Week 19	84/112 (75.0%)	75/117 (64.1%)	159/229 (69.4%)
Week 22	71/107 (66.4%)	65/115 (56.5%)	136/222 (61.3%)
Week 25	63/107 (58.9%)	57/111 (51.4%)	120/218 (55.0%)
Week 28	32/105 (30.5%)	40/111 (36.0%)	72/216 (33.3%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.15. Table 1.1.4.6: — Summary of Modified Available Data Rates of PGIC by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Visit	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
Week 13	61/119 (51.3%)	56/121 (46.3%)	117/240 (48.8%)
Week 16	79/116 (68.1%)	68/120 (56.7%)	147/236 (62.3%)
Week 19	84/112 (75.0%)	75/117 (64.1%)	159/229 (69.4%)
Week 22	71/107 (66.4%)	65/115 (56.5%)	136/222 (61.3%)
Week 25	63/107 (58.9%)	57/111 (51.4%)	120/218 (55.0%)
Week 28	32/105 (30.5%)	40/111 (36.0%)	72/216 (33.3%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.16. Table 1.1.9: PGI-Change | Observed Scores and Change from Baseline by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Item	Visit	Response Level	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
PGIC	Week 13		N=61	N=56	N=117
		Very much improved	7 (11.5%)	8 (14.3%)	15 (12.8%)
		Much improved	24 (39.3%)	20 (35.7%)	44 (37.6%)
		Minimally improved	12 (19.7%)	14 (25.0%)	26 (22.2%)
		No change	11 (18.0%)	7 (12.5%)	18 (15.4%)
		Minimally worsened	6 (9.8%)	5 (8.9%)	11 (9.4%)
		Much worsened	1 (1.6%)	2 (3.6%)	3 (2.6%)
		Very much worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 16		N=79	N=68	N=147
		Very much improved	13 (16.5%)	8 (11.8%)	21 (14.3%)
		Much improved	24 (30.4%)	17 (25.0%)	41 (27.9%)
		Minimally improved	20 (25.3%)	16 (23.5%)	36 (24.5%)
		No change	10 (12.7%)	13 (19.1%)	23 (15.6%)
		Minimally worsened	10 (12.7%)	11 (16.2%)	21 (14.3%)
		Much worsened	2 (2.5%)	3 (4.4%)	5 (3.4%)
		Very much worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 19		N=84	N=75	N=159
		Very much improved	9 (10.7%)	8 (10.7%)	17 (10.7%)
		Much improved	24 (28.6%)	24 (32.0%)	48 (30.2%)
		Minimally improved	27 (32.1%)	21 (28.0%)	48 (30.2%)
		No change	16 (19.0%)	14 (18.7%)	30 (18.9%)
		Minimally worsened	5 (6.0%)	5 (6.7%)	10 (6.3%)
		Much worsened	3 (3.6%)	2 (2.7%)	5 (3.1%)

Item	Visit	Response Level	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
		Very much worsened	0 (0.0%)	1 (1.3%)	1 (0.6%)
	Week 22		N=71	N=65	N=136
		Very much improved	15 (21.1%)	8 (12.3%)	23 (16.9%)
		Much improved	18 (25.4%)	18 (27.7%)	36 (26.5%)
		Minimally improved	17 (23.9%)	16 (24.6%)	33 (24.3%)
		No change	13 (18.3%)	16 (24.6%)	29 (21.3%)
		Minimally worsened	4 (5.6%)	5 (7.7%)	9 (6.6%)
		Much worsened	4 (5.6%)	2 (3.1%)	6 (4.4%)
		Very much worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 25		N=63	N=57	N=120
		Very much improved	7 (11.1%)	4 (7.0%)	11 (9.2%)
		Much improved	23 (36.5%)	20 (35.1%)	43 (35.8%)
		Minimally improved	17 (27.0%)	12 (21.1%)	29 (24.2%)
		No change	10 (15.9%)	11 (19.3%)	21 (17.5%)
		Minimally worsened	4 (6.3%)	5 (8.8%)	9 (7.5%)
		Much worsened	2 (3.2%)	4 (7.0%)	6 (5.0%)
		Very much worsened	0 (0.0%)	1 (1.8%)	1 (0.8%)
	Week 28		N=32	N=40	N=72
		Very much improved	5 (15.6%)	6 (15.0%)	11 (15.3%)
		Much improved	14 (43.8%)	14 (35.0%)	28 (38.9%)
		Minimally improved	4 (12.5%)	7 (17.5%)	11 (15.3%)
		No change	5 (15.6%)	4 (10.0%)	9 (12.5%)
		Minimally worsened	3 (9.4%)	6 (15.0%)	9 (12.5%)
		Much worsened	0 (0.0%)	3 (7.5%)	3 (4.2%)

Item	Visit	Response Level	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
		Very much worsened	1 (3.1%)	0 (0.0%)	1 (1.4%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Data cut off: 22 APR 2026

4.17. Table 1.1.10: PGI-Severity | Observed Scores and Change from Baseline by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

Item	Visit	Response Level	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
PGIS	Baseline (Week 1)		N=118	N=119	N=237
		Very Poor	5 (4.2%)	5 (4.2%)	10 (4.2%)
		Poor	10 (8.5%)	21 (17.6%)	31 (13.1%)
		Fair	47 (39.8%)	41 (34.5%)	88 (37.1%)
		Good	43 (36.4%)	43 (36.1%)	86 (36.3%)
		Excellent	13 (11.0%)	9 (7.6%)	22 (9.3%)
	Week 13		N=61	N=56	N=117
		Very Poor	0 (0.0%)	2 (3.6%)	2 (1.7%)
		Poor	1 (1.6%)	7 (12.5%)	8 (6.8%)
		Fair	30 (49.2%)	16 (28.6%)	46 (39.3%)
		Good	26 (42.6%)	24 (42.9%)	50 (42.7%)
		Excellent	4 (6.6%)	7 (12.5%)	11 (9.4%)
	Week 16		N=79	N=68	N=147
		Very Poor	1 (1.3%)	0 (0.0%)	1 (0.7%)
		Poor	5 (6.3%)	5 (7.4%)	10 (6.8%)
		Fair	42 (53.2%)	41 (60.3%)	83 (56.5%)
		Good	24 (30.4%)	18 (26.5%)	42 (28.6%)
		Excellent	7 (8.9%)	4 (5.9%)	11 (7.5%)
	Week 19		N=84	N=75	N=159

Item	Visit	Response Level	Sacituzumab Govitecan (N=125)	Treatment Physician Choice (N=124)	Overall (N=249)
		Very Poor	1 (1.2%)	0 (0.0%)	1 (0.6%)
		Poor	3 (3.6%)	6 (8.0%)	9 (5.7%)
		Fair	45 (53.6%)	38 (50.7%)	83 (52.2%)
		Good	29 (34.5%)	24 (32.0%)	53 (33.3%)
		Excellent	6 (7.1%)	7 (9.3%)	13 (8.2%)
	Week 22		N=71	N=65	N=136
		Very Poor	1 (1.4%)	1 (1.5%)	2 (1.5%)
		Poor	4 (5.6%)	8 (12.3%)	12 (8.8%)
		Fair	27 (38.0%)	26 (40.0%)	53 (39.0%)
		Good	35 (49.3%)	27 (41.5%)	62 (45.6%)
		Excellent	4 (5.6%)	3 (4.6%)	7 (5.1%)
	Week 25		N=63	N=57	N=120
		Very Poor	0 (0.0%)	3 (5.3%)	3 (2.5%)
		Poor	1 (1.6%)	7 (12.3%)	8 (6.7%)
		Fair	32 (50.8%)	24 (42.1%)	56 (46.7%)
		Good	27 (42.9%)	19 (33.3%)	46 (38.3%)
		Excellent	3 (4.8%)	4 (7.0%)	7 (5.8%)
	Week 28		N=32	N=40	N=72
		Very Poor	1 (3.1%)	0 (0.0%)	1 (1.4%)
		Poor	2 (6.2%)	5 (12.5%)	7 (9.7%)
		Fair	12 (37.5%)	20 (50.0%)	32 (44.4%)
		Good	12 (37.5%)	13 (32.5%)	25 (34.7%)
		Excellent	5 (15.6%)	2 (5.0%)	7 (9.7%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Data cut off: 22 APR 2026

4.18. Table 1.1.14.1: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Global Health Status/QoL | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	70 (56.0%)	73 (58.9%)
A meaningful deterioration	70 (56.0%)	73 (58.9%)
Censored, n (%)	55 (44.0%)	51 (41.1%)
Not at risk at baseline	2 (1.6%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	13 (10.4%)	4 (3.2%)
Premature treatment discontinuation	28 (22.4%)	36 (29.0%)
Others	4 (3.2%)	1 (0.8%)
Median TTD, months (95% CI)	4.1 (2.1, 6.3)	3.3 (2.1, 4.9)
Q1	0.8 (0.8, 1.5)	0.9 (0.8, 1.4)
Q3	NE	13.2 (6.9, NE)
Event-free rate, % (95% CI)		
At 3 months	53.0 (43.2, 61.8)	53.3 (43.6, 62.1)
At 6 months	45.3 (35.5, 54.5)	35.3 (25.8, 44.8)
At 12 months	32.8 (23.2, 42.8)	30.9 (21.0, 41.3)
At 18 months	27.8 (17.8, 38.6)	17.7 (7.2, 31.9)
At 24 months	27.8 (17.8, 38.6)	17.7 (7.2, 31.9)
p-value (two-sided, stratified log-rank)	0.6493	
Adjusted HR (95% CI), SG vs TPC	0.8903 (0.6392, 1.2401)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; QoL = Quality of life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.19. Table 1.1.14.2: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Physical Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	58 (46.4%)	70 (56.5%)
A meaningful deterioration	58 (46.4%)	70 (56.5%)
Censored, n (%)	67 (53.6%)	54 (43.5%)
Not at risk at baseline	1 (0.8%)	1 (0.8%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	13 (10.4%)	8 (6.5%)
Premature treatment discontinuation	42 (33.6%)	39 (31.5%)
Others	3 (2.4%)	0 (0.0%)
Median TTD, months (95% CI)	7.5 (3.6, 20.1)	4.9 (2.8, 8.3)
Q1	1.4 (0.9, 2.2)	1.4 (0.9, 1.6)
Q3	NE	19.4 (12.4, NE)
Event-free rate, % (95% CI)		
At 3 months	64.3 (54.7, 72.4)	58.6 (48.8, 67.1)
At 6 months	57.1 (47.2, 65.8)	43.6 (33.8, 53.0)
At 12 months	44.0 (33.0, 54.4)	36.4 (26.2, 46.7)
At 18 months	41.1 (29.5, 52.3)	26.1 (14.7, 39.0)
At 24 months	30.0 (15.5, 45.8)	20.9 (9.3, 35.5)

	SG (N=125)	TPC (N=124)
p-value (two-sided, stratified log-rank)	0.1963	
Adjusted HR (95% CI), SG vs TPC	0.7723 (0.5423, 1.0999)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.20. Table 1.1.14.3: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Role Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	72 (57.6%)	84 (67.7%)
A meaningful deterioration	72 (57.6%)	84 (67.7%)
Censored, n (%)	53 (42.4%)	40 (32.3%)
Not at risk at baseline	5 (4.0%)	3 (2.4%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	12 (9.6%)	4 (3.2%)
Premature treatment discontinuation	26 (20.8%)	27 (21.8%)
Others	2 (1.6%)	0 (0.0%)
Median TTD, months (95% CI)	1.7 (1.4, 2.8)	3.5 (1.7, 5.0)
Q1	0.8 (0.8, 1.0)	0.9 (0.8, 1.0)
Q3	20.8 (8.4, NE)	7.8 (5.6, 10.6)
Event-free rate, % (95% CI)		

	SG (N=125)	TPC (N=124)
At 3 months	40.2 (30.8, 49.3)	51.9 (42.2, 60.7)
At 6 months	36.8 (27.6, 46.0)	32.3 (23.5, 41.5)
At 12 months	31.3 (21.8, 41.3)	14.1 (6.9, 23.8)
At 18 months	28.2 (18.2, 39.0)	14.1 (6.9, 23.8)
At 24 months	23.5 (12.6, 36.4)	14.1 (6.9, 23.8)
p-value (two-sided, stratified log-rank)	0.9588	
Adjusted HR (95% CI), SG vs TPC	0.9727 (0.7064, 1.3393)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.21. Table 1.1.14.4: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Emotional Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	59 (47.2%)	56 (45.2%)
A meaningful deterioration	59 (47.2%)	56 (45.2%)
Censored, n (%)	66 (52.8%)	68 (54.8%)
Not at risk at baseline	0 (0.0%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	12 (9.6%)	6 (4.8%)
Premature treatment discontinuation	43 (34.4%)	52 (41.9%)

	SG (N=125)	TPC (N=124)
Others	3 (2.4%)	0 (0.0%)
Median TTD, months (95% CI)	7.8 (4.4, 11.4)	9.1 (4.7, 12.3)
Q1	2.8 (1.5, 3.4)	3.0 (1.6, 3.8)
Q3	NE	14.0 (10.8, NE)
Event-free rate, % (95% CI)		
At 3 months	73.1 (63.8, 80.4)	76.6 (67.3, 83.6)
At 6 months	55.6 (45.2, 64.7)	54.9 (44.2, 64.4)
At 12 months	35.9 (24.2, 47.7)	37.7 (24.0, 51.4)
At 18 months	28.0 (16.6, 40.5)	7.5 (0.7, 25.8)
At 24 months	28.0 (16.6, 40.5)	7.5 (0.7, 25.8)
p-value (two-sided, stratified log-rank)	0.8268	
Adjusted HR (95% CI), SG vs TPC	1.0088 (0.6953, 1.4636)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.22. Table 1.1.14.5: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Cognitive Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	69 (55.2%)	79 (63.7%)
A meaningful deterioration	69 (55.2%)	79 (63.7%)
Censored, n (%)	56 (44.8%)	45 (36.3%)
Not at risk at baseline	1 (0.8%)	0 (0.0%)

	SG (N=125)	TPC (N=124)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	10 (8.0%)	5 (4.0%)
Premature treatment discontinuation	34 (27.2%)	33 (26.6%)
Others	3 (2.4%)	1 (0.8%)
Median TTD, months (95% CI)	4.5 (2.8, 6.9)	2.9 (2.1, 4.1)
Q1	1.6 (1.0, 2.2)	1.0 (0.8, 1.7)
Q3	18.5 (9.8, NE)	11.8 (7.0, NE)
Event-free rate, % (95% CI)		
At 3 months	57.8 (47.9, 66.5)	49.2 (39.6, 58.1)
At 6 months	42.7 (32.7, 52.3)	35.5 (26.5, 44.5)
At 12 months	34.3 (24.2, 44.7)	23.9 (14.6, 34.5)
At 18 months	25.4 (14.8, 37.5)	20.5 (11.1, 32.0)
At 24 months	15.9 (5.7, 30.6)	15.4 (5.9, 28.9)
p-value (two-sided, stratified log-rank)	0.1605	
Adjusted HR (95% CI), SG vs TPC	0.7630 (0.5508, 1.0568)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.23. Table 1.1.14.6: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Social Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	68 (54.4%)	77 (62.1%)
A meaningful deterioration	68 (54.4%)	77 (62.1%)
Censored, n (%)	57 (45.6%)	47 (37.9%)
Not at risk at baseline	5 (4.0%)	0 (0.0%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	12 (9.6%)	7 (5.6%)
Premature treatment discontinuation	29 (23.2%)	33 (26.6%)
Others	3 (2.4%)	1 (0.8%)
Median TTD, months (95% CI)	2.8 (1.4, 7.5)	3.5 (2.2, 4.9)
Q1	0.8 (0.8, 1.0)	0.8 (0.8, 1.0)
Q3	24.4 (16.1, NE)	15.2 (5.8, NE)
Event-free rate, % (95% CI)		
At 3 months	49.1 (39.4, 58.2)	55.4 (45.8, 64.0)
At 6 months	41.5 (31.9, 50.8)	33.5 (24.3, 43.0)
At 12 months	38.3 (28.6, 47.9)	26.4 (17.2, 36.5)
At 18 months	31.8 (20.7, 43.5)	22.0 (11.9, 34.0)
At 24 months	26.5 (14.2, 40.5)	14.7 (4.3, 31.1)
p-value (two-sided, stratified log-rank)	0.4218	
Adjusted HR (95% CI), SG vs TPC	0.8334 (0.5977, 1.1621)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.24. Table 1.1.14.7: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Fatigue | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	83 (66.4%)	92 (74.2%)
A meaningful deterioration	83 (66.4%)	92 (74.2%)
Censored, n (%)	42 (33.6%)	32 (25.8%)
Not at risk at baseline	2 (1.6%)	1 (0.8%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	10 (8.0%)	1 (0.8%)
Premature treatment discontinuation	20 (16.0%)	23 (18.5%)
Others	2 (1.6%)	1 (0.8%)
Median TTD, months (95% CI)	1.4 (1.0, 1.8)	1.4 (1.0, 2.1)
Q1	0.8 (0.8, 0.8)	0.8 (0.8, 0.9)
Q3	9.8 (3.2, NE)	4.9 (3.5, 7.0)
Event-free rate, % (95% CI)		
At 3 months	35.2 (26.4, 44.0)	37.8 (28.8, 46.7)
At 6 months	28.0 (19.9, 36.7)	18.3 (11.1, 26.8)
At 12 months	24.4 (16.2, 33.5)	9.2 (3.6, 17.9)
At 18 months	24.4 (16.2, 33.5)	9.2 (3.6, 17.9)
At 24 months	19.5 (9.9, 31.5)	9.2 (3.6, 17.9)
p-value (two-sided, stratified log-rank)	0.5648	

	SG (N=125)	TPC (N=124)
Adjusted HR (95% CI), SG vs TPC	0.8928 (0.6604, 1.2070)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.25. Table 1.1.14.8: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Nausea and Vomiting | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	81 (64.8%)	79 (63.7%)
A meaningful deterioration	81 (64.8%)	79 (63.7%)
Censored, n (%)	44 (35.2%)	45 (36.3%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	7 (5.6%)	8 (6.5%)
Premature treatment discontinuation	28 (22.4%)	31 (25.0%)
Others	1 (0.8%)	0 (0.0%)
Median TTD, months (95% CI)	1.7 (1.4, 2.6)	1.7 (1.4, 3.1)
Q1	0.8 (0.8, 0.9)	0.8 (0.8, 1.0)
Q3	11.2 (3.5, NE)	19.6 (8.1, NE)
Event-free rate, % (95% CI)		
At 3 months	37.4 (28.4, 46.3)	41.4 (32.2, 50.2)

	SG (N=125)	TPC (N=124)
At 6 months	30.6 (22.0, 39.6)	34.2 (25.4, 43.1)
At 12 months	20.1 (11.0, 31.1)	26.2 (16.4, 37.0)
At 18 months	20.1 (11.0, 31.1)	26.2 (16.4, 37.0)
At 24 months	20.1 (11.0, 31.1)	9.8 (1.1, 30.4)
p-value (two-sided, stratified log-rank)	0.9806	
Adjusted HR (95% CI), SG vs TPC	0.9951 (0.7236, 1.3685)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.26. Table 1.1.14.9: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Pain | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	59 (47.2%)	76 (61.3%)
A meaningful deterioration	59 (47.2%)	76 (61.3%)
Censored, n (%)	66 (52.8%)	48 (38.7%)
Not at risk at baseline	8 (6.4%)	5 (4.0%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	12 (9.6%)	3 (2.4%)
Premature treatment discontinuation	36 (28.8%)	34 (27.4%)
Others	2 (1.6%)	0 (0.0%)

	SG (N=125)	TPC (N=124)
Median TTD, months (95% CI)	7.7 (2.5, 11.8)	2.8 (2.1, 5.1)
Q1	1.4 (0.8, 1.6)	1.1 (0.8, 1.6)
Q3	26.1 (15.5, NE)	10.9 (6.5, NE)
Event-free rate, % (95% CI)		
At 3 months	58.4 (48.2, 67.3)	48.0 (38.3, 57.1)
At 6 months	53.6 (43.3, 62.9)	37.5 (28.2, 46.8)
At 12 months	38.5 (27.1, 49.8)	22.7 (13.4, 33.5)
At 18 months	29.3 (17.5, 42.2)	14.2 (5.2, 27.5)
At 24 months	29.3 (17.5, 42.2)	14.2 (5.2, 27.5)
p-value (two-sided, stratified log-rank)	0.1658	
Adjusted HR (95% CI), SG vs TPC	0.7470 (0.5271, 1.0588)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.27. Table 1.1.14.10: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Dyspnoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	43 (34.4%)	65 (52.4%)
A meaningful deterioration	43 (34.4%)	65 (52.4%)
Censored, n (%)	82 (65.6%)	59 (47.6%)
Not at risk at baseline	1 (0.8%)	3 (2.4%)
Missing baseline only	2 (1.6%)	2 (1.6%)

	SG (N=125)	TPC (N=124)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	14 (11.2%)	8 (6.5%)
Premature treatment discontinuation	55 (44.0%)	42 (33.9%)
Others	4 (3.2%)	0 (0.0%)
Median TTD, months (95% CI)	15.5 (9.6, NE)	4.9 (3.3, 6.7)
Q1	2.8 (1.4, 6.7)	1.4 (0.9, 2.1)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	73.7 (64.4, 81.0)	61.7 (51.9, 70.1)
At 6 months	66.8 (56.7, 75.0)	44.5 (34.4, 54.1)
At 12 months	55.2 (43.1, 65.7)	33.6 (23.1, 44.5)
At 18 months	49.7 (36.7, 61.5)	30.3 (19.2, 42.0)
At 24 months	49.7 (36.7, 61.5)	25.2 (13.3, 39.0)
p-value (two-sided, stratified log-rank)	0.0026	
Adjusted HR (95% CI), SG vs TPC	0.5322 (0.3596, 0.7875)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.28. Table 1.1.14.11: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Insomnia | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	59 (47.2%)	67 (54.0%)
A meaningful deterioration	59 (47.2%)	67 (54.0%)
Censored, n (%)	66 (52.8%)	57 (46.0%)
Not at risk at baseline	6 (4.8%)	7 (5.6%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	10 (8.0%)	7 (5.6%)
Premature treatment discontinuation	41 (32.8%)	37 (29.8%)
Others	1 (0.8%)	0 (0.0%)
Median TTD, months (95% CI)	5.3 (3.5, 10.8)	4.2 (3.3, 6.0)
Q1	1.4 (1.0, 2.3)	1.2 (0.9, 1.9)
Q3	18.0 (14.4, NE)	13.8 (7.0, NE)
Event-free rate, % (95% CI)		
At 3 months	63.7 (53.7, 72.1)	62.2 (52.2, 70.7)
At 6 months	49.6 (39.1, 59.2)	41.2 (31.2, 50.9)
At 12 months	37.3 (26.0, 48.6)	31.2 (21.2, 41.7)
At 18 months	28.4 (15.6, 42.6)	22.3 (11.0, 35.9)
At 24 months	23.7 (11.1, 38.8)	22.3 (11.0, 35.9)
p-value (two-sided, stratified log-rank)	0.2777	
Adjusted HR (95% CI), SG vs TPC	0.8102 (0.5679, 1.1560)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.29. Table 1.1.14.12: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Appetite Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	64 (51.2%)	68 (54.8%)
A meaningful deterioration	64 (51.2%)	68 (54.8%)
Censored, n (%)	61 (48.8%)	56 (45.2%)
Not at risk at baseline	1 (0.8%)	3 (2.4%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	12 (9.6%)	6 (4.8%)
Premature treatment discontinuation	35 (28.0%)	40 (32.3%)
Others	5 (4.0%)	1 (0.8%)
Median TTD, months (95% CI)	3.4 (1.8, 11.8)	3.5 (2.1, 7.9)
Q1	0.9 (0.8, 1.4)	1.0 (0.8, 1.4)
Q3	NE	14.5 (11.1, NE)
Event-free rate, % (95% CI)		
At 3 months	53.1 (43.4, 61.9)	55.3 (45.5, 64.1)
At 6 months	43.3 (33.6, 52.6)	43.2 (33.3, 52.6)
At 12 months	39.1 (28.8, 49.3)	33.0 (21.4, 45.1)
At 18 months	35.2 (23.7, 46.9)	16.5 (5.3, 33.1)
At 24 months	35.2 (23.7, 46.9)	11.0 (2.3, 27.6)

	SG (N=125)	TPC (N=124)
p-value (two-sided, stratified log-rank)	0.6802	
Adjusted HR (95% CI), SG vs TPC	0.9084 (0.6438, 1.2817)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.30. Table 1.1.14.13: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Constipation | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	67 (53.6%)	73 (58.9%)
A meaningful deterioration	67 (53.6%)	73 (58.9%)
Censored, n (%)	58 (46.4%)	51 (41.1%)
Not at risk at baseline	4 (3.2%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	9 (7.2%)	7 (5.6%)
Premature treatment discontinuation	35 (28.0%)	32 (25.8%)
Others	2 (1.6%)	2 (1.6%)
Median TTD, months (95% CI)	2.5 (1.8, 6.9)	2.3 (1.5, 6.2)
Q1	1.0 (0.8, 1.4)	0.8 (0.8, 0.9)
Q3	NE	13.3 (6.6, NE)
Event-free rate, % (95% CI)		

	SG (N=125)	TPC (N=124)
At 3 months	46.4 (36.7, 55.5)	44.3 (34.8, 53.4)
At 6 months	40.8 (31.3, 50.2)	41.0 (31.5, 50.2)
At 12 months	39.2 (29.6, 48.7)	30.4 (20.6, 40.8)
At 18 months	32.5 (21.2, 44.4)	21.7 (10.8, 35.1)
At 24 months	26.0 (12.8, 41.4)	16.3 (5.9, 31.3)
p-value (two-sided, stratified log-rank)	0.3640	
Adjusted HR (95% CI), SG vs TPC	0.8239 (0.5883, 1.1539)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.31. Table 1.1.14.14: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Diarrhoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	84 (67.2%)	47 (37.9%)
A meaningful deterioration	84 (67.2%)	47 (37.9%)
Censored, n (%)	41 (32.8%)	77 (62.1%)
Not at risk at baseline	1 (0.8%)	0 (0.0%)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	7 (5.6%)	12 (9.7%)
Premature treatment discontinuation	22 (17.6%)	58 (46.8%)

	SG (N=125)	TPC (N=124)
Others	3 (2.4%)	1 (0.8%)
Median TTD, months (95% CI)	1.6 (1.0, 2.8)	10.1 (5.8, NE)
Q1	0.8 (0.8, 0.9)	2.5 (1.6, 4.2)
Q3	7.2 (3.7, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	38.1 (29.1, 47.1)	72.1 (62.8, 79.5)
At 6 months	26.9 (18.7, 35.8)	59.2 (48.7, 68.2)
At 12 months	22.1 (14.1, 31.3)	49.6 (36.3, 61.6)
At 18 months	16.8 (8.9, 27.0)	44.1 (28.6, 58.5)
At 24 months	16.8 (8.9, 27.0)	44.1 (28.6, 58.5)
p-value (two-sided, stratified log-rank)	0.0000	
Adjusted HR (95% CI), SG vs TPC	2.7082 (1.8775, 3.9065)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.32. Table 1.1.14.15: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Financial Difficulties | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	42 (33.6%)	45 (36.3%)
A meaningful deterioration	42 (33.6%)	45 (36.3%)
Censored, n (%)	83 (66.4%)	79 (63.7%)
Not at risk at baseline	10 (8.0%)	9 (7.3%)

	SG (N=125)	TPC (N=124)
Missing baseline only	2 (1.6%)	2 (1.6%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
No baseline or any postbaseline	0 (0.0%)	1 (0.8%)
Missing PRO for two consecutive visits	10 (8.0%)	10 (8.1%)
Premature treatment discontinuation	52 (41.6%)	53 (42.7%)
Others	3 (2.4%)	1 (0.8%)
Median TTD, months (95% CI)	19.0 (7.9, NE)	19.4 (5.1, NE)
Q1	2.8 (1.7, 5.1)	2.4 (1.4, 3.7)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	75.0 (65.2, 82.4)	72.4 (62.6, 80.1)
At 6 months	65.2 (54.5, 74.0)	56.8 (45.9, 66.3)
At 12 months	56.2 (44.4, 66.5)	51.0 (39.4, 61.5)
At 18 months	52.7 (39.7, 64.2)	51.0 (39.4, 61.5)
At 24 months	41.9 (25.3, 57.7)	25.5 (2.2, 61.3)
p-value (two-sided, stratified log-rank)	0.3121	
Adjusted HR (95% CI), SG vs TPC	0.7708 (0.4985, 1.1918)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.33. Table 1.1.15.1: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Body Image | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	68 (54.4%)	55 (44.4%)
A meaningful deterioration	68 (54.4%)	55 (44.4%)
Censored, n (%)	57 (45.6%)	69 (55.6%)
Not at risk at baseline	6 (4.8%)	4 (3.2%)
Having baseline but no postbaseline visit	6 (4.8%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits	7 (5.6%)	4 (3.2%)
Premature treatment discontinuation	29 (23.2%)	41 (33.1%)
Others	6 (4.8%)	13 (10.5%)
Median TTFD, months (95% CI)	3.0 (1.7, 4.6)	5.4 (3.3, 17.1)
Q1	1.0 (0.8, 1.5)	1.4 (0.9, 2.0)
Q3	13.3 (6.9, NE)	24.4 (17.1, NE)
Event-free rate, % (95% CI)		
At 3 months	50.6 (40.4, 60.0)	61.3 (51.2, 69.8)
At 6 months	37.2 (27.4, 47.0)	49.7 (39.0, 59.4)
At 12 months	30.7 (21.0, 40.9)	45.7 (34.7, 56.1)
At 18 months	22.3 (12.5, 33.9)	32.0 (15.5, 49.9)
At 24 months	22.3 (12.5, 33.9)	32.0 (15.5, 49.9)
p-value (two-sided, stratified log-rank)	0.0343	
Adjusted HR (95% CI), SG vs TPC	1.4795 (1.0278, 2.1299)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.

Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.34. Table 1.1.15.2: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Sexual Functioning | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	35 (28.0%)	36 (29.0%)
A meaningful deterioration	35 (28.0%)	36 (29.0%)
Censored, n (%)	90 (72.0%)	88 (71.0%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (4.8%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits	11 (8.8%)	8 (6.5%)
Premature treatment discontinuation	52 (41.6%)	50 (40.3%)
Others	18 (14.4%)	23 (18.5%)
Median TTFD, months (95% CI)	NE	NE
Q1	3.7 (1.8, 10.0)	3.5 (1.5, 6.2)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	80.5 (71.7, 86.9)	79.0 (70.0, 85.5)
At 6 months	71.2 (61.1, 79.1)	66.8 (56.2, 75.3)
At 12 months	61.7 (49.5, 71.7)	61.4 (50.0, 71.0)
At 18 months	58.4 (45.2, 69.5)	61.4 (50.0, 71.0)

	SG (N=125)	TPC (N=124)
At 24 months	58.4 (45.2, 69.5)	61.4 (50.0, 71.0)
p-value (two-sided, stratified log-rank)	0.6921	
Adjusted HR (95% CI), SG vs TPC	0.9026 (0.5653, 1.4412)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.35. Table 1.1.15.3: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Sexual Enjoyment | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	6 (4.8%)	5 (4.0%)
A meaningful deterioration	6 (4.8%)	5 (4.0%)
Censored, n (%)	119 (95.2%)	119 (96.0%)
Not at risk at baseline	3 (2.4%)	6 (4.8%)
Having baseline but no postbaseline visit	8 (6.4%)	14 (11.3%)
Missing baseline only	16 (12.8%)	14 (11.3%)
No baseline or any postbaseline	62 (49.6%)	54 (43.5%)
Missing PRO for two consecutive visits	17 (13.6%)	17 (13.7%)
Premature treatment discontinuation	9 (7.2%)	9 (7.3%)
Others	4 (3.2%)	5 (4.0%)
Median TTFD, months (95% CI)	NE	NE
Q1	1.6 (0.7, NE)	NE
Q3	NE	NE

	SG (N=125)	TPC (N=124)
Event-free rate, % (95% CI)		
At 3 months	74.8 (52.2, 87.9)	88.6 (68.6, 96.2)
At 6 months	74.8 (52.2, 87.9)	77.4 (53.0, 90.2)
At 12 months	74.8 (52.2, 87.9)	77.4 (53.0, 90.2)
At 18 months	74.8 (52.2, 87.9)	77.4 (53.0, 90.2)
At 24 months	74.8 (52.2, 87.9)	77.4 (53.0, 90.2)
p-value (two-sided, stratified log-rank)	0.2955	
Adjusted HR (95% CI), SG vs TPC	2.1562 (0.6257, 7.4305)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.36. Table 1.1.15.4: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Future Perspective | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	46 (36.8%)	52 (41.9%)
A meaningful deterioration	46 (36.8%)	52 (41.9%)
Censored, n (%)	79 (63.2%)	72 (58.1%)
Not at risk at baseline	26 (20.8%)	20 (16.1%)
Having baseline but no postbaseline visit	6 (4.8%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits	7 (5.6%)	3 (2.4%)

	SG (N=125)	TPC (N=124)
Premature treatment discontinuation	23 (18.4%)	32 (25.8%)
Others	14 (11.2%)	10 (8.1%)
Median TTFD, months (95% CI)	6.3 (2.2, 13.1)	5.4 (2.5, 10.2)
Q1	1.4 (1.1, 1.7)	1.4 (0.9, 1.6)
Q3	27.9 (13.1, NE)	13.8 (10.2, NE)
Event-free rate, % (95% CI)		
At 3 months	58.2 (46.6, 68.1)	58.9 (48.1, 68.2)
At 6 months	50.3 (38.5, 61.0)	49.1 (38.0, 59.3)
At 12 months	42.6 (30.7, 54.1)	33.0 (18.9, 47.7)
At 18 months	36.3 (23.6, 49.0)	22.0 (6.2, 43.7)
At 24 months	36.3 (23.6, 49.0)	22.0 (6.2, 43.7)
p-value (two-sided, stratified log-rank)	0.7689	
Adjusted HR (95% CI), SG vs TPC	0.8761 (0.5804, 1.3224)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.37. Table 1.1.15.5: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Systemic Therapy Side Effects | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	91 (72.8%)	73 (58.9%)
A meaningful deterioration	91 (72.8%)	73 (58.9%)
Censored, n (%)	34 (27.2%)	51 (41.1%)

	SG (N=125)	TPC (N=124)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	6 (4.8%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits	5 (4.0%)	2 (1.6%)
Premature treatment discontinuation	16 (12.8%)	32 (25.8%)
Others	4 (3.2%)	10 (8.1%)
Median TTFD, months (95% CI)	0.9 (0.8, 1.1)	3.1 (1.7, 5.1)
Q1	0.8 (0.8, 0.8)	0.9 (0.8, 1.4)
Q3	2.8 (1.5, 8.5)	15.0 (6.5, NE)
Event-free rate, % (95% CI)		
At 3 months	24.3 (16.7, 32.6)	51.7 (42.0, 60.5)
At 6 months	19.1 (12.0, 27.5)	34.7 (25.2, 44.4)
At 12 months	14.9 (8.0, 23.9)	26.4 (15.9, 38.2)
At 18 months	14.9 (8.0, 23.9)	15.9 (5.5, 31.1)
At 24 months	14.9 (8.0, 23.9)	15.9 (5.5, 31.1)
p-value (two-sided, stratified log-rank)	0.0000	
Adjusted HR (95% CI), SG vs TPC	1.9058 (1.3892, 2.6144)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.38. Table 1.1.15.6: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Breast Symptoms | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	36 (28.8%)	33 (26.6%)
A meaningful deterioration	36 (28.8%)	33 (26.6%)
Censored, n (%)	89 (71.2%)	91 (73.4%)
Not at risk at baseline	5 (4.0%)	3 (2.4%)
Having baseline but no postbaseline visit	6 (4.8%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits	12 (9.6%)	9 (7.3%)
Premature treatment discontinuation	40 (32.0%)	48 (38.7%)
Others	23 (18.4%)	24 (19.4%)
Median TTFD, months (95% CI)	24.7 (17.1, NE)	NE
Q1	3.9 (1.8, 9.3)	3.9 (2.1, 8.7)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	78.3 (68.9, 85.2)	77.8 (68.4, 84.7)
At 6 months	67.9 (57.1, 76.5)	68.3 (57.5, 76.9)
At 12 months	62.0 (50.1, 71.9)	63.2 (50.7, 73.3)
At 18 months	56.1 (42.7, 67.6)	56.9 (40.0, 70.6)
At 24 months	56.1 (42.7, 67.6)	56.9 (40.0, 70.6)
p-value (two-sided, stratified log-rank)	0.8344	
Adjusted HR (95% CI), SG vs TPC	0.9575 (0.5903, 1.5533)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.39. Table 1.1.15.7: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Arm Symptoms | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	59 (47.2%)	68 (54.8%)
A meaningful deterioration	59 (47.2%)	68 (54.8%)
Censored, n (%)	66 (52.8%)	56 (45.2%)
Not at risk at baseline	2 (1.6%)	3 (2.4%)
Having baseline but no postbaseline visit	6 (4.8%)	4 (3.2%)
Missing baseline only	2 (1.6%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	1 (0.8%)
Missing PRO for two consecutive visits	7 (5.6%)	7 (5.6%)
Premature treatment discontinuation	32 (25.6%)	30 (24.2%)
Others	16 (12.8%)	9 (7.3%)
Median TTFD, months (95% CI)	6.8 (4.0, 10.8)	3.7 (2.8, 5.6)
Q1	1.6 (1.1, 2.9)	1.2 (0.9, 1.7)
Q3	NE	12.7 (6.3, NE)
Event-free rate, % (95% CI)		
At 3 months	66.5 (56.7, 74.6)	56.7 (46.6, 65.5)
At 6 months	54.5 (44.0, 63.9)	38.1 (28.0, 48.0)
At 12 months	38.7 (27.4, 49.8)	25.3 (14.9, 37.2)
At 18 months	27.9 (16.6, 40.4)	21.1 (10.5, 34.1)
At 24 months	27.9 (16.6, 40.4)	21.1 (10.5, 34.1)
p-value (two-sided, stratified log-rank)	0.0542	

	SG (N=125)	TPC (N=124)
Adjusted HR (95% CI), SG vs TPC	0.7027 (0.4924, 1.0028)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.40. Table 1.1.15.8: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Upset By Hair Loss | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	13 (10.4%)	13 (10.5%)
A meaningful deterioration	13 (10.4%)	13 (10.5%)
Censored, n (%)	112 (89.6%)	111 (89.5%)
Not at risk at baseline	1 (0.8%)	2 (1.6%)
Having baseline but no postbaseline visit	1 (0.8%)	3 (2.4%)
Missing baseline only	96 (76.8%)	64 (51.6%)
No baseline or any postbaseline	6 (4.8%)	31 (25.0%)
Missing PRO for two consecutive visits	3 (2.4%)	5 (4.0%)
Premature treatment discontinuation	3 (2.4%)	5 (4.0%)
Others	2 (1.6%)	1 (0.8%)
Median TTFD, months (95% CI)	2.2 (0.9, NE)	1.4 (0.8, NE)
Q1	0.9 (0.1, 1.0)	0.8 (0.7, 1.4)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	45.4 (23.4, 65.1)	42.1 (20.4, 62.5)

	SG (N=125)	TPC (N=124)
At 6 months	39.7 (18.8, 60.0)	31.6 (12.9, 52.2)
At 12 months	33.1 (13.6, 54.2)	31.6 (12.9, 52.2)
At 18 months	33.1 (13.6, 54.2)	31.6 (12.9, 52.2)
At 24 months	33.1 (13.6, 54.2)	31.6 (12.9, 52.2)
p-value (two-sided, stratified log-rank)	0.4629	
Adjusted HR (95% CI), SG vs TPC	0.8690 (0.3973, 1.9005)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.41. Table 1.1.16: Time to First Deterioration of EQ-5D VAS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	44 (35.2%)	45 (36.3%)
A meaningful deterioration	44 (35.2%)	45 (36.3%)
Censored, n (%)	81 (64.8%)	79 (63.7%)
Not at risk at baseline	1 (0.8%)	1 (0.8%)
Having baseline but no postbaseline visit	6 (4.8%)	3 (2.4%)
Missing baseline only	3 (2.4%)	2 (1.6%)
No baseline or any postbaseline	1 (0.8%)	2 (1.6%)
Missing PRO for two consecutive visits	12 (9.6%)	10 (8.1%)
Premature treatment discontinuation	49 (39.2%)	59 (47.6%)
Others	9 (7.2%)	2 (1.6%)

	SG (N=125)	TPC (N=124)
Median TTD, months (95% CI)	18.7 (8.9, NE)	12.4 (9.5, NE)
Q1	2.3 (1.3, 4.9)	2.5 (1.1, 5.1)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	71.5 (62.0, 79.1)	73.8 (64.5, 81.0)
At 6 months	64.5 (54.3, 73.0)	65.0 (54.9, 73.4)
At 12 months	55.3 (43.6, 65.4)	50.8 (36.7, 63.3)
At 18 months	52.3 (40.0, 63.3)	34.2 (17.0, 52.3)
At 24 months	48.3 (34.6, 60.7)	34.2 (17.0, 52.3)
p-value (two-sided, stratified log-rank)	0.8474	
Adjusted HR (95% CI), SG vs TPC	0.9374 (0.6154, 1.4278)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EQ-5D VAS is ≥15 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; VAS = Visual analogue scale; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.42. Table 1.1.18: Time to First Deterioration of PGI-Change — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	26 (20.8%)	30 (24.2%)
A meaningful deterioration	26 (20.8%)	30 (24.2%)
Censored, n (%)	99 (79.2%)	94 (75.8%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	0 (0.0%)	0 (0.0%)

	SG (N=125)	TPC (N=124)
Missing baseline only	0 (0.0%)	0 (0.0%)
No baseline or any postbaseline	29 (23.2%)	24 (19.4%)
Missing PRO for two consecutive visits	10 (8.0%)	9 (7.3%)
Premature treatment discontinuation	60 (48.0%)	61 (49.2%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	NE	NE
Q1	5.4 (3.6, NE)	5.3 (3.6, 6.3)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	91.6 (83.8, 95.7)	94.9 (88.1, 97.8)
At 6 months	70.2 (58.5, 79.2)	67.4 (55.6, 76.7)
At 12 months	66.9 (53.6, 77.1)	58.0 (43.5, 70.0)
At 18 months	66.9 (53.6, 77.1)	58.0 (43.5, 70.0)
At 24 months	66.9 (53.6, 77.1)	58.0 (43.5, 70.0)
p-value (two-sided, stratified log-rank)	0.7067	
Adjusted HR (95% CI), SG vs TPC	0.9257 (0.5437, 1.5760)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
For PGIC, "minimally worsened", "much worsened," and "very much worsened" are classified as responders.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.43. Table 1.1.19: Time to First Deterioration of PGI-Severity — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)
Events, n (%)	11 (8.8%)	12 (9.7%)
A meaningful deterioration	11 (8.8%)	12 (9.7%)
Censored, n (%)	114 (91.2%)	112 (90.3%)
Not at risk at baseline	12 (9.6%)	20 (16.1%)
Having baseline but no postbaseline visit	26 (20.8%)	23 (18.5%)
Missing baseline only	3 (2.4%)	2 (1.6%)
No baseline or any postbaseline	3 (2.4%)	1 (0.8%)
Missing PRO for two consecutive visits	8 (6.4%)	9 (7.3%)
Premature treatment discontinuation	62 (49.6%)	57 (46.0%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	NE	NE
Q1	NE	6.6 (5.8, NE)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	98.8 (91.5, 99.8)	97.3 (89.7, 99.3)
At 6 months	86.3 (76.1, 92.4)	84.0 (71.8, 91.2)
At 12 months	78.5 (56.5, 90.3)	72.0 (50.4, 85.4)
At 18 months	78.5 (56.5, 90.3)	72.0 (50.4, 85.4)
At 24 months	78.5 (56.5, 90.3)	72.0 (50.4, 85.4)
p-value (two-sided, stratified log-rank)	0.8507	
Adjusted HR (95% CI), SG vs TPC	1.0213 (0.4451, 2.3436)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
For PGIS, "very poor" and "poor" were classified as responders.

Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel or paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.44. Table 1.1.20.1: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Global Health Status/QoL | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.4766
Number (%) of Participants with Events (Deterioration)	13 (44.8%)	11 (42.3%)	
Number (%) of Participants Censored	16 (55.2%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.82 (1.68, NR)	10.94 (2.33, NR)	
Log-Rank Test p-value (unstratified)	0.9907		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.011 (0.449, 2.277)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	21 (67.7%)	23 (74.2%)	
Number (%) of Participants Censored	10 (32.3%)	8 (25.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.39 (0.95, 7.72)	1.68 (0.85, 3.02)	
Log-Rank Test p-value (unstratified)	0.1747		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.669 (0.367, 1.218)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	36 (55.4%)	39 (58.2%)	
Number (%) of Participants Censored	29 (44.6%)	28 (41.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	2.30 (1.58, 6.31)	3.91 (1.71, 5.75)	
Log-Rank Test p-value (unstratified)	0.9302		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.020 (0.646, 1.608)		
Geographic region			
US/Canada/Western Europe	30	35	0.0909
Number (%) of Participants with Events (Deterioration)	14 (46.7%)	24 (68.6%)	
Number (%) of Participants Censored	16 (53.3%)	11 (31.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.93 (1.68, NR)	1.41 (0.89, 4.86)	
Log-Rank Test p-value (unstratified)	0.0652		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.542 (0.277, 1.061)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	56 (58.9%)	49 (55.1%)	
Number (%) of Participants Censored	39 (41.1%)	40 (44.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.84, 7.20)	4.21 (2.46, 13.01)	
Log-Rank Test p-value (unstratified)	0.7680		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.060 (0.721, 1.558)		
Age group			
< 65	98	96	0.8087
Number (%) of Participants with Events (Deterioration)	58 (59.2%)	55 (57.3%)	
Number (%) of Participants Censored	40 (40.8%)	41 (42.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.99 (2.10, 7.66)	3.71 (2.14, 5.59)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.6095		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.912 (0.629, 1.322)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	12 (44.4%)	18 (64.3%)	
Number (%) of Participants Censored	15 (55.6%)	10 (35.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.30 (1.02, NR)	2.63 (1.05, 10.94)	
Log-Rank Test p-value (unstratified)	0.6328		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.833 (0.398, 1.743)		
Race			
White	81	77	0.7750
Number (%) of Participants with Events (Deterioration)	46 (56.8%)	52 (67.5%)	
Number (%) of Participants Censored	35 (43.2%)	25 (32.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.43 (1.41, 6.01)	2.69 (1.41, 3.91)	
Log-Rank Test p-value (unstratified)	0.2547		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.797 (0.534, 1.189)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	14 (53.8%)	
Number (%) of Participants Censored	11 (42.3%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (1.84, 15.51)	5.59 (1.61, 14.03)	
Log-Rank Test p-value (unstratified)	0.8340		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.924 (0.442, 1.933)		

	SG (N=125)	TPC (N=124)	Interaction
Other	16	21	
Number (%) of Participants with Events (Deterioration)	7 (43.8%)	7 (33.3%)	
Number (%) of Participants Censored	9 (56.2%)	14 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.24 (2.40, NR)	NR (0.82, NR)	
Log-Rank Test p-value (unstratified)	0.8389		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.116 (0.389, 3.204)		
Baseline ECOG status			
0	81	80	0.3009
Number (%) of Participants with Events (Deterioration)	48 (59.3%)	54 (67.5%)	
Number (%) of Participants Censored	33 (40.7%)	26 (32.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.93 (1.84, 7.20)	2.46 (1.61, 4.21)	
Log-Rank Test p-value (unstratified)	0.2385		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.796 (0.539, 1.175)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	22 (50.0%)	19 (43.2%)	
Number (%) of Participants Censored	22 (50.0%)	25 (56.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.19 (1.41, NR)	10.94 (2.69, NR)	
Log-Rank Test p-value (unstratified)	0.7132		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.124 (0.600, 2.107)		
History of liver metastasis			
Yes	36	26	0.5182

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	18 (50.0%)	9 (34.6%)	
Number (%) of Participants Censored	18 (50.0%)	17 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.01 (2.30, 15.24)	5.75 (2.07, NR)	
Log-Rank Test p-value (unstratified)	0.9007		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.057 (0.468, 2.387)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	52 (58.4%)	64 (65.3%)	
Number (%) of Participants Censored	37 (41.6%)	34 (34.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.43 (1.61, 7.20)	2.69 (1.64, 4.21)	
Log-Rank Test p-value (unstratified)	0.5727		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.903 (0.625, 1.303)		
History of brain metastasis			
Yes	6	7	0.7480
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	3 (42.9%)	
Number (%) of Participants Censored	4 (66.7%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.30 (0.76, NR)	5.62 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.9473		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.021 (0.170, 6.142)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	68 (57.1%)	70 (59.8%)	
Number (%) of Participants Censored	51 (42.9%)	47 (40.2%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (2.10, 6.34)	3.25 (2.07, 4.86)	
Log-Rank Test p-value (unstratified)	0.4477		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.629, 1.231)		
PD-L1 Status			
CPS < 1	44	52	0.5621
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	33 (63.5%)	
Number (%) of Participants Censored	18 (40.9%)	19 (36.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (1.48, 7.72)	3.02 (1.61, 4.21)	
Log-Rank Test p-value (unstratified)	0.4642		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.824 (0.491, 1.384)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	44 (54.3%)	40 (55.6%)	
Number (%) of Participants Censored	37 (45.7%)	32 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.90 (1.68, 7.66)	4.21 (1.71, 13.01)	
Log-Rank Test p-value (unstratified)	0.7931		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.947 (0.615, 1.459)		
BRCA 1/2 status			
Wild-Type	42	46	0.3118
Number (%) of Participants with Events (Deterioration)	29 (69.0%)	32 (69.6%)	
Number (%) of Participants Censored	13 (31.0%)	14 (30.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	1.84 (0.82, 3.58)	1.71 (0.99, 3.09)	
Log-Rank Test p-value (unstratified)	0.9870		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.002 (0.602, 1.667)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	2 (28.6%)	
Number (%) of Participants Censored	4 (44.4%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.30 (0.79, NR)	NR (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.4436		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.902 (0.366, 9.877)		
Menopausal status			
Pre-menopausal	29	35	0.6675
Number (%) of Participants with Events (Deterioration)	14 (48.3%)	18 (51.4%)	
Number (%) of Participants Censored	15 (51.7%)	17 (48.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.01 (1.58, NR)	5.59 (2.14, NR)	
Log-Rank Test p-value (unstratified)	0.9612		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.985 (0.489, 1.986)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	56 (58.3%)	55 (62.5%)	
Number (%) of Participants Censored	40 (41.7%)	33 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (1.84, 6.34)	3.09 (1.54, 4.21)	
Log-Rank Test p-value (unstratified)	0.2660		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.810 (0.556, 1.181)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.45. Table 1.1.20.2: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Physical Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.4654
Number (%) of Participants with Events (Deterioration)	12 (41.4%)	14 (53.8%)	
Number (%) of Participants Censored	17 (58.6%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	20.07 (2.10, NR)	2.56 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.0947		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.519 (0.237, 1.136)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	19 (61.3%)	17 (54.8%)	
Number (%) of Participants Censored	12 (38.7%)	14 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.45, NR)	5.13 (1.25, NR)	
Log-Rank Test p-value (unstratified)	0.7971		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.918 (0.477, 1.770)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	27 (41.5%)	39 (58.2%)	
Number (%) of Participants Censored	38 (58.5%)	28 (41.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.46 (3.58, NR)	5.42 (3.48, 12.35)	
Log-Rank Test p-value (unstratified)	0.5254		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.853 (0.520, 1.399)		
Geographic region			
US/Canada/Western Europe	30	35	0.2617
Number (%) of Participants with Events (Deterioration)	13 (43.3%)	23 (65.7%)	
Number (%) of Participants Censored	17 (56.7%)	12 (34.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.39 (1.74, NR)	2.37 (1.41, 4.40)	
Log-Rank Test p-value (unstratified)	0.0940		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.564 (0.285, 1.119)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	45 (47.4%)	47 (52.8%)	
Number (%) of Participants Censored	50 (52.6%)	42 (47.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (3.58, 21.45)	5.78 (3.09, 13.83)	
Log-Rank Test p-value (unstratified)	0.5295		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.877 (0.581, 1.325)		
Age group			

	SG (N=125)	TPC (N=124)	Interaction
< 65	98	96	0.4161
Number (%) of Participants with Events (Deterioration)	47 (48.0%)	55 (57.3%)	
Number (%) of Participants Censored	51 (52.0%)	41 (42.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (5.29, 21.45)	4.40 (2.56, 6.97)	
Log-Rank Test p-value (unstratified)	0.1013		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.724 (0.489, 1.071)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	11 (40.7%)	15 (53.6%)	
Number (%) of Participants Censored	16 (59.3%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.27 (0.95, NR)	5.13 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.7691		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.125 (0.513, 2.467)		
Race			
White	81	77	0.2948
Number (%) of Participants with Events (Deterioration)	36 (44.4%)	43 (55.8%)	
Number (%) of Participants Censored	45 (55.6%)	34 (44.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.39 (3.52, NR)	3.71 (2.20, 9.00)	
Log-Rank Test p-value (unstratified)	0.2071		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.756 (0.485, 1.179)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	16 (61.5%)	14 (53.8%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	10 (38.5%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (0.85, 8.84)	5.59 (1.64, 14.03)	
Log-Rank Test p-value (unstratified)	0.6487		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.179 (0.572, 2.428)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	6 (37.5%)	13 (61.9%)	
Number (%) of Participants Censored	10 (62.5%)	8 (38.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (2.40, NR)	5.13 (0.79, NR)	
Log-Rank Test p-value (unstratified)	0.1092		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.454 (0.169, 1.218)		
Baseline ECOG status			
0	81	80	0.6429
Number (%) of Participants with Events (Deterioration)	38 (46.9%)	45 (56.2%)	
Number (%) of Participants Censored	43 (53.1%)	35 (43.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (4.27, NR)	5.42 (2.83, 12.35)	
Log-Rank Test p-value (unstratified)	0.3360		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.810 (0.524, 1.250)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	25 (56.8%)	
Number (%) of Participants Censored	24 (54.5%)	19 (43.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	6.41 (1.28, NR)	3.48 (1.48, 5.78)	
Log-Rank Test p-value (unstratified)	0.2164		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.684 (0.368, 1.270)		
History of liver metastasis			
Yes	36	26	0.6683
Number (%) of Participants with Events (Deterioration)	14 (38.9%)	11 (42.3%)	
Number (%) of Participants Censored	22 (61.1%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (6.41, NR)	4.40 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.3524		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.682 (0.302, 1.539)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	44 (49.4%)	59 (60.2%)	
Number (%) of Participants Censored	45 (50.6%)	39 (39.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.46 (2.40, 21.45)	4.90 (2.86, 8.31)	
Log-Rank Test p-value (unstratified)	0.2929		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.813 (0.549, 1.204)		
History of brain metastasis			
Yes	6	7	0.7535
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	4 (57.1%)	
Number (%) of Participants Censored	4 (66.7%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.76, NR)	3.15 (0.76, NR)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.5621		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.653 (0.119, 3.581)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	56 (47.1%)	66 (56.4%)	
Number (%) of Participants Censored	63 (52.9%)	51 (43.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.46 (3.65, 20.07)	4.90 (2.83, 8.31)	
Log-Rank Test p-value (unstratified)	0.1751		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.783 (0.547, 1.120)		
PD-L1 Status			
CPS < 1	44	52	0.6348
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	29 (55.8%)	
Number (%) of Participants Censored	24 (54.5%)	23 (44.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (3.58, NR)	4.86 (2.86, 19.38)	
Log-Rank Test p-value (unstratified)	0.1821		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.680 (0.383, 1.205)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	38 (46.9%)	41 (56.9%)	
Number (%) of Participants Censored	43 (53.1%)	31 (43.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.46 (3.02, 21.45)	5.13 (2.10, 12.35)	
Log-Rank Test p-value (unstratified)	0.3666		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.817 (0.522, 1.279)		

	SG (N=125)	TPC (N=124)	Interaction
BRCA 1/2 status			
Wild-Type	42	46	0.3116
Number (%) of Participants with Events (Deterioration)	21 (50.0%)	28 (60.9%)	
Number (%) of Participants Censored	21 (50.0%)	18 (39.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.46 (1.74, NR)	3.29 (1.48, 6.93)	
Log-Rank Test p-value (unstratified)	0.1401		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.652 (0.363, 1.171)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	4 (44.4%)	3 (42.9%)	
Number (%) of Participants Censored	5 (55.6%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (0.79, NR)	19.38 (2.10, NR)	
Log-Rank Test p-value (unstratified)	0.5642		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.642 (0.299, 9.013)		
Menopausal status			
Pre-menopausal	29	35	0.7162
Number (%) of Participants with Events (Deterioration)	11 (37.9%)	20 (57.1%)	
Number (%) of Participants Censored	18 (62.1%)	15 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (3.58, NR)	5.59 (2.10, NR)	
Log-Rank Test p-value (unstratified)	0.2648		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.658 (0.313, 1.383)		
Post-menopausal	96	88	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	47 (49.0%)	49 (55.7%)	
Number (%) of Participants Censored	49 (51.0%)	39 (44.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.39 (2.40, 20.07)	4.86 (2.37, 9.00)	
Log-Rank Test p-value (unstratified)	0.2528		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.794 (0.530, 1.189)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.46. Table 1.1.20.3: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Role Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.1400
Number (%) of Participants with Events (Deterioration)	11 (37.9%)	16 (61.5%)	
Number (%) of Participants Censored	18 (62.1%)	10 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.77 (1.48, NR)	3.71 (0.89, 6.01)	
Log-Rank Test p-value (unstratified)	0.0516		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.462 (0.209, 1.020)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	23 (74.2%)	20 (64.5%)	
Number (%) of Participants Censored	8 (25.8%)	11 (35.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.35 (0.85, 5.09)	1.68 (0.85, 5.59)	
Log-Rank Test p-value (unstratified)	0.7055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.127 (0.618, 2.057)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	38 (58.5%)	48 (71.6%)	
Number (%) of Participants Censored	27 (41.5%)	19 (28.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.99, 2.73)	3.29 (1.74, 5.13)	
Log-Rank Test p-value (unstratified)	0.6251		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.117 (0.728, 1.714)		
Geographic region			
US/Canada/Western Europe	30	35	0.5072
Number (%) of Participants with Events (Deterioration)	17 (56.7%)	28 (80.0%)	
Number (%) of Participants Censored	13 (43.3%)	7 (20.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.43 (0.82, NR)	2.46 (0.89, 5.09)	
Log-Rank Test p-value (unstratified)	0.4064		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.774 (0.421, 1.424)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	55 (57.9%)	56 (62.9%)	
Number (%) of Participants Censored	40 (42.1%)	33 (37.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.41, 3.22)	3.71 (2.00, 5.59)	
Log-Rank Test p-value (unstratified)	0.9376		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.015 (0.698, 1.475)		
Age group			
< 65	98	96	0.5797
Number (%) of Participants with Events (Deterioration)	59 (60.2%)	65 (67.7%)	
Number (%) of Participants Censored	39 (39.8%)	31 (32.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.28, 5.09)	3.52 (1.74, 5.09)	
Log-Rank Test p-value (unstratified)	0.5568		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.905 (0.635, 1.290)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	13 (48.1%)	19 (67.9%)	
Number (%) of Participants Censored	14 (51.9%)	9 (32.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 2.40)	3.06 (0.85, 7.75)	
Log-Rank Test p-value (unstratified)	0.6638		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.164 (0.566, 2.395)		
Race			
White	81	77	0.0611
Number (%) of Participants with Events (Deterioration)	48 (59.3%)	49 (63.6%)	
Number (%) of Participants Censored	33 (40.7%)	28 (36.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	1.45 (1.02, 2.40)	3.84 (1.64, 5.13)	
Log-Rank Test p-value (unstratified)	0.5378		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.138 (0.763, 1.699)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	18 (69.2%)	
Number (%) of Participants Censored	11 (42.3%)	8 (30.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.22 (0.85, 8.38)	3.52 (0.85, 7.82)	
Log-Rank Test p-value (unstratified)	0.8798		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.939 (0.473, 1.865)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	7 (43.8%)	17 (81.0%)	
Number (%) of Participants Censored	9 (56.2%)	4 (19.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.77 (0.99, NR)	3.06 (0.79, 4.11)	
Log-Rank Test p-value (unstratified)	0.0171		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.353 (0.144, 0.865)		
Baseline ECOG status			
0	81	80	0.9749
Number (%) of Participants with Events (Deterioration)	49 (60.5%)	57 (71.2%)	
Number (%) of Participants Censored	32 (39.5%)	23 (28.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.41, 5.09)	4.11 (1.74, 5.42)	
Log-Rank Test p-value (unstratified)	0.7068		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.933 (0.636, 1.369)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	27 (61.4%)	
Number (%) of Participants Censored	21 (47.7%)	17 (38.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.85, 17.77)	2.46 (0.85, 5.09)	
Log-Rank Test p-value (unstratified)	0.9160		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.969 (0.549, 1.710)		
History of liver metastasis			
Yes	36	26	0.4988
Number (%) of Participants with Events (Deterioration)	19 (52.8%)	12 (46.2%)	
Number (%) of Participants Censored	17 (47.2%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (0.85, NR)	8.57 (1.58, NR)	
Log-Rank Test p-value (unstratified)	0.6294		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.189 (0.571, 2.477)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	53 (59.6%)	72 (73.5%)	
Number (%) of Participants Censored	36 (40.4%)	26 (26.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.51 (1.28, 2.79)	3.06 (1.54, 4.17)	
Log-Rank Test p-value (unstratified)	0.5723		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.906 (0.635, 1.294)		
History of brain metastasis			

	SG (N=125)	TPC (N=124)	Interaction
Yes	6	7	0.6364
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	4 (57.1%)	
Number (%) of Participants Censored	4 (66.7%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.76, NR)	4.11 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.6081		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.689 (0.125, 3.781)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	70 (58.8%)	80 (68.4%)	
Number (%) of Participants Censored	49 (41.2%)	37 (31.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.51 (1.41, 2.73)	3.29 (1.68, 4.96)	
Log-Rank Test p-value (unstratified)	0.7349		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.949 (0.687, 1.311)		
PD-L1 Status			
CPS < 1	44	52	0.5129
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	34 (65.4%)	
Number (%) of Participants Censored	20 (45.5%)	18 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.73 (1.05, NR)	3.71 (0.99, 5.59)	
Log-Rank Test p-value (unstratified)	0.4242		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.809 (0.479, 1.366)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	48 (59.3%)	50 (69.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	33 (40.7%)	22 (30.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.99, 2.53)	2.83 (1.64, 4.21)	
Log-Rank Test p-value (unstratified)	0.9908		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.008 (0.676, 1.503)		
BRCA 1/2 status			
Wild-Type	42	46	0.4859
Number (%) of Participants with Events (Deterioration)	27 (64.3%)	31 (67.4%)	
Number (%) of Participants Censored	15 (35.7%)	15 (32.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 2.79)	1.68 (0.95, 5.59)	
Log-Rank Test p-value (unstratified)	0.9428		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.022 (0.608, 1.718)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	3 (42.9%)	
Number (%) of Participants Censored	4 (44.4%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.07 (0.79, NR)	10.64 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.4009		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.043 (0.382, 10.927)		
Menopausal status			
Pre-menopausal	29	35	0.2879
Number (%) of Participants with Events (Deterioration)	14 (48.3%)	23 (65.7%)	
Number (%) of Participants Censored	15 (51.7%)	12 (34.3%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.38 (1.74, NR)	3.71 (1.64, 5.82)	
Log-Rank Test p-value (unstratified)	0.2283		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.667 (0.342, 1.300)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	58 (60.4%)	60 (68.2%)	
Number (%) of Participants Censored	38 (39.6%)	28 (31.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.99, 1.91)	2.56 (1.18, 4.96)	
Log-Rank Test p-value (unstratified)	0.9335		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.020 (0.709, 1.468)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.47. Table 1.1.20.4: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Emotional Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.2566
Number (%) of Participants with Events (Deterioration)	8 (27.6%)	9 (34.6%)	
Number (%) of Participants Censored	21 (72.4%)	17 (65.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (7.33, NR)	9.95 (3.78, NR)	
Log-Rank Test p-value (unstratified)	0.2934		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.600 (0.229, 1.572)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	20 (64.5%)	13 (41.9%)	
Number (%) of Participants Censored	11 (35.5%)	18 (58.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.14 (2.96, 12.16)	5.59 (2.37, NR)	
Log-Rank Test p-value (unstratified)	0.6284		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.189 (0.590, 2.397)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	31 (47.7%)	34 (50.7%)	
Number (%) of Participants Censored	34 (52.3%)	33 (49.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (4.17, 11.37)	9.13 (4.44, 12.39)	
Log-Rank Test p-value (unstratified)	0.6799		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.111 (0.680, 1.813)		
Geographic region			
US/Canada/Western Europe	30	35	0.9018
Number (%) of Participants with Events (Deterioration)	12 (40.0%)	14 (40.0%)	
Number (%) of Participants Censored	18 (60.0%)	21 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.45 (3.19, NR)	10.84 (3.09, NR)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.9832		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.992 (0.458, 2.149)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	47 (49.5%)	42 (47.2%)	
Number (%) of Participants Censored	48 (50.5%)	47 (52.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (4.27, 11.76)	9.13 (4.44, 12.25)	
Log-Rank Test p-value (unstratified)	0.7601		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.937 (0.616, 1.427)		
Age group			
< 65	98	96	0.3915
Number (%) of Participants with Events (Deterioration)	53 (54.1%)	44 (45.8%)	
Number (%) of Participants Censored	45 (45.9%)	52 (54.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.69 (4.17, 11.27)	9.95 (4.37, 12.25)	
Log-Rank Test p-value (unstratified)	0.9936		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.999 (0.669, 1.494)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	6 (22.2%)	12 (42.9%)	
Number (%) of Participants Censored	21 (77.8%)	16 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (4.27, NR)	9.13 (4.21, NR)	
Log-Rank Test p-value (unstratified)	0.4802		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.699 (0.257, 1.898)		

	SG (N=125)	TPC (N=124)	Interaction
Race			
White	81	77	0.9527
Number (%) of Participants with Events (Deterioration)	37 (45.7%)	34 (44.2%)	
Number (%) of Participants Censored	44 (54.3%)	43 (55.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (3.35, NR)	5.95 (3.52, 12.71)	
Log-Rank Test p-value (unstratified)	0.9307		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.980 (0.614, 1.563)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	14 (53.8%)	
Number (%) of Participants Censored	14 (53.8%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.27 (4.14, 15.51)	9.13 (4.90, 12.39)	
Log-Rank Test p-value (unstratified)	0.3629		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.693 (0.314, 1.532)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	8 (50.0%)	8 (38.1%)	
Number (%) of Participants Censored	8 (50.0%)	13 (61.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.33 (3.06, NR)	13.96 (1.31, NR)	
Log-Rank Test p-value (unstratified)	0.9236		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.051 (0.391, 2.825)		
Baseline ECOG status			
0	81	80	0.5283

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	41 (50.6%)	36 (45.0%)	
Number (%) of Participants Censored	40 (49.4%)	44 (55.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (4.27, 11.37)	9.95 (5.09, 12.25)	
Log-Rank Test p-value (unstratified)	0.9410		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.018 (0.648, 1.600)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	18 (40.9%)	20 (45.5%)	
Number (%) of Participants Censored	26 (59.1%)	24 (54.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (2.96, NR)	4.90 (2.60, NR)	
Log-Rank Test p-value (unstratified)	0.5793		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.834 (0.439, 1.586)		
History of liver metastasis			
Yes	36	26	0.0826
Number (%) of Participants with Events (Deterioration)	17 (47.2%)	4 (15.4%)	
Number (%) of Participants Censored	19 (52.8%)	22 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.69 (3.19, 11.76)	NR (3.02, NR)	
Log-Rank Test p-value (unstratified)	0.1214		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.314 (0.777, 6.890)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	42 (47.2%)	52 (53.1%)	
Number (%) of Participants Censored	47 (52.8%)	46 (46.9%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.03 (4.21, 12.48)	8.34 (4.40, 10.84)	
Log-Rank Test p-value (unstratified)	0.4199		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.846 (0.561, 1.276)		
History of brain metastasis			
Yes	6	7	0.3153
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	2 (28.6%)	
Number (%) of Participants Censored	3 (50.0%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (0.76, NR)	NR (2.14, NR)	
Log-Rank Test p-value (unstratified)	0.4861		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.872 (0.312, 11.246)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	56 (47.1%)	54 (46.2%)	
Number (%) of Participants Censored	63 (52.9%)	63 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (4.40, 11.76)	9.13 (4.70, 12.25)	
Log-Rank Test p-value (unstratified)	0.6499		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.917 (0.629, 1.337)		
PD-L1 Status			
CPS < 1	44	52	0.6640
Number (%) of Participants with Events (Deterioration)	25 (56.8%)	25 (48.1%)	
Number (%) of Participants Censored	19 (43.2%)	27 (51.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	4.96 (3.35, 11.37)	5.59 (3.61, 12.71)	
Log-Rank Test p-value (unstratified)	0.7534		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.092 (0.627, 1.902)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	34 (42.0%)	31 (43.1%)	
Number (%) of Participants Censored	47 (58.0%)	41 (56.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.03 (6.05, 15.51)	10.18 (5.09, 12.39)	
Log-Rank Test p-value (unstratified)	0.5907		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.876 (0.533, 1.438)		
BRCA 1/2 status			
Wild-Type	42	46	0.6766
Number (%) of Participants with Events (Deterioration)	24 (57.1%)	21 (45.7%)	
Number (%) of Participants Censored	18 (42.9%)	25 (54.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (3.19, 11.27)	9.13 (3.32, 12.25)	
Log-Rank Test p-value (unstratified)	0.7330		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.109 (0.615, 2.000)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	4 (44.4%)	3 (42.9%)	
Number (%) of Participants Censored	5 (55.6%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.24 (0.79, NR)	8.34 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.6556		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.491 (0.271, 8.197)		
Menopausal status			
Pre-menopausal	29	35	0.2945
Number (%) of Participants with Events (Deterioration)	14 (48.3%)	13 (37.1%)	
Number (%) of Participants Censored	15 (51.7%)	22 (62.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.33 (4.14, 15.51)	13.96 (5.59, NR)	
Log-Rank Test p-value (unstratified)	0.4233		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.362 (0.637, 2.910)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	45 (46.9%)	42 (47.7%)	
Number (%) of Participants Censored	51 (53.1%)	46 (52.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (4.21, 11.76)	9.13 (4.21, 10.84)	
Log-Rank Test p-value (unstratified)	0.4977		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.567, 1.322)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.48. Table 1.1.20.5: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Cognitive Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.2749
Number (%) of Participants with Events (Deterioration)	16 (55.2%)	19 (73.1%)	
Number (%) of Participants Censored	13 (44.8%)	7 (26.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.77 (0.85, NR)	2.10 (0.95, 3.09)	
Log-Rank Test p-value (unstratified)	0.1467		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.605 (0.301, 1.215)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	21 (67.7%)	16 (51.6%)	
Number (%) of Participants Censored	10 (32.3%)	15 (48.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (2.83, 8.41)	6.97 (2.20, NR)	
Log-Rank Test p-value (unstratified)	0.8268		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.074 (0.556, 2.076)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	32 (49.2%)	44 (65.7%)	
Number (%) of Participants Censored	33 (50.8%)	23 (34.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.83, 12.62)	2.69 (1.77, 4.90)	
Log-Rank Test p-value (unstratified)	0.2518		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.764 (0.484, 1.206)		
Geographic region			

	SG (N=125)	TPC (N=124)	Interaction
US/Canada/Western Europe	30	35	0.1575
Number (%) of Participants with Events (Deterioration)	14 (46.7%)	23 (65.7%)	
Number (%) of Participants Censored	16 (53.3%)	12 (34.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.41 (2.83, NR)	2.23 (1.48, 3.29)	
Log-Rank Test p-value (unstratified)	0.0601		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.531 (0.272, 1.038)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	55 (57.9%)	56 (62.9%)	
Number (%) of Participants Censored	40 (42.1%)	33 (37.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.56, 6.93)	3.48 (2.14, 4.90)	
Log-Rank Test p-value (unstratified)	0.5477		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.891 (0.614, 1.293)		
Age group			
< 65	98	96	0.6931
Number (%) of Participants with Events (Deterioration)	62 (63.3%)	64 (66.7%)	
Number (%) of Participants Censored	36 (36.7%)	32 (33.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (2.83, 6.41)	2.37 (1.94, 3.48)	
Log-Rank Test p-value (unstratified)	0.1520		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.775 (0.546, 1.100)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	7 (25.9%)	15 (53.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	20 (74.1%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	22.37 (2.10, NR)	8.38 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.2183		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.549 (0.209, 1.441)		
Race			
White	81	77	0.7441
Number (%) of Participants with Events (Deterioration)	41 (50.6%)	49 (63.6%)	
Number (%) of Participants Censored	40 (49.4%)	28 (36.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.83, 9.76)	2.20 (1.68, 3.48)	
Log-Rank Test p-value (unstratified)	0.1093		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.713 (0.471, 1.081)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	17 (65.4%)	
Number (%) of Participants Censored	11 (42.3%)	9 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.30, 18.46)	4.21 (2.23, 8.44)	
Log-Rank Test p-value (unstratified)	0.5641		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.811 (0.400, 1.644)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	11 (68.8%)	13 (61.9%)	
Number (%) of Participants Censored	5 (31.2%)	8 (38.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	4.34 (0.99, 13.14)	3.25 (1.41, 8.38)	
Log-Rank Test p-value (unstratified)	0.7506		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.870 (0.380, 1.994)		
Baseline ECOG status			
0	81	80	0.8200
Number (%) of Participants with Events (Deterioration)	45 (55.6%)	48 (60.0%)	
Number (%) of Participants Censored	36 (44.4%)	32 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (2.83, 12.62)	3.09 (2.14, 6.97)	
Log-Rank Test p-value (unstratified)	0.3424		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.820 (0.546, 1.233)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	31 (70.5%)	
Number (%) of Participants Censored	20 (45.5%)	13 (29.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.35 (2.20, 4.57)	2.37 (1.41, 3.52)	
Log-Rank Test p-value (unstratified)	0.3050		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.756 (0.443, 1.289)		
History of liver metastasis			
Yes	36	26	0.8058
Number (%) of Participants with Events (Deterioration)	17 (47.2%)	13 (50.0%)	
Number (%) of Participants Censored	19 (52.8%)	13 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.93 (2.56, 13.14)	3.02 (1.48, NR)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.3422		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.694 (0.332, 1.448)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	52 (58.4%)	66 (67.3%)	
Number (%) of Participants Censored	37 (41.6%)	32 (32.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (2.79, 6.93)	2.60 (2.10, 4.21)	
Log-Rank Test p-value (unstratified)	0.2638		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.814 (0.565, 1.171)		
History of brain metastasis			
Yes	6	7	0.4134
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	5 (71.4%)	
Number (%) of Participants Censored	4 (66.7%)	2 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.76, NR)	2.04 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.3110		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.469 (0.090, 2.451)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	67 (56.3%)	74 (63.2%)	
Number (%) of Participants Censored	52 (43.7%)	43 (36.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.47 (2.83, 6.93)	3.02 (2.14, 4.21)	
Log-Rank Test p-value (unstratified)	0.1991		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.805 (0.578, 1.121)		

	SG (N=125)	TPC (N=124)	Interaction
PD-L1 Status			
CPS < 1	44	52	0.9339
Number (%) of Participants with Events (Deterioration)	27 (61.4%)	33 (63.5%)	
Number (%) of Participants Censored	17 (38.6%)	19 (36.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.93 (2.30, 9.76)	2.69 (1.74, 4.63)	
Log-Rank Test p-value (unstratified)	0.3575		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.786 (0.472, 1.310)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	42 (51.9%)	46 (63.9%)	
Number (%) of Participants Censored	39 (48.1%)	26 (36.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.79, 13.14)	2.92 (2.10, 4.37)	
Log-Rank Test p-value (unstratified)	0.2035		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.763 (0.502, 1.160)		
BRCA 1/2 status			
Wild-Type	42	46	0.0919
Number (%) of Participants with Events (Deterioration)	29 (69.0%)	29 (63.0%)	
Number (%) of Participants Censored	13 (31.0%)	17 (37.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.83, 5.65)	2.69 (1.58, 4.17)	
Log-Rank Test p-value (unstratified)	0.7235		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.909 (0.542, 1.525)		
Mutant	9	7	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	6 (85.7%)	
Number (%) of Participants Censored	4 (44.4%)	1 (14.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (0.79, NR)	1.68 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.0339		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.274 (0.076, 0.982)		
Menopausal status			
Pre-menopausal	29	35	0.1745
Number (%) of Participants with Events (Deterioration)	13 (44.8%)	23 (65.7%)	
Number (%) of Participants Censored	16 (55.2%)	12 (34.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.41 (2.83, NR)	2.23 (0.95, 7.26)	
Log-Rank Test p-value (unstratified)	0.0627		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.528 (0.266, 1.045)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	56 (58.3%)	55 (62.5%)	
Number (%) of Participants Censored	40 (41.7%)	33 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (2.56, 6.93)	3.09 (2.10, 4.17)	
Log-Rank Test p-value (unstratified)	0.5427		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.891 (0.614, 1.293)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.

Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.49. Table 1.1.20.6: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Social Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0644
Number (%) of Participants with Events (Deterioration)	14 (48.3%)	19 (73.1%)	
Number (%) of Participants Censored	15 (51.7%)	7 (26.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (0.82, NR)	2.40 (0.82, 4.47)	
Log-Rank Test p-value (unstratified)	0.1556		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.615 (0.308, 1.231)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	19 (61.3%)	22 (71.0%)	
Number (%) of Participants Censored	12 (38.7%)	9 (29.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.24 (0.95, 12.16)	1.41 (0.85, 3.84)	
Log-Rank Test p-value (unstratified)	0.0782		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.567 (0.299, 1.077)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	35 (53.8%)	36 (53.7%)	
Number (%) of Participants Censored	30 (46.2%)	31 (46.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.41, 16.07)	4.90 (3.09, 15.18)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.3836		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.226 (0.768, 1.956)		
Geographic region			
US/Canada/Western Europe	30	35	0.4464
Number (%) of Participants with Events (Deterioration)	12 (40.0%)	21 (60.0%)	
Number (%) of Participants Censored	18 (60.0%)	14 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (0.82, NR)	3.29 (0.92, 6.28)	
Log-Rank Test p-value (unstratified)	0.4037		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.739 (0.361, 1.510)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	56 (58.9%)	56 (62.9%)	
Number (%) of Participants Censored	39 (41.1%)	33 (37.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.40 (1.45, 7.46)	3.52 (1.64, 5.42)	
Log-Rank Test p-value (unstratified)	0.7046		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.929 (0.640, 1.347)		
Age group			
< 65	98	96	0.2942
Number (%) of Participants with Events (Deterioration)	53 (54.1%)	59 (61.5%)	
Number (%) of Participants Censored	45 (45.9%)	37 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.48, 12.16)	3.29 (1.64, 5.42)	
Log-Rank Test p-value (unstratified)	0.2600		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.808 (0.557, 1.172)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	15 (55.6%)	18 (64.3%)	
Number (%) of Participants Censored	12 (44.4%)	10 (35.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 24.44)	3.58 (0.85, 15.18)	
Log-Rank Test p-value (unstratified)	0.6475		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.180 (0.580, 2.400)		
Race			
White	81	77	0.5722
Number (%) of Participants with Events (Deterioration)	40 (49.4%)	45 (58.4%)	
Number (%) of Participants Censored	41 (50.6%)	32 (41.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.41, NR)	3.58 (1.41, 6.93)	
Log-Rank Test p-value (unstratified)	0.7462		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.934 (0.609, 1.431)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	16 (61.5%)	
Number (%) of Participants Censored	11 (42.3%)	10 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.02, NR)	4.90 (2.23, 7.13)	
Log-Rank Test p-value (unstratified)	0.7500		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.886 (0.435, 1.803)		
Other	16	21	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	11 (68.8%)	16 (76.2%)	
Number (%) of Participants Censored	5 (31.2%)	5 (23.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.40 (0.99, 21.45)	1.41 (0.76, 3.06)	
Log-Rank Test p-value (unstratified)	0.1750		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.574 (0.253, 1.301)		
Baseline ECOG status			
0	81	80	0.6922
Number (%) of Participants with Events (Deterioration)	46 (56.8%)	49 (61.3%)	
Number (%) of Participants Censored	35 (43.2%)	31 (38.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.45, 12.16)	3.52 (1.41, 5.59)	
Log-Rank Test p-value (unstratified)	0.6470		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.908 (0.607, 1.360)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	22 (50.0%)	28 (63.6%)	
Number (%) of Participants Censored	22 (50.0%)	16 (36.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.02, 21.45)	3.58 (0.89, 5.78)	
Log-Rank Test p-value (unstratified)	0.4377		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.800 (0.451, 1.420)		
History of liver metastasis			
Yes	36	26	0.8250
Number (%) of Participants with Events (Deterioration)	15 (41.7%)	10 (38.5%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	21 (58.3%)	16 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (1.48, NR)	NR (0.82, NR)	
Log-Rank Test p-value (unstratified)	0.9469		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.019 (0.457, 2.275)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	53 (59.6%)	67 (68.4%)	
Number (%) of Participants Censored	36 (40.4%)	31 (31.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.05, 4.80)	3.25 (1.64, 4.47)	
Log-Rank Test p-value (unstratified)	0.5203		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.889 (0.618, 1.278)		
History of brain metastasis			
Yes	6	7	0.5572
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	5 (71.4%)	
Number (%) of Participants Censored	4 (66.7%)	2 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.30 (0.76, NR)	1.81 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.4277		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.577 (0.112, 2.986)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	66 (55.5%)	72 (61.5%)	
Number (%) of Participants Censored	53 (44.5%)	45 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	2.83 (1.45, 7.46)	3.58 (2.23, 5.32)	
Log-Rank Test p-value (unstratified)	0.5013		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.892 (0.637, 1.249)		
PD-L1 Status			
CPS < 1	44	52	0.3896
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	36 (69.2%)	
Number (%) of Participants Censored	18 (40.9%)	16 (30.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.05, 16.07)	2.86 (0.85, 3.58)	
Log-Rank Test p-value (unstratified)	0.3083		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.767 (0.462, 1.272)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	42 (51.9%)	41 (56.9%)	
Number (%) of Participants Censored	39 (48.1%)	31 (43.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.41, 12.16)	4.44 (2.79, 6.93)	
Log-Rank Test p-value (unstratified)	0.9063		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.978 (0.634, 1.508)		
BRCA 1/2 status			
Wild-Type	42	46	0.4464
Number (%) of Participants with Events (Deterioration)	25 (59.5%)	27 (58.7%)	
Number (%) of Participants Censored	17 (40.5%)	19 (41.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (0.95, 7.46)	3.29 (0.95, 5.78)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.8834		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.041 (0.603, 1.798)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	6 (66.7%)	6 (85.7%)	
Number (%) of Participants Censored	3 (33.3%)	1 (14.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, NR)	1.08 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.5122		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.685 (0.205, 2.284)		
Menopausal status			
Pre-menopausal	29	35	0.3227
Number (%) of Participants with Events (Deterioration)	15 (51.7%)	25 (71.4%)	
Number (%) of Participants Censored	14 (48.3%)	10 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (1.48, 16.07)	3.09 (0.85, 5.78)	
Log-Rank Test p-value (unstratified)	0.1129		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.584 (0.298, 1.144)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	53 (55.2%)	51 (58.0%)	
Number (%) of Participants Censored	43 (44.8%)	37 (42.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.05, 4.80)	3.58 (1.41, 5.32)	
Log-Rank Test p-value (unstratified)	0.9195		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.981 (0.667, 1.444)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.

Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.50. Table 1.1.20.7: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Fatigue | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0946
Number (%) of Participants with Events (Deterioration)	16 (55.2%)	18 (69.2%)	
Number (%) of Participants Censored	13 (44.8%)	8 (30.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.88 (1.68, NR)	1.41 (0.79, 1.64)	
Log-Rank Test p-value (unstratified)	0.0231		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.463 (0.234, 0.918)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	22 (71.0%)	24 (77.4%)	
Number (%) of Participants Censored	9 (29.0%)	7 (22.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.28 (0.82, 1.84)	1.22 (0.85, 3.22)	
Log-Rank Test p-value (unstratified)	0.5064		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.816 (0.456, 1.460)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	45 (69.2%)	50 (74.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	20 (30.8%)	17 (25.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.79, 1.61)	1.64 (0.95, 3.48)	
Log-Rank Test p-value (unstratified)	0.5536		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.141 (0.762, 1.709)		
Geographic region			
US/Canada/Western Europe	30	35	0.3697
Number (%) of Participants with Events (Deterioration)	18 (60.0%)	29 (82.9%)	
Number (%) of Participants Censored	12 (40.0%)	6 (17.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.85 (0.79, 5.65)	1.05 (0.85, 1.45)	
Log-Rank Test p-value (unstratified)	0.2293		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.699 (0.378, 1.293)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	65 (68.4%)	63 (70.8%)	
Number (%) of Participants Censored	30 (31.6%)	26 (29.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.99, 2.20)	1.94 (0.95, 3.48)	
Log-Rank Test p-value (unstratified)	0.7434		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.947 (0.669, 1.339)		
Age group			
< 65	98	96	0.8370
Number (%) of Participants with Events (Deterioration)	67 (68.4%)	69 (71.9%)	
Number (%) of Participants Censored	31 (31.6%)	27 (28.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 2.20)	1.45 (0.92, 2.69)	
Log-Rank Test p-value (unstratified)	0.4711		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.889 (0.635, 1.245)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	16 (59.3%)	23 (82.1%)	
Number (%) of Participants Censored	11 (40.7%)	5 (17.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 2.60)	1.05 (0.85, 3.06)	
Log-Rank Test p-value (unstratified)	0.6145		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.449, 1.614)		
Race			
White	81	77	0.0937
Number (%) of Participants with Events (Deterioration)	53 (65.4%)	58 (75.3%)	
Number (%) of Participants Censored	28 (34.6%)	19 (24.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.82, 2.30)	1.22 (0.92, 1.64)	
Log-Rank Test p-value (unstratified)	0.1418		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.762 (0.523, 1.109)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	19 (73.1%)	18 (69.2%)	
Number (%) of Participants Censored	7 (26.9%)	8 (30.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 1.81)	4.11 (0.85, 6.97)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.1817		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.562 (0.813, 3.002)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	9 (56.2%)	16 (76.2%)	
Number (%) of Participants Censored	7 (43.8%)	5 (23.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.33 (0.79, NR)	2.14 (0.79, 3.06)	
Log-Rank Test p-value (unstratified)	0.1376		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.543 (0.238, 1.236)		
Baseline ECOG status			
0	81	80	0.6962
Number (%) of Participants with Events (Deterioration)	58 (71.6%)	62 (77.5%)	
Number (%) of Participants Censored	23 (28.4%)	18 (22.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.95, 2.30)	1.41 (0.92, 2.14)	
Log-Rank Test p-value (unstratified)	0.5053		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.891 (0.622, 1.274)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	25 (56.8%)	30 (68.2%)	
Number (%) of Participants Censored	19 (43.2%)	14 (31.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.82, 4.17)	1.41 (0.85, 3.48)	
Log-Rank Test p-value (unstratified)	0.3924		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.797 (0.463, 1.371)		

	SG (N=125)	TPC (N=124)	Interaction
History of liver metastasis			
Yes	36	26	0.0317
Number (%) of Participants with Events (Deterioration)	24 (66.7%)	12 (46.2%)	
Number (%) of Participants Censored	12 (33.3%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.85 (0.79, 1.45)	2.14 (0.92, NR)	
Log-Rank Test p-value (unstratified)	0.1305		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.725 (0.861, 3.455)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	59 (66.3%)	80 (81.6%)	
Number (%) of Participants Censored	30 (33.7%)	18 (18.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.99, 2.33)	1.41 (0.89, 2.14)	
Log-Rank Test p-value (unstratified)	0.0661		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.732 (0.522, 1.026)		
History of brain metastasis			
Yes	6	7	0.0211
Number (%) of Participants with Events (Deterioration)	4 (66.7%)	4 (57.1%)	
Number (%) of Participants Censored	2 (33.3%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.77 (0.76, NR)	4.11 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.0135		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	9.688 (1.042, 90.094)		
No	119	117	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	79 (66.4%)	88 (75.2%)	
Number (%) of Participants Censored	40 (33.6%)	29 (24.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.95, 2.20)	1.41 (0.92, 2.14)	
Log-Rank Test p-value (unstratified)	0.1748		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.815 (0.601, 1.105)		
PD-L1 Status			
CPS < 1	44	52	0.2945
Number (%) of Participants with Events (Deterioration)	27 (61.4%)	39 (75.0%)	
Number (%) of Participants Censored	17 (38.6%)	13 (25.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.61 (0.85, 5.65)	1.45 (0.85, 3.06)	
Log-Rank Test p-value (unstratified)	0.1523		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.704 (0.430, 1.154)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	56 (69.1%)	53 (73.6%)	
Number (%) of Participants Censored	25 (30.9%)	19 (26.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.82, 1.81)	1.41 (0.89, 2.37)	
Log-Rank Test p-value (unstratified)	0.8731		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.977 (0.670, 1.423)		
BRCA 1/2 status			
Wild-Type	42	46	0.7712
Number (%) of Participants with Events (Deterioration)	28 (66.7%)	35 (76.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	14 (33.3%)	11 (23.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.82, 3.12)	1.25 (0.89, 3.22)	
Log-Rank Test p-value (unstratified)	0.7522		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.932 (0.565, 1.537)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	6 (66.7%)	4 (57.1%)	
Number (%) of Participants Censored	3 (33.3%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.76, NR)	1.41 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.7625		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.828 (0.231, 2.974)		
Menopausal status			
Pre-menopausal	29	35	0.7917
Number (%) of Participants with Events (Deterioration)	16 (55.2%)	24 (68.6%)	
Number (%) of Participants Censored	13 (44.8%)	11 (31.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (0.79, NR)	1.64 (0.85, 3.48)	
Log-Rank Test p-value (unstratified)	0.5016		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.810 (0.430, 1.526)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	67 (69.8%)	67 (76.1%)	
Number (%) of Participants Censored	29 (30.2%)	21 (23.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	1.28 (0.85, 1.74)	1.25 (0.92, 2.14)	
Log-Rank Test p-value (unstratified)	0.3357		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.855 (0.608, 1.202)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.51. Table 1.1.20.8: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Nausea and Vomiting | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0127
Number (%) of Participants with Events (Deterioration)	20 (69.0%)	20 (76.9%)	
Number (%) of Participants Censored	9 (31.0%)	6 (23.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (1.05, 4.24)	1.41 (0.76, 1.68)	
Log-Rank Test p-value (unstratified)	0.0067		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.412 (0.212, 0.798)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	25 (80.6%)	17 (54.8%)	
Number (%) of Participants Censored	6 (19.4%)	14 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	1.45 (0.85, 1.97)	2.07 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.1763		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.522 (0.820, 2.827)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	36 (55.4%)	42 (62.7%)	
Number (%) of Participants Censored	29 (44.6%)	25 (37.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (0.89, 4.47)	3.45 (1.31, 8.11)	
Log-Rank Test p-value (unstratified)	0.4557		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.194 (0.760, 1.876)		
Geographic region			
US/Canada/Western Europe	30	35	0.5733
Number (%) of Participants with Events (Deterioration)	16 (53.3%)	19 (54.3%)	
Number (%) of Participants Censored	14 (46.7%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.22 (0.89, NR)	2.10 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.5555		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.815 (0.405, 1.637)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	65 (68.4%)	60 (67.4%)	
Number (%) of Participants Censored	30 (31.6%)	29 (32.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 1.91)	1.68 (0.95, 2.83)	
Log-Rank Test p-value (unstratified)	0.5696		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.105 (0.777, 1.572)		
Age group			
< 65	98	96	0.7031
Number (%) of Participants with Events (Deterioration)	71 (72.4%)	64 (66.7%)	
Number (%) of Participants Censored	27 (27.6%)	32 (33.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 2.40)	1.54 (1.22, 2.10)	
Log-Rank Test p-value (unstratified)	0.7824		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.052 (0.749, 1.476)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	10 (37.0%)	15 (53.6%)	
Number (%) of Participants Censored	17 (63.0%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.22 (1.45, NR)	4.90 (0.89, NR)	
Log-Rank Test p-value (unstratified)	0.8184		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.903 (0.392, 2.080)		
Race			
White	81	77	0.5601
Number (%) of Participants with Events (Deterioration)	55 (67.9%)	48 (62.3%)	
Number (%) of Participants Censored	26 (32.1%)	29 (37.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.54 (0.89, 2.83)	2.10 (1.41, 3.84)	
Log-Rank Test p-value (unstratified)	0.4791		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.153 (0.781, 1.702)		

	SG (N=125)	TPC (N=124)	Interaction
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	17 (65.4%)	
Number (%) of Participants Censored	12 (46.2%)	9 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.97 (0.95, NR)	1.61 (0.79, 4.90)	
Log-Rank Test p-value (unstratified)	0.5736		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.812 (0.397, 1.660)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	10 (62.5%)	14 (66.7%)	
Number (%) of Participants Censored	6 (37.5%)	7 (33.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.15 (0.76, 3.06)	1.31 (0.76, 3.45)	
Log-Rank Test p-value (unstratified)	0.7795		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.387, 2.024)		
Baseline ECOG status			
0	81	80	0.5478
Number (%) of Participants with Events (Deterioration)	58 (71.6%)	56 (70.0%)	
Number (%) of Participants Censored	23 (28.4%)	24 (30.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.45, 2.83)	1.66 (1.05, 2.83)	
Log-Rank Test p-value (unstratified)	0.8901		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.973 (0.672, 1.409)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	23 (52.3%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	21 (47.7%)	21 (47.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.38 (0.79, NR)	2.50 (1.41, 8.11)	
Log-Rank Test p-value (unstratified)	0.4703		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.249 (0.699, 2.230)		
History of liver metastasis			
Yes	36	26	0.5472
Number (%) of Participants with Events (Deterioration)	23 (63.9%)	15 (57.7%)	
Number (%) of Participants Censored	13 (36.1%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.82, 3.06)	2.83 (1.22, 9.23)	
Log-Rank Test p-value (unstratified)	0.5459		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.229 (0.636, 2.375)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	58 (65.2%)	64 (65.3%)	
Number (%) of Participants Censored	31 (34.8%)	34 (34.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.41, 2.83)	1.64 (1.25, 2.63)	
Log-Rank Test p-value (unstratified)	0.9571		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.990 (0.692, 1.415)		
History of brain metastasis			
Yes	6	7	0.9260
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	4 (57.1%)	
Number (%) of Participants Censored	3 (50.0%)	3 (42.9%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.79 (0.76, NR)	4.44 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.9460		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.951 (0.191, 4.726)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	78 (65.5%)	75 (64.1%)	
Number (%) of Participants Censored	41 (34.5%)	42 (35.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.41, 2.63)	1.68 (1.41, 2.83)	
Log-Rank Test p-value (unstratified)	0.7481		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.055 (0.767, 1.450)		
PD-L1 Status			
CPS < 1	44	52	0.0729
Number (%) of Participants with Events (Deterioration)	33 (75.0%)	34 (65.4%)	
Number (%) of Participants Censored	11 (25.0%)	18 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.05 (0.79, 1.71)	3.09 (1.54, 4.90)	
Log-Rank Test p-value (unstratified)	0.0884		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.522 (0.934, 2.480)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	48 (59.3%)	45 (62.5%)	
Number (%) of Participants Censored	33 (40.7%)	27 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.40 (1.45, 3.55)	1.45 (1.18, 2.17)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.4424		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.566, 1.283)		
BRCA 1/2 status			
Wild-Type	42	46	0.5525
Number (%) of Participants with Events (Deterioration)	26 (61.9%)	27 (58.7%)	
Number (%) of Participants Censored	16 (38.1%)	19 (41.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.97 (1.05, 4.24)	2.07 (1.25, 8.11)	
Log-Rank Test p-value (unstratified)	0.7776		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.085 (0.633, 1.861)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	4 (44.4%)	4 (57.1%)	
Number (%) of Participants Censored	5 (55.6%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.79, NR)	5.47 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.5387		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.656 (0.159, 2.699)		
Menopausal status			
Pre-menopausal	29	35	0.3746
Number (%) of Participants with Events (Deterioration)	19 (65.5%)	25 (71.4%)	
Number (%) of Participants Censored	10 (34.5%)	10 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (0.82, 11.24)	1.41 (0.85, 2.83)	
Log-Rank Test p-value (unstratified)	0.5713		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.843 (0.460, 1.543)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	62 (64.6%)	53 (60.2%)	
Number (%) of Participants Censored	34 (35.4%)	35 (39.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.54 (1.05, 2.63)	2.14 (1.45, 4.21)	
Log-Rank Test p-value (unstratified)	0.4268		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.161 (0.803, 1.680)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.52. Table 1.1.20.9: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Pain | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.2554
Number (%) of Participants with Events (Deterioration)	10 (34.5%)	11 (42.3%)	
Number (%) of Participants Censored	19 (65.5%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.77 (7.82, NR)	6.28 (2.10, NR)	
Log-Rank Test p-value (unstratified)	0.0470		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.390 (0.149, 1.020)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	16 (51.6%)	20 (64.5%)	
Number (%) of Participants Censored	15 (48.4%)	11 (35.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.30 (1.45, NR)	1.41 (0.85, 5.59)	
Log-Rank Test p-value (unstratified)	0.2180		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.665 (0.344, 1.287)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	33 (50.8%)	45 (67.2%)	
Number (%) of Participants Censored	32 (49.2%)	22 (32.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.37 (1.41, 9.10)	2.79 (2.14, 5.75)	
Log-Rank Test p-value (unstratified)	0.8063		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.949 (0.605, 1.488)		
Geographic region			
US/Canada/Western Europe	30	35	0.9253
Number (%) of Participants with Events (Deterioration)	13 (43.3%)	22 (62.9%)	
Number (%) of Participants Censored	17 (56.7%)	13 (37.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.97 (1.68, NR)	2.96 (1.77, 9.23)	
Log-Rank Test p-value (unstratified)	0.1895		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.621 (0.298, 1.294)		
Rest of the world	95	89	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	46 (48.4%)	54 (60.7%)	
Number (%) of Participants Censored	49 (51.6%)	35 (39.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.54 (2.40, 11.76)	2.79 (1.94, 5.09)	
Log-Rank Test p-value (unstratified)	0.1101		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.726 (0.489, 1.078)		
Age group			
< 65	98	96	0.7049
Number (%) of Participants with Events (Deterioration)	48 (49.0%)	57 (59.4%)	
Number (%) of Participants Censored	50 (51.0%)	39 (40.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.72 (2.79, 15.51)	2.83 (1.91, 5.75)	
Log-Rank Test p-value (unstratified)	0.0736		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.707 (0.480, 1.040)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	11 (40.7%)	19 (67.9%)	
Number (%) of Participants Censored	16 (59.3%)	9 (32.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.76 (1.02, NR)	2.63 (1.84, 6.51)	
Log-Rank Test p-value (unstratified)	0.5023		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.767 (0.351, 1.680)		
Race			
White	81	77	0.7307
Number (%) of Participants with Events (Deterioration)	40 (49.4%)	49 (63.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	41 (50.6%)	28 (36.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.37 (1.77, 9.82)	2.37 (1.64, 4.90)	
Log-Rank Test p-value (unstratified)	0.1396		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.731 (0.479, 1.114)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	17 (65.4%)	
Number (%) of Participants Censored	14 (53.8%)	9 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (1.45, NR)	2.53 (1.74, 8.77)	
Log-Rank Test p-value (unstratified)	0.1059		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.532 (0.245, 1.157)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	5 (31.2%)	10 (47.6%)	
Number (%) of Participants Censored	11 (68.8%)	11 (52.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.77 (0.76, NR)	6.51 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.4464		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.657 (0.221, 1.952)		
Baseline ECOG status			
0	81	80	0.8465
Number (%) of Participants with Events (Deterioration)	43 (53.1%)	51 (63.7%)	
Number (%) of Participants Censored	38 (46.9%)	29 (36.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

		SG (N=125)	TPC (N=124)	Interaction
	Median	7.72 (2.53, 11.76)	2.79 (1.84, 5.59)	
	Log-Rank Test p-value (unstratified)	0.0941		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.707 (0.468, 1.066)		
1		44	44	
	Number (%) of Participants with Events (Deterioration)	16 (36.4%)	25 (56.8%)	
	Number (%) of Participants Censored	28 (63.6%)	19 (43.2%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	17.77 (1.48, NR)	3.58 (1.61, 6.51)	
	Log-Rank Test p-value (unstratified)	0.2968		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.719 (0.380, 1.361)		
History of liver metastasis				
Yes		36	26	0.5591
	Number (%) of Participants with Events (Deterioration)	16 (44.4%)	11 (42.3%)	
	Number (%) of Participants Censored	20 (55.6%)	15 (57.7%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	8.84 (1.87, 17.77)	4.90 (1.48, NR)	
	Log-Rank Test p-value (unstratified)	0.7518		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.396, 1.955)		
No		89	98	
	Number (%) of Participants with Events (Deterioration)	43 (48.3%)	65 (66.3%)	
	Number (%) of Participants Censored	46 (51.7%)	33 (33.7%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	6.54 (1.74, 15.51)	2.53 (1.91, 4.40)	
	Log-Rank Test p-value (unstratified)	0.0521		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.684 (0.463, 1.010)		
History of brain metastasis			
Yes	6	7	0.7494
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	4 (57.1%)	
Number (%) of Participants Censored	4 (66.7%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.76, NR)	4.55 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.9942		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.026 (0.170, 6.195)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	57 (47.9%)	72 (61.5%)	
Number (%) of Participants Censored	62 (52.1%)	45 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.72 (2.53, 11.76)	2.79 (2.14, 4.90)	
Log-Rank Test p-value (unstratified)	0.0439		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.699 (0.492, 0.995)		
PD-L1 Status			
CPS < 1	44	52	0.4038
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	32 (61.5%)	
Number (%) of Participants Censored	21 (47.7%)	20 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.72 (2.79, 11.76)	2.37 (1.74, 3.58)	
Log-Rank Test p-value (unstratified)	0.0468		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.583 (0.339, 1.001)		

	SG (N=125)	TPC (N=124)	Interaction
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	36 (44.4%)	44 (61.1%)	
Number (%) of Participants Censored	45 (55.6%)	28 (38.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.30 (1.51, 26.05)	4.07 (2.10, 6.51)	
Log-Rank Test p-value (unstratified)	0.2472		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.772 (0.492, 1.211)		
BRCA 1/2 status			
Wild-Type	42	46	0.2863
Number (%) of Participants with Events (Deterioration)	21 (50.0%)	30 (65.2%)	
Number (%) of Participants Censored	21 (50.0%)	16 (34.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (1.51, 15.97)	2.30 (1.41, 5.75)	
Log-Rank Test p-value (unstratified)	0.2222		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.711 (0.405, 1.250)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	6 (66.7%)	4 (57.1%)	
Number (%) of Participants Censored	3 (33.3%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.00 (0.79, NR)	1.94 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.6310		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.385 (0.380, 5.048)		
Menopausal status			
Pre-menopausal	29	35	0.2505

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	10 (34.5%)	20 (57.1%)	
Number (%) of Participants Censored	19 (65.5%)	15 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.51 (2.53, NR)	2.68 (1.45, 6.28)	
Log-Rank Test p-value (unstratified)	0.0799		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.508 (0.236, 1.098)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	49 (51.0%)	56 (63.6%)	
Number (%) of Participants Censored	47 (49.0%)	32 (36.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.47 (1.77, 9.82)	2.79 (2.14, 5.09)	
Log-Rank Test p-value (unstratified)	0.1493		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.756 (0.513, 1.115)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.53. Table 1.1.20.10: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Dyspnoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.4188

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	9 (31.0%)	14 (53.8%)	
Number (%) of Participants Censored	20 (69.0%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (5.32, NR)	2.83 (1.41, 6.28)	
Log-Rank Test p-value (unstratified)	0.0312		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.403 (0.172, 0.946)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	13 (41.9%)	18 (58.1%)	
Number (%) of Participants Censored	18 (58.1%)	13 (41.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (3.48, NR)	4.44 (1.45, 5.78)	
Log-Rank Test p-value (unstratified)	0.0204		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.437 (0.212, 0.900)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	21 (32.3%)	33 (49.3%)	
Number (%) of Participants Censored	44 (67.7%)	34 (50.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (6.67, NR)	6.74 (3.71, 18.46)	
Log-Rank Test p-value (unstratified)	0.1737		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.685 (0.396, 1.185)		
Geographic region			
US/Canada/Western Europe	30	35	0.4823
Number (%) of Participants with Events (Deterioration)	11 (36.7%)	22 (62.9%)	
Number (%) of Participants Censored	19 (63.3%)	13 (37.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (1.48, NR)	3.09 (1.25, 4.96)	
Log-Rank Test p-value (unstratified)	0.0274		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.442 (0.208, 0.936)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	32 (33.7%)	43 (48.3%)	
Number (%) of Participants Censored	63 (66.3%)	46 (51.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (7.72, NR)	6.74 (3.75, 13.83)	
Log-Rank Test p-value (unstratified)	0.0265		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.598 (0.378, 0.947)		
Age group			
< 65	98	96	0.6592
Number (%) of Participants with Events (Deterioration)	36 (36.7%)	50 (52.1%)	
Number (%) of Participants Censored	62 (63.3%)	46 (47.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (7.72, NR)	4.90 (2.83, 8.02)	
Log-Rank Test p-value (unstratified)	0.0033		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.530 (0.345, 0.816)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	7 (25.9%)	15 (53.6%)	
Number (%) of Participants Censored	20 (74.1%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (3.12, NR)	4.96 (1.84, NR)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.3256		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.622 (0.239, 1.617)		
Race			
White	81	77	0.5663
Number (%) of Participants with Events (Deterioration)	27 (33.3%)	42 (54.5%)	
Number (%) of Participants Censored	54 (66.7%)	35 (45.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (7.72, NR)	4.86 (2.07, 8.02)	
Log-Rank Test p-value (unstratified)	0.0060		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.514 (0.317, 0.836)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	11 (42.3%)	12 (46.2%)	
Number (%) of Participants Censored	15 (57.7%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (3.48, NR)	5.78 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.5057		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.752 (0.328, 1.723)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	5 (31.2%)	11 (52.4%)	
Number (%) of Participants Censored	11 (68.8%)	10 (47.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.48, NR)	4.37 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.1821		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.493 (0.171, 1.422)		

	SG (N=125)	TPC (N=124)	Interaction
Baseline ECOG status			
0	81	80	0.2150
Number (%) of Participants with Events (Deterioration)	28 (34.6%)	46 (57.5%)	
Number (%) of Participants Censored	53 (65.4%)	34 (42.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (9.72, NR)	4.37 (2.43, 6.97)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.458 (0.286, 0.736)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	15 (34.1%)	19 (43.2%)	
Number (%) of Participants Censored	29 (65.9%)	25 (56.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.23 (3.12, NR)	5.78 (3.25, 13.83)	
Log-Rank Test p-value (unstratified)	0.4487		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.771 (0.390, 1.524)		
History of liver metastasis			
Yes	36	26	0.2103
Number (%) of Participants with Events (Deterioration)	12 (33.3%)	7 (26.9%)	
Number (%) of Participants Censored	24 (66.7%)	19 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.63 (3.65, NR)	NR (2.83, NR)	
Log-Rank Test p-value (unstratified)	0.9937		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.995 (0.385, 2.573)		
No	89	98	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	31 (34.8%)	58 (59.2%)	
Number (%) of Participants Censored	58 (65.2%)	40 (40.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (9.72, NR)	4.86 (2.79, 6.28)	
Log-Rank Test p-value (unstratified)	0.0013		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.495 (0.319, 0.767)		
History of brain metastasis			
Yes	6	7	0.9755
Number (%) of Participants with Events (Deterioration)	1 (16.7%)	3 (42.9%)	
Number (%) of Participants Censored	5 (83.3%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.79, NR)	6.26 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.4766		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.449 (0.047, 4.326)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	42 (35.3%)	62 (53.0%)	
Number (%) of Participants Censored	77 (64.7%)	55 (47.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (9.63, NR)	4.90 (3.29, 6.74)	
Log-Rank Test p-value (unstratified)	0.0020		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.542 (0.366, 0.804)		
PD-L1 Status			
CPS < 1	44	52	0.3532
Number (%) of Participants with Events (Deterioration)	12 (27.3%)	25 (48.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	32 (72.7%)	27 (51.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (11.37, NR)	4.96 (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.0133		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.427 (0.214, 0.854)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	31 (38.3%)	40 (55.6%)	
Number (%) of Participants Censored	50 (61.7%)	32 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (5.32, NR)	4.44 (2.40, 8.02)	
Log-Rank Test p-value (unstratified)	0.0354		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.607 (0.379, 0.973)		
BRCA 1/2 status			
Wild-Type	42	46	0.2874
Number (%) of Participants with Events (Deterioration)	10 (23.8%)	25 (54.3%)	
Number (%) of Participants Censored	32 (76.2%)	21 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (9.63, NR)	3.09 (1.41, 9.00)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.295 (0.140, 0.618)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	3 (33.3%)	3 (42.9%)	
Number (%) of Participants Censored	6 (66.7%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	7.23 (1.91, NR)	6.28 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.7387		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.762 (0.153, 3.791)		
Menopausal status			
Pre-menopausal	29	35	0.2830
Number (%) of Participants with Events (Deterioration)	9 (31.0%)	21 (60.0%)	
Number (%) of Participants Censored	20 (69.0%)	14 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (3.65, NR)	4.90 (1.41, 6.97)	
Log-Rank Test p-value (unstratified)	0.0198		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.407 (0.185, 0.892)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	34 (35.4%)	43 (48.9%)	
Number (%) of Participants Censored	62 (64.6%)	45 (51.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (7.23, NR)	4.96 (3.29, 9.00)	
Log-Rank Test p-value (unstratified)	0.0331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.615 (0.391, 0.967)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.54. Table 1.1.20.11: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Insomnia | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.2069
Number (%) of Participants with Events (Deterioration)	12 (41.4%)	12 (46.2%)	
Number (%) of Participants Censored	17 (58.6%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.84 (3.12, NR)	4.40 (1.64, NR)	
Log-Rank Test p-value (unstratified)	0.1985		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.586 (0.259, 1.327)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	16 (51.6%)	20 (64.5%)	
Number (%) of Participants Censored	15 (48.4%)	11 (35.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.48, NR)	1.22 (0.85, 6.05)	
Log-Rank Test p-value (unstratified)	0.0891		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.560 (0.290, 1.083)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	31 (47.7%)	35 (52.2%)	
Number (%) of Participants Censored	34 (52.3%)	32 (47.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.01 (1.74, 14.36)	4.57 (3.29, 13.01)	
Log-Rank Test p-value (unstratified)	0.6479		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.123 (0.692, 1.823)		
Geographic region			

	SG (N=125)	TPC (N=124)	Interaction
US/Canada/Western Europe	30	35	0.2701
Number (%) of Participants with Events (Deterioration)	15 (50.0%)	16 (45.7%)	
Number (%) of Participants Censored	15 (50.0%)	19 (54.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.50, NR)	6.05 (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.6930		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.149 (0.567, 2.329)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	44 (46.3%)	51 (57.3%)	
Number (%) of Participants Censored	51 (53.7%)	38 (42.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.20 (3.22, 14.36)	4.11 (2.10, 5.55)	
Log-Rank Test p-value (unstratified)	0.1180		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.725 (0.484, 1.087)		
Age group			
< 65	98	96	0.9443
Number (%) of Participants with Events (Deterioration)	51 (52.0%)	52 (54.2%)	
Number (%) of Participants Censored	47 (48.0%)	44 (45.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (3.22, 10.84)	4.37 (3.09, 6.05)	
Log-Rank Test p-value (unstratified)	0.3063		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.818 (0.555, 1.204)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	8 (29.6%)	15 (53.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	19 (70.4%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.01 (1.02, NR)	3.58 (1.77, NR)	
Log-Rank Test p-value (unstratified)	0.6580		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.828 (0.348, 1.968)		
Race			
White	81	77	0.7160
Number (%) of Participants with Events (Deterioration)	38 (46.9%)	42 (54.5%)	
Number (%) of Participants Censored	43 (53.1%)	35 (45.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (3.12, 9.07)	3.48 (2.10, 6.05)	
Log-Rank Test p-value (unstratified)	0.5551		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.879 (0.567, 1.364)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	15 (57.7%)	
Number (%) of Participants Censored	14 (53.8%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.13 (1.84, NR)	6.05 (0.85, 13.01)	
Log-Rank Test p-value (unstratified)	0.1634		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.573 (0.262, 1.255)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	8 (50.0%)	10 (47.6%)	
Number (%) of Participants Censored	8 (50.0%)	11 (52.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	6.59 (1.12, NR)	4.44 (3.35, NR)	
Log-Rank Test p-value (unstratified)	0.9358		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.962 (0.374, 2.475)		
Baseline ECOG status			
0	81	80	0.7496
Number (%) of Participants with Events (Deterioration)	42 (51.9%)	44 (55.0%)	
Number (%) of Participants Censored	39 (48.1%)	36 (45.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (3.22, 14.36)	4.11 (2.73, 6.97)	
Log-Rank Test p-value (unstratified)	0.4763		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.856 (0.560, 1.307)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	17 (38.6%)	23 (52.3%)	
Number (%) of Participants Censored	27 (61.4%)	21 (47.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.13 (1.41, 16.82)	4.37 (2.10, 6.01)	
Log-Rank Test p-value (unstratified)	0.3862		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.400, 1.427)		
History of liver metastasis			
Yes	36	26	0.8720
Number (%) of Participants with Events (Deterioration)	18 (50.0%)	12 (46.2%)	
Number (%) of Participants Censored	18 (50.0%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (2.33, 10.84)	3.09 (1.22, NR)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.5954		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.816 (0.391, 1.702)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	41 (46.1%)	55 (56.1%)	
Number (%) of Participants Censored	48 (53.9%)	43 (43.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.20 (3.22, 16.82)	4.40 (3.29, 6.05)	
Log-Rank Test p-value (unstratified)	0.3448		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.824 (0.549, 1.235)		
History of brain metastasis			
Yes	6	7	0.1634
Number (%) of Participants with Events (Deterioration)	1 (16.7%)	4 (57.1%)	
Number (%) of Participants Censored	5 (83.3%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.55 (5.26, NR)	2.78 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.1177		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.202 (0.022, 1.841)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	58 (48.7%)	63 (53.8%)	
Number (%) of Participants Censored	61 (51.3%)	54 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (3.12, 10.84)	4.37 (3.25, 6.05)	
Log-Rank Test p-value (unstratified)	0.4128		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.862 (0.603, 1.232)		

	SG (N=125)	TPC (N=124)	Interaction
PD-L1 Status			
CPS < 1	44	52	0.4345
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	25 (48.1%)	
Number (%) of Participants Censored	21 (47.7%)	27 (51.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (3.48, 16.82)	4.40 (3.29, NR)	
Log-Rank Test p-value (unstratified)	0.9128		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.970 (0.550, 1.710)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	36 (44.4%)	42 (58.3%)	
Number (%) of Participants Censored	45 (55.6%)	30 (41.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.50 (2.33, 14.36)	3.48 (1.64, 5.59)	
Log-Rank Test p-value (unstratified)	0.1536		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.724 (0.463, 1.133)		
BRCA 1/2 status			
Wild-Type	42	46	0.0418
Number (%) of Participants with Events (Deterioration)	20 (47.6%)	26 (56.5%)	
Number (%) of Participants Censored	22 (52.4%)	20 (43.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.50, NR)	3.58 (1.45, 6.05)	
Log-Rank Test p-value (unstratified)	0.2752		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.722 (0.402, 1.295)		
Mutant	9	7	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (66.7%)	3 (42.9%)	
Number (%) of Participants Censored	3 (33.3%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (0.79, NR)	9.03 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.0571		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	6.221 (0.734, 52.690)		
Menopausal status			
Pre-menopausal	29	35	0.3905
Number (%) of Participants with Events (Deterioration)	12 (41.4%)	19 (54.3%)	
Number (%) of Participants Censored	17 (58.6%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	14.36 (3.48, NR)	4.57 (3.09, 9.03)	
Log-Rank Test p-value (unstratified)	0.2639		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.661 (0.318, 1.374)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	47 (49.0%)	47 (53.4%)	
Number (%) of Participants Censored	49 (51.0%)	41 (46.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.56, 9.13)	4.11 (2.33, 6.05)	
Log-Rank Test p-value (unstratified)	0.6394		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.909 (0.606, 1.362)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.

Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.55. Table 1.1.20.12: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Appetite Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.2942
Number (%) of Participants with Events (Deterioration)	13 (44.8%)	15 (57.7%)	
Number (%) of Participants Censored	16 (55.2%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.77 (1.41, NR)	2.56 (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.2054		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.624 (0.297, 1.315)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	19 (61.3%)	13 (41.9%)	
Number (%) of Participants Censored	12 (38.7%)	18 (58.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.35 (0.89, NR)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.3602		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.392 (0.687, 2.821)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	32 (49.2%)	40 (59.7%)	
Number (%) of Participants Censored	33 (50.8%)	27 (40.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.61, 13.63)	4.07 (1.71, 9.23)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.6570		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.904 (0.567, 1.440)		
Geographic region			
US/Canada/Western Europe	30	35	0.1571
Number (%) of Participants with Events (Deterioration)	11 (36.7%)	20 (57.1%)	
Number (%) of Participants Censored	19 (63.3%)	15 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.68, NR)	3.48 (1.77, 9.23)	
Log-Rank Test p-value (unstratified)	0.1331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.573 (0.273, 1.205)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	53 (55.8%)	48 (53.9%)	
Number (%) of Participants Censored	42 (44.2%)	41 (46.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (1.48, 4.21)	3.48 (1.45, 11.10)	
Log-Rank Test p-value (unstratified)	0.8443		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.042 (0.704, 1.541)		
Age group			
< 65	98	96	0.0215
Number (%) of Participants with Events (Deterioration)	51 (52.0%)	57 (59.4%)	
Number (%) of Participants Censored	47 (48.0%)	39 (40.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.61, NR)	2.37 (1.41, 6.93)	
Log-Rank Test p-value (unstratified)	0.1252		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.748 (0.512, 1.092)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	13 (48.1%)	11 (39.3%)	
Number (%) of Participants Censored	14 (51.9%)	17 (60.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.45, 4.01)	14.52 (4.07, NR)	
Log-Rank Test p-value (unstratified)	0.0175		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.636 (1.154, 6.023)		
Race			
White	81	77	0.9786
Number (%) of Participants with Events (Deterioration)	43 (53.1%)	46 (59.7%)	
Number (%) of Participants Censored	38 (46.9%)	31 (40.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.41, 13.63)	2.56 (1.45, 6.93)	
Log-Rank Test p-value (unstratified)	0.4896		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.871 (0.574, 1.323)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	12 (46.2%)	13 (50.0%)	
Number (%) of Participants Censored	14 (53.8%)	13 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.84, NR)	5.59 (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.9365		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.017 (0.463, 2.235)		
Other	16	21	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	8 (50.0%)	9 (42.9%)	
Number (%) of Participants Censored	8 (50.0%)	12 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.45, NR)	NR (0.79, NR)	
Log-Rank Test p-value (unstratified)	0.9260		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.038 (0.399, 2.700)		
Baseline ECOG status			
0	81	80	0.1090
Number (%) of Participants with Events (Deterioration)	41 (50.6%)	49 (61.3%)	
Number (%) of Participants Censored	40 (49.4%)	31 (38.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (1.84, NR)	3.09 (1.45, 7.85)	
Log-Rank Test p-value (unstratified)	0.1788		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.498, 1.145)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	19 (43.2%)	
Number (%) of Participants Censored	21 (47.7%)	25 (56.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (0.95, 3.78)	5.19 (2.10, NR)	
Log-Rank Test p-value (unstratified)	0.2811		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.403 (0.762, 2.583)		
History of liver metastasis			
Yes	36	26	0.0795
Number (%) of Participants with Events (Deterioration)	19 (52.8%)	7 (26.9%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	17 (47.2%)	19 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (1.48, NR)	9.23 (1.45, NR)	
Log-Rank Test p-value (unstratified)	0.1824		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.798 (0.750, 4.308)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	45 (50.6%)	61 (62.2%)	
Number (%) of Participants Censored	44 (49.4%)	37 (37.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (1.48, NR)	3.09 (1.71, 5.59)	
Log-Rank Test p-value (unstratified)	0.2555		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.803 (0.546, 1.182)		
History of brain metastasis			
Yes	6	7	0.8451
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	4 (57.1%)	
Number (%) of Participants Censored	3 (50.0%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.79 (0.76, NR)	1.41 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.8327		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.898 (0.200, 4.028)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	61 (51.3%)	64 (54.7%)	
Number (%) of Participants Censored	58 (48.7%)	53 (45.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	3.65 (1.84, 11.76)	4.07 (2.37, 9.23)	
Log-Rank Test p-value (unstratified)	0.6389		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.921 (0.648, 1.310)		
PD-L1 Status			
CPS < 1	44	52	0.3438
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	29 (55.8%)	
Number (%) of Participants Censored	18 (40.9%)	23 (44.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (0.95, 11.76)	4.96 (1.45, 9.23)	
Log-Rank Test p-value (unstratified)	0.6486		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.134 (0.667, 1.928)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	38 (46.9%)	39 (54.2%)	
Number (%) of Participants Censored	43 (53.1%)	33 (45.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.97, NR)	3.35 (1.64, 14.52)	
Log-Rank Test p-value (unstratified)	0.3764		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.820 (0.524, 1.283)		
BRCA 1/2 status			
Wild-Type	42	46	0.5103
Number (%) of Participants with Events (Deterioration)	22 (52.4%)	26 (56.5%)	
Number (%) of Participants Censored	20 (47.6%)	20 (43.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.71, NR)	3.09 (1.45, 6.93)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.7059		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.898 (0.509, 1.586)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	4 (57.1%)	
Number (%) of Participants Censored	4 (44.4%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (0.79, NR)	2.10 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.3381		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.529 (0.140, 1.990)		
Menopausal status			
Pre-menopausal	29	35	0.9619
Number (%) of Participants with Events (Deterioration)	15 (51.7%)	19 (54.3%)	
Number (%) of Participants Censored	14 (48.3%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (1.02, NR)	3.48 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.9463		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.979 (0.497, 1.929)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	49 (51.0%)	48 (54.5%)	
Number (%) of Participants Censored	47 (49.0%)	40 (45.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.22 (1.84, 13.63)	4.90 (2.07, 11.10)	
Log-Rank Test p-value (unstratified)	0.6459		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.915 (0.614, 1.363)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.

Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.56. Table 1.1.20.13: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Constipation | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0953
Number (%) of Participants with Events (Deterioration)	13 (44.8%)	17 (65.4%)	
Number (%) of Participants Censored	16 (55.2%)	9 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.35 (1.74, NR)	1.05 (0.76, 2.83)	
Log-Rank Test p-value (unstratified)	0.0113		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.387 (0.180, 0.829)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	21 (67.7%)	14 (45.2%)	
Number (%) of Participants Censored	10 (32.3%)	17 (54.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.28, 3.75)	2.20 (0.85, NR)	
Log-Rank Test p-value (unstratified)	0.5993		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.188 (0.600, 2.354)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	33 (50.8%)	42 (62.7%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	32 (49.2%)	25 (37.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (1.45, NR)	2.79 (1.48, 6.60)	
Log-Rank Test p-value (unstratified)	0.6002		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.557, 1.390)		
Geographic region			
US/Canada/Western Europe	30	35	0.8007
Number (%) of Participants with Events (Deterioration)	15 (50.0%)	23 (65.7%)	
Number (%) of Participants Censored	15 (50.0%)	12 (34.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.09 (1.45, NR)	1.68 (1.22, 5.29)	
Log-Rank Test p-value (unstratified)	0.4376		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.774 (0.403, 1.484)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	52 (54.7%)	50 (56.2%)	
Number (%) of Participants Censored	43 (45.3%)	39 (43.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.84, 12.35)	2.60 (1.02, 6.60)	
Log-Rank Test p-value (unstratified)	0.4462		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.851 (0.577, 1.256)		
Age group			
< 65	98	96	0.5258
Number (%) of Participants with Events (Deterioration)	55 (56.1%)	57 (59.4%)	
Number (%) of Participants Censored	43 (43.9%)	39 (40.6%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.84, 12.35)	2.10 (1.45, 6.24)	
Log-Rank Test p-value (unstratified)	0.1927		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.777 (0.536, 1.125)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	12 (44.4%)	16 (57.1%)	
Number (%) of Participants Censored	15 (55.6%)	12 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (1.02, NR)	3.48 (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.8580		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.069 (0.503, 2.271)		
Race			
White	81	77	0.9753
Number (%) of Participants with Events (Deterioration)	43 (53.1%)	47 (61.0%)	
Number (%) of Participants Censored	38 (46.9%)	30 (39.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.71, 6.93)	2.20 (1.45, 5.29)	
Log-Rank Test p-value (unstratified)	0.3457		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.815 (0.539, 1.233)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	14 (53.8%)	15 (57.7%)	
Number (%) of Participants Censored	12 (46.2%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (0.99, NR)	6.47 (0.85, 13.34)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.6885		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.855 (0.412, 1.776)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	9 (56.2%)	11 (52.4%)	
Number (%) of Participants Censored	7 (43.8%)	10 (47.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.09 (0.99, 19.38)	2.15 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.5836		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.771 (0.316, 1.881)		
Baseline ECOG status			
0	81	80	0.1034
Number (%) of Participants with Events (Deterioration)	43 (53.1%)	52 (65.0%)	
Number (%) of Participants Censored	38 (46.9%)	28 (35.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.09 (1.91, NR)	2.23 (0.95, 3.48)	
Log-Rank Test p-value (unstratified)	0.0651		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.680 (0.454, 1.019)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	21 (47.7%)	
Number (%) of Participants Censored	20 (45.5%)	23 (52.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.99, 4.57)	3.29 (1.48, 13.34)	
Log-Rank Test p-value (unstratified)	0.5412		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.197 (0.662, 2.165)		

	SG (N=125)	TPC (N=124)	Interaction
History of liver metastasis			
Yes	36	26	0.4845
Number (%) of Participants with Events (Deterioration)	20 (55.6%)	15 (57.7%)	
Number (%) of Participants Censored	16 (44.4%)	11 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (1.71, 12.35)	1.45 (0.76, 2.83)	
Log-Rank Test p-value (unstratified)	0.1713		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.614 (0.309, 1.220)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	47 (52.8%)	58 (59.2%)	
Number (%) of Participants Censored	42 (47.2%)	40 (40.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.54, 19.38)	2.69 (1.68, 6.47)	
Log-Rank Test p-value (unstratified)	0.4419		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.856 (0.583, 1.258)		
History of brain metastasis			
Yes	6	7	0.5730
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	4 (57.1%)	
Number (%) of Participants Censored	3 (50.0%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (2.14, NR)	3.63 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.6779		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.492 (0.294, 7.556)		
No	119	117	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	64 (53.8%)	69 (59.0%)	
Number (%) of Participants Censored	55 (46.2%)	48 (41.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.69 (1.74, 12.35)	2.33 (1.51, 5.29)	
Log-Rank Test p-value (unstratified)	0.2448		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.813 (0.578, 1.143)		
PD-L1 Status			
CPS < 1	44	52	0.8379
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	30 (57.7%)	
Number (%) of Participants Censored	20 (45.5%)	22 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.28, NR)	2.10 (1.02, 6.47)	
Log-Rank Test p-value (unstratified)	0.3993		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.790 (0.460, 1.355)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	43 (53.1%)	43 (59.7%)	
Number (%) of Participants Censored	38 (46.9%)	29 (40.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.91, 6.93)	2.33 (1.48, 6.47)	
Log-Rank Test p-value (unstratified)	0.4661		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.849 (0.556, 1.297)		
BRCA 1/2 status			
Wild-Type	42	46	0.4388
Number (%) of Participants with Events (Deterioration)	24 (57.1%)	26 (56.5%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	18 (42.9%)	20 (43.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (1.28, 6.93)	2.23 (1.41, 6.47)	
Log-Rank Test p-value (unstratified)	0.7472		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.912 (0.523, 1.588)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	6 (85.7%)	
Number (%) of Participants Censored	4 (44.4%)	1 (14.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.00 (0.72, NR)	0.76 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.3326		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.524 (0.148, 1.846)		
Menopausal status			
Pre-menopausal	29	35	0.5605
Number (%) of Participants with Events (Deterioration)	10 (34.5%)	17 (48.6%)	
Number (%) of Participants Censored	19 (65.5%)	18 (51.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.45, NR)	6.93 (0.82, NR)	
Log-Rank Test p-value (unstratified)	0.2459		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.632 (0.289, 1.384)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	57 (59.4%)	55 (62.5%)	
Number (%) of Participants Censored	39 (40.6%)	33 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	2.27 (1.61, 3.75)	1.91 (1.41, 3.48)	
Log-Rank Test p-value (unstratified)	0.4079		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.586, 1.230)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.57. Table 1.1.20.14: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Diarrhoea | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0138
Number (%) of Participants with Events (Deterioration)	15 (51.7%)	13 (50.0%)	
Number (%) of Participants Censored	14 (48.3%)	13 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.02, NR)	6.01 (1.74, NR)	
Log-Rank Test p-value (unstratified)	0.8634		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.073 (0.501, 2.296)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	23 (74.2%)	11 (35.5%)	
Number (%) of Participants Censored	8 (25.8%)	20 (64.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	2.10 (0.99, 4.44)	NR (2.40, NR)	
Log-Rank Test p-value (unstratified)	0.0340		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.146 (1.042, 4.422)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	46 (70.8%)	23 (34.3%)	
Number (%) of Participants Censored	19 (29.2%)	44 (65.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.03 (0.82, 2.40)	NR (5.52, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	4.174 (2.513, 6.934)		
Geographic region			
US/Canada/Western Europe	30	35	0.2434
Number (%) of Participants with Events (Deterioration)	23 (76.7%)	11 (31.4%)	
Number (%) of Participants Censored	7 (23.3%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.43 (0.82, 2.86)	10.12 (4.17, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.488 (1.677, 7.253)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	61 (64.2%)	36 (40.4%)	
Number (%) of Participants Censored	34 (35.8%)	53 (59.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.64 (1.02, 3.32)	13.21 (5.09, NR)	
Log-Rank Test p-value (unstratified)	<0.001		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.284 (1.509, 3.457)		
Age group			
< 65	98	96	0.1962
Number (%) of Participants with Events (Deterioration)	71 (72.4%)	39 (40.6%)	
Number (%) of Participants Censored	27 (27.6%)	57 (59.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.05, 2.83)	7.36 (4.37, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.279 (1.539, 3.374)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	13 (48.1%)	8 (28.6%)	
Number (%) of Participants Censored	14 (51.9%)	20 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 3.32)	NR (5.09, NR)	
Log-Rank Test p-value (unstratified)	0.0024		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.760 (1.512, 9.355)		
Race			
White	81	77	0.5929
Number (%) of Participants with Events (Deterioration)	52 (64.2%)	23 (29.9%)	
Number (%) of Participants Censored	29 (35.8%)	54 (70.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.02, 3.58)	13.21 (10.12, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.095 (1.890, 5.067)		

	SG (N=125)	TPC (N=124)	Interaction
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	17 (65.4%)	11 (42.3%)	
Number (%) of Participants Censored	9 (34.6%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (0.79, 5.85)	6.24 (2.30, NR)	
Log-Rank Test p-value (unstratified)	0.0346		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.240 (1.045, 4.804)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	13 (81.2%)	13 (61.9%)	
Number (%) of Participants Censored	3 (18.8%)	8 (38.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.00 (0.76, 1.45)	3.06 (0.79, NR)	
Log-Rank Test p-value (unstratified)	0.0452		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.226 (1.008, 4.915)		
Baseline ECOG status			
0	81	80	0.9607
Number (%) of Participants with Events (Deterioration)	57 (70.4%)	31 (38.8%)	
Number (%) of Participants Censored	24 (29.6%)	49 (61.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.99, 3.32)	10.12 (5.55, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.535 (1.631, 3.939)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	27 (61.4%)	16 (36.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	17 (38.6%)	28 (63.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.85, 2.83)	NR (3.25, NR)	
Log-Rank Test p-value (unstratified)	0.0022		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.545 (1.366, 4.743)		
History of liver metastasis			
Yes	36	26	0.4848
Number (%) of Participants with Events (Deterioration)	25 (69.4%)	7 (26.9%)	
Number (%) of Participants Censored	11 (30.6%)	19 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.82, 2.56)	10.12 (10.12, NR)	
Log-Rank Test p-value (unstratified)	0.0062		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.034 (1.302, 7.070)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	59 (66.3%)	40 (40.8%)	
Number (%) of Participants Censored	30 (33.7%)	58 (59.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.05, 3.58)	13.21 (5.09, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.459 (1.642, 3.681)		
History of brain metastasis			
Yes	6	7	0.1283
Number (%) of Participants with Events (Deterioration)	5 (83.3%)	2 (28.6%)	
Number (%) of Participants Censored	1 (16.7%)	5 (71.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.76, NR)	NR (5.55, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	119	117	
Number (%) of Participants with Events (Deterioration)	79 (66.4%)	45 (38.5%)	
Number (%) of Participants Censored	40 (33.6%)	72 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.02, 2.86)	10.12 (5.52, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.423 (1.677, 3.500)		
PD-L1 Status			
CPS < 1	44	52	0.8062
Number (%) of Participants with Events (Deterioration)	28 (63.6%)	18 (34.6%)	
Number (%) of Participants Censored	16 (36.4%)	34 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.99, 3.68)	NR (5.52, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.767 (1.522, 5.029)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	56 (69.1%)	29 (40.3%)	
Number (%) of Participants Censored	25 (30.9%)	43 (59.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.54 (0.95, 2.86)	13.21 (4.37, NR)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.419 (1.541, 3.796)		
BRCA 1/2 status			
Wild-Type	42	46	0.5897
Number (%) of Participants with Events (Deterioration)	30 (71.4%)	19 (41.3%)	
Number (%) of Participants Censored	12 (28.6%)	27 (58.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.82, 2.83)	5.78 (4.17, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.645 (1.481, 4.725)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	8 (88.9%)	2 (28.6%)	
Number (%) of Participants Censored	1 (11.1%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (0.76, 5.85)	NR (1.74, NR)	
Log-Rank Test p-value (unstratified)	0.0404		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	4.492 (0.939, 21.486)		
Menopausal status			
Pre-menopausal	29	35	0.6994
Number (%) of Participants with Events (Deterioration)	20 (69.0%)	15 (42.9%)	
Number (%) of Participants Censored	9 (31.0%)	20 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.82, 2.86)	7.36 (2.89, NR)	
Log-Rank Test p-value (unstratified)	0.0188		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.235 (1.129, 4.424)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	64 (66.7%)	31 (35.2%)	
Number (%) of Participants Censored	32 (33.3%)	57 (64.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.61 (1.02, 3.32)	NR (5.52, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.738 (1.780, 4.213)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.58. Table 1.1.20.15: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Financial Difficulties | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.1640
Number (%) of Participants with Events (Deterioration)	8 (27.6%)	9 (34.6%)	
Number (%) of Participants Censored	21 (72.4%)	17 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (4.27, NR)	5.19 (1.64, NR)	
Log-Rank Test p-value (unstratified)	0.1166		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.461 (0.171, 1.244)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	13 (41.9%)	13 (41.9%)	
Number (%) of Participants Censored	18 (58.1%)	18 (58.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (3.65, NR)	3.06 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.2308		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.621 (0.281, 1.370)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	21 (32.3%)	23 (34.3%)	
Number (%) of Participants Censored	44 (67.7%)	44 (65.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (5.06, NR)	19.38 (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.6430		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.150 (0.636, 2.080)		
Geographic region			
US/Canada/Western Europe	30	35	0.8889
Number (%) of Participants with Events (Deterioration)	8 (26.7%)	11 (31.4%)	
Number (%) of Participants Censored	22 (73.3%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (3.78, NR)	NR (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.7156		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.845 (0.340, 2.103)		
Rest of the world	95	89	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	34 (35.8%)	34 (38.2%)	
Number (%) of Participants Censored	61 (64.2%)	55 (61.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.02 (6.97, 27.89)	8.67 (3.98, NR)	
Log-Rank Test p-value (unstratified)	0.3907		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.810 (0.501, 1.310)		
Age group			
< 65	98	96	0.9483
Number (%) of Participants with Events (Deterioration)	37 (37.8%)	36 (37.5%)	
Number (%) of Participants Censored	61 (62.2%)	60 (62.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (6.93, NR)	6.47 (3.84, NR)	
Log-Rank Test p-value (unstratified)	0.2806		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.775 (0.488, 1.234)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	5 (18.5%)	9 (32.1%)	
Number (%) of Participants Censored	22 (81.5%)	19 (67.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	27.89 (2.40, NR)	19.38 (5.19, NR)	
Log-Rank Test p-value (unstratified)	0.4137		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.609 (0.184, 2.017)		
Race			
White	81	77	0.4218
Number (%) of Participants with Events (Deterioration)	27 (33.3%)	33 (42.9%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	54 (66.7%)	44 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (5.06, NR)	5.19 (3.48, NR)	
Log-Rank Test p-value (unstratified)	0.1105		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.660 (0.395, 1.104)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	10 (38.5%)	7 (26.9%)	
Number (%) of Participants Censored	16 (61.5%)	19 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (3.65, NR)	NR (5.82, NR)	
Log-Rank Test p-value (unstratified)	0.5214		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.371 (0.520, 3.613)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	4 (25.0%)	5 (23.8%)	
Number (%) of Participants Censored	12 (75.0%)	16 (76.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	27.89 (1.45, NR)	NR (2.89, NR)	
Log-Rank Test p-value (unstratified)	0.5912		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.640 (0.124, 3.307)		
Baseline ECOG status			
0	81	80	0.5522
Number (%) of Participants with Events (Deterioration)	24 (29.6%)	26 (32.5%)	
Number (%) of Participants Censored	57 (70.4%)	54 (67.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

		SG (N=125)	TPC (N=124)	Interaction
	Median	27.89 (8.51, NR)	19.38 (5.82, NR)	
	Log-Rank Test p-value (unstratified)	0.2837		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.735 (0.420, 1.287)		
1		44	44	
	Number (%) of Participants with Events (Deterioration)	18 (40.9%)	19 (43.2%)	
	Number (%) of Participants Censored	26 (59.1%)	25 (56.8%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	3.65 (1.28, NR)	3.98 (1.91, NR)	
	Log-Rank Test p-value (unstratified)	0.9375		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.032 (0.535, 1.991)		
History of liver metastasis				
Yes		36	26	0.5017
	Number (%) of Participants with Events (Deterioration)	12 (33.3%)	5 (19.2%)	
	Number (%) of Participants Censored	24 (66.7%)	21 (80.8%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	19.02 (4.27, NR)	NR (3.94, NR)	
	Log-Rank Test p-value (unstratified)	0.8320		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.122 (0.387, 3.256)		
No		89	98	
	Number (%) of Participants with Events (Deterioration)	30 (33.7%)	40 (40.8%)	
	Number (%) of Participants Censored	59 (66.3%)	58 (59.2%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	21.45 (7.89, NR)	8.67 (3.84, NR)	
	Log-Rank Test p-value (unstratified)	0.3136		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.783 (0.485, 1.264)		
History of brain metastasis			
Yes	6	7	0.0656
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	2 (28.6%)	
Number (%) of Participants Censored	3 (50.0%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.79, NR)	NR (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.1609		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.389 (0.556, 20.654)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	39 (32.8%)	43 (36.8%)	
Number (%) of Participants Censored	80 (67.2%)	74 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.02 (8.38, NR)	19.38 (4.17, NR)	
Log-Rank Test p-value (unstratified)	0.1980		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.750 (0.483, 1.164)		
PD-L1 Status			
CPS < 1	44	52	0.1887
Number (%) of Participants with Events (Deterioration)	17 (38.6%)	24 (46.2%)	
Number (%) of Participants Censored	27 (61.4%)	28 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (4.44, NR)	5.82 (2.89, NR)	
Log-Rank Test p-value (unstratified)	0.1014		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.593 (0.316, 1.111)		

	SG (N=125)	TPC (N=124)	Interaction
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	25 (30.9%)	21 (29.2%)	
Number (%) of Participants Censored	56 (69.1%)	51 (70.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (6.97, NR)	NR (5.13, NR)	
Log-Rank Test p-value (unstratified)	0.7141		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.115 (0.622, 1.998)		
BRCA 1/2 status			
Wild-Type	42	46	0.9592
Number (%) of Participants with Events (Deterioration)	12 (28.6%)	21 (45.7%)	
Number (%) of Participants Censored	30 (71.4%)	25 (54.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (4.27, NR)	3.98 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.0933		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.549 (0.270, 1.119)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	3 (33.3%)	5 (71.4%)	
Number (%) of Participants Censored	6 (66.7%)	2 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.79, NR)	4.35 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.5553		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.637 (0.141, 2.882)		
Menopausal status			
Pre-menopausal	29	35	0.1634

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	11 (37.9%)	18 (51.4%)	
Number (%) of Participants Censored	18 (62.1%)	17 (48.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (3.65, NR)	3.84 (1.64, 6.47)	
Log-Rank Test p-value (unstratified)	0.0269		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.414 (0.185, 0.928)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	31 (32.3%)	27 (30.7%)	
Number (%) of Participants Censored	65 (67.7%)	61 (69.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (7.89, NR)	19.38 (8.67, NR)	
Log-Rank Test p-value (unstratified)	0.9766		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.008 (0.598, 1.698)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.59. Table 1.1.21.1: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Body Image | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.3802

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	14 (48.3%)	9 (34.6%)	
Number (%) of Participants Censored	15 (51.7%)	17 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.57 (1.68, NE)	NE (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.5571		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.287 (0.554, 2.991)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	17 (54.8%)	12 (38.7%)	
Number (%) of Participants Censored	14 (45.2%)	19 (61.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.87 (1.45, NE)	12.75 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.9106		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.957 (0.448, 2.043)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	37 (56.9%)	34 (50.7%)	
Number (%) of Participants Censored	28 (43.1%)	33 (49.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.77 (1.45, 2.89)	5.19 (2.37, NE)	
Log-Rank Test p-value (unstratified)	0.0120		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.812 (1.132, 2.902)		
Geographic region			
US/Canada/Western Europe	30	35	0.4051
Number (%) of Participants with Events (Deterioration)	13 (43.3%)	17 (48.6%)	
Number (%) of Participants Censored	17 (56.7%)	18 (51.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.15, NE)	4.40 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.8121		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.090 (0.529, 2.246)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	55 (57.9%)	38 (42.7%)	
Number (%) of Participants Censored	40 (42.1%)	51 (57.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.77, 4.96)	12.75 (3.48, NE)	
Log-Rank Test p-value (unstratified)	0.0628		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.474 (0.973, 2.234)		
Age group			
< 65	98	96	0.0810
Number (%) of Participants with Events (Deterioration)	56 (57.1%)	44 (45.8%)	
Number (%) of Participants Censored	42 (42.9%)	52 (54.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.14, 6.31)	5.19 (2.37, 17.08)	
Log-Rank Test p-value (unstratified)	0.4381		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.168 (0.786, 1.736)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	12 (44.4%)	11 (39.3%)	
Number (%) of Participants Censored	15 (55.6%)	17 (60.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.95, 2.10)	24.44 (2.56, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.0486		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.361 (0.992, 5.618)		
Race			
White	81	77	0.2001
Number (%) of Participants with Events (Deterioration)	39 (48.1%)	37 (48.1%)	
Number (%) of Participants Censored	42 (51.9%)	40 (51.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.71, 4.96)	4.96 (2.37, 24.44)	
Log-Rank Test p-value (unstratified)	0.2691		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.291 (0.823, 2.026)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	20 (76.9%)	10 (38.5%)	
Number (%) of Participants Censored	6 (23.1%)	16 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.89 (1.28, 5.06)	17.08 (1.74, NE)	
Log-Rank Test p-value (unstratified)	0.0295		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.267 (1.058, 4.861)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	8 (50.0%)	8 (38.1%)	
Number (%) of Participants Censored	8 (50.0%)	13 (61.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.04 (0.99, NE)	5.19 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.9211		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.949 (0.356, 2.532)		

	SG (N=125)	TPC (N=124)	Interaction
Baseline ECOG status			
0	81	80	0.9718
Number (%) of Participants with Events (Deterioration)	48 (59.3%)	36 (45.0%)	
Number (%) of Participants Censored	33 (40.7%)	44 (55.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.77, 5.06)	12.75 (3.02, 24.44)	
Log-Rank Test p-value (unstratified)	0.1410		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.380 (0.895, 2.127)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	19 (43.2%)	
Number (%) of Participants Censored	24 (54.5%)	25 (56.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (0.95, 12.58)	5.39 (1.97, NE)	
Log-Rank Test p-value (unstratified)	0.3521		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.352 (0.716, 2.553)		
History of liver metastasis			
Yes	36	26	0.1032
Number (%) of Participants with Events (Deterioration)	20 (55.6%)	6 (23.1%)	
Number (%) of Participants Censored	16 (44.4%)	20 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.15, 6.31)	NE (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.0481		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.463 (0.972, 6.243)		
No	89	98	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	48 (53.9%)	49 (50.0%)	
Number (%) of Participants Censored	41 (46.1%)	49 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.74, 5.06)	5.09 (2.14, 17.08)	
Log-Rank Test p-value (unstratified)	0.4115		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.182 (0.794, 1.761)		
History of brain metastasis			
Yes	6	7	0.7370
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	3 (42.9%)	
Number (%) of Participants Censored	3 (50.0%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.79, NE)	5.24 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.6847		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.333 (0.266, 6.685)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	65 (54.6%)	52 (44.4%)	
Number (%) of Participants Censored	54 (45.4%)	65 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (1.74, 4.96)	5.39 (3.32, 17.08)	
Log-Rank Test p-value (unstratified)	0.1052		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.352 (0.938, 1.949)		
PD-L1 Status			
CPS < 1	44	52	0.7856
Number (%) of Participants with Events (Deterioration)	28 (63.6%)	25 (48.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	16 (36.4%)	27 (51.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.51, 4.57)	4.96 (1.77, 24.44)	
Log-Rank Test p-value (unstratified)	0.1552		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.476 (0.859, 2.536)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	40 (49.4%)	30 (41.7%)	
Number (%) of Participants Censored	41 (50.6%)	42 (58.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.71, 6.87)	6.47 (3.32, NE)	
Log-Rank Test p-value (unstratified)	0.2747		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.300 (0.808, 2.092)		
BRCA 1/2 status			
Wild-Type	42	46	0.7318
Number (%) of Participants with Events (Deterioration)	26 (61.9%)	22 (47.8%)	
Number (%) of Participants Censored	16 (38.1%)	24 (52.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (0.99, 5.06)	2.14 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.3596		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.304 (0.738, 2.302)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	5 (71.4%)	
Number (%) of Participants Censored	4 (44.4%)	2 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	1.31 (0.72, NE)	2.38 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.4020		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.765 (0.460, 6.765)		
Menopausal status			
Pre-menopausal	29	35	0.2474
Number (%) of Participants with Events (Deterioration)	13 (44.8%)	17 (48.6%)	
Number (%) of Participants Censored	16 (55.2%)	18 (51.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (0.89, NE)	3.84 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.8052		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.912 (0.435, 1.914)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	55 (57.3%)	38 (43.2%)	
Number (%) of Participants Censored	41 (42.7%)	50 (56.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.89 (1.74, 4.57)	6.01 (3.02, 24.44)	
Log-Rank Test p-value (unstratified)	0.0461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.520 (1.005, 2.299)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.60. Table 1.1.21.2: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Sexual Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.1864
Number (%) of Participants with Events (Deterioration)	9 (31.0%)	8 (30.8%)	
Number (%) of Participants Censored	20 (69.0%)	18 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (2.10, NE)	
Log-Rank Test p-value (unstratified)	0.7440		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.325, 2.214)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	12 (38.7%)	5 (16.1%)	
Number (%) of Participants Censored	19 (61.3%)	26 (83.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.06, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.1768		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.032 (0.715, 5.773)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	14 (21.5%)	23 (34.3%)	
Number (%) of Participants Censored	51 (78.5%)	44 (65.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (13.34, NE)	NE (5.39, NE)	
Log-Rank Test p-value (unstratified)	0.1951		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.647 (0.332, 1.258)		
Geographic region			

	SG (N=125)	TPC (N=124)	Interaction
US/Canada/Western Europe	30	35	0.1306
Number (%) of Participants with Events (Deterioration)	7 (23.3%)	13 (37.1%)	
Number (%) of Participants Censored	23 (76.7%)	22 (62.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	5.29 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.1521		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.517 (0.205, 1.301)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	28 (29.5%)	23 (25.8%)	
Number (%) of Participants Censored	67 (70.5%)	66 (74.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (11.66, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6794		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.123 (0.646, 1.952)		
Age group			
< 65	98	96	0.9473
Number (%) of Participants with Events (Deterioration)	30 (30.6%)	27 (28.1%)	
Number (%) of Participants Censored	68 (69.4%)	69 (71.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (11.66, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7079		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.905 (0.537, 1.524)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	5 (18.5%)	9 (32.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	22 (81.5%)	19 (67.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.71, NE)	NE (5.29, NE)	
Log-Rank Test p-value (unstratified)	0.7737		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.178 (0.386, 3.589)		
Race			
White	81	77	0.9845
Number (%) of Participants with Events (Deterioration)	26 (32.1%)	26 (33.8%)	
Number (%) of Participants Censored	55 (67.9%)	51 (66.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.34 (6.05, NE)	NE (5.09, NE)	
Log-Rank Test p-value (unstratified)	0.6187		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.869 (0.504, 1.499)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	4 (15.4%)	5 (19.2%)	
Number (%) of Participants Censored	22 (84.6%)	21 (80.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (7.00, NE)	
Log-Rank Test p-value (unstratified)	0.6415		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.732 (0.195, 2.749)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	4 (25.0%)	5 (23.8%)	
Number (%) of Participants Censored	12 (75.0%)	16 (76.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	NE (3.02, NE)	NE (3.81, NE)	
Log-Rank Test p-value (unstratified)	0.9249		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.939 (0.252, 3.501)		
Baseline ECOG status			
0	81	80	0.1462
Number (%) of Participants with Events (Deterioration)	27 (33.3%)	22 (27.5%)	
Number (%) of Participants Censored	54 (66.7%)	58 (72.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6654		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.131 (0.643, 1.990)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	8 (18.2%)	14 (31.8%)	
Number (%) of Participants Censored	36 (81.8%)	30 (68.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.09, NE)	
Log-Rank Test p-value (unstratified)	0.1518		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.535 (0.224, 1.277)		
History of liver metastasis			
Yes	36	26	0.1609
Number (%) of Participants with Events (Deterioration)	8 (22.2%)	8 (30.8%)	
Number (%) of Participants Censored	28 (77.8%)	18 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.31, NE)	6.24 (1.87, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.1074		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.448 (0.164, 1.226)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	27 (30.3%)	28 (28.6%)	
Number (%) of Participants Censored	62 (69.7%)	70 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7932		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.073 (0.632, 1.822)		
History of brain metastasis			
Yes	6	7	0.8721
Number (%) of Participants with Events (Deterioration)	1 (16.7%)	2 (28.6%)	
Number (%) of Participants Censored	5 (83.3%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.06, NE)	NE (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.9013		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.855 (0.072, 10.204)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	34 (28.6%)	34 (29.1%)	
Number (%) of Participants Censored	85 (71.4%)	83 (70.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (11.66, NE)	NE (7.00, NE)	
Log-Rank Test p-value (unstratified)	0.7126		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.914 (0.567, 1.471)		

	SG (N=125)	TPC (N=124)	Interaction
PD-L1 Status			
CPS < 1	44	52	0.2290
Number (%) of Participants with Events (Deterioration)	16 (36.4%)	13 (25.0%)	
Number (%) of Participants Censored	28 (63.6%)	39 (75.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.34 (6.31, NE)	NE (6.24, NE)	
Log-Rank Test p-value (unstratified)	0.5783		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.230 (0.590, 2.565)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	19 (23.5%)	23 (31.9%)	
Number (%) of Participants Censored	62 (76.5%)	49 (68.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.47, NE)	
Log-Rank Test p-value (unstratified)	0.3185		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.735 (0.400, 1.349)		
BRCA 1/2 status			
Wild-Type	42	46	0.0073
Number (%) of Participants with Events (Deterioration)	11 (26.2%)	13 (28.3%)	
Number (%) of Participants Censored	31 (73.8%)	33 (71.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.31, NE)	NE (5.29, NE)	
Log-Rank Test p-value (unstratified)	0.7794		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.891 (0.399, 1.991)		
Mutant	9	7	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	0	4 (57.1%)	
Number (%) of Participants Censored	9 (100.0%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	3.71 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.0068		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
Menopausal status			
Pre-menopausal	29	35	0.2365
Number (%) of Participants with Events (Deterioration)	8 (27.6%)	14 (40.0%)	
Number (%) of Participants Censored	21 (72.4%)	21 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.34 (6.05, NE)	NE (1.48, NE)	
Log-Rank Test p-value (unstratified)	0.2069		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.574 (0.239, 1.378)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	27 (28.1%)	22 (25.0%)	
Number (%) of Participants Censored	69 (71.9%)	66 (75.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7355		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.102 (0.628, 1.937)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.

Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.61. Table 1.1.21.3: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Sexual Enjoyment | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.7565
Number (%) of Participants with Events (Deterioration)	1 (3.4%)	0	
Number (%) of Participants Censored	28 (96.6%)	26 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.45, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4795		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	1 (3.2%)	1 (3.2%)	
Number (%) of Participants Censored	30 (96.8%)	30 (96.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.58, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.8055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.414 (0.088, 22.637)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	4 (6.2%)	4 (6.0%)	
Number (%) of Participants Censored	61 (93.8%)	63 (94.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (3.09, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.5016		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.618 (0.403, 6.498)		
Geographic region			
US/Canada/Western Europe	30	35	0.4884
Number (%) of Participants with Events (Deterioration)	1 (3.3%)	3 (8.6%)	
Number (%) of Participants Censored	29 (96.7%)	32 (91.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.8902		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.185 (0.107, 13.163)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	5 (5.3%)	2 (2.2%)	
Number (%) of Participants Censored	90 (94.7%)	87 (97.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.58, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.2387		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.587 (0.501, 13.348)		
Age group			
< 65	98	96	1.0000
Number (%) of Participants with Events (Deterioration)	6 (6.1%)	5 (5.2%)	
Number (%) of Participants Censored	92 (93.9%)	91 (94.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4348		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.604 (0.489, 5.262)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	27 (100.0%)	28 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
Race			
White	81	77	0.2183
Number (%) of Participants with Events (Deterioration)	5 (6.2%)	3 (3.9%)	
Number (%) of Participants Censored	76 (93.8%)	74 (96.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.79, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.2053		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.467 (0.587, 10.376)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	0	1 (3.8%)	
Number (%) of Participants Censored	26 (100.0%)	25 (96.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.2636		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
Other	16	21	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	1 (6.2%)	1 (4.8%)	
Number (%) of Participants Censored	15 (93.8%)	20 (95.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.88 (1.45, NE)	NE (1.18, NE)	
Log-Rank Test p-value (unstratified)	0.5596		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.236 (0.139, 35.904)		
Baseline ECOG status			
0	81	80	0.0714
Number (%) of Participants with Events (Deterioration)	4 (4.9%)	2 (2.5%)	
Number (%) of Participants Censored	77 (95.1%)	78 (97.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.79, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.1634		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.193 (0.576, 17.705)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	2 (4.5%)	3 (6.8%)	
Number (%) of Participants Censored	42 (95.5%)	41 (93.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.45, NE)	3.09 (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.1998		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.316 (0.050, 2.000)		
History of liver metastasis			
Yes	36	26	0.4138
Number (%) of Participants with Events (Deterioration)	1 (2.8%)	0	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	35 (97.2%)	26 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.45, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4142		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	89	98	
Number (%) of Participants with Events (Deterioration)	5 (5.6%)	5 (5.1%)	
Number (%) of Participants Censored	84 (94.4%)	93 (94.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.79, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.4625		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.593 (0.461, 5.512)		
History of brain metastasis			
Yes	6	7	1.0000
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	6 (100.0%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
No	119	117	
Number (%) of Participants with Events (Deterioration)	6 (5.0%)	5 (4.3%)	
Number (%) of Participants Censored	113 (95.0%)	112 (95.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4595		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.565 (0.477, 5.132)		
PD-L1 Status			
CPS < 1	44	52	0.7998
Number (%) of Participants with Events (Deterioration)	3 (6.8%)	2 (3.8%)	
Number (%) of Participants Censored	41 (93.2%)	50 (96.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.4838		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.879 (0.312, 11.305)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	3 (3.7%)	3 (4.2%)	
Number (%) of Participants Censored	78 (96.3%)	69 (95.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.7144		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.347 (0.271, 6.693)		
BRCA 1/2 status			
Wild-Type	42	46	1.0000
Number (%) of Participants with Events (Deterioration)	3 (7.1%)	2 (4.3%)	
Number (%) of Participants Censored	39 (92.9%)	44 (95.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (3.09, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.6318		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.547 (0.256, 9.338)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	9 (100.0%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
Menopausal status			
Pre-menopausal	29	35	0.6198
Number (%) of Participants with Events (Deterioration)	2 (6.9%)	3 (8.6%)	
Number (%) of Participants Censored	27 (93.1%)	32 (91.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.9211		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.120 (0.187, 6.716)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	4 (4.2%)	2 (2.3%)	
Number (%) of Participants Censored	92 (95.8%)	86 (97.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.45, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.3752		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.122 (0.387, 11.635)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.

Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.62. Table 1.1.21.4: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Future Perspective | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.4303
Number (%) of Participants with Events (Deterioration)	12 (41.4%)	13 (50.0%)	
Number (%) of Participants Censored	17 (58.6%)	13 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (1.68, NE)	6.28 (0.89, 13.80)	
Log-Rank Test p-value (unstratified)	0.3487		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.684 (0.311, 1.505)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	12 (38.7%)	13 (41.9%)	
Number (%) of Participants Censored	19 (61.3%)	18 (58.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.38 (1.45, NE)	3.75 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.3021		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.651 (0.286, 1.482)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	22 (33.8%)	26 (38.8%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	43 (66.2%)	41 (61.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.71, NE)	6.34 (2.46, NE)	
Log-Rank Test p-value (unstratified)	0.5739		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.181 (0.663, 2.104)		
Geographic region			
US/Canada/Western Europe	30	35	0.4776
Number (%) of Participants with Events (Deterioration)	10 (33.3%)	15 (42.9%)	
Number (%) of Participants Censored	20 (66.7%)	20 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.15, NE)	6.28 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.6132		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.235 (0.539, 2.827)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	36 (37.9%)	37 (41.6%)	
Number (%) of Participants Censored	59 (62.1%)	52 (58.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.03 (2.23, 27.89)	5.39 (2.00, 10.15)	
Log-Rank Test p-value (unstratified)	0.4715		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.838 (0.525, 1.339)		
Age group			
< 65	98	96	0.7923
Number (%) of Participants with Events (Deterioration)	40 (40.8%)	40 (41.7%)	
Number (%) of Participants Censored	58 (59.2%)	56 (58.3%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.93 (2.14, 13.14)	5.39 (2.00, 8.77)	
Log-Rank Test p-value (unstratified)	0.5807		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.881 (0.565, 1.375)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	6 (22.2%)	12 (42.9%)	
Number (%) of Participants Censored	21 (77.8%)	16 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	27.89 (1.25, NE)	4.90 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.4214		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.646 (0.225, 1.854)		
Race			
White	81	77	0.1694
Number (%) of Participants with Events (Deterioration)	30 (37.0%)	31 (40.3%)	
Number (%) of Participants Censored	51 (63.0%)	46 (59.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.43 (1.61, NE)	6.28 (1.64, 13.80)	
Log-Rank Test p-value (unstratified)	0.5120		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.180 (0.713, 1.951)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	9 (34.6%)	12 (46.2%)	
Number (%) of Participants Censored	17 (65.4%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.58 (1.51, NE)	4.90 (1.54, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.5028		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.737 (0.304, 1.784)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	6 (37.5%)	9 (42.9%)	
Number (%) of Participants Censored	10 (62.5%)	12 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.14 (4.93, NE)	3.75 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.1062		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.387 (0.119, 1.265)		
Baseline ECOG status			
0	81	80	0.5879
Number (%) of Participants with Events (Deterioration)	32 (39.5%)	32 (40.0%)	
Number (%) of Participants Censored	49 (60.5%)	48 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.03 (2.23, NE)	8.38 (1.74, NE)	
Log-Rank Test p-value (unstratified)	0.7932		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.932 (0.568, 1.530)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	14 (31.8%)	20 (45.5%)	
Number (%) of Participants Censored	30 (68.2%)	24 (54.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.28, NE)	4.90 (1.48, 6.34)	
Log-Rank Test p-value (unstratified)	0.4530		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.762 (0.376, 1.545)		

	SG (N=125)	TPC (N=124)	Interaction
History of liver metastasis			
Yes	36	26	0.0759
Number (%) of Participants with Events (Deterioration)	14 (38.9%)	5 (19.2%)	
Number (%) of Participants Censored	22 (61.1%)	21 (80.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.38 (1.25, 13.14)	13.80 (1.64, NE)	
Log-Rank Test p-value (unstratified)	0.2383		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.834 (0.655, 5.139)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	32 (36.0%)	47 (48.0%)	
Number (%) of Participants Censored	57 (64.0%)	51 (52.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (1.74, NE)	4.57 (1.74, 8.38)	
Log-Rank Test p-value (unstratified)	0.2478		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.764 (0.484, 1.206)		
History of brain metastasis			
Yes	6	7	0.6336
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	3 (42.9%)	
Number (%) of Participants Censored	4 (66.7%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (0.79, NE)	5.26 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.9560		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.928 (0.155, 5.562)		
No	119	117	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	44 (37.0%)	49 (41.9%)	
Number (%) of Participants Censored	75 (63.0%)	68 (58.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (2.20, 13.14)	5.39 (2.46, 10.15)	
Log-Rank Test p-value (unstratified)	0.4566		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.853 (0.564, 1.290)		
PD-L1 Status			
CPS < 1	44	52	0.5154
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	23 (44.2%)	
Number (%) of Participants Censored	24 (54.5%)	29 (55.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.28, NE)	4.90 (1.48, NE)	
Log-Rank Test p-value (unstratified)	0.8162		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.077 (0.589, 1.969)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	26 (32.1%)	29 (40.3%)	
Number (%) of Participants Censored	55 (67.9%)	43 (59.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (4.27, NE)	5.39 (1.74, 8.77)	
Log-Rank Test p-value (unstratified)	0.3617		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.775 (0.452, 1.329)		
BRCA 1/2 status			
Wild-Type	42	46	0.1378
Number (%) of Participants with Events (Deterioration)	16 (38.1%)	20 (43.5%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	26 (61.9%)	26 (56.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.27 (1.74, NE)	3.29 (1.64, NE)	
Log-Rank Test p-value (unstratified)	0.7762		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.904 (0.468, 1.748)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	4 (44.4%)	3 (42.9%)	
Number (%) of Participants Censored	5 (55.6%)	4 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.25 (0.95, NE)	4.01 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.1435		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.622 (0.623, 21.041)		
Menopausal status			
Pre-menopausal	29	35	0.2400
Number (%) of Participants with Events (Deterioration)	11 (37.9%)	18 (51.4%)	
Number (%) of Participants Censored	18 (62.1%)	17 (48.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.51, NE)	2.79 (1.48, 6.28)	
Log-Rank Test p-value (unstratified)	0.2838		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.660 (0.308, 1.411)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	35 (36.5%)	33 (37.5%)	
Number (%) of Participants Censored	61 (63.5%)	55 (62.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	7.03 (2.20, 13.14)	8.77 (3.29, NE)	
Log-Rank Test p-value (unstratified)	0.9322		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.020 (0.630, 1.652)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.63. Table 1.1.21.5: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Systemic Therapy Side Effects | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0857
Number (%) of Participants with Events (Deterioration)	21 (72.4%)	18 (69.2%)	
Number (%) of Participants Censored	8 (27.6%)	8 (30.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.79, 3.15)	1.74 (0.79, 5.09)	
Log-Rank Test p-value (unstratified)	0.8711		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.054 (0.560, 1.982)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	26 (83.9%)	18 (58.1%)	
Number (%) of Participants Censored	5 (16.1%)	13 (41.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	0.89 (0.76, 1.28)	2.86 (0.99, 5.59)	
Log-Rank Test p-value (unstratified)	0.0155		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.092 (1.140, 3.839)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	44 (67.7%)	37 (55.2%)	
Number (%) of Participants Censored	21 (32.3%)	30 (44.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.80 (0.79, 1.15)	4.93 (1.97, 14.98)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.395 (1.522, 3.767)		
Geographic region			
US/Canada/Western Europe	30	35	0.3791
Number (%) of Participants with Events (Deterioration)	23 (76.7%)	19 (54.3%)	
Number (%) of Participants Censored	7 (23.3%)	16 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.76, 1.25)	3.09 (1.35, 9.23)	
Log-Rank Test p-value (unstratified)	0.0027		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.550 (1.364, 4.767)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	68 (71.6%)	54 (60.7%)	
Number (%) of Participants Censored	27 (28.4%)	35 (39.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.79, 1.45)	3.02 (1.45, 5.09)	
Log-Rank Test p-value (unstratified)	0.0025		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.740 (1.214, 2.495)		
Age group			
< 65	98	96	0.9324
Number (%) of Participants with Events (Deterioration)	78 (79.6%)	59 (61.5%)	
Number (%) of Participants Censored	20 (20.4%)	37 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.79, 1.05)	2.73 (1.41, 3.98)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.853 (1.317, 2.606)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	13 (48.1%)	14 (50.0%)	
Number (%) of Participants Censored	14 (51.9%)	14 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.30 (0.79, NE)	5.09 (2.10, NE)	
Log-Rank Test p-value (unstratified)	0.0655		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.064 (0.941, 4.527)		
Race			
White	81	77	0.4818
Number (%) of Participants with Events (Deterioration)	58 (71.6%)	47 (61.0%)	
Number (%) of Participants Censored	23 (28.4%)	30 (39.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.79, 1.45)	3.12 (1.74, 5.09)	
Log-Rank Test p-value (unstratified)	0.0017		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.857 (1.260, 2.737)		

	SG (N=125)	TPC (N=124)	Interaction
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	20 (76.9%)	14 (53.8%)	
Number (%) of Participants Censored	6 (23.1%)	12 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.76, 1.28)	5.59 (0.92, 17.08)	
Log-Rank Test p-value (unstratified)	0.0073		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.518 (1.259, 5.035)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	12 (75.0%)	12 (57.1%)	
Number (%) of Participants Censored	4 (25.0%)	9 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.18 (0.79, 5.19)	1.41 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.4987		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.305 (0.580, 2.932)		
Baseline ECOG status			
0	81	80	0.1402
Number (%) of Participants with Events (Deterioration)	65 (80.2%)	50 (62.5%)	
Number (%) of Participants Censored	16 (19.8%)	30 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.79, 0.99)	2.86 (1.45, 5.09)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.222 (1.520, 3.249)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	23 (52.3%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	18 (40.9%)	21 (47.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.82, 4.57)	3.48 (1.74, 5.39)	
Log-Rank Test p-value (unstratified)	0.2680		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.380 (0.785, 2.426)		
History of liver metastasis			
Yes	36	26	0.9653
Number (%) of Participants with Events (Deterioration)	25 (69.4%)	12 (46.2%)	
Number (%) of Participants Censored	11 (30.6%)	14 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.79, 1.48)	5.09 (1.64, NE)	
Log-Rank Test p-value (unstratified)	0.0506		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.975 (0.988, 3.947)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	66 (74.2%)	61 (62.2%)	
Number (%) of Participants Censored	23 (25.8%)	37 (37.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.79, 1.25)	3.09 (1.45, 4.96)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.950 (1.369, 2.777)		
History of brain metastasis			
Yes	6	7	0.5865
Number (%) of Participants with Events (Deterioration)	3 (50.0%)	2 (28.6%)	
Number (%) of Participants Censored	3 (50.0%)	5 (71.4%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.79 (0.76, NE)	NE (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.3372		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.367 (0.390, 14.372)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	88 (73.9%)	71 (60.7%)	
Number (%) of Participants Censored	31 (26.1%)	46 (39.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.79, 1.12)	3.02 (1.74, 4.96)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.858 (1.356, 2.547)		
PD-L1 Status			
CPS < 1	44	52	0.9387
Number (%) of Participants with Events (Deterioration)	34 (77.3%)	31 (59.6%)	
Number (%) of Participants Censored	10 (22.7%)	21 (40.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.79, 1.48)	3.12 (1.74, 5.09)	
Log-Rank Test p-value (unstratified)	0.0056		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.020 (1.226, 3.328)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	57 (70.4%)	42 (58.3%)	
Number (%) of Participants Censored	24 (29.6%)	30 (41.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.87 (0.79, 1.25)	2.73 (1.41, 5.39)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.0040		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.802 (1.205, 2.694)		
BRCA 1/2 status			
Wild-Type	42	46	0.5024
Number (%) of Participants with Events (Deterioration)	31 (73.8%)	25 (54.3%)	
Number (%) of Participants Censored	11 (26.2%)	21 (45.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.79, 1.48)	3.09 (1.41, 14.98)	
Log-Rank Test p-value (unstratified)	0.0025		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.264 (1.324, 3.870)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	8 (88.9%)	4 (57.1%)	
Number (%) of Participants Censored	1 (11.1%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.72, 1.25)	2.38 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.0473		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.825 (0.939, 15.587)		
Menopausal status			
Pre-menopausal	29	35	0.2002
Number (%) of Participants with Events (Deterioration)	23 (79.3%)	21 (60.0%)	
Number (%) of Participants Censored	6 (20.7%)	14 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.79 (0.72, 0.82)	1.74 (0.92, 5.59)	
Log-Rank Test p-value (unstratified)	0.0035		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.430 (1.329, 4.441)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	68 (70.8%)	51 (58.0%)	
Number (%) of Participants Censored	28 (29.2%)	37 (42.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.82, 1.48)	3.12 (1.97, 5.09)	
Log-Rank Test p-value (unstratified)	0.0025		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.756 (1.218, 2.532)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.64. Table 1.1.21.6: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Breast Symptoms | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0552
Number (%) of Participants with Events (Deterioration)	4 (13.8%)	8 (30.8%)	
Number (%) of Participants Censored	25 (86.2%)	18 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	7.36 (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.0810		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.354 (0.105, 1.194)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	13 (41.9%)	10 (32.3%)	
Number (%) of Participants Censored	18 (58.1%)	21 (67.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.48 (3.88, NE)	12.75 (2.86, NE)	
Log-Rank Test p-value (unstratified)	0.4953		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.743 (0.316, 1.748)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	19 (29.2%)	15 (22.4%)	
Number (%) of Participants Censored	46 (70.8%)	52 (77.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.05 (5.13, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.1926		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.564 (0.795, 3.079)		
Geographic region			
US/Canada/Western Europe	30	35	0.1502
Number (%) of Participants with Events (Deterioration)	7 (23.3%)	11 (31.4%)	
Number (%) of Participants Censored	23 (76.7%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.13, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.2082		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.543 (0.206, 1.428)		
Rest of the world	95	89	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	29 (30.5%)	22 (24.7%)	
Number (%) of Participants Censored	66 (69.5%)	67 (75.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (9.30, NE)	NE (12.75, NE)	
Log-Rank Test p-value (unstratified)	0.5112		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.206 (0.690, 2.109)		
Age group			
< 65	98	96	0.9294
Number (%) of Participants with Events (Deterioration)	29 (29.6%)	23 (24.0%)	
Number (%) of Participants Censored	69 (70.4%)	73 (76.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (17.05, NE)	NE (12.75, NE)	
Log-Rank Test p-value (unstratified)	0.9902		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.996 (0.574, 1.730)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	7 (25.9%)	10 (35.7%)	
Number (%) of Participants Censored	20 (74.1%)	18 (64.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.48, NE)	NE (2.63, NE)	
Log-Rank Test p-value (unstratified)	0.6910		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.216 (0.458, 3.227)		
Race			
White	81	77	0.8512
Number (%) of Participants with Events (Deterioration)	26 (32.1%)	24 (31.2%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	55 (67.9%)	53 (68.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.05 (5.59, NE)	12.75 (5.13, NE)	
Log-Rank Test p-value (unstratified)	0.6561		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.503, 1.540)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	6 (23.1%)	5 (19.2%)	
Number (%) of Participants Censored	20 (76.9%)	21 (80.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (17.48, NE)	NE (8.71, NE)	
Log-Rank Test p-value (unstratified)	0.7219		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.243 (0.375, 4.123)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	4 (25.0%)	4 (19.0%)	
Number (%) of Participants Censored	12 (75.0%)	17 (81.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (5.62, NE)	NE (2.86, NE)	
Log-Rank Test p-value (unstratified)	0.7386		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.270 (0.311, 5.180)		
Baseline ECOG status			
0	81	80	0.9537
Number (%) of Participants with Events (Deterioration)	25 (30.9%)	23 (28.7%)	
Number (%) of Participants Censored	56 (69.1%)	57 (71.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

		SG (N=125)	TPC (N=124)	Interaction
	Median	NE (10.18, NE)	NE (8.71, NE)	
	Log-Rank Test p-value (unstratified)	0.9123		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.969 (0.548, 1.713)		
1		44	44	
	Number (%) of Participants with Events (Deterioration)	11 (25.0%)	10 (22.7%)	
	Number (%) of Participants Censored	33 (75.0%)	34 (77.3%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	24.67 (5.06, NE)	NE (5.19, NE)	
	Log-Rank Test p-value (unstratified)	0.9751		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.983 (0.408, 2.373)		
History of liver metastasis				
Yes		36	26	0.7265
	Number (%) of Participants with Events (Deterioration)	9 (25.0%)	4 (15.4%)	
	Number (%) of Participants Censored	27 (75.0%)	22 (84.6%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	NE (2.83, NE)	NE (3.94, NE)	
	Log-Rank Test p-value (unstratified)	0.5291		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.458 (0.448, 4.750)		
No		89	98	
	Number (%) of Participants with Events (Deterioration)	27 (30.3%)	29 (29.6%)	
	Number (%) of Participants Censored	62 (69.7%)	69 (70.4%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	24.67 (10.18, NE)	NE (12.75, NE)	
	Log-Rank Test p-value (unstratified)	0.8311		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.944 (0.556, 1.602)		
History of brain metastasis			
Yes	6	7	0.7248
Number (%) of Participants with Events (Deterioration)	1 (16.7%)	1 (14.3%)	
Number (%) of Participants Censored	5 (83.3%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.88, NE)	NE (2.14, NE)	
Log-Rank Test p-value (unstratified)	0.8055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.414 (0.088, 22.637)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	35 (29.4%)	32 (27.4%)	
Number (%) of Participants Censored	84 (70.6%)	85 (72.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (10.18, NE)	NE (8.71, NE)	
Log-Rank Test p-value (unstratified)	0.8663		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.959 (0.591, 1.557)		
PD-L1 Status			
CPS < 1	44	52	0.6410
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	17 (32.7%)	
Number (%) of Participants Censored	25 (56.8%)	35 (67.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.05 (3.12, NE)	12.75 (5.13, NE)	
Log-Rank Test p-value (unstratified)	0.7237		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.128 (0.581, 2.188)		

	SG (N=125)	TPC (N=124)	Interaction
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	17 (21.0%)	16 (22.2%)	
Number (%) of Participants Censored	64 (79.0%)	56 (77.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (24.67, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7736		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.904 (0.454, 1.800)		
BRCA 1/2 status			
Wild-Type	42	46	0.8699
Number (%) of Participants with Events (Deterioration)	12 (28.6%)	15 (32.6%)	
Number (%) of Participants Censored	30 (71.4%)	31 (67.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.13, NE)	8.71 (5.13, NE)	
Log-Rank Test p-value (unstratified)	0.4435		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.744 (0.348, 1.593)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	3 (33.3%)	2 (28.6%)	
Number (%) of Participants Censored	6 (66.7%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.30 (0.95, NE)	NE (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.9245		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.916 (0.150, 5.582)		
Menopausal status			
Pre-menopausal	29	35	0.9604

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	5 (17.2%)	7 (20.0%)	
Number (%) of Participants Censored	24 (82.8%)	28 (80.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (7.36, NE)	
Log-Rank Test p-value (unstratified)	0.9850		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.011 (0.320, 3.193)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	31 (32.3%)	26 (29.5%)	
Number (%) of Participants Censored	65 (67.7%)	62 (70.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (9.30, NE)	12.75 (8.71, NE)	
Log-Rank Test p-value (unstratified)	0.6956		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.899 (0.529, 1.529)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.65. Table 1.1.21.7: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Arm Symptoms | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0645

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	13 (44.8%)	16 (61.5%)	
Number (%) of Participants Censored	16 (55.2%)	10 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.80 (3.15, NE)	2.79 (0.82, 4.17)	
Log-Rank Test p-value (unstratified)	0.0138		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.400 (0.187, 0.852)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	21 (67.7%)	17 (54.8%)	
Number (%) of Participants Censored	10 (32.3%)	14 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (1.51, 6.70)	3.75 (1.74, 12.75)	
Log-Rank Test p-value (unstratified)	0.7471		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.112 (0.584, 2.116)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	25 (38.5%)	35 (52.2%)	
Number (%) of Participants Censored	40 (61.5%)	32 (47.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.30 (4.57, NE)	4.90 (2.53, 9.69)	
Log-Rank Test p-value (unstratified)	0.1693		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.698 (0.417, 1.169)		
Geographic region			
US/Canada/Western Europe	30	35	0.5342
Number (%) of Participants with Events (Deterioration)	12 (40.0%)	19 (54.3%)	
Number (%) of Participants Censored	18 (60.0%)	16 (45.7%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.85 (2.83, NE)	4.17 (2.10, 6.24)	
Log-Rank Test p-value (unstratified)	0.1141		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.548 (0.259, 1.159)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	47 (49.5%)	49 (55.1%)	
Number (%) of Participants Censored	48 (50.5%)	40 (44.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.80 (3.15, 13.34)	3.52 (2.20, 5.59)	
Log-Rank Test p-value (unstratified)	0.1948		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.765 (0.512, 1.144)		
Age group			
< 65	98	96	0.9240
Number (%) of Participants with Events (Deterioration)	50 (51.0%)	53 (55.2%)	
Number (%) of Participants Censored	48 (49.0%)	43 (44.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.93 (3.55, 13.34)	3.52 (2.53, 5.59)	
Log-Rank Test p-value (unstratified)	0.1054		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.727 (0.493, 1.072)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	9 (33.3%)	15 (53.6%)	
Number (%) of Participants Censored	18 (66.7%)	13 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.80 (1.71, NE)	3.75 (1.02, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.3626		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.679 (0.295, 1.560)		
Race			
White	81	77	0.6346
Number (%) of Participants with Events (Deterioration)	38 (46.9%)	41 (53.2%)	
Number (%) of Participants Censored	43 (53.1%)	36 (46.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.47 (3.61, 9.30)	3.75 (2.79, 5.59)	
Log-Rank Test p-value (unstratified)	0.2219		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.758 (0.487, 1.181)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	15 (57.7%)	17 (65.4%)	
Number (%) of Participants Censored	11 (42.3%)	9 (34.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (1.12, NE)	1.71 (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.4318		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.752 (0.373, 1.517)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	5 (31.2%)	10 (47.6%)	
Number (%) of Participants Censored	11 (68.8%)	11 (52.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.51, NE)	6.54 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.1107		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.410 (0.133, 1.263)		

	SG (N=125)	TPC (N=124)	Interaction
Baseline ECOG status			
0	81	80	0.1034
Number (%) of Participants with Events (Deterioration)	36 (44.4%)	48 (60.0%)	
Number (%) of Participants Censored	45 (55.6%)	32 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.85 (3.61, 16.46)	3.48 (2.20, 5.59)	
Log-Rank Test p-value (unstratified)	0.0136		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.581 (0.376, 0.898)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	20 (45.5%)	
Number (%) of Participants Censored	21 (47.7%)	24 (54.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.28, 9.30)	4.17 (1.74, NE)	
Log-Rank Test p-value (unstratified)	0.9446		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.025 (0.560, 1.877)		
History of liver metastasis			
Yes	36	26	0.2539
Number (%) of Participants with Events (Deterioration)	17 (47.2%)	9 (34.6%)	
Number (%) of Participants Censored	19 (52.8%)	17 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.80 (2.86, 15.90)	4.21 (3.48, NE)	
Log-Rank Test p-value (unstratified)	0.9999		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.999 (0.429, 2.325)		
No	89	98	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	42 (47.2%)	59 (60.2%)	
Number (%) of Participants Censored	47 (52.8%)	39 (39.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.93 (3.61, 15.24)	3.09 (2.10, 5.13)	
Log-Rank Test p-value (unstratified)	0.0438		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.665 (0.447, 0.990)		
History of brain metastasis			
Yes	6	7	0.9010
Number (%) of Participants with Events (Deterioration)	2 (33.3%)	4 (57.1%)	
Number (%) of Participants Censored	4 (66.7%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	3.17 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.5121		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.576 (0.105, 3.160)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	57 (47.9%)	64 (54.7%)	
Number (%) of Participants Censored	62 (52.1%)	53 (45.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.80 (4.01, 10.84)	3.75 (2.79, 5.59)	
Log-Rank Test p-value (unstratified)	0.0727		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.720 (0.503, 1.032)		
PD-L1 Status			
CPS < 1	44	52	0.1147
Number (%) of Participants with Events (Deterioration)	25 (56.8%)	26 (50.0%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	19 (43.2%)	26 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.01 (1.71, 13.34)	4.90 (3.09, 7.85)	
Log-Rank Test p-value (unstratified)	0.9150		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.028 (0.593, 1.781)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	34 (42.0%)	42 (58.3%)	
Number (%) of Participants Censored	47 (58.0%)	30 (41.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.16 (4.96, 15.90)	2.83 (2.10, 5.59)	
Log-Rank Test p-value (unstratified)	0.0133		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.564 (0.356, 0.894)		
BRCA 1/2 status			
Wild-Type	42	46	0.7400
Number (%) of Participants with Events (Deterioration)	22 (52.4%)	26 (56.5%)	
Number (%) of Participants Censored	20 (47.6%)	20 (43.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.96 (3.06, 9.63)	3.09 (1.41, 5.09)	
Log-Rank Test p-value (unstratified)	0.2353		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.706 (0.399, 1.251)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	6 (66.7%)	4 (57.1%)	
Number (%) of Participants Censored	3 (33.3%)	3 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	2.83 (0.79, NE)	2.10 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.7245		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.779 (0.217, 2.797)		
Menopausal status			
Pre-menopausal	29	35	0.0609
Number (%) of Participants with Events (Deterioration)	10 (34.5%)	24 (68.6%)	
Number (%) of Participants Censored	19 (65.5%)	11 (31.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.15, NE)	2.83 (1.64, 5.59)	
Log-Rank Test p-value (unstratified)	0.0185		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.415 (0.195, 0.881)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	49 (51.0%)	43 (48.9%)	
Number (%) of Participants Censored	47 (49.0%)	45 (51.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.70 (3.06, 9.63)	4.21 (2.86, 7.85)	
Log-Rank Test p-value (unstratified)	0.5491		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.881 (0.584, 1.329)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.66. Table 1.1.21.8: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Upset By Hair Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.9376
Number (%) of Participants with Events (Deterioration)	3 (10.3%)	3 (11.5%)	
Number (%) of Participants Censored	26 (89.7%)	23 (88.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.23 (0.76, NE)	6.98 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.9170		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.890 (0.172, 4.606)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	3 (9.7%)	3 (9.7%)	
Number (%) of Participants Censored	28 (90.3%)	28 (90.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.82, NE)	2.23 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.8740		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.144 (0.229, 5.726)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	7 (10.8%)	7 (10.4%)	
Number (%) of Participants Censored	58 (89.2%)	60 (89.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.10 (0.07, NE)	0.79 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.6426		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.759 (0.264, 2.182)		
Geographic region			

	SG (N=125)	TPC (N=124)	Interaction
US/Canada/Western Europe	30	35	0.1624
Number (%) of Participants with Events (Deterioration)	5 (16.7%)	2 (5.7%)	
Number (%) of Participants Censored	25 (83.3%)	33 (94.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.72, NE)	1.41 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.1538		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.228 (0.597, 17.449)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	8 (8.4%)	11 (12.4%)	
Number (%) of Participants Censored	87 (91.6%)	78 (87.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (0.82, NE)	1.45 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.4441		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.691 (0.278, 1.721)		
Age group			
< 65	98	96	0.1335
Number (%) of Participants with Events (Deterioration)	9 (9.2%)	10 (10.4%)	
Number (%) of Participants Censored	89 (90.8%)	86 (89.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.82, NE)	1.41 (0.76, 3.32)	
Log-Rank Test p-value (unstratified)	0.3673		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.649 (0.260, 1.620)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	4 (14.8%)	3 (10.7%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	23 (85.2%)	25 (89.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.25 (0.07, NE)	8.79 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.1972		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.646 (0.572, 12.232)		
Race			
White	81	77	0.4851
Number (%) of Participants with Events (Deterioration)	9 (11.1%)	8 (10.4%)	
Number (%) of Participants Censored	72 (88.9%)	69 (89.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.76, NE)	1.41 (0.76, 1.48)	
Log-Rank Test p-value (unstratified)	0.6140		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.200 (0.457, 3.151)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	2 (7.7%)	1 (3.8%)	
Number (%) of Participants Censored	24 (92.3%)	25 (96.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.28 (1.25, NE)	NE (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.6195		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.823 (0.165, 20.199)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	2 (12.5%)	4 (19.0%)	
Number (%) of Participants Censored	14 (87.5%)	17 (81.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	17.33 (0.99, NE)	3.06 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.2602		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.375 (0.066, 2.127)		
Baseline ECOG status			
0	81	80	0.1661
Number (%) of Participants with Events (Deterioration)	4 (4.9%)	10 (12.5%)	
Number (%) of Participants Censored	77 (95.1%)	70 (87.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.23 (0.72, NE)	1.41 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.2876		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.514 (0.158, 1.666)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	9 (20.5%)	3 (6.8%)	
Number (%) of Participants Censored	35 (79.5%)	41 (93.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.82, NE)	3.06 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.4437		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.662 (0.444, 6.215)		
History of liver metastasis			
Yes	36	26	0.1383
Number (%) of Participants with Events (Deterioration)	2 (5.6%)	0	
Number (%) of Participants Censored	34 (94.4%)	26 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.68 (0.89, NE)	NE (NE, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.2807		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	89	98	
Number (%) of Participants with Events (Deterioration)	11 (12.4%)	13 (13.3%)	
Number (%) of Participants Censored	78 (87.6%)	85 (86.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.82, NE)	1.41 (0.76, 3.32)	
Log-Rank Test p-value (unstratified)	0.7371		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.849 (0.379, 1.902)		
History of brain metastasis			
Yes	6	7	0.0078
Number (%) of Participants with Events (Deterioration)	0	2 (28.6%)	
Number (%) of Participants Censored	6 (100.0%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	0.76 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.1573		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
No	119	117	
Number (%) of Participants with Events (Deterioration)	13 (10.9%)	11 (9.4%)	
Number (%) of Participants Censored	106 (89.1%)	106 (90.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.25 (0.82, NE)	1.48 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.5857		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.213 (0.541, 2.718)		

	SG (N=125)	TPC (N=124)	Interaction
PD-L1 Status			
CPS < 1	44	52	0.1163
Number (%) of Participants with Events (Deterioration)	6 (13.6%)	6 (11.5%)	
Number (%) of Participants Censored	38 (86.4%)	46 (88.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.72 (0.07, NE)	0.79 (0.72, 1.48)	
Log-Rank Test p-value (unstratified)	0.1965		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.471 (0.149, 1.486)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	7 (8.6%)	7 (9.7%)	
Number (%) of Participants Censored	74 (91.4%)	65 (90.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (0.76, NE)	3.19 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.4323		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.488 (0.518, 4.272)		
BRCA 1/2 status			
Wild-Type	42	46	1.0000
Number (%) of Participants with Events (Deterioration)	6 (14.3%)	5 (10.9%)	
Number (%) of Participants Censored	36 (85.7%)	41 (89.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.85 (0.72, 0.99)	1.45 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.1811		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.308 (0.672, 7.931)		
Mutant	9	7	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	1 (11.1%)	0	
Number (%) of Participants Censored	8 (88.9%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.81 (1.25, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
Menopausal status			
Pre-menopausal	29	35	0.8595
Number (%) of Participants with Events (Deterioration)	2 (6.9%)	6 (17.1%)	
Number (%) of Participants Censored	27 (93.1%)	29 (82.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.72, NE)	1.45 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.7491		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.230 (0.243, 6.240)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	11 (11.5%)	7 (8.0%)	
Number (%) of Participants Censored	85 (88.5%)	81 (92.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.82, NE)	1.41 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.8907		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.931 (0.360, 2.404)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).

Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.67. Table 1.1.22: Subgroup Analysis of Time to First Deterioration by response threshold in EQ-5D-VAS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.1464
Number (%) of Participants with Events (Deterioration)	6 (20.7%)	11 (42.3%)	
Number (%) of Participants Censored	23 (79.3%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (18.73, NE)	10.48 (2.50, NE)	
Log-Rank Test p-value (unstratified)	0.0541		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.367 (0.126, 1.064)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	15 (48.4%)	12 (38.7%)	
Number (%) of Participants Censored	16 (51.6%)	19 (61.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.68, NE)	NE (2.14, NE)	
Log-Rank Test p-value (unstratified)	0.7379		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.141 (0.534, 2.439)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	23 (35.4%)	22 (32.8%)	
Number (%) of Participants Censored	42 (64.6%)	45 (67.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (7.23, NE)	13.01 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.5554		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.193 (0.663, 2.146)		
Geographic region			
US/Canada/Western Europe	30	35	0.5361
Number (%) of Participants with Events (Deterioration)	10 (33.3%)	14 (40.0%)	
Number (%) of Participants Censored	20 (66.7%)	21 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (3.88, NE)	5.13 (2.37, NE)	
Log-Rank Test p-value (unstratified)	0.4535		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.729 (0.312, 1.704)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	34 (35.8%)	31 (34.8%)	
Number (%) of Participants Censored	61 (64.2%)	58 (65.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (7.23, NE)	12.39 (10.28, NE)	
Log-Rank Test p-value (unstratified)	0.9242		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.023 (0.627, 1.670)		
Age group			
< 65	98	96	0.8467
Number (%) of Participants with Events (Deterioration)	38 (38.8%)	35 (36.5%)	
Number (%) of Participants Censored	60 (61.2%)	61 (63.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (8.84, NE)	12.39 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.7739		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.935 (0.589, 1.486)		

	SG (N=125)	TPC (N=124)	Interaction
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	6 (22.2%)	10 (35.7%)	
Number (%) of Participants Censored	21 (77.8%)	18 (64.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.71, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.9545		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.971 (0.350, 2.695)		
Race			
White	81	77	0.8843
Number (%) of Participants with Events (Deterioration)	29 (35.8%)	31 (40.3%)	
Number (%) of Participants Censored	52 (64.2%)	46 (59.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (4.90, NE)	10.28 (3.29, NE)	
Log-Rank Test p-value (unstratified)	0.5403		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.856 (0.515, 1.425)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	11 (42.3%)	11 (42.3%)	
Number (%) of Participants Censored	15 (57.7%)	15 (57.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (2.86, NE)	12.39 (6.97, NE)	
Log-Rank Test p-value (unstratified)	0.7449		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.362, 2.071)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	3 (18.8%)	3 (14.3%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	13 (81.2%)	18 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.68, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.229 (0.248, 6.100)		
Baseline ECOG status			
0	81	80	0.7678
Number (%) of Participants with Events (Deterioration)	29 (35.8%)	31 (38.8%)	
Number (%) of Participants Censored	52 (64.2%)	49 (61.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (8.87, NE)	11.56 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.6314		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.532, 1.474)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	15 (34.1%)	14 (31.8%)	
Number (%) of Participants Censored	29 (65.9%)	30 (68.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.30, NE)	15.41 (3.29, NE)	
Log-Rank Test p-value (unstratified)	0.8453		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.074 (0.516, 2.237)		
History of liver metastasis			
Yes	36	26	0.6152
Number (%) of Participants with Events (Deterioration)	14 (38.9%)	7 (26.9%)	
Number (%) of Participants Censored	22 (61.1%)	19 (73.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (3.88, NE)	NE (2.50, NE)	
Log-Rank Test p-value (unstratified)	0.7768		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.142 (0.454, 2.874)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	30 (33.7%)	38 (38.8%)	
Number (%) of Participants Censored	59 (66.3%)	60 (61.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (8.87, NE)	12.39 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.5829		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.875 (0.541, 1.415)		
History of brain metastasis			
Yes	6	7	0.6220
Number (%) of Participants with Events (Deterioration)	1 (16.7%)	1 (14.3%)	
Number (%) of Participants Censored	5 (83.3%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	NE (2.14, NE)	
Log-Rank Test p-value (unstratified)	0.7570		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.549 (0.095, 25.335)		
No	119	117	
Number (%) of Participants with Events (Deterioration)	43 (36.1%)	44 (37.6%)	
Number (%) of Participants Censored	76 (63.9%)	73 (62.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (8.84, NE)	11.56 (9.46, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.6539		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.909 (0.595, 1.387)		
PD-L1 Status			
CPS < 1	44	52	0.2002
Number (%) of Participants with Events (Deterioration)	14 (31.8%)	20 (38.5%)	
Number (%) of Participants Censored	30 (68.2%)	32 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (8.87, NE)	11.56 (3.29, NE)	
Log-Rank Test p-value (unstratified)	0.2725		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.681 (0.342, 1.358)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	30 (37.0%)	25 (34.7%)	
Number (%) of Participants Censored	51 (63.0%)	47 (65.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (5.09, NE)	13.01 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.6461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.135 (0.665, 1.939)		
BRCA 1/2 status			
Wild-Type	42	46	0.0534
Number (%) of Participants with Events (Deterioration)	21 (50.0%)	20 (43.5%)	
Number (%) of Participants Censored	21 (50.0%)	26 (56.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (3.65, 15.51)	9.46 (2.50, NE)	
Log-Rank Test p-value (unstratified)	0.7438		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.108 (0.598, 2.052)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	5 (55.6%)	1 (14.3%)	
Number (%) of Participants Censored	4 (44.4%)	6 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.23 (0.72, NE)	NE (11.56, NE)	
Log-Rank Test p-value (unstratified)	0.0331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Menopausal status			
Pre-menopausal	29	35	0.1518
Number (%) of Participants with Events (Deterioration)	6 (20.7%)	14 (40.0%)	
Number (%) of Participants Censored	23 (79.3%)	21 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.51, NE)	10.48 (6.97, NE)	
Log-Rank Test p-value (unstratified)	0.0928		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.441 (0.165, 1.174)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	38 (39.6%)	31 (35.2%)	
Number (%) of Participants Censored	58 (60.4%)	57 (64.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (5.09, NE)	13.01 (5.39, NE)	
Log-Rank Test p-value (unstratified)	0.7451		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.084 (0.673, 1.745)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.68. Table 1.1.24: Subgroup Analysis of Time to First Deterioration by response threshold in PGIC — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.0537
Number (%) of Participants with Events (Deterioration)	2 (6.9%)	7 (26.9%)	
Number (%) of Participants Censored	27 (93.1%)	19 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.0297		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.206 (0.043, 0.995)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	6 (19.4%)	7 (22.6%)	
Number (%) of Participants Censored	25 (80.6%)	24 (77.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.85, NE)	6.47 (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.6575		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.785 (0.263, 2.339)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	18 (27.7%)	16 (23.9%)	
Number (%) of Participants Censored	47 (72.3%)	51 (76.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.06, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.3097		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.426 (0.719, 2.829)		
Geographic region			
US/Canada/Western Europe	30	35	0.4133
Number (%) of Participants with Events (Deterioration)	8 (26.7%)	11 (31.4%)	
Number (%) of Participants Censored	22 (73.3%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.96, NE)	6.41 (3.48, NE)	
Log-Rank Test p-value (unstratified)	0.3217		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.630 (0.253, 1.571)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	18 (18.9%)	19 (21.3%)	
Number (%) of Participants Censored	77 (81.1%)	70 (78.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.47, NE)	
Log-Rank Test p-value (unstratified)	0.9712		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.011 (0.528, 1.938)		
Age group			
< 65	98	96	0.2041
Number (%) of Participants with Events (Deterioration)	22 (22.4%)	25 (26.0%)	
Number (%) of Participants Censored	76 (77.6%)	71 (74.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	NE (NE, NE)	NE (5.82, NE)	
Log-Rank Test p-value (unstratified)	0.3066		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.741 (0.416, 1.318)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	4 (14.8%)	5 (17.9%)	
Number (%) of Participants Censored	23 (85.2%)	23 (82.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.96, NE)	NE (6.41, NE)	
Log-Rank Test p-value (unstratified)	0.2731		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.067 (0.550, 7.766)		
Race			
White	81	77	0.4149
Number (%) of Participants with Events (Deterioration)	18 (22.2%)	22 (28.6%)	
Number (%) of Participants Censored	63 (77.8%)	55 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (5.32, NE)	
Log-Rank Test p-value (unstratified)	0.2884		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.715 (0.383, 1.335)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	5 (19.2%)	4 (15.4%)	
Number (%) of Participants Censored	21 (80.8%)	22 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	NE (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.5572		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.462 (0.392, 5.451)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	1 (6.2%)	4 (19.0%)	
Number (%) of Participants Censored	15 (93.8%)	17 (81.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.5156		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.483 (0.052, 4.518)		
Baseline ECOG status			
0	81	80	0.0715
Number (%) of Participants with Events (Deterioration)	22 (27.2%)	20 (25.0%)	
Number (%) of Participants Censored	59 (72.8%)	60 (75.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.85, NE)	NE (6.41, NE)	
Log-Rank Test p-value (unstratified)	0.5631		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.195 (0.649, 2.199)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	4 (9.1%)	10 (22.7%)	
Number (%) of Participants Censored	40 (90.9%)	34 (77.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.1258		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.414 (0.129, 1.328)		
History of liver metastasis			

	SG (N=125)	TPC (N=124)	Interaction
Yes	36	26	0.9403
Number (%) of Participants with Events (Deterioration)	5 (13.9%)	3 (11.5%)	
Number (%) of Participants Censored	31 (86.1%)	23 (88.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (3.75, NE)	
Log-Rank Test p-value (unstratified)	0.9455		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.049 (0.251, 4.394)		
No	89	98	
Number (%) of Participants with Events (Deterioration)	21 (23.6%)	27 (27.6%)	
Number (%) of Participants Censored	68 (76.4%)	71 (72.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.8017		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.929 (0.523, 1.648)		
History of brain metastasis			
Yes	6	7	0.1735
Number (%) of Participants with Events (Deterioration)	0	2 (28.6%)	
Number (%) of Participants Censored	6 (100.0%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (3.35, NE)	
Log-Rank Test p-value (unstratified)	0.3124		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
No	119	117	
Number (%) of Participants with Events (Deterioration)	26 (21.8%)	28 (23.9%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	93 (78.2%)	89 (76.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.41, NE)	
Log-Rank Test p-value (unstratified)	0.8340		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.944 (0.552, 1.616)		
PD-L1 Status			
CPS < 1	44	52	0.8282
Number (%) of Participants with Events (Deterioration)	10 (22.7%)	12 (23.1%)	
Number (%) of Participants Censored	34 (77.3%)	40 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.7515		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.871 (0.376, 2.019)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	16 (19.8%)	18 (25.0%)	
Number (%) of Participants Censored	65 (80.2%)	54 (75.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.7216		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.449, 1.745)		
BRCA 1/2 status			
Wild-Type	42	46	0.4146
Number (%) of Participants with Events (Deterioration)	12 (28.6%)	13 (28.3%)	
Number (%) of Participants Censored	30 (71.4%)	33 (71.7%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.96, NE)	6.41 (3.68, NE)	
Log-Rank Test p-value (unstratified)	0.4970		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.765 (0.349, 1.679)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	3 (33.3%)	2 (28.6%)	
Number (%) of Participants Censored	6 (66.7%)	5 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.25, NE)	NE (3.45, NE)	
Log-Rank Test p-value (unstratified)	0.7206		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.385 (0.231, 8.304)		
Menopausal status			
Pre-menopausal	29	35	0.1865
Number (%) of Participants with Events (Deterioration)	4 (13.8%)	11 (31.4%)	
Number (%) of Participants Censored	25 (86.2%)	24 (68.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.1847		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.467 (0.149, 1.470)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	22 (22.9%)	19 (21.6%)	
Number (%) of Participants Censored	74 (77.1%)	69 (78.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.41, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.7527		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.106 (0.592, 2.065)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.69. Table 1.1.25: Subgroup Analysis of Time to First Deterioration by response threshold in PGIS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

	SG (N=125)	TPC (N=124)	Interaction
Disease stratification			
De novo	29	26	0.5075
Number (%) of Participants with Events (Deterioration)	1 (3.4%)	1 (3.8%)	
Number (%) of Participants Censored	28 (96.6%)	25 (96.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.82, NE)	
Log-Rank Test p-value (unstratified)	0.7771		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.671 (0.042, 10.810)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	31	31	
Number (%) of Participants with Events (Deterioration)	2 (6.5%)	4 (12.9%)	
Number (%) of Participants Censored	29 (93.5%)	27 (87.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	

	SG (N=125)	TPC (N=124)	Interaction
Log-Rank Test p-value (unstratified)	0.3412		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.448 (0.082, 2.447)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	65	67	
Number (%) of Participants with Events (Deterioration)	8 (12.3%)	7 (10.4%)	
Number (%) of Participants Censored	57 (87.7%)	60 (89.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.4515		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.480 (0.530, 4.133)		
Geographic region			
US/Canada/Western Europe	30	35	0.8834
Number (%) of Participants with Events (Deterioration)	2 (6.7%)	3 (8.6%)	
Number (%) of Participants Censored	28 (93.3%)	32 (91.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7605		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.757 (0.126, 4.547)		
Rest of the world	95	89	
Number (%) of Participants with Events (Deterioration)	9 (9.5%)	9 (10.1%)	
Number (%) of Participants Censored	86 (90.5%)	80 (89.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=125)	TPC (N=124)	Interaction
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8950		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.940 (0.370, 2.389)		
Age group			
< 65	98	96	0.6550
Number (%) of Participants with Events (Deterioration)	9 (9.2%)	8 (8.3%)	
Number (%) of Participants Censored	89 (90.8%)	88 (91.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.9680		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.980 (0.374, 2.570)		
>= 65	27	28	
Number (%) of Participants with Events (Deterioration)	2 (7.4%)	4 (14.3%)	
Number (%) of Participants Censored	25 (92.6%)	24 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.48, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7377		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.336 (0.244, 7.315)		
Race			
White	81	77	0.6434
Number (%) of Participants with Events (Deterioration)	8 (9.9%)	7 (9.1%)	

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants Censored	73 (90.1%)	70 (90.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8867		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.077 (0.387, 3.000)		
Asian	26	26	
Number (%) of Participants with Events (Deterioration)	2 (7.7%)	4 (15.4%)	
Number (%) of Participants Censored	24 (92.3%)	22 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.90, NE)	
Log-Rank Test p-value (unstratified)	0.3463		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.451 (0.082, 2.470)		
Other	16	21	
Number (%) of Participants with Events (Deterioration)	1 (6.2%)	1 (4.8%)	
Number (%) of Participants Censored	15 (93.8%)	20 (95.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	6.67 (6.60, NE)	
Log-Rank Test p-value (unstratified)	0.2207		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Baseline ECOG status			
0	81	80	0.7372

	SG (N=125)	TPC (N=124)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (7.4%)	7 (8.8%)	
Number (%) of Participants Censored	75 (92.6%)	73 (91.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8760		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.916 (0.305, 2.753)		
1	44	44	
Number (%) of Participants with Events (Deterioration)	5 (11.4%)	5 (11.4%)	
Number (%) of Participants Censored	39 (88.6%)	39 (88.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.9522		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.963 (0.279, 3.328)		
History of liver metastasis			
Yes	36	26	0.8501
Number (%) of Participants with Events (Deterioration)	2 (5.6%)	1 (3.8%)	
Number (%) of Participants Censored	34 (94.4%)	25 (96.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.9720		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.958 (0.087, 10.566)		

	SG (N=125)	TPC (N=124)	Interaction
No	89	98	
Number (%) of Participants with Events (Deterioration)	9 (10.1%)	11 (11.2%)	
Number (%) of Participants Censored	80 (89.9%)	87 (88.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8749		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.931 (0.384, 2.258)		
History of brain metastasis			
Yes	6	7	1.0000
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	6 (100.0%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
No	119	117	
Number (%) of Participants with Events (Deterioration)	11 (9.2%)	12 (10.3%)	
Number (%) of Participants Censored	108 (90.8%)	105 (89.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8394		

	SG (N=125)	TPC (N=124)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.919 (0.402, 2.098)		
PD-L1 Status			
CPS < 1	44	52	0.2339
Number (%) of Participants with Events (Deterioration)	5 (11.4%)	3 (5.8%)	
Number (%) of Participants Censored	39 (88.6%)	49 (94.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4403		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.759 (0.412, 7.511)		
CPS ≥ 1	81	72	
Number (%) of Participants with Events (Deterioration)	6 (7.4%)	9 (12.5%)	
Number (%) of Participants Censored	75 (92.6%)	63 (87.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.60, NE)	
Log-Rank Test p-value (unstratified)	0.4142		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.653 (0.231, 1.841)		
BRCA 1/2 status			
Wild-Type	42	46	0.2366
Number (%) of Participants with Events (Deterioration)	7 (16.7%)	5 (10.9%)	
Number (%) of Participants Censored	35 (83.3%)	41 (89.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

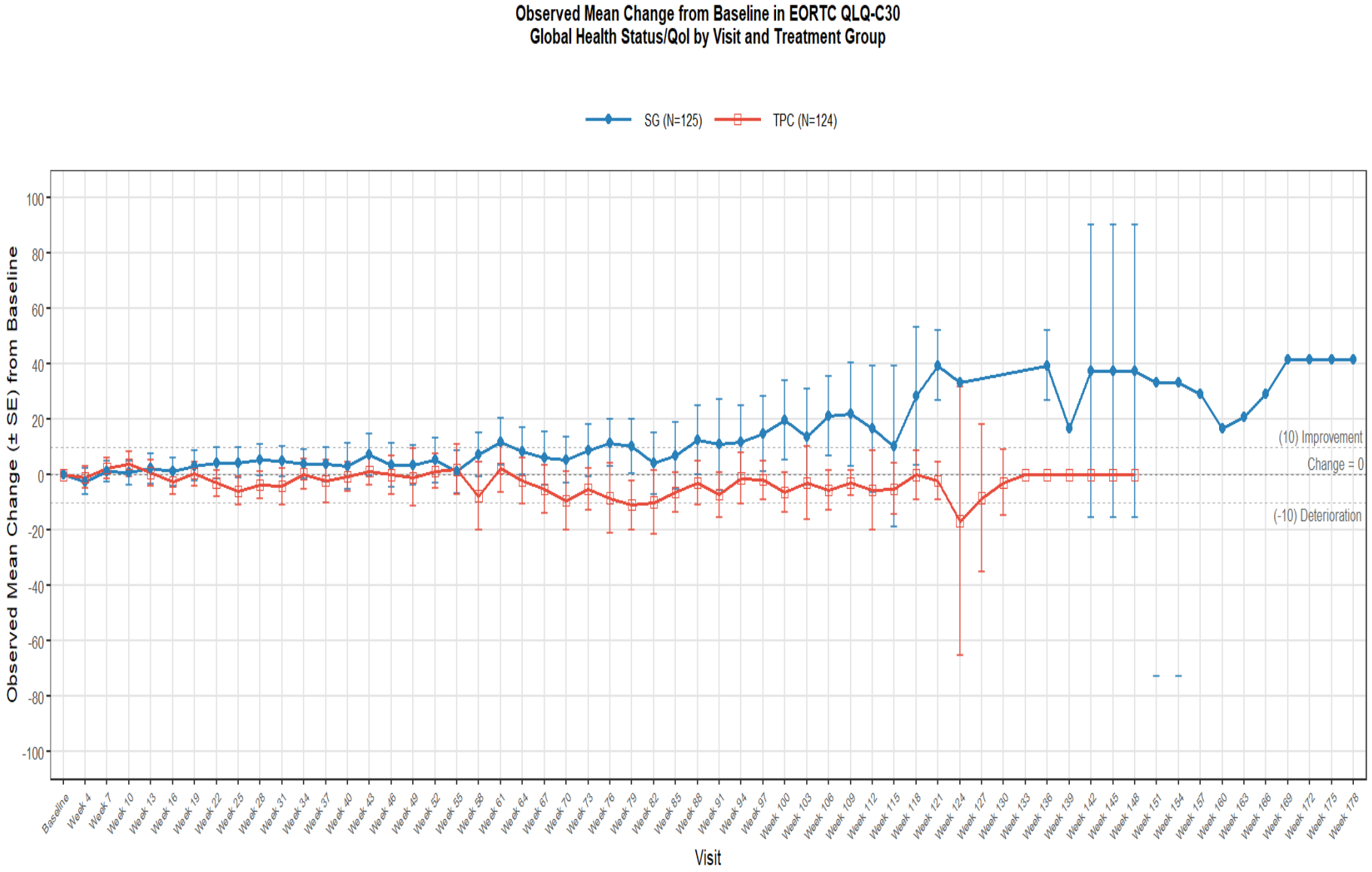
	SG (N=125)	TPC (N=124)	Interaction
Median	NE (6.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8625		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.107 (0.350, 3.502)		
Mutant	9	7	
Number (%) of Participants with Events (Deterioration)	1 (11.1%)	0	
Number (%) of Participants Censored	8 (88.9%)	7 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.50, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.3173		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Menopausal status			
Pre-menopausal	29	35	0.1916
Number (%) of Participants with Events (Deterioration)	1 (3.4%)	5 (14.3%)	
Number (%) of Participants Censored	28 (96.6%)	30 (85.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.82, NE)	
Log-Rank Test p-value (unstratified)	0.2697		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.318 (0.037, 2.724)		
Post-menopausal	96	88	
Number (%) of Participants with Events (Deterioration)	10 (10.4%)	7 (8.0%)	
Number (%) of Participants Censored	86 (89.6%)	81 (92.0%)	

	SG (N=125)	TPC (N=124)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.5670		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.337 (0.495, 3.614)		

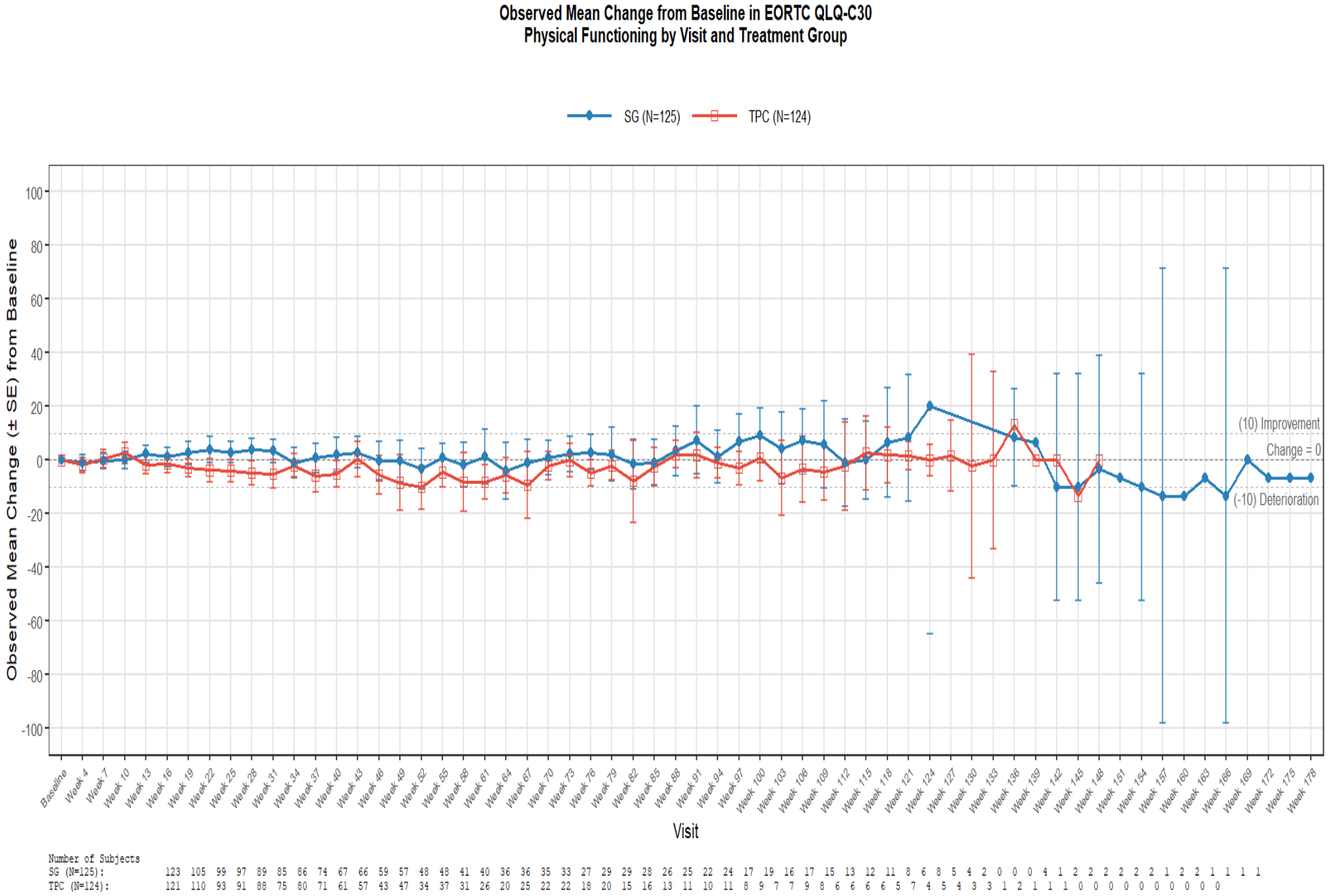
SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

5. KM FIGURES — PRO

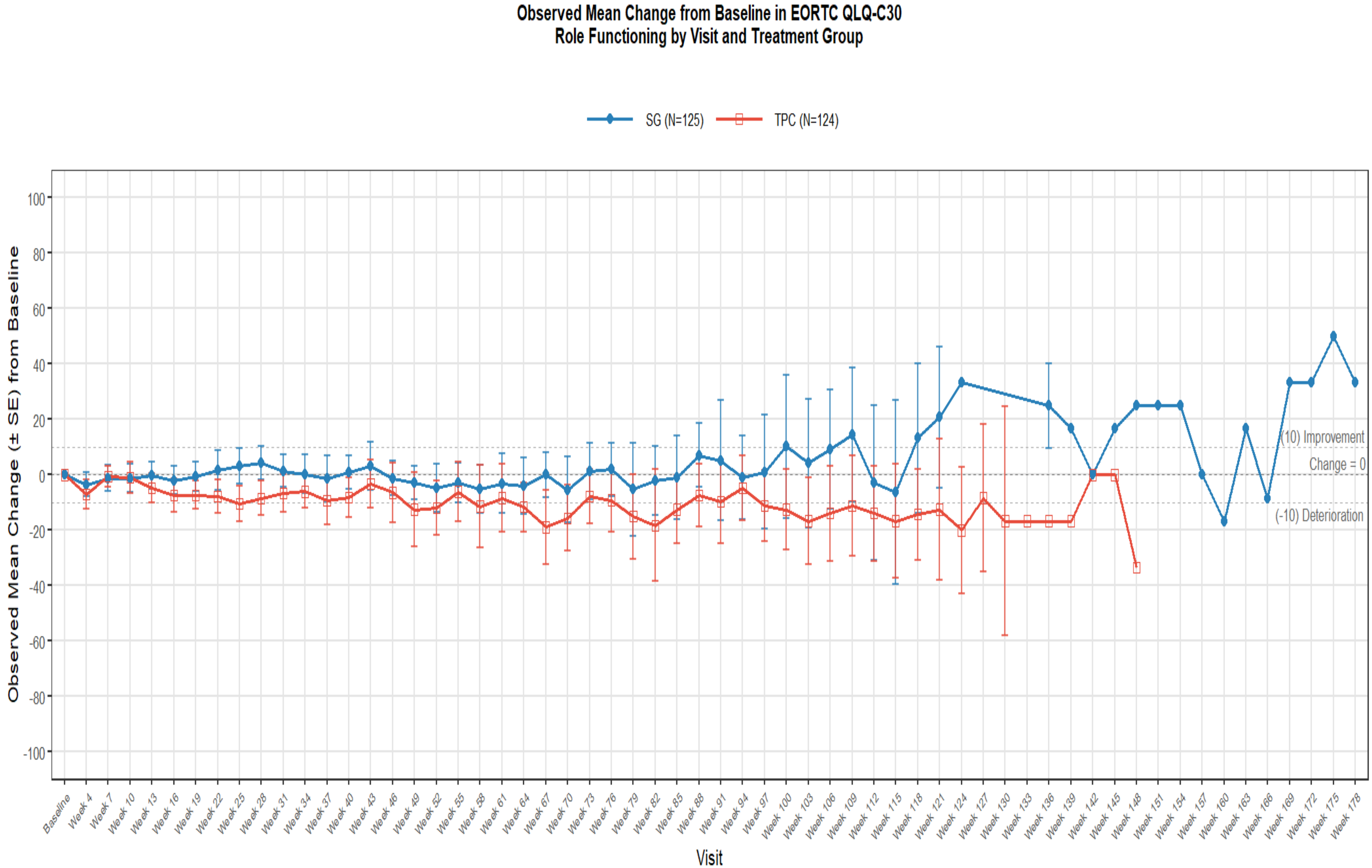
5.1. Figure 1.1.1: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 GLOBAL HEALTH STATUS QOL — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



5.2. Figure 1.1.2: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 PHYSICAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



5.3. Figure 1.1.3: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 ROLE FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

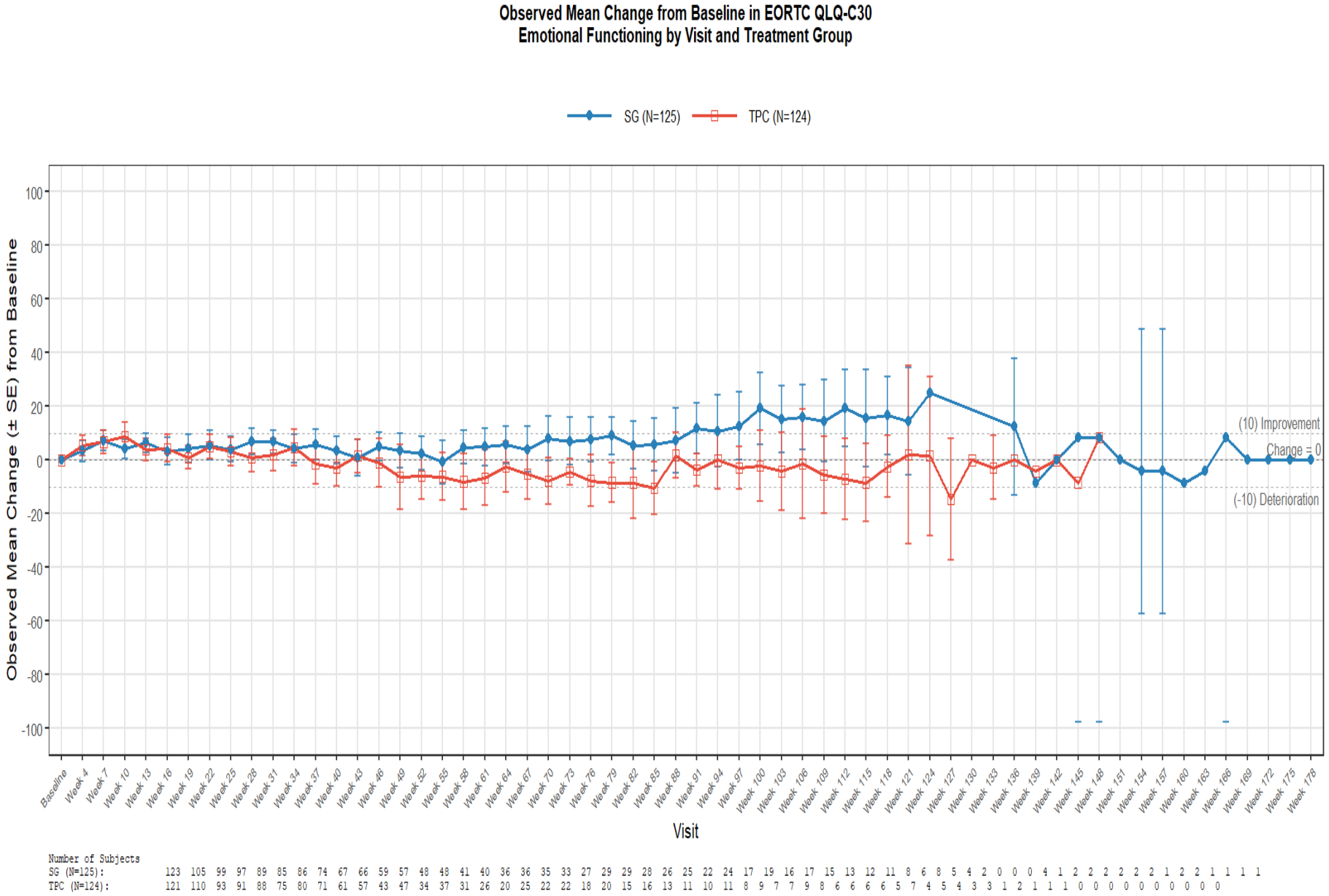


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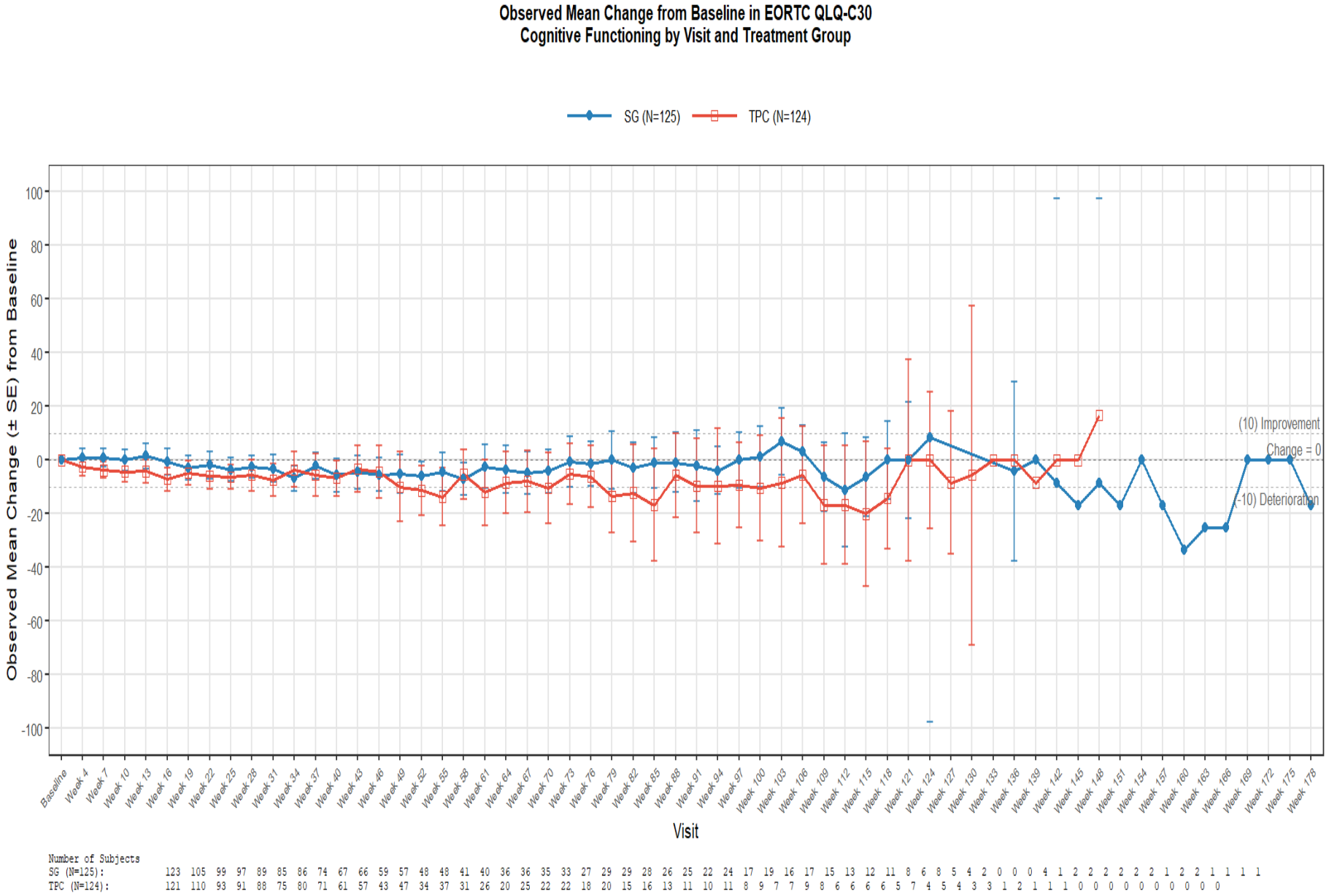
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TPC (N=124): 121 110 93 91 88 75 80 71 61 57 43 47 34 37 31 26 20 25 22 22 18 20 15 16 13 11 10 11 8 9 7 7 9 8 6 6 6 6 5 7 4 5 4 3 3 1 2 1 1 1 0 0 0 0 0 0 0 0 0 0

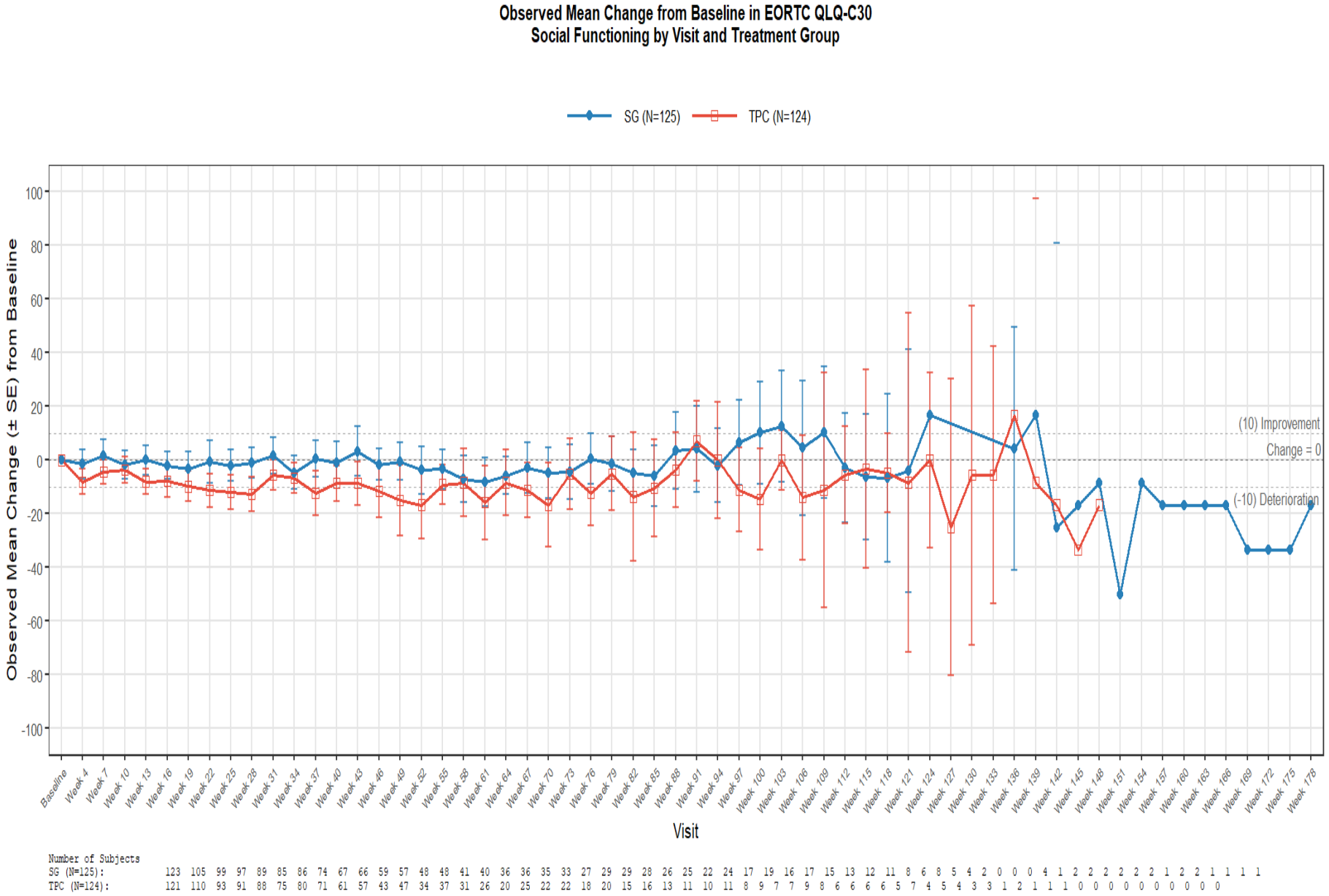
5.4. Figure 1.1.4: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 EMOTIONAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



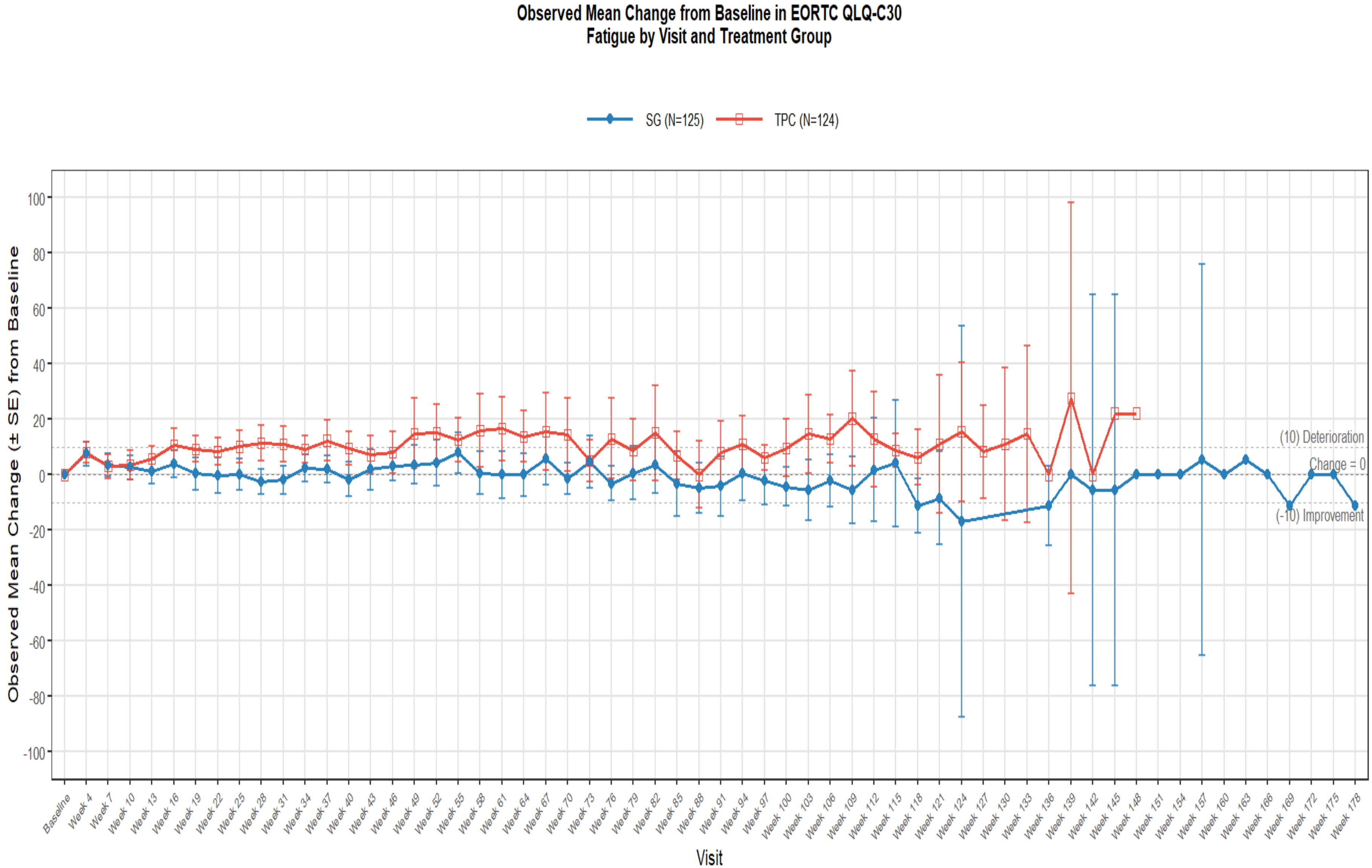
5.5. Figure 1.1.5: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 COGNITIVE FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



5.6. Figure 1.1.6: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 SOCIAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

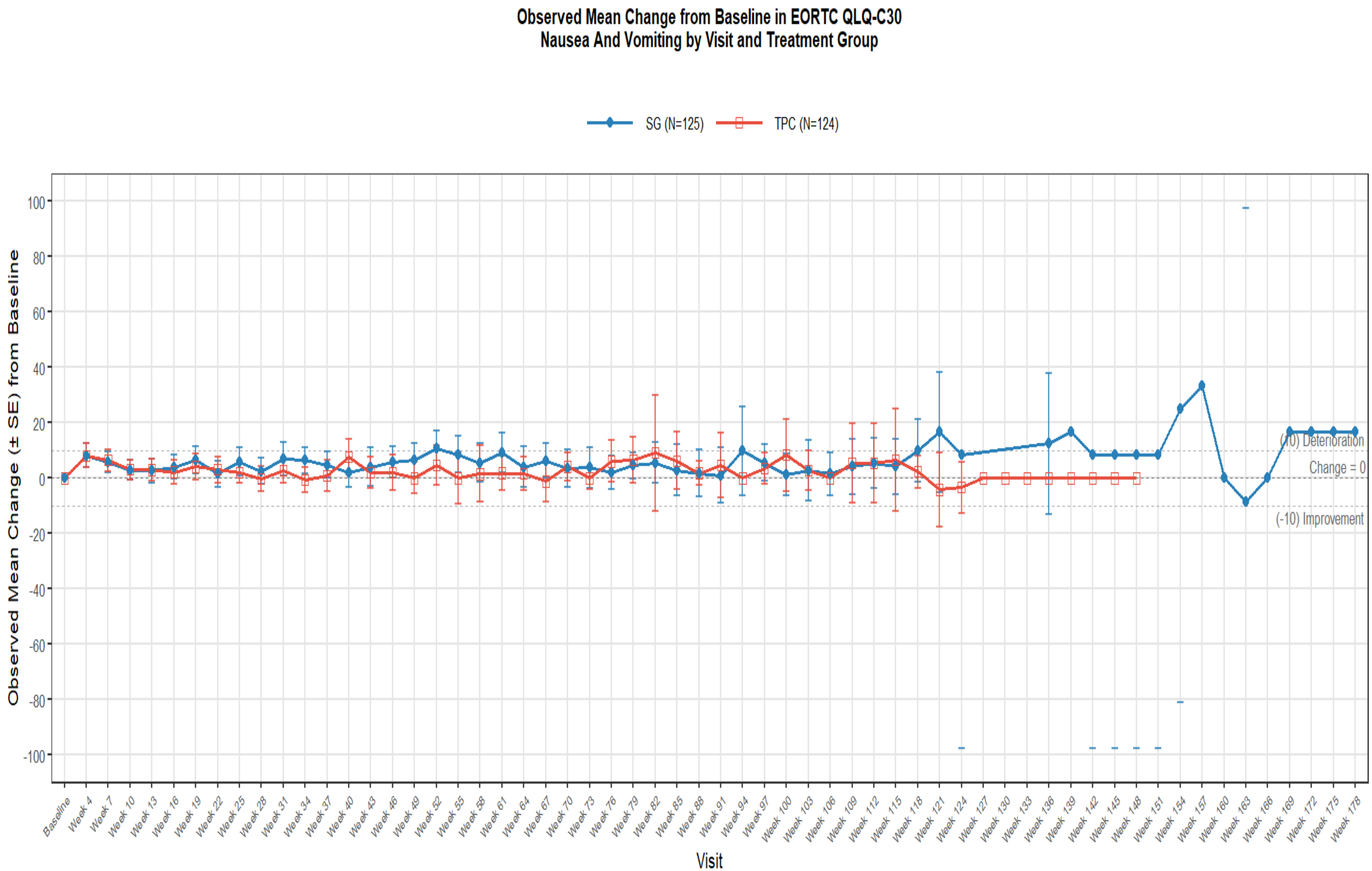


5.7. Figure 1.1.7: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 FATIGUE — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



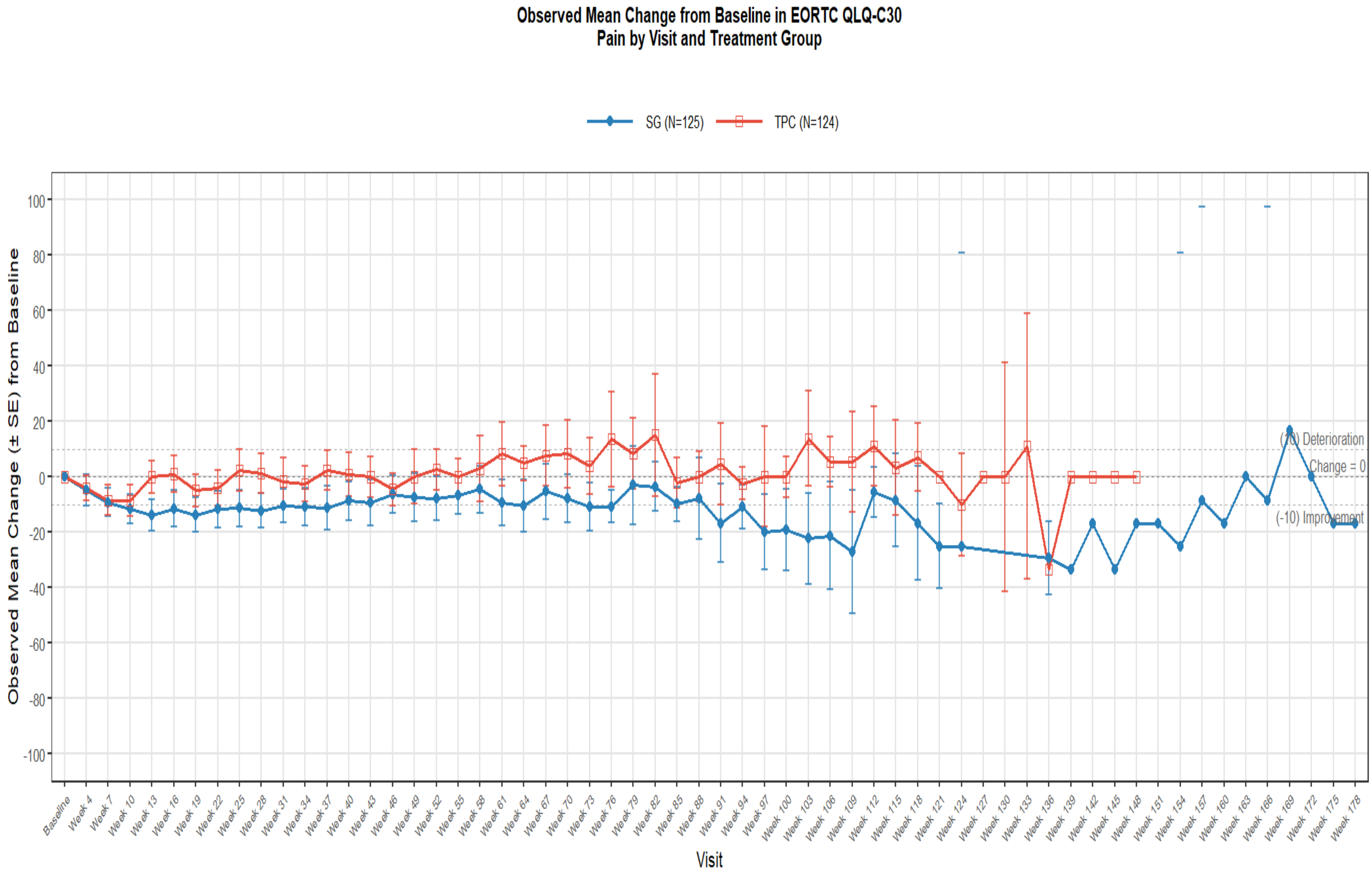
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5.8. Figure 1.1.8: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 NAUSEA AND VOMITING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



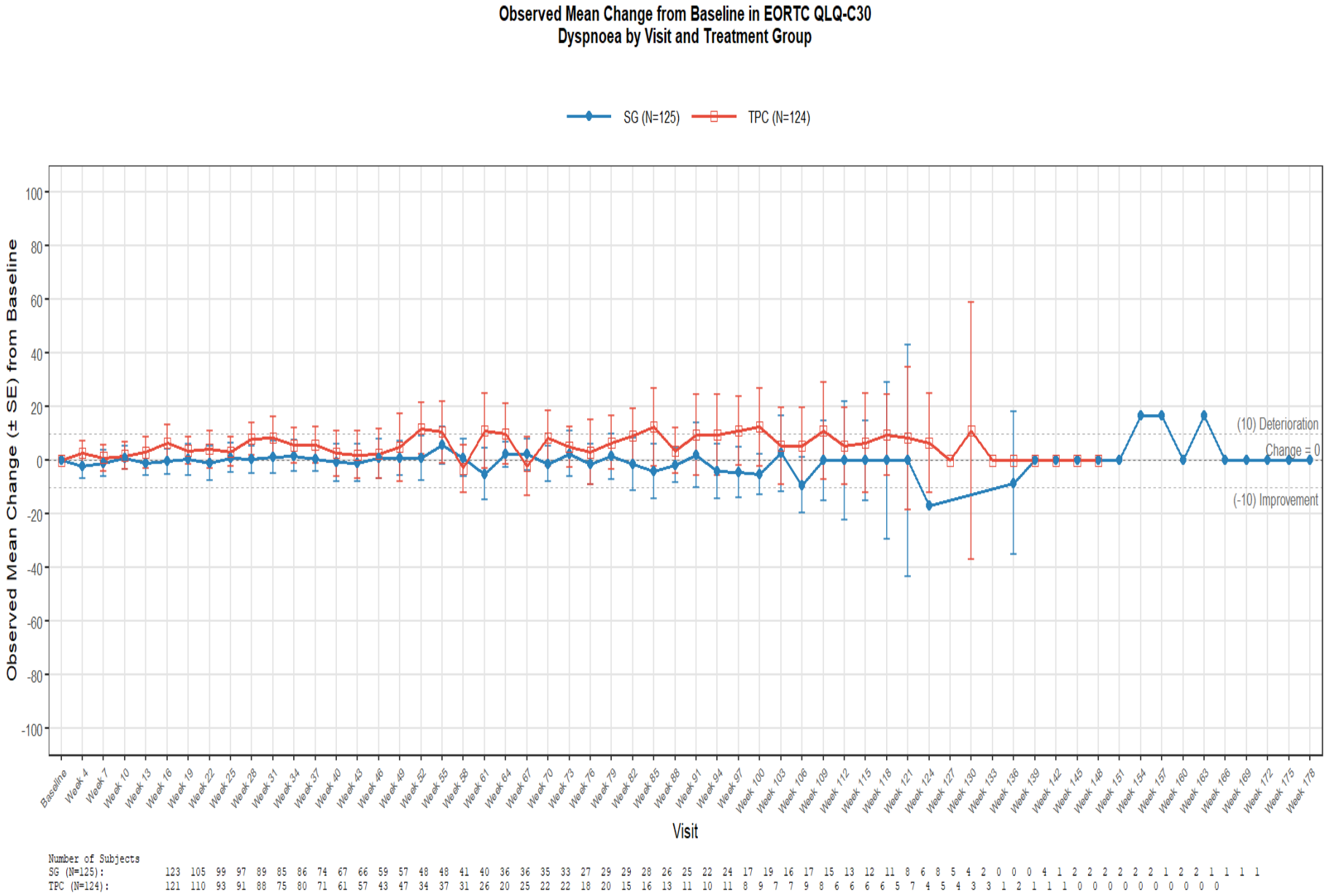
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5.9. Figure 1.1.9: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 PAIN — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

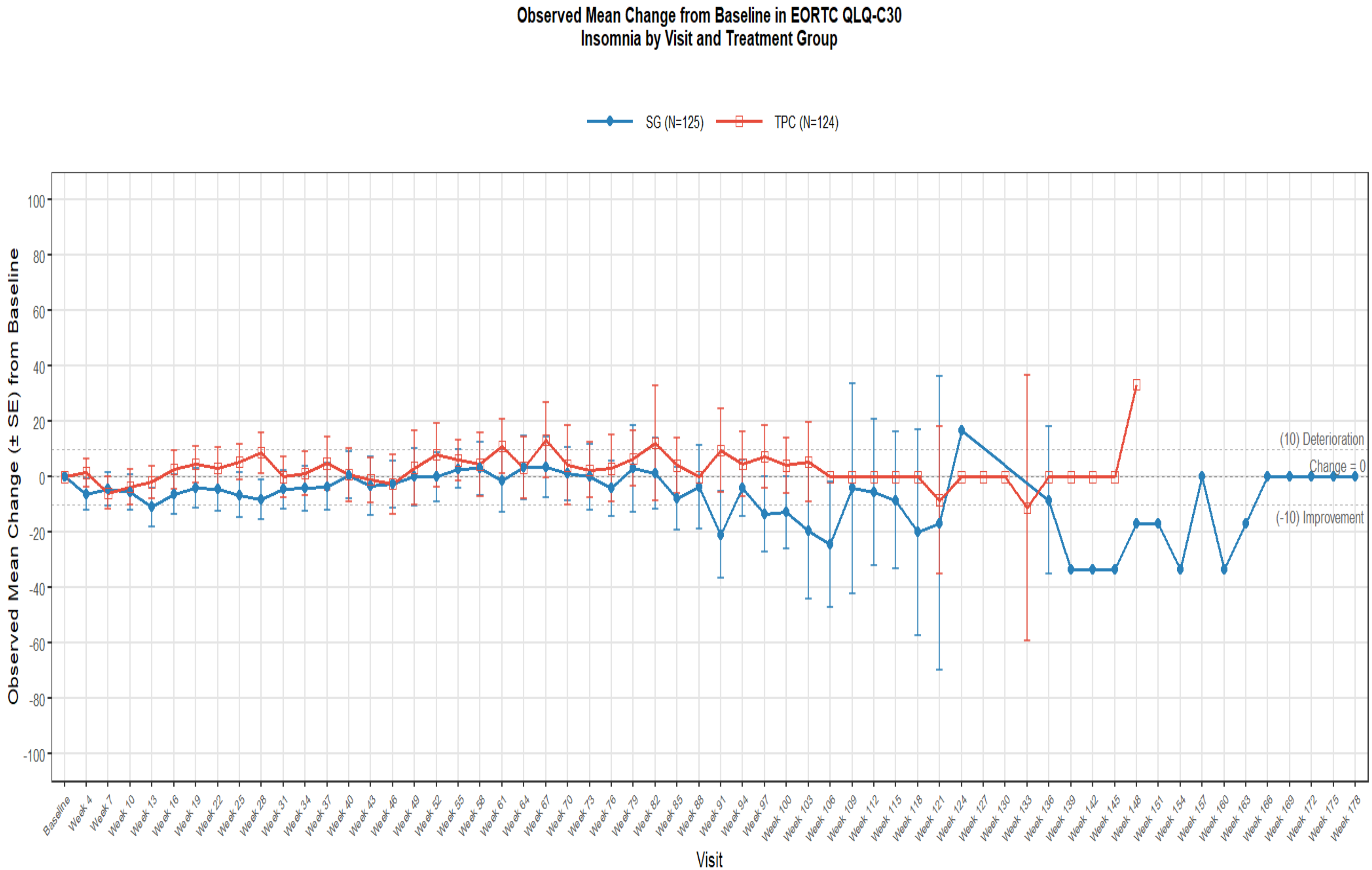


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5.10. Figure 1.1.10: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 DYSPNOEA — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

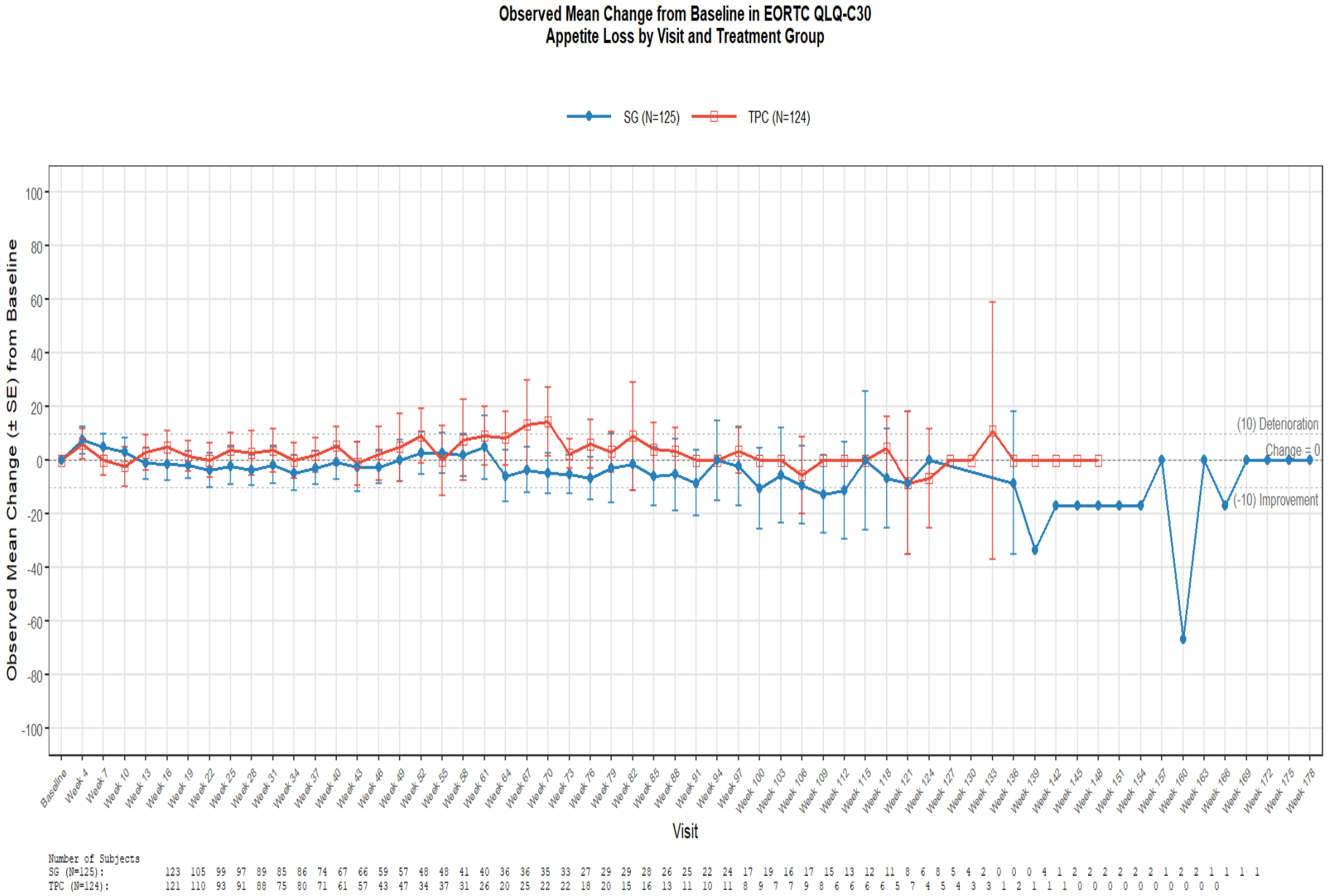


5.11. Figure 1.1.11: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 INSOMNIA — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

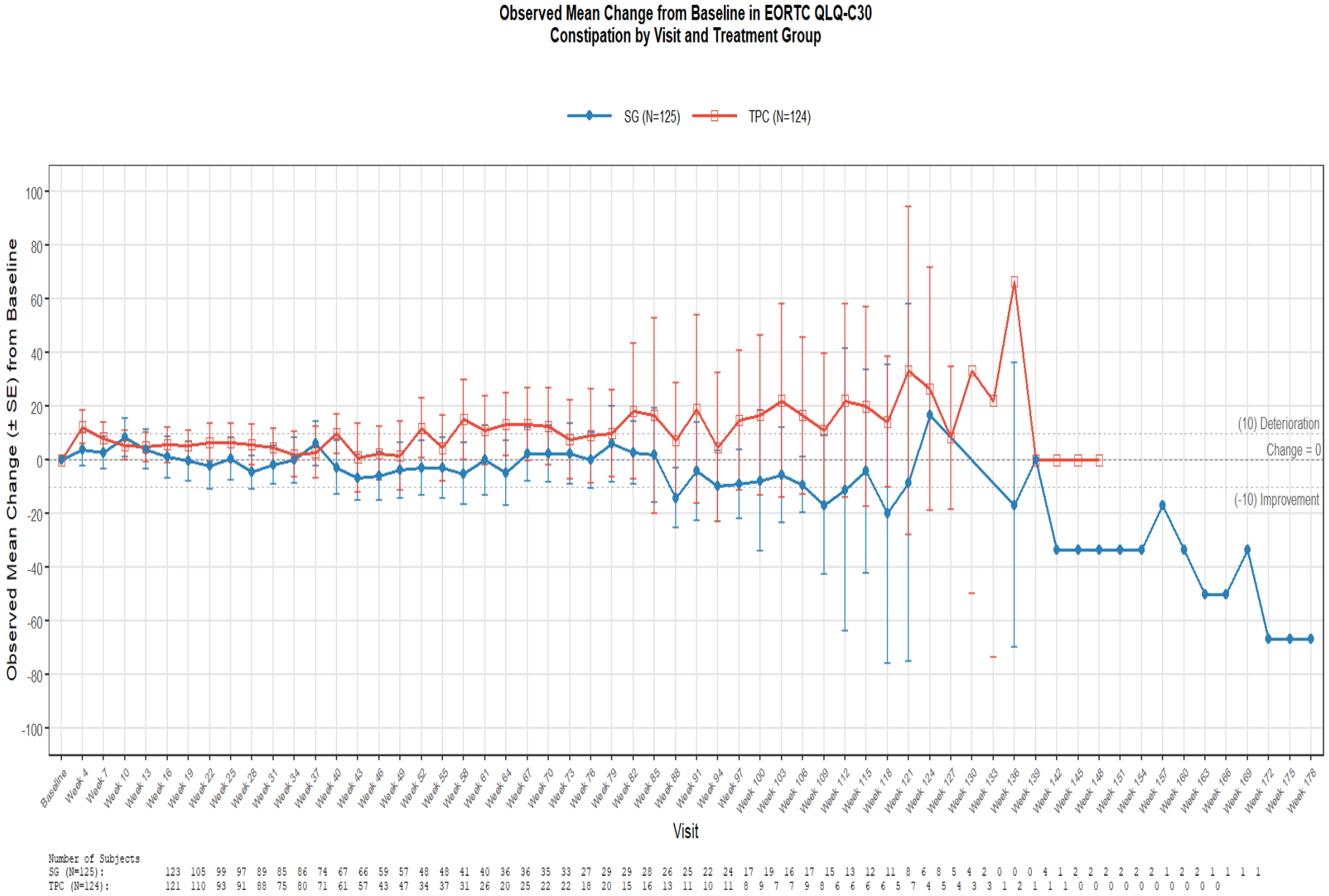


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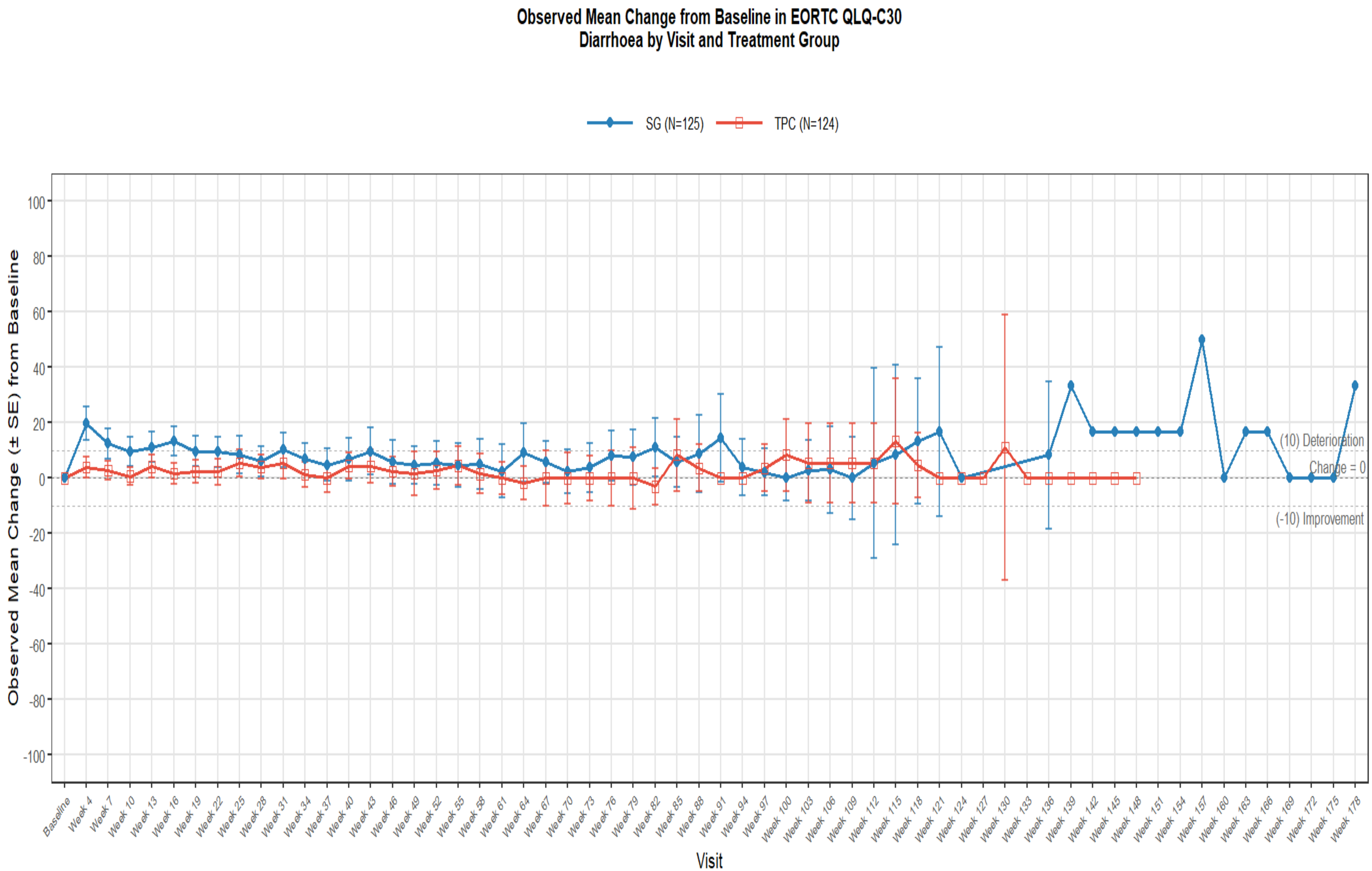
5.12. Figure 1.1.12: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 APPETITE LOSS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



5.13. Figure 1.1.13: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 CONSTIPATION — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel

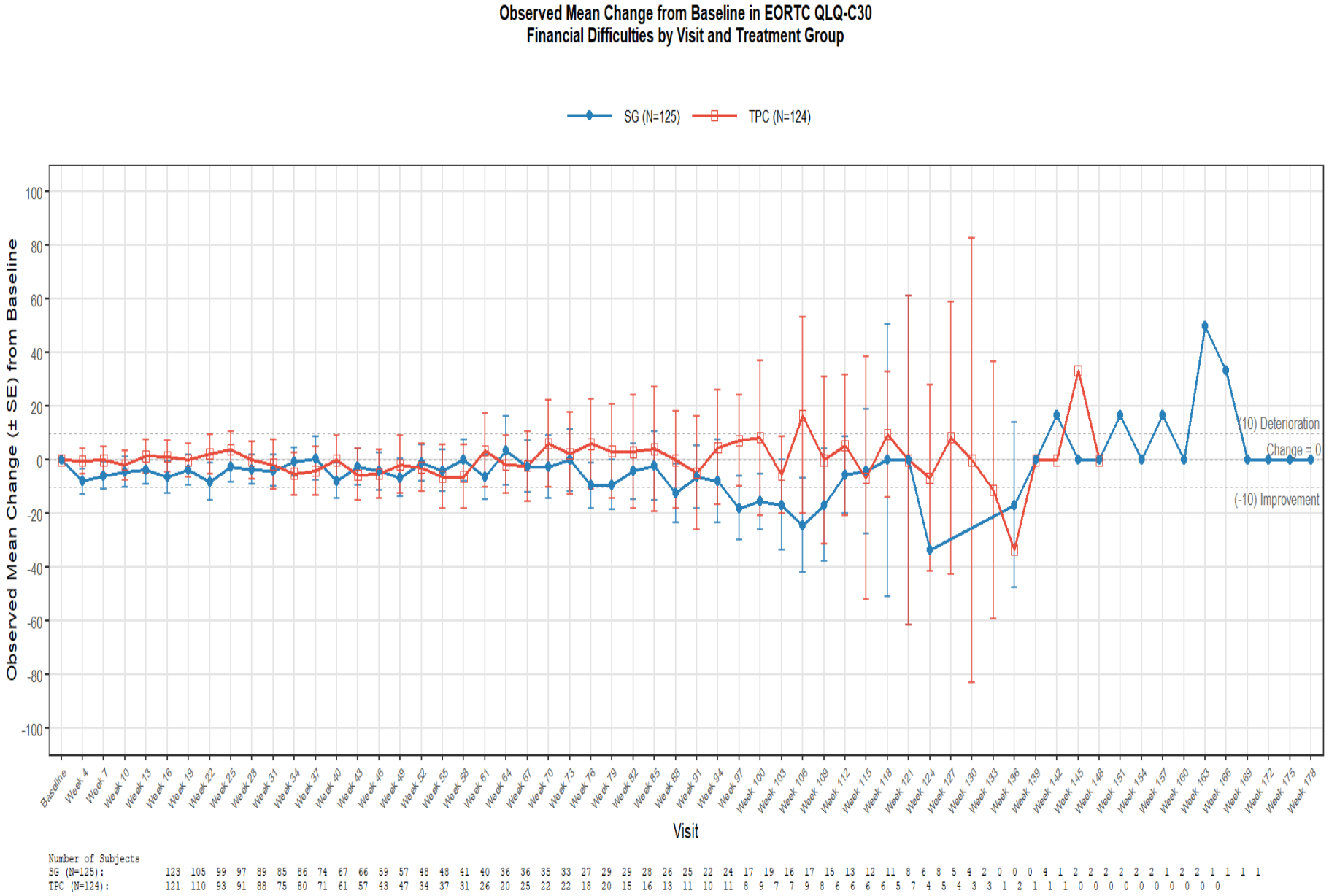


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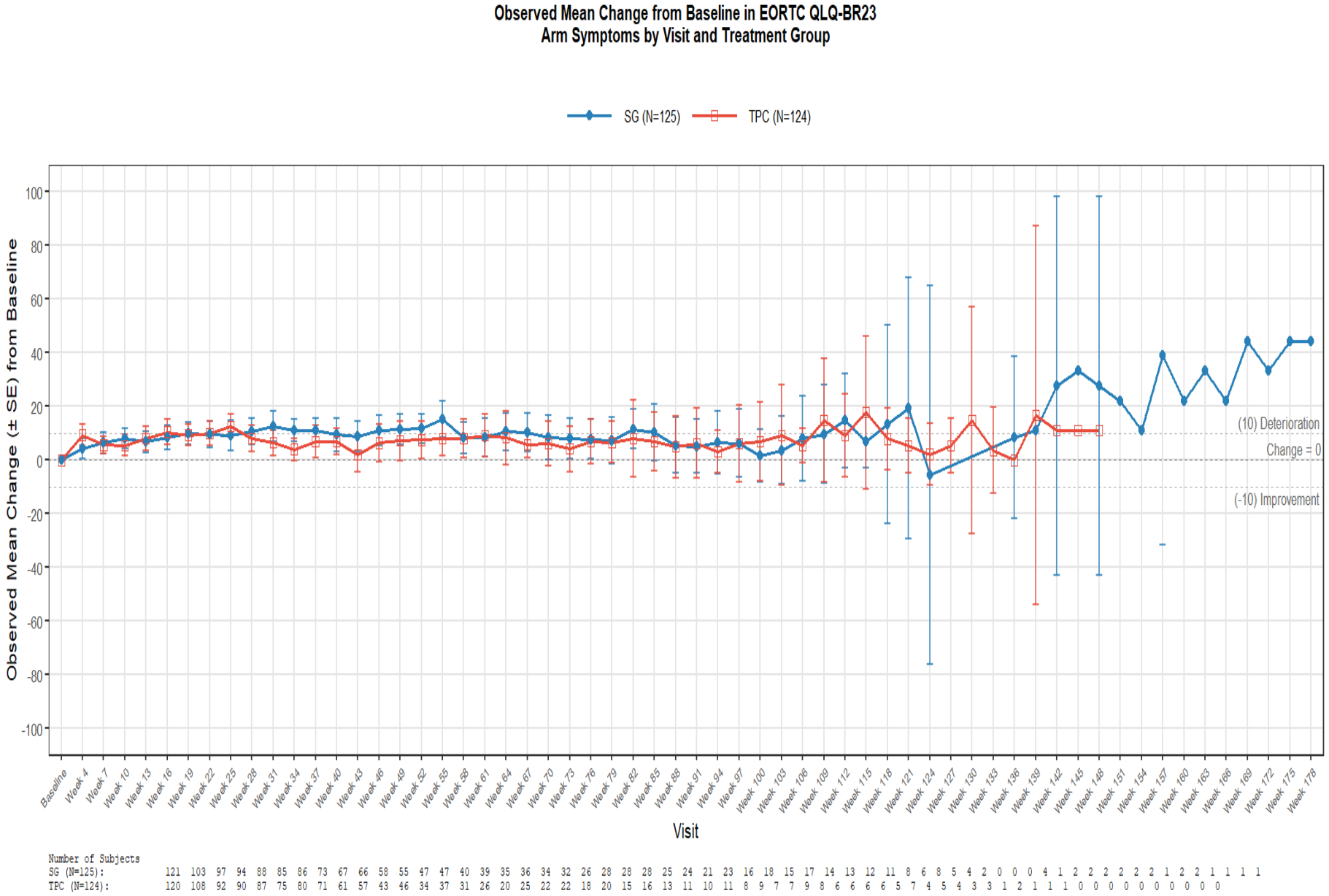


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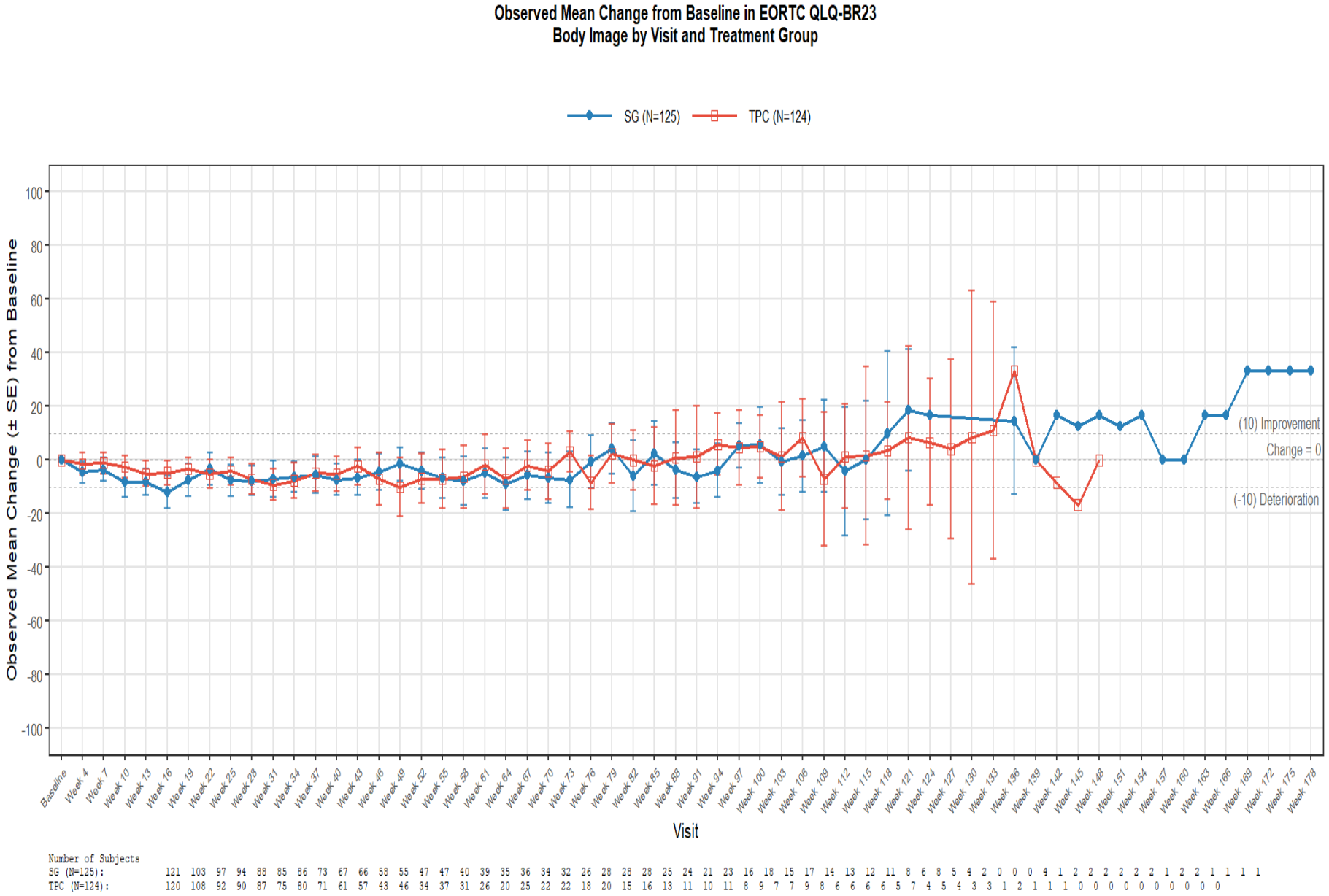
5.15. Figure 1.1.15: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 FINANCIAL DIFFICULTIES — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



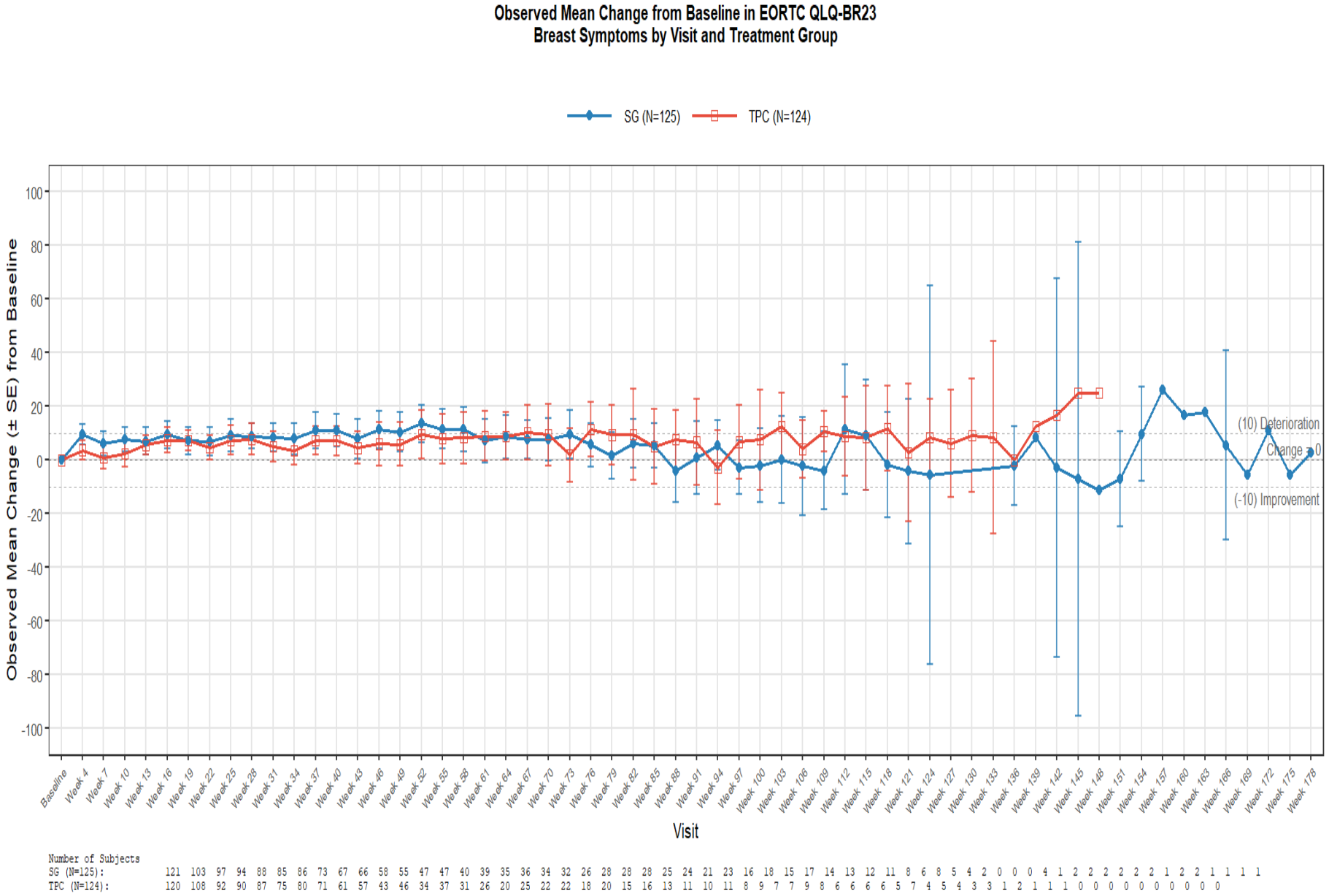
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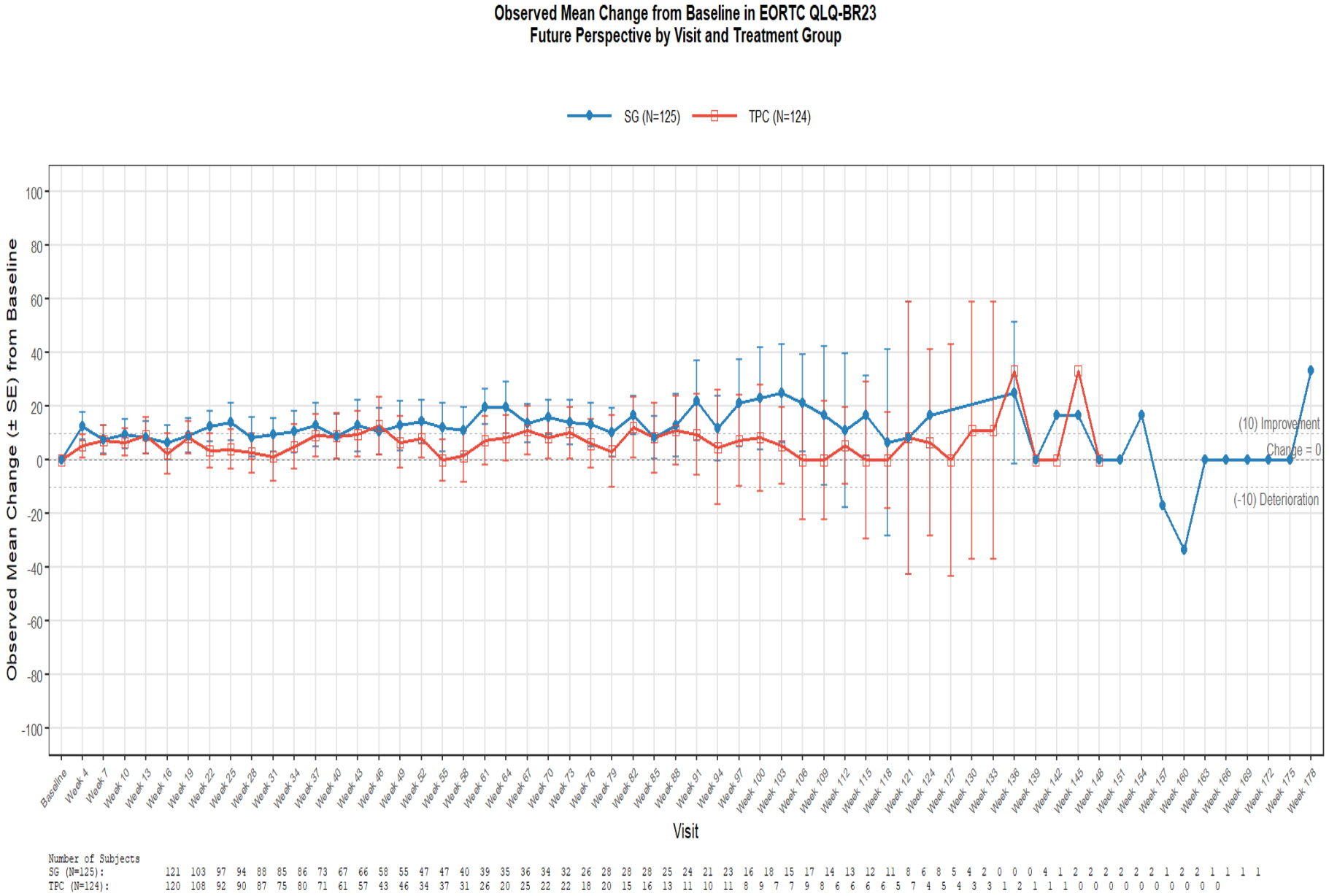
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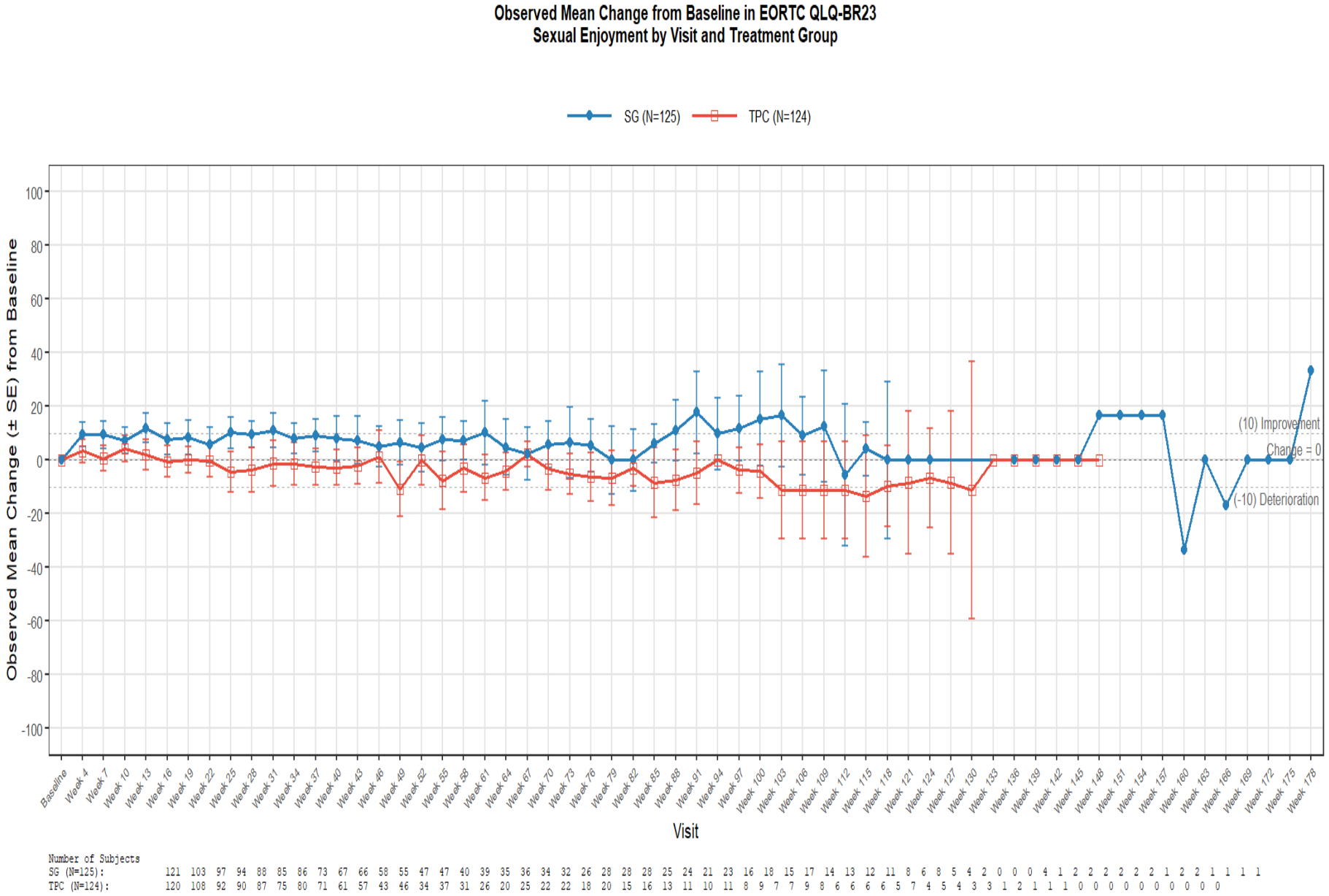
5.18. Figure 1.1.18: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 BREAST SYMPTOMS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



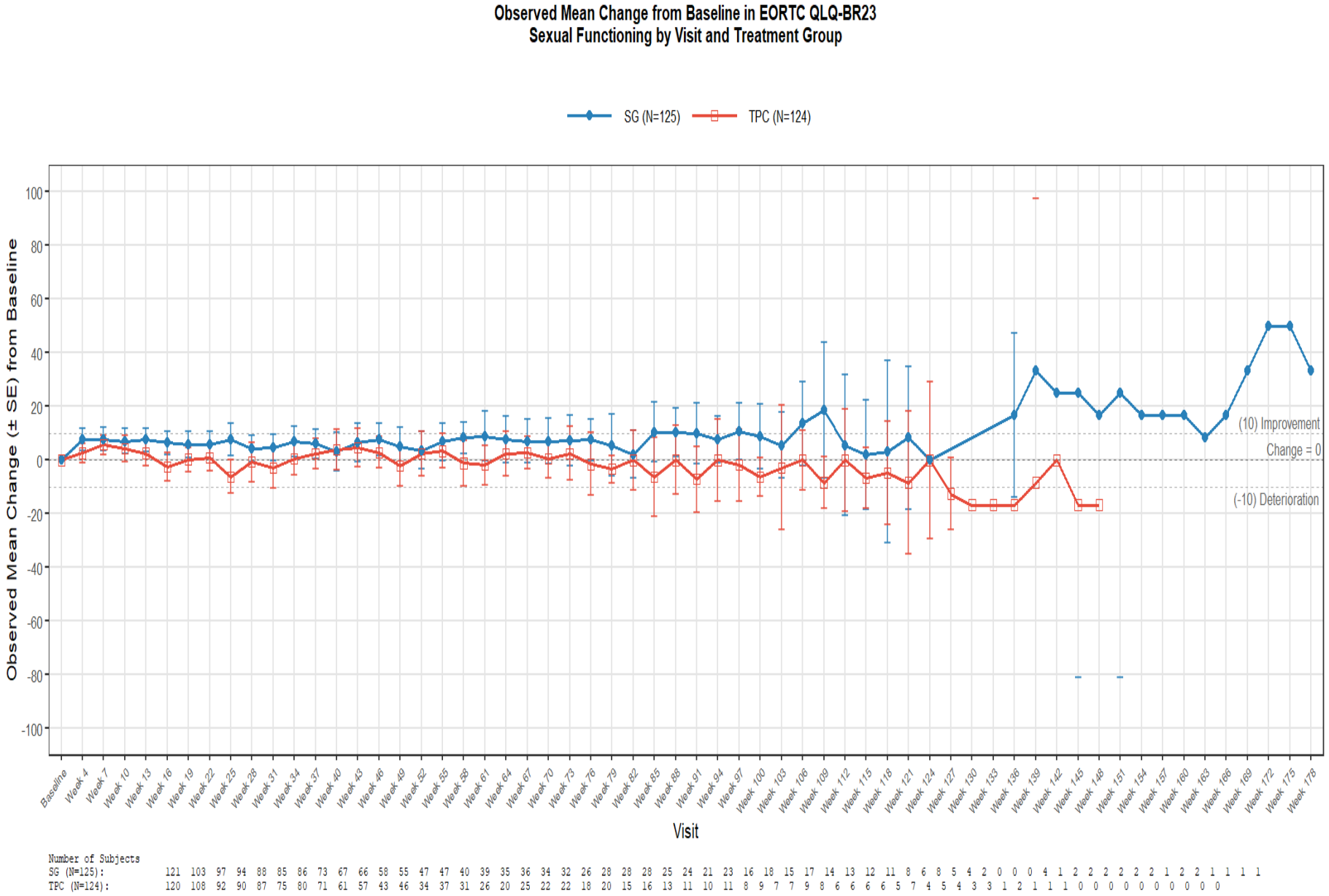
5.19. Figure 1.1.19: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 FUTURE PERSPECTIVE — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



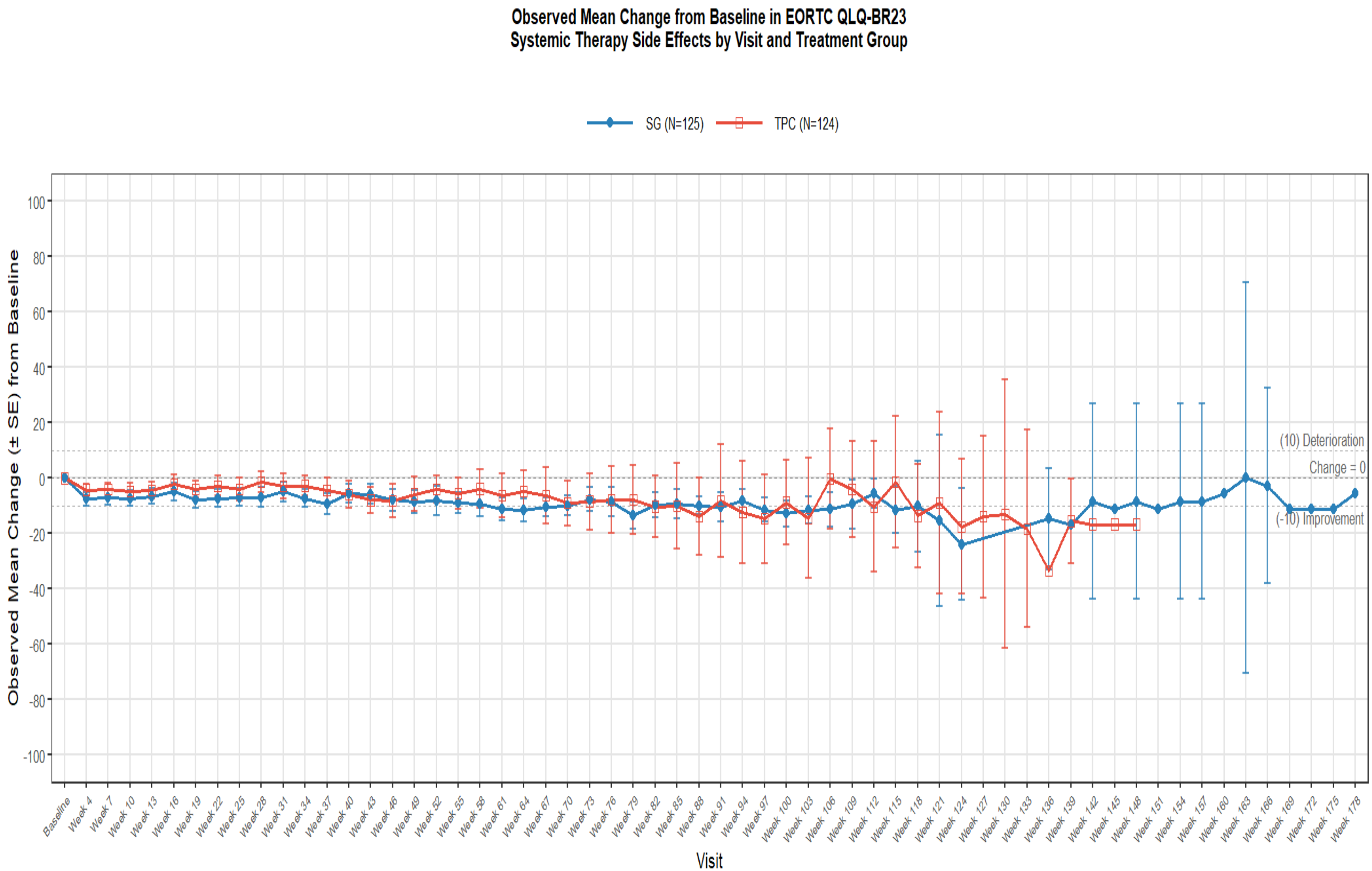
5.20. Figure 1.1.20: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SEXUAL ENJOYMENT — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



5.21. Figure 1.1.21: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SEXUAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



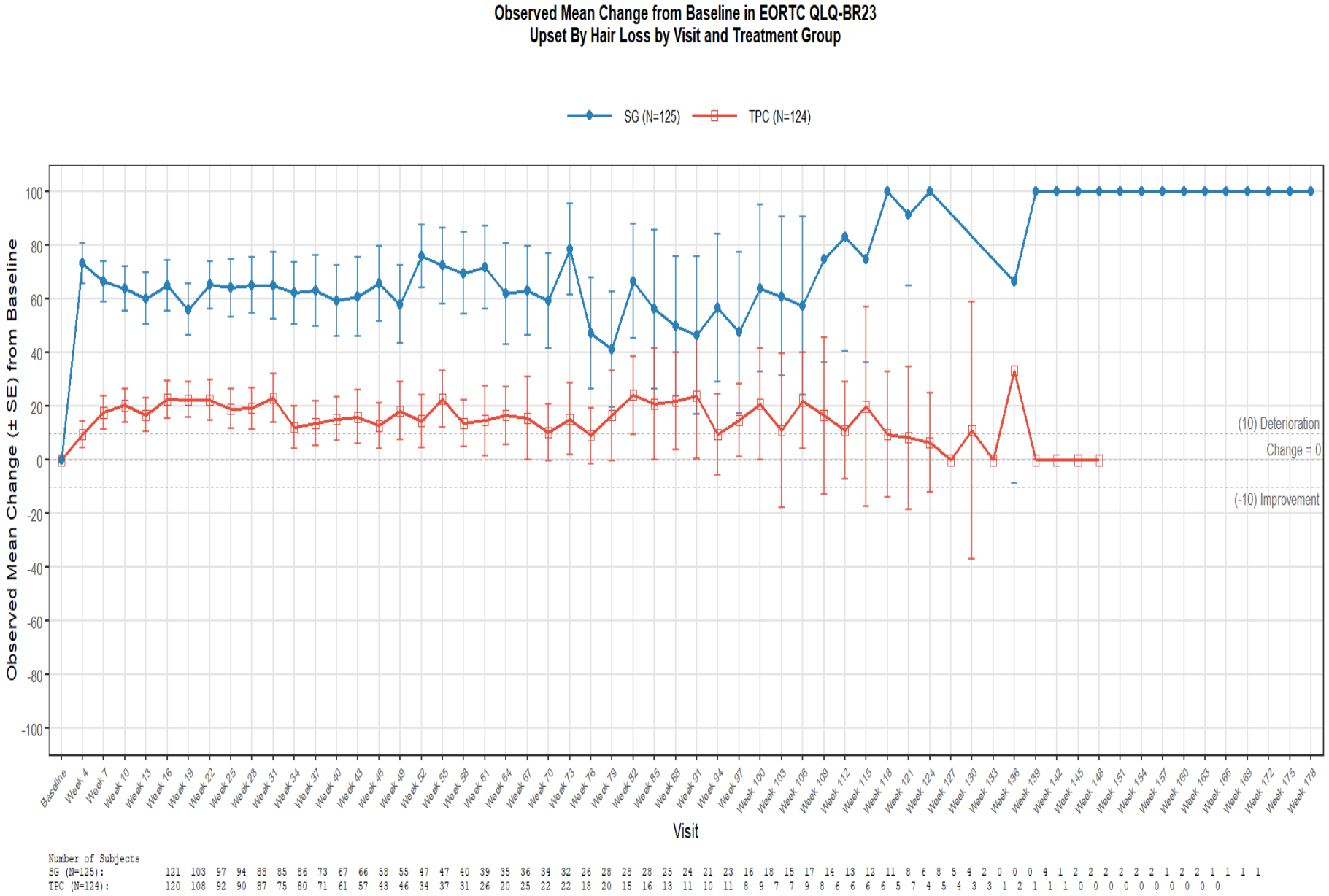
5.22. Figure 1.1.22: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SYSTEMIC THERAPY SIDE EFFECTS — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



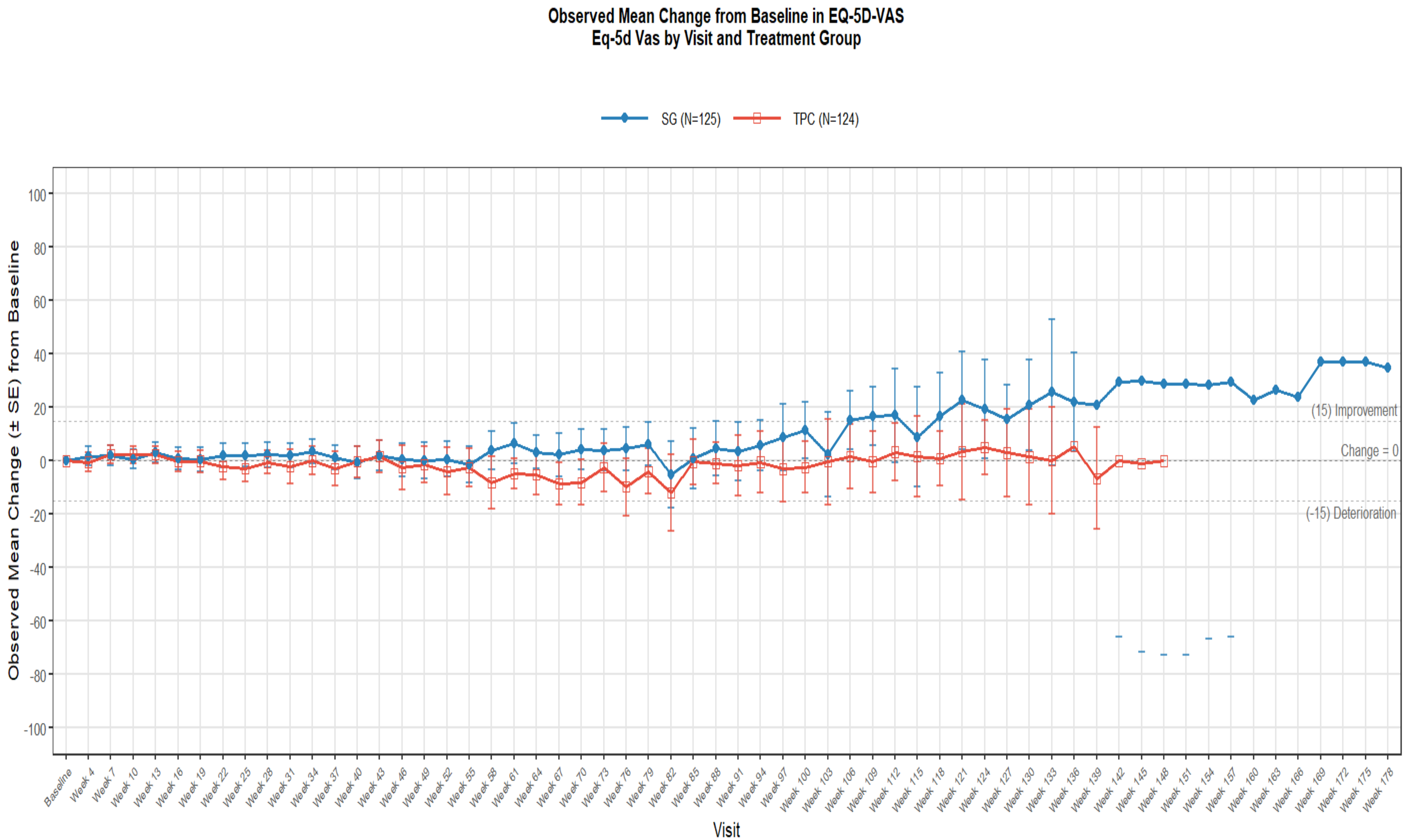
Number of Subjects

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TPC (N=124):	120	108	92	90	87	75	80	71	61	57	43	46	34	37	31	26	20	25	22	22	18	20	15	16	13	11	10	11	8	9	7	7	9	8	6	6	6	6	5	7	4	5	4	3	3	1	2	1	1	1	0	0	0	0	0	0	0	0	0	0	

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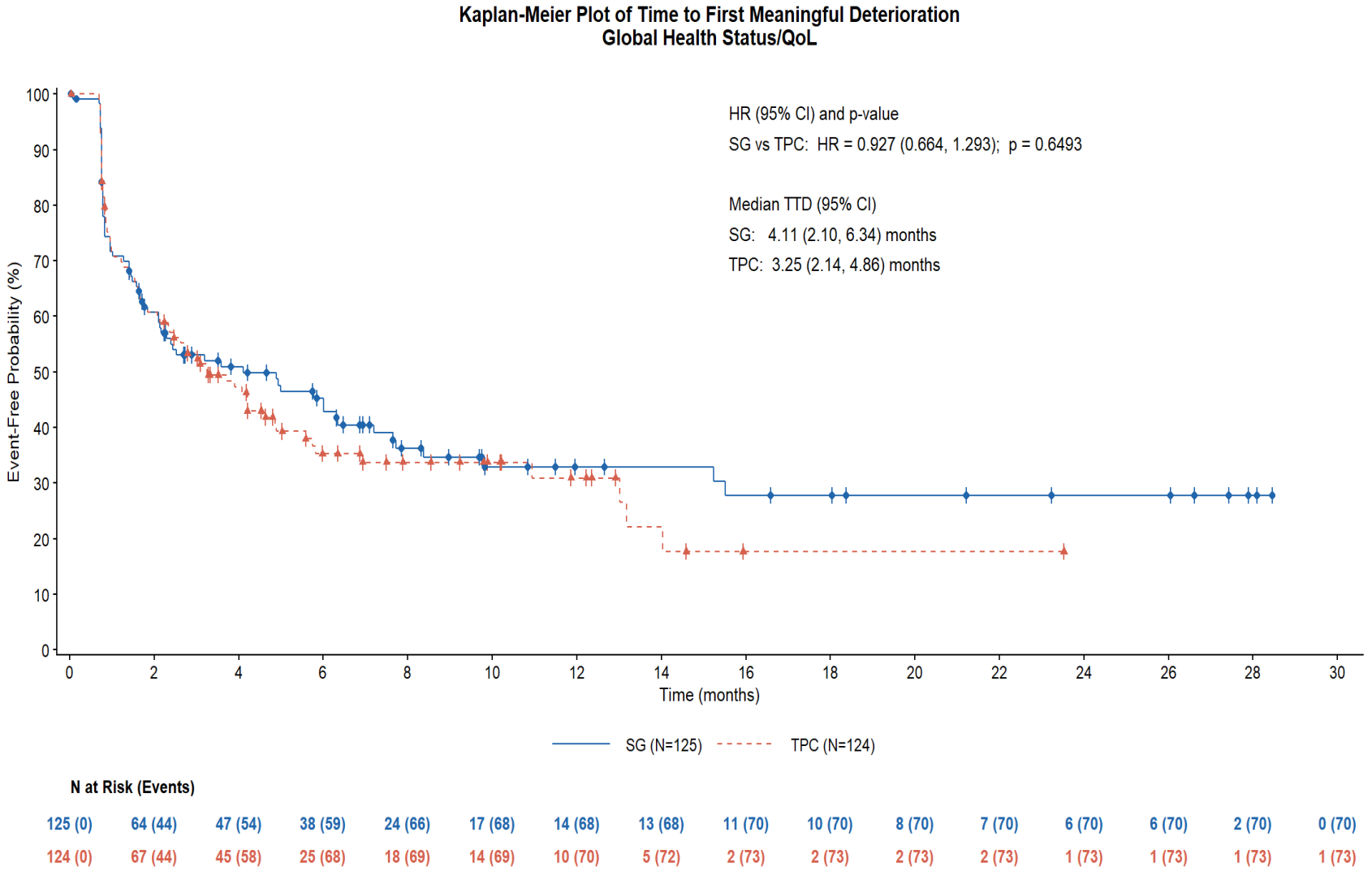


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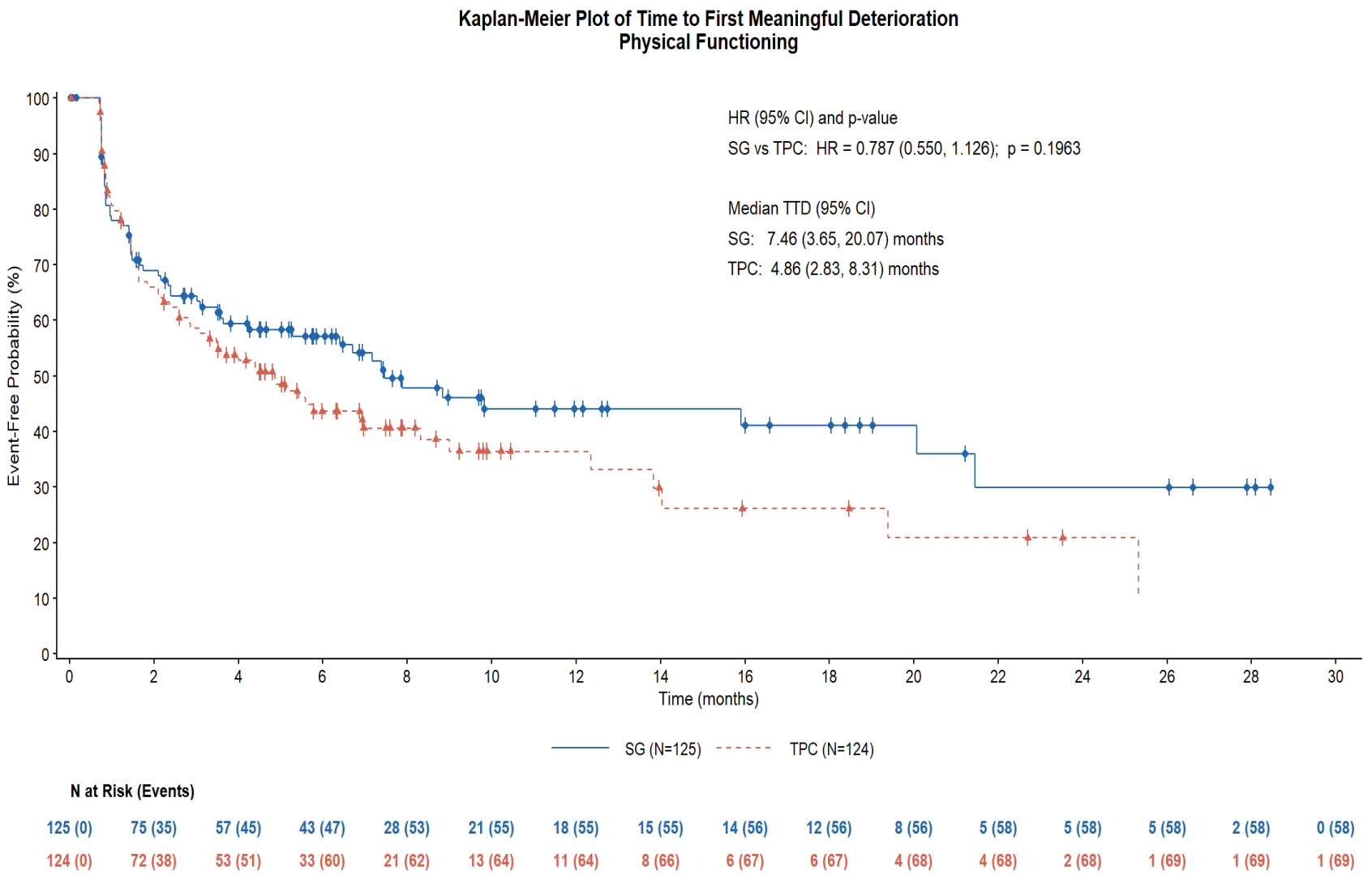


Number of Subjects
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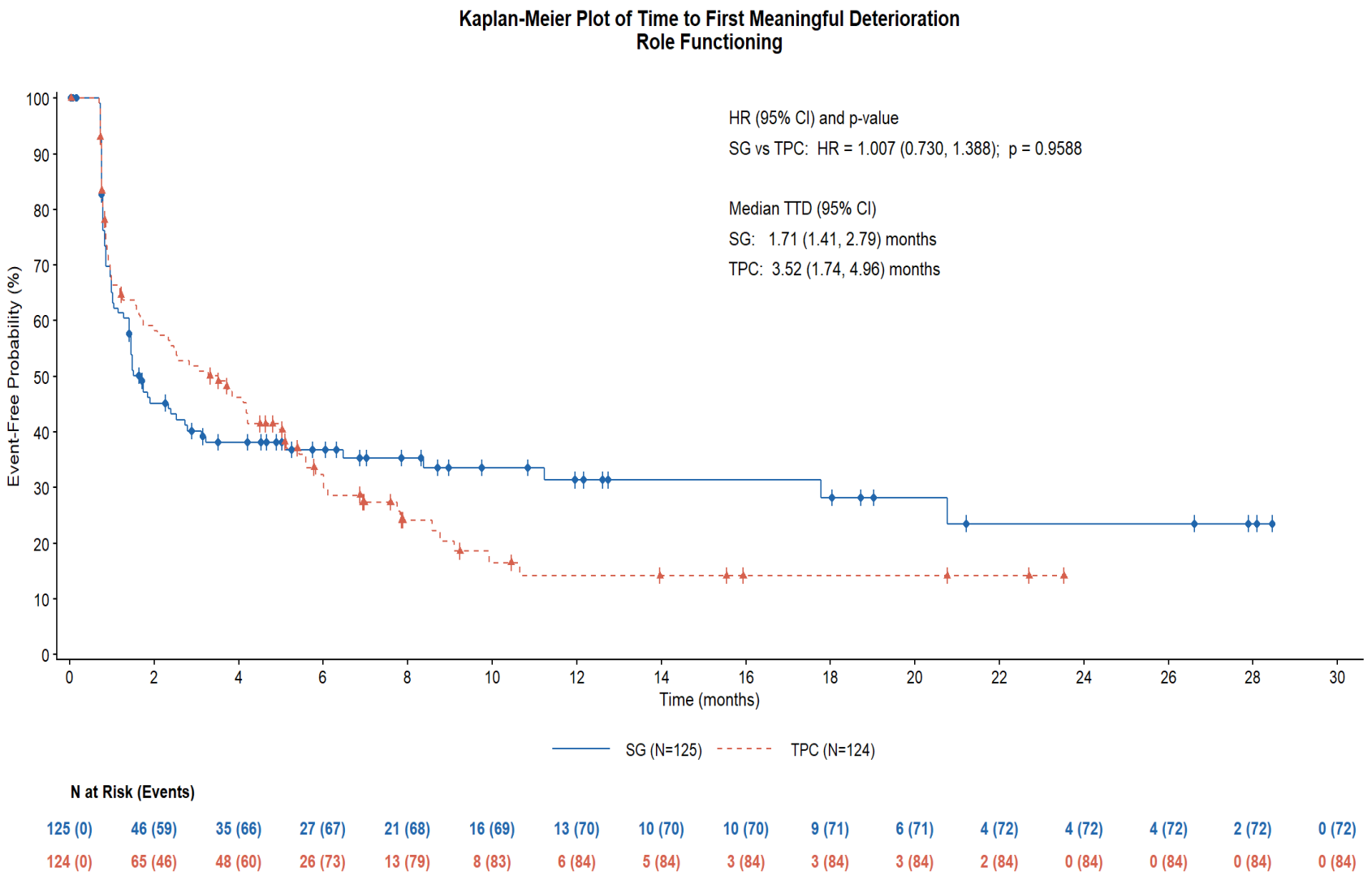
5.25. Figure 1.1.1: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Global Health Status QoL — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



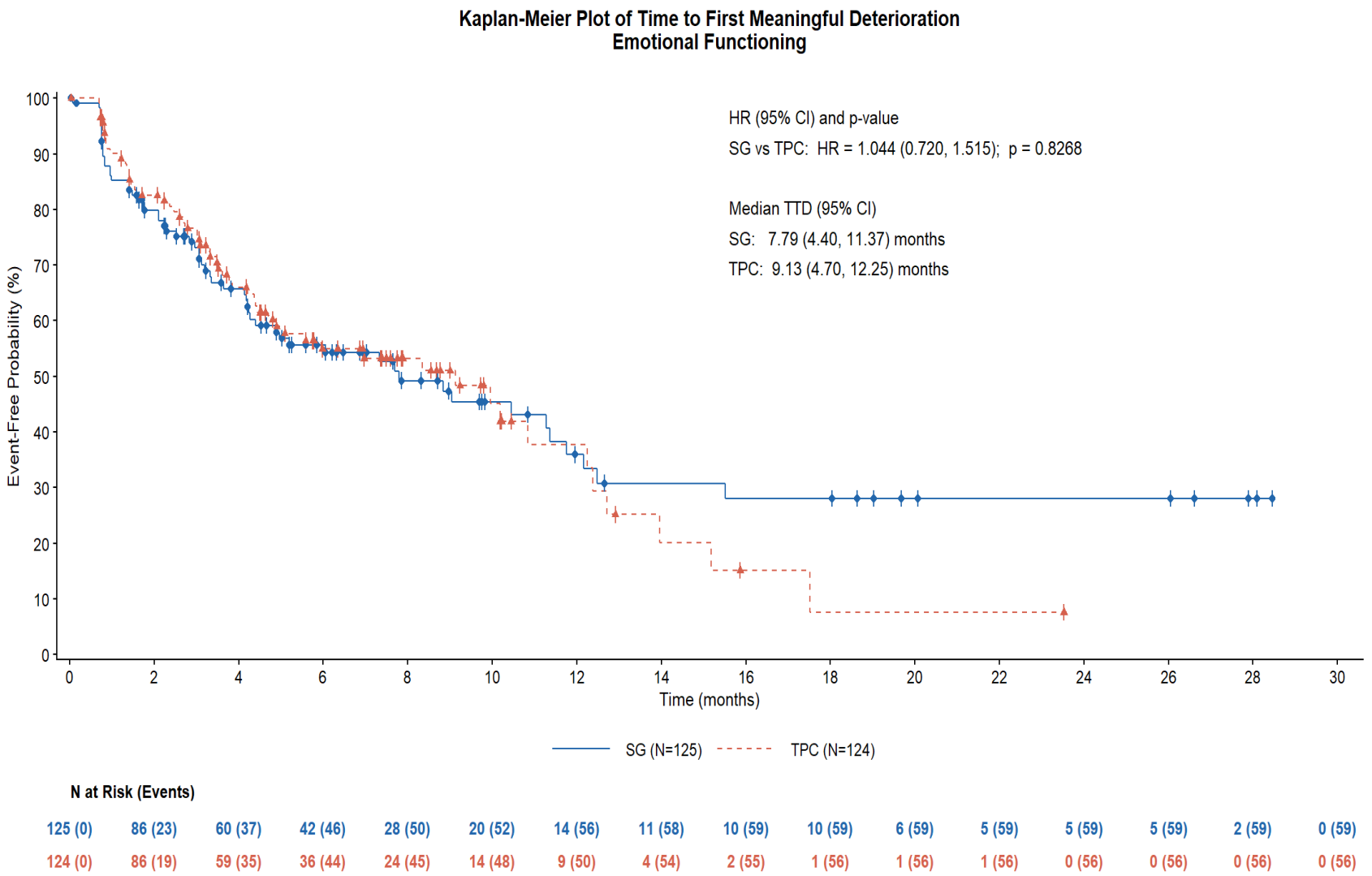
5.26. Figure 1.1.2: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Physical Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



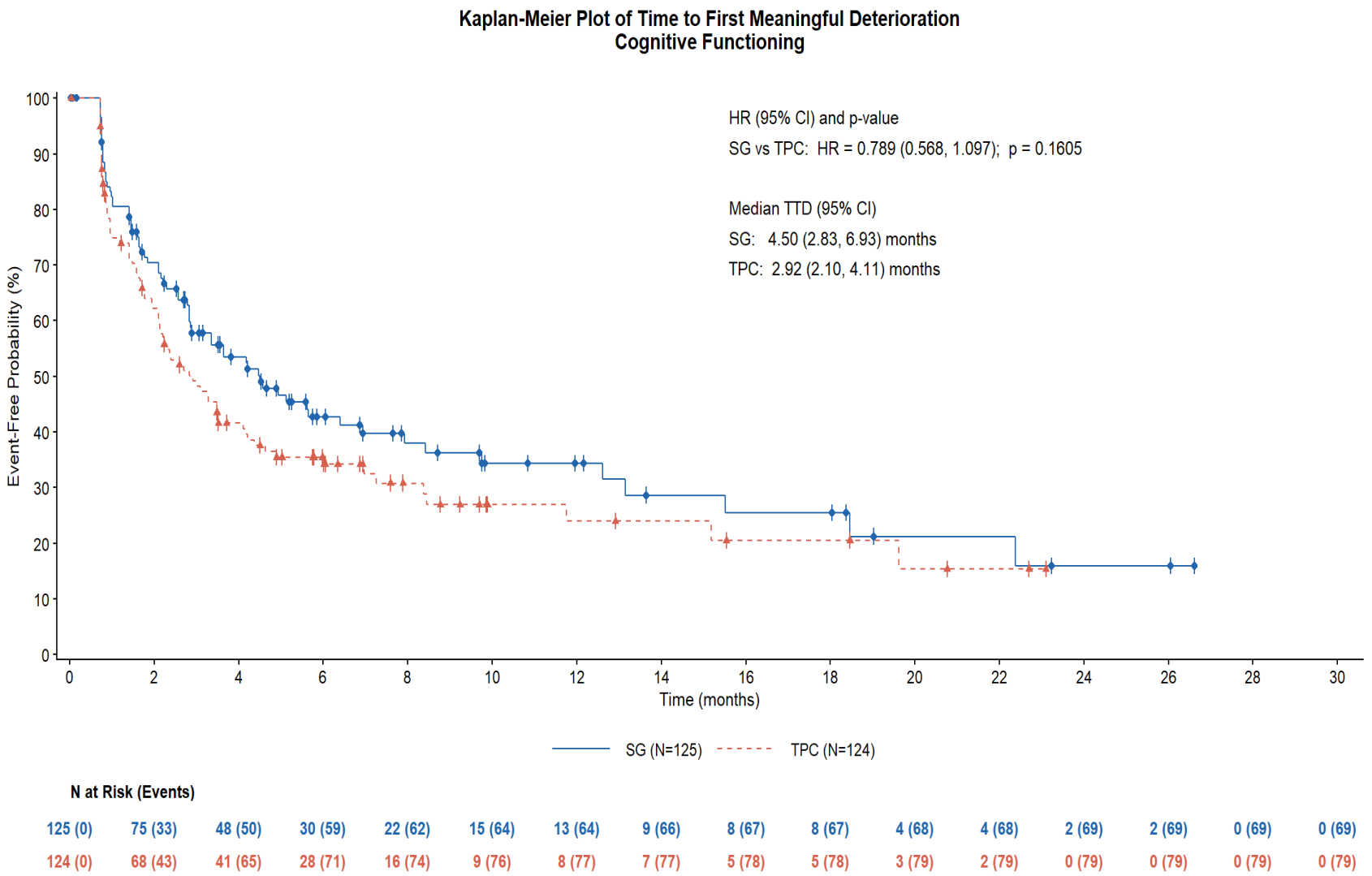
5.27. Figure 1.1.3: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Role Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



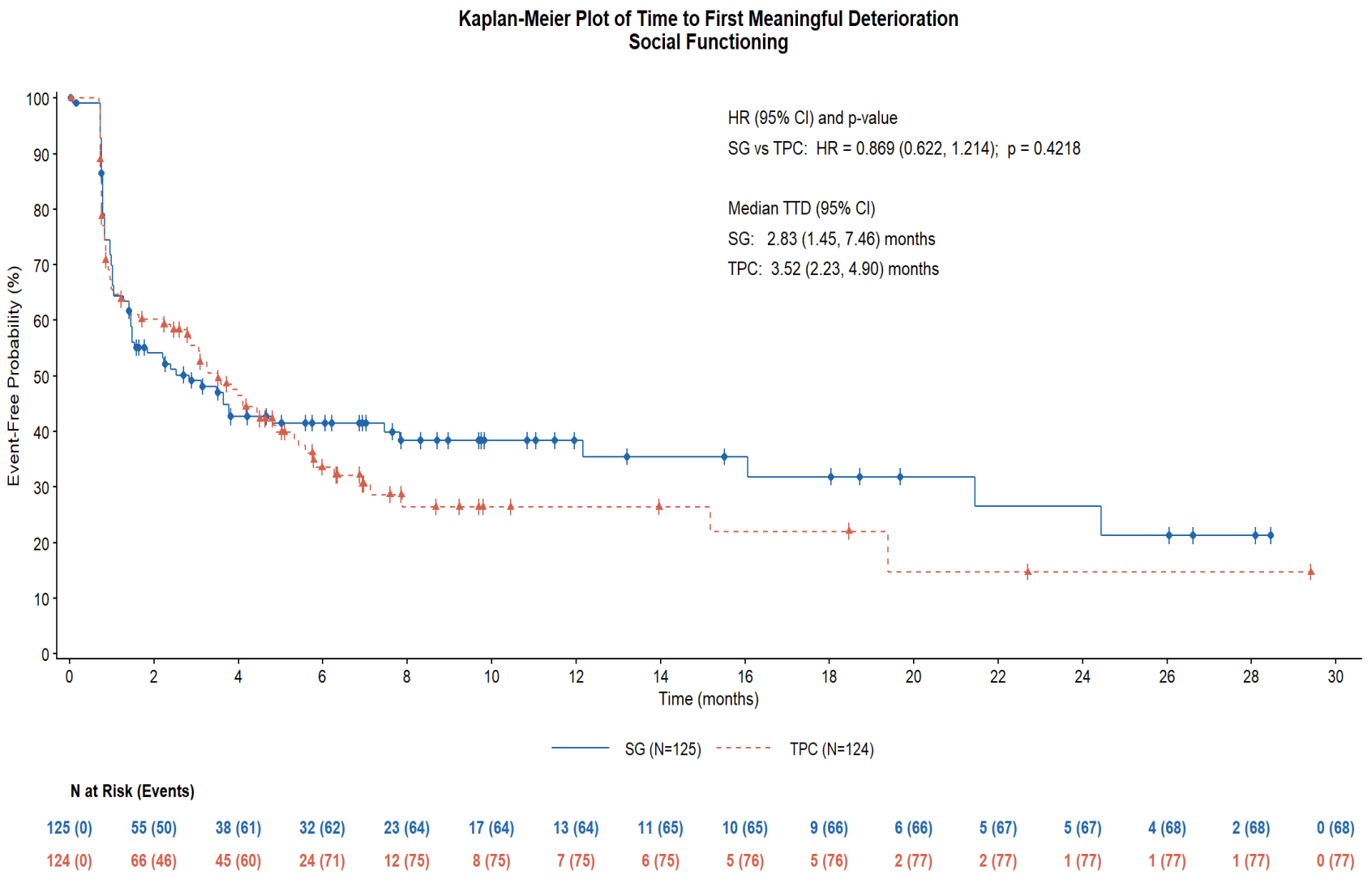
5.28. Figure 1.1.4: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Emotional Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



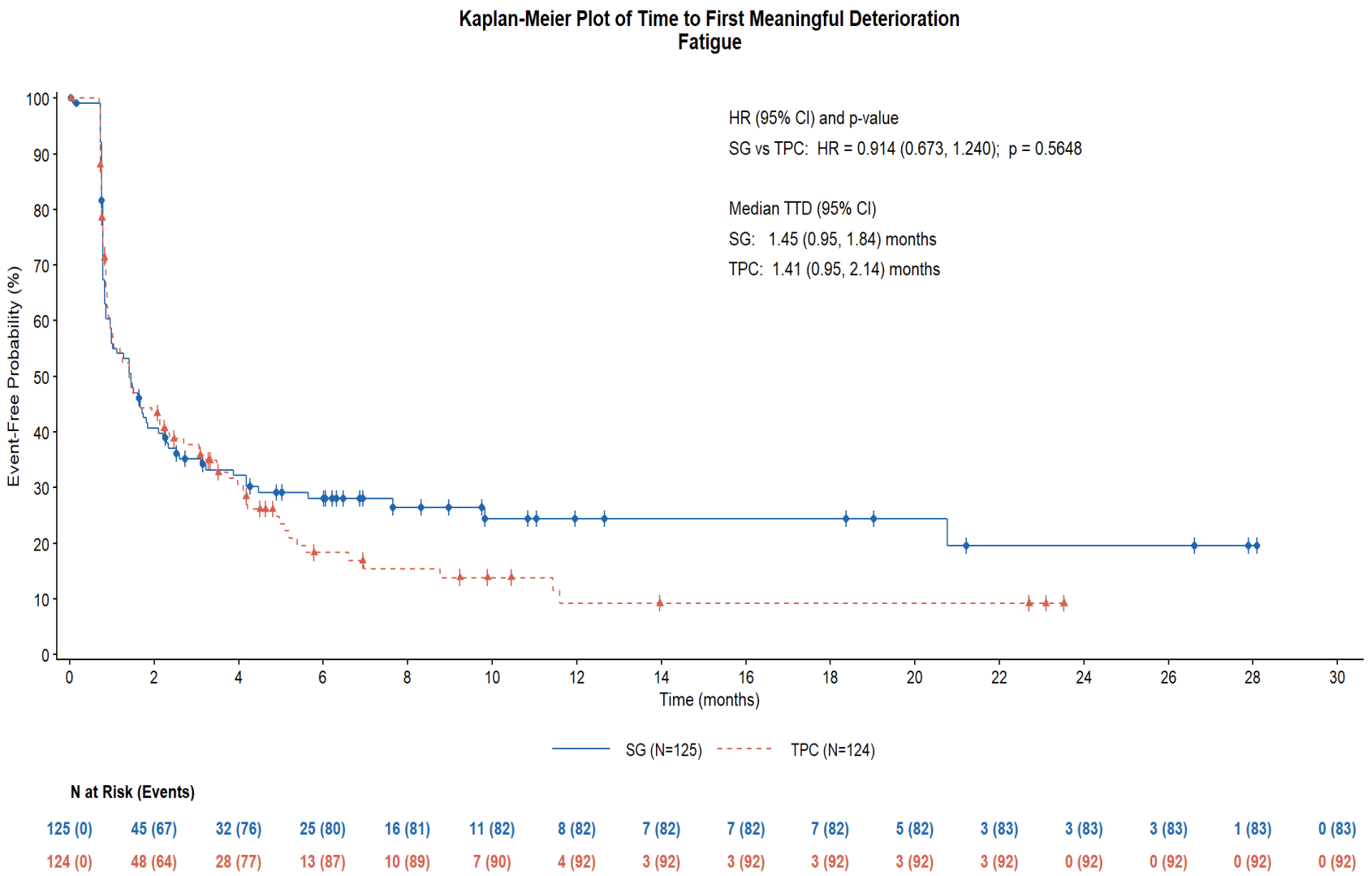
5.29. Figure 1.1.5: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Cognitive Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



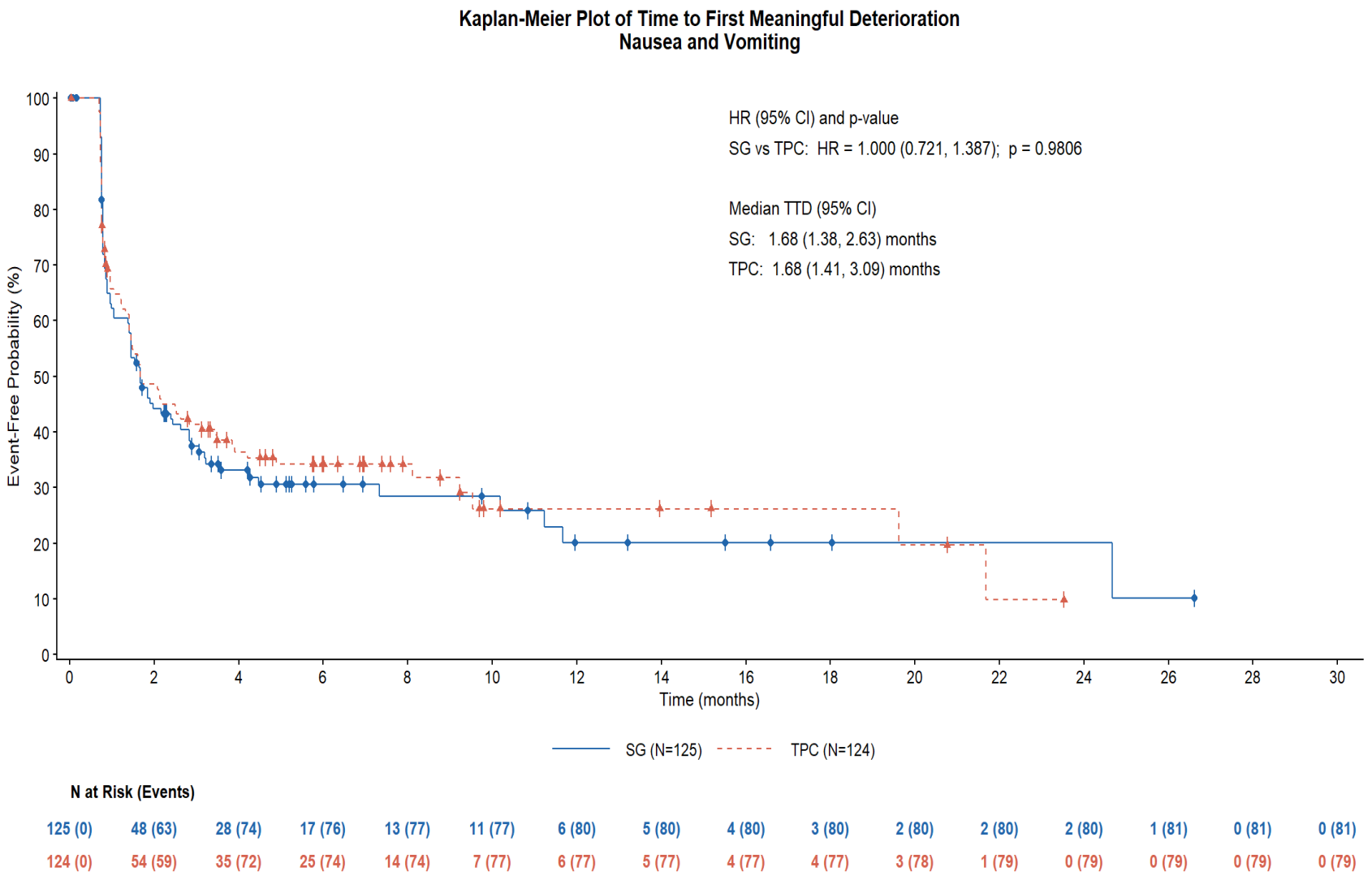
5.30. Figure 1.1.6: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Social Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



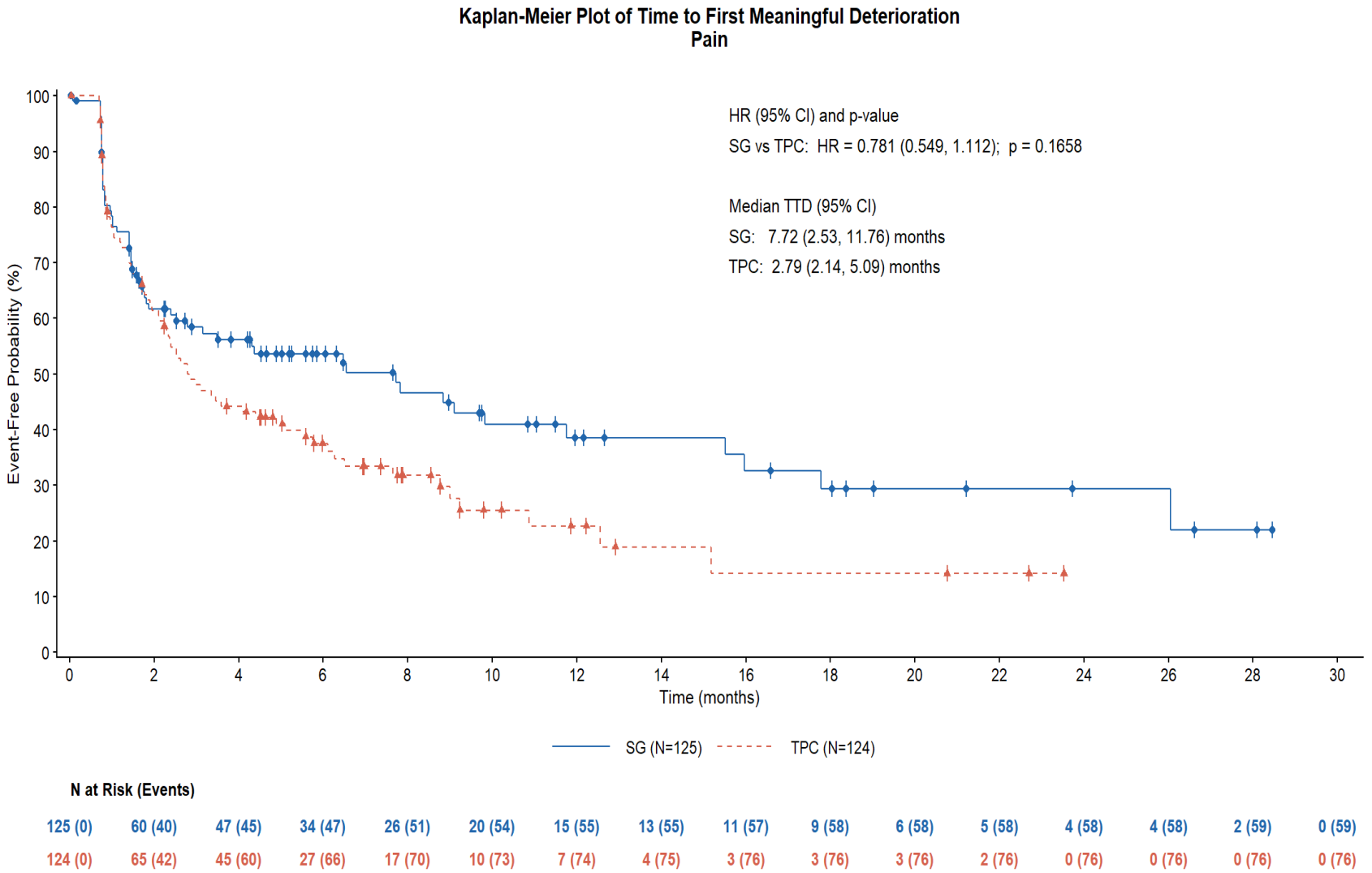
5.31. Figure 1.1.7: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Fatigue — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



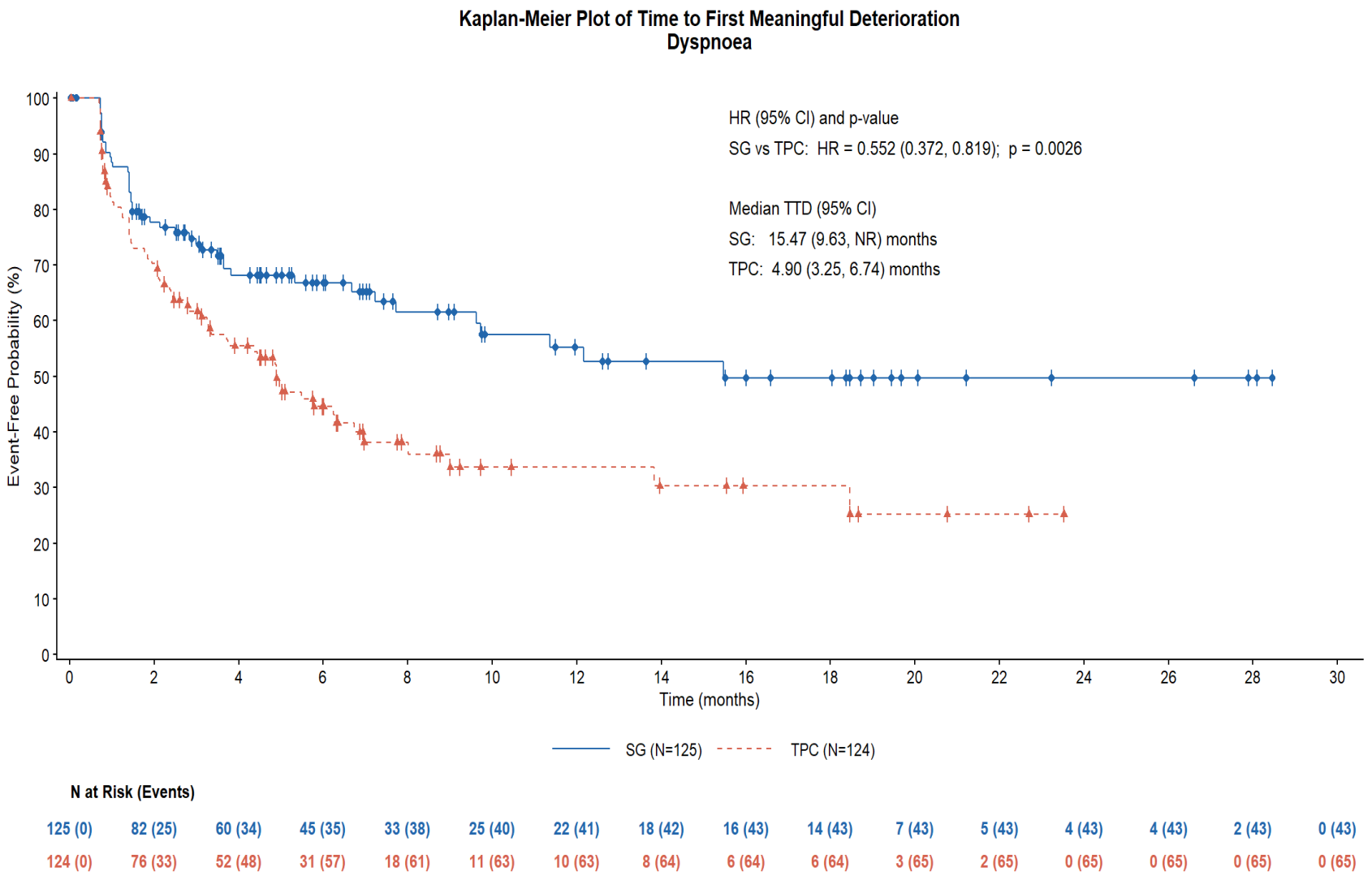
5.32. Figure 1.1.8: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Nausea and Vomiting — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



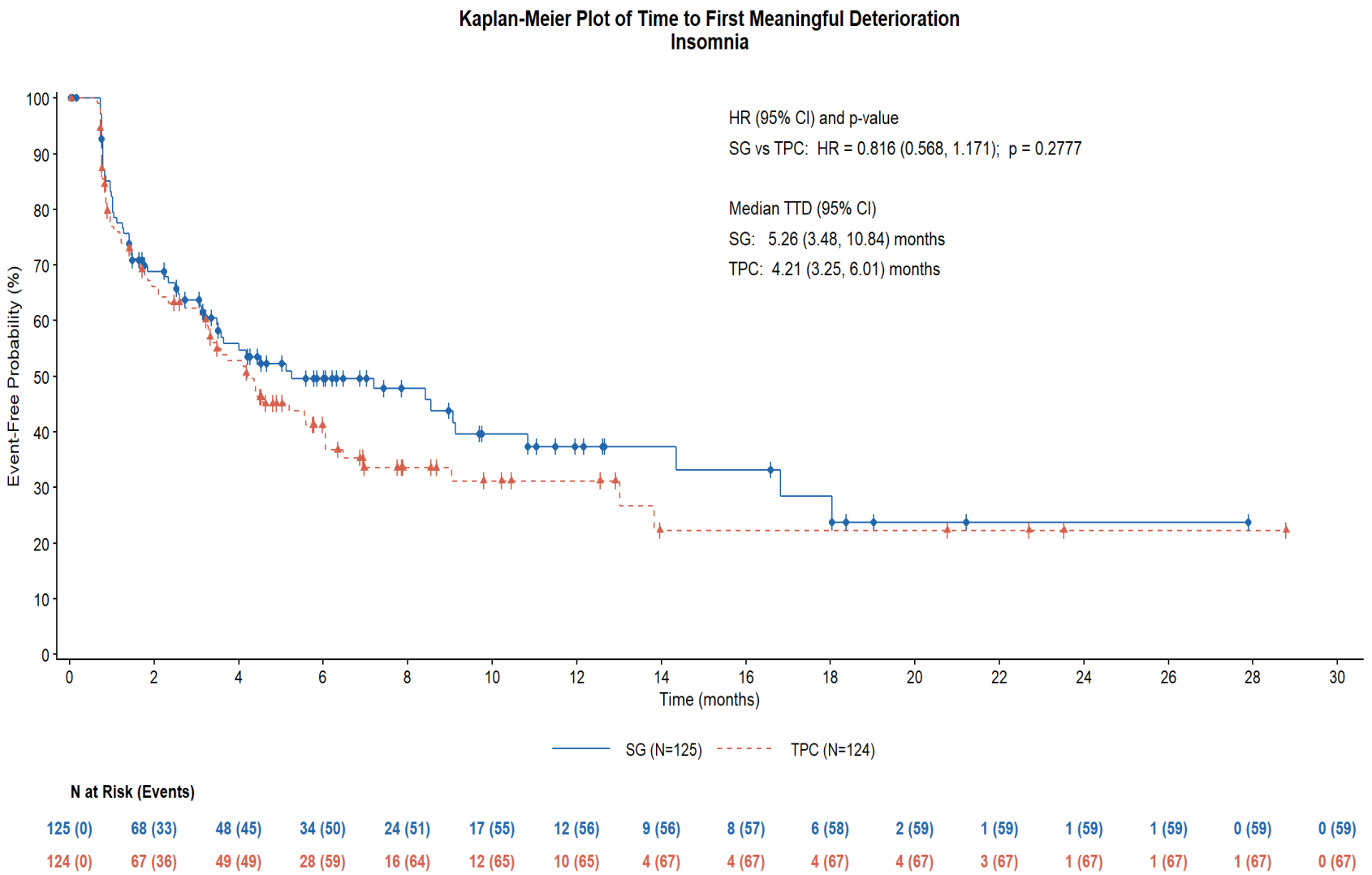
5.33. Figure 1.1.9: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Pain — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



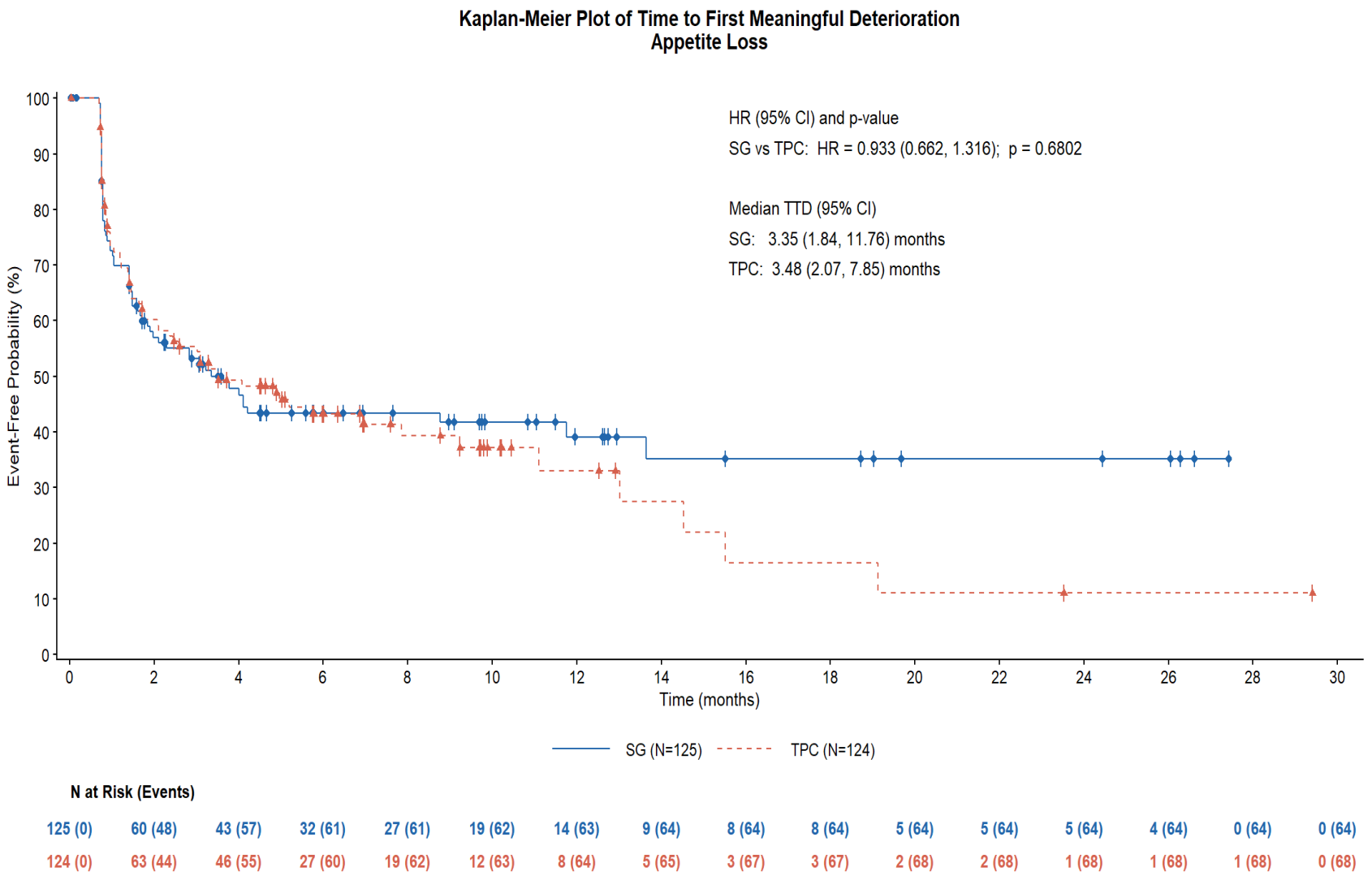
5.34. Figure 1.1.10: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Dyspnoea — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



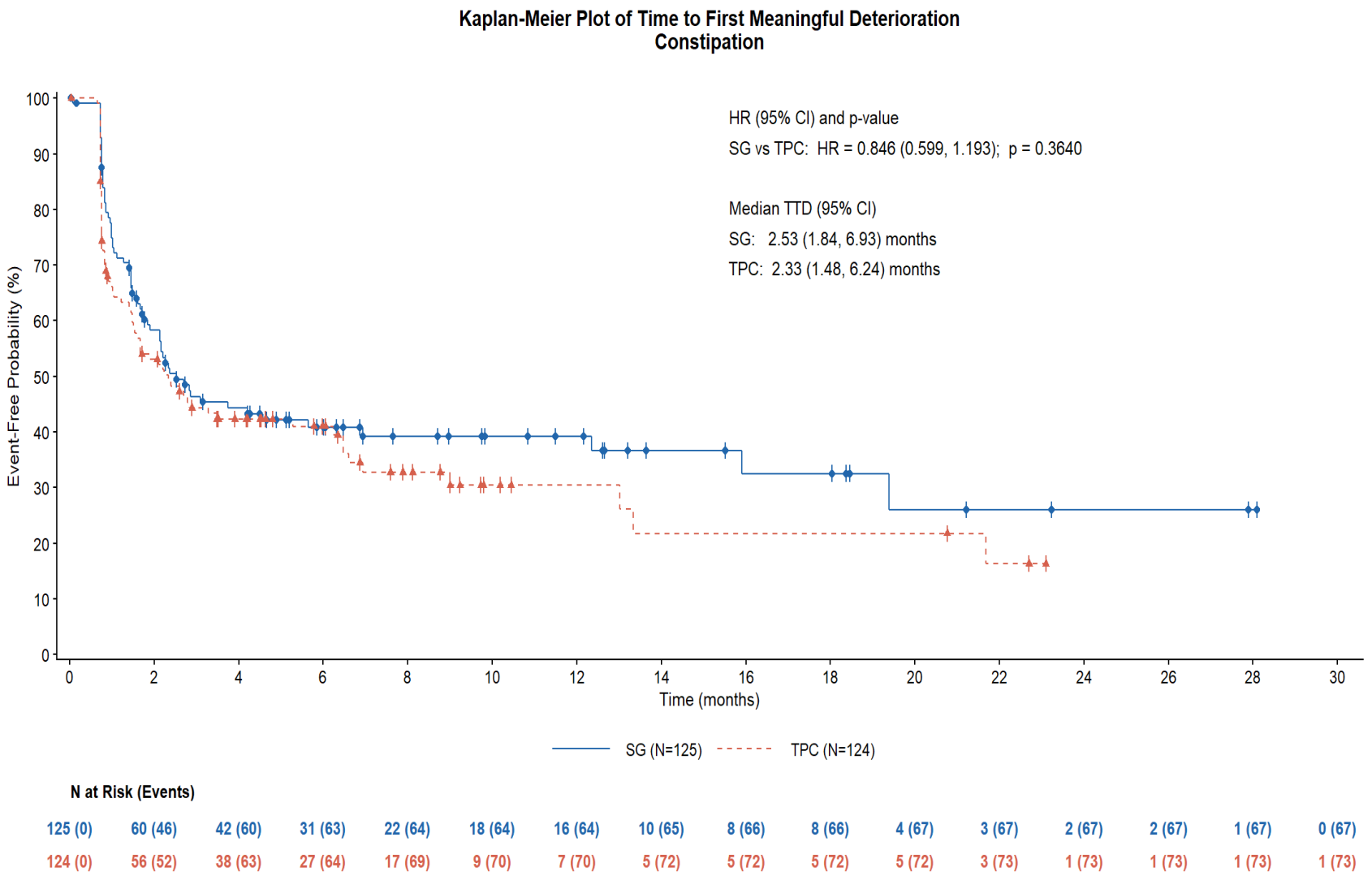
5.35. Figure 1.1.11: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFUL DETERIORATION EORTC QLQ C30 Insomnia — mITT — Excluding patients preselected to receive nab-paclitaxel or paclitaxel



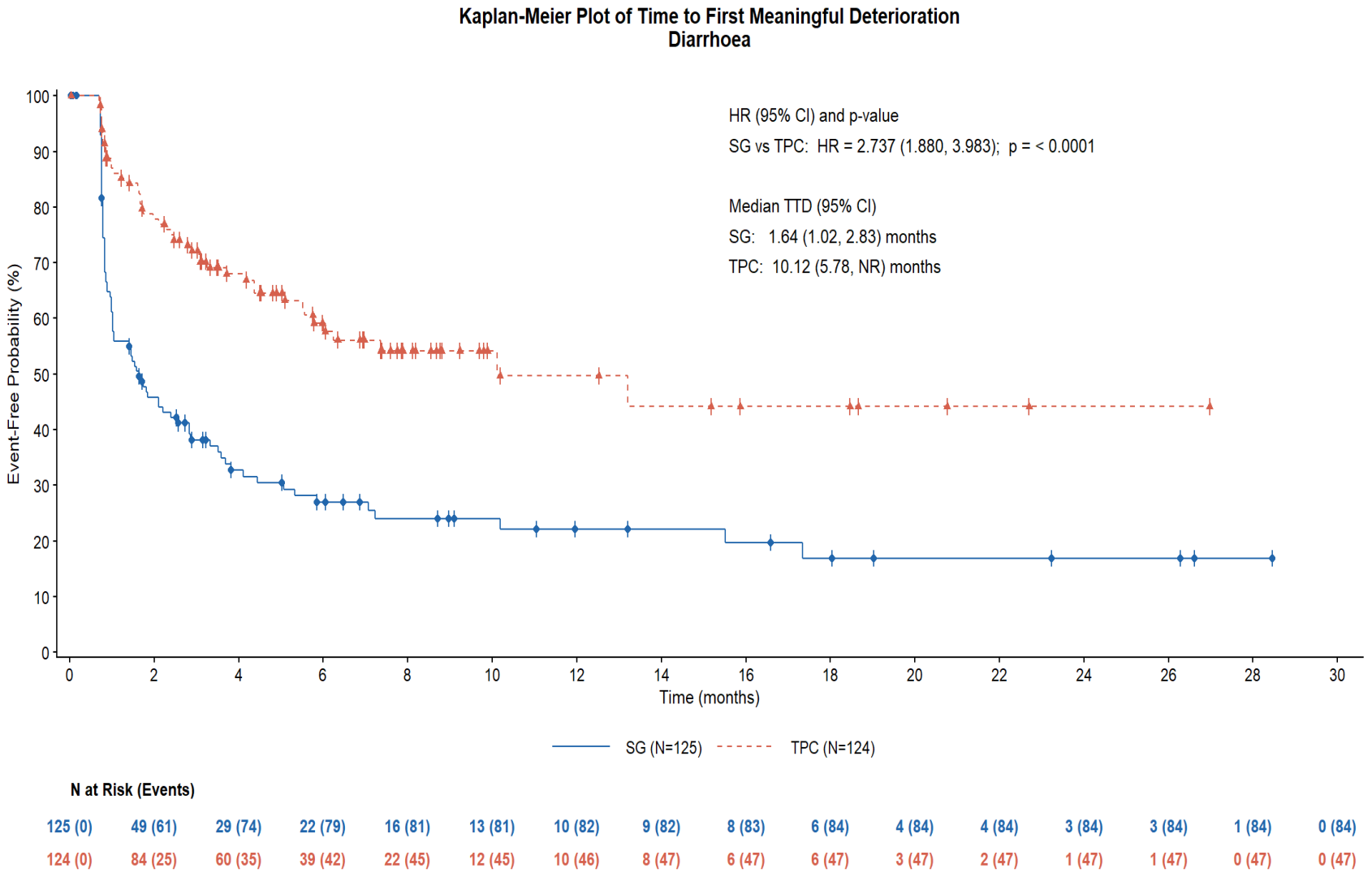
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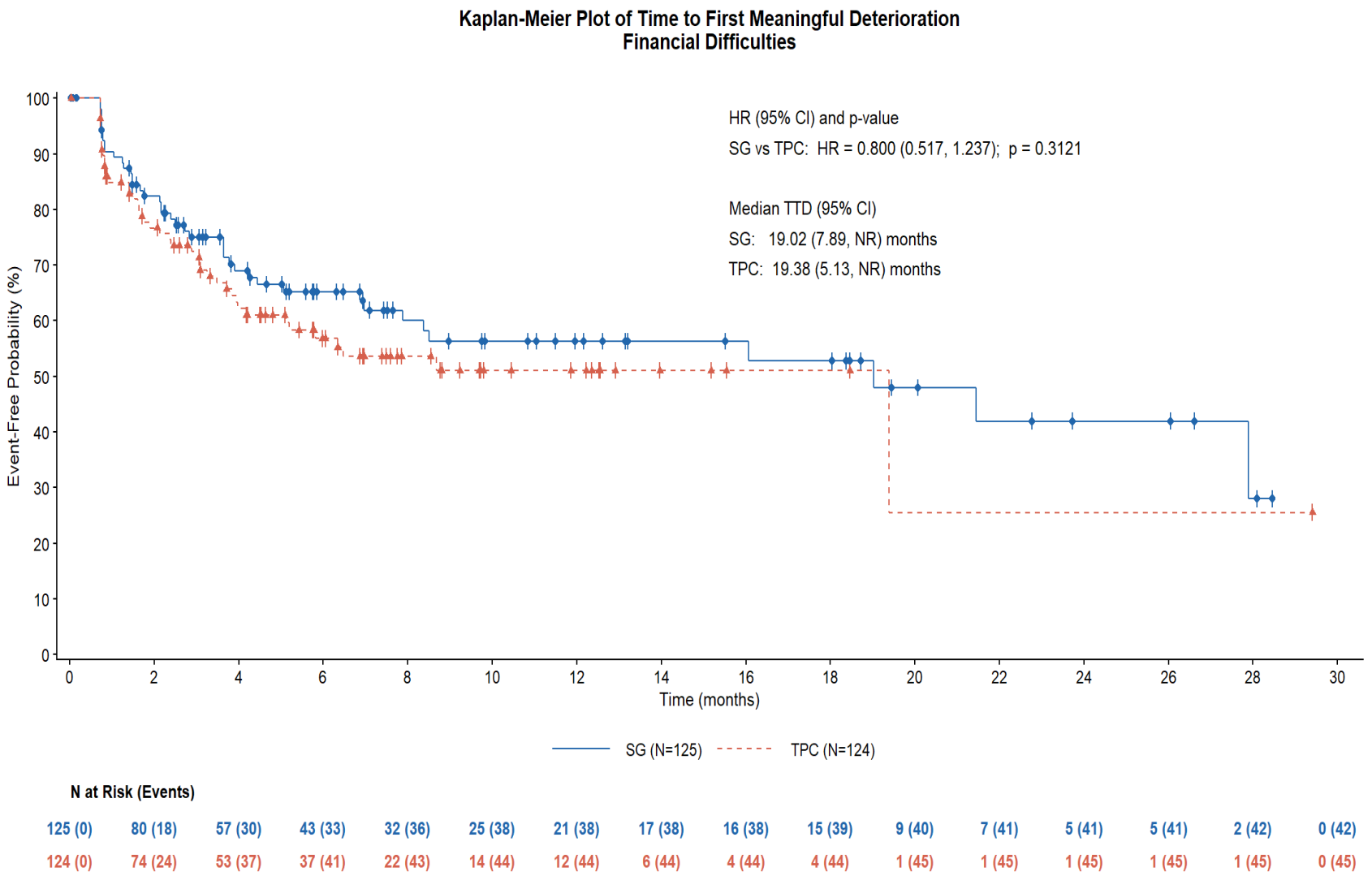
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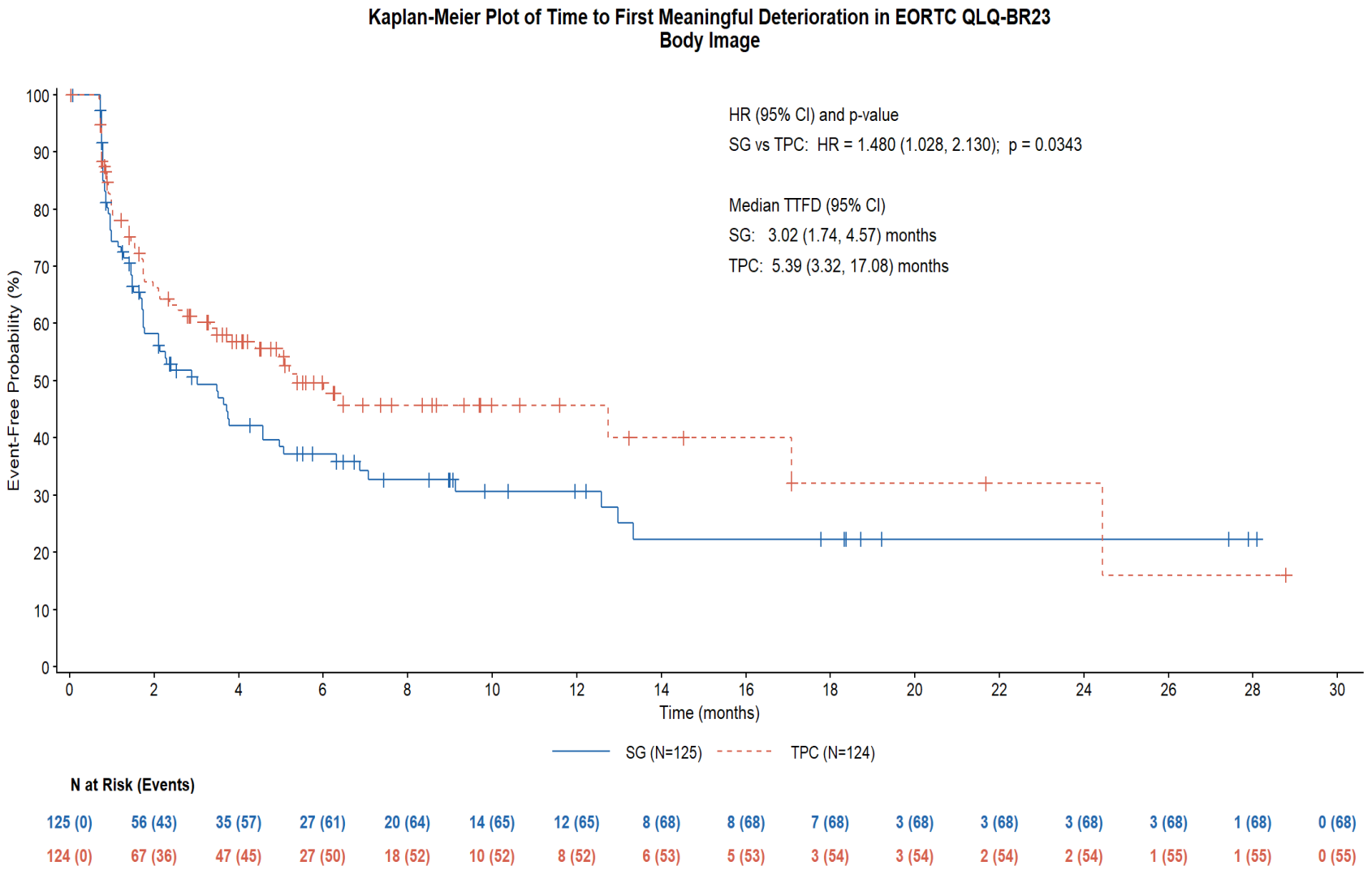
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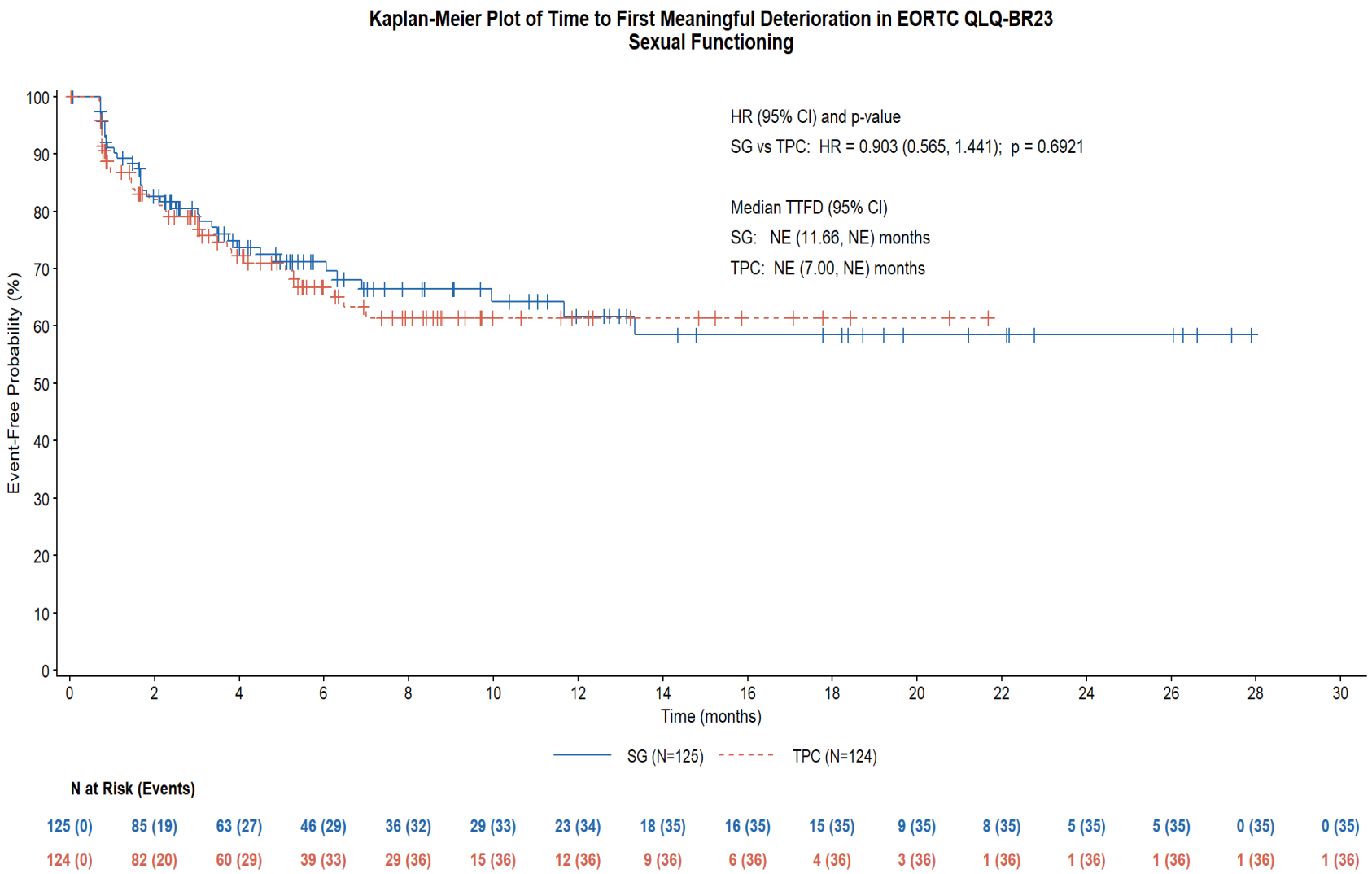
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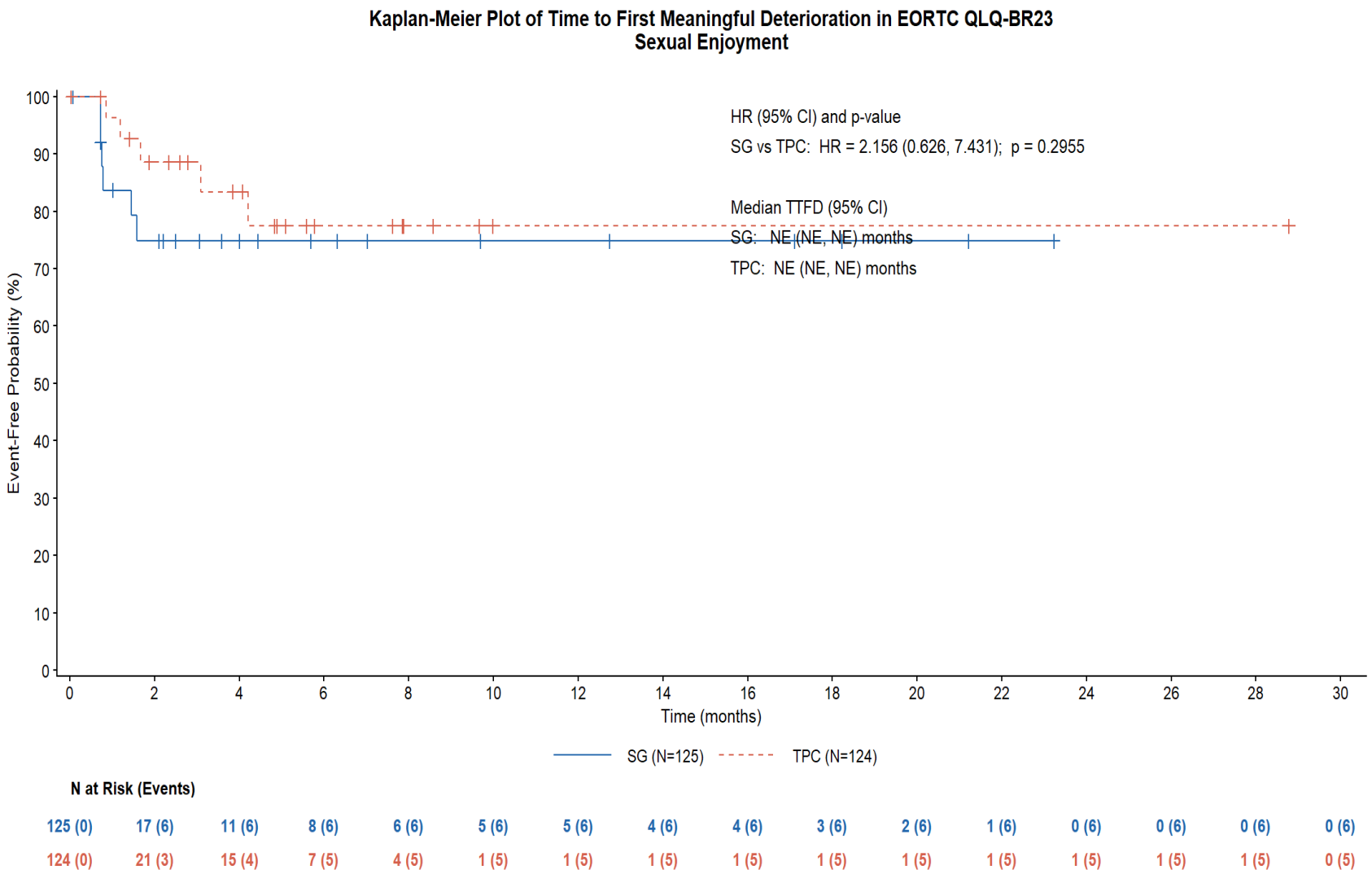
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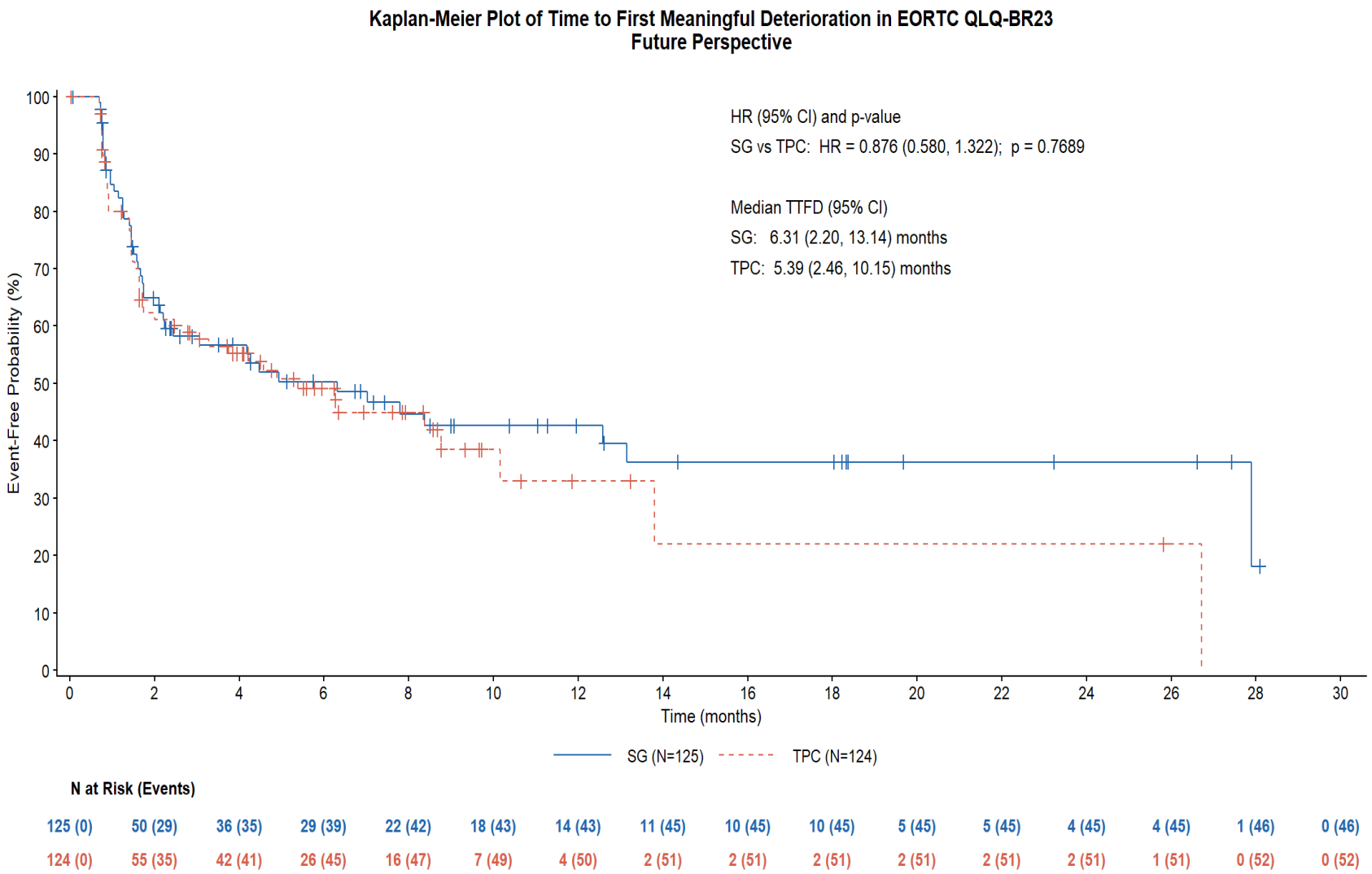
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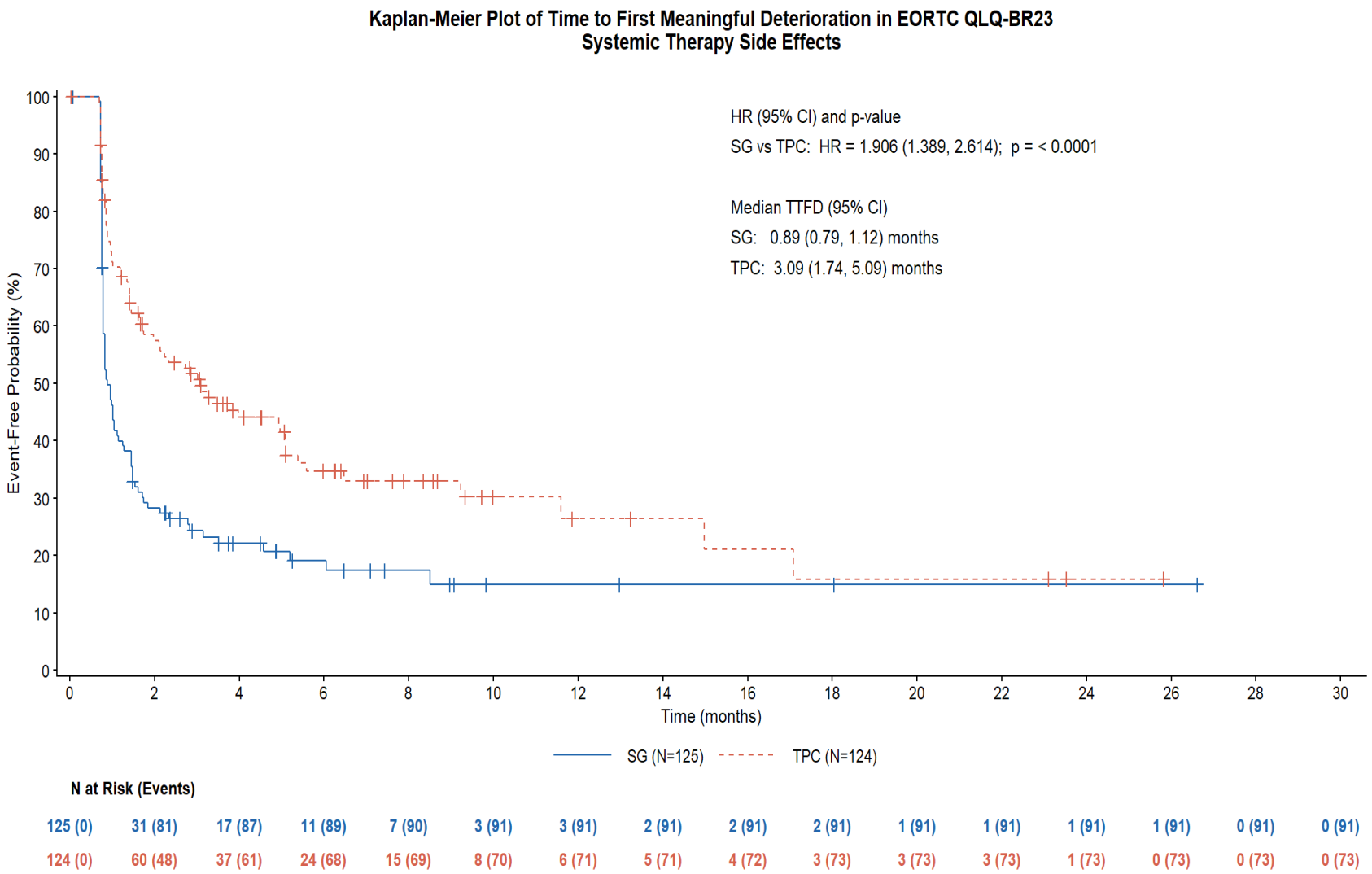
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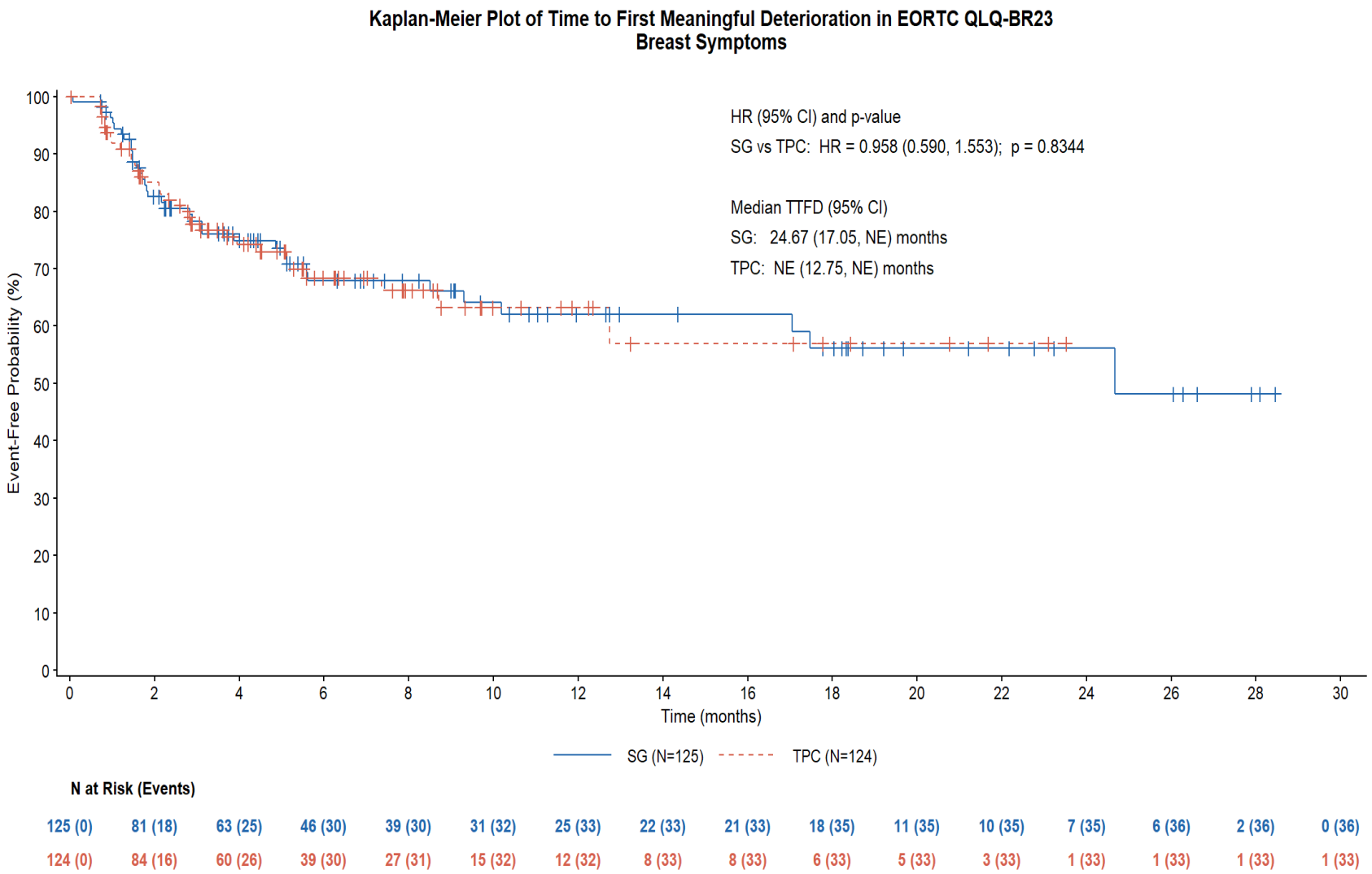
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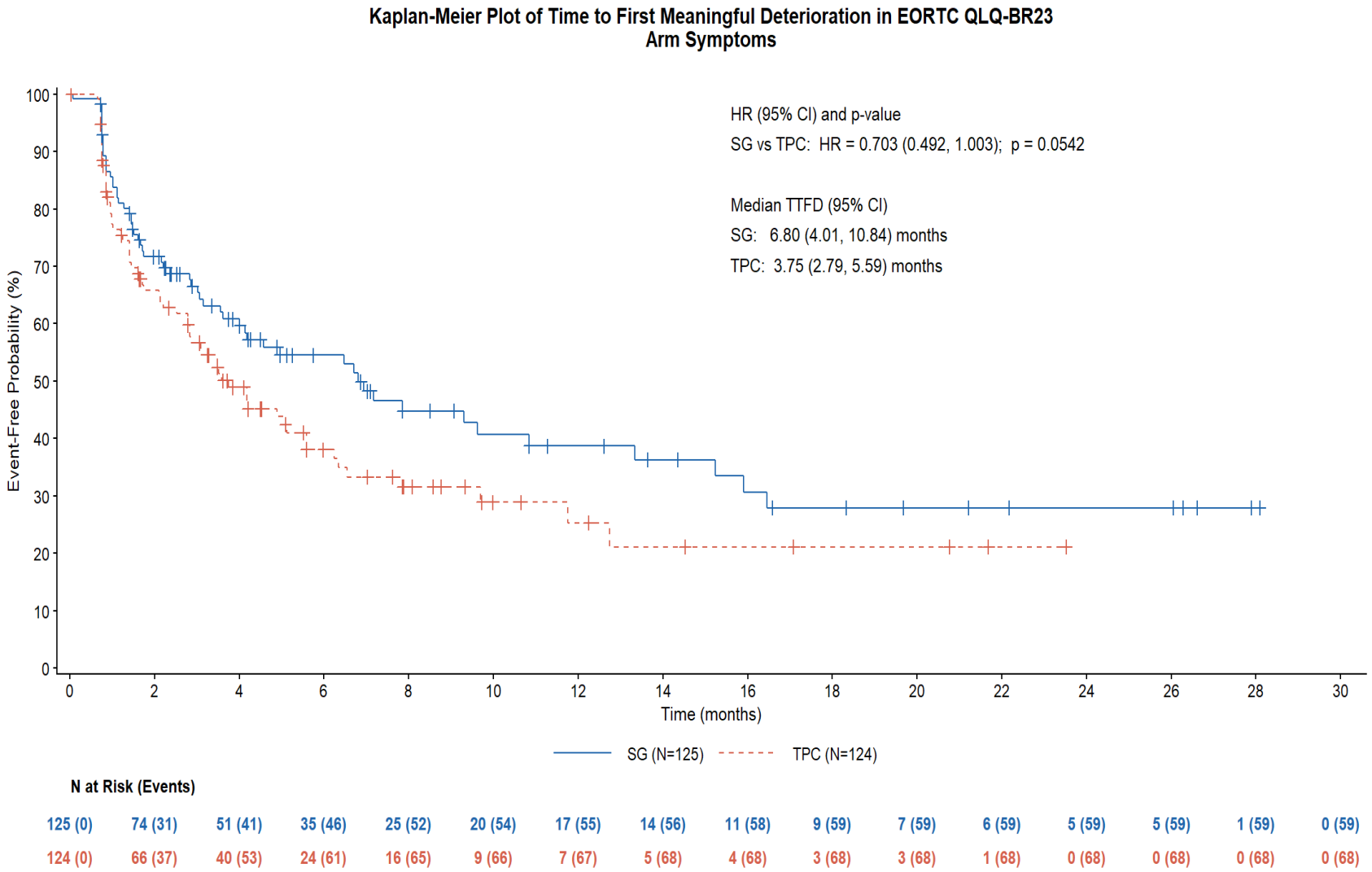
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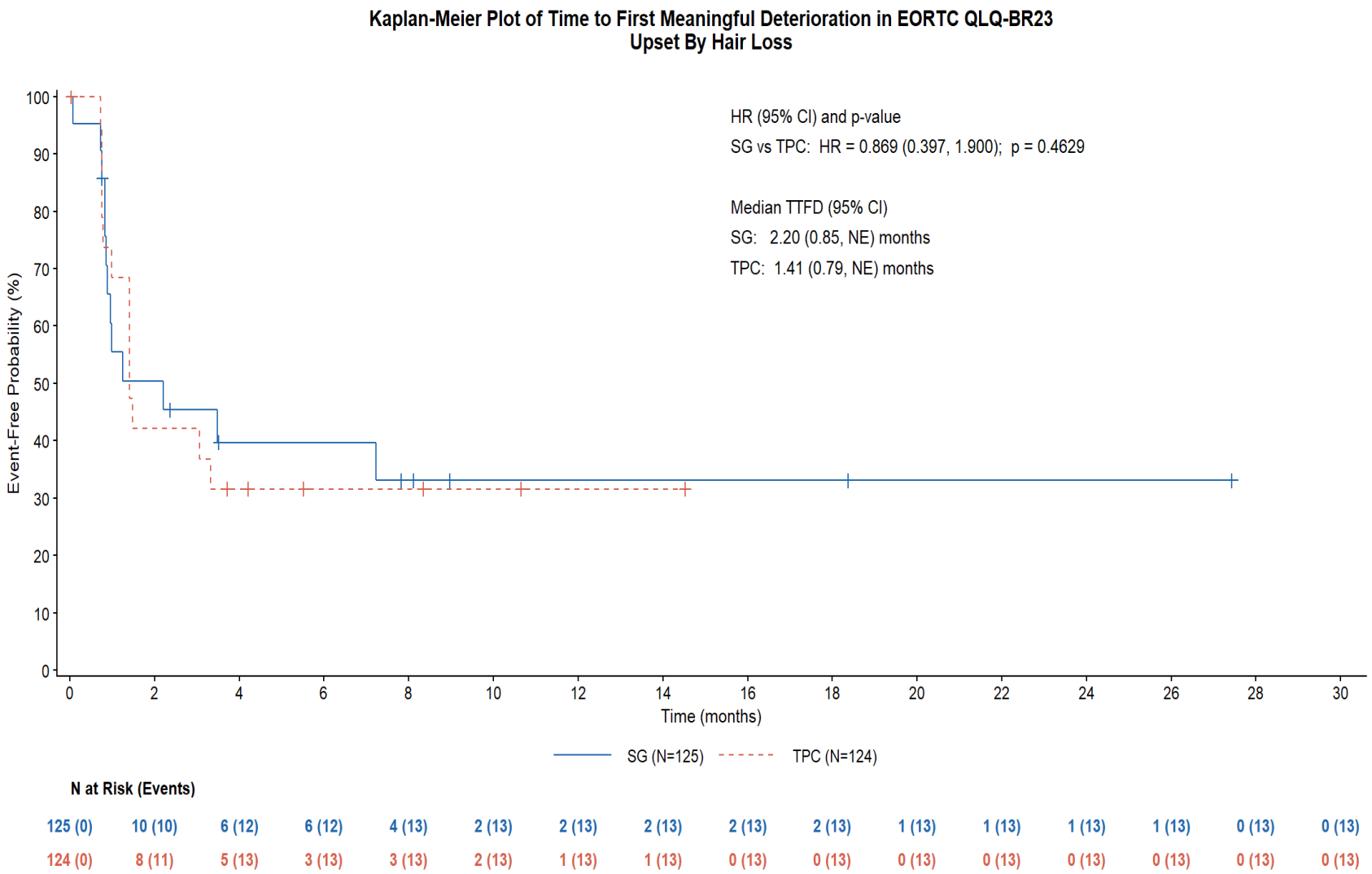
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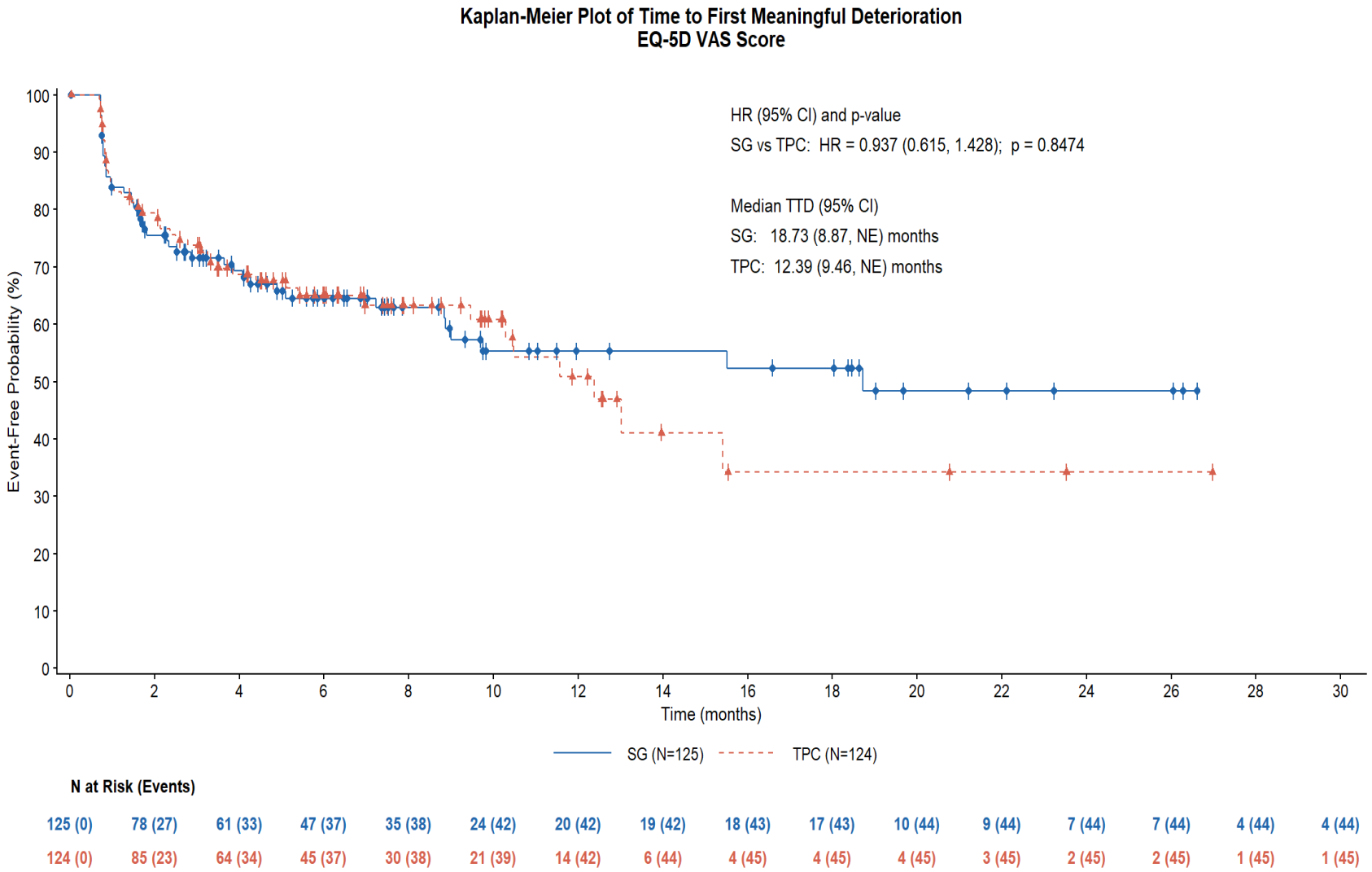
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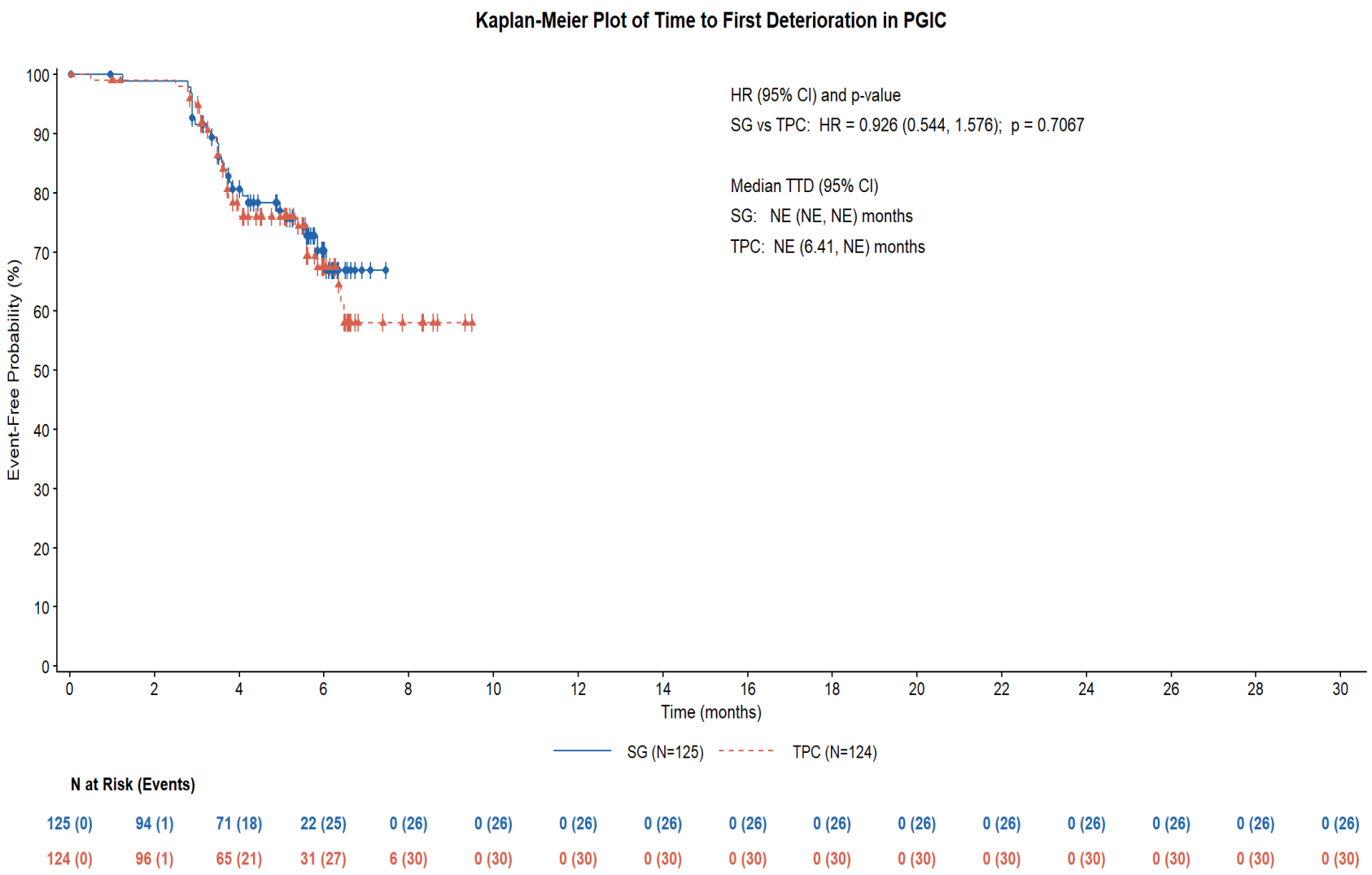
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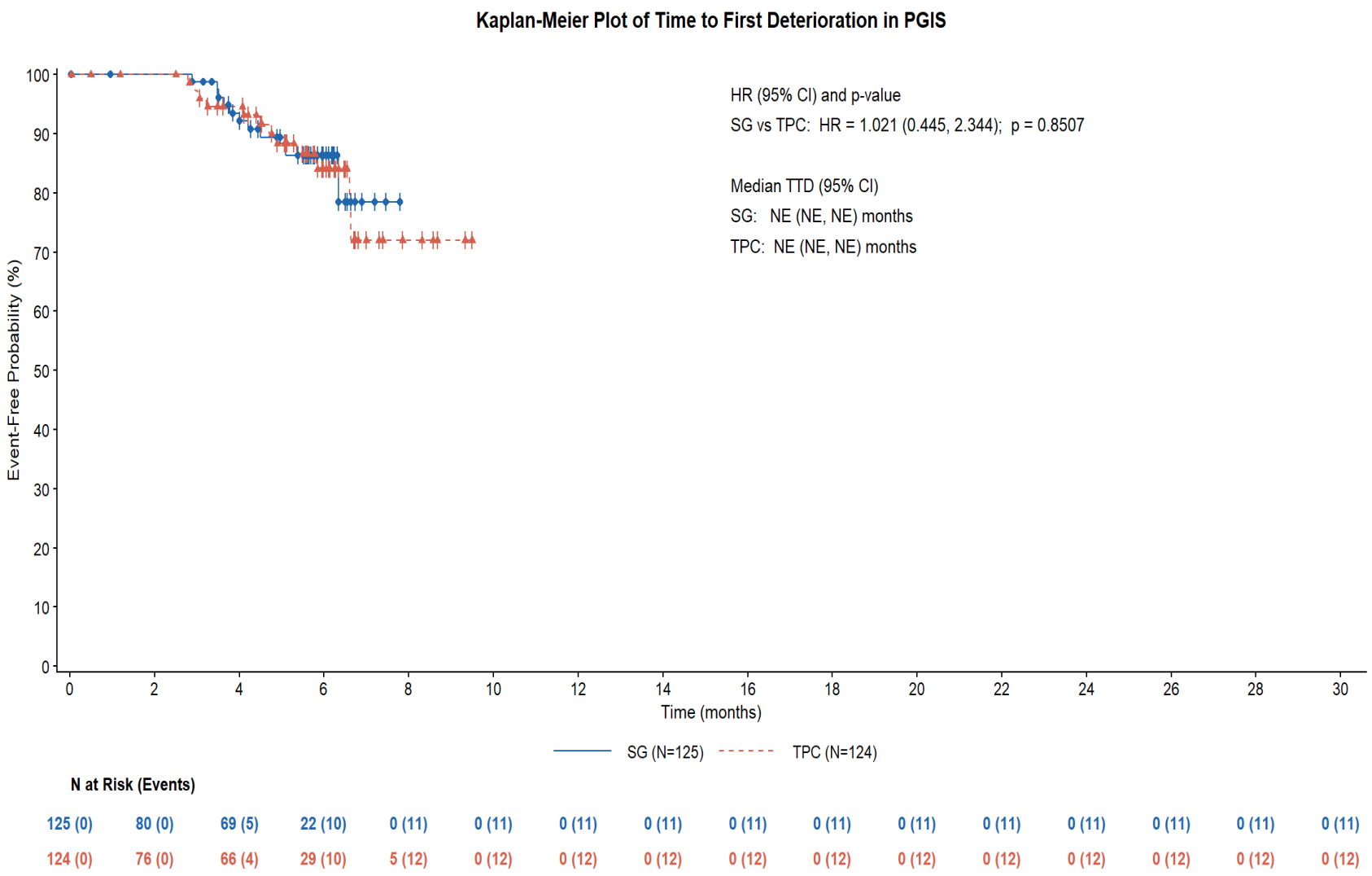
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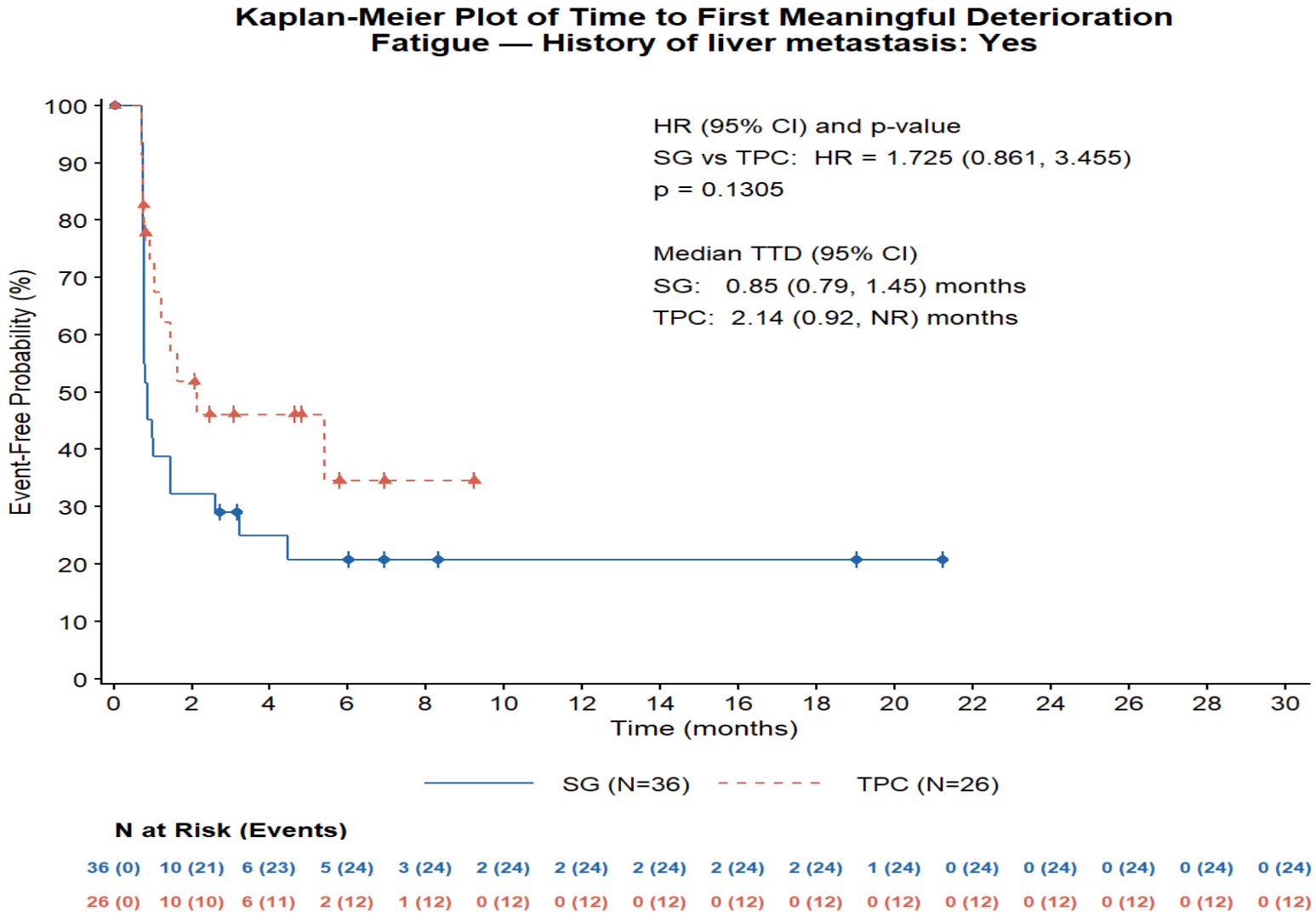
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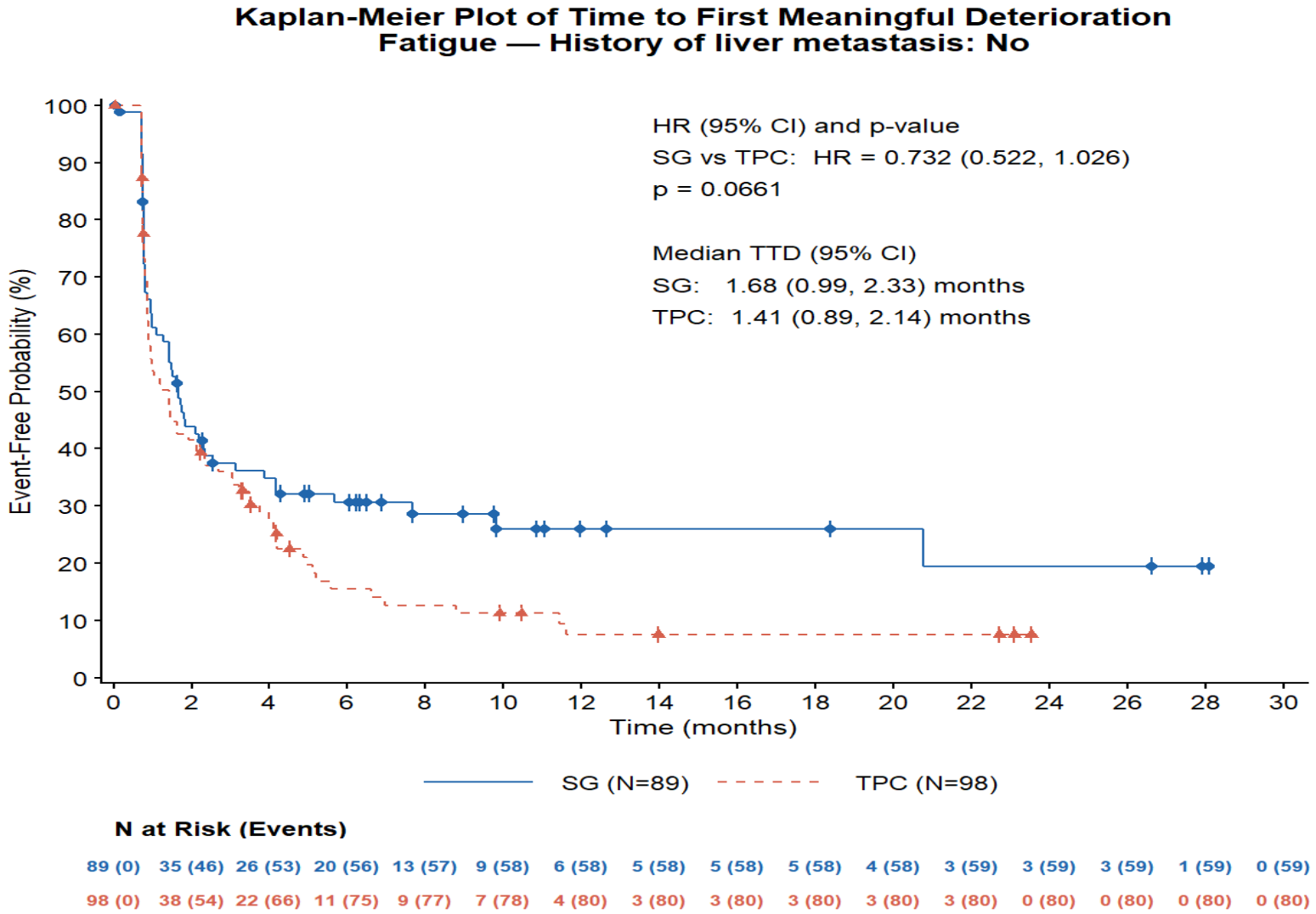
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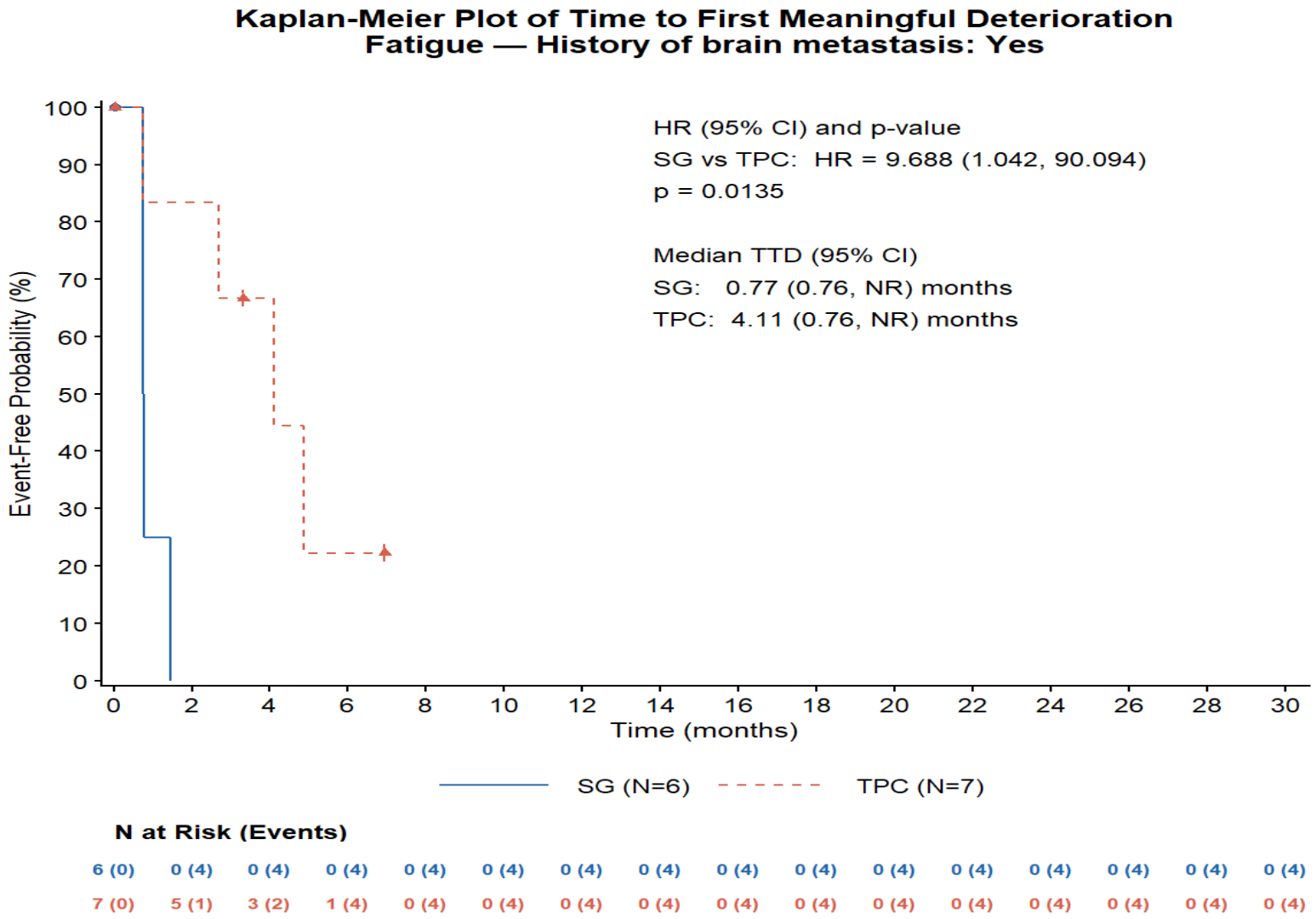
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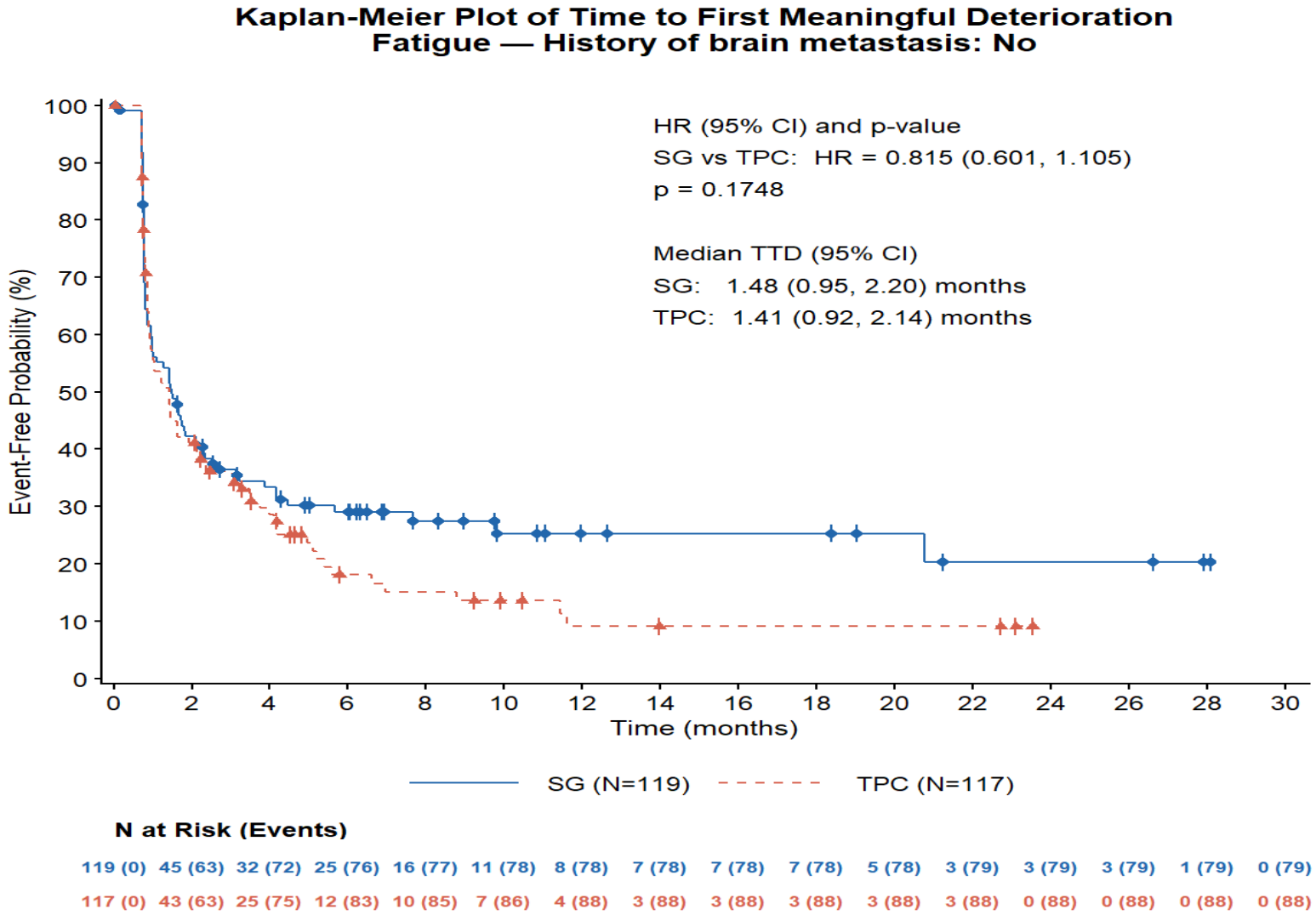
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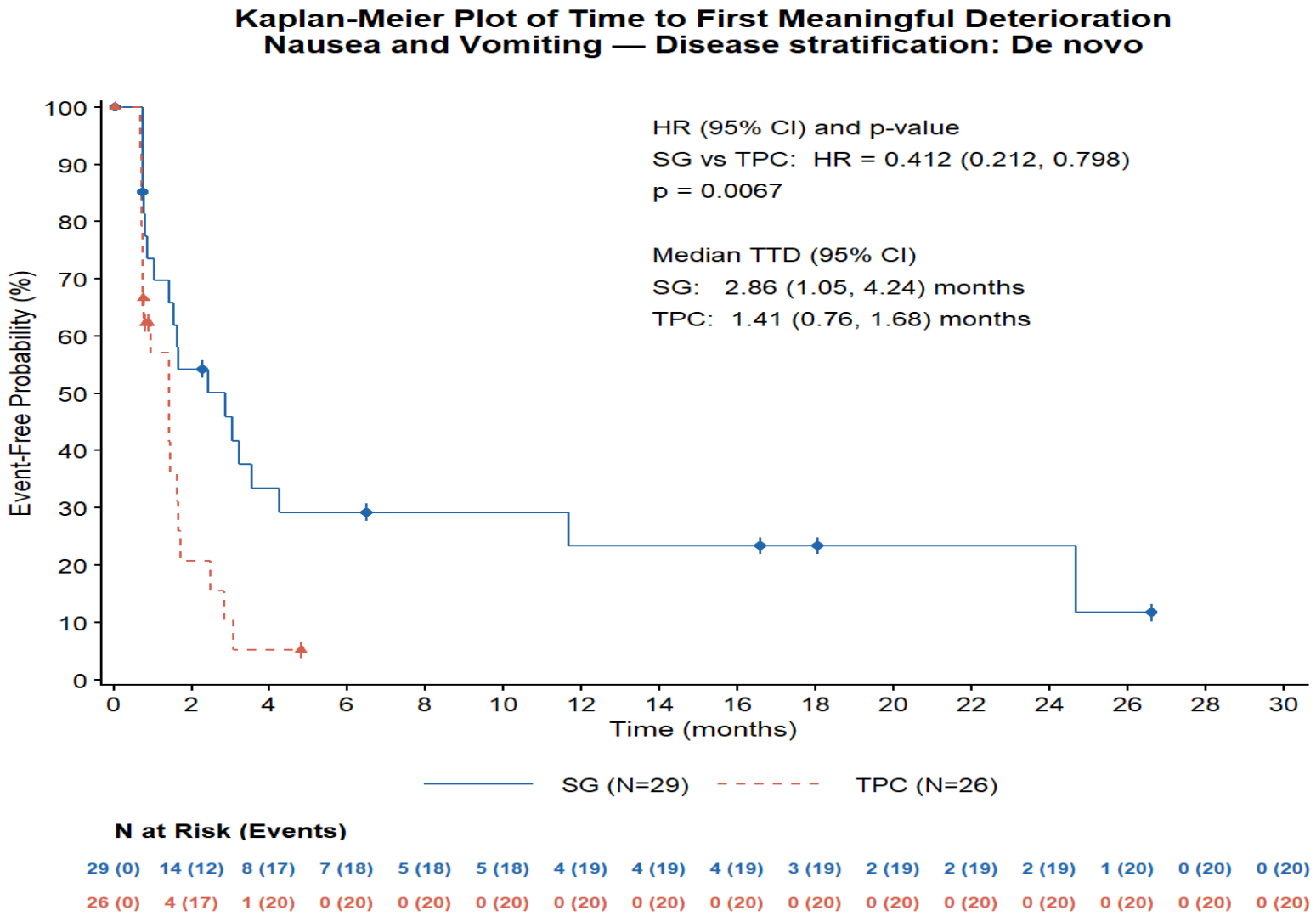
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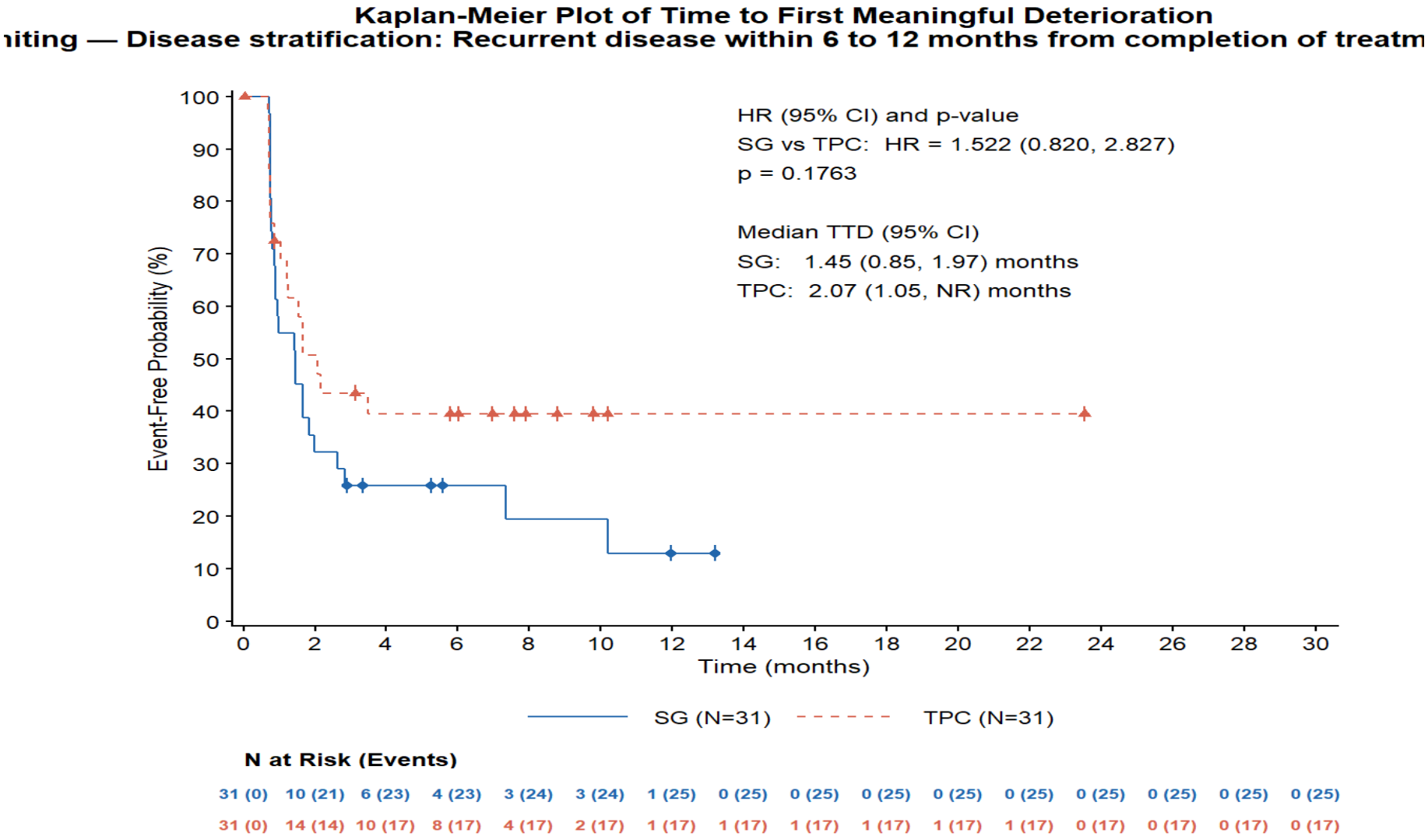
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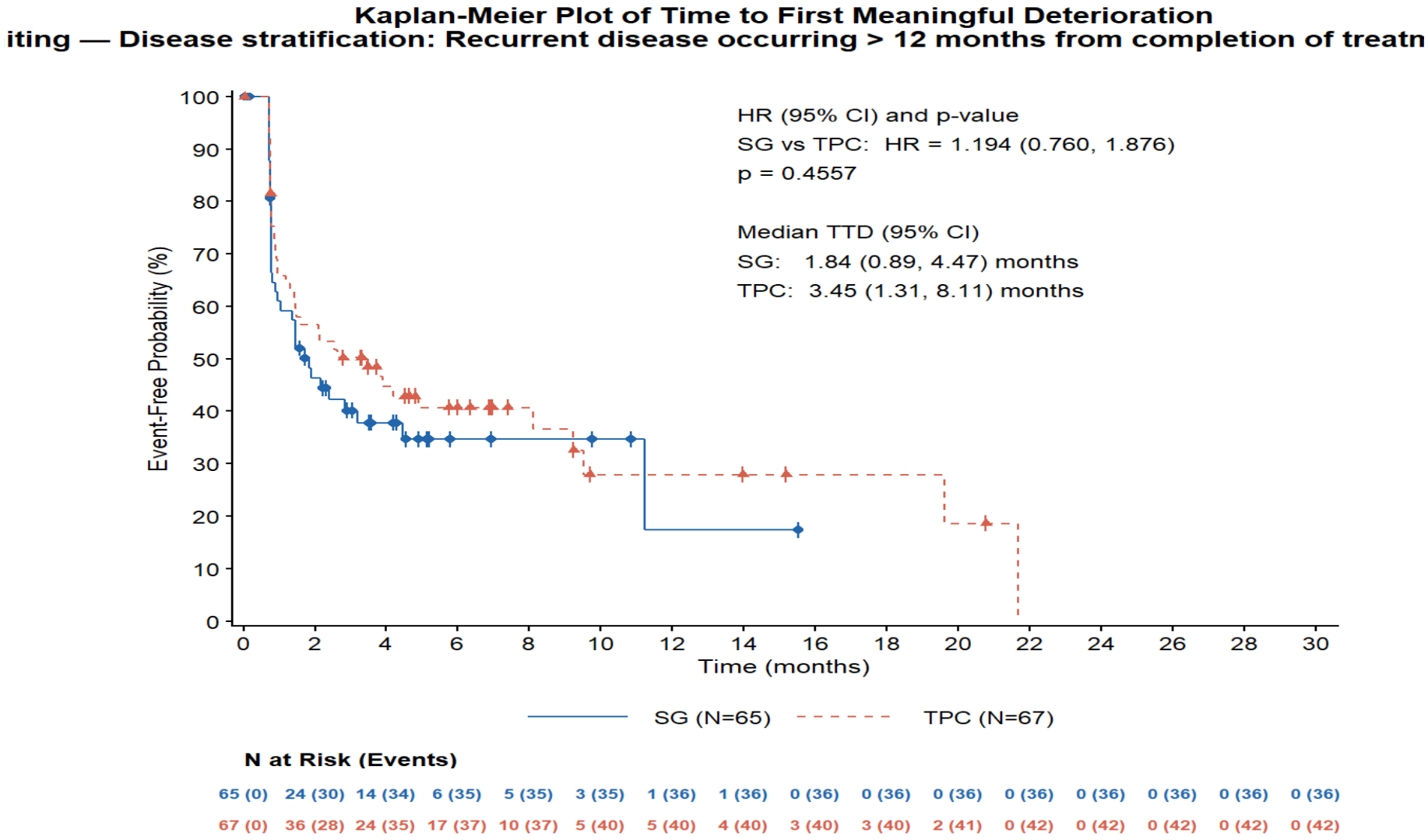
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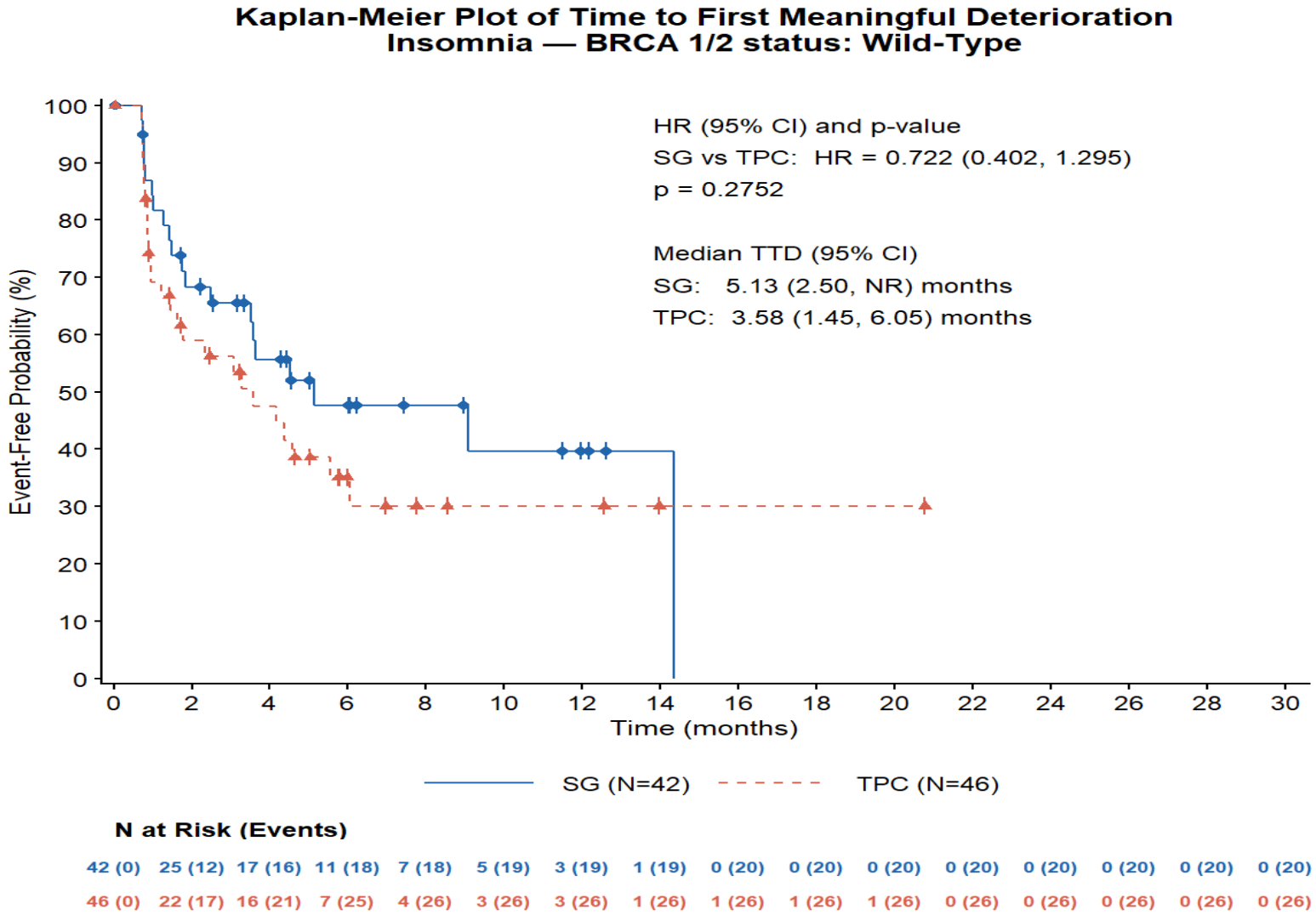
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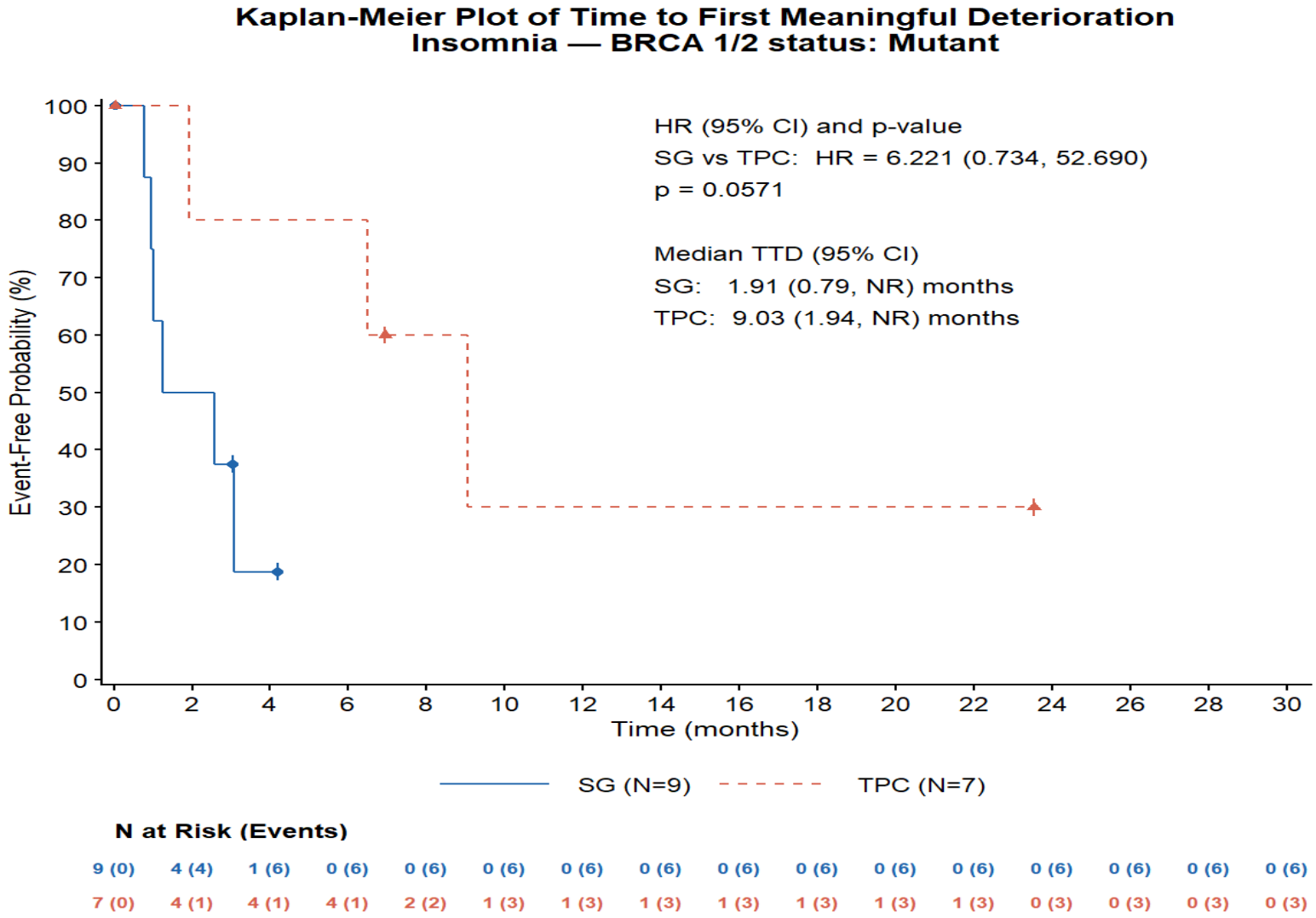
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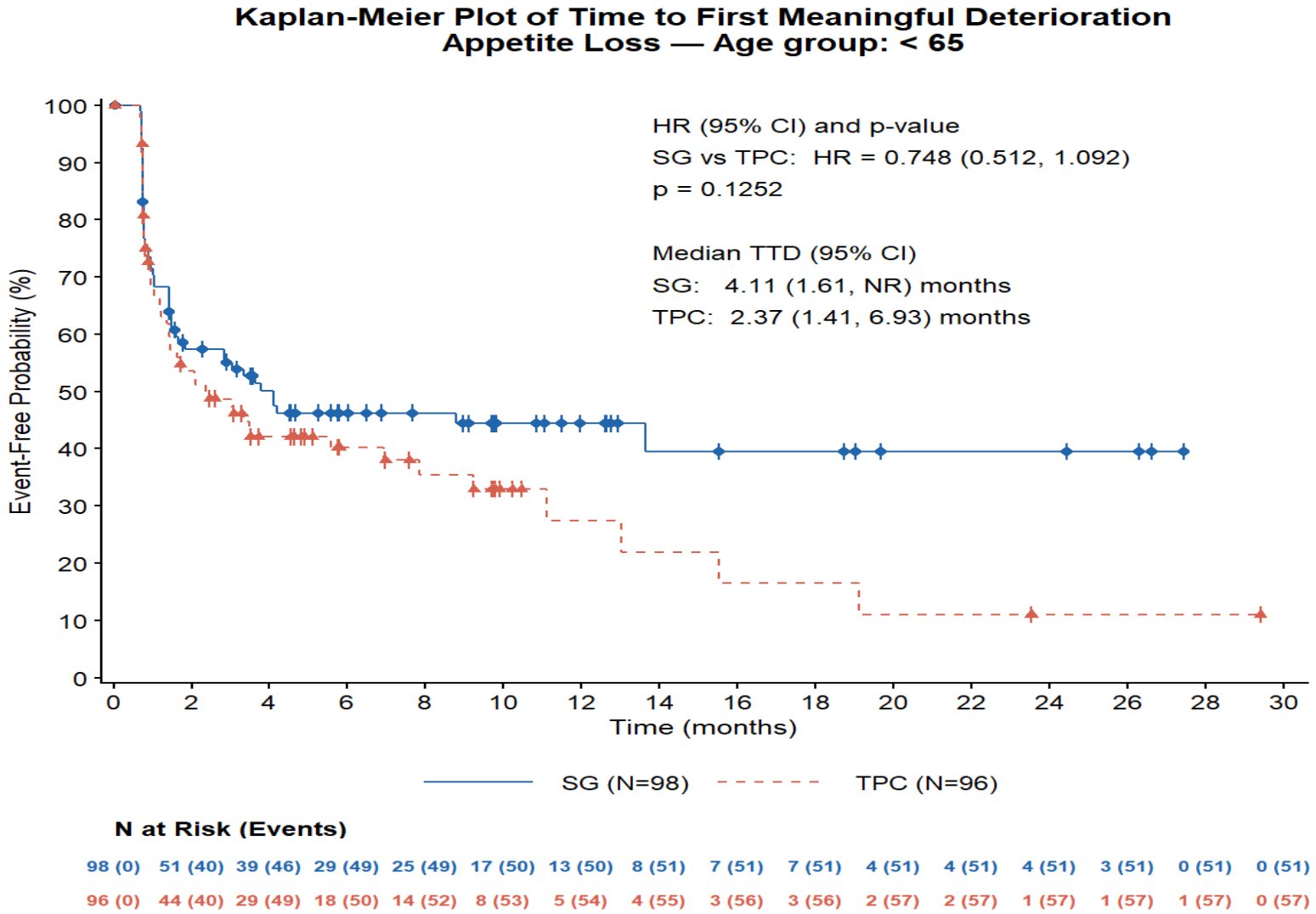
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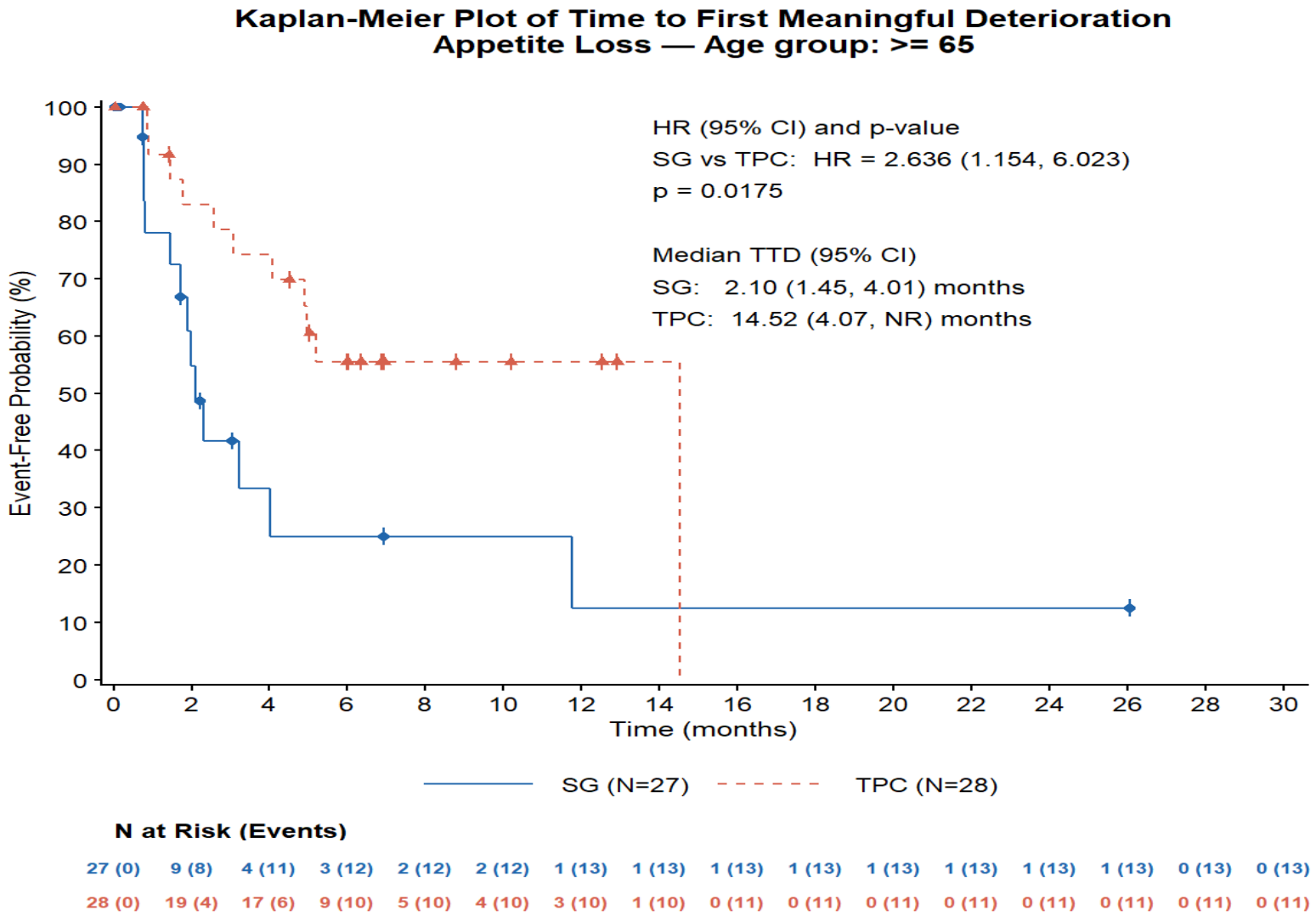
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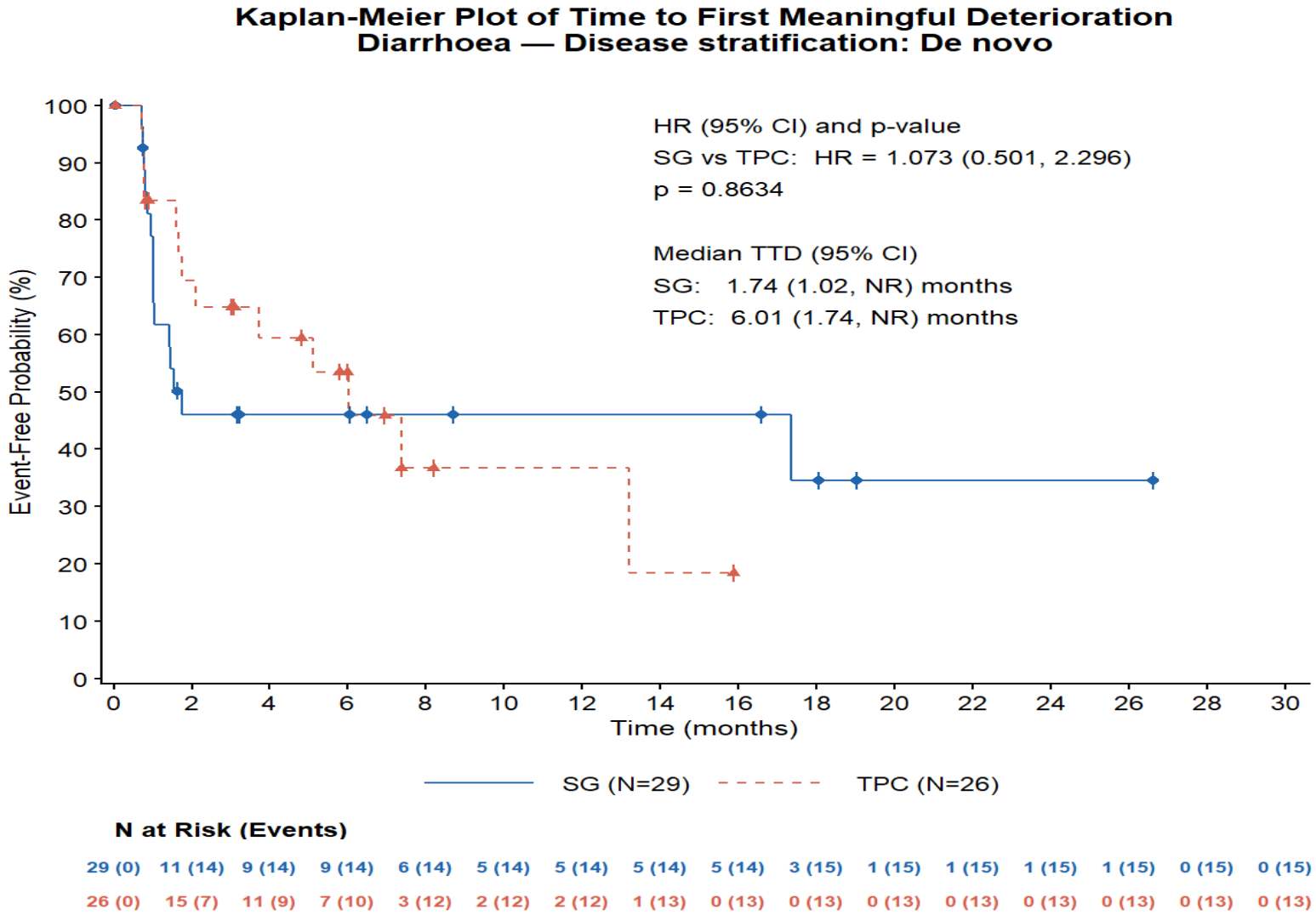
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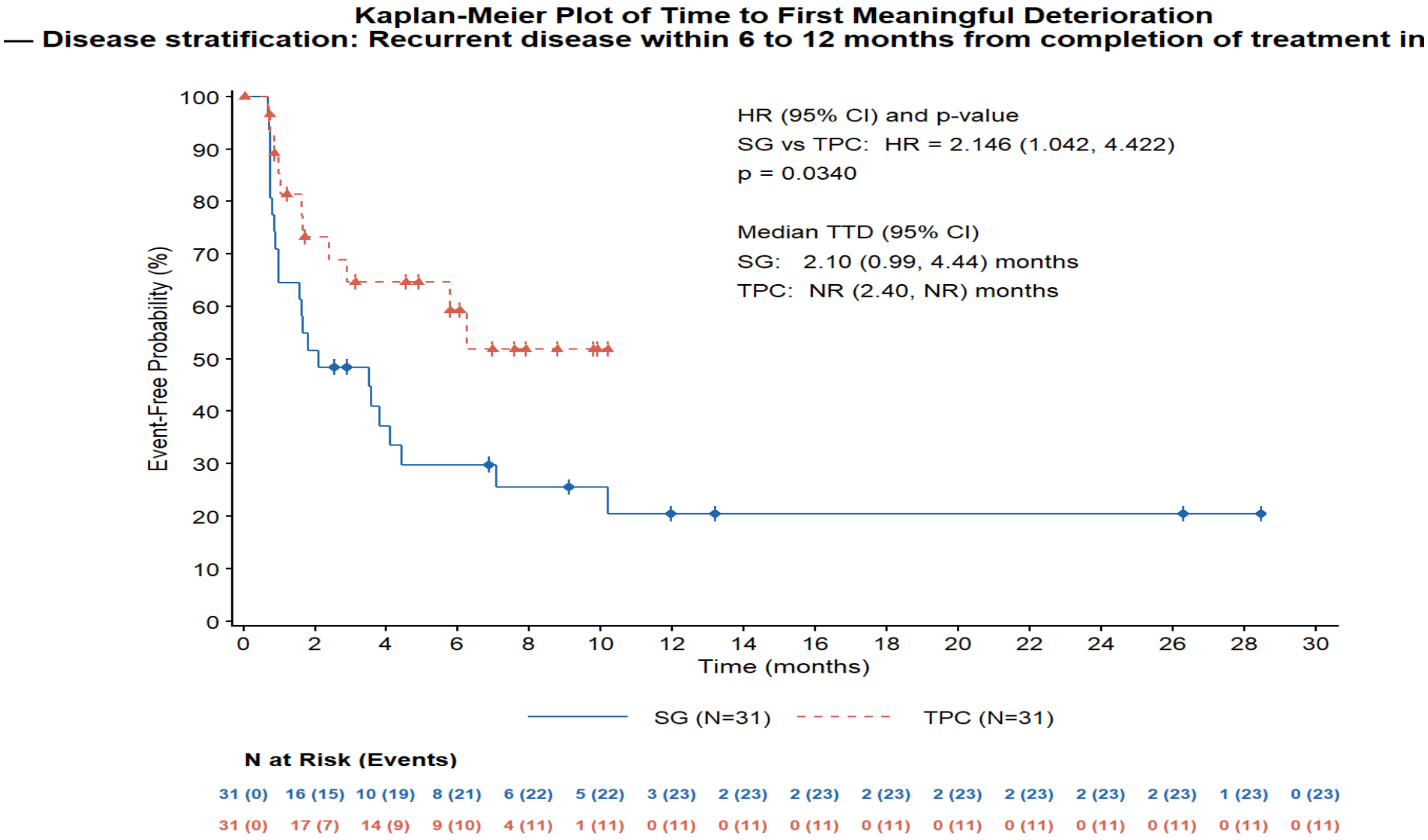
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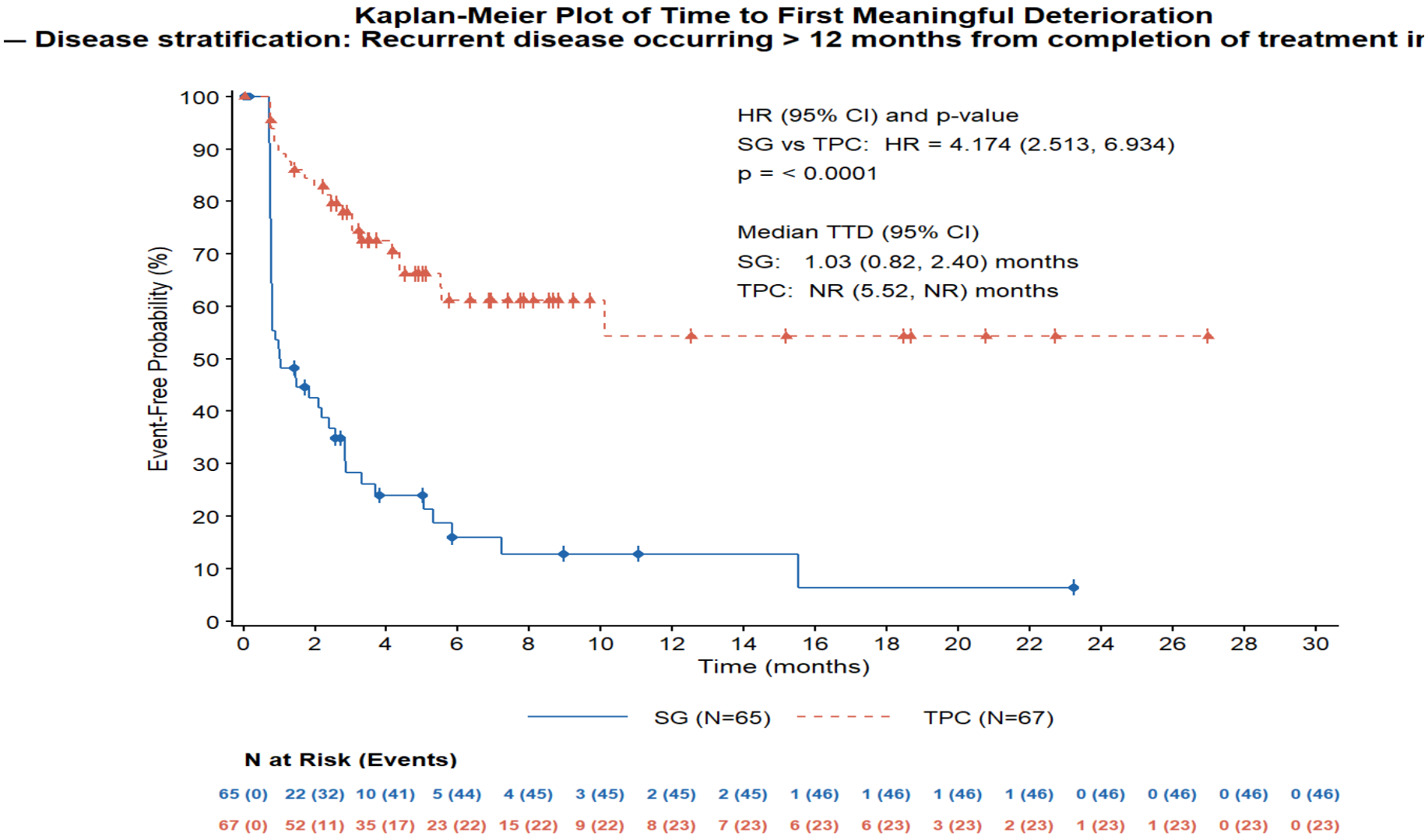
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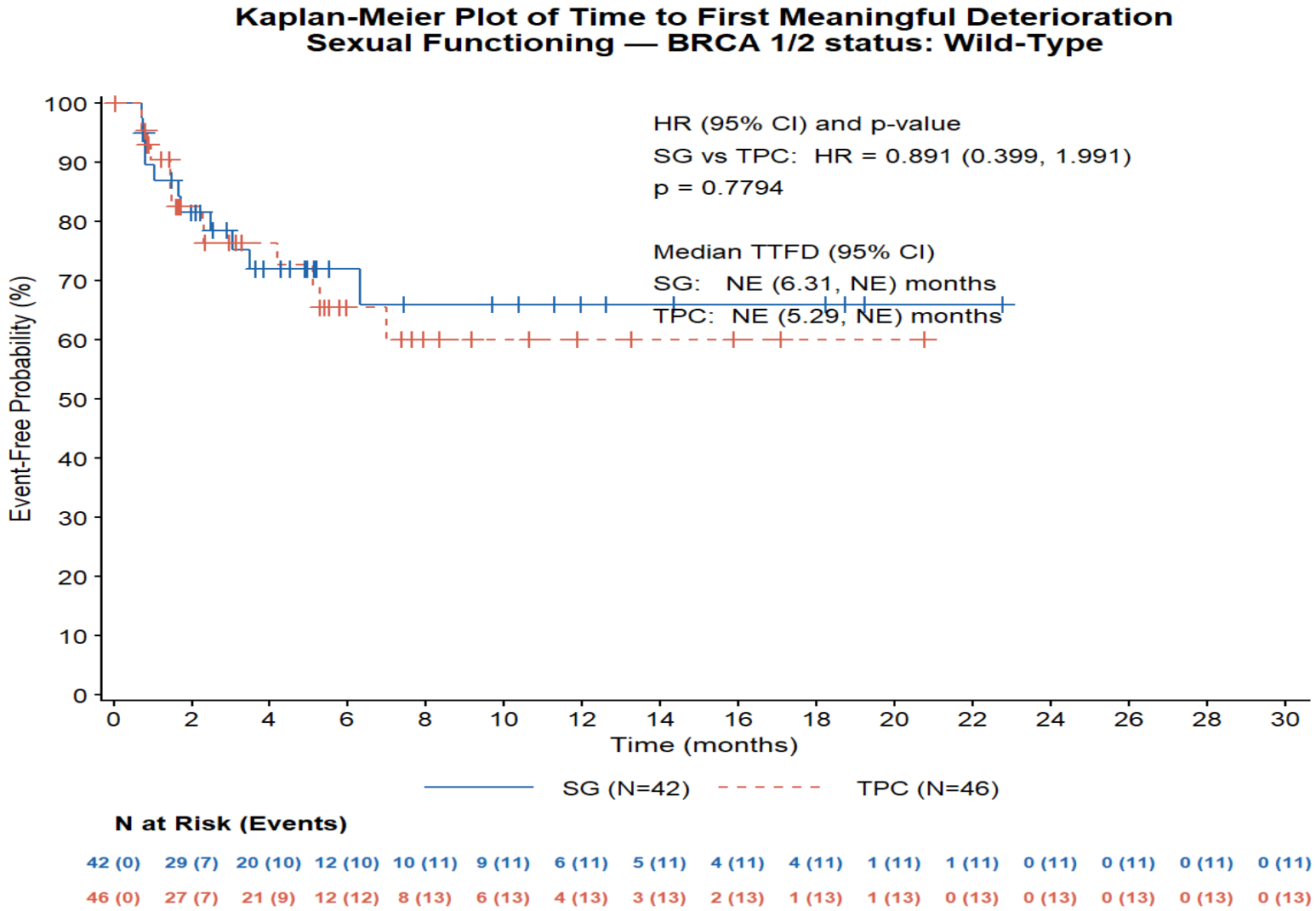
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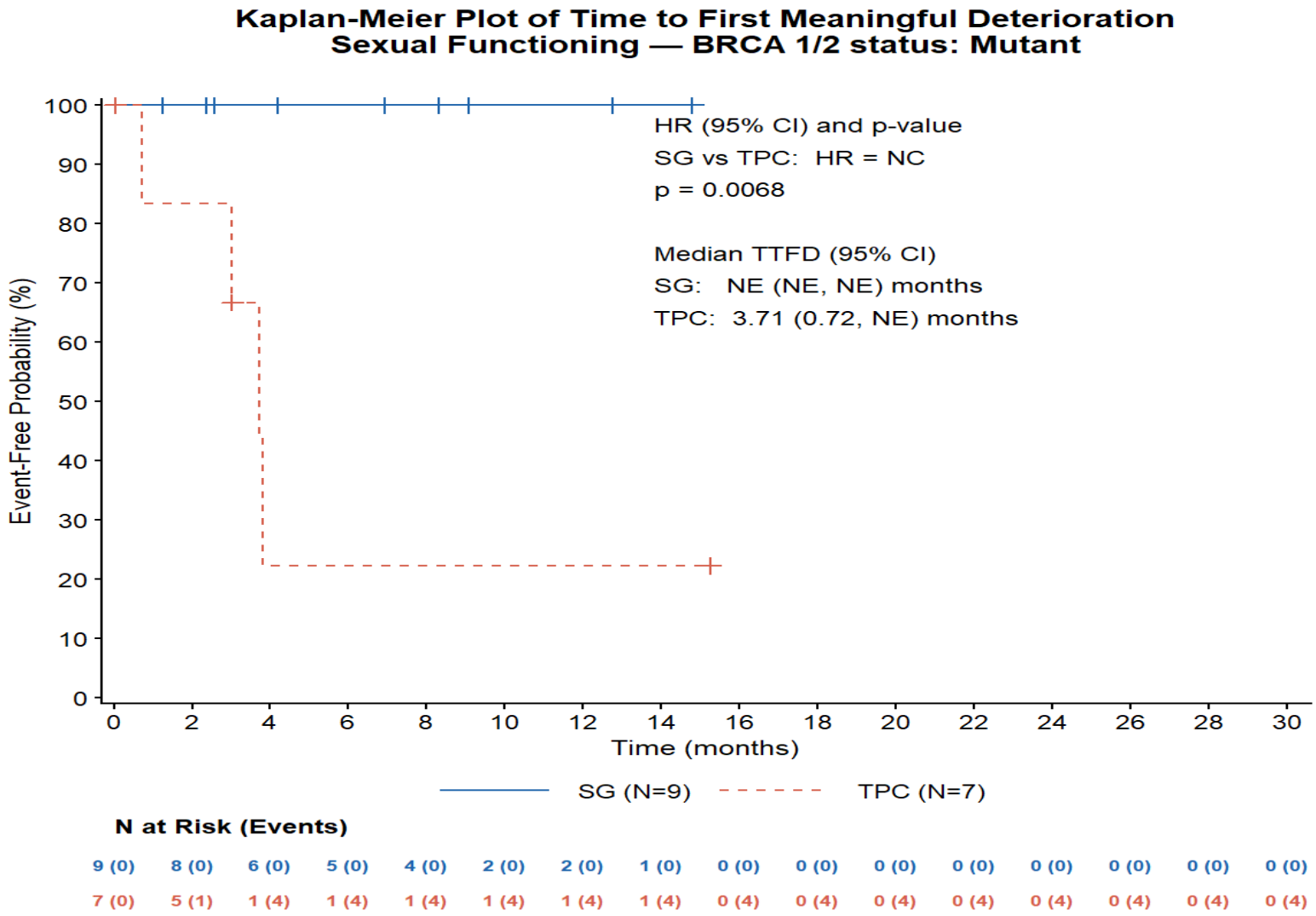
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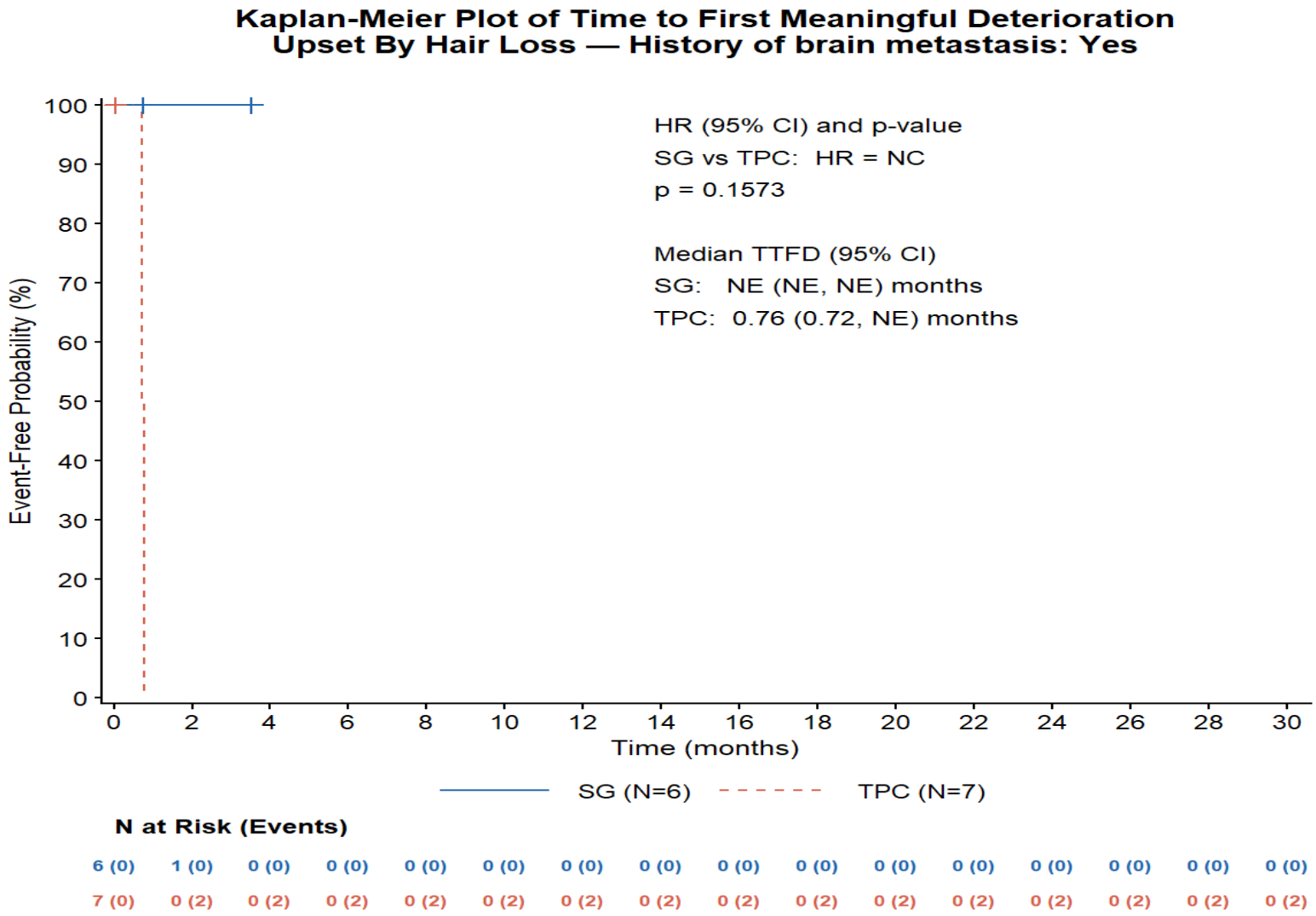
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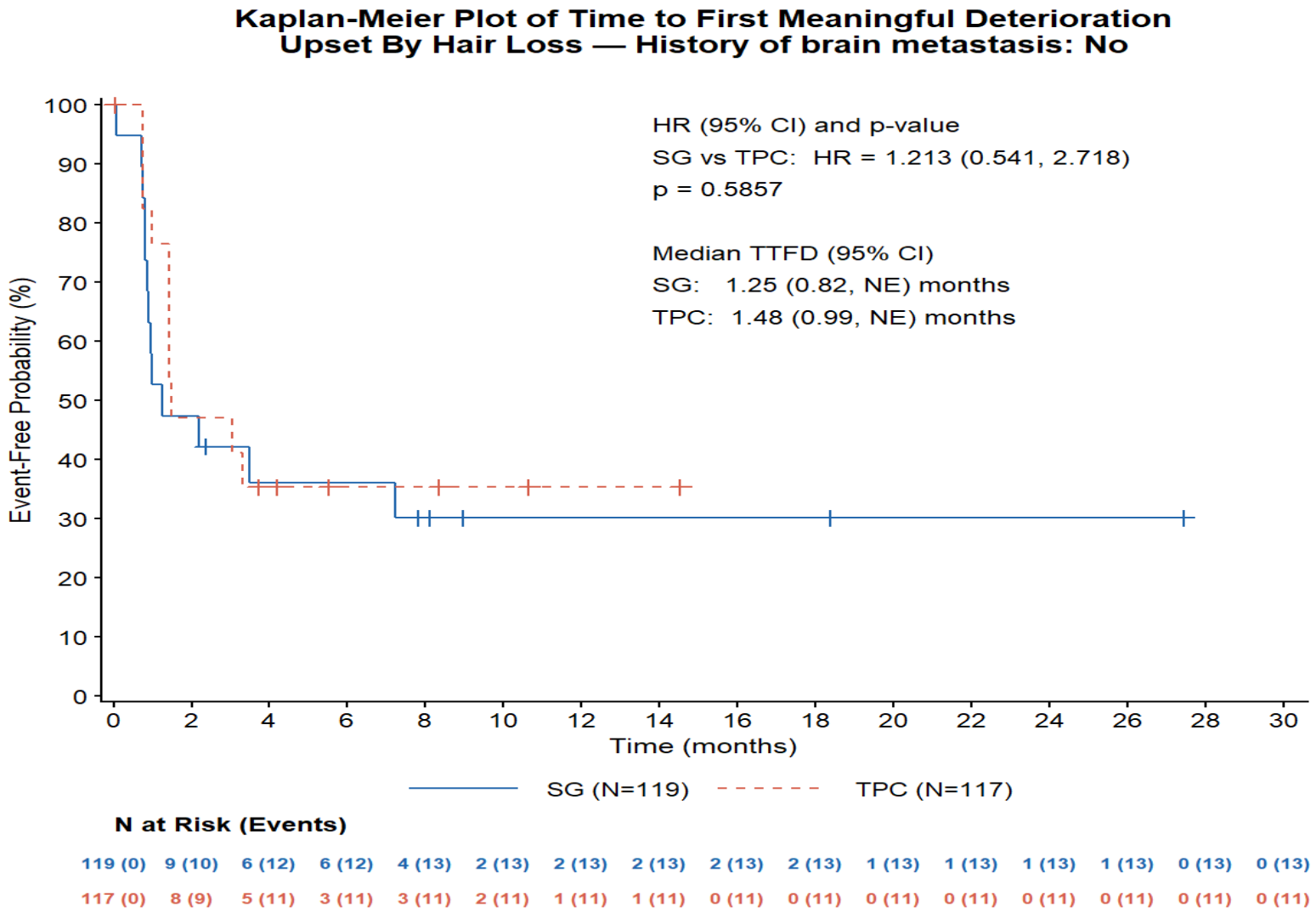
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1. Statistical Analysis for German Submission of ASCENT-03

2. TFLs

Population: Triple-negative breast cancer (mTNBC)

Sub-Populations:
— Excluding patients preselected to receive nab-paclitaxel

Data Cut Date: 22 APR 2026

Version 1.0

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4.1. Table 1.1.1.1: — Observation Period (Months) — EORTC QLQ-C30 — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
N	176	167	343
Mean (SD)	10.7 (8.82)	8.1 (6.83)	9.4 (8.01)
95% CI	9.4, 12.0	7.0, 9.1	8.6, 10.3
Median	8.1	6.1	6.9
Q1, Q3	4.2, 17.7	3.7, 9.9	4.1, 12.9
Min, Max	0.0, 40.7	0.0, 33.4	0.0, 40.7

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.2. Table 1.1.1.2: — Observation Period (Months) — EORTC QLQ-BR23 — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
N	175	167	342
Mean (SD)	10.7 (8.79)	8.0 (6.85)	9.4 (8.00)
95% CI	9.4, 12.0	7.0, 9.1	8.5, 10.2
Median	7.9	6.1	6.9
Q1, Q3	4.2, 17.1	3.7, 9.9	4.1, 12.8
Min, Max	0.0, 40.7	0.0, 33.4	0.0, 40.7

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.3. Table 1.1.1.3: — Observation Period (Months) — EQ-5D-5L-VAS — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
N	175	167	342
Mean (SD)	10.8 (8.80)	8.0 (6.85)	9.4 (8.02)
95% CI	9.5, 12.1	7.0, 9.1	8.6, 10.3
Median	8.5	6.1	6.9
Q1, Q3	4.3, 17.8	3.7, 9.9	4.1, 12.9
Min, Max	0.0, 40.7	0.0, 33.4	0.0, 40.7

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; VAS = Visual analogue scale; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.4. Table 1.1.1.5: — Observation Period (Months) — PGI-Change — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
N	136	133	269
Mean (SD)	6.9 (5.31)	6.1 (3.57)	6.5 (4.54)
95% CI	6.0, 7.8	5.5, 6.7	6.0, 7.1
Median	5.7	5.6	5.7
Q1, Q3	5.3, 6.3	4.9, 6.3	5.1, 6.3
Min, Max	1.2, 37.3	0.0, 30.9	0.0, 37.3

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.5. Table 1.1.1.6: — Observation Period (Months) — PGI-Severity — mITT — Excluding patients preselected to receive nab-paclitaxel

Statistic	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
N	171	166	337
Mean (SD)	5.5 (5.50)	4.9 (4.03)	5.2 (4.83)
95% CI	4.7, 6.3	4.3, 5.5	4.7, 5.7
Median	5.6	5.5	5.6
Q1, Q3	3.7, 6.0	3.0, 6.2	3.5, 6.1
Min, Max	0.0, 37.3	0.0, 30.9	0.0, 37.3

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Observation period is defined as time from start of treatment until final study visit and shortened to date of last questionnaire completion if occured earlier.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Data Cut off : 22 APR 2026

4.6. Table 1.1.3.1: — Summary of Available Data Rates of EORTC QLQ-C30 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	173/177 (97.7%)	165/169 (97.6%)	338/346 (97.7%)
Week 4	144/177 (81.4%)	140/169 (82.8%)	284/346 (82.1%)
Week 7	139/177 (78.5%)	103/169 (60.9%)	242/346 (69.9%)
Week 10	130/177 (73.4%)	122/169 (72.2%)	252/346 (72.8%)
Week 13	119/177 (67.2%)	118/169 (69.8%)	237/346 (68.5%)
Week 16	118/177 (66.7%)	92/169 (54.4%)	210/346 (60.7%)
Week 19	116/177 (65.5%)	90/169 (53.3%)	206/346 (59.5%)
Week 22	102/177 (57.6%)	88/169 (52.1%)	190/346 (54.9%)
Week 25	93/177 (52.5%)	75/169 (44.4%)	168/346 (48.6%)
Week 28	90/177 (50.8%)	62/169 (36.7%)	152/346 (43.9%)
Week 31	86/177 (48.6%)	43/169 (25.4%)	129/346 (37.3%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 34	78/177 (44.1%)	54/169 (32.0%)	132/346 (38.2%)
Week 37	75/177 (42.4%)	41/169 (24.3%)	116/346 (33.5%)
Week 40	68/177 (38.4%)	36/169 (21.3%)	104/346 (30.1%)
Week 43	57/177 (32.2%)	32/169 (18.9%)	89/346 (25.7%)
Week 46	63/177 (35.6%)	28/169 (16.6%)	91/346 (26.3%)
Week 49	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 52	50/177 (28.2%)	26/169 (15.4%)	76/346 (22.0%)
Week 55	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 58	49/177 (27.7%)	21/169 (12.4%)	70/346 (20.2%)
Week 61	42/177 (23.7%)	20/169 (11.8%)	62/346 (17.9%)
Week 64	42/177 (23.7%)	20/169 (11.8%)	62/346 (17.9%)
Week 67	43/177 (24.3%)	15/169 (8.9%)	58/346 (16.8%)
Week 70	44/177 (24.9%)	14/169 (8.3%)	58/346 (16.8%)
Week 73	42/177 (23.7%)	15/169 (8.9%)	57/346 (16.5%)
Week 76	37/177 (20.9%)	13/169 (7.7%)	50/346 (14.5%)
Week 79	34/177 (19.2%)	10/169 (5.9%)	44/346 (12.7%)
Week 82	32/177 (18.1%)	9/169 (5.3%)	41/346 (11.8%)
Week 85	26/177 (14.7%)	8/169 (4.7%)	34/346 (9.8%)
Week 88	24/177 (13.6%)	9/169 (5.3%)	33/346 (9.5%)
Week 91	23/177 (13.0%)	7/169 (4.1%)	30/346 (8.7%)
Week 94	23/177 (13.0%)	7/169 (4.1%)	30/346 (8.7%)
Week 97	22/177 (12.4%)	9/169 (5.3%)	31/346 (9.0%)
Week 100	20/177 (11.3%)	7/169 (4.1%)	27/346 (7.8%)
Week 103	16/177 (9.0%)	6/169 (3.6%)	22/346 (6.4%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 106	15/177 (8.5%)	6/169 (3.6%)	21/346 (6.1%)
Week 109	12/177 (6.8%)	6/169 (3.6%)	18/346 (5.2%)
Week 112	9/177 (5.1%)	6/169 (3.6%)	15/346 (4.3%)
Week 115	12/177 (6.8%)	5/169 (3.0%)	17/346 (4.9%)
Week 118	6/177 (3.4%)	6/169 (3.6%)	12/346 (3.5%)
Week 121	6/177 (3.4%)	4/169 (2.4%)	10/346 (2.9%)
Week 124	5/177 (2.8%)	5/169 (3.0%)	10/346 (2.9%)
Week 127	2/177 (1.1%)	3/169 (1.8%)	5/346 (1.4%)
Week 130	1/177 (0.6%)	2/169 (1.2%)	3/346 (0.9%)
Week 133	2/177 (1.1%)	2/169 (1.2%)	4/346 (1.2%)
Week 136	5/177 (2.8%)	1/169 (0.6%)	6/346 (1.7%)
Week 139	2/177 (1.1%)	2/169 (1.2%)	4/346 (1.2%)
Week 142	3/177 (1.7%)	1/169 (0.6%)	4/346 (1.2%)
Week 145	2/177 (1.1%)	1/169 (0.6%)	3/346 (0.9%)
Week 148	2/177 (1.1%)	1/169 (0.6%)	3/346 (0.9%)
Week 151	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 154	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 157	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 160	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 163	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 166	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 169	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 172	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 175	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 178	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
End of Treatment	104/177 (58.8%)	116/169 (68.6%)	220/346 (63.6%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.7. Table 1.1.3.2: — Summary of Available Data Rates of EORTC QLQ-BR23 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	172/177 (97.2%)	165/169 (97.6%)	337/346 (97.4%)
Week 4	142/177 (80.2%)	138/169 (81.7%)	280/346 (80.9%)
Week 7	137/177 (77.4%)	101/169 (59.8%)	238/346 (68.8%)
Week 10	127/177 (71.8%)	121/169 (71.6%)	248/346 (71.7%)
Week 13	118/177 (66.7%)	117/169 (69.2%)	235/346 (67.9%)
Week 16	118/177 (66.7%)	91/169 (53.8%)	209/346 (60.4%)
Week 19	116/177 (65.5%)	90/169 (53.3%)	206/346 (59.5%)
Week 22	101/177 (57.1%)	87/169 (51.5%)	188/346 (54.3%)
Week 25	93/177 (52.5%)	75/169 (44.4%)	168/346 (48.6%)
Week 28	90/177 (50.8%)	62/169 (36.7%)	152/346 (43.9%)
Week 31	85/177 (48.0%)	43/169 (25.4%)	128/346 (37.0%)
Week 34	76/177 (42.9%)	53/169 (31.4%)	129/346 (37.3%)
Week 37	74/177 (41.8%)	41/169 (24.3%)	115/346 (33.2%)
Week 40	67/177 (37.9%)	36/169 (21.3%)	103/346 (29.8%)
Week 43	56/177 (31.6%)	32/169 (18.9%)	88/346 (25.4%)
Week 46	62/177 (35.0%)	28/169 (16.6%)	90/346 (26.0%)
Week 49	50/177 (28.2%)	22/169 (13.0%)	72/346 (20.8%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 52	50/177 (28.2%)	26/169 (15.4%)	76/346 (22.0%)
Week 55	50/177 (28.2%)	22/169 (13.0%)	72/346 (20.8%)
Week 58	48/177 (27.1%)	21/169 (12.4%)	69/346 (19.9%)
Week 61	41/177 (23.2%)	20/169 (11.8%)	61/346 (17.6%)
Week 64	41/177 (23.2%)	20/169 (11.8%)	61/346 (17.6%)
Week 67	42/177 (23.7%)	15/169 (8.9%)	57/346 (16.5%)
Week 70	44/177 (24.9%)	14/169 (8.3%)	58/346 (16.8%)
Week 73	41/177 (23.2%)	15/169 (8.9%)	56/346 (16.2%)
Week 76	36/177 (20.3%)	13/169 (7.7%)	49/346 (14.2%)
Week 79	33/177 (18.6%)	10/169 (5.9%)	43/346 (12.4%)
Week 82	31/177 (17.5%)	9/169 (5.3%)	40/346 (11.6%)
Week 85	25/177 (14.1%)	8/169 (4.7%)	33/346 (9.5%)
Week 88	23/177 (13.0%)	9/169 (5.3%)	32/346 (9.2%)
Week 91	22/177 (12.4%)	7/169 (4.1%)	29/346 (8.4%)
Week 94	23/177 (13.0%)	7/169 (4.1%)	30/346 (8.7%)
Week 97	21/177 (11.9%)	9/169 (5.3%)	30/346 (8.7%)
Week 100	20/177 (11.3%)	7/169 (4.1%)	27/346 (7.8%)
Week 103	16/177 (9.0%)	6/169 (3.6%)	22/346 (6.4%)
Week 106	15/177 (8.5%)	6/169 (3.6%)	21/346 (6.1%)
Week 109	12/177 (6.8%)	6/169 (3.6%)	18/346 (5.2%)
Week 112	9/177 (5.1%)	6/169 (3.6%)	15/346 (4.3%)
Week 115	12/177 (6.8%)	5/169 (3.0%)	17/346 (4.9%)
Week 118	6/177 (3.4%)	6/169 (3.6%)	12/346 (3.5%)
Week 121	6/177 (3.4%)	4/169 (2.4%)	10/346 (2.9%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 124	5/177 (2.8%)	5/169 (3.0%)	10/346 (2.9%)
Week 127	2/177 (1.1%)	3/169 (1.8%)	5/346 (1.4%)
Week 130	1/177 (0.6%)	2/169 (1.2%)	3/346 (0.9%)
Week 133	2/177 (1.1%)	2/169 (1.2%)	4/346 (1.2%)
Week 136	5/177 (2.8%)	1/169 (0.6%)	6/346 (1.7%)
Week 139	2/177 (1.1%)	2/169 (1.2%)	4/346 (1.2%)
Week 142	3/177 (1.7%)	1/169 (0.6%)	4/346 (1.2%)
Week 145	2/177 (1.1%)	1/169 (0.6%)	3/346 (0.9%)
Week 148	2/177 (1.1%)	1/169 (0.6%)	3/346 (0.9%)
Week 151	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 154	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 157	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 160	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 163	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 166	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 169	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 172	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 175	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 178	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
End of Treatment	104/177 (58.8%)	114/169 (67.5%)	218/346 (63.0%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.8. Table 1.1.3.3: — Summary of Available Data Rates of EQ-5D-VAS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	171/177 (96.6%)	164/169 (97.0%)	335/346 (96.8%)
Week 4	142/177 (80.2%)	136/169 (80.5%)	278/346 (80.3%)
Week 7	137/177 (77.4%)	101/169 (59.8%)	238/346 (68.8%)
Week 10	127/177 (71.8%)	121/169 (71.6%)	248/346 (71.7%)
Week 13	118/177 (66.7%)	117/169 (69.2%)	235/346 (67.9%)
Week 16	118/177 (66.7%)	91/169 (53.8%)	209/346 (60.4%)
Week 19	116/177 (65.5%)	90/169 (53.3%)	206/346 (59.5%)
Week 22	101/177 (57.1%)	87/169 (51.5%)	188/346 (54.3%)
Week 25	93/177 (52.5%)	75/169 (44.4%)	168/346 (48.6%)
Week 28	90/177 (50.8%)	62/169 (36.7%)	152/346 (43.9%)
Week 31	86/177 (48.6%)	43/169 (25.4%)	129/346 (37.3%)
Week 34	77/177 (43.5%)	53/169 (31.4%)	130/346 (37.6%)
Week 37	75/177 (42.4%)	41/169 (24.3%)	116/346 (33.5%)
Week 40	68/177 (38.4%)	36/169 (21.3%)	104/346 (30.1%)
Week 43	57/177 (32.2%)	32/169 (18.9%)	89/346 (25.7%)
Week 46	63/177 (35.6%)	28/169 (16.6%)	91/346 (26.3%)
Week 49	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 52	50/177 (28.2%)	26/169 (15.4%)	76/346 (22.0%)
Week 55	51/177 (28.8%)	22/169 (13.0%)	73/346 (21.1%)
Week 58	49/177 (27.7%)	21/169 (12.4%)	70/346 (20.2%)
Week 61	42/177 (23.7%)	20/169 (11.8%)	62/346 (17.9%)
Week 64	42/177 (23.7%)	20/169 (11.8%)	62/346 (17.9%)
Week 67	43/177 (24.3%)	15/169 (8.9%)	58/346 (16.8%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 70	44/177 (24.9%)	14/169 (8.3%)	58/346 (16.8%)
Week 73	42/177 (23.7%)	15/169 (8.9%)	57/346 (16.5%)
Week 76	37/177 (20.9%)	13/169 (7.7%)	50/346 (14.5%)
Week 79	34/177 (19.2%)	10/169 (5.9%)	44/346 (12.7%)
Week 82	32/177 (18.1%)	9/169 (5.3%)	41/346 (11.8%)
Week 85	26/177 (14.7%)	8/169 (4.7%)	34/346 (9.8%)
Week 88	24/177 (13.6%)	9/169 (5.3%)	33/346 (9.5%)
Week 91	23/177 (13.0%)	7/169 (4.1%)	30/346 (8.7%)
Week 94	23/177 (13.0%)	7/169 (4.1%)	30/346 (8.7%)
Week 97	22/177 (12.4%)	9/169 (5.3%)	31/346 (9.0%)
Week 100	20/177 (11.3%)	7/169 (4.1%)	27/346 (7.8%)
Week 103	16/177 (9.0%)	6/169 (3.6%)	22/346 (6.4%)
Week 106	15/177 (8.5%)	6/169 (3.6%)	21/346 (6.1%)
Week 109	12/177 (6.8%)	6/169 (3.6%)	18/346 (5.2%)
Week 112	9/177 (5.1%)	6/169 (3.6%)	15/346 (4.3%)
Week 115	12/177 (6.8%)	5/169 (3.0%)	17/346 (4.9%)
Week 118	6/177 (3.4%)	6/169 (3.6%)	12/346 (3.5%)
Week 121	6/177 (3.4%)	4/169 (2.4%)	10/346 (2.9%)
Week 124	5/177 (2.8%)	5/169 (3.0%)	10/346 (2.9%)
Week 127	2/177 (1.1%)	3/169 (1.8%)	5/346 (1.4%)
Week 130	1/177 (0.6%)	2/169 (1.2%)	3/346 (0.9%)
Week 133	2/177 (1.1%)	2/169 (1.2%)	4/346 (1.2%)
Week 136	5/177 (2.8%)	1/169 (0.6%)	6/346 (1.7%)
Week 139	2/177 (1.1%)	2/169 (1.2%)	4/346 (1.2%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 142	3/177 (1.7%)	1/169 (0.6%)	4/346 (1.2%)
Week 145	2/177 (1.1%)	1/169 (0.6%)	3/346 (0.9%)
Week 148	2/177 (1.1%)	1/169 (0.6%)	3/346 (0.9%)
Week 151	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 154	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 157	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 160	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 163	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 166	2/177 (1.1%)	0/169 (0.0%)	2/346 (0.6%)
Week 169	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 172	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 175	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
Week 178	1/177 (0.6%)	0/169 (0.0%)	1/346 (0.3%)
End of Treatment	103/177 (58.2%)	114/169 (67.5%)	217/346 (62.7%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.9. Table 1.1.3.5: — Summary of Available Data Rates of PGIS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	166/177 (93.8%)	162/169 (95.9%)	328/346 (94.8%)
Week 13	84/177 (47.5%)	85/169 (50.3%)	169/346 (48.8%)
Week 16	114/177 (64.4%)	87/169 (51.5%)	201/346 (58.1%)
Week 19	115/177 (65.0%)	86/169 (50.9%)	201/346 (58.1%)
Week 22	101/177 (57.1%)	86/169 (50.9%)	187/346 (54.0%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 25	93/177 (52.5%)	74/169 (43.8%)	167/346 (48.3%)
Week 28	47/177 (26.6%)	43/169 (25.4%)	90/346 (26.0%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.10. Table 1.1.3.6: — Summary of Available Data Rates of PGIC by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 13	84/177 (47.5%)	85/169 (50.3%)	169/346 (48.8%)
Week 16	114/177 (64.4%)	87/169 (51.5%)	201/346 (58.1%)
Week 19	115/177 (65.0%)	86/169 (50.9%)	201/346 (58.1%)
Week 22	101/177 (57.1%)	86/169 (50.9%)	187/346 (54.0%)
Week 25	93/177 (52.5%)	74/169 (43.8%)	167/346 (48.3%)
Week 28	47/177 (26.6%)	43/169 (25.4%)	90/346 (26.0%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set.
Data cut off: 22 APR 2026

4.11. Table 1.1.4.1: — Summary of Modified Available Data Rates of EORTC QLQ-C30 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	173/177 (97.7%)	165/169 (97.6%)	338/346 (97.7%)
Week 4	144/174 (82.8%)	140/168 (83.3%)	284/342 (83.0%)
Week 7	139/171 (81.3%)	103/167 (61.7%)	242/338 (71.6%)
Week 10	130/170 (76.5%)	122/166 (73.5%)	252/336 (75.0%)
Week 13	119/170 (70.0%)	118/164 (72.0%)	237/334 (71.0%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 16	118/167 (70.7%)	92/163 (56.4%)	210/330 (63.6%)
Week 19	116/163 (71.2%)	90/158 (57.0%)	206/321 (64.2%)
Week 22	102/158 (64.6%)	88/156 (56.4%)	190/314 (60.5%)
Week 25	93/157 (59.2%)	75/152 (49.3%)	168/309 (54.4%)
Week 28	90/154 (58.4%)	62/151 (41.1%)	152/305 (49.8%)
Week 31	86/153 (56.2%)	43/147 (29.3%)	129/300 (43.0%)
Week 34	78/151 (51.7%)	54/144 (37.5%)	132/295 (44.7%)
Week 37	75/150 (50.0%)	41/143 (28.7%)	116/293 (39.6%)
Week 40	68/148 (45.9%)	36/142 (25.4%)	104/290 (35.9%)
Week 43	57/147 (38.8%)	32/138 (23.2%)	89/285 (31.2%)
Week 46	63/144 (43.8%)	28/137 (20.4%)	91/281 (32.4%)
Week 49	51/141 (36.2%)	22/132 (16.7%)	73/273 (26.7%)
Week 52	50/135 (37.0%)	26/127 (20.5%)	76/262 (29.0%)
Week 55	51/133 (38.3%)	22/124 (17.7%)	73/257 (28.4%)
Week 58	49/129 (38.0%)	21/121 (17.4%)	70/250 (28.0%)
Week 61	42/125 (33.6%)	20/117 (17.1%)	62/242 (25.6%)
Week 64	42/125 (33.6%)	20/114 (17.5%)	62/239 (25.9%)
Week 67	43/122 (35.2%)	15/109 (13.8%)	58/231 (25.1%)
Week 70	44/117 (37.6%)	14/105 (13.3%)	58/222 (26.1%)
Week 73	42/112 (37.5%)	15/102 (14.7%)	57/214 (26.6%)
Week 76	37/110 (33.6%)	13/100 (13.0%)	50/210 (23.8%)
Week 79	34/103 (33.0%)	10/97 (10.3%)	44/200 (22.0%)
Week 82	32/99 (32.3%)	9/93 (9.7%)	41/192 (21.4%)
Week 85	26/94 (27.7%)	8/91 (8.8%)	34/185 (18.4%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 88	24/94 (25.5%)	9/84 (10.7%)	33/178 (18.5%)
Week 91	23/91 (25.3%)	7/82 (8.5%)	30/173 (17.3%)
Week 94	23/87 (26.4%)	7/77 (9.1%)	30/164 (18.3%)
Week 97	22/85 (25.9%)	9/75 (12.0%)	31/160 (19.4%)
Week 100	20/84 (23.8%)	7/72 (9.7%)	27/156 (17.3%)
Week 103	16/81 (19.8%)	6/69 (8.7%)	22/150 (14.7%)
Week 106	15/79 (19.0%)	6/69 (8.7%)	21/148 (14.2%)
Week 109	12/79 (15.2%)	6/66 (9.1%)	18/145 (12.4%)
Week 112	9/76 (11.8%)	6/64 (9.4%)	15/140 (10.7%)
Week 115	12/75 (16.0%)	5/64 (7.8%)	17/139 (12.2%)
Week 118	6/73 (8.2%)	6/62 (9.7%)	12/135 (8.9%)
Week 121	6/73 (8.2%)	4/60 (6.7%)	10/133 (7.5%)
Week 124	5/72 (6.9%)	5/59 (8.5%)	10/131 (7.6%)
Week 127	2/70 (2.9%)	3/56 (5.4%)	5/126 (4.0%)
Week 130	1/69 (1.4%)	2/54 (3.7%)	3/123 (2.4%)
Week 133	2/69 (2.9%)	2/54 (3.7%)	4/123 (3.3%)
Week 136	5/69 (7.2%)	1/54 (1.9%)	6/123 (4.9%)
Week 139	2/69 (2.9%)	2/54 (3.7%)	4/123 (3.3%)
Week 142	3/69 (4.3%)	1/54 (1.9%)	4/123 (3.3%)
Week 145	2/67 (3.0%)	1/54 (1.9%)	3/121 (2.5%)
Week 148	2/67 (3.0%)	1/53 (1.9%)	3/120 (2.5%)
Week 151	2/67 (3.0%)	0/53 (0.0%)	2/120 (1.7%)
Week 154	2/67 (3.0%)	0/52 (0.0%)	2/119 (1.7%)
Week 157	2/67 (3.0%)	0/52 (0.0%)	2/119 (1.7%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 160	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 163	2/66 (3.0%)	0/52 (0.0%)	2/118 (1.7%)
Week 166	2/66 (3.0%)	0/52 (0.0%)	2/118 (1.7%)
Week 169	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 172	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 175	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 178	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
End of Treatment	104/147 (70.7%)	116/157 (73.9%)	220/304 (72.4%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.12. Table 1.1.4.2: — Summary of Modified Available Data Rates of EORTC QLQ-BR23 by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	172/177 (97.2%)	165/169 (97.6%)	337/346 (97.4%)
Week 4	142/174 (81.6%)	138/168 (82.1%)	280/342 (81.9%)
Week 7	137/171 (80.1%)	101/167 (60.5%)	238/338 (70.4%)
Week 10	127/170 (74.7%)	121/166 (72.9%)	248/336 (73.8%)
Week 13	118/170 (69.4%)	117/164 (71.3%)	235/334 (70.4%)
Week 16	118/167 (70.7%)	91/163 (55.8%)	209/330 (63.3%)
Week 19	116/163 (71.2%)	90/158 (57.0%)	206/321 (64.2%)
Week 22	101/158 (63.9%)	87/156 (55.8%)	188/314 (59.9%)
Week 25	93/157 (59.2%)	75/152 (49.3%)	168/309 (54.4%)
Week 28	90/154 (58.4%)	62/151 (41.1%)	152/305 (49.8%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 31	85/153 (55.6%)	43/147 (29.3%)	128/300 (42.7%)
Week 34	76/151 (50.3%)	53/144 (36.8%)	129/295 (43.7%)
Week 37	74/150 (49.3%)	41/143 (28.7%)	115/293 (39.2%)
Week 40	67/148 (45.3%)	36/142 (25.4%)	103/290 (35.5%)
Week 43	56/147 (38.1%)	32/138 (23.2%)	88/285 (30.9%)
Week 46	62/144 (43.1%)	28/137 (20.4%)	90/281 (32.0%)
Week 49	50/141 (35.5%)	22/132 (16.7%)	72/273 (26.4%)
Week 52	50/135 (37.0%)	26/127 (20.5%)	76/262 (29.0%)
Week 55	50/133 (37.6%)	22/124 (17.7%)	72/257 (28.0%)
Week 58	48/129 (37.2%)	21/121 (17.4%)	69/250 (27.6%)
Week 61	41/125 (32.8%)	20/117 (17.1%)	61/242 (25.2%)
Week 64	41/125 (32.8%)	20/114 (17.5%)	61/239 (25.5%)
Week 67	42/122 (34.4%)	15/109 (13.8%)	57/231 (24.7%)
Week 70	44/117 (37.6%)	14/105 (13.3%)	58/222 (26.1%)
Week 73	41/112 (36.6%)	15/102 (14.7%)	56/214 (26.2%)
Week 76	36/110 (32.7%)	13/100 (13.0%)	49/210 (23.3%)
Week 79	33/103 (32.0%)	10/97 (10.3%)	43/200 (21.5%)
Week 82	31/99 (31.3%)	9/93 (9.7%)	40/192 (20.8%)
Week 85	25/94 (26.6%)	8/91 (8.8%)	33/185 (17.8%)
Week 88	23/94 (24.5%)	9/84 (10.7%)	32/178 (18.0%)
Week 91	22/91 (24.2%)	7/82 (8.5%)	29/173 (16.8%)
Week 94	23/87 (26.4%)	7/77 (9.1%)	30/164 (18.3%)
Week 97	21/85 (24.7%)	9/75 (12.0%)	30/160 (18.8%)
Week 100	20/84 (23.8%)	7/72 (9.7%)	27/156 (17.3%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 103	16/81 (19.8%)	6/69 (8.7%)	22/150 (14.7%)
Week 106	15/79 (19.0%)	6/69 (8.7%)	21/148 (14.2%)
Week 109	12/79 (15.2%)	6/66 (9.1%)	18/145 (12.4%)
Week 112	9/76 (11.8%)	6/64 (9.4%)	15/140 (10.7%)
Week 115	12/75 (16.0%)	5/64 (7.8%)	17/139 (12.2%)
Week 118	6/73 (8.2%)	6/62 (9.7%)	12/135 (8.9%)
Week 121	6/73 (8.2%)	4/60 (6.7%)	10/133 (7.5%)
Week 124	5/72 (6.9%)	5/59 (8.5%)	10/131 (7.6%)
Week 127	2/70 (2.9%)	3/56 (5.4%)	5/126 (4.0%)
Week 130	1/69 (1.4%)	2/54 (3.7%)	3/123 (2.4%)
Week 133	2/69 (2.9%)	2/54 (3.7%)	4/123 (3.3%)
Week 136	5/69 (7.2%)	1/54 (1.9%)	6/123 (4.9%)
Week 139	2/69 (2.9%)	2/54 (3.7%)	4/123 (3.3%)
Week 142	3/69 (4.3%)	1/54 (1.9%)	4/123 (3.3%)
Week 145	2/67 (3.0%)	1/54 (1.9%)	3/121 (2.5%)
Week 148	2/67 (3.0%)	1/53 (1.9%)	3/120 (2.5%)
Week 151	2/67 (3.0%)	0/53 (0.0%)	2/120 (1.7%)
Week 154	2/67 (3.0%)	0/52 (0.0%)	2/119 (1.7%)
Week 157	2/67 (3.0%)	0/52 (0.0%)	2/119 (1.7%)
Week 160	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 163	2/66 (3.0%)	0/52 (0.0%)	2/118 (1.7%)
Week 166	2/66 (3.0%)	0/52 (0.0%)	2/118 (1.7%)
Week 169	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 172	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 175	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 178	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
End of Treatment	104/147 (70.7%)	114/157 (72.6%)	218/304 (71.7%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.13. Table 1.1.4.3: — Summary of Modified Available Data Rates of EQ-5D-VAS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	171/177 (96.6%)	164/169 (97.0%)	335/346 (96.8%)
Week 4	142/174 (81.6%)	136/168 (81.0%)	278/342 (81.3%)
Week 7	137/171 (80.1%)	101/167 (60.5%)	238/338 (70.4%)
Week 10	127/170 (74.7%)	121/166 (72.9%)	248/336 (73.8%)
Week 13	118/170 (69.4%)	117/164 (71.3%)	235/334 (70.4%)
Week 16	118/167 (70.7%)	91/163 (55.8%)	209/330 (63.3%)
Week 19	116/163 (71.2%)	90/158 (57.0%)	206/321 (64.2%)
Week 22	101/158 (63.9%)	87/156 (55.8%)	188/314 (59.9%)
Week 25	93/157 (59.2%)	75/152 (49.3%)	168/309 (54.4%)
Week 28	90/154 (58.4%)	62/151 (41.1%)	152/305 (49.8%)
Week 31	86/153 (56.2%)	43/147 (29.3%)	129/300 (43.0%)
Week 34	77/151 (51.0%)	53/144 (36.8%)	130/295 (44.1%)
Week 37	75/150 (50.0%)	41/143 (28.7%)	116/293 (39.6%)
Week 40	68/148 (45.9%)	36/142 (25.4%)	104/290 (35.9%)
Week 43	57/147 (38.8%)	32/138 (23.2%)	89/285 (31.2%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 46	63/144 (43.8%)	28/137 (20.4%)	91/281 (32.4%)
Week 49	51/141 (36.2%)	22/132 (16.7%)	73/273 (26.7%)
Week 52	50/135 (37.0%)	26/127 (20.5%)	76/262 (29.0%)
Week 55	51/133 (38.3%)	22/124 (17.7%)	73/257 (28.4%)
Week 58	49/129 (38.0%)	21/121 (17.4%)	70/250 (28.0%)
Week 61	42/125 (33.6%)	20/117 (17.1%)	62/242 (25.6%)
Week 64	42/125 (33.6%)	20/114 (17.5%)	62/239 (25.9%)
Week 67	43/122 (35.2%)	15/109 (13.8%)	58/231 (25.1%)
Week 70	44/117 (37.6%)	14/105 (13.3%)	58/222 (26.1%)
Week 73	42/112 (37.5%)	15/102 (14.7%)	57/214 (26.6%)
Week 76	37/110 (33.6%)	13/100 (13.0%)	50/210 (23.8%)
Week 79	34/103 (33.0%)	10/97 (10.3%)	44/200 (22.0%)
Week 82	32/99 (32.3%)	9/93 (9.7%)	41/192 (21.4%)
Week 85	26/94 (27.7%)	8/91 (8.8%)	34/185 (18.4%)
Week 88	24/94 (25.5%)	9/84 (10.7%)	33/178 (18.5%)
Week 91	23/91 (25.3%)	7/82 (8.5%)	30/173 (17.3%)
Week 94	23/87 (26.4%)	7/77 (9.1%)	30/164 (18.3%)
Week 97	22/85 (25.9%)	9/75 (12.0%)	31/160 (19.4%)
Week 100	20/84 (23.8%)	7/72 (9.7%)	27/156 (17.3%)
Week 103	16/81 (19.8%)	6/69 (8.7%)	22/150 (14.7%)
Week 106	15/79 (19.0%)	6/69 (8.7%)	21/148 (14.2%)
Week 109	12/79 (15.2%)	6/66 (9.1%)	18/145 (12.4%)
Week 112	9/76 (11.8%)	6/64 (9.4%)	15/140 (10.7%)
Week 115	12/75 (16.0%)	5/64 (7.8%)	17/139 (12.2%)

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 118	6/73 (8.2%)	6/62 (9.7%)	12/135 (8.9%)
Week 121	6/73 (8.2%)	4/60 (6.7%)	10/133 (7.5%)
Week 124	5/72 (6.9%)	5/59 (8.5%)	10/131 (7.6%)
Week 127	2/70 (2.9%)	3/56 (5.4%)	5/126 (4.0%)
Week 130	1/69 (1.4%)	2/54 (3.7%)	3/123 (2.4%)
Week 133	2/69 (2.9%)	2/54 (3.7%)	4/123 (3.3%)
Week 136	5/69 (7.2%)	1/54 (1.9%)	6/123 (4.9%)
Week 139	2/69 (2.9%)	2/54 (3.7%)	4/123 (3.3%)
Week 142	3/69 (4.3%)	1/54 (1.9%)	4/123 (3.3%)
Week 145	2/67 (3.0%)	1/54 (1.9%)	3/121 (2.5%)
Week 148	2/67 (3.0%)	1/53 (1.9%)	3/120 (2.5%)
Week 151	2/67 (3.0%)	0/53 (0.0%)	2/120 (1.7%)
Week 154	2/67 (3.0%)	0/52 (0.0%)	2/119 (1.7%)
Week 157	2/67 (3.0%)	0/52 (0.0%)	2/119 (1.7%)
Week 160	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 163	2/66 (3.0%)	0/52 (0.0%)	2/118 (1.7%)
Week 166	2/66 (3.0%)	0/52 (0.0%)	2/118 (1.7%)
Week 169	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 172	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 175	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
Week 178	1/66 (1.5%)	0/52 (0.0%)	1/118 (0.8%)
End of Treatment	103/147 (70.1%)	114/157 (72.6%)	217/304 (71.4%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.14. Table 1.1.4.5: — Summary of Modified Available Data Rates of PGIS by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Baseline (Week 1)	166/177 (93.8%)	162/169 (95.9%)	328/346 (94.8%)
Week 13	84/170 (49.4%)	85/164 (51.8%)	169/334 (50.6%)
Week 16	114/167 (68.3%)	87/163 (53.4%)	201/330 (60.9%)
Week 19	115/163 (70.6%)	86/158 (54.4%)	201/321 (62.6%)
Week 22	101/158 (63.9%)	86/156 (55.1%)	187/314 (59.6%)
Week 25	93/157 (59.2%)	74/152 (48.7%)	167/309 (54.0%)
Week 28	47/154 (30.5%)	43/151 (28.5%)	90/305 (29.5%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.15. Table 1.1.4.6: — Summary of Modified Available Data Rates of PGIC by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Visit	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
Week 13	84/170 (49.4%)	85/164 (51.8%)	169/334 (50.6%)
Week 16	114/167 (68.3%)	87/163 (53.4%)	201/330 (60.9%)
Week 19	115/163 (70.6%)	86/158 (54.4%)	201/321 (62.6%)
Week 22	101/158 (63.9%)	86/156 (55.1%)	187/314 (59.6%)
Week 25	93/157 (59.2%)	74/152 (48.7%)	167/309 (54.0%)
Week 28	47/154 (30.5%)	43/151 (28.5%)	90/305 (29.5%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
A modified available data rate is defined as the number of patients in the mITT Analysis Set submitting an evaluable PRO at a given timepoint over the number of patients in the mITT Analysis Set still alive at the corresponding timepoint
Data cut off: 22 APR 2026

4.16. Table 1.1.9: PGI-Change | Observed Scores and Change from Baseline by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Item	Visit	Response Level	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
PGIC	Week 13		N=84	N=85	N=169
		Very much improved	8 (9.5%)	11 (12.9%)	19 (11.2%)
		Much improved	28 (33.3%)	25 (29.4%)	53 (31.4%)
		Minimally improved	22 (26.2%)	23 (27.1%)	45 (26.6%)
		No change	15 (17.9%)	11 (12.9%)	26 (15.4%)
		Minimally worsened	9 (10.7%)	12 (14.1%)	21 (12.4%)
		Much worsened	2 (2.4%)	3 (3.5%)	5 (3.0%)
		Very much worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 16		N=114	N=87	N=201
		Very much improved	17 (14.9%)	9 (10.3%)	26 (12.9%)
		Much improved	31 (27.2%)	23 (26.4%)	54 (26.9%)
		Minimally improved	33 (28.9%)	21 (24.1%)	54 (26.9%)
		No change	15 (13.2%)	16 (18.4%)	31 (15.4%)
		Minimally worsened	14 (12.3%)	14 (16.1%)	28 (13.9%)
		Much worsened	4 (3.5%)	4 (4.6%)	8 (4.0%)
		Very much worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 19		N=115	N=86	N=201
		Very much improved	11 (9.6%)	8 (9.3%)	19 (9.5%)
		Much improved	34 (29.6%)	26 (30.2%)	60 (29.9%)
		Minimally improved	33 (28.7%)	23 (26.7%)	56 (27.9%)
		No change	21 (18.3%)	18 (20.9%)	39 (19.4%)
		Minimally worsened	12 (10.4%)	7 (8.1%)	19 (9.5%)
		Much worsened	4 (3.5%)	3 (3.5%)	7 (3.5%)

Item	Visit	Response Level	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
		Very much worsened	0 (0.0%)	1 (1.2%)	1 (0.5%)
	Week 22		N=101	N=86	N=187
		Very much improved	17 (16.8%)	10 (11.6%)	27 (14.4%)
		Much improved	30 (29.7%)	24 (27.9%)	54 (28.9%)
		Minimally improved	21 (20.8%)	19 (22.1%)	40 (21.4%)
		No change	19 (18.8%)	20 (23.3%)	39 (20.9%)
		Minimally worsened	9 (8.9%)	9 (10.5%)	18 (9.6%)
		Much worsened	5 (5.0%)	4 (4.7%)	9 (4.8%)
		Very much worsened	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Week 25		N=93	N=74	N=167
		Very much improved	10 (10.8%)	5 (6.8%)	15 (9.0%)
		Much improved	35 (37.6%)	26 (35.1%)	61 (36.5%)
		Minimally improved	24 (25.8%)	14 (18.9%)	38 (22.8%)
		No change	15 (16.1%)	13 (17.6%)	28 (16.8%)
		Minimally worsened	6 (6.5%)	10 (13.5%)	16 (9.6%)
		Much worsened	3 (3.2%)	5 (6.8%)	8 (4.8%)
		Very much worsened	0 (0.0%)	1 (1.4%)	1 (0.6%)
	Week 28		N=47	N=43	N=90
		Very much improved	6 (12.8%)	6 (14.0%)	12 (13.3%)
		Much improved	17 (36.2%)	16 (37.2%)	33 (36.7%)
		Minimally improved	11 (23.4%)	8 (18.6%)	19 (21.1%)
		No change	7 (14.9%)	4 (9.3%)	11 (12.2%)
		Minimally worsened	4 (8.5%)	6 (14.0%)	10 (11.1%)
		Much worsened	1 (2.1%)	3 (7.0%)	4 (4.4%)

Item	Visit	Response Level	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
		Very much worsened	1 (2.1%)	0 (0.0%)	1 (1.1%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Data cut off: 22 APR 2026

4.17. Table 1.1.10: PGI-Severity | Observed Scores and Change from Baseline by Visit — mITT — Excluding patients preselected to receive nab-paclitaxel

Item	Visit	Response Level	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
PGIS	Baseline (Week 1)		N=166	N=162	N=328
		Very Poor	5 (3.0%)	5 (3.1%)	10 (3.0%)
		Poor	18 (10.8%)	29 (17.9%)	47 (14.3%)
		Fair	61 (36.7%)	54 (33.3%)	115 (35.1%)
		Good	65 (39.2%)	58 (35.8%)	123 (37.5%)
		Excellent	17 (10.2%)	16 (9.9%)	33 (10.1%)
	Week 13		N=84	N=85	N=169
		Very Poor	1 (1.2%)	2 (2.4%)	3 (1.8%)
		Poor	4 (4.8%)	9 (10.6%)	13 (7.7%)
		Fair	40 (47.6%)	30 (35.3%)	70 (41.4%)
		Good	34 (40.5%)	36 (42.4%)	70 (41.4%)
		Excellent	5 (6.0%)	8 (9.4%)	13 (7.7%)
	Week 16		N=114	N=87	N=201
		Very Poor	2 (1.8%)	0 (0.0%)	2 (1.0%)
		Poor	9 (7.9%)	9 (10.3%)	18 (9.0%)
		Fair	63 (55.3%)	47 (54.0%)	110 (54.7%)
		Good	31 (27.2%)	27 (31.0%)	58 (28.9%)
		Excellent	9 (7.9%)	4 (4.6%)	13 (6.5%)
	Week 19		N=115	N=86	N=201

Item	Visit	Response Level	Sacituzumab Govitecan (N=177)	Treatment Physician Choice (N=169)	Overall (N=346)
		Very Poor	1 (0.9%)	2 (2.3%)	3 (1.5%)
		Poor	7 (6.1%)	6 (7.0%)	13 (6.5%)
		Fair	57 (49.6%)	43 (50.0%)	100 (49.8%)
		Good	43 (37.4%)	28 (32.6%)	71 (35.3%)
		Excellent	7 (6.1%)	7 (8.1%)	14 (7.0%)
	Week 22		N=101	N=86	N=187
		Very Poor	2 (2.0%)	1 (1.2%)	3 (1.6%)
		Poor	6 (5.9%)	14 (16.3%)	20 (10.7%)
		Fair	43 (42.6%)	32 (37.2%)	75 (40.1%)
		Good	46 (45.5%)	36 (41.9%)	82 (43.9%)
		Excellent	4 (4.0%)	3 (3.5%)	7 (3.7%)
	Week 25		N=93	N=74	N=167
		Very Poor	0 (0.0%)	3 (4.1%)	3 (1.8%)
		Poor	7 (7.5%)	11 (14.9%)	18 (10.8%)
		Fair	42 (45.2%)	29 (39.2%)	71 (42.5%)
		Good	41 (44.1%)	27 (36.5%)	68 (40.7%)
		Excellent	3 (3.2%)	4 (5.4%)	7 (4.2%)
	Week 28		N=47	N=43	N=90
		Very Poor	1 (2.1%)	0 (0.0%)	1 (1.1%)
		Poor	3 (6.4%)	5 (11.6%)	8 (8.9%)
		Fair	22 (46.8%)	20 (46.5%)	42 (46.7%)
		Good	16 (34.0%)	15 (34.9%)	31 (34.4%)
		Excellent	5 (10.6%)	3 (7.0%)	8 (8.9%)

SG = Sacituzumab Govitecan, TPC = Treatment Physician Choice,
Data cut off: 22 APR 2026

4.18. Table 1.1.14.1: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Global Health Status/QoL | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	102 (57.6%)	96 (56.8%)
A meaningful deterioration	102 (57.6%)	96 (56.8%)
Censored, n (%)	75 (42.4%)	73 (43.2%)
Not at risk at baseline	2 (1.1%)	5 (3.0%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	15 (8.5%)	6 (3.6%)
Premature treatment discontinuation	38 (21.5%)	51 (30.2%)
Others	4 (2.3%)	1 (0.6%)
Median TTD, months (95% CI)	3.6 (2.1, 5.7)	4.1 (2.6, 4.9)
Q1	1.0 (0.8, 1.4)	1.0 (0.9, 1.6)
Q3	16.7 (8.3, NE)	13.0 (7.3, NE)
Event-free rate, % (95% CI)		
At 3 months	52.8 (44.6, 60.3)	56.6 (48.2, 64.2)
At 6 months	41.1 (33.0, 49.1)	36.5 (28.1, 44.9)
At 12 months	30.5 (22.6, 38.7)	28.0 (19.4, 37.3)
At 18 months	24.5 (16.1, 33.8)	16.0 (6.6, 29.0)
At 24 months	24.5 (16.1, 33.8)	16.0 (6.6, 29.0)
p-value (two-sided, stratified log-rank)	0.7667	
Adjusted HR (95% CI), SG vs TPC	0.9594 (0.7237, 1.2718)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; QoL = Quality of life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.19. Table 1.1.14.2: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Physical Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	89 (50.3%)	93 (55.0%)
A meaningful deterioration	89 (50.3%)	93 (55.0%)
Censored, n (%)	88 (49.7%)	76 (45.0%)
Not at risk at baseline	1 (0.6%)	1 (0.6%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	15 (8.5%)	9 (5.3%)
Premature treatment discontinuation	53 (29.9%)	56 (33.1%)
Others	3 (1.7%)	0 (0.0%)
Median TTD, months (95% CI)	5.6 (3.3, 9.2)	4.6 (2.9, 6.0)
Q1	1.4 (0.8, 1.6)	1.4 (1.1, 1.9)
Q3	NE	14.0 (11.1, NE)
Event-free rate, % (95% CI)		
At 3 months	60.3 (52.1, 67.5)	58.2 (49.8, 65.7)
At 6 months	49.7 (41.4, 57.5)	41.5 (33.0, 49.8)
At 12 months	37.0 (27.9, 46.2)	33.2 (23.6, 43.0)
At 18 months	34.7 (25.2, 44.4)	23.7 (13.4, 35.8)
At 24 months	25.3 (13.4, 39.1)	19.0 (8.5, 32.6)

	SG (N=177)	TPC (N=169)
p-value (two-sided, stratified log-rank)	0.5070	
Adjusted HR (95% CI), SG vs TPC	0.9003 (0.6709, 1.2080)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.20. Table 1.1.14.3: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Role Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	103 (58.2%)	115 (68.0%)
A meaningful deterioration	103 (58.2%)	115 (68.0%)
Censored, n (%)	74 (41.8%)	54 (32.0%)
Not at risk at baseline	5 (2.8%)	4 (2.4%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	12 (6.8%)	5 (3.0%)
Premature treatment discontinuation	38 (21.5%)	35 (20.7%)
Others	3 (1.7%)	0 (0.0%)
Median TTD, months (95% CI)	1.6 (1.4, 2.4)	2.8 (1.9, 3.8)
Q1	0.8 (0.8, 1.0)	1.0 (0.9, 1.1)
Q3	20.8 (8.4, NE)	6.9 (5.1, 9.9)
Event-free rate, % (95% CI)		

	SG (N=177)	TPC (N=169)
At 3 months	39.1 (31.2, 46.8)	47.9 (39.6, 55.6)
At 6 months	35.0 (27.3, 42.8)	28.2 (20.9, 35.9)
At 12 months	30.0 (22.1, 38.3)	13.6 (7.3, 21.9)
At 18 months	27.7 (19.4, 36.6)	13.6 (7.3, 21.9)
At 24 months	23.7 (14.3, 34.6)	13.6 (7.3, 21.9)
p-value (two-sided, stratified log-rank)	0.8829	
Adjusted HR (95% CI), SG vs TPC	0.9637 (0.7366, 1.2608)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.21. Table 1.1.14.4: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Emotional Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	83 (46.9%)	68 (40.2%)
A meaningful deterioration	83 (46.9%)	68 (40.2%)
Censored, n (%)	94 (53.1%)	101 (59.8%)
Not at risk at baseline	1 (0.6%)	6 (3.6%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	15 (8.5%)	8 (4.7%)
Premature treatment discontinuation	56 (31.6%)	77 (45.6%)

	SG (N=177)	TPC (N=169)
Others	6 (3.4%)	0 (0.0%)
Median TTD, months (95% CI)	8.4 (4.9, 11.4)	9.1 (6.5, 12.3)
Q1	2.8 (1.7, 3.6)	3.5 (2.6, 4.4)
Q3	NE	14.0 (12.3, NE)
Event-free rate, % (95% CI)		
At 3 months	74.0 (66.3, 80.2)	80.2 (72.6, 85.9)
At 6 months	55.4 (46.7, 63.2)	60.0 (50.7, 68.1)
At 12 months	38.2 (28.7, 47.7)	38.0 (25.5, 50.5)
At 18 months	31.5 (22.0, 41.5)	12.6 (3.1, 29.3)
At 24 months	29.3 (19.6, 39.6)	12.6 (3.1, 29.3)
p-value (two-sided, stratified log-rank)	0.7514	
Adjusted HR (95% CI), SG vs TPC	1.0661 (0.7694, 1.4771)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.22. Table 1.1.14.5: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Cognitive Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	98 (55.4%)	104 (61.5%)
A meaningful deterioration	98 (55.4%)	104 (61.5%)
Censored, n (%)	79 (44.6%)	65 (38.5%)

	SG (N=177)	TPC (N=169)
Not at risk at baseline	1 (0.6%)	0 (0.0%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	12 (6.8%)	6 (3.6%)
Premature treatment discontinuation	45 (25.4%)	48 (28.4%)
Others	5 (2.8%)	1 (0.6%)
Median TTD, months (95% CI)	4.2 (2.9, 5.7)	3.5 (2.4, 4.1)
Q1	1.6 (1.0, 1.8)	1.4 (0.9, 1.9)
Q3	18.5 (12.6, NE)	10.2 (6.5, NE)
Event-free rate, % (95% CI)		
At 3 months	57.4 (49.1, 64.8)	53.0 (44.6, 60.7)
At 6 months	40.2 (31.8, 48.4)	34.3 (26.4, 42.3)
At 12 months	33.4 (25.0, 41.9)	21.3 (12.9, 31.2)
At 18 months	27.3 (18.5, 36.9)	18.3 (9.8, 28.8)
At 24 months	17.7 (8.6, 29.5)	13.7 (5.3, 26.0)
p-value (two-sided, stratified log-rank)	0.1305	
Adjusted HR (95% CI), SG vs TPC	0.8166 (0.6185, 1.0781)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.23. Table 1.1.14.6: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Social Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	102 (57.6%)	100 (59.2%)
A meaningful deterioration	102 (57.6%)	100 (59.2%)
Censored, n (%)	75 (42.4%)	69 (40.8%)
Not at risk at baseline	5 (2.8%)	1 (0.6%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	14 (7.9%)	8 (4.7%)
Premature treatment discontinuation	36 (20.3%)	49 (29.0%)
Others	4 (2.3%)	1 (0.6%)
Median TTD, months (95% CI)	2.4 (1.5, 3.6)	3.3 (2.2, 4.5)
Q1	1.0 (0.8, 1.1)	0.9 (0.8, 1.0)
Q3	18.2 (12.2, NE)	15.2 (6.3, NE)
Event-free rate, % (95% CI)		
At 3 months	47.8 (39.6, 55.5)	53.6 (45.3, 61.3)
At 6 months	37.9 (30.0, 45.8)	34.0 (25.9, 42.2)
At 12 months	33.5 (25.6, 41.7)	25.7 (17.1, 35.1)
At 18 months	27.0 (18.1, 36.6)	21.4 (11.8, 32.9)
At 24 months	20.8 (11.5, 32.0)	14.3 (4.2, 30.2)
p-value (two-sided, stratified log-rank)	0.9345	
Adjusted HR (95% CI), SG vs TPC	0.9527 (0.7207, 1.2594)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.24. Table 1.1.14.7: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Fatigue | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	119 (67.2%)	124 (73.4%)
A meaningful deterioration	119 (67.2%)	124 (73.4%)
Censored, n (%)	58 (32.8%)	45 (26.6%)
Not at risk at baseline	3 (1.7%)	2 (1.2%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	11 (6.2%)	3 (1.8%)
Premature treatment discontinuation	26 (14.7%)	29 (17.2%)
Others	2 (1.1%)	1 (0.6%)
Median TTD, months (95% CI)	1.4 (1.0, 1.7)	1.4 (1.1, 1.9)
Q1	0.8 (0.8, 0.8)	0.9 (0.8, 1.0)
Q3	5.7 (2.6, NE)	4.9 (3.5, 5.6)
Event-free rate, % (95% CI)		
At 3 months	31.9 (24.7, 39.3)	36.6 (28.9, 44.3)
At 6 months	24.0 (17.4, 31.2)	16.5 (10.5, 23.7)
At 12 months	21.0 (14.3, 28.7)	7.9 (3.2, 15.4)
At 18 months	21.0 (14.3, 28.7)	7.9 (3.2, 15.4)
At 24 months	16.8 (8.7, 27.2)	7.9 (3.2, 15.4)
p-value (two-sided, stratified log-rank)	0.8787	

	SG (N=177)	TPC (N=169)
Adjusted HR (95% CI), SG vs TPC	0.9783 (0.7593, 1.2606)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.25. Table 1.1.14.8: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Nausea and Vomiting | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	110 (62.1%)	93 (55.0%)
A meaningful deterioration	110 (62.1%)	93 (55.0%)
Censored, n (%)	67 (37.9%)	76 (45.0%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	10 (5.6%)	10 (5.9%)
Premature treatment discontinuation	39 (22.0%)	56 (33.1%)
Others	2 (1.1%)	0 (0.0%)
Median TTD, months (95% CI)	1.9 (1.4, 2.8)	2.6 (1.7, 5.6)
Q1	0.8 (0.8, 0.9)	0.9 (0.8, 1.3)
Q3	11.7 (5.7, NE)	19.6 (9.5, NE)
Event-free rate, % (95% CI)		
At 3 months	40.0 (32.2, 47.6)	49.1 (40.9, 56.9)

	SG (N=177)	TPC (N=169)
At 6 months	31.6 (24.0, 39.4)	40.8 (32.5, 48.8)
At 12 months	23.4 (15.4, 32.3)	32.3 (22.6, 42.4)
At 18 months	19.5 (10.6, 30.2)	32.3 (22.6, 42.4)
At 24 months	19.5 (10.6, 30.2)	12.1 (1.3, 36.0)
p-value (two-sided, stratified log-rank)	0.1124	
Adjusted HR (95% CI), SG vs TPC	1.2418 (0.9401, 1.6405)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.26. Table 1.1.14.9: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Pain | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	89 (50.3%)	100 (59.2%)
A meaningful deterioration	89 (50.3%)	100 (59.2%)
Censored, n (%)	88 (49.7%)	69 (40.8%)
Not at risk at baseline	11 (6.2%)	5 (3.0%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	16 (9.0%)	5 (3.0%)
Premature treatment discontinuation	43 (24.3%)	49 (29.0%)
Others	2 (1.1%)	0 (0.0%)

	SG (N=177)	TPC (N=169)
Median TTD, months (95% CI)	5.6 (2.4, 8.8)	3.0 (2.4, 4.4)
Q1	1.2 (0.8, 1.5)	1.1 (1.0, 1.5)
Q3	17.8 (10.8, NE)	10.9 (6.9, NE)
Event-free rate, % (95% CI)		
At 3 months	56.1 (47.6, 63.9)	49.4 (41.0, 57.3)
At 6 months	48.1 (39.4, 56.3)	36.8 (28.7, 44.9)
At 12 months	30.8 (21.7, 40.3)	23.5 (15.0, 33.1)
At 18 months	24.3 (15.1, 34.6)	14.7 (5.7, 27.8)
At 24 months	24.3 (15.1, 34.6)	14.7 (5.7, 27.8)
p-value (two-sided, stratified log-rank)	0.2987	
Adjusted HR (95% CI), SG vs TPC	0.8525 (0.6373, 1.1403)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.27. Table 1.1.14.10: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Dyspnoea | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	65 (36.7%)	89 (52.7%)
A meaningful deterioration	65 (36.7%)	89 (52.7%)
Censored, n (%)	112 (63.3%)	80 (47.3%)
Not at risk at baseline	2 (1.1%)	4 (2.4%)
Missing baseline only	3 (1.7%)	2 (1.2%)

	SG (N=177)	TPC (N=169)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	16 (9.0%)	10 (5.9%)
Premature treatment discontinuation	72 (40.7%)	56 (33.1%)
Others	6 (3.4%)	0 (0.0%)
Median TTD, months (95% CI)	12.2 (7.7, NE)	4.7 (2.8, 5.8)
Q1	2.1 (1.4, 3.6)	1.4 (1.0, 1.9)
Q3	NE	18.5 (8.0, NE)
Event-free rate, % (95% CI)		
At 3 months	71.3 (63.4, 77.8)	58.1 (49.6, 65.7)
At 6 months	64.0 (55.6, 71.3)	41.5 (32.8, 49.9)
At 12 months	50.7 (40.6, 59.9)	31.4 (22.3, 40.8)
At 18 months	47.0 (36.4, 56.8)	28.2 (18.5, 38.7)
At 24 months	47.0 (36.4, 56.8)	23.5 (12.8, 36.1)
p-value (two-sided, stratified log-rank)	0.0003	
Adjusted HR (95% CI), SG vs TPC	0.5568 (0.4025, 0.7701)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.28. Table 1.1.14.11: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Insomnia | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	80 (45.2%)	87 (51.5%)
A meaningful deterioration	80 (45.2%)	87 (51.5%)
Censored, n (%)	97 (54.8%)	82 (48.5%)
Not at risk at baseline	10 (5.6%)	10 (5.9%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	15 (8.5%)	9 (5.3%)
Premature treatment discontinuation	53 (29.9%)	53 (31.4%)
Others	3 (1.7%)	0 (0.0%)
Median TTD, months (95% CI)	5.5 (3.6, 10.8)	4.2 (3.1, 5.7)
Q1	1.4 (1.0, 2.3)	1.2 (1.0, 1.9)
Q3	NE	13.8 (9.0, NE)
Event-free rate, % (95% CI)		
At 3 months	63.8 (55.4, 71.1)	60.1 (51.5, 67.7)
At 6 months	49.1 (40.2, 57.4)	41.4 (32.7, 49.8)
At 12 months	39.3 (29.8, 48.7)	32.2 (23.2, 41.4)
At 18 months	33.6 (23.0, 44.6)	23.0 (11.8, 36.3)
At 24 months	25.5 (13.5, 39.2)	23.0 (11.8, 36.3)
p-value (two-sided, stratified log-rank)	0.1326	
Adjusted HR (95% CI), SG vs TPC	0.7985 (0.5878, 1.0848)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.29. Table 1.1.14.12: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Appetite Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	87 (49.2%)	84 (49.7%)
A meaningful deterioration	87 (49.2%)	84 (49.7%)
Censored, n (%)	90 (50.8%)	85 (50.3%)
Not at risk at baseline	3 (1.7%)	6 (3.6%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	16 (9.0%)	8 (4.7%)
Premature treatment discontinuation	49 (27.7%)	60 (35.5%)
Others	6 (3.4%)	1 (0.6%)
Median TTD, months (95% CI)	3.6 (2.1, 8.8)	4.9 (2.4, 7.9)
Q1	0.9 (0.8, 1.4)	1.0 (0.9, 1.4)
Q3	NE	15.5 (11.1, NE)
Event-free rate, % (95% CI)		
At 3 months	52.7 (44.4, 60.3)	56.8 (48.2, 64.5)
At 6 months	43.9 (35.7, 51.9)	45.5 (36.8, 53.8)
At 12 months	39.7 (30.9, 48.3)	35.1 (24.2, 46.2)
At 18 months	37.0 (27.5, 46.6)	18.8 (6.7, 35.5)
At 24 months	37.0 (27.5, 46.6)	12.5 (2.8, 30.0)
p-value (two-sided, stratified log-rank)	0.8822	

	SG (N=177)	TPC (N=169)
Adjusted HR (95% CI), SG vs TPC	0.9836 (0.7276, 1.3297)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.30. Table 1.1.14.13: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Constipation | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	97 (54.8%)	90 (53.3%)
A meaningful deterioration	97 (54.8%)	90 (53.3%)
Censored, n (%)	80 (45.2%)	79 (46.7%)
Not at risk at baseline	4 (2.3%)	6 (3.6%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	12 (6.8%)	8 (4.7%)
Premature treatment discontinuation	45 (25.4%)	53 (31.4%)
Others	3 (1.7%)	2 (1.2%)
Median TTD, months (95% CI)	2.4 (1.7, 3.6)	3.3 (1.9, 6.5)
Q1	1.0 (0.8, 1.4)	0.9 (0.8, 1.1)
Q3	NE	13.3 (9.0, NE)
Event-free rate, % (95% CI)		
At 3 months	44.4 (36.3, 52.2)	50.3 (41.8, 58.2)

	SG (N=177)	TPC (N=169)
At 6 months	38.0 (30.1, 46.0)	44.0 (35.4, 52.2)
At 12 months	35.1 (26.8, 43.5)	32.5 (23.3, 41.9)
At 18 months	30.4 (21.2, 40.1)	24.4 (13.5, 37.0)
At 24 months	26.0 (15.6, 37.8)	18.3 (7.1, 33.5)
p-value (two-sided, stratified log-rank)	0.8950	
Adjusted HR (95% CI), SG vs TPC	0.9963 (0.7469, 1.3290)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.31. Table 1.1.14.14: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Diarrhoea | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	119 (67.2%)	71 (42.0%)
A meaningful deterioration	119 (67.2%)	71 (42.0%)
Censored, n (%)	58 (32.8%)	98 (58.0%)
Not at risk at baseline	1 (0.6%)	0 (0.0%)
Missing baseline only	3 (1.7%)	2 (1.2%)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	10 (5.6%)	14 (8.3%)
Premature treatment discontinuation	28 (15.8%)	73 (43.2%)
Others	3 (1.7%)	1 (0.6%)

	SG (N=177)	TPC (N=169)
Median TTD, months (95% CI)	1.7 (1.2, 2.2)	6.9 (4.7, NE)
Q1	0.8 (0.8, 0.9)	1.9 (1.4, 2.8)
Q3	5.8 (3.8, NE)	NE
Event-free rate, % (95% CI)		
At 3 months	37.5 (29.9, 45.1)	66.6 (58.3, 73.6)
At 6 months	24.5 (17.6, 31.9)	53.5 (44.5, 61.6)
At 12 months	20.7 (13.9, 28.4)	43.7 (32.7, 54.2)
At 18 months	16.7 (9.9, 25.1)	39.3 (26.7, 51.7)
At 24 months	16.7 (9.9, 25.1)	39.3 (26.7, 51.7)
p-value (two-sided, stratified log-rank)	0.0000	
Adjusted HR (95% CI), SG vs TPC	2.3595 (1.7500, 3.1812)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.32. Table 1.1.14.15: — Time to First Meaningful Deterioration — EORTC QLQ-C30: Financial Difficulties | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	65 (36.7%)	63 (37.3%)
A meaningful deterioration	65 (36.7%)	63 (37.3%)
Censored, n (%)	112 (63.3%)	106 (62.7%)
Not at risk at baseline	10 (5.6%)	10 (5.9%)
Missing baseline only	3 (1.7%)	2 (1.2%)

	SG (N=177)	TPC (N=169)
Having baseline but no postbaseline visit	12 (6.8%)	6 (3.6%)
No baseline or any postbaseline	1 (0.6%)	2 (1.2%)
Missing PRO for two consecutive visits	14 (7.9%)	12 (7.1%)
Premature treatment discontinuation	67 (37.9%)	73 (43.2%)
Others	5 (2.8%)	1 (0.6%)
Median TTD, months (95% CI)	10.5 (7.4, 27.9)	8.7 (4.6, NE)
Q1	2.9 (1.7, 4.5)	1.9 (1.4, 3.3)
Q3	NE	19.4 (19.4, NE)
Event-free rate, % (95% CI)		
At 3 months	74.8 (66.8, 81.2)	70.7 (62.2, 77.6)
At 6 months	63.4 (54.4, 71.1)	54.3 (44.9, 62.7)
At 12 months	48.8 (38.8, 58.1)	46.6 (35.5, 56.9)
At 18 months	46.7 (36.3, 56.4)	46.6 (35.5, 56.9)
At 24 months	39.2 (26.4, 51.7)	23.3 (2.2, 57.4)
p-value (two-sided, stratified log-rank)	0.2481	
Adjusted HR (95% CI), SG vs TPC	0.8063 (0.5653, 1.1501)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-C30 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.33. Table 1.1.15.1: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Body Image | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	99 (55.9%)	76 (45.0%)
A meaningful deterioration	99 (55.9%)	76 (45.0%)
Censored, n (%)	78 (44.1%)	93 (55.0%)
Not at risk at baseline	8 (4.5%)	5 (3.0%)
Having baseline but no postbaseline visit	12 (6.8%)	9 (5.3%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits	9 (5.1%)	7 (4.1%)
Premature treatment discontinuation	34 (19.2%)	54 (32.0%)
Others	10 (5.6%)	14 (8.3%)
Median TTFD, months (95% CI)	2.3 (1.7, 3.7)	5.1 (3.0, 9.3)
Q1	1.0 (0.8, 1.3)	1.4 (1.0, 1.9)
Q3	13.0 (6.3, NE)	24.4 (12.7, NE)
Event-free rate, % (95% CI)		
At 3 months	48.0 (39.5, 56.0)	58.9 (50.2, 66.6)
At 6 months	33.3 (25.2, 41.5)	46.9 (37.7, 55.6)
At 12 months	28.6 (20.7, 37.0)	39.6 (29.3, 49.6)
At 18 months	22.5 (14.3, 31.9)	27.7 (13.5, 44.0)
At 24 months	22.5 (14.3, 31.9)	27.7 (13.5, 44.0)
p-value (two-sided, stratified log-rank)	0.0202	
Adjusted HR (95% CI), SG vs TPC	1.4523 (1.0727, 1.9662)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.

Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.34. Table 1.1.15.2: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Sexual Functioning | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	46 (26.0%)	46 (27.2%)
A meaningful deterioration	46 (26.0%)	46 (27.2%)
Censored, n (%)	131 (74.0%)	123 (72.8%)
Not at risk at baseline	1 (0.6%)	0 (0.0%)
Having baseline but no postbaseline visit	12 (6.8%)	9 (5.3%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits	13 (7.3%)	11 (6.5%)
Premature treatment discontinuation	65 (36.7%)	70 (41.4%)
Others	35 (19.8%)	29 (17.2%)
Median TTFD, months (95% CI)	NE	NE
Q1	3.9 (3.0, 10.0)	3.5 (1.9, 5.4)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	81.7 (74.4, 87.1)	77.5 (69.6, 83.5)
At 6 months	71.6 (63.1, 78.5)	67.1 (58.0, 74.6)
At 12 months	65.0 (55.3, 73.2)	62.7 (52.9, 71.1)
At 18 months	60.5 (49.4, 69.9)	62.7 (52.9, 71.1)

	SG (N=177)	TPC (N=169)
At 24 months	60.5 (49.4, 69.9)	62.7 (52.9, 71.1)
p-value (two-sided, stratified log-rank)	0.4553	
Adjusted HR (95% CI), SG vs TPC	0.8406 (0.5566, 1.2693)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.35. Table 1.1.15.3: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Sexual Enjoyment | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	7 (4.0%)	9 (5.3%)
A meaningful deterioration	7 (4.0%)	9 (5.3%)
Censored, n (%)	170 (96.0%)	160 (94.7%)
Not at risk at baseline	4 (2.3%)	7 (4.1%)
Having baseline but no postbaseline visit	13 (7.3%)	17 (10.1%)
Missing baseline only	24 (13.6%)	19 (11.2%)
No baseline or any postbaseline	93 (52.5%)	80 (47.3%)
Missing PRO for two consecutive visits	22 (12.4%)	20 (11.8%)
Premature treatment discontinuation	9 (5.1%)	12 (7.1%)
Others	5 (2.8%)	5 (3.0%)
Median TTFD, months (95% CI)	NE	NE
Q1	NE	4.2 (1.0, NE)
Q3	NE	NE

	SG (N=177)	TPC (N=169)
Event-free rate, % (95% CI)		
At 3 months	75.6 (55.5, 87.6)	79.8 (62.2, 89.9)
At 6 months	75.6 (55.5, 87.6)	69.8 (48.4, 83.6)
At 12 months	75.6 (55.5, 87.6)	69.8 (48.4, 83.6)
At 18 months	75.6 (55.5, 87.6)	69.8 (48.4, 83.6)
At 24 months	75.6 (55.5, 87.6)	69.8 (48.4, 83.6)
p-value (two-sided, stratified log-rank)	0.7707	
Adjusted HR (95% CI), SG vs TPC	1.1171 (0.4079, 3.0599)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.36. Table 1.1.15.4: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Future Perspective | Functional scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	66 (37.3%)	60 (35.5%)
A meaningful deterioration	66 (37.3%)	60 (35.5%)
Censored, n (%)	111 (62.7%)	109 (64.5%)
Not at risk at baseline	37 (20.9%)	32 (18.9%)
Having baseline but no postbaseline visit	12 (6.8%)	9 (5.3%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits	9 (5.1%)	6 (3.6%)

	SG (N=177)	TPC (N=169)
Premature treatment discontinuation	29 (16.4%)	45 (26.6%)
Others	19 (10.7%)	13 (7.7%)
Median TTFD, months (95% CI)	5.5 (2.4, 11.3)	6.3 (3.3, 10.2)
Q1	1.4 (1.0, 1.7)	1.5 (1.0, 1.9)
Q3	27.9 (17.8, NE)	26.7 (10.2, NE)
Event-free rate, % (95% CI)		
At 3 months	59.5 (49.8, 67.9)	61.8 (52.2, 70.0)
At 6 months	48.5 (38.6, 57.7)	52.9 (42.9, 61.9)
At 12 months	40.0 (29.8, 49.9)	36.1 (22.7, 49.7)
At 18 months	33.1 (22.4, 44.2)	27.1 (11.0, 46.1)
At 24 months	33.1 (22.4, 44.2)	27.1 (11.0, 46.1)
p-value (two-sided, stratified log-rank)	0.6871	
Adjusted HR (95% CI), SG vs TPC	1.0127 (0.7086, 1.4472)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.37. Table 1.1.15.5: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Systemic Therapy Side Effects | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	130 (73.4%)	105 (62.1%)
A meaningful deterioration	130 (73.4%)	105 (62.1%)
Censored, n (%)	47 (26.6%)	64 (37.9%)

	SG (N=177)	TPC (N=169)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	12 (6.8%)	9 (5.3%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits	6 (3.4%)	3 (1.8%)
Premature treatment discontinuation	17 (9.6%)	38 (22.5%)
Others	7 (4.0%)	10 (5.9%)
Median TTFD, months (95% CI)	1.0 (0.8, 1.1)	2.0 (1.4, 3.5)
Q1	0.8 (0.8, 0.8)	1.0 (0.9, 1.0)
Q3	2.2 (1.6, 5.2)	9.2 (5.1, NE)
Event-free rate, % (95% CI)		
At 3 months	22.4 (16.2, 29.3)	45.2 (37.0, 53.1)
At 6 months	17.3 (11.5, 24.0)	27.8 (20.2, 36.0)
At 12 months	12.6 (7.0, 20.1)	21.2 (12.8, 31.0)
At 18 months	12.6 (7.0, 20.1)	12.7 (4.5, 25.3)
At 24 months	12.6 (7.0, 20.1)	12.7 (4.5, 25.3)
p-value (two-sided, stratified log-rank)	0.0001	
Adjusted HR (95% CI), SG vs TPC	1.7170 (1.3243, 2.2262)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.38. Table 1.1.15.6: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Breast Symptoms | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	53 (29.9%)	40 (23.7%)
A meaningful deterioration	53 (29.9%)	40 (23.7%)
Censored, n (%)	124 (70.1%)	129 (76.3%)
Not at risk at baseline	8 (4.5%)	5 (3.0%)
Having baseline but no postbaseline visit	12 (6.8%)	9 (5.3%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits	15 (8.5%)	12 (7.1%)
Premature treatment discontinuation	52 (29.4%)	70 (41.4%)
Others	32 (18.1%)	29 (17.2%)
Median TTFD, months (95% CI)	24.7 (10.2, NE)	NE
Q1	3.9 (1.9, 5.6)	5.1 (2.6, 8.7)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	77.4 (69.6, 83.5)	79.8 (71.9, 85.7)
At 6 months	67.6 (58.6, 75.0)	71.5 (62.3, 78.8)
At 12 months	58.6 (48.6, 67.4)	62.9 (51.0, 72.7)
At 18 months	54.3 (43.3, 64.1)	57.7 (42.5, 70.2)
At 24 months	54.3 (43.3, 64.1)	57.7 (42.5, 70.2)
p-value (two-sided, stratified log-rank)	0.6149	
Adjusted HR (95% CI), SG vs TPC	1.1046 (0.7279, 1.6760)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.39. Table 1.1.15.7: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Arm Symptoms | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	86 (48.6%)	85 (50.3%)
A meaningful deterioration	86 (48.6%)	85 (50.3%)
Censored, n (%)	91 (51.4%)	84 (49.7%)
Not at risk at baseline	2 (1.1%)	4 (2.4%)
Having baseline but no postbaseline visit	12 (6.8%)	9 (5.3%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	2 (1.1%)	2 (1.2%)
Missing PRO for two consecutive visits	10 (5.6%)	9 (5.3%)
Premature treatment discontinuation	41 (23.2%)	47 (27.8%)
Others	21 (11.9%)	11 (6.5%)
Median TTFD, months (95% CI)	6.5 (4.1, 9.6)	3.8 (2.8, 5.6)
Q1	1.5 (1.1, 2.2)	1.4 (1.0, 1.9)
Q3	NE	12.7 (7.9, NE)
Event-free rate, % (95% CI)		
At 3 months	64.1 (55.8, 71.2)	56.7 (47.9, 64.5)
At 6 months	50.5 (41.7, 58.6)	39.9 (30.9, 48.8)
At 12 months	38.1 (28.8, 47.3)	27.1 (17.1, 38.1)
At 18 months	26.9 (17.5, 37.3)	23.2 (12.8, 35.4)
At 24 months	26.9 (17.5, 37.3)	23.2 (12.8, 35.4)
p-value (two-sided, stratified log-rank)	0.1429	

	SG (N=177)	TPC (N=169)
Adjusted HR (95% CI), SG vs TPC	0.7910 (0.5835, 1.0723)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.40. Table 1.1.15.8: — Time to First Meaningful Deterioration for EORTC QLQ-BR23: Upset By Hair Loss | Symptom scale — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	16 (9.0%)	20 (11.8%)
A meaningful deterioration	16 (9.0%)	20 (11.8%)
Censored, n (%)	161 (91.0%)	149 (88.2%)
Not at risk at baseline	2 (1.1%)	2 (1.2%)
Having baseline but no postbaseline visit	3 (1.7%)	6 (3.6%)
Missing baseline only	132 (74.6%)	95 (56.2%)
No baseline or any postbaseline	11 (6.2%)	34 (20.1%)
Missing PRO for two consecutive visits	5 (2.8%)	5 (3.0%)
Premature treatment discontinuation	5 (2.8%)	6 (3.6%)
Others	3 (1.7%)	1 (0.6%)
Median TTFD, months (95% CI)	3.5 (0.9, NE)	1.4 (1.0, 3.3)
Q1	0.8 (0.7, 1.2)	1.0 (0.8, 1.4)
Q3	NE	5.6 (1.5, NE)
Event-free rate, % (95% CI)		
At 3 months	52.3 (32.3, 68.9)	39.2 (21.0, 57.0)

	SG (N=177)	TPC (N=169)
At 6 months	43.4 (24.2, 61.3)	19.6 (6.1, 38.7)
At 12 months	37.2 (18.2, 56.3)	19.6 (6.1, 38.7)
At 18 months	37.2 (18.2, 56.3)	19.6 (6.1, 38.7)
At 24 months	37.2 (18.2, 56.3)	19.6 (6.1, 38.7)
p-value (two-sided, stratified log-rank)	0.1361	
Adjusted HR (95% CI), SG vs TPC	0.6838 (0.3526, 1.3263)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EORTC QLQ-BR23 domains is ≥10 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; EORTC QLQ-BR23 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.41. Table 1.1.16: Time to First Deterioration of EQ-5D VAS — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	71 (40.1%)	57 (33.7%)
A meaningful deterioration	71 (40.1%)	57 (33.7%)
Censored, n (%)	106 (59.9%)	112 (66.3%)
Not at risk at baseline	1 (0.6%)	1 (0.6%)
Having baseline but no postbaseline visit	11 (6.2%)	7 (4.1%)
Missing baseline only	4 (2.3%)	3 (1.8%)
No baseline or any postbaseline	3 (1.7%)	3 (1.8%)
Missing PRO for two consecutive visits	16 (9.0%)	13 (7.7%)
Premature treatment discontinuation	61 (34.5%)	83 (49.1%)
Others	10 (5.6%)	2 (1.2%)

	SG (N=177)	TPC (N=169)
Median TTD, months (95% CI)	9.8 (6.3, NE)	12.4 (10.3, NE)
Q1	2.2 (1.4, 3.6)	2.8 (1.6, 4.7)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	70.5 (62.6, 77.1)	73.7 (65.7, 80.2)
At 6 months	61.6 (53.0, 69.1)	65.2 (56.4, 72.6)
At 12 months	46.8 (37.0, 56.1)	50.2 (37.0, 61.9)
At 18 months	42.9 (32.6, 52.9)	34.5 (17.8, 51.9)
At 24 months	40.1 (29.1, 50.8)	34.5 (17.8, 51.9)
p-value (two-sided, stratified log-rank)	0.5270	
Adjusted HR (95% CI), SG vs TPC	1.1218 (0.7889, 1.5953)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
The response threshold for EQ-5D VAS is ≥15 points.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; VAS = Visual analogue scale; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.42. Table 1.1.18: Time to First Deterioration of PGI-Change — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	41 (23.2%)	43 (25.4%)
A meaningful deterioration	41 (23.2%)	43 (25.4%)
Censored, n (%)	136 (76.8%)	126 (74.6%)
Not at risk at baseline	0 (0.0%)	0 (0.0%)
Having baseline but no postbaseline visit	0 (0.0%)	0 (0.0%)
Missing baseline only	0 (0.0%)	0 (0.0%)

	SG (N=177)	TPC (N=169)
No baseline or any postbaseline	41 (23.2%)	37 (21.9%)
Missing PRO for two consecutive visits	13 (7.3%)	10 (5.9%)
Premature treatment discontinuation	82 (46.3%)	79 (46.7%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	NE	NE
Q1	5.0 (3.7, 5.9)	4.0 (3.5, 5.6)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	91.0 (84.8, 94.8)	90.7 (84.2, 94.6)
At 6 months	66.7 (56.7, 74.9)	64.1 (53.8, 72.6)
At 12 months	59.5 (45.4, 71.2)	55.1 (42.0, 66.5)
At 18 months	59.5 (45.4, 71.2)	55.1 (42.0, 66.5)
At 24 months	59.5 (45.4, 71.2)	55.1 (42.0, 66.5)
p-value (two-sided, stratified log-rank)	0.3532	
Adjusted HR (95% CI), SG vs TPC	0.8361 (0.5428, 1.2877)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
For PGIC, "minimally worsened", "much worsened," and "very much worsened" are classified as responders.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; PGIC = Patient Global Impression of Change; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.43. Table 1.1.19: Time to First Deterioration of PGI-Severity — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)
Events, n (%)	17 (9.6%)	15 (8.9%)

	SG (N=177)	TPC (N=169)
A meaningful deterioration	17 (9.6%)	15 (8.9%)
Censored, n (%)	160 (90.4%)	154 (91.1%)
Not at risk at baseline	19 (10.7%)	26 (15.4%)
Having baseline but no postbaseline visit	35 (19.8%)	34 (20.1%)
Missing baseline only	3 (1.7%)	2 (1.2%)
No baseline or any postbaseline	6 (3.4%)	3 (1.8%)
Missing PRO for two consecutive visits	12 (6.8%)	10 (5.9%)
Premature treatment discontinuation	85 (48.0%)	79 (46.7%)
Others	0 (0.0%)	0 (0.0%)
Median TTD, months (95% CI)	NE	NE
Q1	NE	6.6 (5.8, NE)
Q3	NE	NE
Event-free rate, % (95% CI)		
At 3 months	97.3 (91.9, 99.1)	98.0 (92.2, 99.5)
At 6 months	84.3 (75.6, 90.1)	83.3 (72.3, 90.2)
At 12 months	79.6 (65.6, 88.4)	71.4 (50.5, 84.7)
At 18 months	79.6 (65.6, 88.4)	71.4 (50.5, 84.7)
At 24 months	79.6 (65.6, 88.4)	71.4 (50.5, 84.7)
p-value (two-sided, stratified log-rank)	0.9903	
Adjusted HR (95% CI), SG vs TPC	1.0500 (0.5218, 2.1129)	

Time to first deterioration (TTFD) is defined as the time between the date of randomization and the date of assessment at which a participant experienced a first deterioration (i.e., ≥ the threshold for Deterioration from baseline (if applicable); based on the assessments after applying analysis visit window).
For PGIS, "very poor" and "poor" were classified as responders.
Denominator was the number of patients in the mITT excluding patients preselected to receive nab-paclitaxel.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
P-value was estimated from the stratified log-rank test by randomization stratification factors.
CI = Confidence Interval; PGIS = Patient Global Impression of Severity; HR = hazard ratio; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice
Note that deaths are not considered as events.
Data Cut off: 22 APR 2026

4.44. Table 1.1.20.1: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Global Health Status/QoL | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.3874
Number (%) of Participants with Events (Deterioration)	28 (50.9%)	23 (46.9%)	
Number (%) of Participants Censored	27 (49.1%)	26 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.65 (3.25, 15.24)	5.82 (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.9352		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.029 (0.588, 1.803)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	22 (64.7%)	23 (67.6%)	
Number (%) of Participants Censored	12 (35.3%)	11 (32.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.39 (0.95, 7.72)	1.87 (0.85, 4.57)	
Log-Rank Test p-value (unstratified)	0.2467		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.712 (0.395, 1.286)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	52 (59.1%)	50 (58.1%)	
Number (%) of Participants Censored	36 (40.9%)	36 (41.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.45, 3.61)	4.07 (2.00, 5.55)	
Log-Rank Test p-value (unstratified)	0.7002		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.083 (0.733, 1.600)		
Geographic region			

	SG (N=177)	TPC (N=169)	Interaction
US/Canada/Western Europe	56	52	0.1942
Number (%) of Participants with Events (Deterioration)	30 (53.6%)	32 (61.5%)	
Number (%) of Participants Censored	26 (46.4%)	20 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.61 (1.64, 7.62)	3.09 (1.05, 4.86)	
Log-Rank Test p-value (unstratified)	0.1081		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.662 (0.396, 1.107)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	72 (59.5%)	64 (54.7%)	
Number (%) of Participants Censored	49 (40.5%)	53 (45.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.75 (1.84, 6.31)	4.21 (2.69, 6.51)	
Log-Rank Test p-value (unstratified)	0.6052		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.096 (0.781, 1.538)		
Age group			
< 65	133	131	0.8825
Number (%) of Participants with Events (Deterioration)	82 (61.7%)	72 (55.0%)	
Number (%) of Participants Censored	51 (38.3%)	59 (45.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (2.14, 6.31)	4.21 (2.69, 5.55)	
Log-Rank Test p-value (unstratified)	0.9035		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.985 (0.716, 1.355)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	24 (63.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	24 (54.5%)	14 (36.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.02, 5.09)	3.09 (1.18, 6.51)	
Log-Rank Test p-value (unstratified)	0.8367		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.943 (0.518, 1.714)		
Race			
White	115	104	0.9418
Number (%) of Participants with Events (Deterioration)	67 (58.3%)	63 (60.6%)	
Number (%) of Participants Censored	48 (41.7%)	41 (39.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.48, 4.99)	3.25 (1.84, 4.21)	
Log-Rank Test p-value (unstratified)	0.6448		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.927 (0.655, 1.311)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	24 (63.2%)	23 (60.5%)	
Number (%) of Participants Censored	14 (36.8%)	15 (39.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.84, 8.38)	4.90 (1.91, 13.01)	
Log-Rank Test p-value (unstratified)	0.9857		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.007 (0.565, 1.795)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	7 (36.8%)	8 (33.3%)	
Number (%) of Participants Censored	12 (63.2%)	16 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	15.24 (2.40, NR)	NR (0.82, NR)	
Log-Rank Test p-value (unstratified)	0.9395		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.962 (0.347, 2.672)		
Baseline ECOG status			
0	116	106	0.2768
Number (%) of Participants with Events (Deterioration)	71 (61.2%)	70 (66.0%)	
Number (%) of Participants Censored	45 (38.8%)	36 (34.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.94 (1.74, 6.01)	2.73 (1.84, 4.47)	
Log-Rank Test p-value (unstratified)	0.3639		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.862 (0.619, 1.201)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	31 (50.8%)	26 (41.3%)	
Number (%) of Participants Censored	30 (49.2%)	37 (58.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.25 (1.58, 15.24)	7.49 (3.25, NR)	
Log-Rank Test p-value (unstratified)	0.4648		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.222 (0.718, 2.079)		
Physician's choice of chemotherapy			
Taxane	52	45	0.2825
Number (%) of Participants with Events (Deterioration)	32 (61.5%)	23 (51.1%)	
Number (%) of Participants Censored	20 (38.5%)	22 (48.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.25 (1.48, 5.55)	4.67 (2.00, 7.26)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5304		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.197 (0.696, 2.057)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	70 (56.0%)	73 (58.9%)	
Number (%) of Participants Censored	55 (44.0%)	51 (41.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (2.10, 6.34)	3.25 (2.14, 4.86)	
Log-Rank Test p-value (unstratified)	0.4909		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.893 (0.642, 1.242)		
History of liver metastasis			
Yes	47	39	0.3390
Number (%) of Participants with Events (Deterioration)	26 (55.3%)	14 (35.9%)	
Number (%) of Participants Censored	21 (44.7%)	25 (64.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.99 (1.74, 8.38)	5.75 (2.07, NR)	
Log-Rank Test p-value (unstratified)	0.5154		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.250 (0.647, 2.414)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	76 (58.5%)	82 (63.1%)	
Number (%) of Participants Censored	54 (41.5%)	48 (36.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.19 (1.68, 5.55)	3.25 (2.14, 4.57)	
Log-Rank Test p-value (unstratified)	0.6121		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.926 (0.676, 1.267)		

	SG (N=177)	TPC (N=169)	Interaction
History of brain metastasis			
Yes	8	9	0.9381
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	4 (44.4%)	
Number (%) of Participants Censored	5 (62.5%)	5 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.91 (0.72, NR)	2.69 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.9418		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.989 (0.221, 4.431)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	99 (58.6%)	92 (57.5%)	
Number (%) of Participants Censored	70 (41.4%)	68 (42.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.61 (2.10, 5.65)	4.07 (2.63, 4.86)	
Log-Rank Test p-value (unstratified)	0.8056		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.968 (0.727, 1.288)		
PD-L1 Status			
CPS < 1	67	59	0.3108
Number (%) of Participants with Events (Deterioration)	40 (59.7%)	37 (62.7%)	
Number (%) of Participants Censored	27 (40.3%)	22 (37.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (1.61, 6.01)	2.69 (1.61, 4.21)	
Log-Rank Test p-value (unstratified)	0.3686		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.814 (0.518, 1.280)		
CPS ≥ 1	109	110	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	62 (56.9%)	59 (53.6%)	
Number (%) of Participants Censored	47 (43.1%)	51 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.68, 6.31)	4.67 (2.73, 6.93)	
Log-Rank Test p-value (unstratified)	0.7736		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.059 (0.739, 1.517)		
BRCA 1/2 status			
Wild-Type	66	65	0.3642
Number (%) of Participants with Events (Deterioration)	42 (63.6%)	40 (61.5%)	
Number (%) of Participants Censored	24 (36.4%)	25 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (1.41, 5.09)	2.69 (1.61, 4.67)	
Log-Rank Test p-value (unstratified)	0.6163		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.897 (0.578, 1.392)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	6 (50.0%)	4 (40.0%)	
Number (%) of Participants Censored	6 (50.0%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.30 (0.79, NR)	NR (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.5067		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.540 (0.432, 5.486)		
Menopausal status			
Pre-menopausal	37	49	0.4620
Number (%) of Participants with Events (Deterioration)	20 (54.1%)	25 (51.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	17 (45.9%)	24 (49.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.94 (1.68, NR)	5.59 (3.02, 14.03)	
Log-Rank Test p-value (unstratified)	0.6558		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.145 (0.635, 2.067)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	82 (58.6%)	71 (59.7%)	
Number (%) of Participants Censored	58 (41.4%)	48 (40.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.58 (1.68, 5.78)	3.09 (1.68, 4.21)	
Log-Rank Test p-value (unstratified)	0.3636		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.627, 1.194)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.45. Table 1.1.20.2: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Physical Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.7387
Number (%) of Participants with Events (Deterioration)	27 (49.1%)	26 (53.1%)	
Number (%) of Participants Censored	28 (50.9%)	23 (46.9%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.59 (2.14, 20.07)	2.83 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.3602		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.774 (0.448, 1.338)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	21 (61.8%)	18 (52.9%)	
Number (%) of Participants Censored	13 (38.2%)	16 (47.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.91 (1.45, 21.45)	5.13 (1.45, NR)	
Log-Rank Test p-value (unstratified)	0.8808		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.953 (0.507, 1.793)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	41 (46.6%)	49 (57.0%)	
Number (%) of Participants Censored	47 (53.4%)	37 (43.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.16 (2.17, 8.84)	4.90 (3.48, 11.07)	
Log-Rank Test p-value (unstratified)	0.9978		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.004 (0.662, 1.525)		
Geographic region			
US/Canada/Western Europe	56	52	0.7375
Number (%) of Participants with Events (Deterioration)	28 (50.0%)	30 (57.7%)	
Number (%) of Participants Censored	28 (50.0%)	22 (42.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.91 (1.68, 7.39)	3.29 (1.58, 5.55)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5308		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.506, 1.420)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	61 (50.4%)	63 (53.8%)	
Number (%) of Participants Censored	60 (49.6%)	54 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.16 (3.32, 11.63)	5.42 (3.09, 11.07)	
Log-Rank Test p-value (unstratified)	0.6733		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.929 (0.652, 1.325)		
Age group			
< 65	133	131	0.3766
Number (%) of Participants with Events (Deterioration)	70 (52.6%)	71 (54.2%)	
Number (%) of Participants Censored	63 (47.4%)	60 (45.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.39 (3.65, 11.63)	4.67 (2.86, 6.97)	
Log-Rank Test p-value (unstratified)	0.3540		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.857 (0.614, 1.194)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	22 (57.9%)	
Number (%) of Participants Censored	25 (56.8%)	16 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.64 (0.85, 7.16)	4.01 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.5018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.240 (0.669, 2.300)		

	SG (N=177)	TPC (N=169)	Interaction
Race			
White	115	104	0.2249
Number (%) of Participants with Events (Deterioration)	56 (48.7%)	56 (53.8%)	
Number (%) of Participants Censored	59 (51.3%)	48 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.29 (2.79, 9.82)	3.71 (2.56, 9.00)	
Log-Rank Test p-value (unstratified)	0.5696		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.901 (0.621, 1.307)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	24 (63.2%)	22 (57.9%)	
Number (%) of Participants Censored	14 (36.8%)	16 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.32 (0.95, 7.89)	4.86 (2.00, 6.97)	
Log-Rank Test p-value (unstratified)	0.5674		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.186 (0.662, 2.125)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	6 (31.6%)	13 (54.2%)	
Number (%) of Participants Censored	13 (68.4%)	11 (45.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (2.40, NR)	5.13 (0.85, NR)	
Log-Rank Test p-value (unstratified)	0.1025		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.447 (0.166, 1.202)		
Baseline ECOG status			
0	116	106	0.9427

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	60 (51.7%)	61 (57.5%)	
Number (%) of Participants Censored	56 (48.3%)	45 (42.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.70 (3.32, 9.17)	4.67 (2.83, 8.31)	
Log-Rank Test p-value (unstratified)	0.5912		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.908 (0.634, 1.299)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	29 (47.5%)	32 (50.8%)	
Number (%) of Participants Censored	32 (52.5%)	31 (49.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.24 (0.95, 21.45)	4.44 (1.94, 13.83)	
Log-Rank Test p-value (unstratified)	0.7073		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.915 (0.544, 1.537)		
Physician's choice of chemotherapy			
Taxane	52	45	0.0788
Number (%) of Participants with Events (Deterioration)	31 (59.6%)	23 (51.1%)	
Number (%) of Participants Censored	21 (40.4%)	22 (48.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.96 (1.41, 4.34)	4.44 (1.94, 11.07)	
Log-Rank Test p-value (unstratified)	0.2995		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.332 (0.773, 2.295)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	58 (46.4%)	70 (56.5%)	
Number (%) of Participants Censored	67 (53.6%)	54 (43.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.46 (3.65, 20.07)	4.86 (2.83, 8.31)	
Log-Rank Test p-value (unstratified)	0.1411		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.772 (0.544, 1.095)		
History of liver metastasis			
Yes	47	39	0.7070
Number (%) of Participants with Events (Deterioration)	21 (44.7%)	16 (41.0%)	
Number (%) of Participants Censored	26 (55.3%)	23 (59.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.16 (3.52, 15.90)	4.63 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.5375		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.810 (0.413, 1.590)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	68 (52.3%)	77 (59.2%)	
Number (%) of Participants Censored	62 (47.7%)	53 (40.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.24 (2.33, 9.17)	4.86 (2.83, 6.93)	
Log-Rank Test p-value (unstratified)	0.7090		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.943 (0.680, 1.309)		
History of brain metastasis			
Yes	8	9	0.1641
Number (%) of Participants with Events (Deterioration)	2 (25.0%)	5 (55.6%)	
Number (%) of Participants Censored	6 (75.0%)	4 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	NR (0.76, NR)	1.45 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.2058		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.381 (0.074, 1.978)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	87 (51.5%)	88 (55.0%)	
Number (%) of Participants Censored	82 (48.5%)	72 (45.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.29 (3.09, 8.84)	4.67 (3.09, 6.93)	
Log-Rank Test p-value (unstratified)	0.6891		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.944 (0.700, 1.271)		
PD-L1 Status			
CPS < 1	67	59	0.2595
Number (%) of Participants with Events (Deterioration)	31 (46.3%)	33 (55.9%)	
Number (%) of Participants Censored	36 (53.7%)	26 (44.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.41 (3.58, NR)	4.40 (2.86, 8.31)	
Log-Rank Test p-value (unstratified)	0.1952		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.724 (0.442, 1.184)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	58 (53.2%)	60 (54.5%)	
Number (%) of Participants Censored	51 (46.8%)	50 (45.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.10, 9.17)	4.63 (2.56, 9.00)	
Log-Rank Test p-value (unstratified)	0.9225		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.023 (0.710, 1.475)		
BRCA 1/2 status			
Wild-Type	66	65	0.2071
Number (%) of Participants with Events (Deterioration)	34 (51.5%)	36 (55.4%)	
Number (%) of Participants Censored	32 (48.5%)	29 (44.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.59 (1.74, NR)	3.71 (1.91, 6.93)	
Log-Rank Test p-value (unstratified)	0.4207		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.829 (0.514, 1.337)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	6 (50.0%)	4 (40.0%)	
Number (%) of Participants Censored	6 (50.0%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (0.76, NR)	19.38 (2.00, NR)	
Log-Rank Test p-value (unstratified)	0.2621		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.173 (0.541, 8.725)		
Menopausal status			
Pre-menopausal	37	49	0.3105
Number (%) of Participants with Events (Deterioration)	14 (37.8%)	26 (53.1%)	
Number (%) of Participants Censored	23 (62.2%)	23 (46.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.63 (5.59, NR)	5.78 (2.56, NR)	
Log-Rank Test p-value (unstratified)	0.1650		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.631 (0.327, 1.218)		

	SG (N=177)	TPC (N=169)	Interaction
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	75 (53.6%)	66 (55.5%)	
Number (%) of Participants Censored	65 (46.4%)	53 (44.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.17, 7.89)	4.40 (2.83, 6.93)	
Log-Rank Test p-value (unstratified)	0.8216		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.966 (0.693, 1.347)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.46. Table 1.1.20.3: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Role Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.1622
Number (%) of Participants with Events (Deterioration)	25 (45.5%)	32 (65.3%)	
Number (%) of Participants Censored	30 (54.5%)	17 (34.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.59 (1.48, NR)	2.83 (1.18, 4.63)	
Log-Rank Test p-value (unstratified)	0.0695		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.615 (0.361, 1.047)		

	SG (N=177)	TPC (N=169)	Interaction
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	25 (73.5%)	22 (64.7%)	
Number (%) of Participants Censored	9 (26.5%)	12 (35.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.35 (0.82, 3.12)	1.68 (0.92, 4.21)	
Log-Rank Test p-value (unstratified)	0.6547		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.144 (0.644, 2.034)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	53 (60.2%)	61 (70.9%)	
Number (%) of Participants Censored	35 (39.8%)	25 (29.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (1.02, 2.40)	2.79 (1.94, 4.21)	
Log-Rank Test p-value (unstratified)	0.5543		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.124 (0.777, 1.627)		
Geographic region			
US/Canada/Western Europe	56	52	0.5791
Number (%) of Participants with Events (Deterioration)	31 (55.4%)	39 (75.0%)	
Number (%) of Participants Censored	25 (44.6%)	13 (25.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.89, 1.74)	1.94 (1.25, 3.88)	
Log-Rank Test p-value (unstratified)	0.4282		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.828 (0.513, 1.336)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	72 (59.5%)	76 (65.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	49 (40.5%)	41 (35.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (1.45, 3.12)	2.83 (1.91, 4.21)	
Log-Rank Test p-value (unstratified)	0.9999		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.004 (0.726, 1.388)		
Age group			
< 65	133	131	0.1795
Number (%) of Participants with Events (Deterioration)	80 (60.2%)	89 (67.9%)	
Number (%) of Participants Censored	53 (39.8%)	42 (32.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.45, 5.09)	2.79 (1.94, 4.11)	
Log-Rank Test p-value (unstratified)	0.3993		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.883 (0.652, 1.197)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	23 (52.3%)	26 (68.4%)	
Number (%) of Participants Censored	21 (47.7%)	12 (31.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.38 (0.85, 1.48)	2.56 (0.99, 4.96)	
Log-Rank Test p-value (unstratified)	0.2749		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.368 (0.773, 2.420)		
Race			
White	115	104	0.0321
Number (%) of Participants with Events (Deterioration)	68 (59.1%)	66 (63.5%)	
Number (%) of Participants Censored	47 (40.9%)	38 (36.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (1.05, 1.84)	2.79 (1.71, 4.63)	
Log-Rank Test p-value (unstratified)	0.4352		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.151 (0.819, 1.617)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	23 (60.5%)	28 (73.7%)	
Number (%) of Participants Censored	15 (39.5%)	10 (26.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.50 (0.95, 6.47)	1.94 (0.99, 5.59)	
Log-Rank Test p-value (unstratified)	0.6685		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.887 (0.510, 1.543)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	7 (36.8%)	18 (75.0%)	
Number (%) of Participants Censored	12 (63.2%)	6 (25.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.77 (0.99, NR)	2.40 (0.85, 4.11)	
Log-Rank Test p-value (unstratified)	0.0088		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.323 (0.132, 0.787)		
Baseline ECOG status			
0	116	106	0.7029
Number (%) of Participants with Events (Deterioration)	70 (60.3%)	76 (71.7%)	
Number (%) of Participants Censored	46 (39.7%)	30 (28.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (1.45, 3.12)	2.83 (1.87, 4.21)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5672		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.914 (0.660, 1.266)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	33 (54.1%)	39 (61.9%)	
Number (%) of Participants Censored	28 (45.9%)	24 (38.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.28 (0.85, 1.71)	2.46 (1.18, 3.29)	
Log-Rank Test p-value (unstratified)	0.8754		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.043 (0.652, 1.668)		
Physician's choice of chemotherapy			
Taxane	52	45	0.8893
Number (%) of Participants with Events (Deterioration)	31 (59.6%)	31 (68.9%)	
Number (%) of Participants Censored	21 (40.4%)	14 (31.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.53 (0.95, 3.61)	1.94 (1.41, 3.02)	
Log-Rank Test p-value (unstratified)	0.7766		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.934 (0.565, 1.543)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	72 (57.6%)	84 (67.7%)	
Number (%) of Participants Censored	53 (42.4%)	40 (32.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (1.41, 2.79)	3.52 (1.74, 4.96)	
Log-Rank Test p-value (unstratified)	0.6524		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.933 (0.680, 1.281)		

	SG (N=177)	TPC (N=169)	Interaction
History of liver metastasis			
Yes	47	39	0.8593
Number (%) of Participants with Events (Deterioration)	24 (51.1%)	20 (51.3%)	
Number (%) of Participants Censored	23 (48.9%)	19 (48.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.50 (1.15, NR)	2.76 (0.99, 9.10)	
Log-Rank Test p-value (unstratified)	0.8409		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.937 (0.513, 1.711)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	79 (60.8%)	95 (73.1%)	
Number (%) of Participants Censored	51 (39.2%)	35 (26.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (1.38, 2.17)	2.56 (1.87, 3.84)	
Log-Rank Test p-value (unstratified)	0.8491		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.977 (0.724, 1.319)		
History of brain metastasis			
Yes	8	9	0.5137
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	5 (55.6%)	
Number (%) of Participants Censored	5 (62.5%)	4 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.72, NR)	4.11 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.5492		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.673 (0.161, 2.820)		
No	169	160	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	100 (59.2%)	110 (68.8%)	
Number (%) of Participants Censored	69 (40.8%)	50 (31.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.51 (1.41, 2.33)	2.76 (1.87, 3.75)	
Log-Rank Test p-value (unstratified)	0.7815		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.967 (0.736, 1.269)		
PD-L1 Status			
CPS < 1	67	59	0.4338
Number (%) of Participants with Events (Deterioration)	36 (53.7%)	37 (62.7%)	
Number (%) of Participants Censored	31 (46.3%)	22 (37.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.50 (1.28, 11.24)	3.29 (1.05, 5.59)	
Log-Rank Test p-value (unstratified)	0.4494		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.837 (0.529, 1.327)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	67 (61.5%)	78 (70.9%)	
Number (%) of Participants Censored	42 (38.5%)	32 (29.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (1.18, 1.91)	2.53 (1.74, 3.52)	
Log-Rank Test p-value (unstratified)	0.8346		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.045 (0.752, 1.452)		
BRCA 1/2 status			
Wild-Type	66	65	0.0959
Number (%) of Participants with Events (Deterioration)	40 (60.6%)	44 (67.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	26 (39.4%)	21 (32.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (1.02, 3.22)	1.91 (0.99, 3.06)	
Log-Rank Test p-value (unstratified)	0.5739		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.888 (0.576, 1.369)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	7 (58.3%)	4 (40.0%)	
Number (%) of Participants Censored	5 (41.7%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.07 (0.76, NR)	10.64 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.1092		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.978 (0.744, 11.916)		
Menopausal status			
Pre-menopausal	37	49	0.0062
Number (%) of Participants with Events (Deterioration)	15 (40.5%)	34 (69.4%)	
Number (%) of Participants Censored	22 (59.5%)	15 (30.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.24 (2.73, NR)	2.83 (1.41, 4.17)	
Log-Rank Test p-value (unstratified)	0.0063		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.435 (0.235, 0.805)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	88 (62.9%)	80 (67.2%)	
Number (%) of Participants Censored	52 (37.1%)	39 (32.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	1.45 (1.02, 1.58)	2.46 (1.68, 4.11)	
Log-Rank Test p-value (unstratified)	0.3722		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.155 (0.852, 1.567)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.47. Table 1.1.20.4: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Emotional Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.6282
Number (%) of Participants with Events (Deterioration)	20 (36.4%)	16 (32.7%)	
Number (%) of Participants Censored	35 (63.6%)	33 (67.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.45 (4.96, NR)	9.95 (5.68, NR)	
Log-Rank Test p-value (unstratified)	0.6184		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.843 (0.429, 1.657)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	21 (61.8%)	14 (41.2%)	
Number (%) of Participants Censored	13 (38.2%)	20 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	4.14 (2.96, 12.16)	6.90 (2.37, NR)	
Log-Rank Test p-value (unstratified)	0.5816		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.210 (0.613, 2.388)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	42 (47.7%)	38 (44.2%)	
Number (%) of Participants Censored	46 (52.3%)	48 (55.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (4.24, 11.37)	10.18 (4.90, 12.39)	
Log-Rank Test p-value (unstratified)	0.6732		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.102 (0.706, 1.719)		
Geographic region			
US/Canada/Western Europe	56	52	0.4044
Number (%) of Participants with Events (Deterioration)	24 (42.9%)	18 (34.6%)	
Number (%) of Participants Censored	32 (57.1%)	34 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (3.81, 10.45)	7.56 (5.68, NR)	
Log-Rank Test p-value (unstratified)	0.4301		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.280 (0.694, 2.362)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	59 (48.8%)	50 (42.7%)	
Number (%) of Participants Censored	62 (51.2%)	67 (57.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (4.63, 12.48)	9.95 (5.59, 12.25)	
Log-Rank Test p-value (unstratified)	0.7726		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.946 (0.644, 1.389)		
Age group			
< 65	133	131	0.1055
Number (%) of Participants with Events (Deterioration)	73 (54.9%)	51 (38.9%)	
Number (%) of Participants Censored	60 (45.1%)	80 (61.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.33 (4.34, 9.69)	10.18 (6.90, 12.39)	
Log-Rank Test p-value (unstratified)	0.4060		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.167 (0.813, 1.675)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	10 (22.7%)	17 (44.7%)	
Number (%) of Participants Censored	34 (77.3%)	21 (55.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (4.27, NR)	7.56 (4.44, 15.18)	
Log-Rank Test p-value (unstratified)	0.2300		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.617 (0.278, 1.368)		
Race			
White	115	104	0.9140
Number (%) of Participants with Events (Deterioration)	51 (44.3%)	43 (41.3%)	
Number (%) of Participants Censored	64 (55.7%)	61 (58.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (4.24, 11.76)	7.26 (4.44, 12.25)	
Log-Rank Test p-value (unstratified)	0.8915		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.973 (0.647, 1.462)		

	SG (N=177)	TPC (N=169)	Interaction
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	19 (50.0%)	16 (42.1%)	
Number (%) of Participants Censored	19 (50.0%)	22 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (4.86, 18.73)	9.95 (6.97, 12.39)	
Log-Rank Test p-value (unstratified)	0.5627		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.811 (0.398, 1.651)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	9 (47.4%)	8 (33.3%)	
Number (%) of Participants Censored	10 (52.6%)	16 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.33 (3.06, NR)	13.96 (1.35, NR)	
Log-Rank Test p-value (unstratified)	0.7612		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.160 (0.445, 3.027)		
Baseline ECOG status			
0	116	106	0.8116
Number (%) of Participants with Events (Deterioration)	55 (47.4%)	43 (40.6%)	
Number (%) of Participants Censored	61 (52.6%)	63 (59.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.00 (4.96, 12.16)	9.95 (6.97, 12.25)	
Log-Rank Test p-value (unstratified)	0.8531		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.040 (0.694, 1.561)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	28 (45.9%)	25 (39.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	33 (54.1%)	38 (60.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.86 (3.19, 12.48)	4.90 (3.29, NR)	
Log-Rank Test p-value (unstratified)	0.8469		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.054 (0.612, 1.816)		
Physician's choice of chemotherapy			
Taxane	52	45	0.3106
Number (%) of Participants with Events (Deterioration)	24 (46.2%)	12 (26.7%)	
Number (%) of Participants Censored	28 (53.8%)	33 (73.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (4.17, 18.73)	11.10 (6.47, NR)	
Log-Rank Test p-value (unstratified)	0.2367		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.527 (0.753, 3.096)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	59 (47.2%)	56 (45.2%)	
Number (%) of Participants Censored	66 (52.8%)	68 (54.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (4.40, 11.37)	9.13 (4.70, 12.25)	
Log-Rank Test p-value (unstratified)	0.8052		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.956 (0.661, 1.382)		
History of liver metastasis			
Yes	47	39	0.1342
Number (%) of Participants with Events (Deterioration)	22 (46.8%)	6 (15.4%)	
Number (%) of Participants Censored	25 (53.2%)	33 (84.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.69 (3.65, NR)	NR (4.21, NR)	
Log-Rank Test p-value (unstratified)	0.1176		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.034 (0.821, 5.035)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	61 (46.9%)	62 (47.7%)	
Number (%) of Participants Censored	69 (53.1%)	68 (52.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (4.63, 12.16)	8.34 (5.68, 10.84)	
Log-Rank Test p-value (unstratified)	0.7001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.934 (0.652, 1.337)		
History of brain metastasis			
Yes	8	9	0.3590
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	3 (33.3%)	
Number (%) of Participants Censored	3 (37.5%)	6 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (0.76, NR)	NR (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.4230		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.785 (0.424, 7.505)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	78 (46.2%)	65 (40.6%)	
Number (%) of Participants Censored	91 (53.8%)	95 (59.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (4.86, 11.76)	9.13 (6.47, 12.25)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.9868		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.004 (0.719, 1.402)		
PD-L1 Status			
CPS < 1	67	59	0.4595
Number (%) of Participants with Events (Deterioration)	36 (53.7%)	28 (47.5%)	
Number (%) of Participants Censored	31 (46.3%)	31 (52.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (4.21, 11.37)	5.59 (3.81, 12.25)	
Log-Rank Test p-value (unstratified)	0.6673		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.896 (0.545, 1.474)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	47 (43.1%)	40 (36.4%)	
Number (%) of Participants Censored	62 (56.9%)	70 (63.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.00 (5.52, 15.51)	10.18 (7.56, 13.96)	
Log-Rank Test p-value (unstratified)	0.6988		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.092 (0.709, 1.680)		
BRCA 1/2 status			
Wild-Type	66	65	0.9218
Number (%) of Participants with Events (Deterioration)	38 (57.6%)	23 (35.4%)	
Number (%) of Participants Censored	28 (42.4%)	42 (64.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (4.21, 9.00)	9.95 (6.90, 12.25)	
Log-Rank Test p-value (unstratified)	0.1825		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.428 (0.845, 2.413)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	4 (33.3%)	3 (30.0%)	
Number (%) of Participants Censored	8 (66.7%)	7 (70.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.79, NR)	15.93 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.7251		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.324 (0.294, 5.973)		
Menopausal status			
Pre-menopausal	37	49	0.1916
Number (%) of Participants with Events (Deterioration)	19 (51.4%)	15 (30.6%)	
Number (%) of Participants Censored	18 (48.6%)	34 (69.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.33 (4.24, 16.16)	13.96 (6.97, NR)	
Log-Rank Test p-value (unstratified)	0.2330		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.516 (0.763, 3.013)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	64 (45.7%)	52 (43.7%)	
Number (%) of Participants Censored	76 (54.3%)	67 (56.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (4.34, 11.37)	7.56 (4.63, 10.84)	
Log-Rank Test p-value (unstratified)	0.6803		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.927 (0.640, 1.341)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.48. Table 1.1.20.5: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Cognitive Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.3656
Number (%) of Participants with Events (Deterioration)	31 (56.4%)	33 (67.3%)	
Number (%) of Participants Censored	24 (43.6%)	16 (32.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (1.64, 7.62)	3.09 (1.74, 4.21)	
Log-Rank Test p-value (unstratified)	0.2066		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.723 (0.435, 1.202)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	23 (67.6%)	17 (50.0%)	
Number (%) of Participants Censored	11 (32.4%)	17 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.56, 6.41)	6.97 (2.14, NR)	
Log-Rank Test p-value (unstratified)	0.5949		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.186 (0.629, 2.236)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	44 (50.0%)	54 (62.8%)	
Number (%) of Participants Censored	44 (50.0%)	32 (37.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.57 (2.83, 12.62)	3.29 (1.94, 4.17)	
Log-Rank Test p-value (unstratified)	0.1484		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.745 (0.500, 1.110)		
Geographic region			
US/Canada/Western Europe	56	52	0.5868
Number (%) of Participants with Events (Deterioration)	29 (51.8%)	32 (61.5%)	
Number (%) of Participants Censored	27 (48.2%)	20 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.34 (2.10, 7.62)	2.69 (1.58, 3.84)	
Log-Rank Test p-value (unstratified)	0.2527		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.747 (0.451, 1.238)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	69 (57.0%)	72 (61.5%)	
Number (%) of Participants Censored	52 (43.0%)	45 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (2.83, 5.98)	3.71 (2.60, 4.67)	
Log-Rank Test p-value (unstratified)	0.4007		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.868 (0.623, 1.209)		
Age group			
< 65	133	131	0.8017
Number (%) of Participants with Events (Deterioration)	83 (62.4%)	85 (64.9%)	
Number (%) of Participants Censored	50 (37.6%)	46 (35.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	4.21 (2.86, 5.65)	3.02 (2.20, 3.75)	
Log-Rank Test p-value (unstratified)	0.1714		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.810 (0.598, 1.098)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	15 (34.1%)	19 (50.0%)	
Number (%) of Participants Censored	29 (65.9%)	19 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.17, NR)	6.51 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.6353		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.841 (0.419, 1.689)		
Race			
White	115	104	0.5970
Number (%) of Participants with Events (Deterioration)	58 (50.4%)	62 (59.6%)	
Number (%) of Participants Censored	57 (49.6%)	42 (40.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.34 (2.86, 6.93)	2.83 (1.87, 3.75)	
Log-Rank Test p-value (unstratified)	0.1089		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.747 (0.522, 1.069)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	23 (60.5%)	24 (63.2%)	
Number (%) of Participants Censored	15 (39.5%)	14 (36.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.30, 15.51)	4.37 (3.48, 6.97)	
Log-Rank Test p-value (unstratified)	0.8928		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.960 (0.533, 1.727)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	12 (63.2%)	15 (62.5%)	
Number (%) of Participants Censored	7 (36.8%)	9 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (0.95, 13.14)	2.60 (1.02, 8.38)	
Log-Rank Test p-value (unstratified)	0.7714		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.883 (0.404, 1.932)		
Baseline ECOG status			
0	116	106	0.9757
Number (%) of Participants with Events (Deterioration)	65 (56.0%)	65 (61.3%)	
Number (%) of Participants Censored	51 (44.0%)	41 (38.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.86, 8.41)	3.52 (2.40, 4.63)	
Log-Rank Test p-value (unstratified)	0.3260		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.842 (0.596, 1.189)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	33 (54.1%)	39 (61.9%)	
Number (%) of Participants Censored	28 (45.9%)	24 (38.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (2.30, 4.47)	2.92 (1.74, 4.63)	
Log-Rank Test p-value (unstratified)	0.4167		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.824 (0.517, 1.313)		
Physician's choice of chemotherapy			

	SG (N=177)	TPC (N=169)	Interaction
Taxane	52	45	0.4918
Number (%) of Participants with Events (Deterioration)	29 (55.8%)	25 (55.6%)	
Number (%) of Participants Censored	23 (44.2%)	20 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.68, 5.98)	3.84 (2.79, 5.85)	
Log-Rank Test p-value (unstratified)	0.9741		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.989 (0.575, 1.703)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	69 (55.2%)	79 (63.7%)	
Number (%) of Participants Censored	56 (44.8%)	45 (36.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.50 (2.83, 6.93)	2.92 (2.10, 4.11)	
Log-Rank Test p-value (unstratified)	0.1351		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.782 (0.566, 1.080)		
History of liver metastasis			
Yes	47	39	0.9272
Number (%) of Participants with Events (Deterioration)	23 (48.9%)	18 (46.2%)	
Number (%) of Participants Censored	24 (51.1%)	21 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.34 (2.56, 13.14)	3.52 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.4534		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.782 (0.418, 1.464)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	75 (57.7%)	86 (66.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	55 (42.3%)	44 (33.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.83, 5.65)	3.29 (2.20, 4.17)	
Log-Rank Test p-value (unstratified)	0.2776		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.844 (0.619, 1.152)		
History of brain metastasis			
Yes	8	9	0.9246
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	5 (55.6%)	
Number (%) of Participants Censored	4 (50.0%)	4 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.72, NR)	2.14 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.8052		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.872 (0.232, 3.270)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	94 (55.6%)	99 (61.9%)	
Number (%) of Participants Censored	75 (44.4%)	61 (38.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (2.89, 5.65)	3.48 (2.40, 4.21)	
Log-Rank Test p-value (unstratified)	0.1957		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.830 (0.625, 1.102)		
PD-L1 Status			
CPS < 1	67	59	0.9026
Number (%) of Participants with Events (Deterioration)	38 (56.7%)	34 (57.6%)	
Number (%) of Participants Censored	29 (43.3%)	25 (42.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.57 (3.35, 6.93)	3.02 (1.77, 4.90)	
Log-Rank Test p-value (unstratified)	0.4380		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.833 (0.523, 1.325)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	60 (55.0%)	70 (63.6%)	
Number (%) of Participants Censored	49 (45.0%)	40 (36.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.79, 7.62)	3.71 (2.40, 4.21)	
Log-Rank Test p-value (unstratified)	0.2882		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.830 (0.587, 1.174)		
BRCA 1/2 status			
Wild-Type	66	65	0.3779
Number (%) of Participants with Events (Deterioration)	44 (66.7%)	37 (56.9%)	
Number (%) of Participants Censored	22 (33.3%)	28 (43.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (2.83, 4.93)	3.48 (2.10, 4.21)	
Log-Rank Test p-value (unstratified)	0.8963		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.029 (0.664, 1.595)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	6 (50.0%)	7 (70.0%)	
Number (%) of Participants Censored	6 (50.0%)	3 (30.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (0.79, NR)	3.02 (0.72, 7.26)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.3490		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.596 (0.198, 1.788)		
Menopausal status			
Pre-menopausal	37	49	0.0293
Number (%) of Participants with Events (Deterioration)	16 (43.2%)	34 (69.4%)	
Number (%) of Participants Censored	21 (56.8%)	15 (30.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.41 (3.52, NR)	2.83 (1.64, 4.67)	
Log-Rank Test p-value (unstratified)	0.0136		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.478 (0.263, 0.869)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	82 (58.6%)	69 (58.0%)	
Number (%) of Participants Censored	58 (41.4%)	50 (42.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (2.56, 5.13)	3.52 (2.60, 4.63)	
Log-Rank Test p-value (unstratified)	0.9507		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.991 (0.718, 1.367)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.49. Table 1.1.20.6: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Social Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.1392
Number (%) of Participants with Events (Deterioration)	29 (52.7%)	31 (63.3%)	
Number (%) of Participants Censored	26 (47.3%)	18 (36.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.48, 18.23)	2.79 (1.41, 4.80)	
Log-Rank Test p-value (unstratified)	0.5354		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.855 (0.512, 1.428)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	21 (61.8%)	23 (67.6%)	
Number (%) of Participants Censored	13 (38.2%)	11 (32.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.24 (0.95, 12.16)	1.41 (0.85, 4.44)	
Log-Rank Test p-value (unstratified)	0.1261		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.622 (0.336, 1.153)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	52 (59.1%)	46 (53.5%)	
Number (%) of Participants Censored	36 (40.9%)	40 (46.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.45, 3.61)	4.11 (2.86, 15.18)	
Log-Rank Test p-value (unstratified)	0.2802		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.242 (0.834, 1.849)		
Geographic region			

	SG (N=177)	TPC (N=169)	Interaction
US/Canada/Western Europe	56	52	0.7909
Number (%) of Participants with Events (Deterioration)	26 (46.4%)	28 (53.8%)	
Number (%) of Participants Censored	30 (53.6%)	24 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.12 (1.41, NR)	3.58 (1.41, 5.32)	
Log-Rank Test p-value (unstratified)	0.9136		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.972 (0.569, 1.660)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	76 (62.8%)	72 (61.5%)	
Number (%) of Participants Censored	45 (37.2%)	45 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.48, 4.17)	3.09 (1.91, 4.83)	
Log-Rank Test p-value (unstratified)	0.9341		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.986 (0.713, 1.364)		
Age group			
< 65	133	131	0.2724
Number (%) of Participants with Events (Deterioration)	78 (58.6%)	78 (59.5%)	
Number (%) of Participants Censored	55 (41.4%)	53 (40.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.68, 7.16)	3.25 (1.91, 4.83)	
Log-Rank Test p-value (unstratified)	0.5116		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.901 (0.657, 1.235)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	22 (57.9%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	20 (45.5%)	16 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 2.23)	3.58 (0.99, 15.18)	
Log-Rank Test p-value (unstratified)	0.4436		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.256 (0.696, 2.266)		
Race			
White	115	104	0.2287
Number (%) of Participants with Events (Deterioration)	61 (53.0%)	59 (56.7%)	
Number (%) of Participants Censored	54 (47.0%)	45 (43.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.45, 3.94)	3.25 (1.64, 5.82)	
Log-Rank Test p-value (unstratified)	0.8858		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.976 (0.682, 1.397)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	26 (68.4%)	22 (57.9%)	
Number (%) of Participants Censored	12 (31.6%)	16 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.28, 7.46)	4.47 (2.23, NR)	
Log-Rank Test p-value (unstratified)	0.5004		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.217 (0.686, 2.159)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	11 (57.9%)	17 (70.8%)	
Number (%) of Participants Censored	8 (42.1%)	7 (29.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	3.78 (0.99, NR)	1.41 (0.79, 3.06)	
Log-Rank Test p-value (unstratified)	0.1150		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.527 (0.234, 1.188)		
Baseline ECOG status			
0	116	106	0.9007
Number (%) of Participants with Events (Deterioration)	69 (59.5%)	64 (60.4%)	
Number (%) of Participants Censored	47 (40.5%)	42 (39.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.48, 7.16)	3.09 (1.64, 4.83)	
Log-Rank Test p-value (unstratified)	0.9258		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.984 (0.700, 1.385)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	33 (54.1%)	36 (57.1%)	
Number (%) of Participants Censored	28 (45.9%)	27 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.40 (1.28, 3.78)	3.58 (2.23, 5.78)	
Log-Rank Test p-value (unstratified)	0.8835		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.967 (0.598, 1.565)		
Physician's choice of chemotherapy			
Taxane	52	45	0.2604
Number (%) of Participants with Events (Deterioration)	34 (65.4%)	23 (51.1%)	
Number (%) of Participants Censored	18 (34.6%)	22 (48.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.48, 3.61)	2.79 (1.54, NR)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5316		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.185 (0.691, 2.032)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	68 (54.4%)	77 (62.1%)	
Number (%) of Participants Censored	57 (45.6%)	47 (37.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.45, 7.46)	3.52 (2.23, 4.90)	
Log-Rank Test p-value (unstratified)	0.4015		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.869 (0.626, 1.207)		
History of liver metastasis			
Yes	47	39	0.1600
Number (%) of Participants with Events (Deterioration)	25 (53.2%)	13 (33.3%)	
Number (%) of Participants Censored	22 (46.8%)	26 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.58, 7.16)	NR (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.1903		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.554 (0.794, 3.044)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	77 (59.2%)	87 (66.9%)	
Number (%) of Participants Censored	53 (40.8%)	43 (33.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.45, 3.55)	3.06 (1.87, 4.11)	
Log-Rank Test p-value (unstratified)	0.4699		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.895 (0.657, 1.219)		

	SG (N=177)	TPC (N=169)	Interaction
History of brain metastasis			
Yes	8	9	0.9863
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	5 (55.6%)	
Number (%) of Participants Censored	4 (50.0%)	4 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.22 (0.72, NR)	2.86 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.9851		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.028 (0.275, 3.848)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	98 (58.0%)	95 (59.4%)	
Number (%) of Participants Censored	71 (42.0%)	65 (40.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.58, 3.78)	3.29 (2.23, 4.80)	
Log-Rank Test p-value (unstratified)	0.8356		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.972 (0.731, 1.291)		
PD-L1 Status			
CPS < 1	67	59	0.4853
Number (%) of Participants with Events (Deterioration)	41 (61.2%)	38 (64.4%)	
Number (%) of Participants Censored	26 (38.8%)	21 (35.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.05, 7.16)	2.86 (0.92, 3.58)	
Log-Rank Test p-value (unstratified)	0.5420		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.871 (0.559, 1.356)		
CPS ≥ 1	109	110	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	61 (56.0%)	62 (56.4%)	
Number (%) of Participants Censored	48 (44.0%)	48 (43.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.12 (1.64, 4.17)	3.98 (2.79, 5.82)	
Log-Rank Test p-value (unstratified)	0.8658		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.033 (0.724, 1.474)		
BRCA 1/2 status			
Wild-Type	66	65	0.4856
Number (%) of Participants with Events (Deterioration)	40 (60.6%)	34 (52.3%)	
Number (%) of Participants Censored	26 (39.4%)	31 (47.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.48, 3.65)	3.58 (1.64, 6.93)	
Log-Rank Test p-value (unstratified)	0.5065		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.167 (0.737, 1.846)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	7 (58.3%)	7 (70.0%)	
Number (%) of Participants Censored	5 (41.7%)	3 (30.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, NR)	1.41 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.5981		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.755 (0.251, 2.265)		
Menopausal status			
Pre-menopausal	37	49	0.4295
Number (%) of Participants with Events (Deterioration)	22 (59.5%)	33 (67.3%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	15 (40.5%)	16 (32.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (1.61, 12.16)	3.09 (1.41, 5.78)	
Log-Rank Test p-value (unstratified)	0.2182		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.702 (0.397, 1.239)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	80 (57.1%)	66 (55.5%)	
Number (%) of Participants Censored	60 (42.9%)	53 (44.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.45, 3.61)	3.29 (1.91, 4.90)	
Log-Rank Test p-value (unstratified)	0.7478		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.056 (0.761, 1.465)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.50. Table 1.1.20.7: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Fatigue | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.2918
Number (%) of Participants with Events (Deterioration)	33 (60.0%)	34 (69.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	22 (40.0%)	15 (30.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (0.95, 4.47)	1.41 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.1727		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.719 (0.443, 1.166)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	24 (70.6%)	26 (76.5%)	
Number (%) of Participants Censored	10 (29.4%)	8 (23.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.28 (0.82, 1.81)	1.25 (0.85, 3.22)	
Log-Rank Test p-value (unstratified)	0.6737		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.882 (0.505, 1.542)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	62 (70.5%)	64 (74.4%)	
Number (%) of Participants Censored	26 (29.5%)	22 (25.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.79, 1.45)	1.54 (1.02, 3.02)	
Log-Rank Test p-value (unstratified)	0.4018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.176 (0.829, 1.670)		
Geographic region			
US/Canada/Western Europe	56	52	0.7814
Number (%) of Participants with Events (Deterioration)	35 (62.5%)	40 (76.9%)	
Number (%) of Participants Censored	21 (37.5%)	12 (23.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	1.30 (0.79, 1.71)	1.41 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.5902		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.890 (0.560, 1.417)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	84 (69.4%)	84 (71.8%)	
Number (%) of Participants Censored	37 (30.6%)	33 (28.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 1.84)	1.64 (1.05, 2.33)	
Log-Rank Test p-value (unstratified)	0.8982		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.988 (0.730, 1.337)		
Age group			
< 65	133	131	0.9684
Number (%) of Participants with Events (Deterioration)	93 (69.9%)	95 (72.5%)	
Number (%) of Participants Censored	40 (30.1%)	36 (27.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.95, 1.74)	1.45 (1.05, 2.14)	
Log-Rank Test p-value (unstratified)	0.7558		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.964 (0.724, 1.284)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	26 (59.1%)	29 (76.3%)	
Number (%) of Participants Censored	18 (40.9%)	9 (23.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 2.10)	1.41 (0.92, 1.94)	
Log-Rank Test p-value (unstratified)	0.9070		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.975 (0.572, 1.660)		
Race			
White	115	104	0.0924
Number (%) of Participants with Events (Deterioration)	76 (66.1%)	74 (71.2%)	
Number (%) of Participants Censored	39 (33.9%)	30 (28.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.85, 1.74)	1.41 (0.99, 1.71)	
Log-Rank Test p-value (unstratified)	0.4562		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.893 (0.647, 1.232)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	29 (76.3%)	29 (76.3%)	
Number (%) of Participants Censored	9 (23.7%)	9 (23.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.79, 1.81)	3.22 (1.05, 4.86)	
Log-Rank Test p-value (unstratified)	0.1602		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.458 (0.869, 2.448)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	9 (47.4%)	18 (75.0%)	
Number (%) of Participants Censored	10 (52.6%)	6 (25.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.33 (0.79, NR)	1.41 (0.79, 3.06)	
Log-Rank Test p-value (unstratified)	0.1135		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.529 (0.236, 1.186)		
Baseline ECOG status			

	SG (N=177)	TPC (N=169)	Interaction
0	116	106	0.4316
Number (%) of Participants with Events (Deterioration)	84 (72.4%)	81 (76.4%)	
Number (%) of Participants Censored	32 (27.6%)	25 (23.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.95, 1.81)	1.45 (1.02, 2.14)	
Log-Rank Test p-value (unstratified)	0.9396		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.020 (0.751, 1.384)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	35 (57.4%)	43 (68.3%)	
Number (%) of Participants Censored	26 (42.6%)	20 (31.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.82, 1.71)	1.22 (0.95, 3.02)	
Log-Rank Test p-value (unstratified)	0.4888		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.862 (0.547, 1.358)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1280
Number (%) of Participants with Events (Deterioration)	36 (69.2%)	32 (71.1%)	
Number (%) of Participants Censored	16 (30.8%)	13 (28.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.18 (0.79, 1.71)	1.41 (1.05, 1.94)	
Log-Rank Test p-value (unstratified)	0.2995		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.294 (0.802, 2.088)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	83 (66.4%)	92 (74.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	42 (33.6%)	32 (25.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.95, 1.84)	1.41 (0.95, 2.14)	
Log-Rank Test p-value (unstratified)	0.3257		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.867 (0.644, 1.168)		
History of liver metastasis			
Yes	47	39	0.0739
Number (%) of Participants with Events (Deterioration)	32 (68.1%)	20 (51.3%)	
Number (%) of Participants Censored	15 (31.9%)	19 (48.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.85 (0.79, 1.74)	1.87 (1.05, 5.39)	
Log-Rank Test p-value (unstratified)	0.1204		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.573 (0.899, 2.754)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	87 (66.9%)	104 (80.0%)	
Number (%) of Participants Censored	43 (33.1%)	26 (20.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.95, 1.81)	1.25 (0.99, 1.94)	
Log-Rank Test p-value (unstratified)	0.2520		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.640, 1.134)		
History of brain metastasis			
Yes	8	9	0.1650
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	5 (55.6%)	
Number (%) of Participants Censored	3 (37.5%)	4 (44.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.77 (0.72, NR)	4.11 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.2387		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.127 (0.601, 7.535)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	114 (67.5%)	119 (74.4%)	
Number (%) of Participants Censored	55 (32.5%)	41 (25.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.95, 1.71)	1.41 (1.05, 1.87)	
Log-Rank Test p-value (unstratified)	0.5403		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.930 (0.719, 1.203)		
PD-L1 Status			
CPS < 1	67	59	0.1793
Number (%) of Participants with Events (Deterioration)	41 (61.2%)	44 (74.6%)	
Number (%) of Participants Censored	26 (38.8%)	15 (25.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.51 (0.82, 3.88)	1.18 (0.92, 2.69)	
Log-Rank Test p-value (unstratified)	0.2218		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.775 (0.505, 1.188)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	78 (71.6%)	80 (72.7%)	
Number (%) of Participants Censored	31 (28.4%)	30 (27.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.82, 1.68)	1.45 (1.05, 1.94)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5972		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.097 (0.803, 1.500)		
BRCA 1/2 status			
Wild-Type	66	65	0.8364
Number (%) of Participants with Events (Deterioration)	44 (66.7%)	49 (75.4%)	
Number (%) of Participants Censored	22 (33.3%)	16 (24.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.41 (0.82, 2.43)	1.87 (1.05, 3.02)	
Log-Rank Test p-value (unstratified)	0.6410		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.916 (0.606, 1.383)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	8 (66.7%)	6 (60.0%)	
Number (%) of Participants Censored	4 (33.3%)	4 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.76, NR)	1.25 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.8902		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.087 (0.375, 3.149)		
Menopausal status			
Pre-menopausal	37	49	0.4495
Number (%) of Participants with Events (Deterioration)	21 (56.8%)	35 (71.4%)	
Number (%) of Participants Censored	16 (43.2%)	14 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.82, NR)	1.64 (1.05, 3.22)	
Log-Rank Test p-value (unstratified)	0.3364		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.770 (0.448, 1.326)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	98 (70.0%)	88 (73.9%)	
Number (%) of Participants Censored	42 (30.0%)	31 (26.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.12 (0.82, 1.48)	1.22 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.8433		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.981 (0.735, 1.311)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.51. Table 1.1.20.8: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Nausea and Vomiting | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.8761
Number (%) of Participants with Events (Deterioration)	34 (61.8%)	23 (46.9%)	
Number (%) of Participants Censored	21 (38.2%)	26 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (1.48, 4.24)	2.83 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.4528		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.226 (0.717, 2.095)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	26 (76.5%)	19 (55.9%)	
Number (%) of Participants Censored	8 (23.5%)	15 (44.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.45 (0.89, 2.63)	1.87 (1.22, NR)	
Log-Rank Test p-value (unstratified)	0.2847		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.377 (0.761, 2.492)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	50 (56.8%)	51 (59.3%)	
Number (%) of Participants Censored	38 (43.2%)	35 (40.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (1.38, 3.19)	3.84 (1.54, 8.11)	
Log-Rank Test p-value (unstratified)	0.3162		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.230 (0.829, 1.825)		
Geographic region			
US/Canada/Western Europe	56	52	0.5257
Number (%) of Participants with Events (Deterioration)	30 (53.6%)	26 (50.0%)	
Number (%) of Participants Censored	26 (46.4%)	26 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.48, 6.93)	2.50 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.8421		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.058 (0.618, 1.811)		
Rest of the world	121	117	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	80 (66.1%)	67 (57.3%)	
Number (%) of Participants Censored	41 (33.9%)	50 (42.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.41, 2.20)	2.63 (1.64, 6.47)	
Log-Rank Test p-value (unstratified)	0.1066		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.306 (0.943, 1.808)		
Age group			
< 65	133	131	0.5353
Number (%) of Participants with Events (Deterioration)	93 (69.9%)	75 (57.3%)	
Number (%) of Participants Censored	40 (30.1%)	56 (42.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.41, 2.63)	2.10 (1.61, 5.55)	
Log-Rank Test p-value (unstratified)	0.1143		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.281 (0.944, 1.739)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	17 (38.6%)	18 (47.4%)	
Number (%) of Participants Censored	27 (61.4%)	20 (52.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.71, NR)	4.90 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.9078		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.036 (0.527, 2.038)		
Race			
White	115	104	0.8738
Number (%) of Participants with Events (Deterioration)	74 (64.3%)	58 (55.8%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	41 (35.7%)	46 (44.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (1.38, 2.83)	2.53 (1.64, 6.47)	
Log-Rank Test p-value (unstratified)	0.2329		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.237 (0.875, 1.747)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	21 (55.3%)	19 (50.0%)	
Number (%) of Participants Censored	17 (44.7%)	19 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.54, NR)	4.90 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.6700		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.142 (0.611, 2.135)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	11 (57.9%)	15 (62.5%)	
Number (%) of Participants Censored	8 (42.1%)	9 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.76, 3.06)	1.71 (0.76, 3.45)	
Log-Rank Test p-value (unstratified)	0.9845		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.992 (0.450, 2.190)		
Baseline ECOG status			
0	116	106	0.5057
Number (%) of Participants with Events (Deterioration)	77 (66.4%)	64 (60.4%)	
Number (%) of Participants Censored	39 (33.6%)	42 (39.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	1.97 (1.48, 3.06)	2.53 (1.61, 5.59)	
Log-Rank Test p-value (unstratified)	0.4502		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.137 (0.815, 1.587)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	33 (54.1%)	29 (46.0%)	
Number (%) of Participants Censored	28 (45.9%)	34 (54.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.64 (0.85, 4.24)	3.84 (1.48, NR)	
Log-Rank Test p-value (unstratified)	0.1340		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.472 (0.892, 2.428)		
Physician's choice of chemotherapy			
Taxane	52	45	0.0469
Number (%) of Participants with Events (Deterioration)	29 (55.8%)	14 (31.1%)	
Number (%) of Participants Censored	23 (44.2%)	31 (68.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.79 (1.48, 5.65)	NR (5.55, NR)	
Log-Rank Test p-value (unstratified)	0.0117		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.231 (1.177, 4.226)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	81 (64.8%)	79 (63.7%)	
Number (%) of Participants Censored	44 (35.2%)	45 (36.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.38, 2.63)	1.68 (1.41, 3.09)	
Log-Rank Test p-value (unstratified)	0.7761		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.047 (0.767, 1.430)		
History of liver metastasis			
Yes	47	39	0.6334
Number (%) of Participants with Events (Deterioration)	30 (63.8%)	19 (48.7%)	
Number (%) of Participants Censored	17 (36.2%)	20 (51.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (0.85, 3.06)	3.84 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.2649		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.395 (0.781, 2.491)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	80 (61.5%)	74 (56.9%)	
Number (%) of Participants Censored	50 (38.5%)	56 (43.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.97 (1.45, 2.86)	2.53 (1.61, 5.59)	
Log-Rank Test p-value (unstratified)	0.3178		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.176 (0.856, 1.616)		
History of brain metastasis			
Yes	8	9	0.6356
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	4 (44.4%)	
Number (%) of Participants Censored	4 (50.0%)	5 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.76, NR)	8.11 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.7787		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.205, 3.292)		

	SG (N=177)	TPC (N=169)	Interaction
No	169	160	
Number (%) of Participants with Events (Deterioration)	106 (62.7%)	89 (55.6%)	
Number (%) of Participants Censored	63 (37.3%)	71 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.84 (1.45, 2.79)	2.63 (1.68, 5.55)	
Log-Rank Test p-value (unstratified)	0.1317		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.245 (0.938, 1.652)		
PD-L1 Status			
CPS < 1	67	59	0.7146
Number (%) of Participants with Events (Deterioration)	43 (64.2%)	34 (57.6%)	
Number (%) of Participants Censored	24 (35.8%)	25 (42.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.95, 4.24)	3.84 (2.07, 9.23)	
Log-Rank Test p-value (unstratified)	0.3031		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.272 (0.806, 2.007)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	67 (61.5%)	59 (53.6%)	
Number (%) of Participants Censored	42 (38.5%)	51 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.43 (1.54, 2.86)	1.94 (1.48, 6.47)	
Log-Rank Test p-value (unstratified)	0.3418		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.188 (0.836, 1.689)		
BRCA 1/2 status			
Wild-Type	66	65	0.9419

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	40 (60.6%)	34 (52.3%)	
Number (%) of Participants Censored	26 (39.4%)	31 (47.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.48, 5.65)	2.53 (1.68, 8.11)	
Log-Rank Test p-value (unstratified)	0.3609		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.241 (0.785, 1.961)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	5 (41.7%)	4 (40.0%)	
Number (%) of Participants Censored	7 (58.3%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.79, NR)	9.53 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.9011		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.097 (0.292, 4.120)		
Menopausal status			
Pre-menopausal	37	49	0.2885
Number (%) of Participants with Events (Deterioration)	23 (62.2%)	29 (59.2%)	
Number (%) of Participants Censored	14 (37.8%)	20 (40.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.86 (1.68, 11.66)	1.87 (1.41, 8.11)	
Log-Rank Test p-value (unstratified)	0.8493		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.949 (0.542, 1.659)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	87 (62.1%)	63 (52.9%)	
Number (%) of Participants Censored	53 (37.9%)	56 (47.1%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (1.41, 2.63)	3.45 (1.68, 9.23)	
Log-Rank Test p-value (unstratified)	0.0665		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.355 (0.978, 1.878)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.52. Table 1.1.20.9: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Pain | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.2066
Number (%) of Participants with Events (Deterioration)	22 (40.0%)	23 (46.9%)	
Number (%) of Participants Censored	33 (60.0%)	26 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.95 (5.55, 26.05)	3.58 (2.53, 9.23)	
Log-Rank Test p-value (unstratified)	0.0541		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.548 (0.295, 1.019)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	18 (52.9%)	21 (61.8%)	
Number (%) of Participants Censored	16 (47.1%)	13 (38.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.30 (1.45, 7.72)	1.61 (0.85, 5.59)	
Log-Rank Test p-value (unstratified)	0.3525		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.745 (0.396, 1.401)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	49 (55.7%)	56 (65.1%)	
Number (%) of Participants Censored	39 (44.3%)	30 (34.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.45, 6.54)	2.79 (2.23, 4.86)	
Log-Rank Test p-value (unstratified)	0.7562		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.067 (0.727, 1.567)		
Geographic region			
US/Canada/Western Europe	56	52	0.7789
Number (%) of Participants with Events (Deterioration)	25 (44.6%)	31 (59.6%)	
Number (%) of Participants Censored	31 (55.4%)	21 (40.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.74, 15.97)	2.79 (1.54, 5.75)	
Log-Rank Test p-value (unstratified)	0.2521		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.730 (0.423, 1.260)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	64 (52.9%)	69 (59.0%)	
Number (%) of Participants Censored	57 (47.1%)	48 (41.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.55 (2.20, 8.77)	3.35 (2.33, 4.90)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.3375		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.602, 1.194)		
Age group			
< 65	133	131	0.5514
Number (%) of Participants with Events (Deterioration)	70 (52.6%)	76 (58.0%)	
Number (%) of Participants Censored	63 (47.4%)	55 (42.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.47 (2.79, 9.10)	2.96 (2.33, 5.09)	
Log-Rank Test p-value (unstratified)	0.1629		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.795 (0.573, 1.104)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	24 (63.2%)	
Number (%) of Participants Censored	25 (56.8%)	14 (36.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.02, NR)	2.63 (1.77, 6.51)	
Log-Rank Test p-value (unstratified)	0.7968		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.923 (0.498, 1.711)		
Race			
White	115	104	0.8842
Number (%) of Participants with Events (Deterioration)	57 (49.6%)	61 (58.7%)	
Number (%) of Participants Censored	58 (50.4%)	43 (41.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.37 (1.81, 8.77)	2.79 (1.94, 4.86)	
Log-Rank Test p-value (unstratified)	0.3405		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.841 (0.584, 1.210)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	23 (60.5%)	25 (65.8%)	
Number (%) of Participants Censored	15 (39.5%)	13 (34.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.59 (1.68, 10.84)	3.02 (1.94, 5.59)	
Log-Rank Test p-value (unstratified)	0.5035		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.822 (0.460, 1.472)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	6 (31.6%)	11 (45.8%)	
Number (%) of Participants Censored	13 (68.4%)	13 (54.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.77 (1.12, NR)	6.51 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.3300		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.603 (0.216, 1.684)		
Baseline ECOG status			
0	116	106	0.8752
Number (%) of Participants with Events (Deterioration)	65 (56.0%)	66 (62.3%)	
Number (%) of Participants Censored	51 (44.0%)	40 (37.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.59 (2.43, 8.77)	2.83 (2.10, 4.86)	
Log-Rank Test p-value (unstratified)	0.1602		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.782 (0.553, 1.105)		
1	61	63	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	24 (39.3%)	34 (54.0%)	
Number (%) of Participants Censored	37 (60.7%)	29 (46.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.02, NR)	3.06 (2.14, 6.28)	
Log-Rank Test p-value (unstratified)	0.6470		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.892 (0.524, 1.519)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1247
Number (%) of Participants with Events (Deterioration)	30 (57.7%)	24 (53.3%)	
Number (%) of Participants Censored	22 (42.3%)	21 (46.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.64, 6.87)	3.06 (1.94, 6.90)	
Log-Rank Test p-value (unstratified)	0.7299		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.101 (0.637, 1.900)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	59 (47.2%)	76 (61.3%)	
Number (%) of Participants Censored	66 (52.8%)	48 (38.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.72 (2.53, 11.76)	2.79 (2.14, 5.09)	
Log-Rank Test p-value (unstratified)	0.0430		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.704 (0.499, 0.994)		
History of liver metastasis			
Yes	47	39	0.8249
Number (%) of Participants with Events (Deterioration)	22 (46.8%)	17 (43.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	25 (53.2%)	22 (56.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (2.17, 15.97)	3.71 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.7019		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.878 (0.455, 1.697)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	67 (51.5%)	83 (63.8%)	
Number (%) of Participants Censored	63 (48.5%)	47 (36.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.55 (1.81, 7.82)	2.79 (2.23, 4.07)	
Log-Rank Test p-value (unstratified)	0.1963		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.811 (0.586, 1.122)		
History of brain metastasis			
Yes	8	9	0.5784
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	5 (55.6%)	
Number (%) of Participants Censored	4 (50.0%)	4 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.76, NR)	1.45 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.9139		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.079 (0.269, 4.320)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	85 (50.3%)	95 (59.4%)	
Number (%) of Participants Censored	84 (49.7%)	65 (40.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	5.55 (2.43, 8.84)	2.96 (2.40, 4.44)	
Log-Rank Test p-value (unstratified)	0.1377		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.802 (0.596, 1.079)		
PD-L1 Status			
CPS < 1	67	59	0.2708
Number (%) of Participants with Events (Deterioration)	37 (55.2%)	36 (61.0%)	
Number (%) of Participants Censored	30 (44.8%)	23 (39.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.54 (2.79, 9.82)	2.37 (1.61, 3.58)	
Log-Rank Test p-value (unstratified)	0.0535		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.638 (0.402, 1.014)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	52 (47.7%)	64 (58.2%)	
Number (%) of Participants Censored	57 (52.3%)	46 (41.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.61, 15.51)	3.71 (2.79, 6.11)	
Log-Rank Test p-value (unstratified)	0.6454		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.922 (0.635, 1.338)		
BRCA 1/2 status			
Wild-Type	66	65	0.0765
Number (%) of Participants with Events (Deterioration)	35 (53.0%)	40 (61.5%)	
Number (%) of Participants Censored	31 (47.0%)	25 (38.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.59 (2.40, 9.95)	2.79 (1.54, 3.71)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.1878		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.737 (0.465, 1.169)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	8 (66.7%)	5 (50.0%)	
Number (%) of Participants Censored	4 (33.3%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.00 (0.76, 6.87)	4.11 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.2908		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.833 (0.593, 5.666)		
Menopausal status			
Pre-menopausal	37	49	0.2489
Number (%) of Participants with Events (Deterioration)	14 (37.8%)	26 (53.1%)	
Number (%) of Participants Censored	23 (62.2%)	23 (46.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.95 (3.15, NR)	4.40 (1.94, 6.90)	
Log-Rank Test p-value (unstratified)	0.0936		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.569 (0.292, 1.109)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	75 (53.6%)	74 (62.2%)	
Number (%) of Participants Censored	65 (46.4%)	45 (37.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (1.68, 7.72)	2.79 (2.14, 3.75)	
Log-Rank Test p-value (unstratified)	0.3232		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.854 (0.617, 1.180)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.

Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.53. Table 1.1.20.10: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Dyspnoea | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.7676
Number (%) of Participants with Events (Deterioration)	21 (38.2%)	27 (55.1%)	
Number (%) of Participants Censored	34 (61.8%)	22 (44.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.09 (4.34, NR)	2.83 (1.41, 6.24)	
Log-Rank Test p-value (unstratified)	0.0269		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.524 (0.293, 0.937)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	14 (41.2%)	19 (55.9%)	
Number (%) of Participants Censored	20 (58.8%)	15 (44.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (3.48, NR)	4.86 (2.07, 6.90)	
Log-Rank Test p-value (unstratified)	0.0272		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.464 (0.231, 0.935)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	30 (34.1%)	43 (50.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	58 (65.9%)	43 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (7.23, NR)	4.96 (3.35, 13.83)	
Log-Rank Test p-value (unstratified)	0.0540		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.635 (0.397, 1.015)		
Geographic region			
US/Canada/Western Europe	56	52	0.6584
Number (%) of Participants with Events (Deterioration)	24 (42.9%)	31 (59.6%)	
Number (%) of Participants Censored	32 (57.1%)	21 (40.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (1.64, NR)	3.09 (1.41, 4.96)	
Log-Rank Test p-value (unstratified)	0.0646		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.602 (0.348, 1.043)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	41 (33.9%)	58 (49.6%)	
Number (%) of Participants Censored	80 (66.1%)	59 (50.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (9.63, NR)	4.96 (3.25, 9.00)	
Log-Rank Test p-value (unstratified)	0.0022		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.538 (0.359, 0.805)		
Age group			
< 65	133	131	0.7491
Number (%) of Participants with Events (Deterioration)	53 (39.8%)	69 (52.7%)	
Number (%) of Participants Censored	80 (60.2%)	62 (47.3%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (7.72, NR)	4.37 (2.79, 6.28)	
Log-Rank Test p-value (unstratified)	0.0011		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.555 (0.387, 0.797)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	12 (27.3%)	20 (52.6%)	
Number (%) of Participants Censored	32 (72.7%)	18 (47.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (3.09, NR)	4.67 (1.84, 13.83)	
Log-Rank Test p-value (unstratified)	0.2326		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.638 (0.304, 1.338)		
Race			
White	115	104	0.9791
Number (%) of Participants with Events (Deterioration)	41 (35.7%)	52 (50.0%)	
Number (%) of Participants Censored	74 (64.3%)	52 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (6.67, NR)	4.86 (2.83, 6.90)	
Log-Rank Test p-value (unstratified)	0.0122		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.596 (0.395, 0.900)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	16 (42.1%)	22 (57.9%)	
Number (%) of Participants Censored	22 (57.9%)	16 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (3.65, NR)	4.90 (1.97, 18.46)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.0583		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.534 (0.277, 1.030)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	6 (31.6%)	12 (50.0%)	
Number (%) of Participants Censored	13 (68.4%)	12 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (1.02, NR)	4.37 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.2648		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.576 (0.216, 1.537)		
Baseline ECOG status			
0	116	106	0.1932
Number (%) of Participants with Events (Deterioration)	42 (36.2%)	61 (57.5%)	
Number (%) of Participants Censored	74 (63.8%)	45 (42.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (9.72, NR)	4.37 (2.40, 6.24)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.483 (0.325, 0.720)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	23 (37.7%)	28 (44.4%)	
Number (%) of Participants Censored	38 (62.3%)	35 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.34 (3.12, NR)	4.90 (3.25, 13.83)	
Log-Rank Test p-value (unstratified)	0.4024		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.789 (0.453, 1.374)		

	SG (N=177)	TPC (N=169)	Interaction
Physician's choice of chemotherapy			
Taxane	52	45	0.8276
Number (%) of Participants with Events (Deterioration)	22 (42.3%)	24 (53.3%)	
Number (%) of Participants Censored	30 (57.7%)	21 (46.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.20 (2.37, NR)	2.83 (1.54, 5.68)	
Log-Rank Test p-value (unstratified)	0.0767		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.587 (0.324, 1.066)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	43 (34.4%)	65 (52.4%)	
Number (%) of Participants Censored	82 (65.6%)	59 (47.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.47 (9.63, NR)	4.90 (3.25, 6.74)	
Log-Rank Test p-value (unstratified)	0.0018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.545 (0.370, 0.803)		
History of liver metastasis			
Yes	47	39	0.5550
Number (%) of Participants with Events (Deterioration)	15 (31.9%)	12 (30.8%)	
Number (%) of Participants Censored	32 (68.1%)	27 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (3.81, NR)	NR (2.83, NR)	
Log-Rank Test p-value (unstratified)	0.4382		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.735 (0.340, 1.593)		
No	130	130	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	50 (38.5%)	77 (59.2%)	
Number (%) of Participants Censored	80 (61.5%)	53 (40.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (7.23, NR)	4.44 (2.43, 5.49)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.552 (0.385, 0.789)		
History of brain metastasis			
Yes	8	9	0.9751
Number (%) of Participants with Events (Deterioration)	2 (25.0%)	4 (44.4%)	
Number (%) of Participants Censored	6 (75.0%)	5 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.79, NR)	2.79 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.4622		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.534 (0.098, 2.921)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	63 (37.3%)	85 (53.1%)	
Number (%) of Participants Censored	106 (62.7%)	75 (46.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (7.72, NR)	4.86 (3.09, 6.24)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.564 (0.406, 0.784)		
PD-L1 Status			
CPS < 1	67	59	0.9125
Number (%) of Participants with Events (Deterioration)	24 (35.8%)	28 (47.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	43 (64.2%)	31 (52.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (7.20, NR)	4.96 (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.0343		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.556 (0.321, 0.965)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	41 (37.6%)	61 (55.5%)	
Number (%) of Participants Censored	68 (62.4%)	49 (44.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (5.32, NR)	4.37 (2.40, 6.28)	
Log-Rank Test p-value (unstratified)	0.0068		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.581 (0.390, 0.867)		
BRCA 1/2 status			
Wild-Type	66	65	0.9177
Number (%) of Participants with Events (Deterioration)	23 (34.8%)	35 (53.8%)	
Number (%) of Participants Censored	43 (65.2%)	30 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.16 (6.34, NR)	3.09 (1.94, 6.90)	
Log-Rank Test p-value (unstratified)	0.0055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.483 (0.284, 0.820)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	3 (25.0%)	5 (50.0%)	
Number (%) of Participants Censored	9 (75.0%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	NR (1.91, NR)	6.28 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.2385		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.429 (0.101, 1.823)		
Menopausal status			
Pre-menopausal	37	49	0.2467
Number (%) of Participants with Events (Deterioration)	12 (32.4%)	28 (57.1%)	
Number (%) of Participants Censored	25 (67.6%)	21 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (7.20, NR)	4.90 (1.87, 6.97)	
Log-Rank Test p-value (unstratified)	0.0107		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.423 (0.214, 0.837)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	53 (37.9%)	60 (50.4%)	
Number (%) of Participants Censored	87 (62.1%)	59 (49.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.37 (6.67, NR)	4.86 (3.09, 6.74)	
Log-Rank Test p-value (unstratified)	0.0118		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.623 (0.429, 0.905)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.54. Table 1.1.20.11: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Insomnia | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.4550
Number (%) of Participants with Events (Deterioration)	23 (41.8%)	23 (46.9%)	
Number (%) of Participants Censored	32 (58.2%)	26 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.13 (2.79, 18.04)	4.14 (2.83, 9.03)	
Log-Rank Test p-value (unstratified)	0.2840		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.724 (0.400, 1.308)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	17 (50.0%)	21 (61.8%)	
Number (%) of Participants Censored	17 (50.0%)	13 (38.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.48, NR)	1.22 (0.85, 6.05)	
Log-Rank Test p-value (unstratified)	0.1067		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.585 (0.308, 1.112)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	40 (45.5%)	43 (50.0%)	
Number (%) of Participants Censored	48 (54.5%)	43 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.60, 14.36)	4.57 (3.25, 13.01)	
Log-Rank Test p-value (unstratified)	0.8847		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.972 (0.631, 1.496)		
Geographic region			

	SG (N=177)	TPC (N=169)	Interaction
US/Canada/Western Europe	56	52	0.0482
Number (%) of Participants with Events (Deterioration)	26 (46.4%)	21 (40.4%)	
Number (%) of Participants Censored	30 (53.6%)	31 (59.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.50, 9.07)	6.05 (3.29, NR)	
Log-Rank Test p-value (unstratified)	0.3307		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.328 (0.747, 2.362)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	54 (44.6%)	66 (56.4%)	
Number (%) of Participants Censored	67 (55.4%)	51 (43.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.41 (3.58, 16.82)	3.81 (2.10, 5.19)	
Log-Rank Test p-value (unstratified)	0.0284		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.669 (0.466, 0.961)		
Age group			
< 65	133	131	0.6534
Number (%) of Participants with Events (Deterioration)	67 (50.4%)	68 (51.9%)	
Number (%) of Participants Censored	66 (49.6%)	63 (48.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (3.48, 10.84)	4.21 (3.25, 6.01)	
Log-Rank Test p-value (unstratified)	0.2931		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.834 (0.594, 1.170)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	13 (29.5%)	19 (50.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	31 (70.5%)	19 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.42 (2.60, NR)	3.32 (1.77, NR)	
Log-Rank Test p-value (unstratified)	0.3563		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.720 (0.355, 1.461)		
Race			
White	115	104	0.7081
Number (%) of Participants with Events (Deterioration)	53 (46.1%)	54 (51.9%)	
Number (%) of Participants Censored	62 (53.9%)	50 (48.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.47 (3.22, 9.07)	3.48 (2.23, 6.01)	
Log-Rank Test p-value (unstratified)	0.5499		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.892 (0.611, 1.304)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	16 (42.1%)	20 (52.6%)	
Number (%) of Participants Censored	22 (57.9%)	18 (47.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	14.36 (3.09, NR)	6.05 (1.91, 13.01)	
Log-Rank Test p-value (unstratified)	0.1543		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.614 (0.312, 1.208)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	8 (42.1%)	11 (45.8%)	
Number (%) of Participants Censored	11 (57.9%)	13 (54.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	10.84 (1.25, NR)	4.44 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.6837		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.825 (0.327, 2.082)		
Baseline ECOG status			
0	116	106	0.9766
Number (%) of Participants with Events (Deterioration)	55 (47.4%)	56 (52.8%)	
Number (%) of Participants Censored	61 (52.6%)	50 (47.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.20 (3.52, 14.36)	4.14 (3.09, 6.51)	
Log-Rank Test p-value (unstratified)	0.2835		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.814 (0.561, 1.183)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	25 (41.0%)	31 (49.2%)	
Number (%) of Participants Censored	36 (59.0%)	32 (50.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.47 (1.64, 16.82)	4.17 (2.00, 5.59)	
Log-Rank Test p-value (unstratified)	0.4693		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.823 (0.483, 1.401)		
Physician's choice of chemotherapy			
Taxane	52	45	0.8448
Number (%) of Participants with Events (Deterioration)	21 (40.4%)	20 (44.4%)	
Number (%) of Participants Censored	31 (59.6%)	25 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (2.79, NR)	4.14 (1.87, NR)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5479		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.441, 1.529)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	59 (47.2%)	67 (54.0%)	
Number (%) of Participants Censored	66 (52.8%)	57 (46.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (3.48, 10.84)	4.21 (3.25, 6.01)	
Log-Rank Test p-value (unstratified)	0.2669		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.820 (0.577, 1.165)		
History of liver metastasis			
Yes	47	39	0.9273
Number (%) of Participants with Events (Deterioration)	23 (48.9%)	16 (41.0%)	
Number (%) of Participants Censored	24 (51.1%)	23 (59.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.26 (2.33, 19.22)	3.09 (1.22, NR)	
Log-Rank Test p-value (unstratified)	0.5949		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.836 (0.435, 1.603)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	57 (43.8%)	71 (54.6%)	
Number (%) of Participants Censored	73 (56.2%)	59 (45.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (3.58, 14.36)	4.37 (3.29, 6.05)	
Log-Rank Test p-value (unstratified)	0.1983		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.796 (0.561, 1.129)		

	SG (N=177)	TPC (N=169)	Interaction
History of brain metastasis			
Yes	8	9	0.0342
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	5 (55.6%)	
Number (%) of Participants Censored	7 (87.5%)	4 (44.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (5.26, NR)	1.45 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.0241		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.119 (0.014, 1.051)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	79 (46.7%)	82 (51.2%)	
Number (%) of Participants Censored	90 (53.3%)	78 (48.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (3.48, 9.13)	4.21 (3.25, 6.01)	
Log-Rank Test p-value (unstratified)	0.3557		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.864 (0.633, 1.179)		
PD-L1 Status			
CPS < 1	67	59	0.8583
Number (%) of Participants with Events (Deterioration)	31 (46.3%)	30 (50.8%)	
Number (%) of Participants Censored	36 (53.7%)	29 (49.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.20 (3.52, NR)	4.21 (3.09, 6.05)	
Log-Rank Test p-value (unstratified)	0.3631		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.792 (0.479, 1.312)		
CPS ≥ 1	109	110	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	49 (45.0%)	57 (51.8%)	
Number (%) of Participants Censored	60 (55.0%)	53 (48.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.42 (3.09, 14.36)	4.11 (2.10, 6.47)	
Log-Rank Test p-value (unstratified)	0.3141		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.821 (0.558, 1.207)		
BRCA 1/2 status			
Wild-Type	66	65	0.0642
Number (%) of Participants with Events (Deterioration)	31 (47.0%)	31 (47.7%)	
Number (%) of Participants Censored	35 (53.0%)	34 (52.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.42 (3.48, 14.36)	4.17 (1.77, NR)	
Log-Rank Test p-value (unstratified)	0.5405		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.517, 1.404)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	7 (58.3%)	4 (40.0%)	
Number (%) of Participants Censored	5 (41.7%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (0.76, NR)	9.03 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.1130		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.697 (0.758, 9.596)		
Menopausal status			
Pre-menopausal	37	49	0.6551
Number (%) of Participants with Events (Deterioration)	17 (45.9%)	27 (55.1%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	20 (54.1%)	22 (44.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (3.12, NR)	4.40 (2.83, 6.97)	
Log-Rank Test p-value (unstratified)	0.3179		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.732 (0.395, 1.355)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	63 (45.0%)	59 (49.6%)	
Number (%) of Participants Censored	77 (55.0%)	60 (50.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.42 (3.22, 9.13)	4.11 (2.33, 6.05)	
Log-Rank Test p-value (unstratified)	0.3628		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.848 (0.594, 1.211)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.55. Table 1.1.20.12: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Appetite Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.6953
Number (%) of Participants with Events (Deterioration)	25 (45.5%)	23 (46.9%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	30 (54.5%)	26 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.48, NR)	3.48 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.7490		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.916 (0.518, 1.621)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	20 (58.8%)	14 (41.2%)	
Number (%) of Participants Censored	14 (41.2%)	20 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.78 (0.95, NR)	NR (1.05, NR)	
Log-Rank Test p-value (unstratified)	0.4036		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.338 (0.676, 2.651)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	42 (47.7%)	47 (54.7%)	
Number (%) of Participants Censored	46 (52.3%)	39 (45.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.71, NR)	4.86 (1.77, 9.23)	
Log-Rank Test p-value (unstratified)	0.6881		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.923 (0.608, 1.402)		
Geographic region			
US/Canada/Western Europe	56	52	0.4001
Number (%) of Participants with Events (Deterioration)	20 (35.7%)	24 (46.2%)	
Number (%) of Participants Censored	36 (64.3%)	28 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	NR (2.10, NR)	5.19 (1.94, NR)	
Log-Rank Test p-value (unstratified)	0.4189		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.786 (0.432, 1.428)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	67 (55.4%)	60 (51.3%)	
Number (%) of Participants Censored	54 (44.6%)	57 (48.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.61, 4.21)	4.86 (1.77, 11.10)	
Log-Rank Test p-value (unstratified)	0.7768		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.055 (0.743, 1.497)		
Age group			
< 65	133	131	0.0578
Number (%) of Participants with Events (Deterioration)	67 (50.4%)	68 (51.9%)	
Number (%) of Participants Censored	66 (49.6%)	63 (48.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.10, NR)	3.48 (1.94, 7.85)	
Log-Rank Test p-value (unstratified)	0.3413		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.853 (0.607, 1.196)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	20 (45.5%)	16 (42.1%)	
Number (%) of Participants Censored	24 (54.5%)	22 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.97 (1.45, 4.01)	5.19 (2.56, NR)	
Log-Rank Test p-value (unstratified)	0.0582		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.893 (0.971, 3.690)		
Race			
White	115	104	0.8580
Number (%) of Participants with Events (Deterioration)	58 (50.4%)	57 (54.8%)	
Number (%) of Participants Censored	57 (49.6%)	47 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.61, 11.76)	2.56 (1.71, 6.93)	
Log-Rank Test p-value (unstratified)	0.4262		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.868 (0.601, 1.254)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	17 (44.7%)	17 (44.7%)	
Number (%) of Participants Censored	21 (55.3%)	21 (55.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (1.97, NR)	13.01 (3.48, NR)	
Log-Rank Test p-value (unstratified)	0.8053		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.086 (0.551, 2.140)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	9 (47.4%)	10 (41.7%)	
Number (%) of Participants Censored	10 (52.6%)	14 (58.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.02, NR)	3.35 (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.8003		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.117 (0.453, 2.754)		
Baseline ECOG status			

	SG (N=177)	TPC (N=169)	Interaction
0	116	106	0.0454
Number (%) of Participants with Events (Deterioration)	54 (46.6%)	59 (55.7%)	
Number (%) of Participants Censored	62 (53.4%)	47 (44.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (2.10, NR)	4.07 (1.87, 7.85)	
Log-Rank Test p-value (unstratified)	0.2038		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.790 (0.545, 1.145)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	33 (54.1%)	25 (39.7%)	
Number (%) of Participants Censored	28 (45.9%)	38 (60.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.30 (0.89, 3.65)	5.19 (2.10, NR)	
Log-Rank Test p-value (unstratified)	0.0970		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.555 (0.922, 2.621)		
Physician's choice of chemotherapy			
Taxane	52	45	0.3814
Number (%) of Participants with Events (Deterioration)	23 (44.2%)	16 (35.6%)	
Number (%) of Participants Censored	29 (55.8%)	29 (64.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.71, NR)	7.26 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.4100		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.311 (0.691, 2.486)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	64 (51.2%)	68 (54.8%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	61 (48.8%)	56 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.35 (1.84, 11.76)	3.48 (2.07, 7.85)	
Log-Rank Test p-value (unstratified)	0.5863		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.912 (0.648, 1.285)		
History of liver metastasis			
Yes	47	39	0.1639
Number (%) of Participants with Events (Deterioration)	24 (51.1%)	12 (30.8%)	
Number (%) of Participants Censored	23 (48.9%)	27 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (1.48, NR)	9.23 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.2519		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.505 (0.748, 3.028)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	63 (48.5%)	72 (55.4%)	
Number (%) of Participants Censored	67 (51.5%)	58 (44.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.01 (1.97, 13.63)	3.48 (1.94, 7.26)	
Log-Rank Test p-value (unstratified)	0.4678		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.630, 1.244)		
History of brain metastasis			
Yes	8	9	0.3479
Number (%) of Participants with Events (Deterioration)	3 (37.5%)	4 (44.4%)	
Number (%) of Participants Censored	5 (62.5%)	5 (55.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NR (0.76, NR)	1.41 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.4906		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.621 (0.138, 2.801)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	84 (49.7%)	80 (50.0%)	
Number (%) of Participants Censored	85 (50.3%)	80 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.65 (1.97, 8.77)	4.96 (2.56, 9.23)	
Log-Rank Test p-value (unstratified)	0.9761		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.008 (0.741, 1.372)		
PD-L1 Status			
CPS < 1	67	59	0.9090
Number (%) of Participants with Events (Deterioration)	35 (52.2%)	31 (52.5%)	
Number (%) of Participants Censored	32 (47.8%)	28 (47.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.23 (1.48, NR)	4.96 (1.77, 9.23)	
Log-Rank Test p-value (unstratified)	0.9346		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.985 (0.606, 1.601)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	52 (47.7%)	53 (48.2%)	
Number (%) of Participants Censored	57 (52.3%)	57 (51.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (1.97, NR)	4.07 (2.07, 14.52)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.8857		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.976 (0.665, 1.433)		
BRCA 1/2 status			
Wild-Type	66	65	0.7531
Number (%) of Participants with Events (Deterioration)	31 (47.0%)	30 (46.2%)	
Number (%) of Participants Censored	35 (53.0%)	35 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.11 (2.10, NR)	5.19 (2.43, NR)	
Log-Rank Test p-value (unstratified)	0.9275		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.979 (0.592, 1.621)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	6 (50.0%)	5 (50.0%)	
Number (%) of Participants Censored	6 (50.0%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.21 (0.79, NR)	3.53 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.7075		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.794 (0.241, 2.615)		
Menopausal status			
Pre-menopausal	37	49	0.6887
Number (%) of Participants with Events (Deterioration)	18 (48.6%)	21 (42.9%)	
Number (%) of Participants Censored	19 (51.4%)	28 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.89 (1.41, NR)	7.26 (2.10, NR)	
Log-Rank Test p-value (unstratified)	0.7755		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.100 (0.584, 2.070)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	69 (49.3%)	62 (52.1%)	
Number (%) of Participants Censored	71 (50.7%)	57 (47.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.06 (1.91, 11.76)	4.07 (1.94, 7.85)	
Log-Rank Test p-value (unstratified)	0.7244		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.945 (0.670, 1.333)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.56. Table 1.1.20.13: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Constipation | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.7371
Number (%) of Participants with Events (Deterioration)	28 (50.9%)	22 (44.9%)	
Number (%) of Participants Censored	27 (49.1%)	27 (55.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.68, 15.90)	6.24 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.9737		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.005 (0.569, 1.775)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	23 (67.6%)	16 (47.1%)	
Number (%) of Participants Censored	11 (32.4%)	18 (52.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.17 (1.28, 3.75)	2.20 (1.22, NR)	
Log-Rank Test p-value (unstratified)	0.5358		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.215 (0.638, 2.316)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	46 (52.3%)	52 (60.5%)	
Number (%) of Participants Censored	42 (47.7%)	34 (39.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (1.51, 11.40)	2.79 (1.48, 6.47)	
Log-Rank Test p-value (unstratified)	0.5962		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.896 (0.602, 1.333)		
Geographic region			
US/Canada/Western Europe	56	52	0.7182
Number (%) of Participants with Events (Deterioration)	29 (51.8%)	27 (51.9%)	
Number (%) of Participants Censored	27 (48.2%)	25 (48.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.48, 3.75)	2.69 (1.54, 6.24)	
Log-Rank Test p-value (unstratified)	0.7251		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.098 (0.649, 1.856)		
Rest of the world	121	117	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	68 (56.2%)	63 (53.8%)	
Number (%) of Participants Censored	53 (43.8%)	54 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.33 (1.74, 6.93)	3.48 (1.68, 6.70)	
Log-Rank Test p-value (unstratified)	0.8101		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.954 (0.676, 1.345)		
Age group			
< 65	133	131	0.8521
Number (%) of Participants with Events (Deterioration)	78 (58.6%)	70 (53.4%)	
Number (%) of Participants Censored	55 (41.4%)	61 (46.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.74, 3.65)	2.79 (1.68, 6.60)	
Log-Rank Test p-value (unstratified)	0.9079		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.978 (0.708, 1.350)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	20 (52.6%)	
Number (%) of Participants Censored	25 (56.8%)	18 (47.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.02, NR)	3.75 (1.41, NR)	
Log-Rank Test p-value (unstratified)	0.8644		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.053 (0.559, 1.982)		
Race			
White	115	104	0.5442
Number (%) of Participants with Events (Deterioration)	60 (52.2%)	58 (55.8%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	55 (47.8%)	46 (44.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.71, 4.57)	2.79 (1.58, 5.55)	
Log-Rank Test p-value (unstratified)	0.6383		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.914 (0.637, 1.312)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	23 (60.5%)	19 (50.0%)	
Number (%) of Participants Censored	15 (39.5%)	19 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (1.02, NR)	6.70 (1.51, 13.34)	
Log-Rank Test p-value (unstratified)	0.5039		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.229 (0.665, 2.273)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	10 (52.6%)	12 (50.0%)	
Number (%) of Participants Censored	9 (47.4%)	12 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.52 (0.99, 19.38)	1.91 (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.5241		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.753 (0.322, 1.757)		
Baseline ECOG status			
0	116	106	0.2456
Number (%) of Participants with Events (Deterioration)	63 (54.3%)	62 (58.5%)	
Number (%) of Participants Censored	53 (45.7%)	44 (41.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	2.53 (1.71, 5.65)	2.69 (1.51, 5.55)	
Log-Rank Test p-value (unstratified)	0.4889		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.620, 1.251)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	34 (55.7%)	28 (44.4%)	
Number (%) of Participants Censored	27 (44.3%)	35 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.54, 3.65)	6.47 (1.68, 13.34)	
Log-Rank Test p-value (unstratified)	0.4374		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.217 (0.733, 2.021)		
Physician's choice of chemotherapy			
Taxane	52	45	0.0261
Number (%) of Participants with Events (Deterioration)	30 (57.7%)	17 (37.8%)	
Number (%) of Participants Censored	22 (42.3%)	28 (62.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.41, 3.52)	6.70 (3.75, NR)	
Log-Rank Test p-value (unstratified)	0.0414		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.842 (1.012, 3.356)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	67 (53.6%)	73 (58.9%)	
Number (%) of Participants Censored	58 (46.4%)	51 (41.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.84, 6.93)	2.33 (1.48, 6.24)	
Log-Rank Test p-value (unstratified)	0.2709		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.825 (0.592, 1.149)		
History of liver metastasis			
Yes	47	39	0.5828
Number (%) of Participants with Events (Deterioration)	26 (55.3%)	19 (48.7%)	
Number (%) of Participants Censored	21 (44.7%)	20 (51.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.27 (1.58, 12.35)	1.58 (0.95, NR)	
Log-Rank Test p-value (unstratified)	0.4585		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.791 (0.433, 1.445)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	71 (54.6%)	71 (54.6%)	
Number (%) of Participants Censored	59 (45.4%)	59 (45.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.68, 4.21)	4.01 (2.20, 6.60)	
Log-Rank Test p-value (unstratified)	0.8726		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.025 (0.737, 1.425)		
History of brain metastasis			
Yes	8	9	0.7069
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	4 (44.4%)	
Number (%) of Participants Censored	4 (50.0%)	5 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.76, NR)	6.47 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.6628		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.435 (0.319, 6.460)		

	SG (N=177)	TPC (N=169)	Interaction
No	169	160	
Number (%) of Participants with Events (Deterioration)	93 (55.0%)	86 (53.8%)	
Number (%) of Participants Censored	76 (45.0%)	74 (46.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (1.71, 3.75)	3.29 (1.91, 6.47)	
Log-Rank Test p-value (unstratified)	0.9226		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.983 (0.732, 1.318)		
PD-L1 Status			
CPS < 1	67	59	0.9120
Number (%) of Participants with Events (Deterioration)	38 (56.7%)	31 (52.5%)	
Number (%) of Participants Censored	29 (43.3%)	28 (47.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.45, 4.57)	2.69 (1.15, 6.60)	
Log-Rank Test p-value (unstratified)	0.9362		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.977 (0.607, 1.572)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	59 (54.1%)	59 (53.6%)	
Number (%) of Participants Censored	50 (45.9%)	51 (46.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.69 (1.91, 5.65)	3.48 (1.91, 6.70)	
Log-Rank Test p-value (unstratified)	0.9887		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.000 (0.696, 1.435)		
BRCA 1/2 status			
Wild-Type	66	65	0.9577

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	38 (57.6%)	30 (46.2%)	
Number (%) of Participants Censored	28 (42.4%)	35 (53.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.83 (1.68, 6.93)	4.67 (1.87, 9.00)	
Log-Rank Test p-value (unstratified)	0.6311		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.124 (0.695, 1.816)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	7 (58.3%)	7 (70.0%)	
Number (%) of Participants Censored	5 (41.7%)	3 (30.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.00 (0.72, NR)	6.70 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.9335		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.020 (0.340, 3.058)		
Menopausal status			
Pre-menopausal	37	49	0.6900
Number (%) of Participants with Events (Deterioration)	15 (40.5%)	22 (44.9%)	
Number (%) of Participants Censored	22 (59.5%)	27 (55.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.35 (1.45, NR)	6.93 (1.87, NR)	
Log-Rank Test p-value (unstratified)	0.5897		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.837 (0.433, 1.618)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	82 (58.6%)	67 (56.3%)	
Number (%) of Participants Censored	58 (41.4%)	52 (43.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.71, 2.96)	2.69 (1.58, 5.55)	
Log-Rank Test p-value (unstratified)	0.9984		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.995 (0.720, 1.375)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.57. Table 1.1.20.14: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Diarrhoea | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.0040
Number (%) of Participants with Events (Deterioration)	30 (54.5%)	28 (57.1%)	
Number (%) of Participants Censored	25 (45.5%)	21 (42.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (1.05, 17.35)	3.32 (1.87, 6.01)	
Log-Rank Test p-value (unstratified)	0.5730		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.164 (0.691, 1.961)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	25 (73.5%)	12 (35.3%)	
Number (%) of Participants Censored	9 (26.5%)	22 (64.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (0.99, 4.11)	6.90 (2.89, NR)	
Log-Rank Test p-value (unstratified)	0.0191		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.243 (1.122, 4.487)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	64 (72.7%)	31 (36.0%)	
Number (%) of Participants Censored	24 (27.3%)	55 (64.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.18 (0.82, 2.17)	NR (5.52, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.609 (2.337, 5.574)		
Geographic region			
US/Canada/Western Europe	56	52	0.1783
Number (%) of Participants with Events (Deterioration)	40 (71.4%)	19 (36.5%)	
Number (%) of Participants Censored	16 (28.6%)	33 (63.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.85, 2.40)	10.12 (2.79, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.074 (1.767, 5.349)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	79 (65.3%)	52 (44.4%)	
Number (%) of Participants Censored	42 (34.7%)	65 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.05, 2.83)	6.24 (4.37, NR)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.026 (1.424, 2.882)		
Age group			
< 65	133	131	0.7284
Number (%) of Participants with Events (Deterioration)	100 (75.2%)	58 (44.3%)	
Number (%) of Participants Censored	33 (24.8%)	73 (55.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (1.18, 2.10)	6.24 (4.17, 13.21)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.243 (1.620, 3.106)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	13 (34.2%)	
Number (%) of Participants Censored	25 (56.8%)	25 (65.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.94 (0.82, NR)	NR (3.06, NR)	
Log-Rank Test p-value (unstratified)	0.0177		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.312 (1.133, 4.718)		
Race			
White	115	104	0.8918
Number (%) of Participants with Events (Deterioration)	73 (63.5%)	37 (35.6%)	
Number (%) of Participants Censored	42 (36.5%)	67 (64.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.41, 3.52)	10.12 (5.52, NR)	
Log-Rank Test p-value (unstratified)	<0.001		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.416 (1.623, 3.597)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	27 (71.1%)	19 (50.0%)	
Number (%) of Participants Censored	11 (28.9%)	19 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (0.82, 4.11)	5.78 (2.40, NR)	
Log-Rank Test p-value (unstratified)	0.0078		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.202 (1.219, 3.977)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	14 (73.7%)	15 (62.5%)	
Number (%) of Participants Censored	5 (26.3%)	9 (37.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.76, 1.45)	3.06 (1.18, 5.55)	
Log-Rank Test p-value (unstratified)	0.0428		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.172 (1.027, 4.592)		
Baseline ECOG status			
0	116	106	0.7028
Number (%) of Participants with Events (Deterioration)	81 (69.8%)	44 (41.5%)	
Number (%) of Participants Censored	35 (30.2%)	62 (58.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.74 (1.18, 2.40)	7.36 (4.67, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.413 (1.666, 3.495)		
1	61	63	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	38 (62.3%)	27 (42.9%)	
Number (%) of Participants Censored	23 (37.7%)	36 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.85, 2.83)	5.09 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.0024		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.117 (1.290, 3.474)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1446
Number (%) of Participants with Events (Deterioration)	35 (67.3%)	24 (53.3%)	
Number (%) of Participants Censored	17 (32.7%)	21 (46.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.69 (0.89, 2.23)	2.89 (1.87, 6.47)	
Log-Rank Test p-value (unstratified)	0.0446		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.703 (1.007, 2.881)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	84 (67.2%)	47 (37.9%)	
Number (%) of Participants Censored	41 (32.8%)	77 (62.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.64 (1.02, 2.83)	10.12 (5.78, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.575 (1.798, 3.687)		
History of liver metastasis			
Yes	47	39	0.0977
Number (%) of Participants with Events (Deterioration)	35 (74.5%)	10 (25.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	12 (25.5%)	29 (74.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.85, 2.17)	10.12 (3.94, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.681 (1.812, 7.478)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	84 (64.6%)	61 (46.9%)	
Number (%) of Participants Censored	46 (35.4%)	69 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (1.45, 2.86)	6.01 (4.17, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.050 (1.470, 2.857)		
History of brain metastasis			
Yes	8	9	0.0928
Number (%) of Participants with Events (Deterioration)	7 (87.5%)	3 (33.3%)	
Number (%) of Participants Censored	1 (12.5%)	6 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.72, 1.81)	NR (1.18, NR)	
Log-Rank Test p-value (unstratified)	0.0018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	14.740 (1.730, 125.620)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	112 (66.3%)	68 (42.5%)	
Number (%) of Participants Censored	57 (33.7%)	92 (57.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	1.68 (1.18, 2.40)	6.90 (4.37, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.197 (1.623, 2.975)		
PD-L1 Status			
CPS < 1	67	59	0.8219
Number (%) of Participants with Events (Deterioration)	43 (64.2%)	22 (37.3%)	
Number (%) of Participants Censored	24 (35.8%)	37 (62.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.81 (1.05, 3.58)	10.12 (3.25, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.458 (1.463, 4.129)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	76 (69.7%)	49 (44.5%)	
Number (%) of Participants Censored	33 (30.3%)	61 (55.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.56 (0.99, 2.10)	6.24 (4.17, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.258 (1.574, 3.239)		
BRCA 1/2 status			
Wild-Type	66	65	0.8302
Number (%) of Participants with Events (Deterioration)	47 (71.2%)	27 (41.5%)	
Number (%) of Participants Censored	19 (28.8%)	38 (58.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.51 (0.85, 2.10)	5.78 (3.32, NR)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.696 (1.672, 4.347)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	10 (83.3%)	5 (50.0%)	
Number (%) of Participants Censored	2 (16.7%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.56 (0.76, 5.85)	4.86 (0.99, NR)	
Log-Rank Test p-value (unstratified)	0.0864		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.502 (0.846, 7.399)		
Menopausal status			
Pre-menopausal	37	49	0.8886
Number (%) of Participants with Events (Deterioration)	26 (70.3%)	21 (42.9%)	
Number (%) of Participants Censored	11 (29.7%)	28 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.68 (0.82, 2.86)	7.36 (2.89, NR)	
Log-Rank Test p-value (unstratified)	0.0061		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.236 (1.248, 4.007)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	93 (66.4%)	49 (41.2%)	
Number (%) of Participants Censored	47 (33.6%)	70 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.66 (1.05, 2.56)	6.47 (4.37, NR)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.318 (1.637, 3.283)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.

Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.58. Table 1.1.20.15: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-C30: Financial Difficulties | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.1312
Number (%) of Participants with Events (Deterioration)	18 (32.7%)	19 (38.8%)	
Number (%) of Participants Censored	37 (67.3%)	30 (61.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.02 (7.39, NR)	5.19 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.0635		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.538 (0.276, 1.049)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	14 (41.2%)	14 (41.2%)	
Number (%) of Participants Censored	20 (58.8%)	20 (58.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (3.65, NR)	3.06 (1.54, NR)	
Log-Rank Test p-value (unstratified)	0.2006		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.612 (0.286, 1.313)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	33 (37.5%)	30 (34.9%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	55 (62.5%)	56 (65.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (5.06, NR)	19.38 (5.13, NR)	
Log-Rank Test p-value (unstratified)	0.5951		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.145 (0.697, 1.880)		
Geographic region			
US/Canada/Western Europe	56	52	0.8119
Number (%) of Participants with Events (Deterioration)	20 (35.7%)	18 (34.6%)	
Number (%) of Participants Censored	36 (64.3%)	34 (65.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.31 (3.78, NR)	NR (2.37, NR)	
Log-Rank Test p-value (unstratified)	0.7589		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.902 (0.474, 1.717)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	45 (37.2%)	45 (38.5%)	
Number (%) of Participants Censored	76 (62.8%)	72 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (7.89, 27.89)	8.67 (4.17, NR)	
Log-Rank Test p-value (unstratified)	0.2700		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.791 (0.520, 1.203)		
Age group			
< 65	133	131	0.9000
Number (%) of Participants with Events (Deterioration)	55 (41.4%)	49 (37.4%)	
Number (%) of Participants Censored	78 (58.6%)	82 (62.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (7.16, 21.45)	6.47 (3.94, NR)	
Log-Rank Test p-value (unstratified)	0.2912		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.811 (0.549, 1.198)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	10 (22.7%)	14 (36.8%)	
Number (%) of Participants Censored	34 (77.3%)	24 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	27.89 (2.86, NR)	10.15 (3.88, NR)	
Log-Rank Test p-value (unstratified)	0.4338		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.715 (0.305, 1.678)		
Race			
White	115	104	0.1367
Number (%) of Participants with Events (Deterioration)	41 (35.7%)	45 (43.3%)	
Number (%) of Participants Censored	74 (64.3%)	59 (56.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.55 (6.97, NR)	4.17 (3.48, NR)	
Log-Rank Test p-value (unstratified)	0.0305		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.625 (0.407, 0.961)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	16 (42.1%)	10 (26.3%)	
Number (%) of Participants Censored	22 (57.9%)	28 (73.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.79 (5.59, NR)	NR (10.15, NR)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.2826		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.540 (0.697, 3.402)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	5 (26.3%)	7 (29.2%)	
Number (%) of Participants Censored	14 (73.7%)	17 (70.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (0.72, NR)	6.34 (2.40, NR)	
Log-Rank Test p-value (unstratified)	0.5834		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.686 (0.177, 2.657)		
Baseline ECOG status			
0	116	106	0.9074
Number (%) of Participants with Events (Deterioration)	41 (35.3%)	38 (35.8%)	
Number (%) of Participants Censored	75 (64.7%)	68 (64.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (8.31, NR)	19.38 (5.13, NR)	
Log-Rank Test p-value (unstratified)	0.3488		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.808 (0.518, 1.261)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	24 (39.3%)	25 (39.7%)	
Number (%) of Participants Censored	37 (60.7%)	38 (60.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.93 (2.40, NR)	4.63 (3.25, NR)	
Log-Rank Test p-value (unstratified)	0.7563		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.915 (0.516, 1.624)		

	SG (N=177)	TPC (N=169)	Interaction
Physician's choice of chemotherapy			
Taxane	52	45	0.9659
Number (%) of Participants with Events (Deterioration)	23 (44.2%)	18 (40.0%)	
Number (%) of Participants Censored	29 (55.8%)	27 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.92 (5.03, NR)	4.67 (2.79, NR)	
Log-Rank Test p-value (unstratified)	0.3898		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.760 (0.404, 1.428)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	42 (33.6%)	45 (36.3%)	
Number (%) of Participants Censored	83 (66.4%)	79 (63.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	19.02 (7.89, NR)	19.38 (5.13, NR)	
Log-Rank Test p-value (unstratified)	0.3295		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.809 (0.528, 1.239)		
History of liver metastasis			
Yes	47	39	0.1542
Number (%) of Participants with Events (Deterioration)	17 (36.2%)	6 (15.4%)	
Number (%) of Participants Censored	30 (63.8%)	33 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.55 (4.27, NR)	NR (5.19, NR)	
Log-Rank Test p-value (unstratified)	0.4803		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.408 (0.541, 3.665)		
No	130	130	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	48 (36.9%)	57 (43.8%)	
Number (%) of Participants Censored	82 (63.1%)	73 (56.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.79 (7.39, NR)	6.34 (3.75, NR)	
Log-Rank Test p-value (unstratified)	0.1696		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.763 (0.518, 1.126)		
History of brain metastasis			
Yes	8	9	0.0777
Number (%) of Participants with Events (Deterioration)	4 (50.0%)	2 (22.2%)	
Number (%) of Participants Censored	4 (50.0%)	7 (77.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.72, NR)	NR (0.76, NR)	
Log-Rank Test p-value (unstratified)	0.1798		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.993 (0.546, 16.398)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	61 (36.1%)	61 (38.1%)	
Number (%) of Participants Censored	108 (63.9%)	99 (61.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.55 (7.89, 27.89)	8.67 (4.17, NR)	
Log-Rank Test p-value (unstratified)	0.1563		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.772 (0.539, 1.106)		
PD-L1 Status			
CPS < 1	67	59	0.4539
Number (%) of Participants with Events (Deterioration)	29 (43.3%)	26 (44.1%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	38 (56.7%)	33 (55.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (6.93, 19.02)	5.19 (2.89, NR)	
Log-Rank Test p-value (unstratified)	0.1441		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.672 (0.393, 1.148)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	36 (33.0%)	37 (33.6%)	
Number (%) of Participants Censored	73 (67.0%)	73 (66.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	21.45 (5.52, NR)	10.15 (4.63, NR)	
Log-Rank Test p-value (unstratified)	0.8341		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.952 (0.600, 1.512)		
BRCA 1/2 status			
Wild-Type	66	65	0.8026
Number (%) of Participants with Events (Deterioration)	24 (36.4%)	25 (38.5%)	
Number (%) of Participants Censored	42 (63.6%)	40 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.55 (5.52, NR)	5.19 (3.09, NR)	
Log-Rank Test p-value (unstratified)	0.3640		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.771 (0.438, 1.356)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	3 (25.0%)	5 (50.0%)	
Number (%) of Participants Censored	9 (75.0%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	NR (0.79, NR)	19.38 (0.72, NR)	
Log-Rank Test p-value (unstratified)	0.7195		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.760 (0.169, 3.418)		
Menopausal status			
Pre-menopausal	37	49	0.2111
Number (%) of Participants with Events (Deterioration)	14 (37.8%)	22 (44.9%)	
Number (%) of Participants Censored	23 (62.2%)	27 (55.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	16.07 (5.52, NR)	5.13 (1.91, NR)	
Log-Rank Test p-value (unstratified)	0.0437		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.489 (0.241, 0.994)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	51 (36.4%)	41 (34.5%)	
Number (%) of Participants Censored	89 (63.6%)	78 (65.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.79 (7.89, NR)	19.38 (4.67, NR)	
Log-Rank Test p-value (unstratified)	0.8330		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.957 (0.632, 1.450)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.59. Table 1.1.21.1: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Body Image | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.4432
Number (%) of Participants with Events (Deterioration)	29 (52.7%)	21 (42.9%)	
Number (%) of Participants Censored	26 (47.3%)	28 (57.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.48, 5.42)	5.09 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.2695		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.374 (0.781, 2.416)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	19 (55.9%)	13 (38.2%)	
Number (%) of Participants Censored	15 (44.1%)	21 (61.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.58, 12.98)	12.75 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.8949		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.952 (0.463, 1.958)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	51 (58.0%)	42 (48.8%)	
Number (%) of Participants Censored	37 (42.0%)	44 (51.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.91 (1.41, 3.48)	4.96 (2.79, 17.08)	
Log-Rank Test p-value (unstratified)	0.0137		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.673 (1.107, 2.527)		

	SG (N=177)	TPC (N=169)	Interaction
Geographic region			
US/Canada/Western Europe	56	52	0.9349
Number (%) of Participants with Events (Deterioration)	28 (50.0%)	23 (44.2%)	
Number (%) of Participants Censored	28 (50.0%)	29 (55.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.71 (1.18, 3.48)	2.79 (1.71, NE)	
Log-Rank Test p-value (unstratified)	0.2067		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.424 (0.820, 2.475)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	71 (58.7%)	53 (45.3%)	
Number (%) of Participants Censored	50 (41.3%)	64 (54.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.91, 4.57)	6.01 (3.48, 17.08)	
Log-Rank Test p-value (unstratified)	0.0705		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.392 (0.972, 1.992)		
Age group			
< 65	133	131	0.2224
Number (%) of Participants with Events (Deterioration)	80 (60.2%)	60 (45.8%)	
Number (%) of Participants Censored	53 (39.8%)	71 (54.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (1.77, 4.57)	4.70 (2.79, 6.51)	
Log-Rank Test p-value (unstratified)	0.1580		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.275 (0.911, 1.785)		
>= 65	44	38	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	19 (43.2%)	16 (42.1%)	
Number (%) of Participants Censored	25 (56.8%)	22 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.92, 3.19)	9.26 (2.56, NE)	
Log-Rank Test p-value (unstratified)	0.0535		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.931 (0.982, 3.797)		
Race			
White	115	104	0.2508
Number (%) of Participants with Events (Deterioration)	59 (51.3%)	49 (47.1%)	
Number (%) of Participants Censored	56 (48.7%)	55 (52.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.30 (1.68, 4.57)	4.40 (2.56, 6.01)	
Log-Rank Test p-value (unstratified)	0.1977		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.284 (0.878, 1.876)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	28 (73.7%)	17 (44.7%)	
Number (%) of Participants Censored	10 (26.3%)	21 (55.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.89 (1.28, 4.57)	6.51 (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.0195		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.037 (1.110, 3.739)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	9 (47.4%)	8 (33.3%)	
Number (%) of Participants Censored	10 (52.6%)	16 (66.7%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (0.79, NE)	5.19 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.8335		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.107 (0.427, 2.873)		
Baseline ECOG status			
0	116	106	0.6773
Number (%) of Participants with Events (Deterioration)	70 (60.3%)	50 (47.2%)	
Number (%) of Participants Censored	46 (39.7%)	56 (52.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.19 (1.77, 4.57)	4.96 (2.79, 17.08)	
Log-Rank Test p-value (unstratified)	0.1119		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.341 (0.932, 1.929)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	29 (47.5%)	26 (41.3%)	
Number (%) of Participants Censored	32 (52.5%)	37 (58.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.89, 4.57)	5.19 (2.10, NE)	
Log-Rank Test p-value (unstratified)	0.0893		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.591 (0.933, 2.714)		
Physician's choice of chemotherapy			
Taxane	52	45	0.8494
Number (%) of Participants with Events (Deterioration)	31 (59.6%)	21 (46.7%)	
Number (%) of Participants Censored	21 (40.4%)	24 (53.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	1.58 (0.92, 4.21)	3.71 (1.91, 6.51)	
Log-Rank Test p-value (unstratified)	0.1819		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.467 (0.838, 2.569)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	68 (54.4%)	55 (44.4%)	
Number (%) of Participants Censored	57 (45.6%)	69 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (1.74, 4.57)	5.39 (3.32, 17.08)	
Log-Rank Test p-value (unstratified)	0.0898		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.359 (0.951, 1.941)		
History of liver metastasis			
Yes	47	39	0.2711
Number (%) of Participants with Events (Deterioration)	26 (55.3%)	11 (28.2%)	
Number (%) of Participants Censored	21 (44.7%)	28 (71.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (1.22, 5.78)	6.51 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.0904		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.846 (0.899, 3.792)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	73 (56.2%)	65 (50.0%)	
Number (%) of Participants Censored	57 (43.8%)	65 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.53 (1.71, 3.75)	4.63 (2.37, 9.26)	
Log-Rank Test p-value (unstratified)	0.1337		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.295 (0.926, 1.811)		
History of brain metastasis			
Yes	8	9	0.7822
Number (%) of Participants with Events (Deterioration)	5 (62.5%)	3 (33.3%)	
Number (%) of Participants Censored	3 (37.5%)	6 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.14 (0.79, NE)	5.24 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.5233		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.546 (0.362, 6.608)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	94 (55.6%)	73 (45.6%)	
Number (%) of Participants Censored	75 (44.4%)	87 (54.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.30 (1.71, 3.75)	5.09 (3.02, 9.26)	
Log-Rank Test p-value (unstratified)	0.0392		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.383 (1.017, 1.880)		
PD-L1 Status			
CPS < 1	67	59	0.8996
Number (%) of Participants with Events (Deterioration)	41 (61.2%)	27 (45.8%)	
Number (%) of Participants Censored	26 (38.8%)	32 (54.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.45, 4.57)	4.96 (1.77, 24.44)	
Log-Rank Test p-value (unstratified)	0.1451		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.435 (0.881, 2.336)		

	SG (N=177)	TPC (N=169)	Interaction
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	58 (53.2%)	49 (44.5%)	
Number (%) of Participants Censored	51 (46.8%)	61 (55.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (1.68, 5.03)	5.09 (2.79, NE)	
Log-Rank Test p-value (unstratified)	0.1007		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.376 (0.939, 2.016)		
BRCA 1/2 status			
Wild-Type	66	65	0.5954
Number (%) of Participants with Events (Deterioration)	42 (63.6%)	33 (50.8%)	
Number (%) of Participants Censored	24 (36.4%)	32 (49.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.58 (0.95, 2.10)	2.14 (1.41, 5.39)	
Log-Rank Test p-value (unstratified)	0.1696		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.379 (0.873, 2.178)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	6 (50.0%)	5 (50.0%)	
Number (%) of Participants Censored	6 (50.0%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.48 (0.72, NE)	24.44 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.1918		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.301 (0.637, 8.312)		
Menopausal status			
Pre-menopausal	37	49	0.6404

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	20 (54.1%)	23 (46.9%)	
Number (%) of Participants Censored	17 (45.9%)	26 (53.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.10 (1.18, 13.34)	3.84 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.5294		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.220 (0.663, 2.243)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	79 (56.4%)	53 (44.5%)	
Number (%) of Participants Censored	61 (43.6%)	66 (55.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.89 (1.71, 3.78)	5.19 (2.79, 12.75)	
Log-Rank Test p-value (unstratified)	0.0361		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.452 (1.024, 2.058)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.60. Table 1.1.21.2: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Sexual Functioning | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.0473

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	16 (29.1%)	15 (30.6%)	
Number (%) of Participants Censored	39 (70.9%)	34 (69.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (4.80, NE)	
Log-Rank Test p-value (unstratified)	0.5348		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.797 (0.391, 1.625)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	14 (41.2%)	5 (14.7%)	
Number (%) of Participants Censored	20 (58.8%)	29 (85.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.65, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.0754		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.459 (0.885, 6.832)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	16 (18.2%)	26 (30.2%)	
Number (%) of Participants Censored	72 (81.8%)	60 (69.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.24, NE)	
Log-Rank Test p-value (unstratified)	0.0724		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.568 (0.304, 1.062)		
Geographic region			
US/Canada/Western Europe	56	52	0.0699
Number (%) of Participants with Events (Deterioration)	12 (21.4%)	18 (34.6%)	
Number (%) of Participants Censored	44 (78.6%)	34 (65.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.80, NE)	4.80 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.0501		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.486 (0.232, 1.017)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	34 (28.1%)	28 (23.9%)	
Number (%) of Participants Censored	87 (71.9%)	89 (76.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (13.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6784		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.111 (0.672, 1.836)		
Age group			
< 65	133	131	0.3112
Number (%) of Participants with Events (Deterioration)	40 (30.1%)	34 (26.0%)	
Number (%) of Participants Censored	93 (69.9%)	97 (74.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (13.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8522		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.957 (0.604, 1.516)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	6 (13.6%)	12 (31.6%)	
Number (%) of Participants Censored	38 (86.4%)	26 (68.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.90, NE)	NE (5.09, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.3177		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.609 (0.228, 1.628)		
Race			
White	115	104	0.9896
Number (%) of Participants with Events (Deterioration)	35 (30.4%)	35 (33.7%)	
Number (%) of Participants Censored	80 (69.6%)	69 (66.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.90, NE)	NE (5.09, NE)	
Log-Rank Test p-value (unstratified)	0.3007		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.779 (0.487, 1.247)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	4 (10.5%)	5 (13.2%)	
Number (%) of Participants Censored	34 (89.5%)	33 (86.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.5845		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.692 (0.183, 2.613)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	4 (21.1%)	5 (20.8%)	
Number (%) of Participants Censored	15 (78.9%)	19 (79.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.02, NE)	NE (3.81, NE)	
Log-Rank Test p-value (unstratified)	0.8539		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.884 (0.237, 3.297)		

	SG (N=177)	TPC (N=169)	Interaction
Baseline ECOG status			
0	116	106	0.1514
Number (%) of Participants with Events (Deterioration)	35 (30.2%)	28 (26.4%)	
Number (%) of Participants Censored	81 (69.8%)	78 (73.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (11.66, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8572		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.046 (0.635, 1.724)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	11 (18.0%)	18 (28.6%)	
Number (%) of Participants Censored	50 (82.0%)	45 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.09, NE)	
Log-Rank Test p-value (unstratified)	0.1412		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.573 (0.270, 1.214)		
Physician's choice of chemotherapy			
Taxane	52	45	0.7493
Number (%) of Participants with Events (Deterioration)	11 (21.2%)	10 (22.2%)	
Number (%) of Participants Censored	41 (78.8%)	35 (77.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.80, NE)	NE (4.80, NE)	
Log-Rank Test p-value (unstratified)	0.5326		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.757 (0.317, 1.805)		
Gemcitabine/Carboplatin	125	124	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	35 (28.0%)	36 (29.0%)	
Number (%) of Participants Censored	90 (72.0%)	88 (71.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (11.66, NE)	NE (7.00, NE)	
Log-Rank Test p-value (unstratified)	0.6870		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.908 (0.569, 1.447)		
History of liver metastasis			
Yes	47	39	0.2758
Number (%) of Participants with Events (Deterioration)	11 (23.4%)	11 (28.2%)	
Number (%) of Participants Censored	36 (76.6%)	28 (71.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (11.66, NE)	6.24 (2.76, NE)	
Log-Rank Test p-value (unstratified)	0.1564		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.544 (0.232, 1.279)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	35 (26.9%)	35 (26.9%)	
Number (%) of Participants Censored	95 (73.1%)	95 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.80, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8985		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.970 (0.606, 1.552)		
History of brain metastasis			
Yes	8	9	0.6144
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	2 (22.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	7 (87.5%)	7 (77.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.06, NE)	NE (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.6076		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.531 (0.046, 6.164)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	45 (26.6%)	44 (27.5%)	
Number (%) of Participants Censored	124 (73.4%)	116 (72.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (15.80, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.5663		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.885 (0.583, 1.343)		
PD-L1 Status			
CPS < 1	67	59	0.3824
Number (%) of Participants with Events (Deterioration)	21 (31.3%)	14 (23.7%)	
Number (%) of Participants Censored	46 (68.7%)	45 (76.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	15.80 (9.95, NE)	NE (6.24, NE)	
Log-Rank Test p-value (unstratified)	0.9209		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.034 (0.522, 2.046)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	25 (22.9%)	32 (29.1%)	
Number (%) of Participants Censored	84 (77.1%)	78 (70.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	NE (NE, NE)	NE (7.00, NE)	
Log-Rank Test p-value (unstratified)	0.3588		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.783 (0.464, 1.321)		
BRCA 1/2 status			
Wild-Type	66	65	0.0725
Number (%) of Participants with Events (Deterioration)	14 (21.2%)	15 (23.1%)	
Number (%) of Participants Censored	52 (78.8%)	50 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (7.00, NE)	
Log-Rank Test p-value (unstratified)	0.6879		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.861 (0.415, 1.787)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	1 (8.3%)	5 (50.0%)	
Number (%) of Participants Censored	11 (91.7%)	5 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.65, NE)	3.81 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.0402		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.144 (0.017, 1.237)		
Menopausal status			
Pre-menopausal	37	49	0.5384
Number (%) of Participants with Events (Deterioration)	11 (29.7%)	17 (34.7%)	
Number (%) of Participants Censored	26 (70.3%)	32 (65.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (3.81, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.3348		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.688 (0.319, 1.481)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	35 (25.0%)	29 (24.4%)	
Number (%) of Participants Censored	105 (75.0%)	90 (75.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8696		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.960 (0.586, 1.572)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.61. Table 1.1.21.3: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Sexual Enjoyment | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.8970
Number (%) of Participants with Events (Deterioration)	2 (3.6%)	1 (2.0%)	
Number (%) of Participants Censored	53 (96.4%)	48 (98.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	NE (0.99, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.8125		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.336 (0.121, 14.745)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	1 (2.9%)	1 (2.9%)	
Number (%) of Participants Censored	33 (97.1%)	33 (97.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.58, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.8055		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.414 (0.088, 22.637)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	4 (4.5%)	7 (8.1%)	
Number (%) of Participants Censored	84 (95.5%)	79 (91.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	NE (1.68, NE)	
Log-Rank Test p-value (unstratified)	0.8525		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.896 (0.261, 3.071)		
Geographic region			
US/Canada/Western Europe	56	52	0.2405
Number (%) of Participants with Events (Deterioration)	1 (1.8%)	5 (9.6%)	
Number (%) of Participants Censored	55 (98.2%)	47 (90.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.4373		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.435 (0.050, 3.766)		

	SG (N=177)	TPC (N=169)	Interaction
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	6 (5.0%)	4 (3.4%)	
Number (%) of Participants Censored	115 (95.0%)	113 (96.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.58, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.4494		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.622 (0.458, 5.750)		
Age group			
< 65	133	131	0.2277
Number (%) of Participants with Events (Deterioration)	7 (5.3%)	8 (6.1%)	
Number (%) of Participants Censored	126 (94.7%)	123 (93.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.8021		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.141 (0.414, 3.148)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	0	1 (2.6%)	
Number (%) of Participants Censored	44 (100.0%)	37 (97.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	1.20 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.4795		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
Race			
White	115	104	0.2994

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (5.2%)	7 (6.7%)	
Number (%) of Participants Censored	109 (94.8%)	97 (93.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.6553		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.281 (0.430, 3.816)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	0	1 (2.6%)	
Number (%) of Participants Censored	38 (100.0%)	37 (97.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.2636		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	1 (5.3%)	1 (4.2%)	
Number (%) of Participants Censored	18 (94.7%)	23 (95.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.88 (1.45, NE)	NE (1.18, NE)	
Log-Rank Test p-value (unstratified)	0.5596		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.236 (0.139, 35.904)		
Baseline ECOG status			
0	116	106	0.2998
Number (%) of Participants with Events (Deterioration)	5 (4.3%)	6 (5.7%)	
Number (%) of Participants Censored	111 (95.7%)	100 (94.3%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6255		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.343 (0.409, 4.410)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	2 (3.3%)	3 (4.8%)	
Number (%) of Participants Censored	59 (96.7%)	60 (95.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.45, NE)	3.09 (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.1985		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.311 (0.048, 2.007)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1574
Number (%) of Participants with Events (Deterioration)	1 (1.9%)	4 (8.9%)	
Number (%) of Participants Censored	51 (98.1%)	41 (91.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	NE (0.92, NE)	
Log-Rank Test p-value (unstratified)	0.2591		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.296 (0.033, 2.691)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	6 (4.8%)	5 (4.0%)	
Number (%) of Participants Censored	119 (95.2%)	119 (96.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.4739		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.543 (0.470, 5.059)		
History of liver metastasis			
Yes	47	39	0.1697
Number (%) of Participants with Events (Deterioration)	2 (4.3%)	0	
Number (%) of Participants Censored	45 (95.7%)	39 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.05, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.3043		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	130	130	
Number (%) of Participants with Events (Deterioration)	5 (3.8%)	9 (6.9%)	
Number (%) of Participants Censored	125 (96.2%)	121 (93.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.58, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.8948		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.930 (0.311, 2.780)		
History of brain metastasis			
Yes	8	9	1.0000
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	8 (100.0%)	9 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
No	169	160	
Number (%) of Participants with Events (Deterioration)	7 (4.1%)	9 (5.6%)	
Number (%) of Participants Censored	162 (95.9%)	151 (94.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.9844		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.010 (0.376, 2.714)		
PD-L1 Status			
CPS < 1	67	59	0.4682
Number (%) of Participants with Events (Deterioration)	3 (4.5%)	2 (3.4%)	
Number (%) of Participants Censored	64 (95.5%)	57 (96.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (0.85, NE)	
Log-Rank Test p-value (unstratified)	0.5336		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.755 (0.292, 10.561)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	4 (3.7%)	7 (6.4%)	
Number (%) of Participants Censored	105 (96.3%)	103 (93.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.6458		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.748 (0.219, 2.556)		
BRCA 1/2 status			

	SG (N=177)	TPC (N=169)	Interaction
Wild-Type	66	65	1.0000
Number (%) of Participants with Events (Deterioration)	3 (4.5%)	3 (4.6%)	
Number (%) of Participants Censored	63 (95.5%)	62 (95.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.8016		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.228 (0.247, 6.118)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	0	0	
Number (%) of Participants Censored	12 (100.0%)	10 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
Menopausal status			
Pre-menopausal	37	49	0.9019
Number (%) of Participants with Events (Deterioration)	3 (8.1%)	5 (10.2%)	
Number (%) of Participants Censored	34 (91.9%)	44 (89.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	NE (1.68, NE)	
Log-Rank Test p-value (unstratified)	0.8579		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.154 (0.276, 4.835)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	4 (2.9%)	4 (3.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	136 (97.1%)	115 (96.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (4.21, NE)	
Log-Rank Test p-value (unstratified)	0.9743		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.971 (0.242, 3.886)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC= Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.62. Table 1.1.21.4: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Future Perspective | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.6269
Number (%) of Participants with Events (Deterioration)	20 (36.4%)	18 (36.7%)	
Number (%) of Participants Censored	35 (63.6%)	31 (63.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (2.23, 13.14)	8.38 (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.8428		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.936 (0.492, 1.782)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	14 (41.2%)	13 (38.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	20 (58.8%)	21 (61.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.38 (1.45, NE)	3.75 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.4881		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.761 (0.347, 1.666)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	32 (36.4%)	29 (33.7%)	
Number (%) of Participants Censored	56 (63.6%)	57 (66.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.27 (1.74, 27.89)	6.34 (2.83, NE)	
Log-Rank Test p-value (unstratified)	0.4392		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.221 (0.734, 2.033)		
Geographic region			
US/Canada/Western Europe	56	52	0.1077
Number (%) of Participants with Events (Deterioration)	20 (35.7%)	15 (28.8%)	
Number (%) of Participants Censored	36 (64.3%)	37 (71.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.61 (1.41, 5.52)	13.80 (1.64, NE)	
Log-Rank Test p-value (unstratified)	0.0900		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.811 (0.899, 3.646)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	46 (38.0%)	45 (38.5%)	
Number (%) of Participants Censored	75 (62.0%)	72 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	7.79 (3.06, 27.89)	6.34 (2.83, 10.15)	
Log-Rank Test p-value (unstratified)	0.5053		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.567, 1.319)		
Age group			
< 65	133	131	0.7861
Number (%) of Participants with Events (Deterioration)	54 (40.6%)	46 (35.1%)	
Number (%) of Participants Censored	79 (59.4%)	85 (64.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (3.61, 12.58)	6.34 (3.02, NE)	
Log-Rank Test p-value (unstratified)	0.9862		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.996 (0.668, 1.487)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	12 (27.3%)	14 (36.8%)	
Number (%) of Participants Censored	32 (72.7%)	24 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.41, NE)	9.26 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.9590		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.972 (0.439, 2.154)		
Race			
White	115	104	0.1091
Number (%) of Participants with Events (Deterioration)	45 (39.1%)	35 (33.7%)	
Number (%) of Participants Censored	70 (60.9%)	69 (66.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.43 (1.58, 5.52)	6.28 (2.00, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.2109		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.323 (0.849, 2.061)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	13 (34.2%)	16 (42.1%)	
Number (%) of Participants Censored	25 (65.8%)	22 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.58 (4.17, NE)	8.77 (2.79, NE)	
Log-Rank Test p-value (unstratified)	0.3461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.690 (0.317, 1.504)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	6 (31.6%)	9 (37.5%)	
Number (%) of Participants Censored	13 (68.4%)	15 (62.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.14 (4.93, NE)	5.04 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.1183		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.398 (0.122, 1.304)		
Baseline ECOG status			
0	116	106	0.6841
Number (%) of Participants with Events (Deterioration)	44 (37.9%)	35 (33.0%)	
Number (%) of Participants Censored	72 (62.1%)	71 (67.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.79 (4.27, 17.81)	9.26 (4.24, NE)	
Log-Rank Test p-value (unstratified)	0.7903		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.061 (0.676, 1.663)		

	SG (N=177)	TPC (N=169)	Interaction
1	61	63	
Number (%) of Participants with Events (Deterioration)	22 (36.1%)	25 (39.7%)	
Number (%) of Participants Censored	39 (63.9%)	38 (60.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (1.28, 6.31)	3.75 (1.64, 6.34)	
Log-Rank Test p-value (unstratified)	0.9536		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.982 (0.547, 1.763)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1018
Number (%) of Participants with Events (Deterioration)	20 (38.5%)	8 (17.8%)	
Number (%) of Participants Censored	32 (61.5%)	37 (82.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (1.58, 17.81)	9.26 (2.83, NE)	
Log-Rank Test p-value (unstratified)	0.1675		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.796 (0.780, 4.135)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	46 (36.8%)	52 (41.9%)	
Number (%) of Participants Censored	79 (63.2%)	72 (58.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (2.20, 13.14)	5.39 (2.46, 10.15)	
Log-Rank Test p-value (unstratified)	0.4985		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.868 (0.580, 1.299)		
History of liver metastasis			
Yes	47	39	0.1247

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	18 (38.3%)	7 (17.9%)	
Number (%) of Participants Censored	29 (61.7%)	32 (82.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (2.10, 13.14)	13.80 (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.1902		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.781 (0.738, 4.300)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	48 (36.9%)	53 (40.8%)	
Number (%) of Participants Censored	82 (63.1%)	77 (59.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (2.20, 17.81)	5.39 (2.83, 9.26)	
Log-Rank Test p-value (unstratified)	0.6393		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.909 (0.611, 1.352)		
History of brain metastasis			
Yes	8	9	0.6319
Number (%) of Participants with Events (Deterioration)	2 (25.0%)	3 (33.3%)	
Number (%) of Participants Censored	6 (75.0%)	6 (66.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.79, NE)	5.26 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.5211		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.551 (0.092, 3.306)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	64 (37.9%)	57 (35.6%)	
Number (%) of Participants Censored	105 (62.1%)	103 (64.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.52 (2.23, 11.33)	6.34 (3.29, 10.15)	
Log-Rank Test p-value (unstratified)	0.9021		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.022 (0.711, 1.470)		
PD-L1 Status			
CPS < 1	67	59	0.4724
Number (%) of Participants with Events (Deterioration)	28 (41.8%)	25 (42.4%)	
Number (%) of Participants Censored	39 (58.2%)	34 (57.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.53 (1.71, NE)	4.90 (1.74, NE)	
Log-Rank Test p-value (unstratified)	0.7452		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.914 (0.530, 1.577)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	38 (34.9%)	35 (31.8%)	
Number (%) of Participants Censored	71 (65.1%)	75 (68.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (2.43, 13.14)	8.38 (3.75, NE)	
Log-Rank Test p-value (unstratified)	0.6906		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.098 (0.687, 1.752)		
BRCA 1/2 status			
Wild-Type	66	65	0.3454
Number (%) of Participants with Events (Deterioration)	25 (37.9%)	21 (32.3%)	
Number (%) of Participants Censored	41 (62.1%)	44 (67.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	5.52 (2.14, 12.58)	13.80 (2.00, NE)	
Log-Rank Test p-value (unstratified)	0.7459		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.098 (0.613, 1.965)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	5 (41.7%)	4 (40.0%)	
Number (%) of Participants Censored	7 (58.3%)	6 (60.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.25 (0.95, NE)	6.28 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.2011		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.378 (0.624, 9.057)		
Menopausal status			
Pre-menopausal	37	49	0.4289
Number (%) of Participants with Events (Deterioration)	15 (40.5%)	19 (38.8%)	
Number (%) of Participants Censored	22 (59.5%)	30 (61.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.13 (1.68, NE)	4.24 (1.64, NE)	
Log-Rank Test p-value (unstratified)	0.6193		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.836 (0.417, 1.676)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	51 (36.4%)	40 (33.6%)	
Number (%) of Participants Censored	89 (63.6%)	79 (66.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.62 (2.43, 13.14)	9.26 (3.29, NE)	
Log-Rank Test p-value (unstratified)	0.6206		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.112 (0.731, 1.690)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.63. Table 1.1.21.5: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Systemic Therapy Side Effects | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.2034
Number (%) of Participants with Events (Deterioration)	41 (74.5%)	35 (71.4%)	
Number (%) of Participants Censored	14 (25.5%)	14 (28.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.82, 1.58)	1.41 (0.99, 1.91)	
Log-Rank Test p-value (unstratified)	0.3331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.253 (0.796, 1.971)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	27 (79.4%)	20 (58.8%)	
Number (%) of Participants Censored	7 (20.6%)	14 (41.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.76, 1.28)	2.73 (0.95, 5.59)	
Log-Rank Test p-value (unstratified)	0.0354		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.855 (1.037, 3.317)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	62 (70.5%)	50 (58.1%)	
Number (%) of Participants Censored	26 (29.5%)	36 (41.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.79, 1.25)	3.48 (1.54, 4.96)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.045 (1.403, 2.981)		
Geographic region			
US/Canada/Western Europe	56	52	0.6069
Number (%) of Participants with Events (Deterioration)	42 (75.0%)	31 (59.6%)	
Number (%) of Participants Censored	14 (25.0%)	21 (40.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.85 (0.79, 1.25)	1.74 (0.99, 3.12)	
Log-Rank Test p-value (unstratified)	0.0041		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.979 (1.238, 3.162)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	88 (72.7%)	74 (63.2%)	
Number (%) of Participants Censored	33 (27.3%)	43 (36.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.82, 1.45)	2.33 (1.41, 4.01)	
Log-Rank Test p-value (unstratified)	0.0017		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.650 (1.210, 2.251)		
Age group			

	SG (N=177)	TPC (N=169)	Interaction
< 65	133	131	0.5705
Number (%) of Participants with Events (Deterioration)	106 (79.7%)	85 (64.9%)	
Number (%) of Participants Censored	27 (20.3%)	46 (35.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.85 (0.79, 1.05)	1.87 (1.41, 3.12)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.657 (1.244, 2.207)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	24 (54.5%)	20 (52.6%)	
Number (%) of Participants Censored	20 (45.5%)	18 (47.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.79, 1.64)	4.44 (1.02, 6.47)	
Log-Rank Test p-value (unstratified)	0.0101		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.194 (1.185, 4.063)		
Race			
White	115	104	0.4254
Number (%) of Participants with Events (Deterioration)	85 (73.9%)	66 (63.5%)	
Number (%) of Participants Censored	30 (26.1%)	38 (36.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.92 (0.82, 1.41)	2.33 (1.54, 3.84)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.772 (1.283, 2.449)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	29 (76.3%)	23 (60.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	9 (23.7%)	15 (39.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.76, 1.05)	2.23 (0.99, 17.08)	
Log-Rank Test p-value (unstratified)	0.0084		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.098 (1.208, 3.643)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	12 (63.2%)	13 (54.2%)	
Number (%) of Participants Censored	7 (36.8%)	11 (45.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.25 (0.79, 5.19)	1.18 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.8207		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.087 (0.494, 2.390)		
Baseline ECOG status			
0	116	106	0.4444
Number (%) of Participants with Events (Deterioration)	90 (77.6%)	71 (67.0%)	
Number (%) of Participants Censored	26 (22.4%)	35 (33.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.79, 1.05)	1.74 (1.18, 3.02)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.842 (1.345, 2.521)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	40 (65.6%)	34 (54.0%)	
Number (%) of Participants Censored	21 (34.4%)	29 (46.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	1.02 (0.82, 1.58)	3.25 (1.41, 5.09)	
Log-Rank Test p-value (unstratified)	0.0713		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.535 (0.970, 2.430)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1296
Number (%) of Participants with Events (Deterioration)	39 (75.0%)	32 (71.1%)	
Number (%) of Participants Censored	13 (25.0%)	13 (28.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.99 (0.79, 1.48)	1.05 (0.99, 1.87)	
Log-Rank Test p-value (unstratified)	0.2980		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.279 (0.797, 2.053)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	91 (72.8%)	73 (58.9%)	
Number (%) of Participants Censored	34 (27.2%)	51 (41.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.79, 1.12)	3.09 (1.74, 5.09)	
Log-Rank Test p-value (unstratified)	<0.001		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.887 (1.383, 2.575)		
History of liver metastasis			
Yes	47	39	0.7472
Number (%) of Participants with Events (Deterioration)	33 (70.2%)	19 (48.7%)	
Number (%) of Participants Censored	14 (29.8%)	20 (51.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.15 (0.82, 1.58)	2.73 (0.99, NE)	

		SG (N=177)	TPC (N=169)	Interaction
	Log-Rank Test p-value (unstratified)	0.0551		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.731 (0.982, 3.050)		
No		130	130	
	Number (%) of Participants with Events (Deterioration)	97 (74.6%)	86 (66.2%)	
	Number (%) of Participants Censored	33 (25.4%)	44 (33.8%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	0.82 (0.79, 1.05)	1.91 (1.41, 3.48)	
	Log-Rank Test p-value (unstratified)	<0.001		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.820 (1.358, 2.439)		
History of brain metastasis				
Yes		8	9	0.7781
	Number (%) of Participants with Events (Deterioration)	4 (50.0%)	2 (22.2%)	
	Number (%) of Participants Censored	4 (50.0%)	7 (77.8%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	4.21 (0.76, NE)	NE (0.76, NE)	
	Log-Rank Test p-value (unstratified)	0.4215		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.971 (0.360, 10.790)		
No		169	160	
	Number (%) of Participants with Events (Deterioration)	126 (74.6%)	103 (64.4%)	
	Number (%) of Participants Censored	43 (25.4%)	57 (35.6%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	0.95 (0.82, 1.05)	1.91 (1.41, 3.12)	
	Log-Rank Test p-value (unstratified)	<0.001		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.749 (1.346, 2.272)		

	SG (N=177)	TPC (N=169)	Interaction
PD-L1 Status			
CPS < 1	67	59	0.6349
Number (%) of Participants with Events (Deterioration)	50 (74.6%)	33 (55.9%)	
Number (%) of Participants Censored	17 (25.4%)	26 (44.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.82, 1.48)	3.09 (1.74, 5.09)	
Log-Rank Test p-value (unstratified)	0.0036		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.931 (1.240, 3.007)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	80 (73.4%)	72 (65.5%)	
Number (%) of Participants Censored	29 (26.6%)	38 (34.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.89 (0.79, 1.25)	1.64 (1.12, 3.48)	
Log-Rank Test p-value (unstratified)	0.0021		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.658 (1.203, 2.283)		
BRCA 1/2 status			
Wild-Type	66	65	0.5955
Number (%) of Participants with Events (Deterioration)	50 (75.8%)	38 (58.5%)	
Number (%) of Participants Censored	16 (24.2%)	27 (41.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.92 (0.82, 1.45)	1.74 (1.22, 3.98)	
Log-Rank Test p-value (unstratified)	0.0018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.968 (1.285, 3.014)		
Mutant	12	10	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	9 (75.0%)	6 (60.0%)	
Number (%) of Participants Censored	3 (25.0%)	4 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.76, 1.25)	1.91 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.1091		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.350 (0.807, 6.845)		
Menopausal status			
Pre-menopausal	37	49	0.3200
Number (%) of Participants with Events (Deterioration)	31 (83.8%)	32 (65.3%)	
Number (%) of Participants Censored	6 (16.2%)	17 (34.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.76, 1.02)	1.64 (0.99, 3.84)	
Log-Rank Test p-value (unstratified)	0.0027		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.139 (1.299, 3.522)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	99 (70.7%)	72 (60.5%)	
Number (%) of Participants Censored	41 (29.3%)	47 (39.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.02 (0.82, 1.41)	2.23 (1.41, 4.44)	
Log-Rank Test p-value (unstratified)	0.0012		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.655 (1.220, 2.245)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.

Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.64. Table 1.1.21.6: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Breast Symptoms | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.2605
Number (%) of Participants with Events (Deterioration)	11 (20.0%)	12 (24.5%)	
Number (%) of Participants Censored	44 (80.0%)	37 (75.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (5.19, NE)	
Log-Rank Test p-value (unstratified)	0.3464		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.669 (0.289, 1.552)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	14 (41.2%)	10 (29.4%)	
Number (%) of Participants Censored	20 (58.8%)	24 (70.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.48 (3.88, NE)	12.75 (2.86, NE)	
Log-Rank Test p-value (unstratified)	0.7346		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.865 (0.373, 2.004)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	28 (31.8%)	18 (20.9%)	
Number (%) of Participants Censored	60 (68.2%)	68 (79.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	NE (NE, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.1318		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.572 (0.869, 2.843)		
Geographic region			
US/Canada/Western Europe	56	52	0.2205
Number (%) of Participants with Events (Deterioration)	14 (25.0%)	13 (25.0%)	
Number (%) of Participants Censored	42 (75.0%)	39 (75.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (7.16, NE)	9.49 (5.13, NE)	
Log-Rank Test p-value (unstratified)	0.3434		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.690 (0.319, 1.492)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	39 (32.2%)	27 (23.1%)	
Number (%) of Participants Censored	82 (67.8%)	90 (76.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (9.30, NE)	NE (12.75, NE)	
Log-Rank Test p-value (unstratified)	0.2590		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.330 (0.810, 2.182)		
Age group			
< 65	133	131	0.5205
Number (%) of Participants with Events (Deterioration)	43 (32.3%)	29 (22.1%)	
Number (%) of Participants Censored	90 (67.7%)	102 (77.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (10.18, NE)	NE (12.75, NE)	
Log-Rank Test p-value (unstratified)	0.4711		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.191 (0.740, 1.917)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	10 (22.7%)	11 (28.9%)	
Number (%) of Participants Censored	34 (77.3%)	27 (71.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.9357		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.966 (0.410, 2.275)		
Race			
White	115	104	0.6230
Number (%) of Participants with Events (Deterioration)	36 (31.3%)	28 (26.9%)	
Number (%) of Participants Censored	79 (68.7%)	76 (73.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.05 (7.16, NE)	12.75 (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.7608		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.925 (0.561, 1.524)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	12 (31.6%)	8 (21.1%)	
Number (%) of Participants Censored	26 (68.4%)	30 (78.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	NE (8.71, NE)	
Log-Rank Test p-value (unstratified)	0.2998		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.607 (0.650, 3.970)		
Other	19	24	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	4 (21.1%)	4 (16.7%)	
Number (%) of Participants Censored	15 (78.9%)	20 (83.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (5.62, NE)	NE (2.86, NE)	
Log-Rank Test p-value (unstratified)	0.8114		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.186 (0.291, 4.828)		
Baseline ECOG status			
0	116	106	0.7262
Number (%) of Participants with Events (Deterioration)	38 (32.8%)	27 (25.5%)	
Number (%) of Participants Censored	78 (67.2%)	79 (74.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (9.49, NE)	
Log-Rank Test p-value (unstratified)	0.5395		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.168 (0.711, 1.920)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	15 (24.6%)	13 (20.6%)	
Number (%) of Participants Censored	46 (75.4%)	50 (79.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (6.44, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.9586		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.019 (0.477, 2.177)		
Physician's choice of chemotherapy			
Taxane	52	45	0.2573
Number (%) of Participants with Events (Deterioration)	17 (32.7%)	7 (15.6%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	35 (67.3%)	38 (84.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	NE (6.90, NE)	
Log-Rank Test p-value (unstratified)	0.2398		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.699 (0.697, 4.146)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	36 (28.8%)	33 (26.6%)	
Number (%) of Participants Censored	89 (71.2%)	91 (73.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (17.05, NE)	NE (12.75, NE)	
Log-Rank Test p-value (unstratified)	0.9461		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.984 (0.611, 1.585)		
History of liver metastasis			
Yes	47	39	0.4592
Number (%) of Participants with Events (Deterioration)	12 (25.5%)	4 (10.3%)	
Number (%) of Participants Censored	35 (74.5%)	35 (89.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.88, NE)	NE (5.19, NE)	
Log-Rank Test p-value (unstratified)	0.1977		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.072 (0.667, 6.433)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	41 (31.5%)	36 (27.7%)	
Number (%) of Participants Censored	89 (68.5%)	94 (72.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	17.48 (9.95, NE)	NE (9.49, NE)	
Log-Rank Test p-value (unstratified)	0.7865		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.065 (0.678, 1.672)		
History of brain metastasis			
Yes	8	9	0.9488
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	1 (11.1%)	
Number (%) of Participants Censored	7 (87.5%)	8 (88.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.88, NE)	NE (2.14, NE)	
Log-Rank Test p-value (unstratified)	0.9372		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.894 (0.056, 14.361)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	52 (30.8%)	39 (24.4%)	
Number (%) of Participants Censored	117 (69.2%)	121 (75.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (10.09, NE)	NE (9.49, NE)	
Log-Rank Test p-value (unstratified)	0.5887		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.123 (0.738, 1.708)		
PD-L1 Status			
CPS < 1	67	59	0.3689
Number (%) of Participants with Events (Deterioration)	24 (35.8%)	19 (32.2%)	
Number (%) of Participants Censored	43 (64.2%)	40 (67.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.48 (8.51, NE)	12.75 (5.13, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.6799		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.880 (0.477, 1.622)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	29 (26.6%)	21 (19.1%)	
Number (%) of Participants Censored	80 (73.4%)	89 (80.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (10.18, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.3158		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.334 (0.758, 2.347)		
BRCA 1/2 status			
Wild-Type	66	65	0.8492
Number (%) of Participants with Events (Deterioration)	21 (31.8%)	18 (27.7%)	
Number (%) of Participants Censored	45 (68.2%)	47 (72.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.42, NE)	9.49 (7.36, NE)	
Log-Rank Test p-value (unstratified)	0.8566		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.944 (0.502, 1.775)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	3 (25.0%)	2 (20.0%)	
Number (%) of Participants Censored	9 (75.0%)	8 (80.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (2.83, NE)	NE (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.8923		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.133 (0.186, 6.900)		

	SG (N=177)	TPC (N=169)	Interaction
Menopausal status			
Pre-menopausal	37	49	0.9640
Number (%) of Participants with Events (Deterioration)	8 (21.6%)	10 (20.4%)	
Number (%) of Participants Censored	29 (78.4%)	39 (79.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (9.95, NE)	NE (7.36, NE)	
Log-Rank Test p-value (unstratified)	0.9913		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.995 (0.388, 2.552)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	45 (32.1%)	30 (25.2%)	
Number (%) of Participants Censored	95 (67.9%)	89 (74.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	24.67 (9.30, NE)	NE (12.75, NE)	
Log-Rank Test p-value (unstratified)	0.7736		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.071 (0.671, 1.710)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.65. Table 1.1.21.7: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Arm Symptoms | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.1812
Number (%) of Participants with Events (Deterioration)	27 (49.1%)	25 (51.0%)	
Number (%) of Participants Censored	28 (50.9%)	24 (49.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (1.74, 15.90)	3.09 (1.41, 6.54)	
Log-Rank Test p-value (unstratified)	0.1913		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.691 (0.395, 1.209)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	23 (67.6%)	17 (50.0%)	
Number (%) of Participants Censored	11 (32.4%)	17 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (1.51, 6.70)	5.09 (2.20, 12.75)	
Log-Rank Test p-value (unstratified)	0.4142		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.301 (0.692, 2.445)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	36 (40.9%)	43 (50.0%)	
Number (%) of Participants Censored	52 (59.1%)	43 (50.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.63 (5.55, 14.98)	4.17 (2.79, 7.85)	
Log-Rank Test p-value (unstratified)	0.1061		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.695 (0.445, 1.085)		
Geographic region			

	SG (N=177)	TPC (N=169)	Interaction
US/Canada/Western Europe	56	52	0.7298
Number (%) of Participants with Events (Deterioration)	26 (46.4%)	23 (44.2%)	
Number (%) of Participants Censored	30 (53.6%)	29 (55.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.96 (2.89, 12.68)	4.17 (2.79, 6.34)	
Log-Rank Test p-value (unstratified)	0.5130		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.824 (0.466, 1.456)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	60 (49.6%)	62 (53.0%)	
Number (%) of Participants Censored	61 (50.4%)	55 (47.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.93 (3.55, 13.34)	3.75 (2.79, 5.59)	
Log-Rank Test p-value (unstratified)	0.1546		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.772 (0.539, 1.104)		
Age group			
< 65	133	131	0.8357
Number (%) of Participants with Events (Deterioration)	70 (52.6%)	67 (51.1%)	
Number (%) of Participants Censored	63 (47.4%)	64 (48.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.55 (3.55, 9.63)	3.94 (2.83, 6.24)	
Log-Rank Test p-value (unstratified)	0.2391		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.817 (0.583, 1.146)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	16 (36.4%)	18 (47.4%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	28 (63.6%)	20 (52.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.71 (2.10, 12.68)	3.75 (1.41, 6.34)	
Log-Rank Test p-value (unstratified)	0.3162		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.707 (0.358, 1.397)		
Race			
White	115	104	0.6535
Number (%) of Participants with Events (Deterioration)	57 (49.6%)	51 (49.0%)	
Number (%) of Participants Censored	58 (50.4%)	53 (51.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.03 (3.55, 7.85)	3.58 (2.79, 5.59)	
Log-Rank Test p-value (unstratified)	0.3359		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.828 (0.566, 1.212)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	21 (55.3%)	22 (57.9%)	
Number (%) of Participants Censored	17 (44.7%)	16 (42.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.02 (1.45, NE)	3.94 (1.45, NE)	
Log-Rank Test p-value (unstratified)	0.6006		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.852 (0.462, 1.569)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	6 (31.6%)	10 (41.7%)	
Number (%) of Participants Censored	13 (68.4%)	14 (58.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	15.90 (1.51, NE)	6.54 (1.41, NE)	
Log-Rank Test p-value (unstratified)	0.1651		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.481 (0.168, 1.379)		
Baseline ECOG status			
0	116	106	0.0980
Number (%) of Participants with Events (Deterioration)	53 (45.7%)	59 (55.7%)	
Number (%) of Participants Censored	63 (54.3%)	47 (44.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.16 (3.61, 13.34)	3.09 (2.53, 5.59)	
Log-Rank Test p-value (unstratified)	0.0386		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.675 (0.464, 0.981)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	33 (54.1%)	26 (41.3%)	
Number (%) of Participants Censored	28 (45.9%)	37 (58.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (1.61, 9.30)	4.17 (3.48, 11.76)	
Log-Rank Test p-value (unstratified)	0.8235		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.066 (0.633, 1.795)		
Physician's choice of chemotherapy			
Taxane	52	45	0.2543
Number (%) of Participants with Events (Deterioration)	27 (51.9%)	17 (37.8%)	
Number (%) of Participants Censored	25 (48.1%)	28 (62.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.80 (1.68, 12.68)	3.94 (2.76, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.7690		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.097 (0.589, 2.040)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	59 (47.2%)	68 (54.8%)	
Number (%) of Participants Censored	66 (52.8%)	56 (45.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.80 (4.01, 10.84)	3.75 (2.79, 5.59)	
Log-Rank Test p-value (unstratified)	0.0650		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.719 (0.506, 1.022)		
History of liver metastasis			
Yes	47	39	0.5459
Number (%) of Participants with Events (Deterioration)	20 (42.6%)	12 (30.8%)	
Number (%) of Participants Censored	27 (57.4%)	27 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.63 (3.06, NE)	7.85 (3.48, NE)	
Log-Rank Test p-value (unstratified)	0.8497		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.931 (0.442, 1.961)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	66 (50.8%)	73 (56.2%)	
Number (%) of Participants Censored	64 (49.2%)	57 (43.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.80 (3.55, 9.30)	3.48 (2.53, 5.13)	
Log-Rank Test p-value (unstratified)	0.1562		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.785 (0.562, 1.098)		

	SG (N=177)	TPC (N=169)	Interaction
History of brain metastasis			
Yes	8	9	0.3737
Number (%) of Participants with Events (Deterioration)	2 (25.0%)	4 (44.4%)	
Number (%) of Participants Censored	6 (75.0%)	5 (55.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	3.17 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.2209		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.365 (0.067, 1.996)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	84 (49.7%)	81 (50.6%)	
Number (%) of Participants Censored	85 (50.3%)	79 (49.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.55 (4.01, 9.63)	3.94 (2.83, 5.59)	
Log-Rank Test p-value (unstratified)	0.1900		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.814 (0.598, 1.108)		
PD-L1 Status			
CPS < 1	67	59	0.4660
Number (%) of Participants with Events (Deterioration)	36 (53.7%)	29 (49.2%)	
Number (%) of Participants Censored	31 (46.3%)	30 (50.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.17 (2.20, 10.84)	4.21 (2.86, 7.85)	
Log-Rank Test p-value (unstratified)	0.7637		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.927 (0.568, 1.512)		
CPS ≥ 1	109	110	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	50 (45.9%)	56 (50.9%)	
Number (%) of Participants Censored	59 (54.1%)	54 (49.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.93 (4.17, 14.98)	3.52 (2.79, 6.24)	
Log-Rank Test p-value (unstratified)	0.0796		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.706 (0.478, 1.045)		
BRCA 1/2 status			
Wild-Type	66	65	0.7082
Number (%) of Participants with Events (Deterioration)	36 (54.5%)	29 (44.6%)	
Number (%) of Participants Censored	30 (45.5%)	36 (55.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.96 (3.06, 7.85)	3.75 (1.87, NE)	
Log-Rank Test p-value (unstratified)	0.9577		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.986 (0.603, 1.612)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	7 (58.3%)	6 (60.0%)	
Number (%) of Participants Censored	5 (41.7%)	4 (40.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	4.80 (0.95, NE)	3.02 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.5448		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.707 (0.235, 2.122)		
Menopausal status			
Pre-menopausal	37	49	0.0721
Number (%) of Participants with Events (Deterioration)	15 (40.5%)	31 (63.3%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	22 (59.5%)	18 (36.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	13.34 (3.15, NE)	2.83 (1.94, 5.59)	
Log-Rank Test p-value (unstratified)	0.0446		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.530 (0.283, 0.993)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	71 (50.7%)	53 (44.5%)	
Number (%) of Participants Censored	69 (49.3%)	66 (55.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.55 (4.01, 9.30)	4.90 (3.48, 7.85)	
Log-Rank Test p-value (unstratified)	0.7296		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.939 (0.656, 1.343)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.66. Table 1.1.21.8: — Subgroup Analysis of Time to First Meaningful Deterioration | EORTC QLQ-BR23: Upset By Hair Loss | — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.9179
Number (%) of Participants with Events (Deterioration)	4 (7.3%)	6 (12.2%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	51 (92.7%)	43 (87.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	7.23 (0.76, NE)	4.63 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.3241		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.522 (0.143, 1.904)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	3 (8.8%)	4 (11.8%)	
Number (%) of Participants Censored	31 (91.2%)	30 (88.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	14.21 (0.82, NE)	1.41 (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.6474		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.710 (0.158, 3.194)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	9 (10.2%)	10 (11.6%)	
Number (%) of Participants Censored	79 (89.8%)	76 (88.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.95 (0.72, NE)	0.87 (0.76, 1.94)	
Log-Rank Test p-value (unstratified)	0.5786		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.760 (0.307, 1.881)		
Geographic region			
US/Canada/Western Europe	56	52	0.0755
Number (%) of Participants with Events (Deterioration)	5 (8.9%)	2 (3.8%)	
Number (%) of Participants Censored	51 (91.1%)	50 (96.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	0.89 (0.72, NE)	1.41 (0.99, NE)	
Log-Rank Test p-value (unstratified)	0.1538		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	3.228 (0.597, 17.449)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	11 (9.1%)	18 (15.4%)	
Number (%) of Participants Censored	110 (90.9%)	99 (84.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (0.99, NE)	1.41 (0.95, 4.63)	
Log-Rank Test p-value (unstratified)	0.1062		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.538 (0.252, 1.145)		
Age group			
< 65	133	131	0.1806
Number (%) of Participants with Events (Deterioration)	12 (9.0%)	16 (12.2%)	
Number (%) of Participants Censored	121 (91.0%)	115 (87.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (0.82, NE)	1.41 (0.95, 3.32)	
Log-Rank Test p-value (unstratified)	0.1170		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.546 (0.254, 1.175)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	4 (9.1%)	4 (10.5%)	
Number (%) of Participants Censored	40 (90.9%)	34 (89.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.37 (0.07, NE)	3.06 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.5611		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.475 (0.367, 5.922)		
Race			
White	115	104	0.5971
Number (%) of Participants with Events (Deterioration)	11 (9.6%)	13 (12.5%)	
Number (%) of Participants Censored	104 (90.4%)	91 (87.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (0.82, NE)	1.41 (0.95, 4.63)	
Log-Rank Test p-value (unstratified)	0.5074		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.742 (0.329, 1.671)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	3 (7.9%)	3 (7.9%)	
Number (%) of Participants Censored	35 (92.1%)	35 (92.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.76, NE)	6.29 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.8876		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.122 (0.226, 5.577)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	2 (10.5%)	4 (16.7%)	
Number (%) of Participants Censored	17 (89.5%)	20 (83.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	17.33 (0.99, NE)	3.06 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.2602		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.375 (0.066, 2.127)		
Baseline ECOG status			

	SG (N=177)	TPC (N=169)	Interaction
0	116	106	0.1724
Number (%) of Participants with Events (Deterioration)	5 (4.3%)	12 (11.3%)	
Number (%) of Participants Censored	111 (95.7%)	94 (88.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	1.41 (0.79, 3.32)	
Log-Rank Test p-value (unstratified)	0.1339		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.444 (0.154, 1.280)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	11 (18.0%)	8 (12.7%)	
Number (%) of Participants Censored	50 (82.0%)	55 (87.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.25 (0.82, NE)	3.06 (0.76, 5.55)	
Log-Rank Test p-value (unstratified)	0.8672		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.078 (0.432, 2.688)		
Physician's choice of chemotherapy			
Taxane	52	45	0.2136
Number (%) of Participants with Events (Deterioration)	3 (5.8%)	7 (15.6%)	
Number (%) of Participants Censored	49 (94.2%)	38 (84.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.72, NE)	1.45 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.1336		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.356 (0.089, 1.424)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	13 (10.4%)	13 (10.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	112 (89.6%)	111 (89.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	2.20 (0.85, NE)	1.41 (0.79, NE)	
Log-Rank Test p-value (unstratified)	0.9341		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.946 (0.437, 2.046)		
History of liver metastasis			
Yes	47	39	0.3936
Number (%) of Participants with Events (Deterioration)	3 (6.4%)	1 (2.6%)	
Number (%) of Participants Censored	44 (93.6%)	38 (97.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (0.89, NE)	NE (0.95, NE)	
Log-Rank Test p-value (unstratified)	0.5138		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.101 (0.215, 20.491)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	13 (10.0%)	19 (14.6%)	
Number (%) of Participants Censored	117 (90.0%)	111 (85.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (0.82, NE)	1.41 (0.95, 3.32)	
Log-Rank Test p-value (unstratified)	0.2576		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.660 (0.324, 1.343)		
History of brain metastasis			
Yes	8	9	0.1001
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	2 (22.2%)	
Number (%) of Participants Censored	7 (87.5%)	7 (77.8%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	0.76 (0.72, NE)	
Log-Rank Test p-value (unstratified)	0.3018		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.293 (0.025, 3.420)		
No	169	160	
Number (%) of Participants with Events (Deterioration)	15 (8.9%)	18 (11.2%)	
Number (%) of Participants Censored	154 (91.1%)	142 (88.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (0.89, NE)	1.48 (0.99, 4.63)	
Log-Rank Test p-value (unstratified)	0.5157		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.783 (0.392, 1.562)		
PD-L1 Status			
CPS < 1	67	59	0.2858
Number (%) of Participants with Events (Deterioration)	7 (10.4%)	6 (10.2%)	
Number (%) of Participants Censored	60 (89.6%)	53 (89.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	1.72 (0.76, NE)	0.79 (0.72, 1.48)	
Log-Rank Test p-value (unstratified)	0.1872		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.477 (0.158, 1.441)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	9 (8.3%)	14 (12.7%)	
Number (%) of Participants Censored	100 (91.7%)	96 (87.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (0.82, NE)	1.94 (0.95, 5.55)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.6672		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.826 (0.356, 1.921)		
BRCA 1/2 status			
Wild-Type	66	65	1.0000
Number (%) of Participants with Events (Deterioration)	8 (12.1%)	7 (10.8%)	
Number (%) of Participants Censored	58 (87.9%)	58 (89.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	0.82 (0.72, 0.99)	1.41 (0.76, NE)	
Log-Rank Test p-value (unstratified)	0.0552		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.679 (0.942, 7.620)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	1 (8.3%)	0	
Number (%) of Participants Censored	11 (91.7%)	10 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.25, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	1.0000		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NEst		
Menopausal status			
Pre-menopausal	37	49	0.7570
Number (%) of Participants with Events (Deterioration)	3 (8.1%)	8 (16.3%)	
Number (%) of Participants Censored	34 (91.9%)	41 (83.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.55 (0.72, NE)	1.45 (0.76, 3.32)	
Log-Rank Test p-value (unstratified)	0.9056		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.894 (0.231, 3.454)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	13 (9.3%)	12 (10.1%)	
Number (%) of Participants Censored	127 (90.7%)	107 (89.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	3.48 (0.85, NE)	1.41 (0.76, 5.55)	
Log-Rank Test p-value (unstratified)	0.3978		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.710 (0.323, 1.559)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.67. Table 1.1.22: Subgroup Analysis of Time to First Deterioration by response threshold in EQ-5D-VAS — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.4385
Number (%) of Participants with Events (Deterioration)	20 (36.4%)	18 (36.7%)	
Number (%) of Participants Censored	35 (63.6%)	31 (63.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	11.30 (6.31, NE)	10.48 (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.5705		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.830 (0.433, 1.592)		

	SG (N=177)	TPC (N=169)	Interaction
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	16 (47.1%)	13 (38.2%)	
Number (%) of Participants Censored	18 (52.9%)	21 (61.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.68, NE)	NE (2.14, NE)	
Log-Rank Test p-value (unstratified)	0.7111		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.153 (0.555, 2.398)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	35 (39.8%)	26 (30.2%)	
Number (%) of Participants Censored	53 (60.2%)	60 (69.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (6.24, NE)	13.01 (10.28, NE)	
Log-Rank Test p-value (unstratified)	0.1942		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.398 (0.840, 2.326)		
Geographic region			
US/Canada/Western Europe	56	52	0.8412
Number (%) of Participants with Events (Deterioration)	21 (37.5%)	16 (30.8%)	
Number (%) of Participants Censored	35 (62.5%)	36 (69.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.15 (3.88, NE)	NE (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.9416		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.031 (0.530, 2.007)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	50 (41.3%)	41 (35.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	71 (58.7%)	76 (65.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (5.78, NE)	11.56 (10.28, NE)	
Log-Rank Test p-value (unstratified)	0.4857		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.159 (0.765, 1.756)		
Age group			
< 65	133	131	0.8617
Number (%) of Participants with Events (Deterioration)	58 (43.6%)	43 (32.8%)	
Number (%) of Participants Censored	75 (56.4%)	88 (67.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.15 (7.23, NE)	12.39 (10.28, NE)	
Log-Rank Test p-value (unstratified)	0.5012		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.147 (0.771, 1.707)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	13 (29.5%)	14 (36.8%)	
Number (%) of Participants Censored	31 (70.5%)	24 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.61, NE)	NE (2.50, NE)	
Log-Rank Test p-value (unstratified)	0.7486		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.137 (0.534, 2.423)		
Race			
White	115	104	0.4996
Number (%) of Participants with Events (Deterioration)	44 (38.3%)	38 (36.5%)	
Number (%) of Participants Censored	71 (61.7%)	66 (63.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.00 (6.31, NE)	10.48 (3.84, NE)	
Log-Rank Test p-value (unstratified)	0.7432		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.933 (0.603, 1.444)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	21 (55.3%)	16 (42.1%)	
Number (%) of Participants Censored	17 (44.7%)	22 (57.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.09 (2.30, 15.51)	12.39 (6.97, NE)	
Log-Rank Test p-value (unstratified)	0.3895		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.341 (0.688, 2.615)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	3 (15.8%)	3 (12.5%)	
Number (%) of Participants Censored	16 (84.2%)	21 (87.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.68, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.7873		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.246 (0.251, 6.175)		
Baseline ECOG status			
0	116	106	0.9585
Number (%) of Participants with Events (Deterioration)	49 (42.2%)	39 (36.8%)	
Number (%) of Participants Censored	67 (57.8%)	67 (63.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.15 (8.08, 18.73)	11.56 (9.46, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.5930		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.125 (0.737, 1.717)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	22 (36.1%)	18 (28.6%)	
Number (%) of Participants Censored	39 (63.9%)	45 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.65, NE)	15.41 (5.39, NE)	
Log-Rank Test p-value (unstratified)	0.5799		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.193 (0.638, 2.231)		
Physician's choice of chemotherapy			
Taxane	52	45	0.1176
Number (%) of Participants with Events (Deterioration)	27 (51.9%)	12 (26.7%)	
Number (%) of Participants Censored	25 (48.1%)	33 (73.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.31 (3.19, 10.15)	11.07 (4.67, NE)	
Log-Rank Test p-value (unstratified)	0.1382		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.675 (0.843, 3.326)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	44 (35.2%)	45 (36.3%)	
Number (%) of Participants Censored	81 (64.8%)	79 (63.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (8.87, NE)	12.39 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.7492		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.935 (0.615, 1.421)		

	SG (N=177)	TPC (N=169)	Interaction
History of liver metastasis			
Yes	47	39	0.5941
Number (%) of Participants with Events (Deterioration)	21 (44.7%)	10 (25.6%)	
Number (%) of Participants Censored	26 (55.3%)	29 (74.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (3.65, 18.73)	NE (4.67, NE)	
Log-Rank Test p-value (unstratified)	0.4354		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.351 (0.630, 2.899)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	50 (38.5%)	47 (36.2%)	
Number (%) of Participants Censored	80 (61.5%)	83 (63.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	12.55 (7.23, NE)	11.56 (10.28, NE)	
Log-Rank Test p-value (unstratified)	0.7539		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.068 (0.716, 1.594)		
History of brain metastasis			
Yes	8	9	0.9986
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	1 (11.1%)	
Number (%) of Participants Censored	7 (87.5%)	8 (88.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.76, NE)	NE (2.14, NE)	
Log-Rank Test p-value (unstratified)	0.9921		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.014 (0.063, 16.374)		
No	169	160	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	70 (41.4%)	56 (35.0%)	
Number (%) of Participants Censored	99 (58.6%)	104 (65.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	9.76 (6.31, 18.73)	11.56 (10.28, NE)	
Log-Rank Test p-value (unstratified)	0.5011		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.131 (0.794, 1.610)		
PD-L1 Status			
CPS < 1	67	59	0.1104
Number (%) of Participants with Events (Deterioration)	24 (35.8%)	21 (35.6%)	
Number (%) of Participants Censored	43 (64.2%)	38 (64.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	18.73 (8.08, NE)	11.56 (4.40, NE)	
Log-Rank Test p-value (unstratified)	0.4274		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.787 (0.435, 1.423)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	47 (43.1%)	36 (32.7%)	
Number (%) of Participants Censored	62 (56.9%)	74 (67.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.84 (4.90, 15.51)	12.39 (10.48, NE)	
Log-Rank Test p-value (unstratified)	0.1286		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.404 (0.907, 2.173)		
BRCA 1/2 status			
Wild-Type	66	65	0.0809
Number (%) of Participants with Events (Deterioration)	34 (51.5%)	25 (38.5%)	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants Censored	32 (48.5%)	40 (61.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	8.08 (4.07, 11.30)	9.46 (3.09, NE)	
Log-Rank Test p-value (unstratified)	0.4698		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.213 (0.722, 2.038)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	5 (41.7%)	1 (10.0%)	
Number (%) of Participants Censored	7 (58.3%)	9 (90.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (0.95, NE)	NE (11.56, NE)	
Log-Rank Test p-value (unstratified)	0.0658		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	6.206 (0.696, 55.363)		
Menopausal status			
Pre-menopausal	37	49	0.8626
Number (%) of Participants with Events (Deterioration)	13 (35.1%)	16 (32.7%)	
Number (%) of Participants Censored	24 (64.9%)	33 (67.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	10.15 (6.34, NE)	10.48 (9.46, NE)	
Log-Rank Test p-value (unstratified)	0.8951		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.952 (0.452, 2.008)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	58 (41.4%)	41 (34.5%)	
Number (%) of Participants Censored	82 (58.6%)	78 (65.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	9.76 (5.78, NE)	12.39 (5.39, NE)	
Log-Rank Test p-value (unstratified)	0.5419		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.135 (0.760, 1.696)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.68. Table 1.1.24: Subgroup Analysis of Time to First Deterioration by response threshold in PGIC — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.1220
Number (%) of Participants with Events (Deterioration)	8 (14.5%)	14 (28.6%)	
Number (%) of Participants Censored	47 (85.5%)	35 (71.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	5.82 (3.98, NE)	
Log-Rank Test p-value (unstratified)	0.0367		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.405 (0.169, 0.971)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	8 (23.5%)	7 (20.6%)	
Number (%) of Participants Censored	26 (76.5%)	27 (79.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.85, NE)	6.47 (6.47, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.9305		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.049 (0.380, 2.896)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	25 (28.4%)	22 (25.6%)	
Number (%) of Participants Censored	63 (71.6%)	64 (74.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.44 (5.59, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.5772		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.178 (0.662, 2.096)		
Geographic region			
US/Canada/Western Europe	56	52	0.9575
Number (%) of Participants with Events (Deterioration)	18 (32.1%)	15 (28.8%)	
Number (%) of Participants Censored	38 (67.9%)	37 (71.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.05 (4.96, NE)	6.41 (3.48, NE)	
Log-Rank Test p-value (unstratified)	0.5893		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.827 (0.415, 1.646)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	23 (19.0%)	28 (23.9%)	
Number (%) of Participants Censored	98 (81.0%)	89 (76.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.4343		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.802 (0.461, 1.394)		

	SG (N=177)	TPC (N=169)	Interaction
Age group			
< 65	133	131	0.3155
Number (%) of Participants with Events (Deterioration)	32 (24.1%)	33 (25.2%)	
Number (%) of Participants Censored	101 (75.9%)	98 (74.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.44, NE)	NE (5.82, NE)	
Log-Rank Test p-value (unstratified)	0.3150		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.779 (0.478, 1.268)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	9 (20.5%)	10 (26.3%)	
Number (%) of Participants Censored	35 (79.5%)	28 (73.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.55, NE)	NE (4.44, NE)	
Log-Rank Test p-value (unstratified)	0.5010		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.353 (0.549, 3.336)		
Race			
White	115	104	0.9676
Number (%) of Participants with Events (Deterioration)	30 (26.1%)	29 (27.9%)	
Number (%) of Participants Censored	85 (73.9%)	75 (72.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.88, NE)	NE (5.32, NE)	
Log-Rank Test p-value (unstratified)	0.3834		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.798 (0.478, 1.330)		
Asian	38	38	

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	7 (18.4%)	9 (23.7%)	
Number (%) of Participants Censored	31 (81.6%)	29 (76.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.7886		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.868 (0.323, 2.334)		
Other	19	24	
Number (%) of Participants with Events (Deterioration)	2 (10.5%)	4 (16.7%)	
Number (%) of Participants Censored	17 (89.5%)	20 (83.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.9186		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.913 (0.159, 5.229)		
Baseline ECOG status			
0	116	106	0.6065
Number (%) of Participants with Events (Deterioration)	30 (25.9%)	29 (27.4%)	
Number (%) of Participants Censored	86 (74.1%)	77 (72.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.44, NE)	NE (6.41, NE)	
Log-Rank Test p-value (unstratified)	0.7863		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.929 (0.557, 1.550)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	11 (18.0%)	14 (22.2%)	
Number (%) of Participants Censored	50 (82.0%)	49 (77.8%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.88, NE)	NE (4.70, NE)	
Log-Rank Test p-value (unstratified)	0.4620		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.743 (0.336, 1.644)		
Physician's choice of chemotherapy			
Taxane	52	45	0.5736
Number (%) of Participants with Events (Deterioration)	15 (28.8%)	13 (28.9%)	
Number (%) of Participants Censored	37 (71.2%)	32 (71.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	6.44 (5.03, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.3478		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.694 (0.324, 1.486)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	26 (20.8%)	30 (24.2%)	
Number (%) of Participants Censored	99 (79.2%)	94 (75.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.41, NE)	
Log-Rank Test p-value (unstratified)	0.6906		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.898 (0.529, 1.523)		
History of liver metastasis			
Yes	47	39	0.8894
Number (%) of Participants with Events (Deterioration)	9 (19.1%)	5 (12.8%)	
Number (%) of Participants Censored	38 (80.9%)	34 (87.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

		SG (N=177)	TPC (N=169)	Interaction
	Median	NE (6.44, NE)	NE (3.75, NE)	
	Log-Rank Test p-value (unstratified)	0.9750		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.017 (0.339, 3.054)		
No		130	130	
	Number (%) of Participants with Events (Deterioration)	32 (24.6%)	38 (29.2%)	
	Number (%) of Participants Censored	98 (75.4%)	92 (70.8%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	NE (6.05, NE)	NE (6.34, NE)	
	Log-Rank Test p-value (unstratified)	0.5672		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.871 (0.544, 1.396)		
History of brain metastasis				
Yes		8	9	0.1058
	Number (%) of Participants with Events (Deterioration)	0	2 (22.2%)	
	Number (%) of Participants Censored	8 (100.0%)	7 (77.8%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	NE (NE, NE)	NE (3.35, NE)	
	Log-Rank Test p-value (unstratified)	0.2000		
	Hazard Ratio of SG vs TPC (95% CI) from Cox Model	-		
No		169	160	
	Number (%) of Participants with Events (Deterioration)	41 (24.3%)	41 (25.6%)	
	Number (%) of Participants Censored	128 (75.7%)	119 (74.4%)	
	Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
	Median	NE (6.44, NE)	NE (6.41, NE)	
	Log-Rank Test p-value (unstratified)	0.6553		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.906 (0.587, 1.398)		
PD-L1 Status			
CPS < 1	67	59	0.8516
Number (%) of Participants with Events (Deterioration)	15 (22.4%)	13 (22.0%)	
Number (%) of Participants Censored	52 (77.6%)	46 (78.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.6619		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.846 (0.402, 1.781)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	26 (23.9%)	30 (27.3%)	
Number (%) of Participants Censored	83 (76.1%)	80 (72.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	6.47 (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.5731		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.860 (0.508, 1.454)		
BRCA 1/2 status			
Wild-Type	66	65	0.2457
Number (%) of Participants with Events (Deterioration)	20 (30.3%)	17 (26.2%)	
Number (%) of Participants Censored	46 (69.7%)	48 (73.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.96, NE)	6.41 (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.6645		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.870 (0.456, 1.662)		

	SG (N=177)	TPC (N=169)	Interaction
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	4 (33.3%)	2 (20.0%)	
Number (%) of Participants Censored	8 (66.7%)	8 (80.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (1.25, NE)	NE (3.45, NE)	
Log-Rank Test p-value (unstratified)	0.3535		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.190 (0.401, 11.965)		
Menopausal status			
Pre-menopausal	37	49	0.0481
Number (%) of Participants with Events (Deterioration)	5 (13.5%)	16 (32.7%)	
Number (%) of Participants Censored	32 (86.5%)	33 (67.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.05, NE)	NE (5.59, NE)	
Log-Rank Test p-value (unstratified)	0.0511		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.380 (0.139, 1.040)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	36 (25.7%)	27 (22.7%)	
Number (%) of Participants Censored	104 (74.3%)	92 (77.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (5.88, NE)	NE (6.34, NE)	
Log-Rank Test p-value (unstratified)	0.7187		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.097 (0.663, 1.815)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.

Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

4.69. Table 1.1.25: Subgroup Analysis of Time to First Deterioration by response threshold in PGIS — mITT — Excluding patients preselected to receive nab-paclitaxel

	SG (N=177)	TPC (N=169)	Interaction
Disease stratification			
De novo	55	49	0.5098
Number (%) of Participants with Events (Deterioration)	4 (7.3%)	2 (4.1%)	
Number (%) of Participants Censored	51 (92.7%)	47 (95.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.82, NE)	
Log-Rank Test p-value (unstratified)	0.7348		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.340 (0.245, 7.321)		
Recurrent disease within 6 to 12 months from completion of treatment in the curative setting	34	34	
Number (%) of Participants with Events (Deterioration)	2 (5.9%)	4 (11.8%)	
Number (%) of Participants Censored	32 (94.1%)	30 (88.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.3477		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.453 (0.083, 2.472)		
Recurrent disease occurring > 12 months from completion of treatment in the curative setting	88	86	
Number (%) of Participants with Events (Deterioration)	11 (12.5%)	9 (10.5%)	
Number (%) of Participants Censored	77 (87.5%)	77 (89.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

	SG (N=177)	TPC (N=169)	Interaction
Median	NE (6.34, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.5253		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.332 (0.549, 3.231)		
Geographic region			
US/Canada/Western Europe	56	52	0.7879
Number (%) of Participants with Events (Deterioration)	4 (7.1%)	3 (5.8%)	
Number (%) of Participants Censored	52 (92.9%)	49 (94.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8606		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.144 (0.254, 5.156)		
Rest of the world	121	117	
Number (%) of Participants with Events (Deterioration)	13 (10.7%)	12 (10.3%)	
Number (%) of Participants Censored	108 (89.3%)	105 (89.7%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8623		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.934 (0.425, 2.053)		
Age group			
< 65	133	131	0.5062
Number (%) of Participants with Events (Deterioration)	13 (9.8%)	11 (8.4%)	
Number (%) of Participants Censored	120 (90.2%)	120 (91.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	

	SG (N=177)	TPC (N=169)	Interaction
Log-Rank Test p-value (unstratified)	0.8587		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.929 (0.416, 2.078)		
>= 65	44	38	
Number (%) of Participants with Events (Deterioration)	4 (9.1%)	4 (10.5%)	
Number (%) of Participants Censored	40 (90.9%)	34 (89.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.01, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.5755		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.483 (0.370, 5.944)		
Race			
White	115	104	0.9293
Number (%) of Participants with Events (Deterioration)	10 (8.7%)	8 (7.7%)	
Number (%) of Participants Censored	105 (91.3%)	96 (92.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.9772		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.987 (0.389, 2.505)		
Asian	38	38	
Number (%) of Participants with Events (Deterioration)	6 (15.8%)	6 (15.8%)	
Number (%) of Participants Censored	32 (84.2%)	32 (84.2%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (5.16, NE)	
Log-Rank Test p-value (unstratified)	0.8469		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.894 (0.287, 2.786)		

	SG (N=177)	TPC (N=169)	Interaction
Other	19	24	
Number (%) of Participants with Events (Deterioration)	1 (5.3%)	1 (4.2%)	
Number (%) of Participants Censored	18 (94.7%)	23 (95.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (3.78, NE)	6.67 (6.60, NE)	
Log-Rank Test p-value (unstratified)	0.2207		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Baseline ECOG status			
0	116	106	0.9237
Number (%) of Participants with Events (Deterioration)	11 (9.5%)	9 (8.5%)	
Number (%) of Participants Censored	105 (90.5%)	97 (91.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.9145		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.049 (0.435, 2.534)		
1	61	63	
Number (%) of Participants with Events (Deterioration)	6 (9.8%)	6 (9.5%)	
Number (%) of Participants Censored	55 (90.2%)	57 (90.5%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8520		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.900 (0.290, 2.794)		
Physician's choice of chemotherapy			
Taxane	52	45	0.7172

	SG (N=177)	TPC (N=169)	Interaction
Number (%) of Participants with Events (Deterioration)	6 (11.5%)	3 (6.7%)	
Number (%) of Participants Censored	46 (88.5%)	42 (93.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6331		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.400 (0.349, 5.612)		
Gemcitabine/Carboplatin	125	124	
Number (%) of Participants with Events (Deterioration)	11 (8.8%)	12 (9.7%)	
Number (%) of Participants Censored	114 (91.2%)	112 (90.3%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.8832		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.941 (0.412, 2.148)		
History of liver metastasis			
Yes	47	39	0.9200
Number (%) of Participants with Events (Deterioration)	4 (8.5%)	2 (5.1%)	
Number (%) of Participants Censored	43 (91.5%)	37 (94.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (3.71, NE)	
Log-Rank Test p-value (unstratified)	0.9367		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.071 (0.196, 5.851)		
No	130	130	
Number (%) of Participants with Events (Deterioration)	13 (10.0%)	13 (10.0%)	
Number (%) of Participants Censored	117 (90.0%)	117 (90.0%)	

	SG (N=177)	TPC (N=169)	Interaction
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.9383		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.970 (0.449, 2.096)		
History of brain metastasis			
Yes	8	9	0.2023
Number (%) of Participants with Events (Deterioration)	1 (12.5%)	0	
Number (%) of Participants Censored	7 (87.5%)	9 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	5.49 (5.36, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.2207		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
No	169	160	
Number (%) of Participants with Events (Deterioration)	16 (9.5%)	15 (9.4%)	
Number (%) of Participants Censored	153 (90.5%)	145 (90.6%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.8565		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.938 (0.463, 1.899)		
PD-L1 Status			
CPS < 1	67	59	0.1057
Number (%) of Participants with Events (Deterioration)	9 (13.4%)	3 (5.1%)	
Number (%) of Participants Censored	58 (86.6%)	56 (94.9%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			

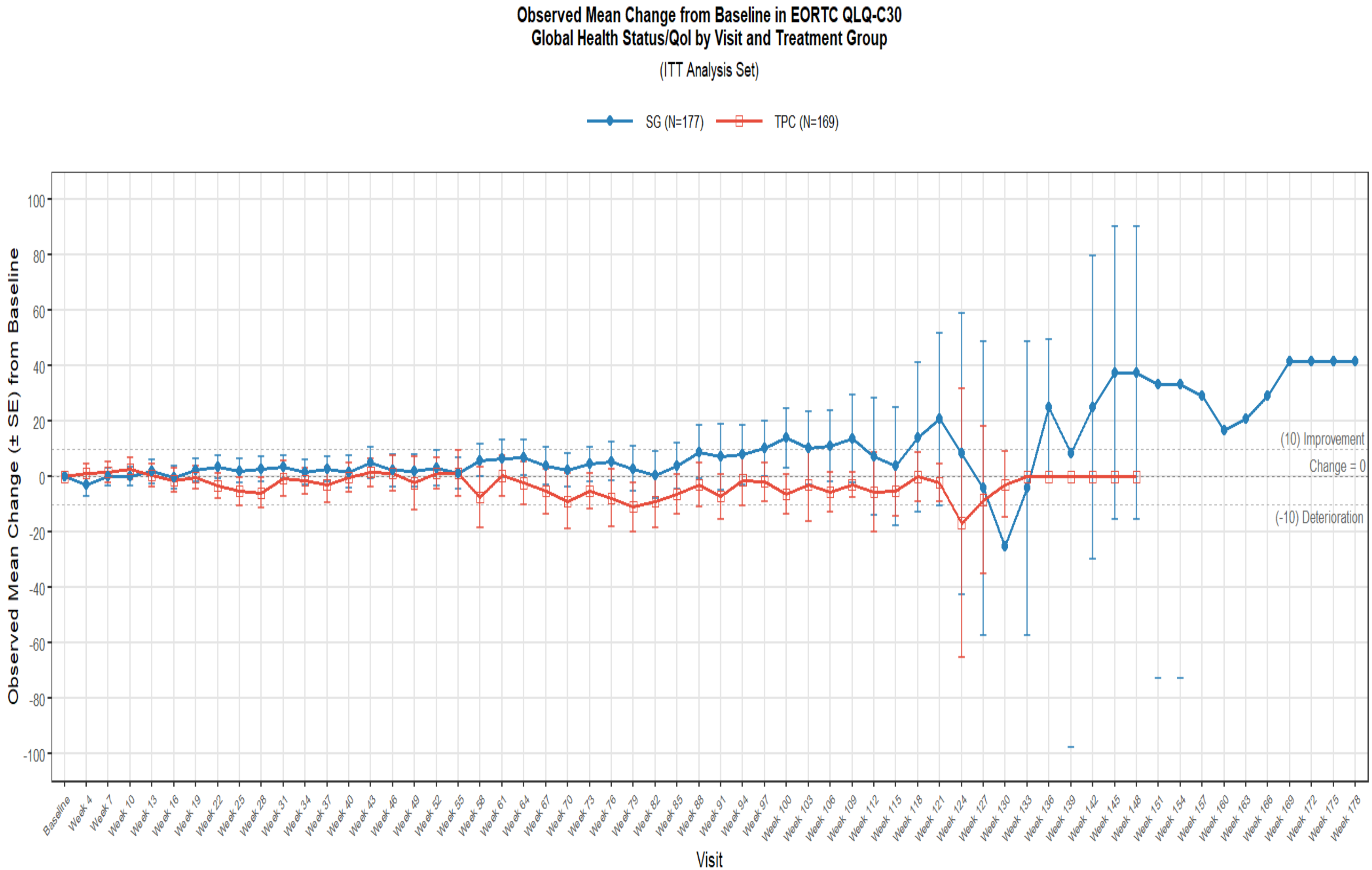
	SG (N=177)	TPC (N=169)	Interaction
Median	NE (6.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.2480		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	2.132 (0.573, 7.936)		
CPS ≥ 1	109	110	
Number (%) of Participants with Events (Deterioration)	8 (7.3%)	12 (10.9%)	
Number (%) of Participants Censored	101 (92.7%)	98 (89.1%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.60, NE)	
Log-Rank Test p-value (unstratified)	0.3408		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.651 (0.266, 1.593)		
BRCA 1/2 status			
Wild-Type	66	65	0.2511
Number (%) of Participants with Events (Deterioration)	10 (15.2%)	6 (9.2%)	
Number (%) of Participants Censored	56 (84.8%)	59 (90.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (6.34, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6471		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.267 (0.460, 3.488)		
Mutant	12	10	
Number (%) of Participants with Events (Deterioration)	1 (8.3%)	0	
Number (%) of Participants Censored	11 (91.7%)	10 (100.0%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (4.50, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.3173		

	SG (N=177)	TPC (N=169)	Interaction
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	NC		
Menopausal status			
Pre-menopausal	37	49	0.4814
Number (%) of Participants with Events (Deterioration)	3 (8.1%)	6 (12.2%)	
Number (%) of Participants Censored	34 (91.9%)	43 (87.8%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (NE, NE)	
Log-Rank Test p-value (unstratified)	0.6423		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	0.721 (0.180, 2.889)		
Post-menopausal	140	119	
Number (%) of Participants with Events (Deterioration)	14 (10.0%)	9 (7.6%)	
Number (%) of Participants Censored	126 (90.0%)	110 (92.4%)	
Kaplan-Meier Estimate of TTFD (Months) (95% CI)			
Median	NE (NE, NE)	NE (6.64, NE)	
Log-Rank Test p-value (unstratified)	0.6329		
Hazard Ratio of SG vs TPC (95% CI) from Cox Model	1.231 (0.526, 2.882)		

SG = sacituzumab govitecan; TPC = treatment of physician's choice; NC = Not Calculable; NEst = Not Estimable; NR = Not Reached.
Denominator of percentages is the number of participants in each treatment group of each subgroup.
Hazard ratio and 95% CIs were calculated by unstratified Cox proportional hazards model without any adjustment. Efron method was used to handle ties.
The two-sided p-value is from Unstratified log-rank test.
Median time to event (95% CI) was estimated from the Kaplan-Meier product-limit method.
Only subgroups where all categories contain ≥ 10 patients (both arms combined) are presented.
Disease stratification and geographic region are collected from IWRS (Interactive Web Response System).
Race subgroup Other - includes American Indian or Alaska Native, Black, Native Hawaiian or Pacific Islander and Other collected in clinical database.
Interaction p-value from a Cox model with treatment, subgroup factor, and treatment×subgroup interaction term; computed via likelihood ratio test (full vs. main-effects model). Displayed once per subgroup variable at first category level.
Data Cut Date: 22 APR 2026.

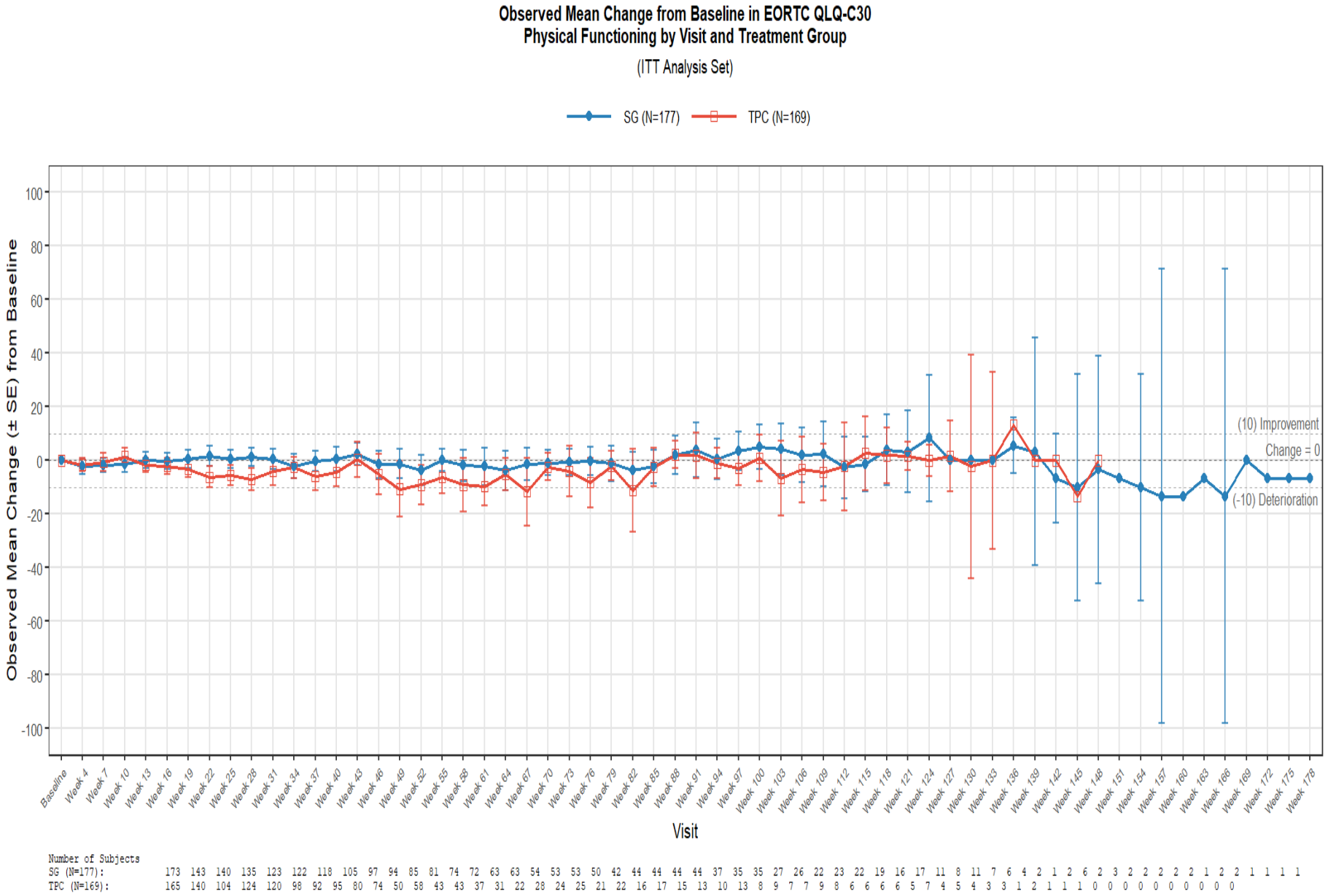
5. KM FIGURES — PRO

5.1. Figure 1.1.1: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 GLOBAL HEALTH STATUS QOL — mITT — Excluding patients preselected to receive nab-paclitaxel

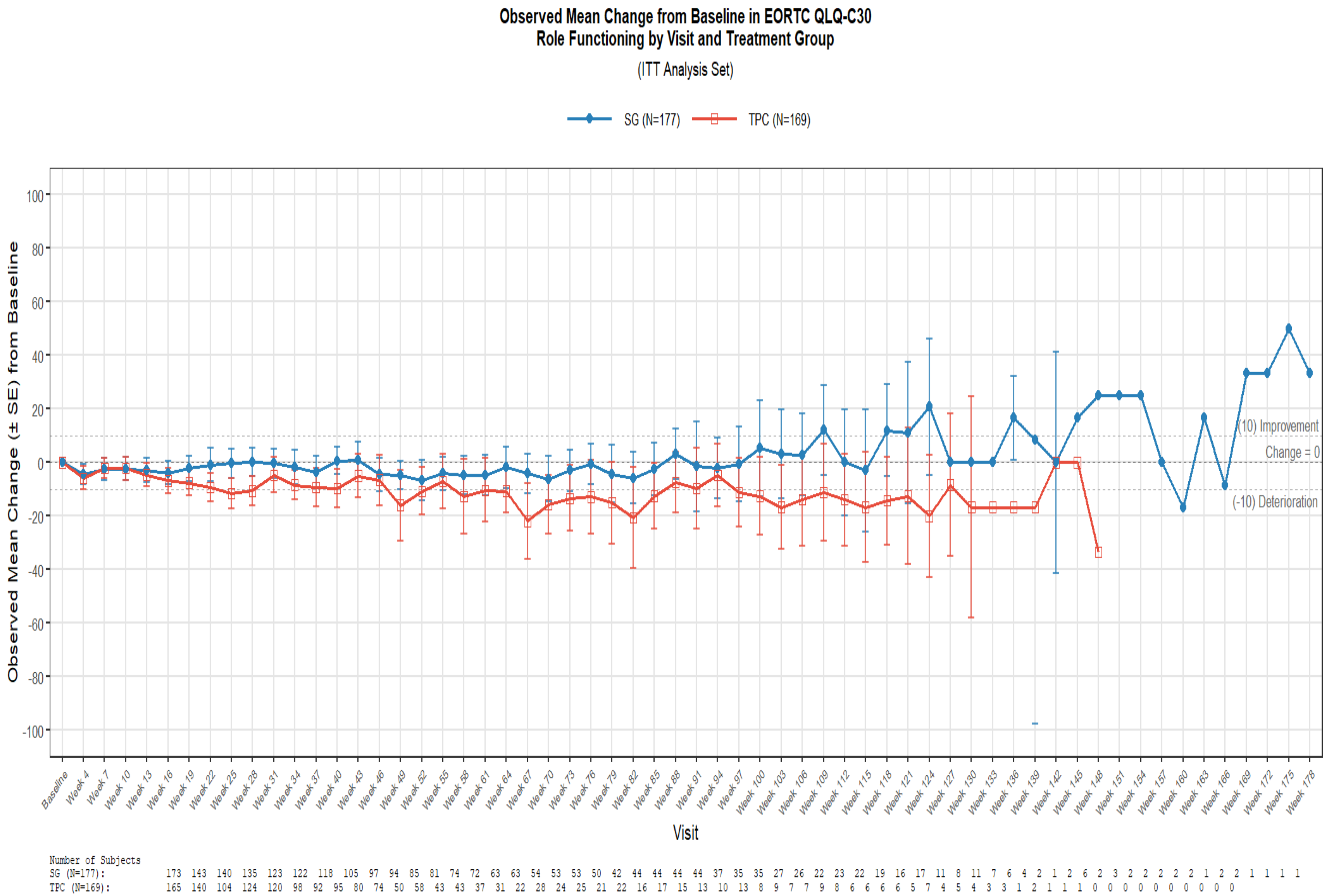


Number of Subjects
SG (N=177): 173 143 140 135 123 122 118 105 97 94 85 81 74 72 63 63 54 53 53 50 42 44 44 44 44 37 35 35 27 26 22 23 22 19 16 17 11 8 11 7 6 4 2 1 2 6 2 3 2 2 2 2 2 1 2 2 1 1 1 1
TPC (N=169): 165 140 104 124 120 98 92 95 80 74 50 58 43 43 37 31 22 28 24 25 21 22 16 17 15 13 10 13 8 9 7 7 9 8 6 6 6 6 5 7 4 5 4 3 3 1 2 1 1 1 0 0 0 0 0 0 0 0 0 0

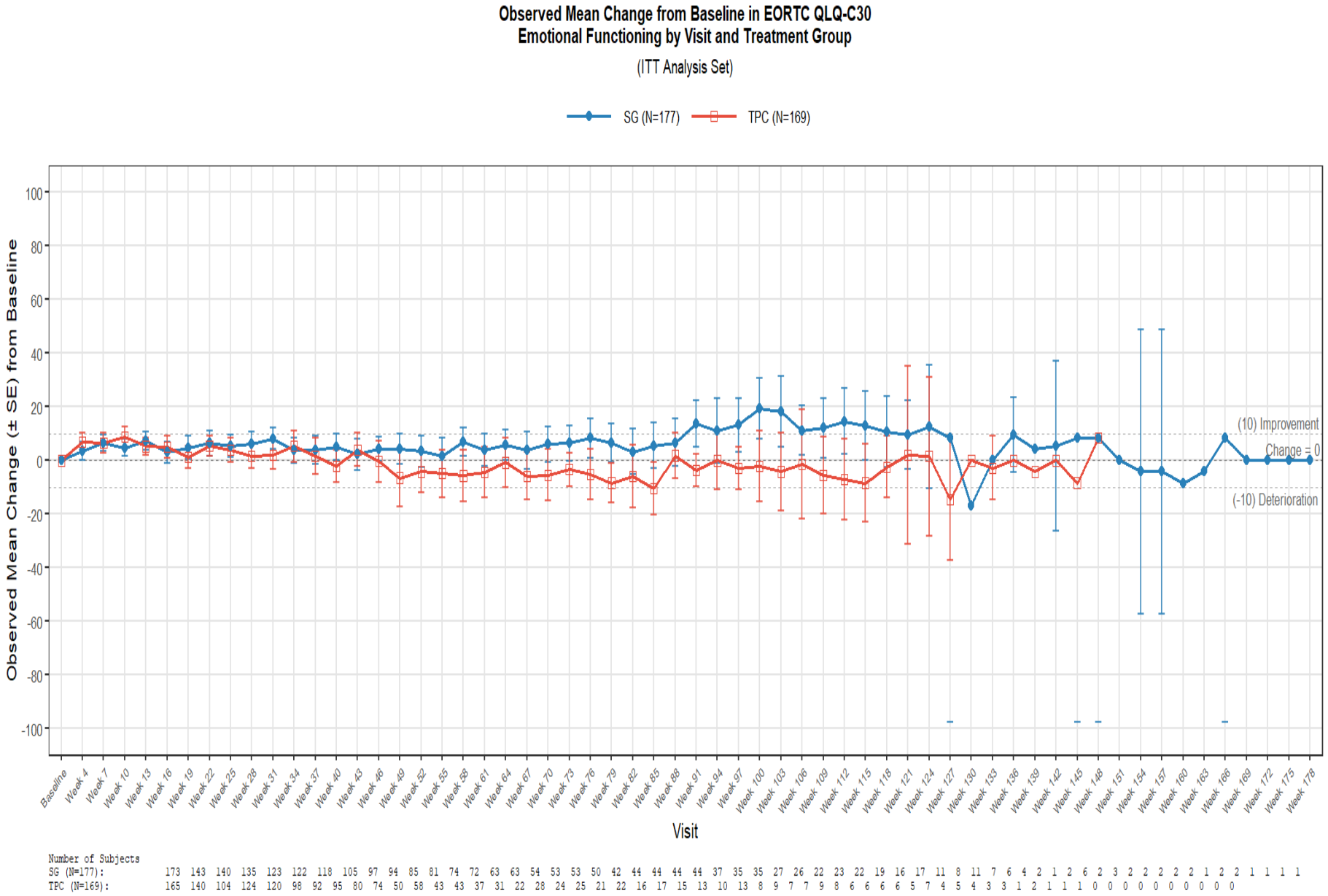
5.2. Figure 1.1.2: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 PHYSICAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel



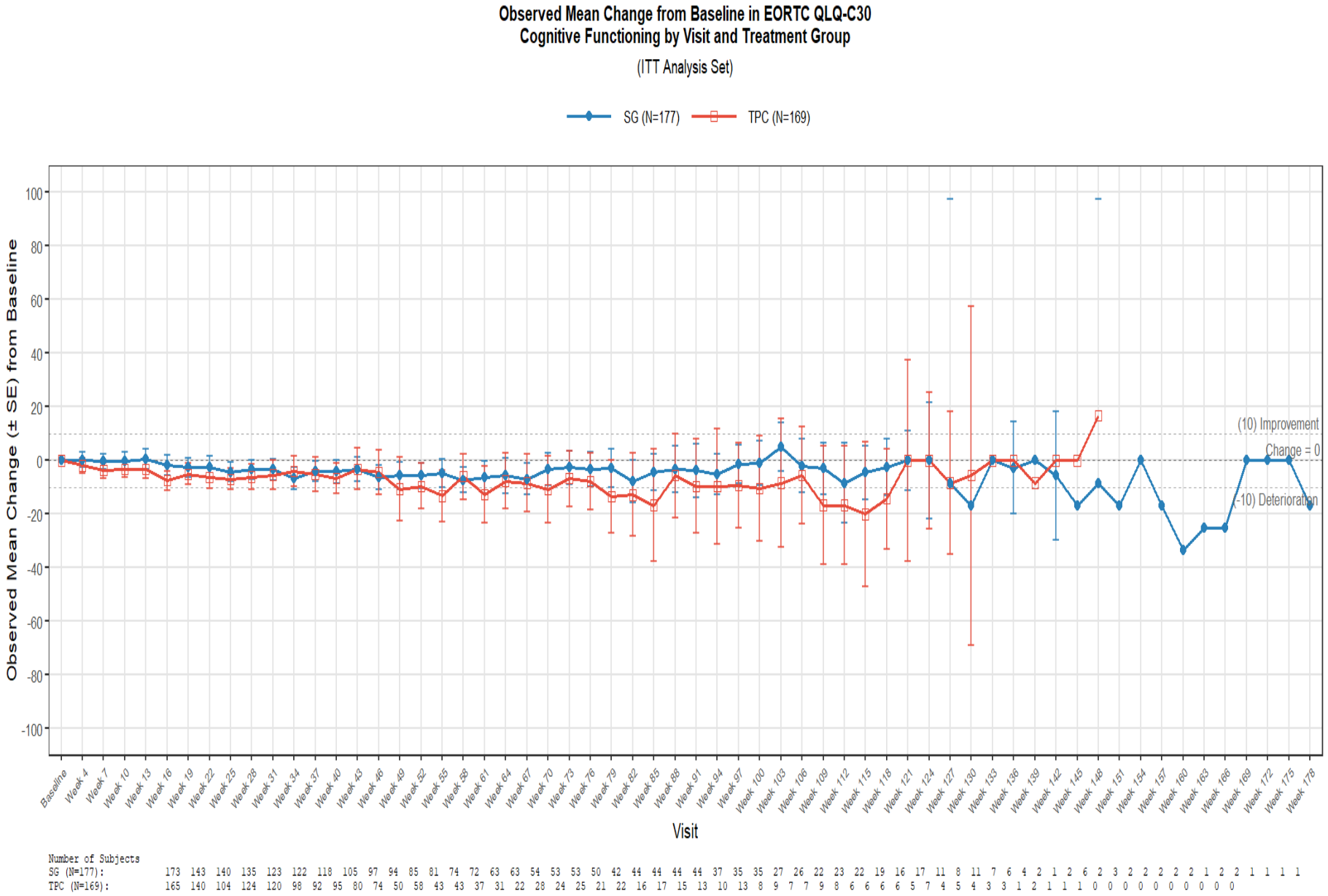
5.3. Figure 1.1.3: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 ROLE FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel



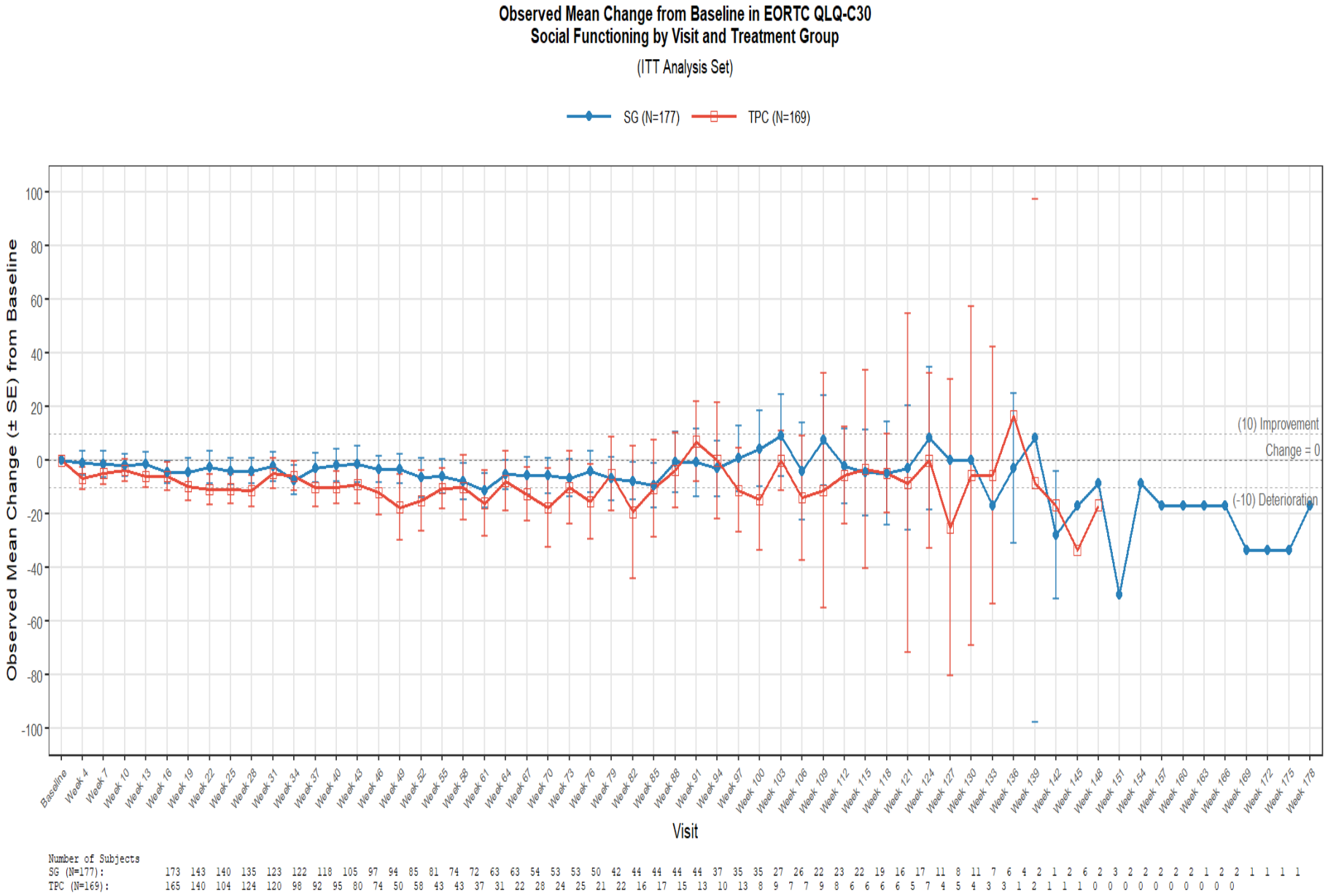
5.4. Figure 1.1.4: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 EMOTIONAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel



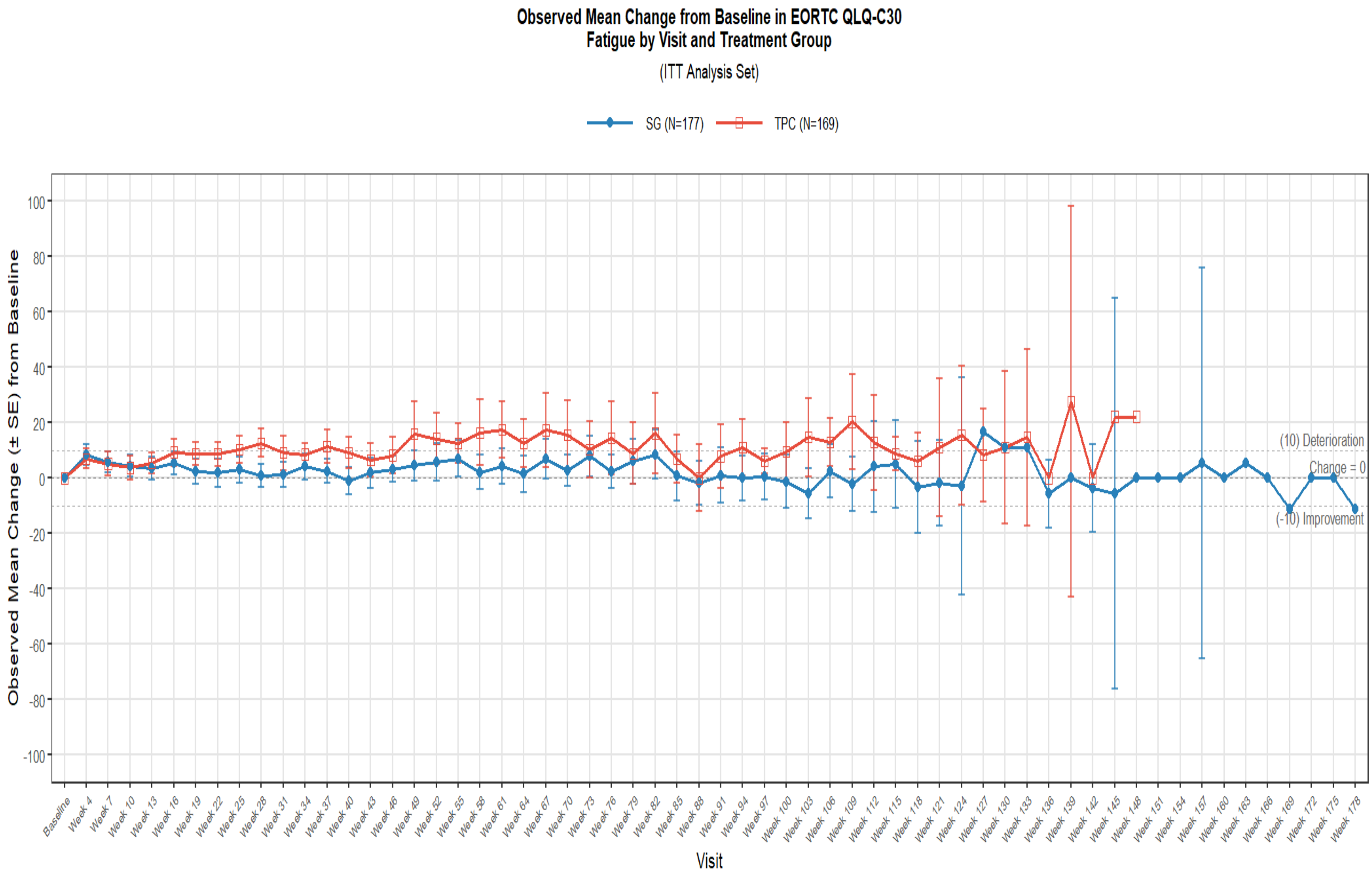
5.5. Figure 1.1.5: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 COGNITIVE FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel



5.6. Figure 1.1.6: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 SOCIAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel

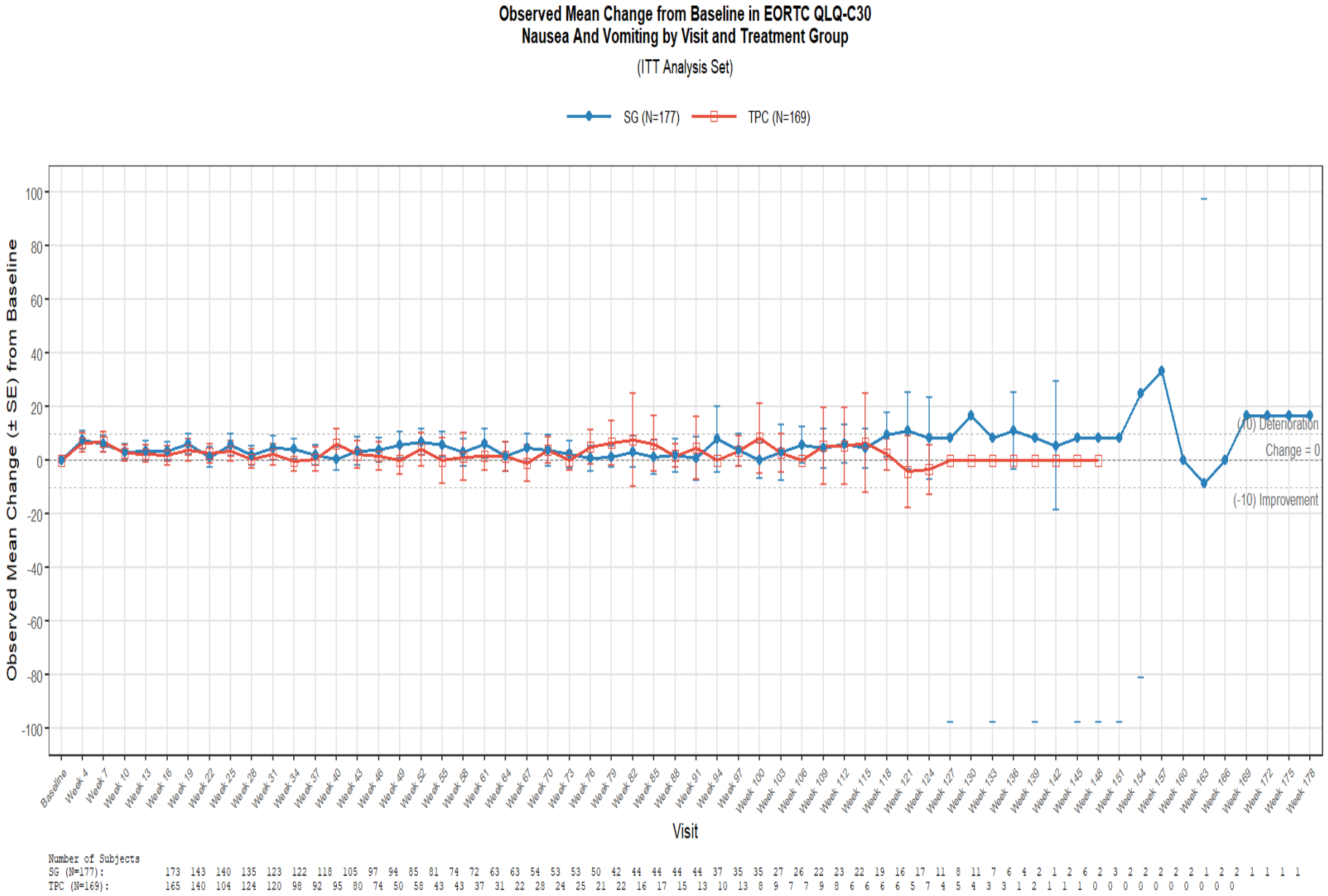


5.7. Figure 1.1.7: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 FATIGUE — mITT — Excluding patients preselected to receive nab-paclitaxel

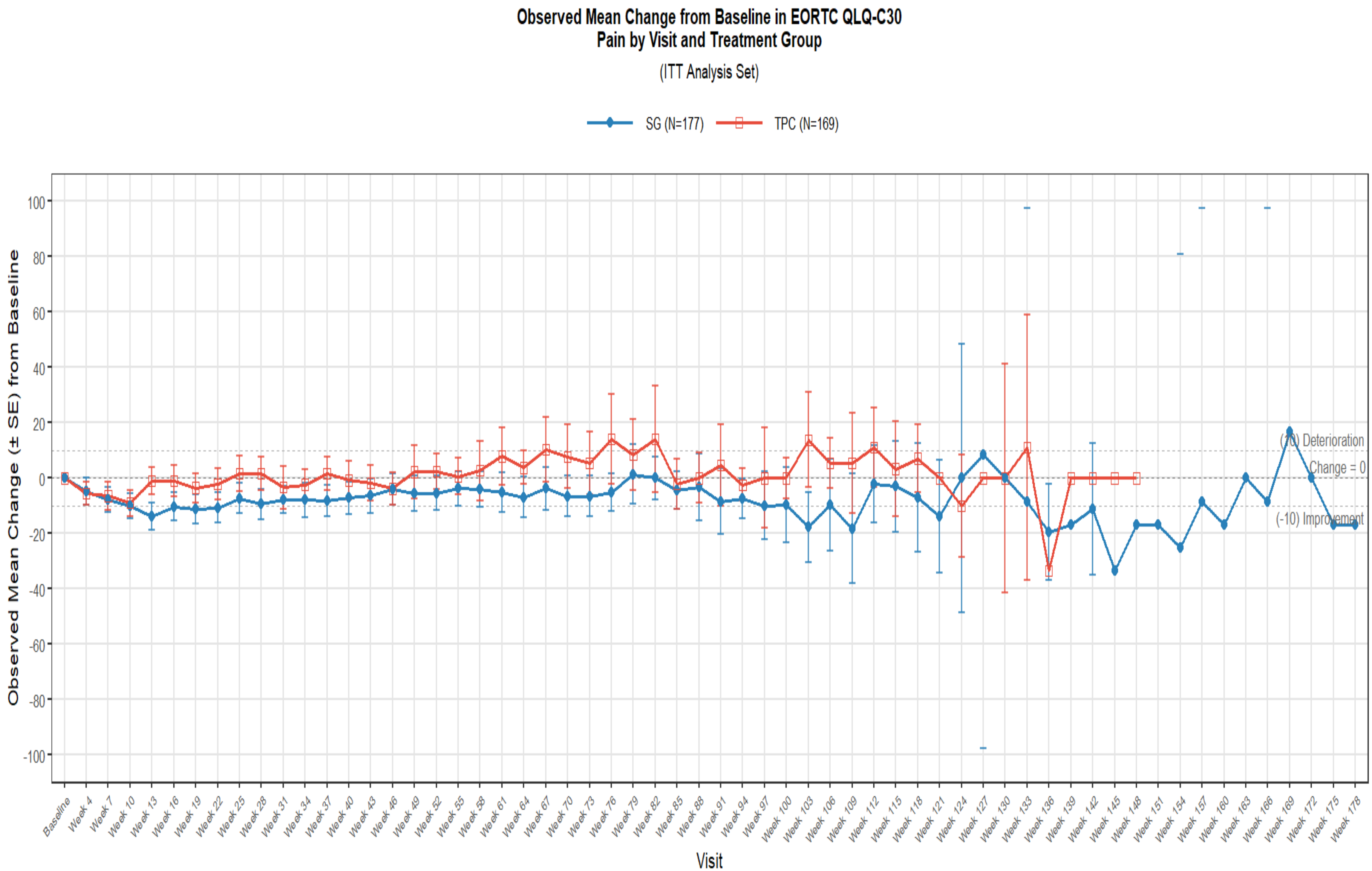


Number of Subjects
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TPC (N=169): 165 140 104 124 120 98 92 95 80 74 50 58 43 43 37 31 22 28 24 25 21 22 16 17 15 13 10 13 8 9 7 7 9 8 6 6 6 6 5 7 4 5 4 3 3 1 2 1 1 1 0 0 0 0 0 0 0 0 0 0

5.8. Figure 1.1.8: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 NAUSEA AND VOMITING — mITT — Excluding patients preselected to receive nab-paclitaxel

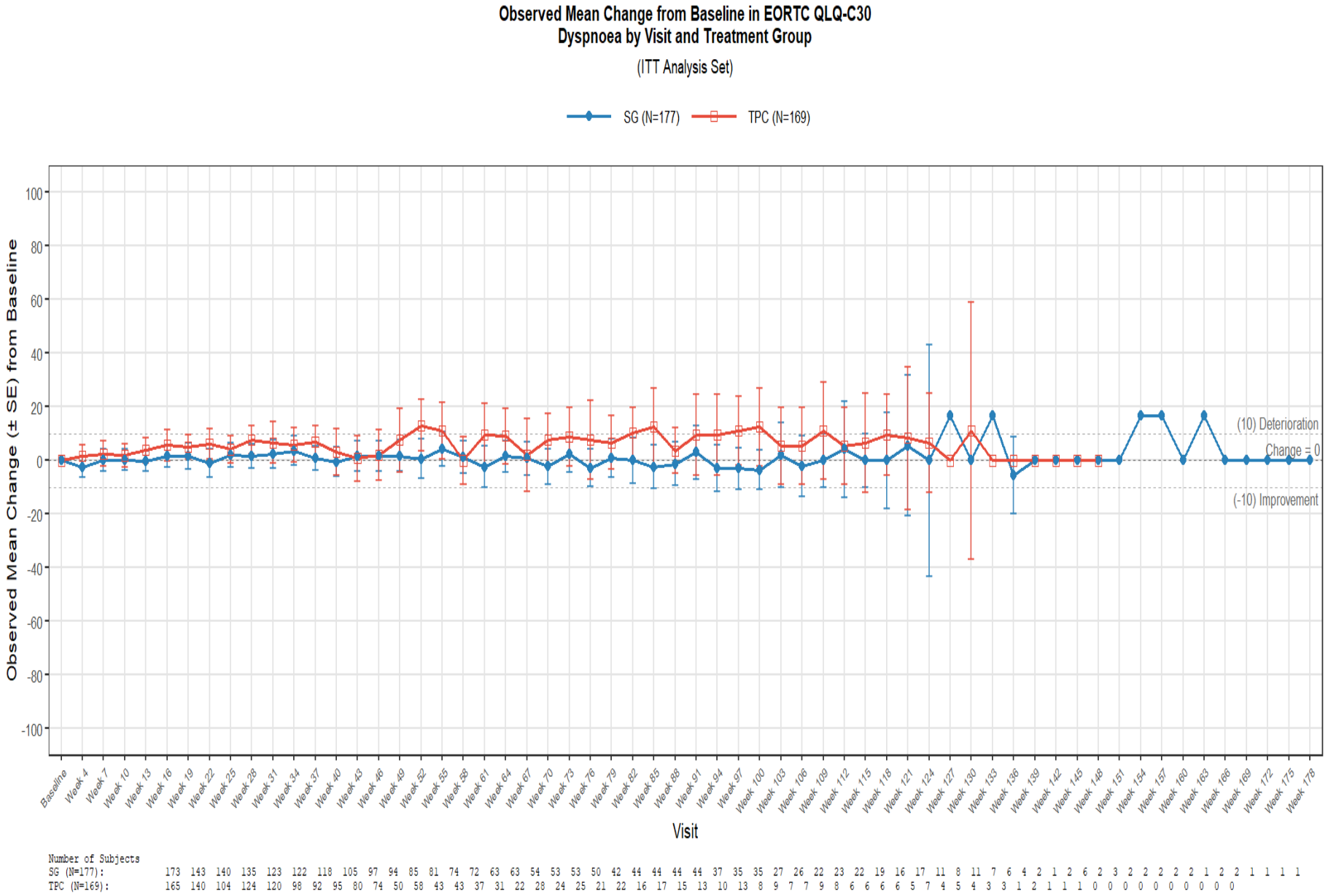


5.9. Figure 1.1.9: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 PAIN — mITT — Excluding patients preselected to receive nab-paclitaxel

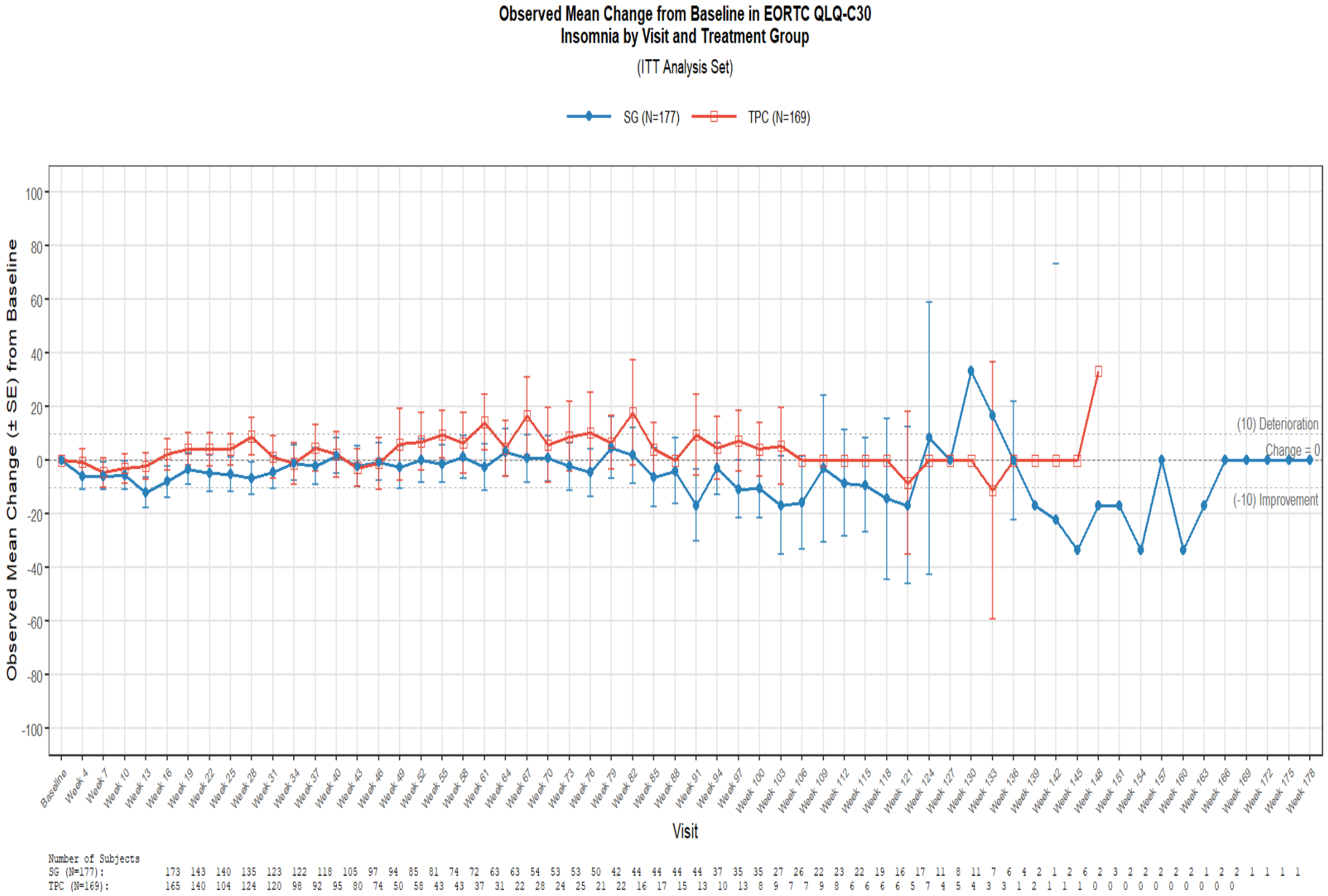


Number of Subjects
SG (N=177): 173 143 140 135 123 122 118 105 97 94 85 81 74 72 63 63 54 53 53 50 42 44 44 44 44 37 35 35 27 26 22 23 22 19 16 17 11 8 11 7 6 4 2 1 2 6 2 3 2 2 2 2 2 1 2 2 1 1 1 1
TPC (N=169): 165 140 104 124 120 98 92 95 80 74 50 58 43 43 37 31 22 28 24 25 21 22 16 17 15 13 10 13 8 9 7 7 9 8 6 6 6 6 5 7 4 5 4 3 3 1 2 1 1 1 0 0 0 0 0 0 0 0 0 0

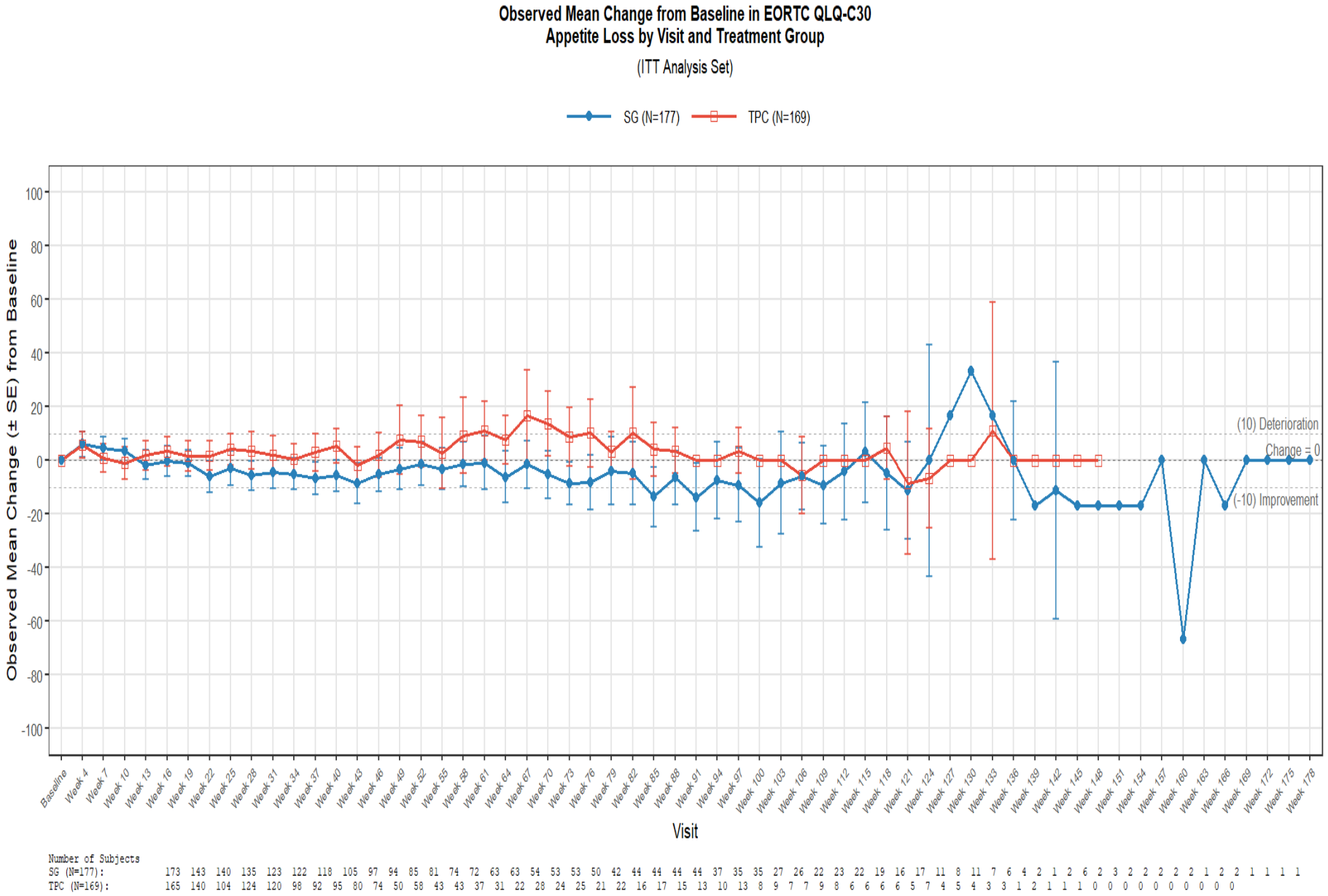
5.10. Figure 1.1.10: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 DYSPNOEA — mITT — Excluding patients preselected to receive nab-paclitaxel



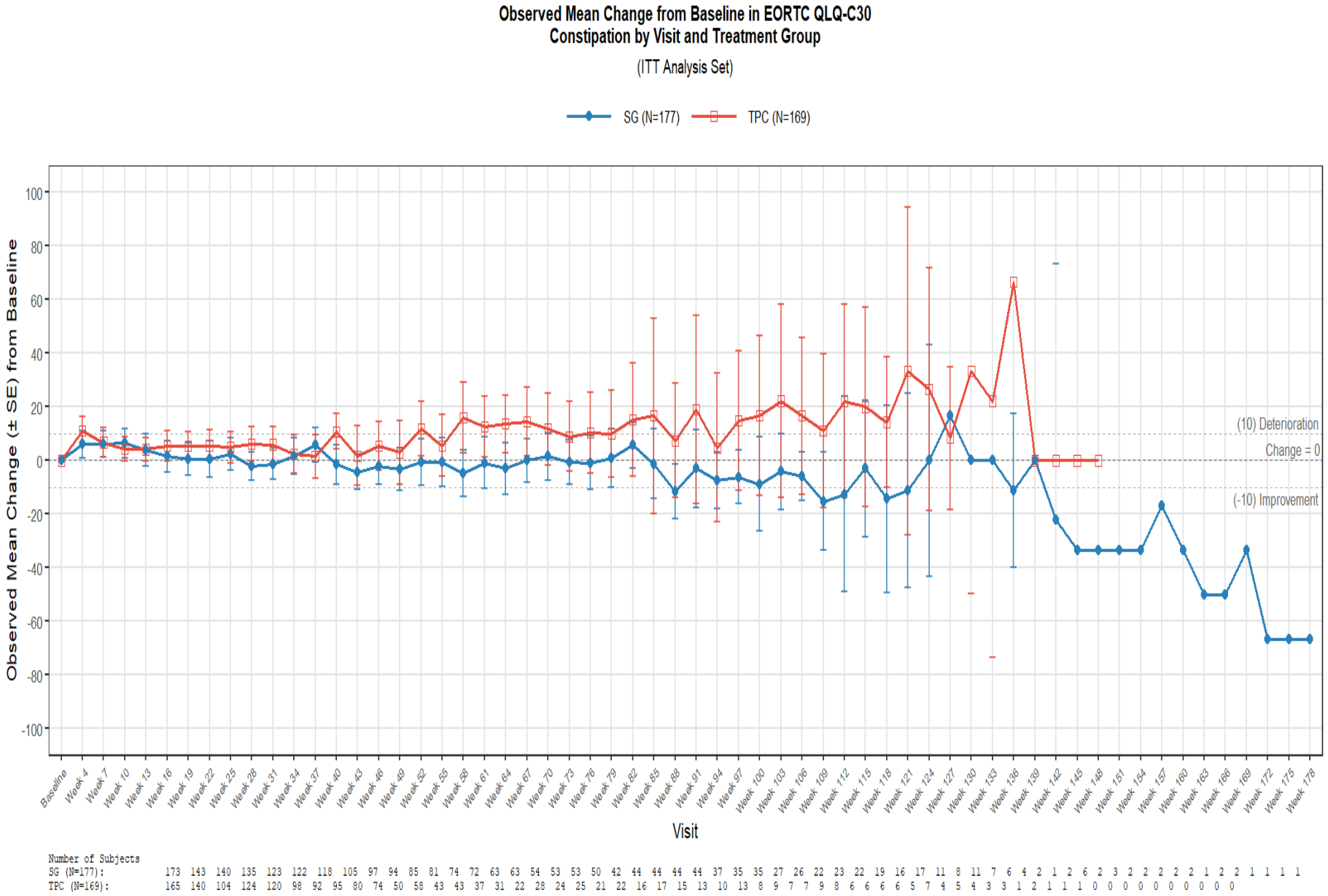
5.11. Figure 1.1.11: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 INSOMNIA — mITT — Excluding patients preselected to receive nab-paclitaxel



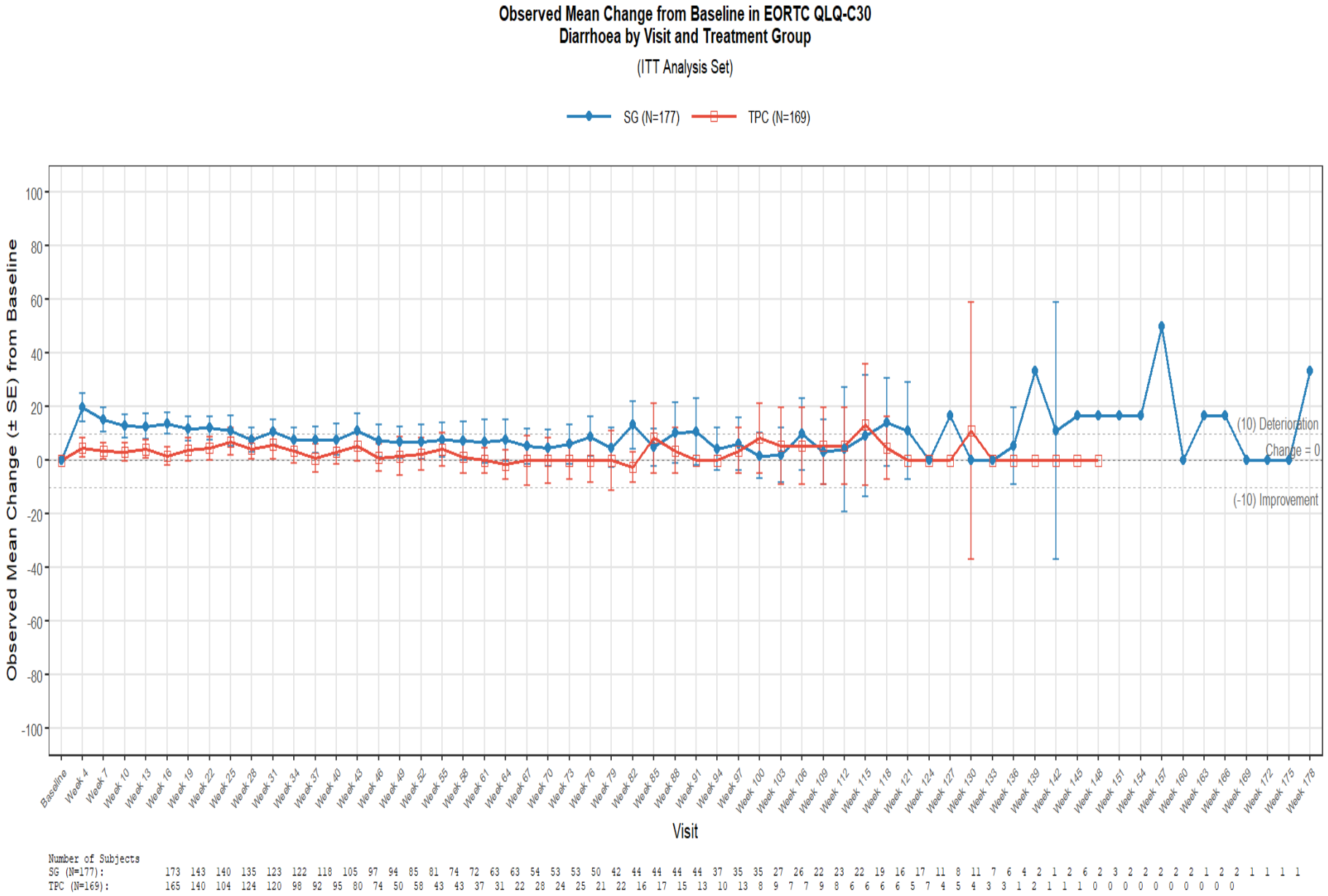
5.12. Figure 1.1.12: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 APPETITE LOSS — mITT — Excluding patients preselected to receive nab-paclitaxel



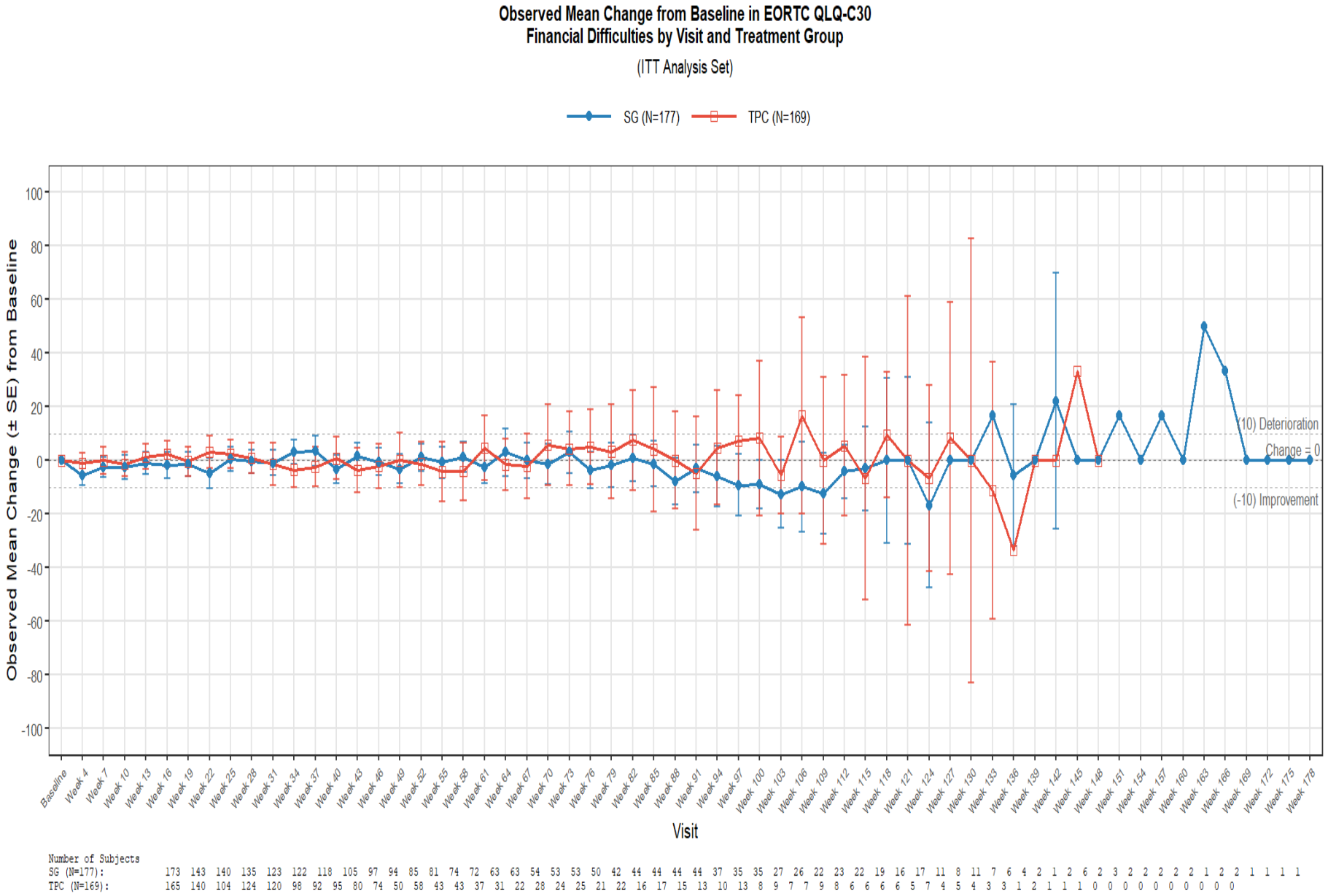
5.13. Figure 1.1.13: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 CONSTIPATION — mITT — Excluding patients preselected to receive nab-paclitaxel



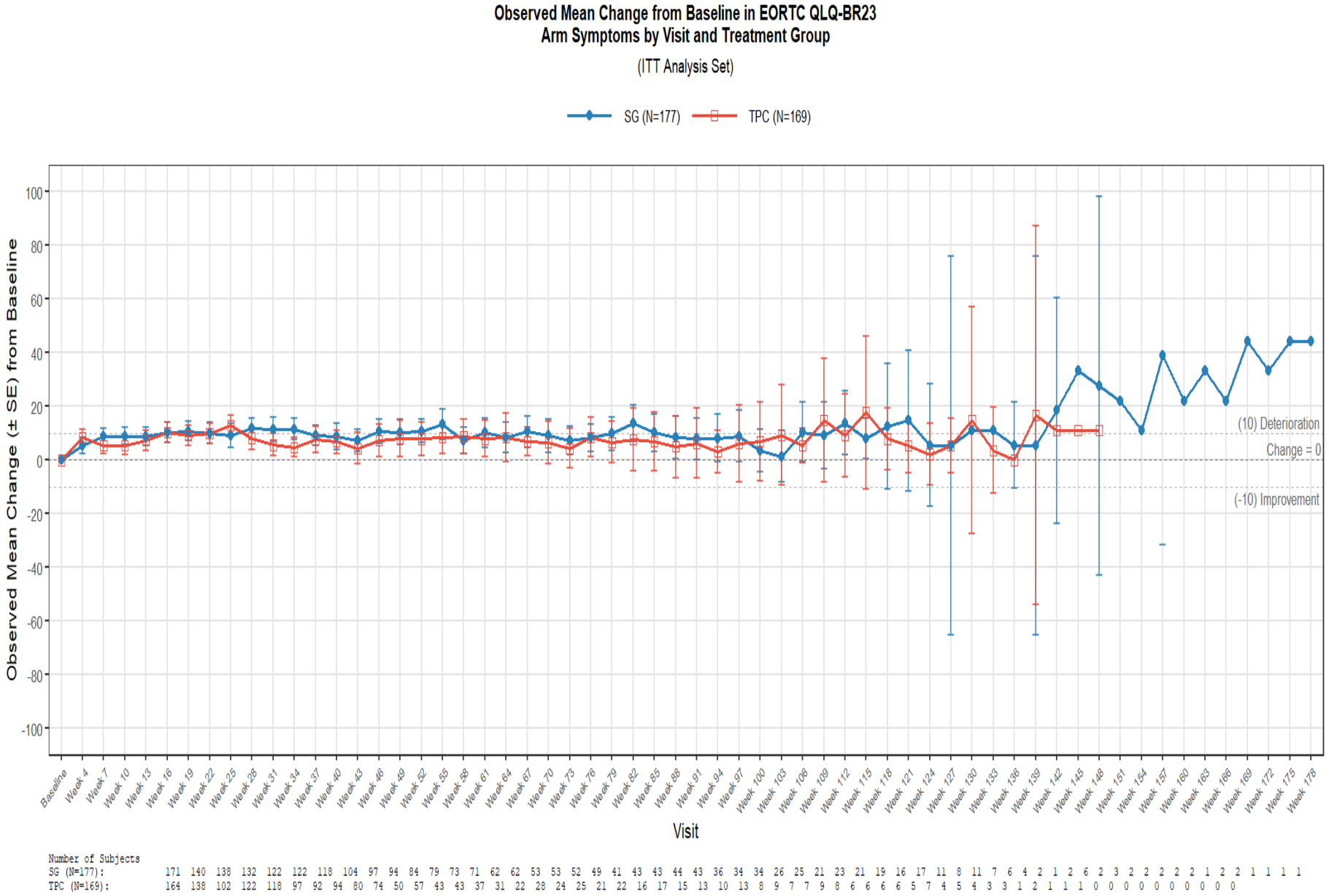
5.14. Figure 1.1.14: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 DIARRHOEA — mITT — Excluding patients preselected to receive nab-paclitaxel



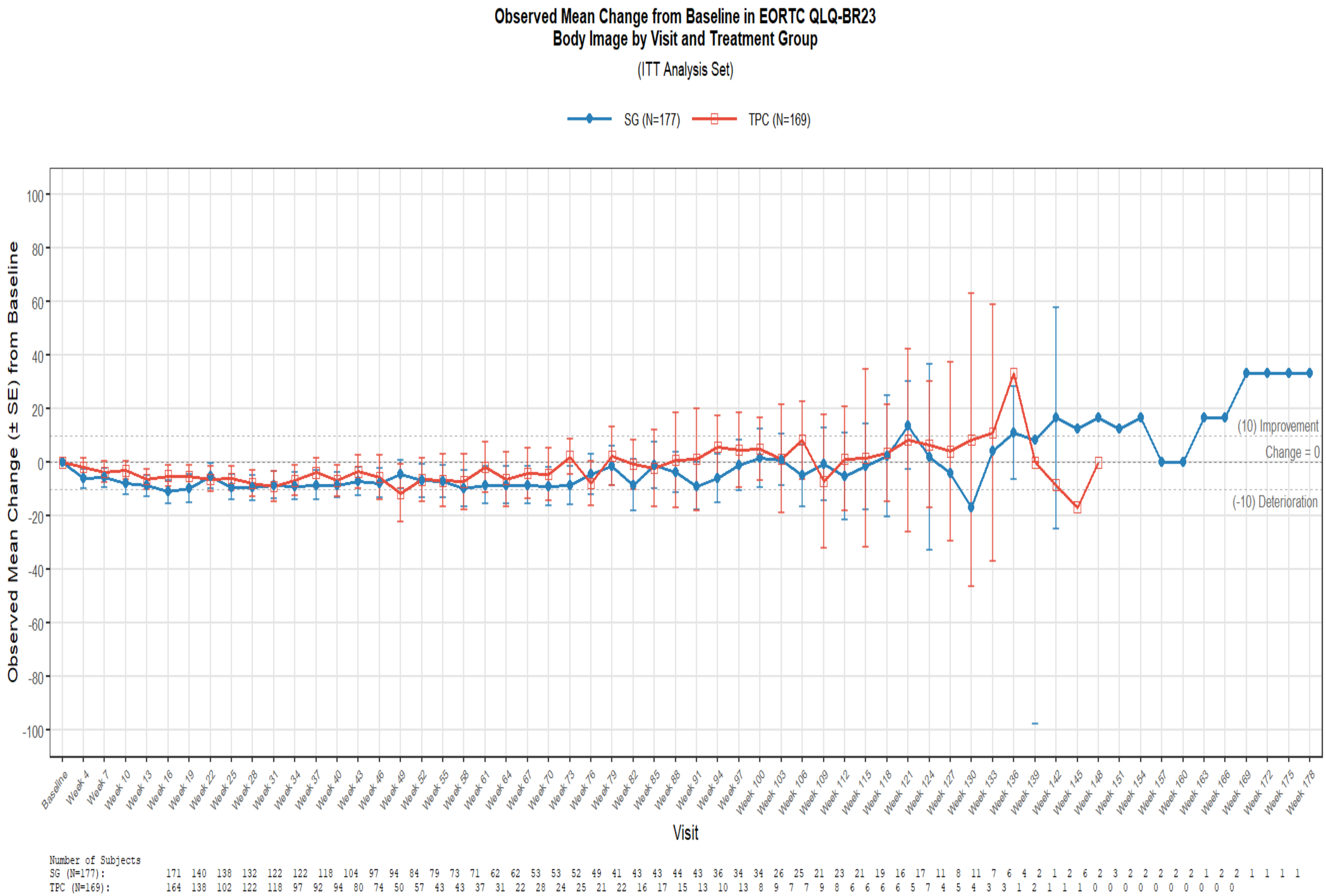
5.15. Figure 1.1.15: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ C30 FINANCIAL DIFFICULTIES — mITT — Excluding patients preselected to receive nab-paclitaxel



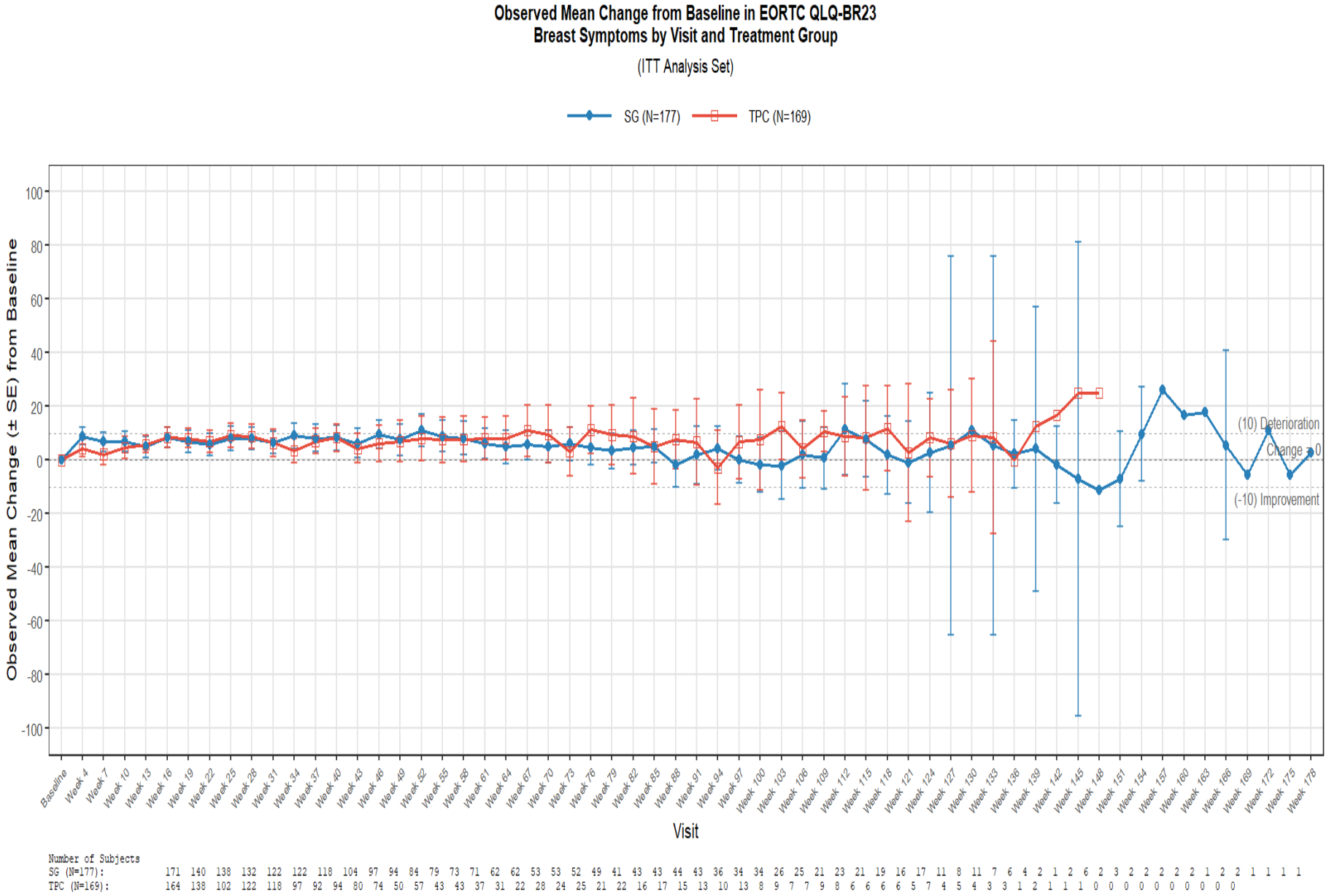
5.16. Figure 1.1.16: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 ARM SYMPTOMS — mITT — Excluding patients preselected to receive nab-paclitaxel



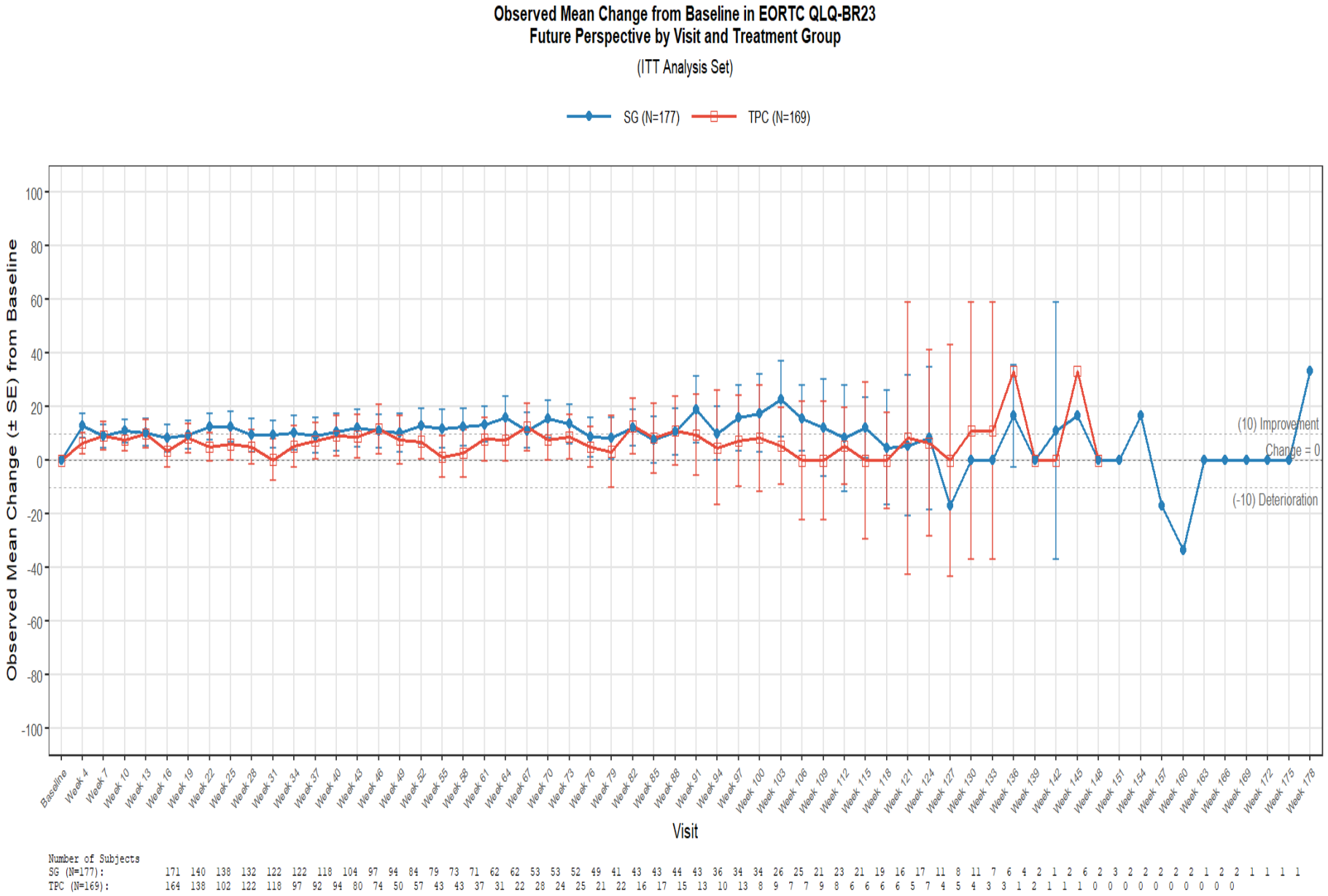
5.17. Figure 1.1.17: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 BODY IMAGE — mITT — Excluding patients preselected to receive nab-paclitaxel



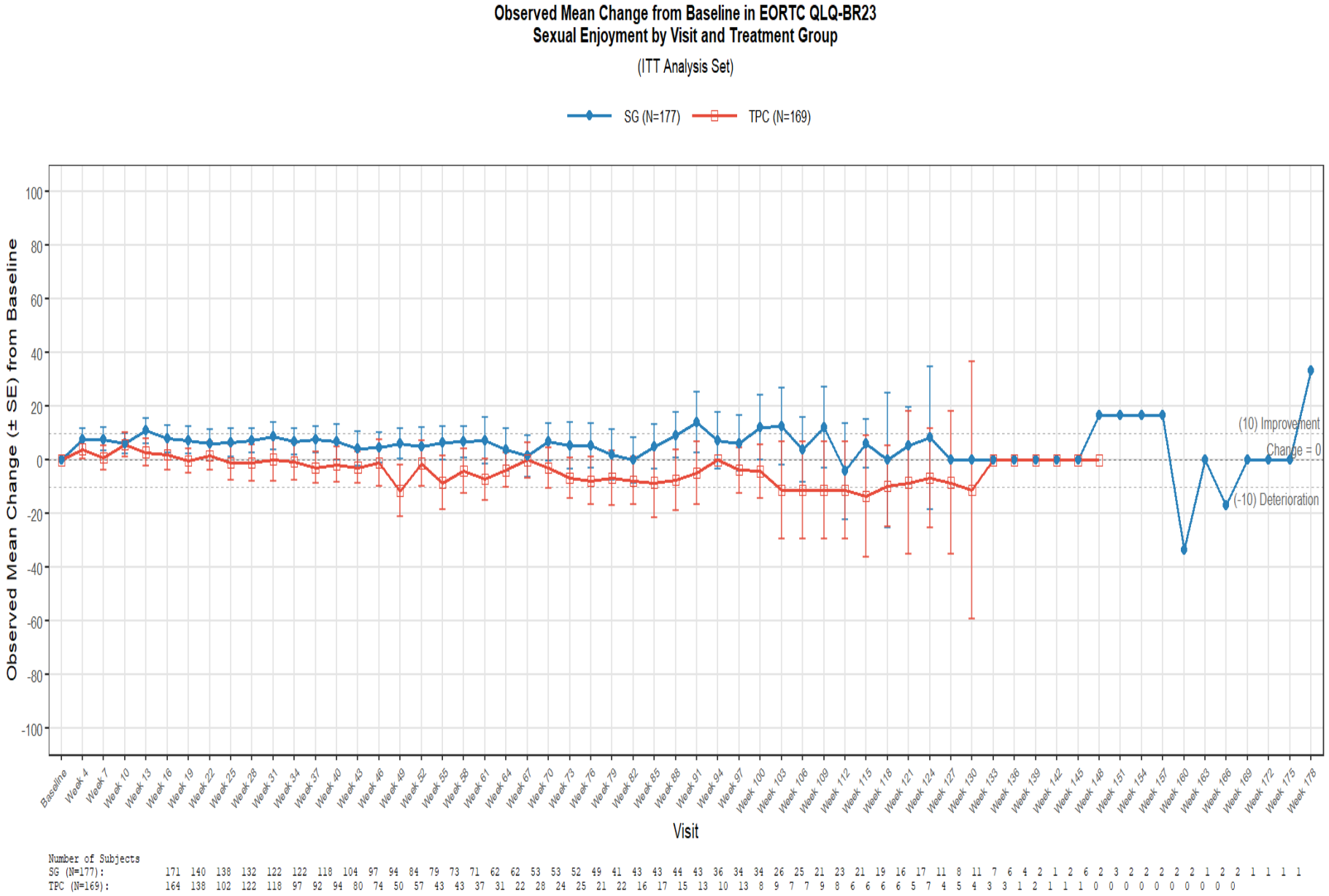
5.18. Figure 1.1.18: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 BREAST SYMPTOMS — mITT — Excluding patients preselected to receive nab-paclitaxel



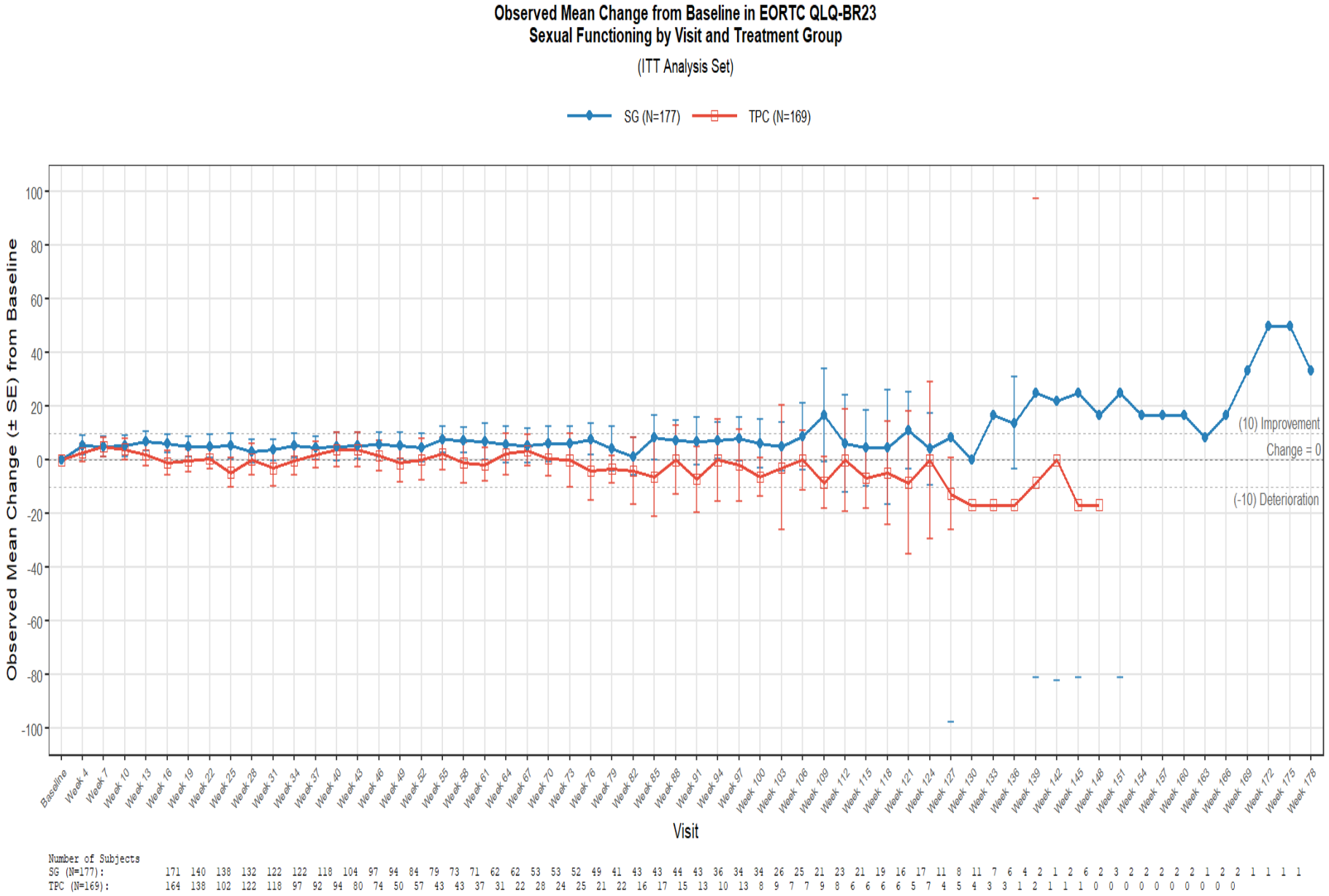
5.19. Figure 1.1.19: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 FUTURE PERSPECTIVE — mITT — Excluding patients preselected to receive nab-paclitaxel



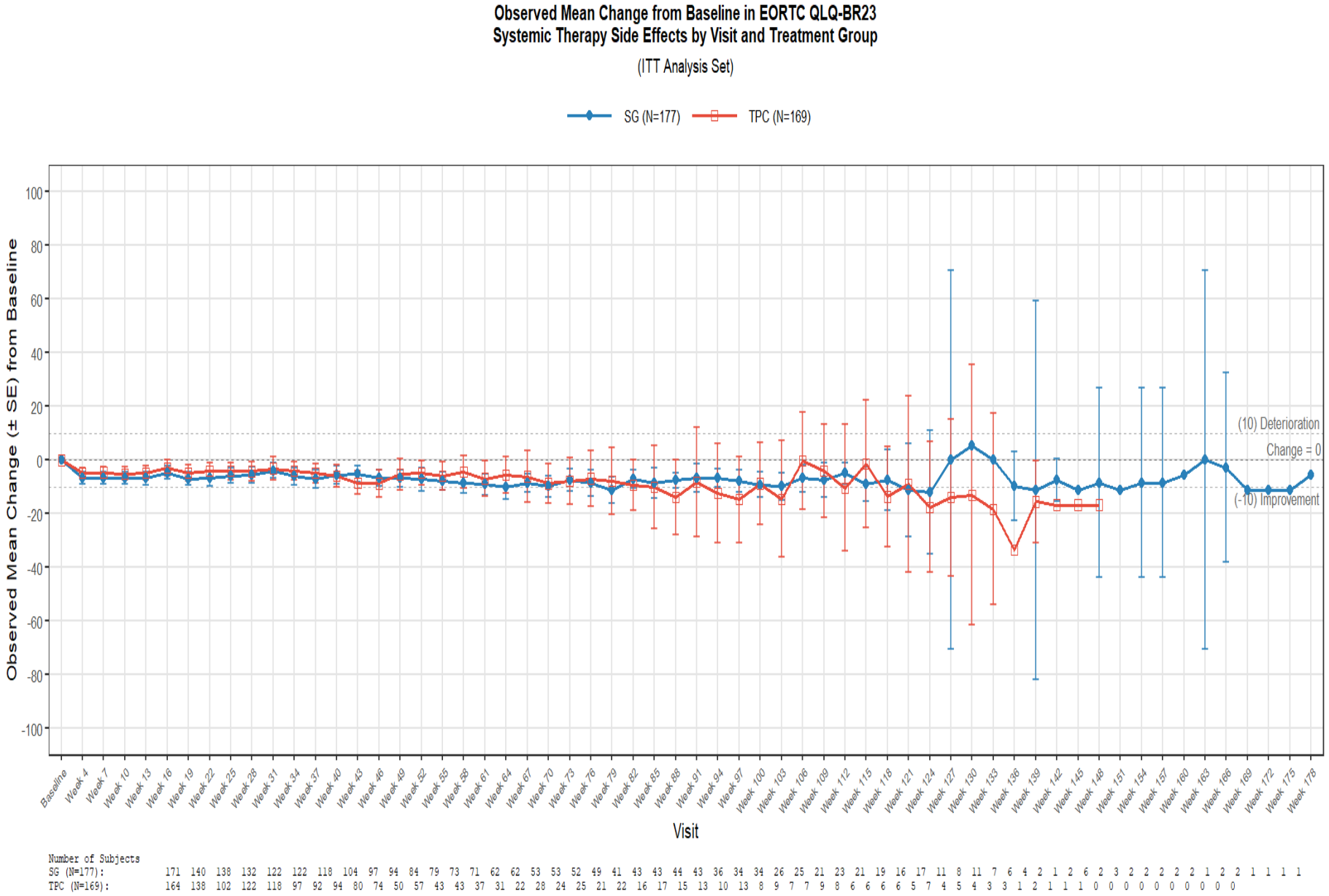
5.20. Figure 1.1.20: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SEXUAL ENJOYMENT — mITT — Excluding patients preselected to receive nab-paclitaxel



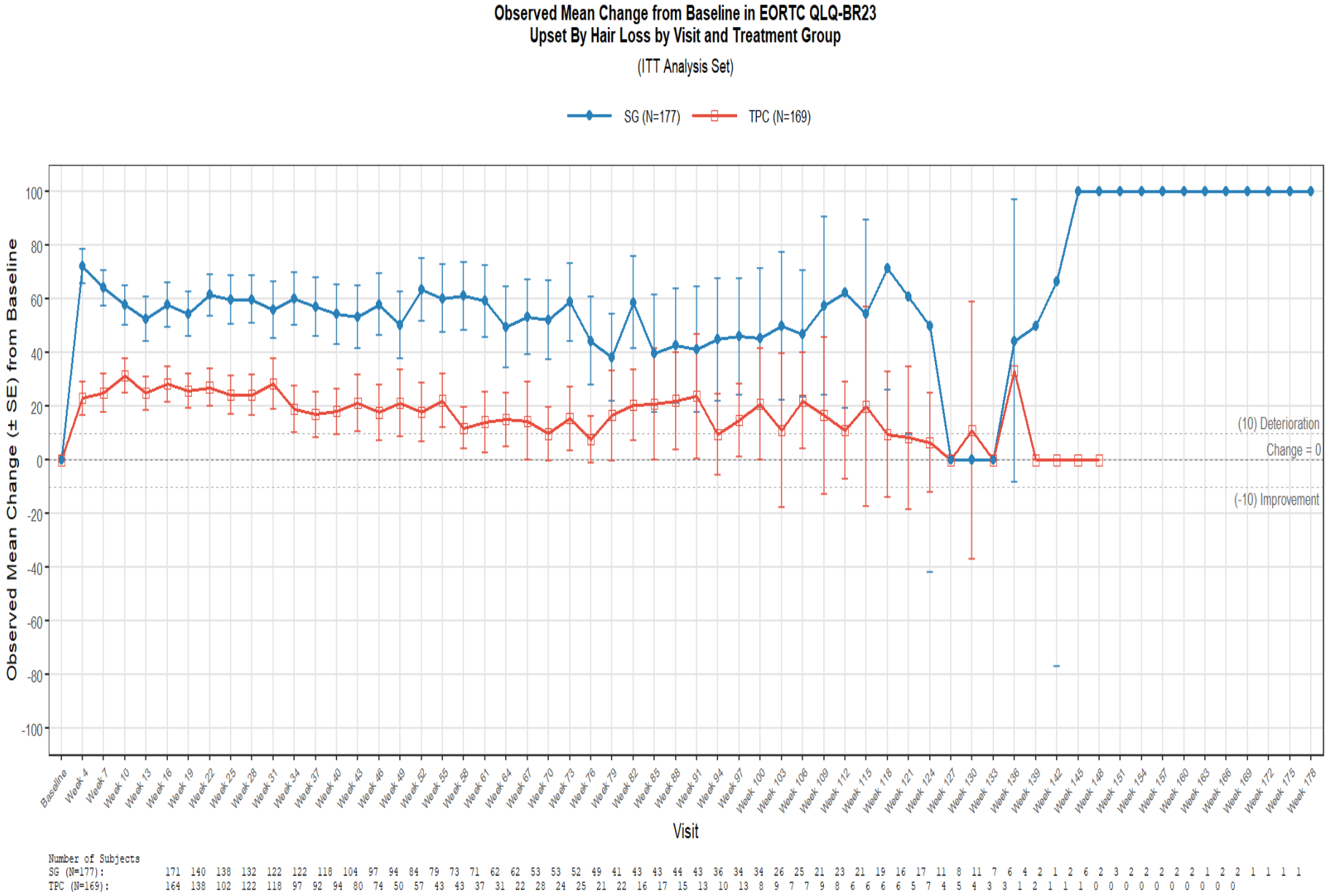
5.21. Figure 1.1.21: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SEXUAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel



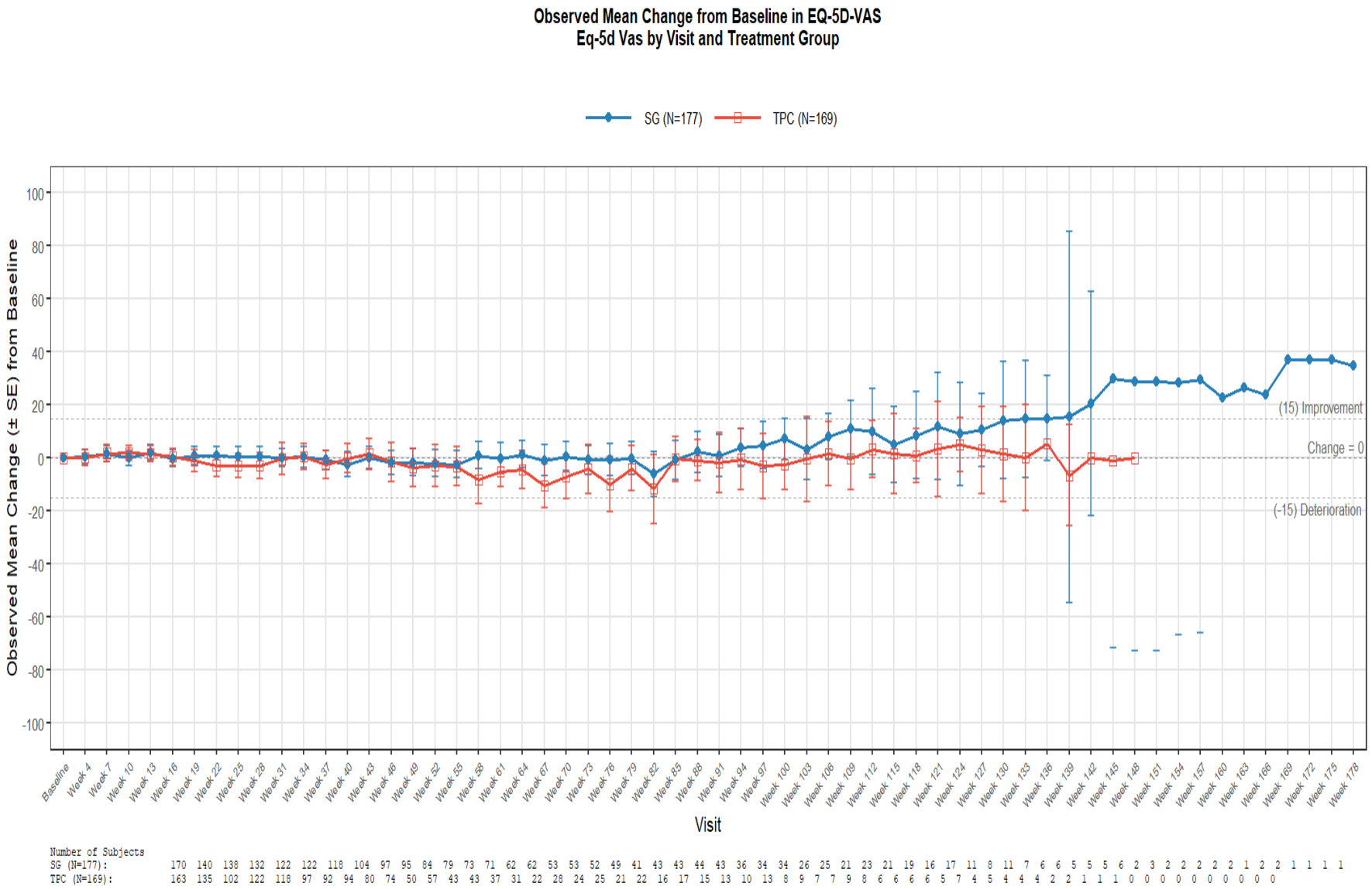
5.22. Figure 1.1.22: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 SYSTEMIC THERAPY SIDE EFFECTS — mITT — Excluding patients preselected to receive nab-paclitaxel



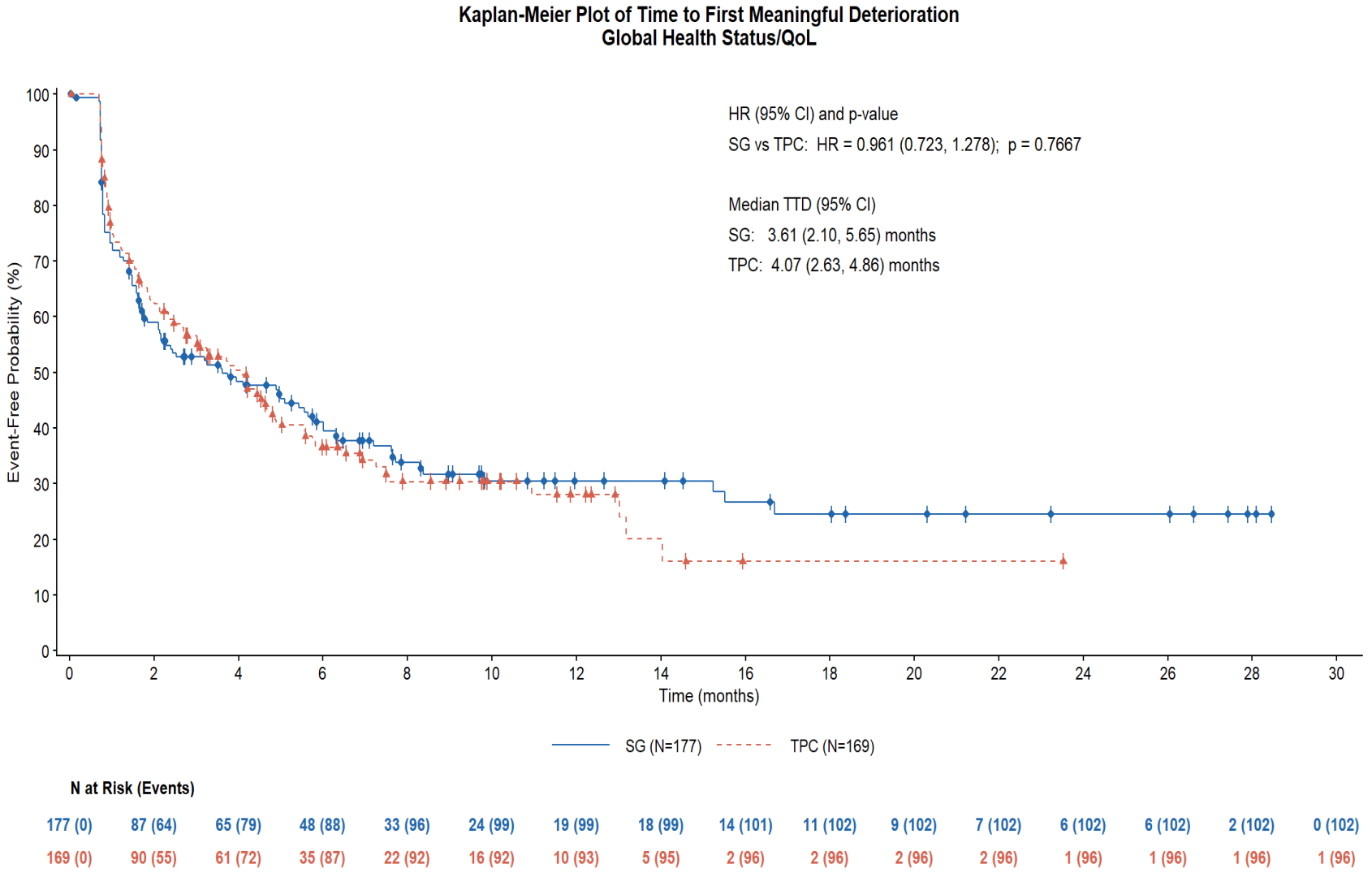
5.23. Figure 1.1.23: OBSERVED MEAN CHANGE FROM BASELINE — EORTC QLQ BR23 UPSET BY HAIR LOSS — mITT — Excluding patients preselected to receive nab-paclitaxel



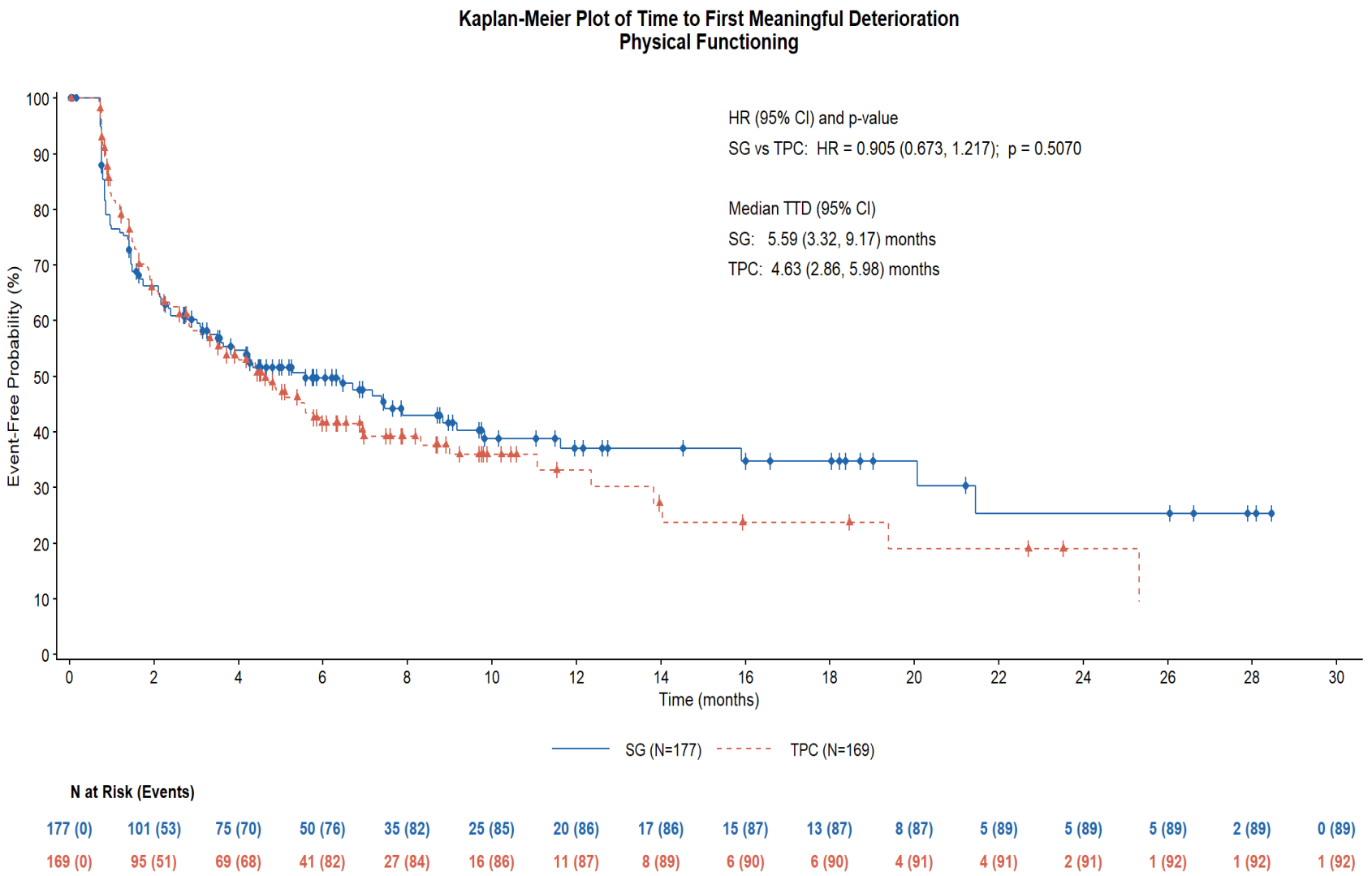
5.24. Figure 1.1.24: OBSERVED MEAN CHANGE FROM BASELINE — EQ 5D VAS — mITT — Excluding patients preselected to receive nab-paclitaxel



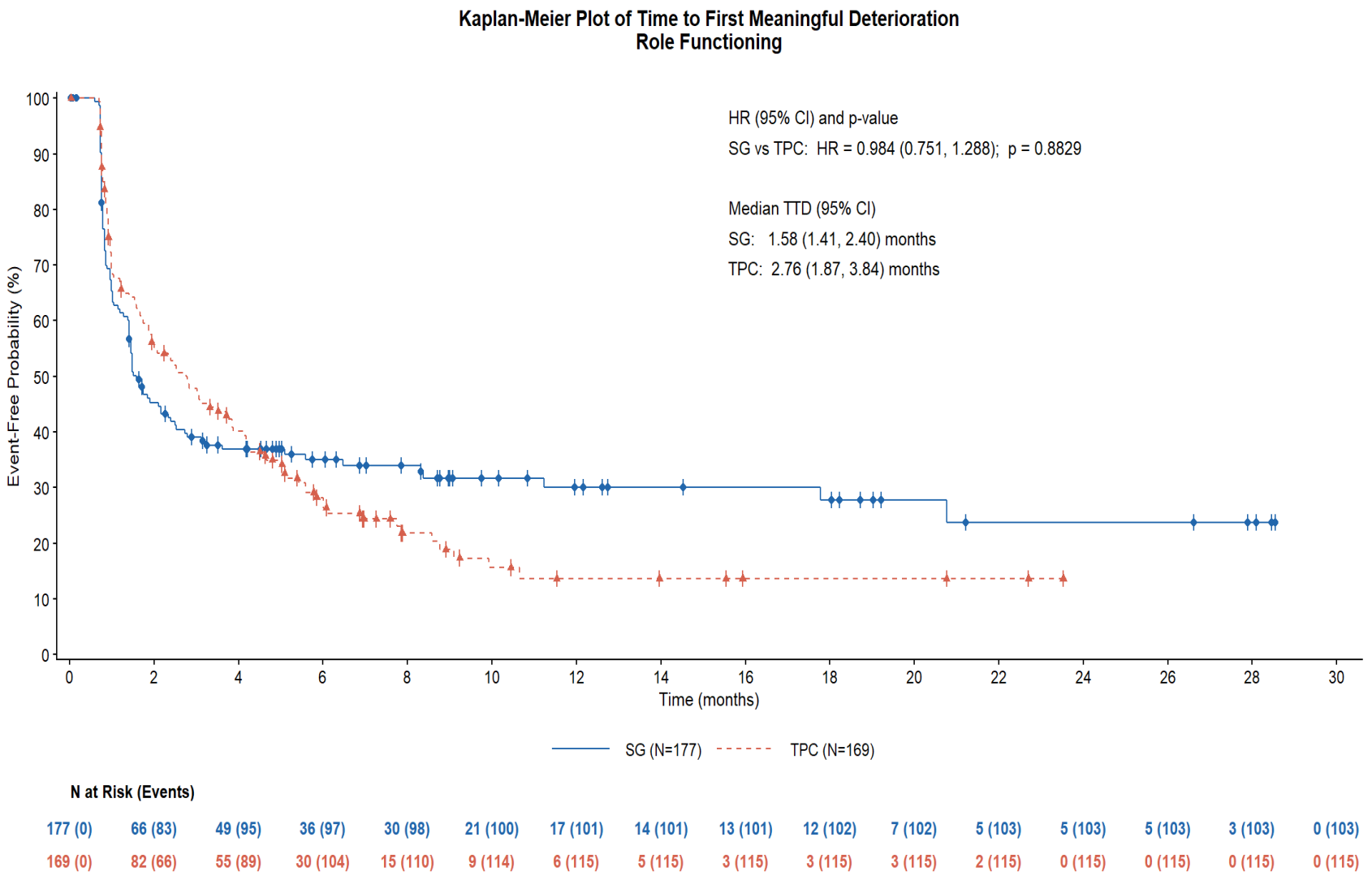
5.25. Figure 1.1.1: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Global Health Status QoL — mITT — Excluding patients preselected to receive nab-paclitaxel



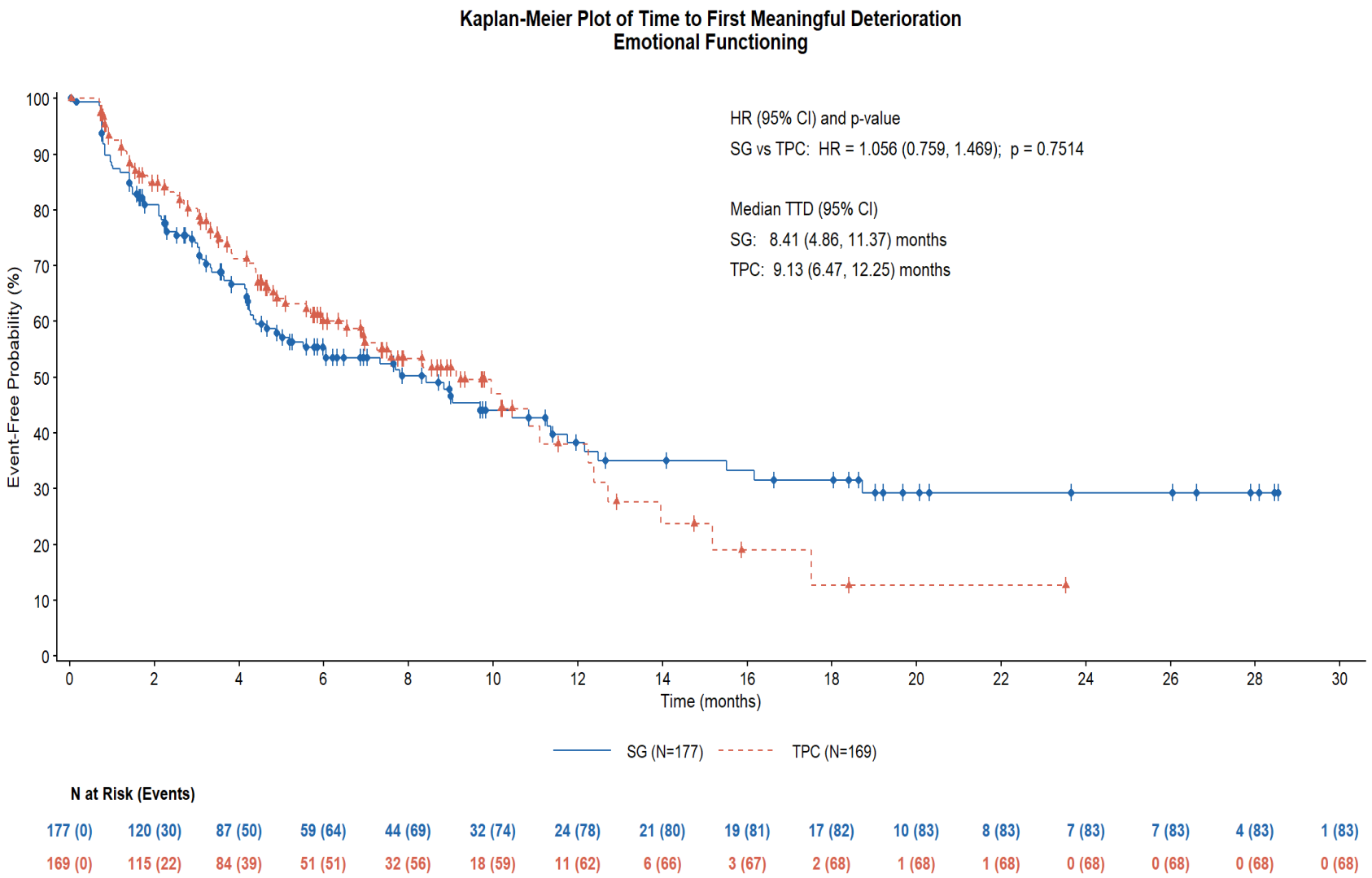
5.26. Figure 1.1.2: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Physical Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel



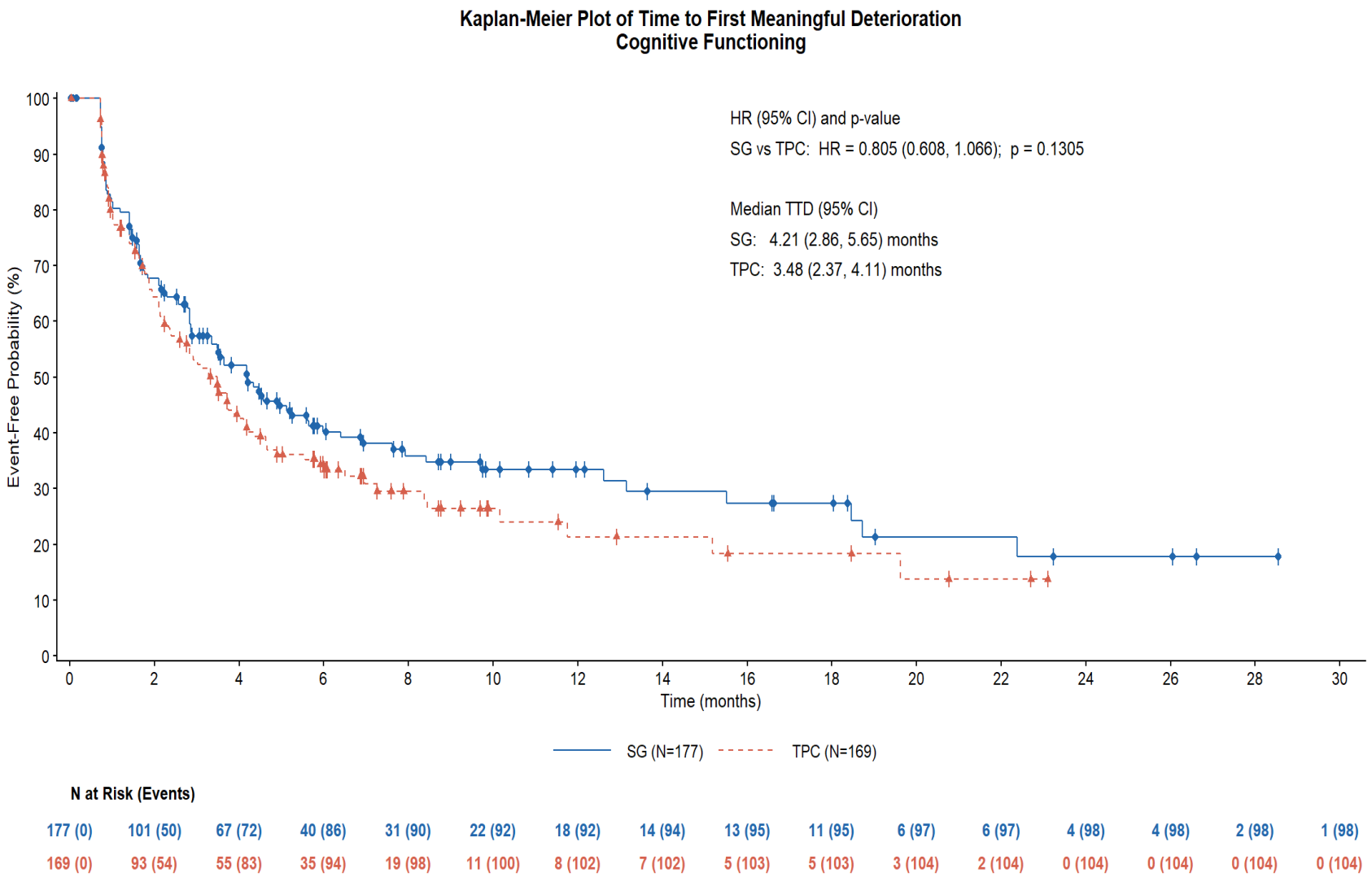
5.27. Figure 1.1.3: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Role Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel



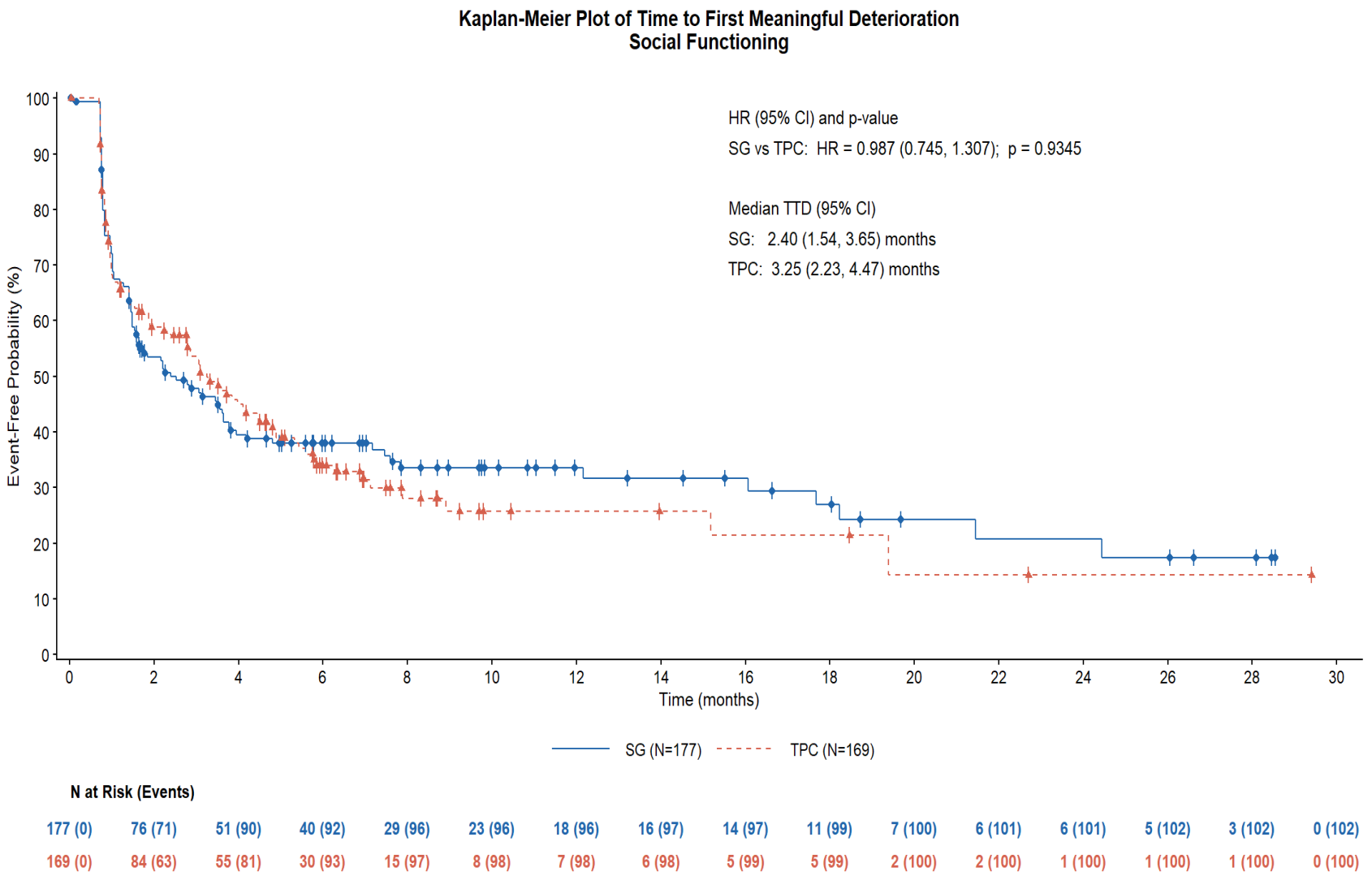
5.28. Figure 1.1.4: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Emotional Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel



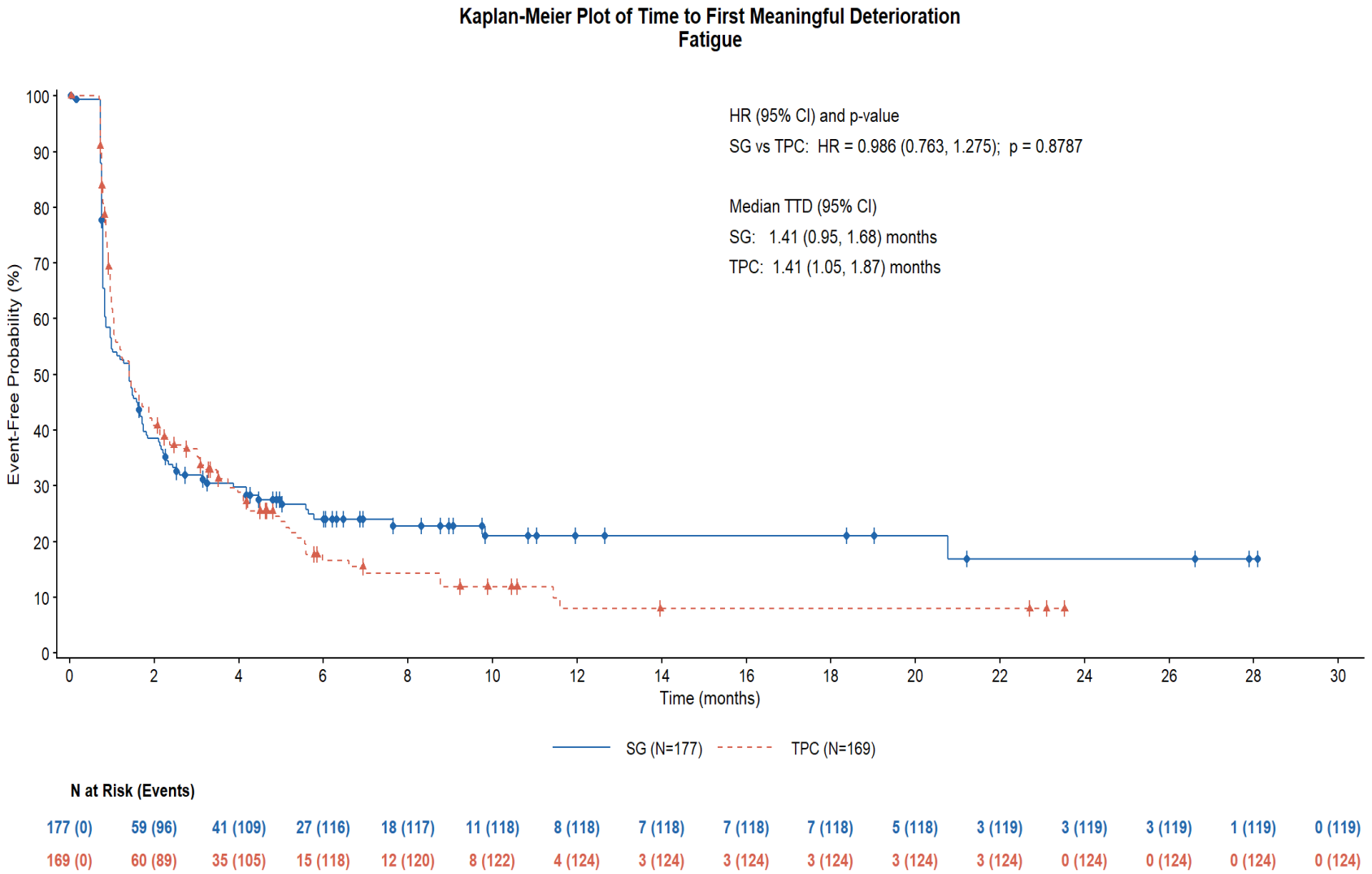
5.29. Figure 1.1.5: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Cognitive Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel



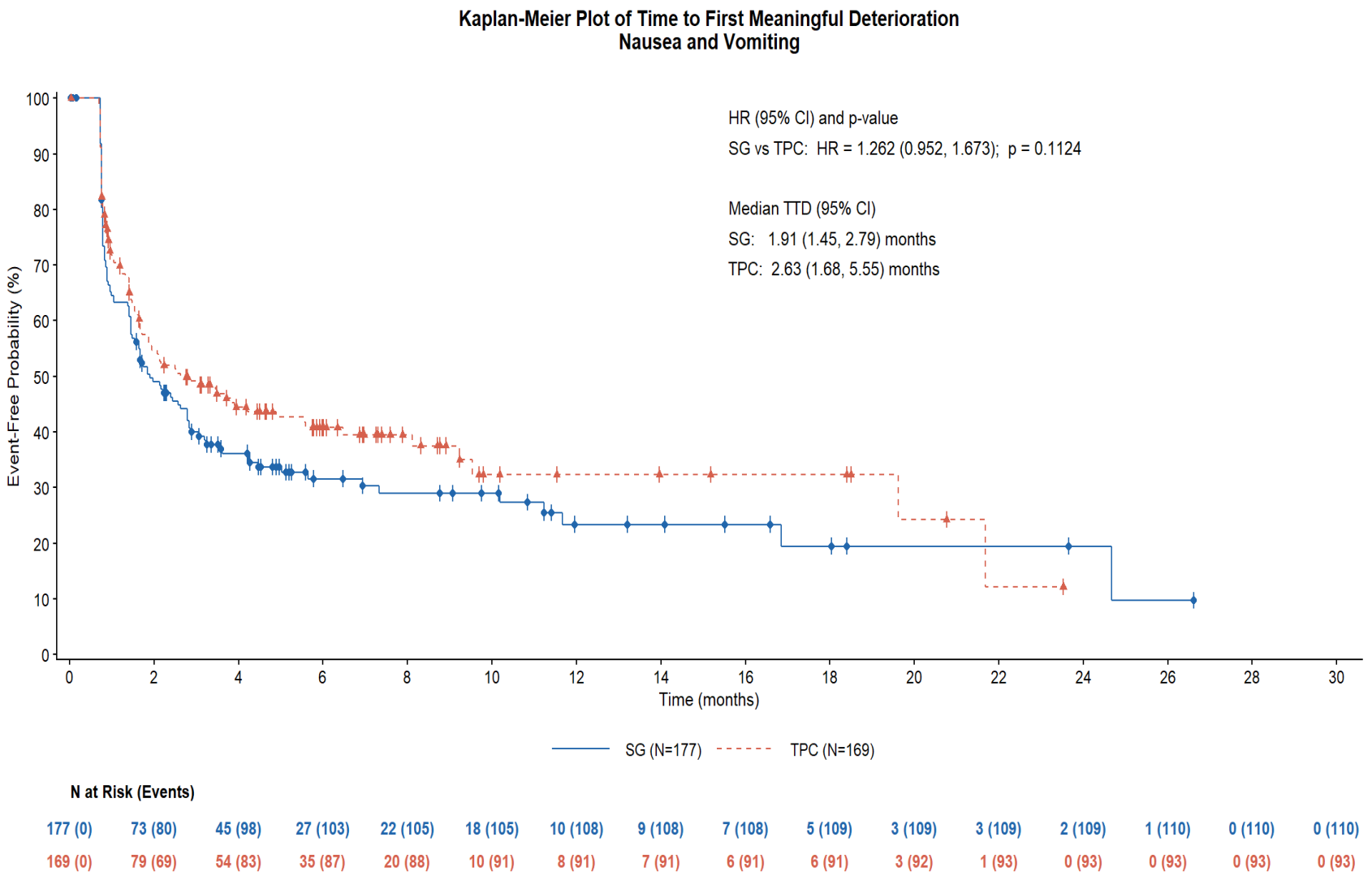
5.30. Figure 1.1.6: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Social Functioning — mITT — Excluding patients preselected to receive nab-paclitaxel



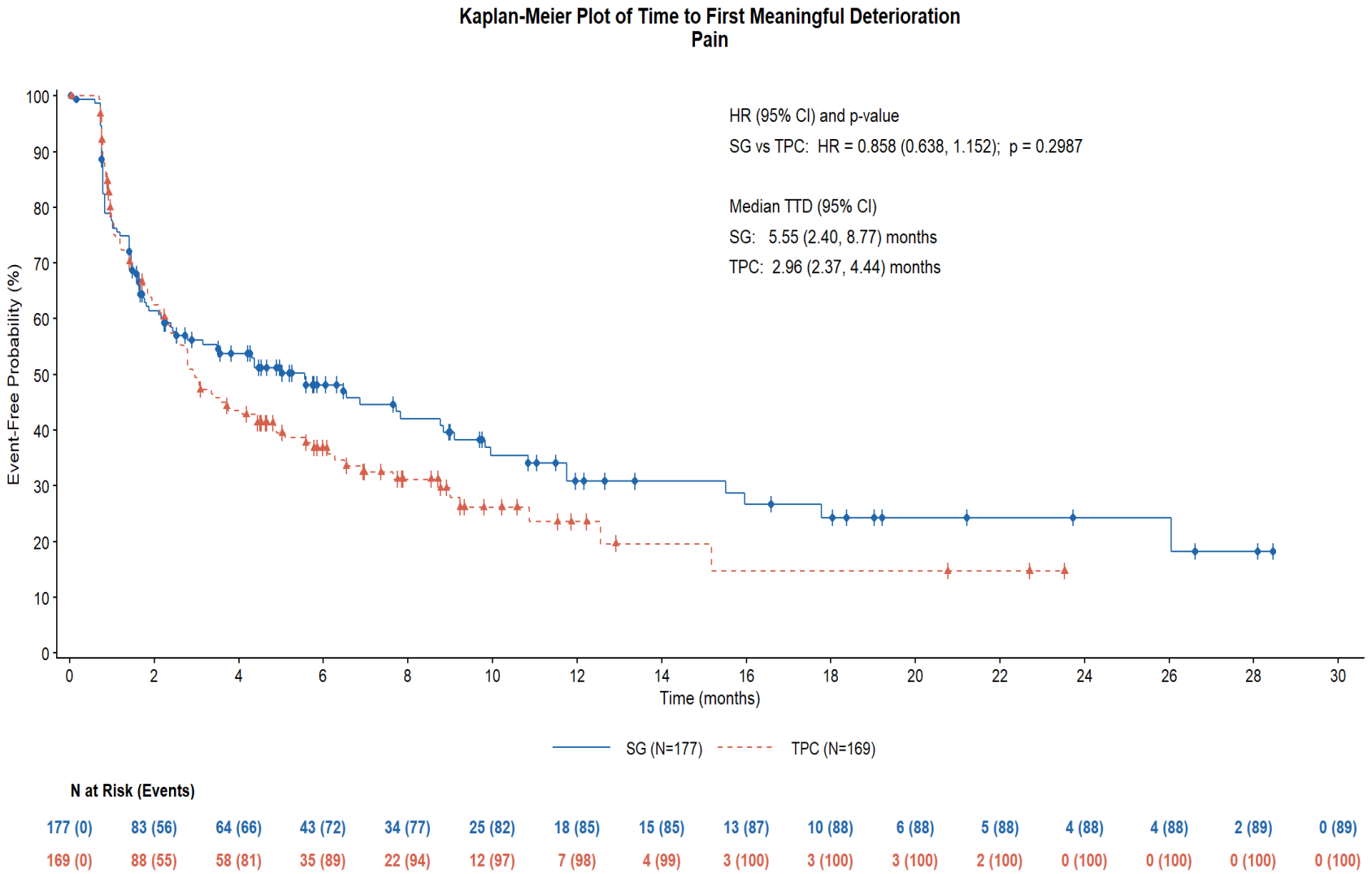
5.31. Figure 1.1.7: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Fatigue — mITT — Excluding patients preselected to receive nab-paclitaxel



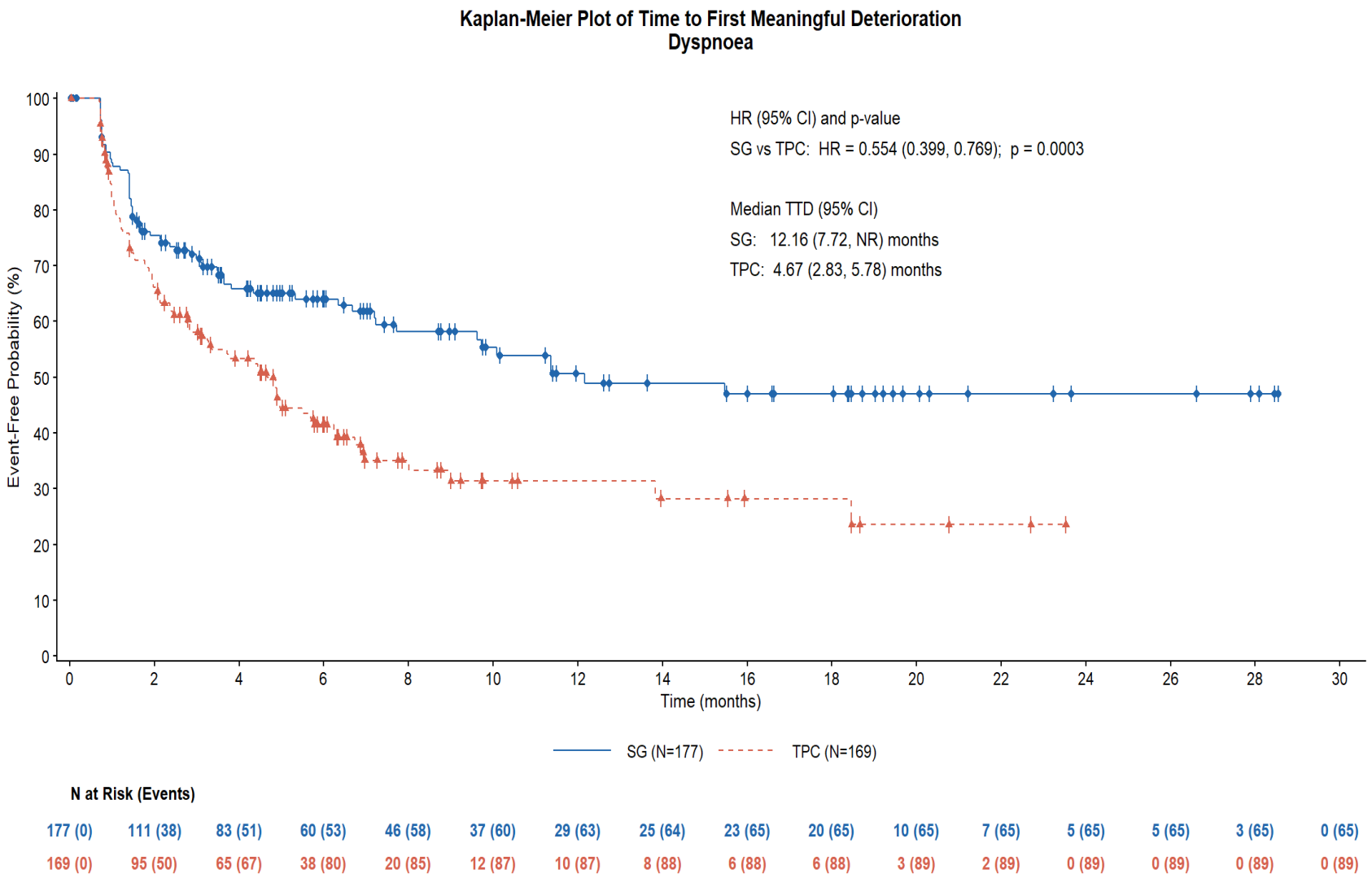
5.32. Figure 1.1.8: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Nausea and Vomiting — mITT — Excluding patients preselected to receive nab-paclitaxel



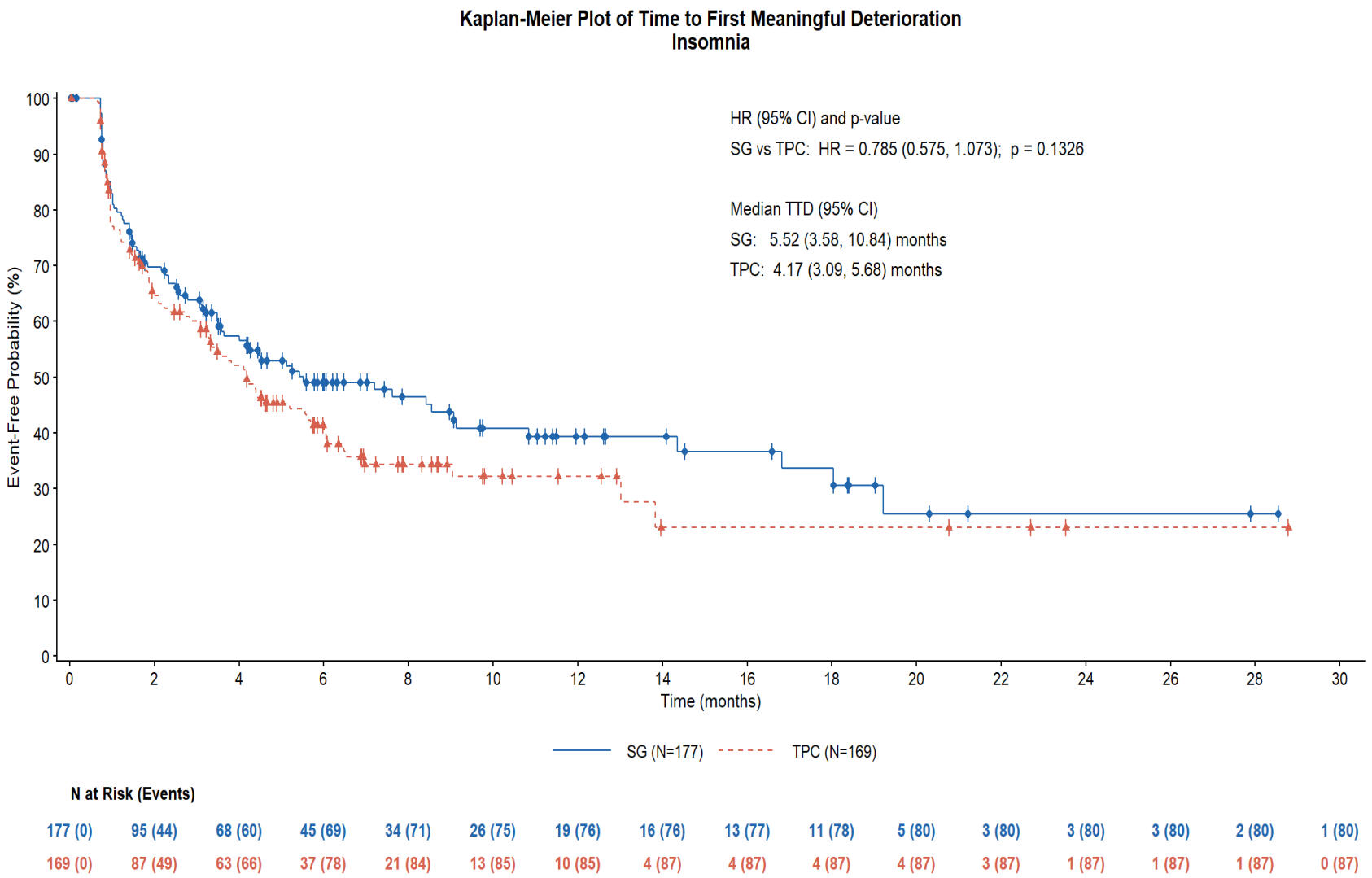
5.33. Figure 1.1.9: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Pain — mITT — Excluding patients preselected to receive nab-paclitaxel



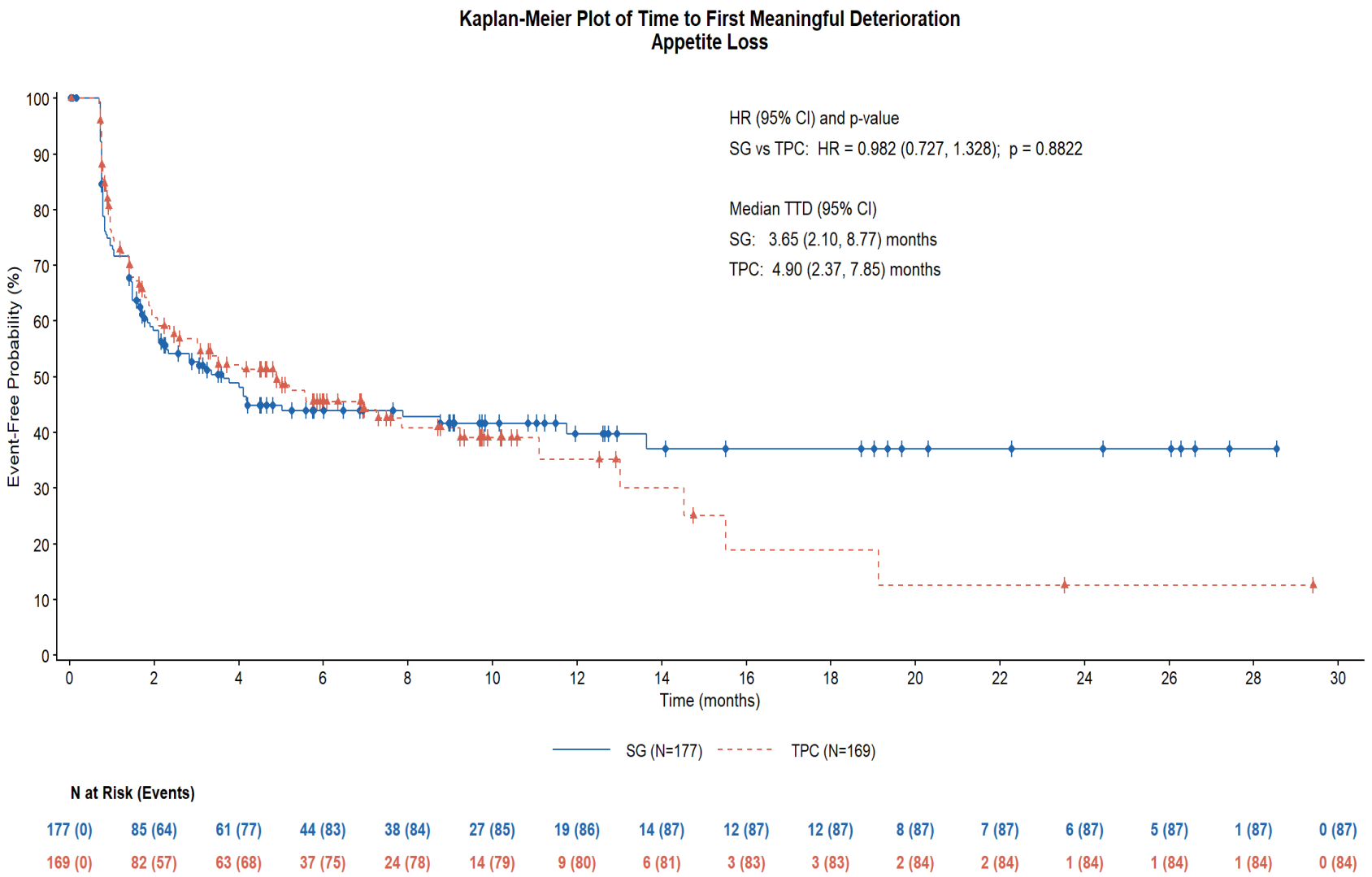
5.34. Figure 1.1.10: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Dyspnoea — mITT — Excluding patients preselected to receive nab-paclitaxel



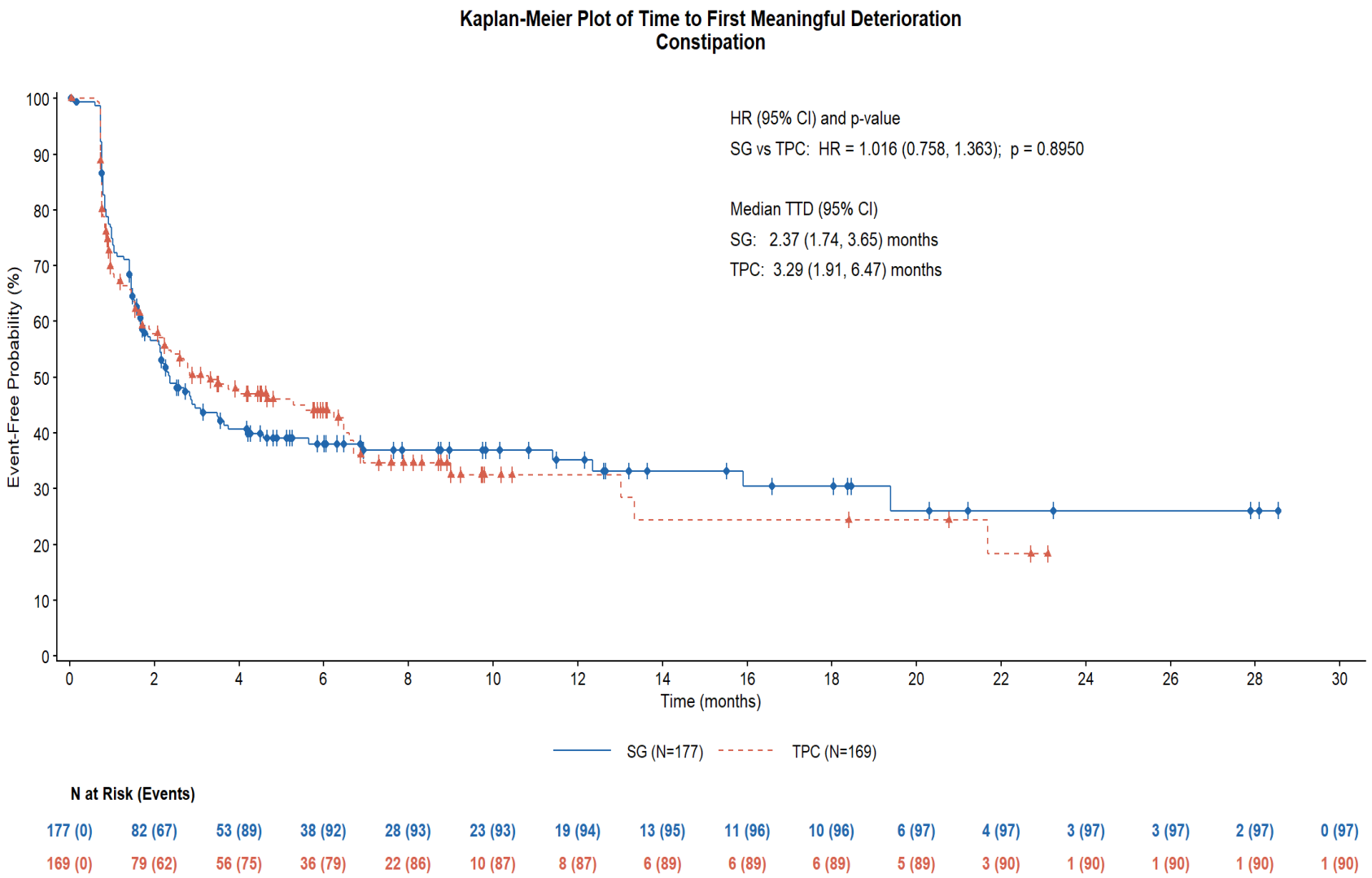
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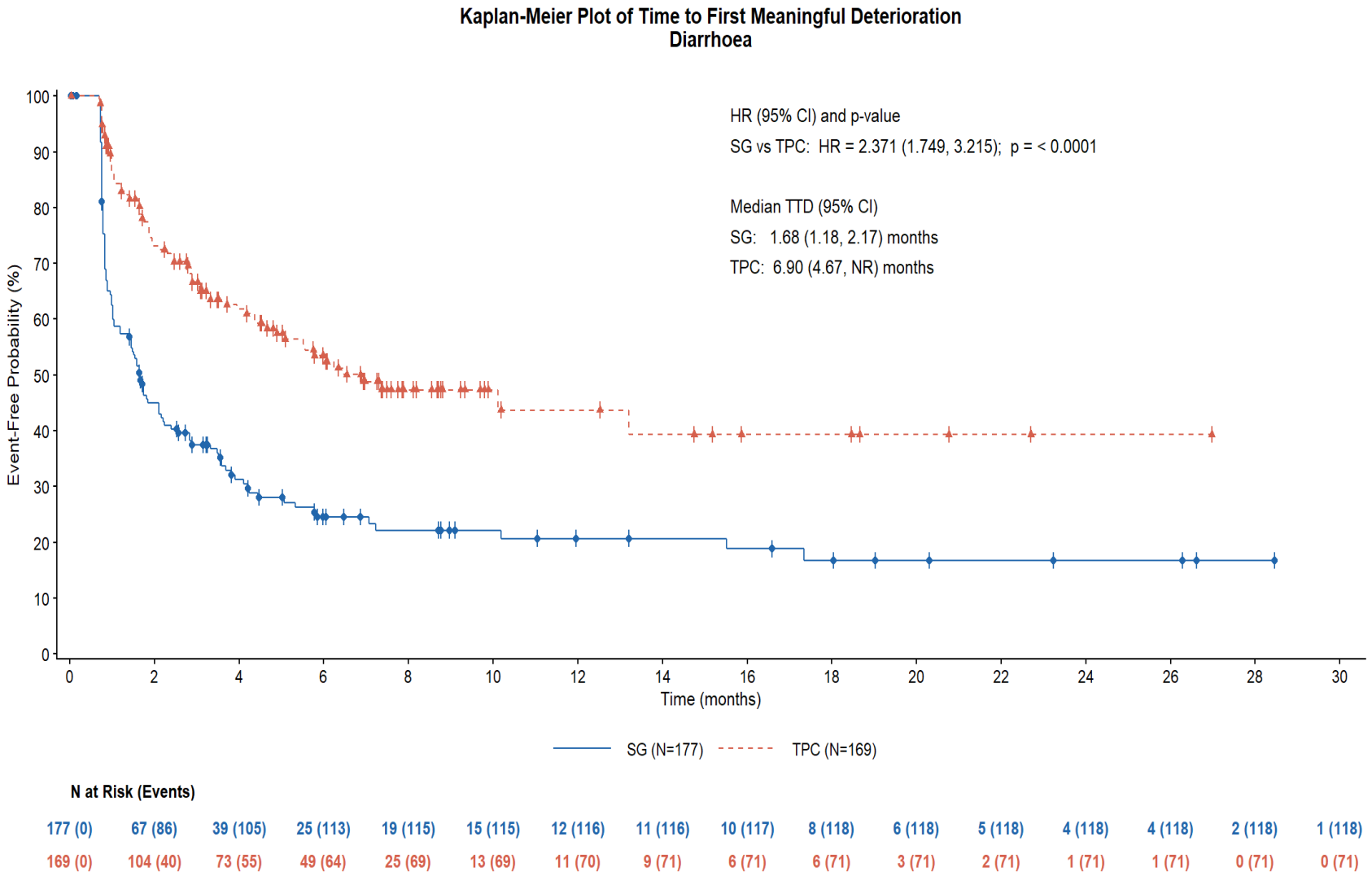
5.36. Figure 1.1.12: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Appetite Loss — mITT — Excluding patients preselected to receive nab-paclitaxel



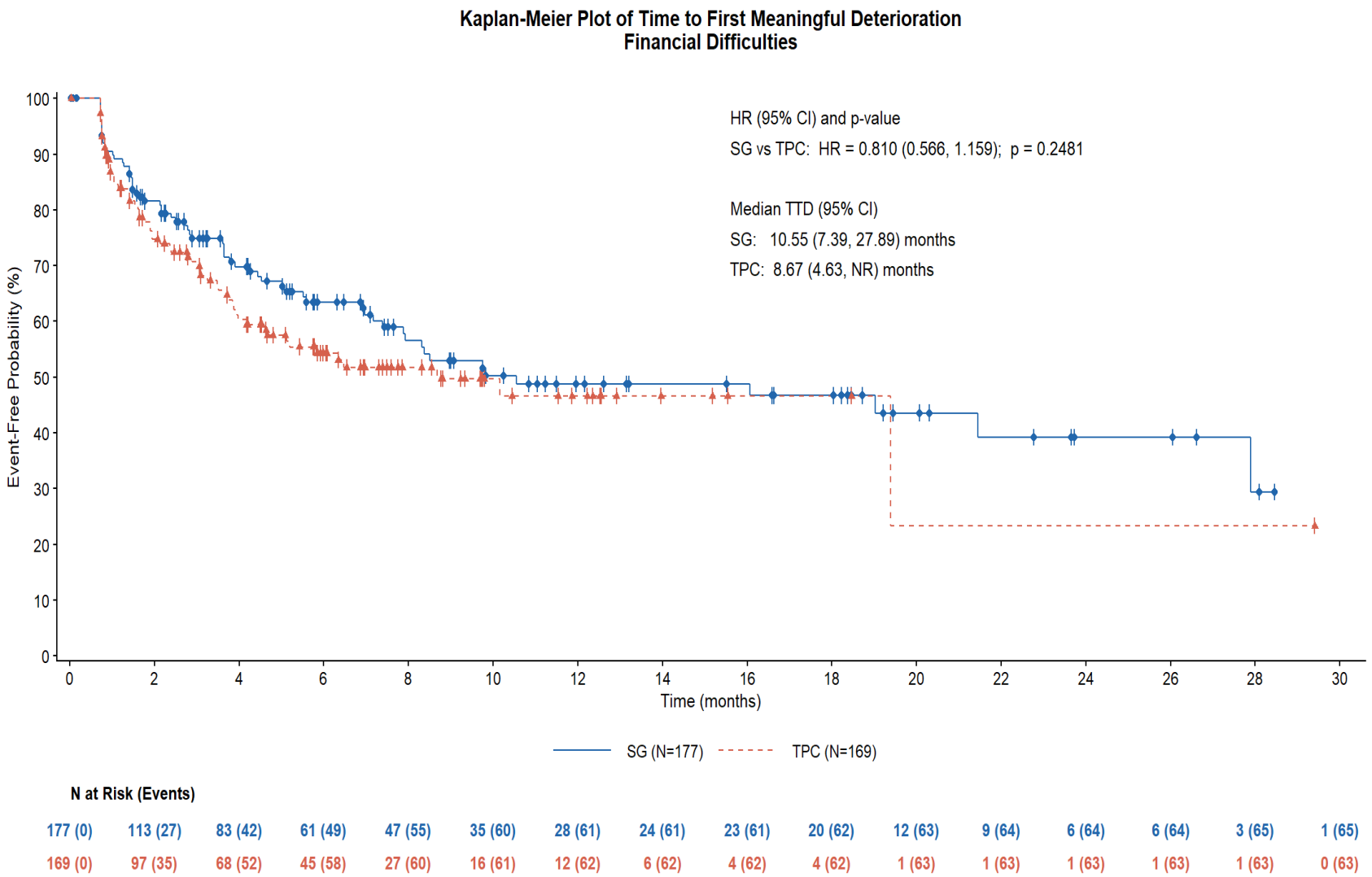
5.37. Figure 1.1.13: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ C30 Constipation — mITT — Excluding patients preselected to receive nab-paclitaxel



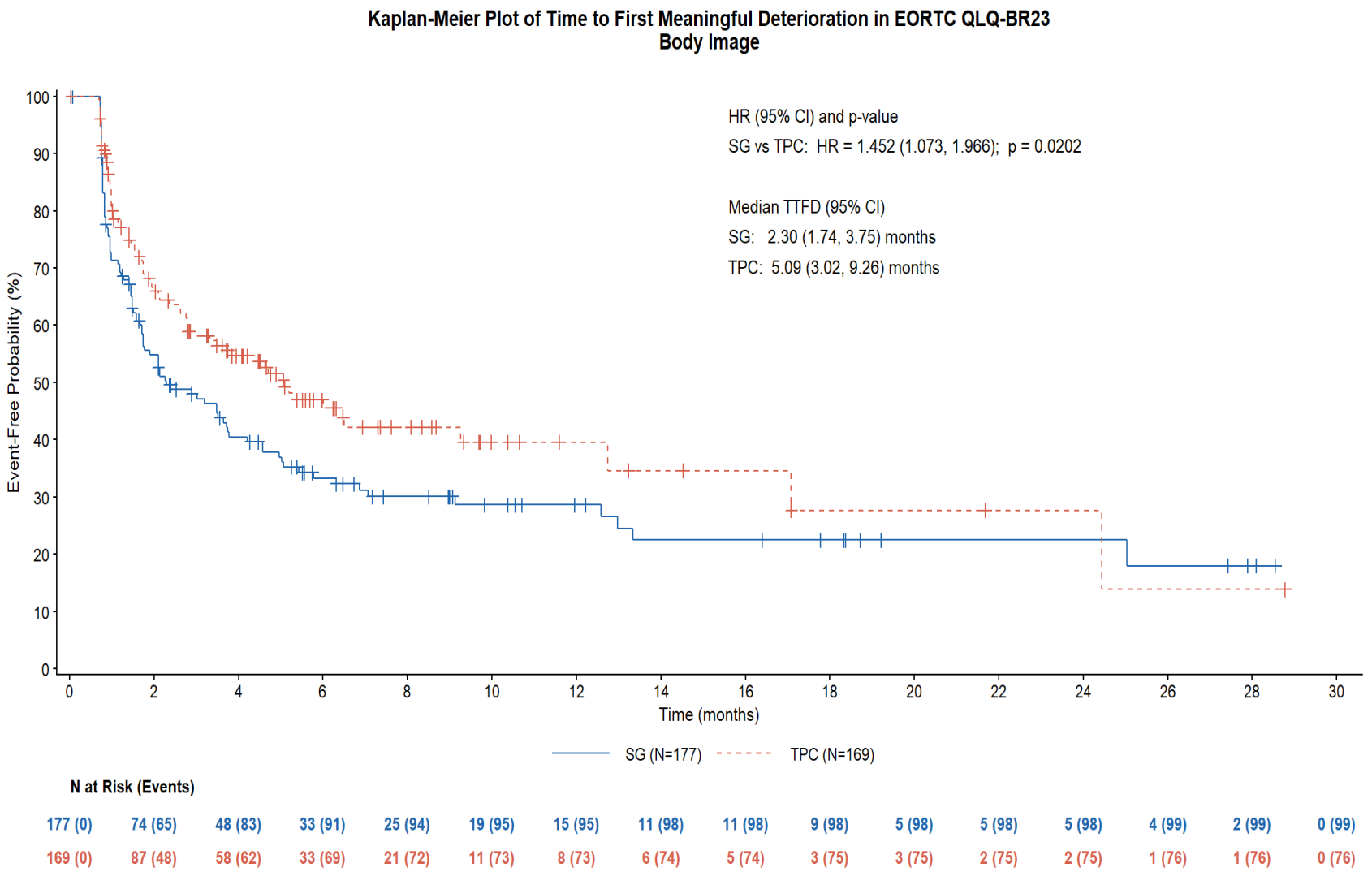
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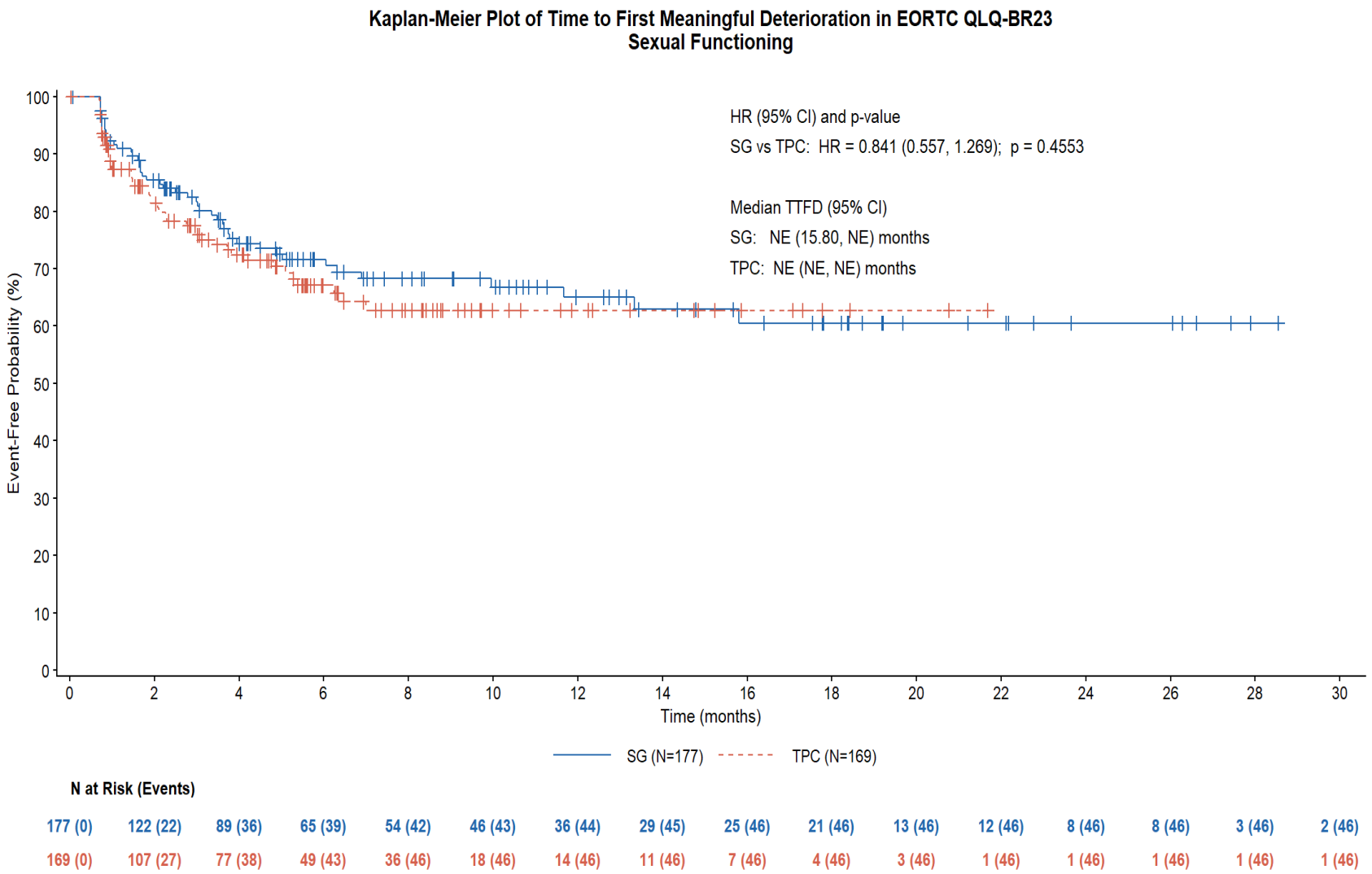
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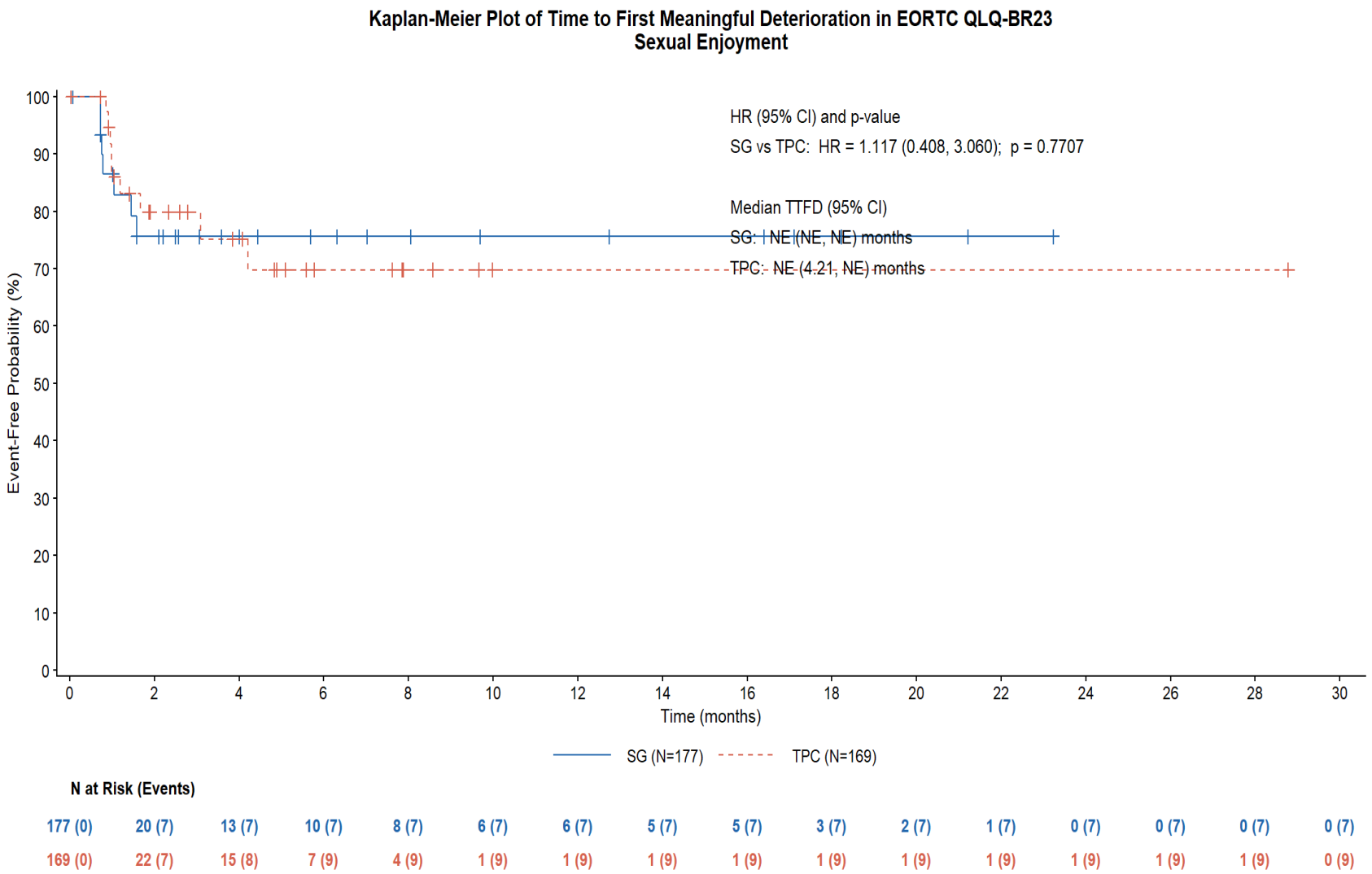
5.40. Figure 1.1.16: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 BODY IMAGE — mITT — Excluding patients preselected to receive nab-paclitaxel



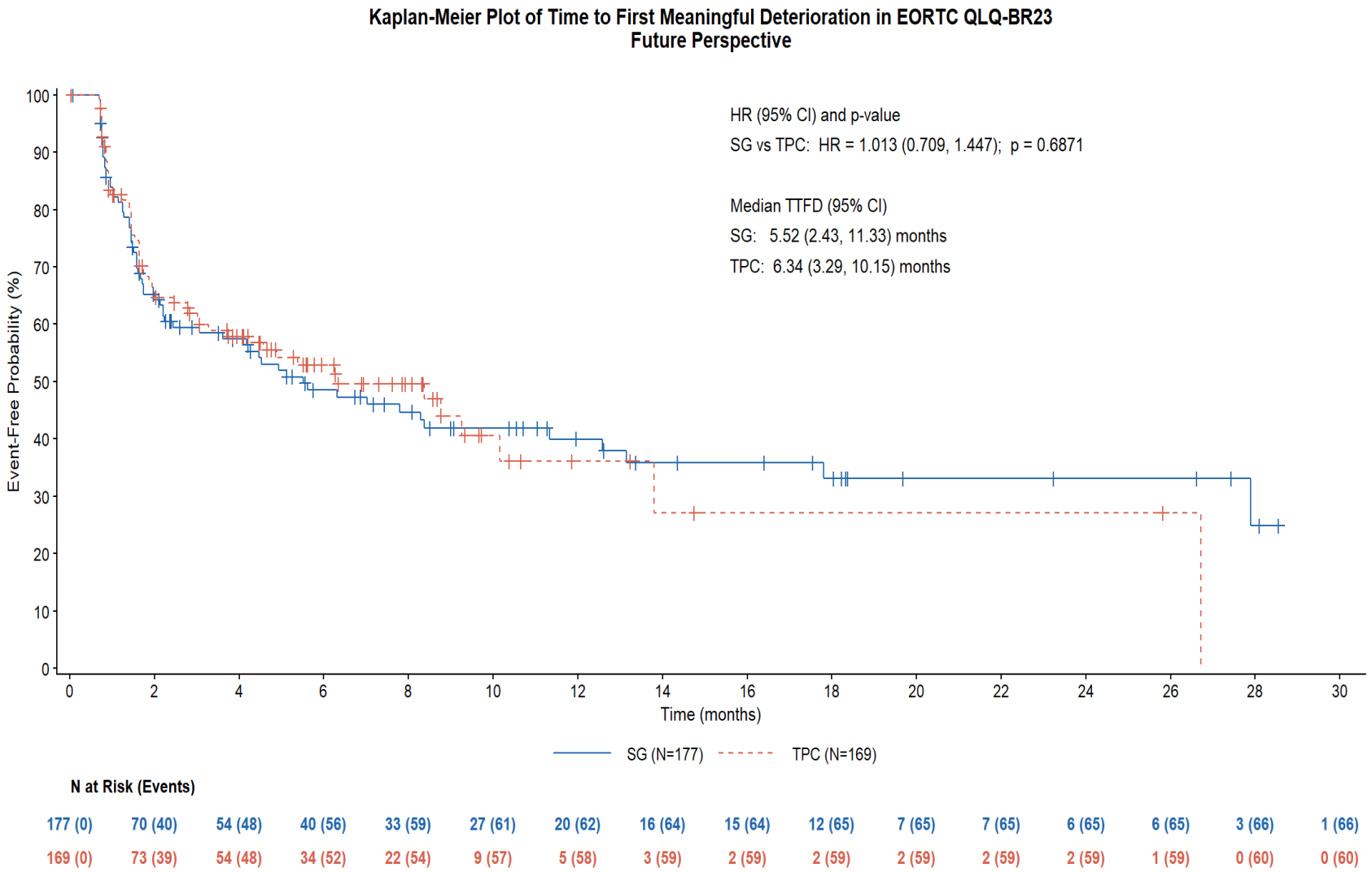
5.41. Figure 1.1.17: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 SEXUAL FUNCTIONING — mITT — Excluding patients preselected to receive nab-paclitaxel



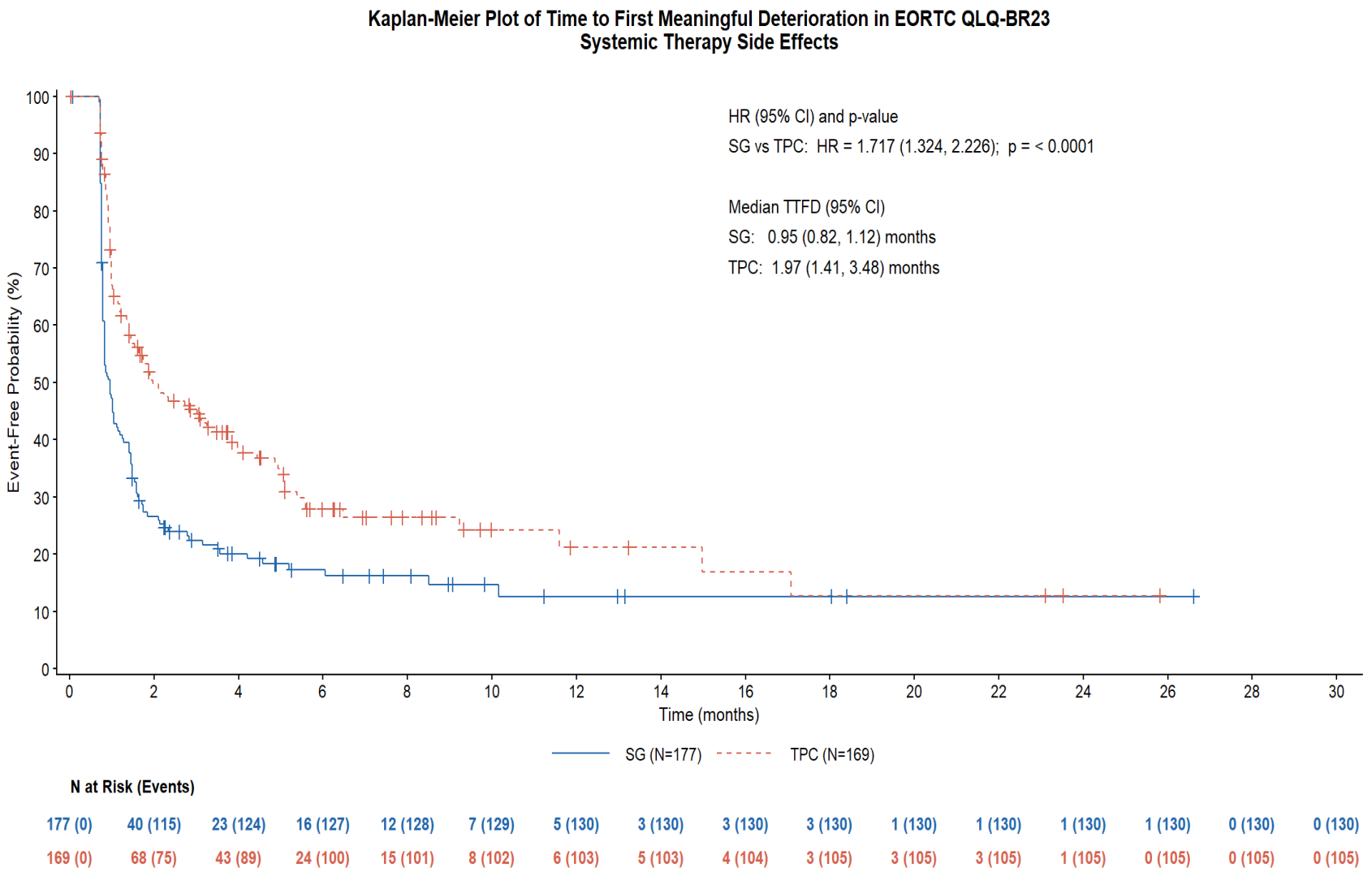
5.42. Figure 1.1.18: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 SEXUAL ENJOYMENT — mITT — Excluding patients preselected to receive nab-paclitaxel



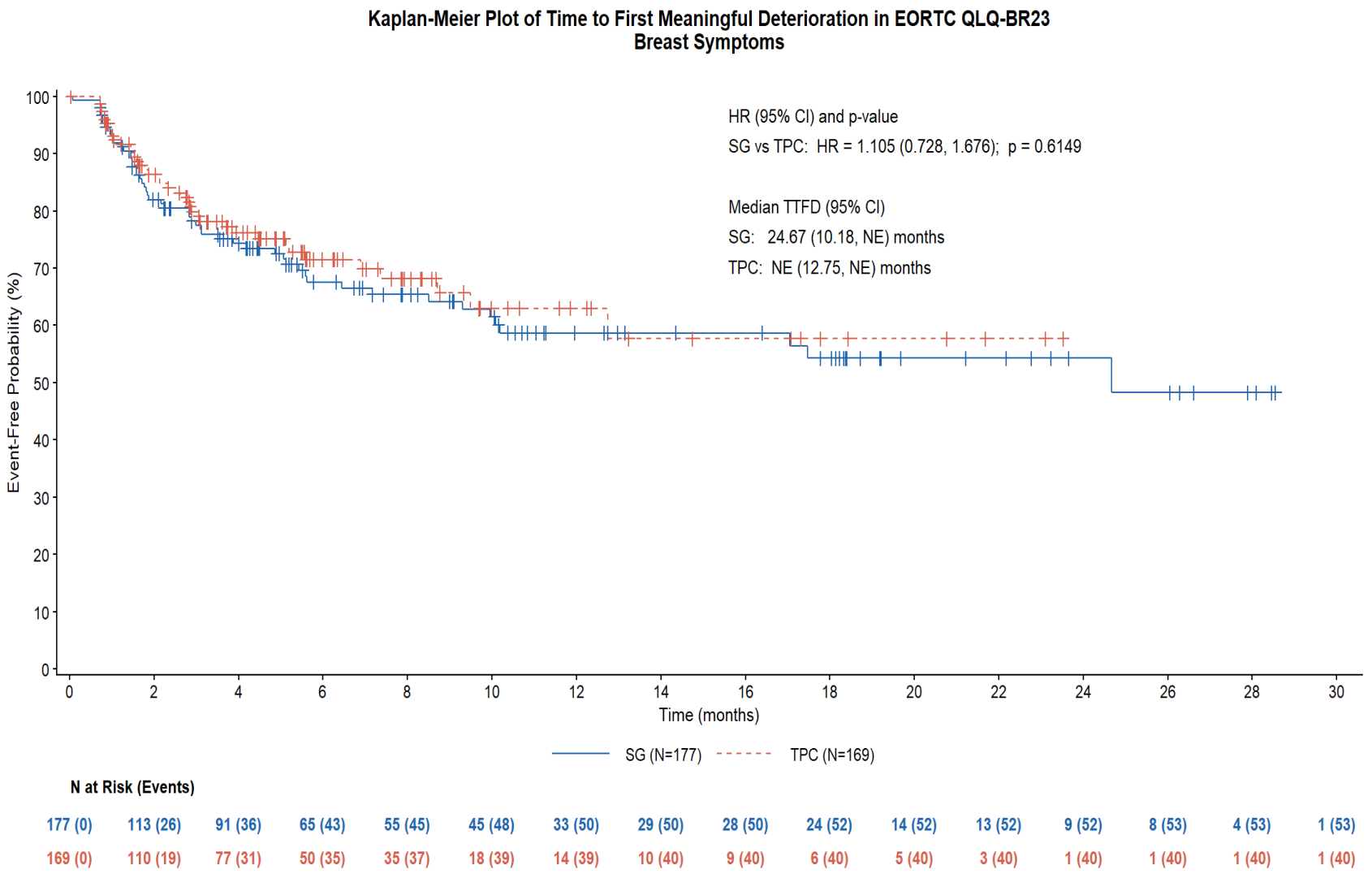
5.43. Figure 1.1.19: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 FUTURE PERSPECTIVE — mITT — Excluding patients preselected to receive nab-paclitaxel



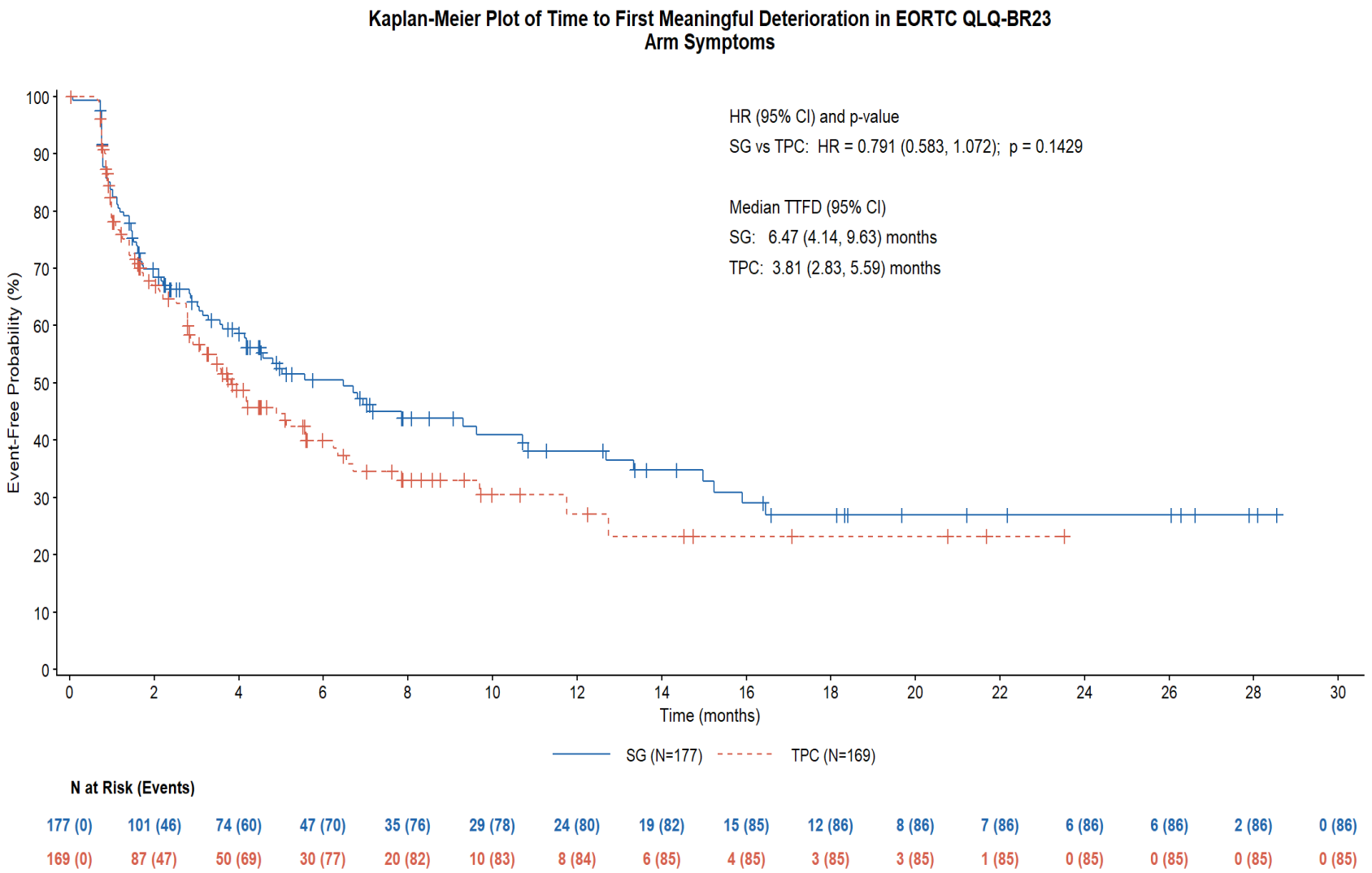
5.44. Figure 1.1.20: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 SYSTEMIC THERAPY SIDE EFFECTS — mITT — Excluding patients preselected to receive nab-paclitaxel



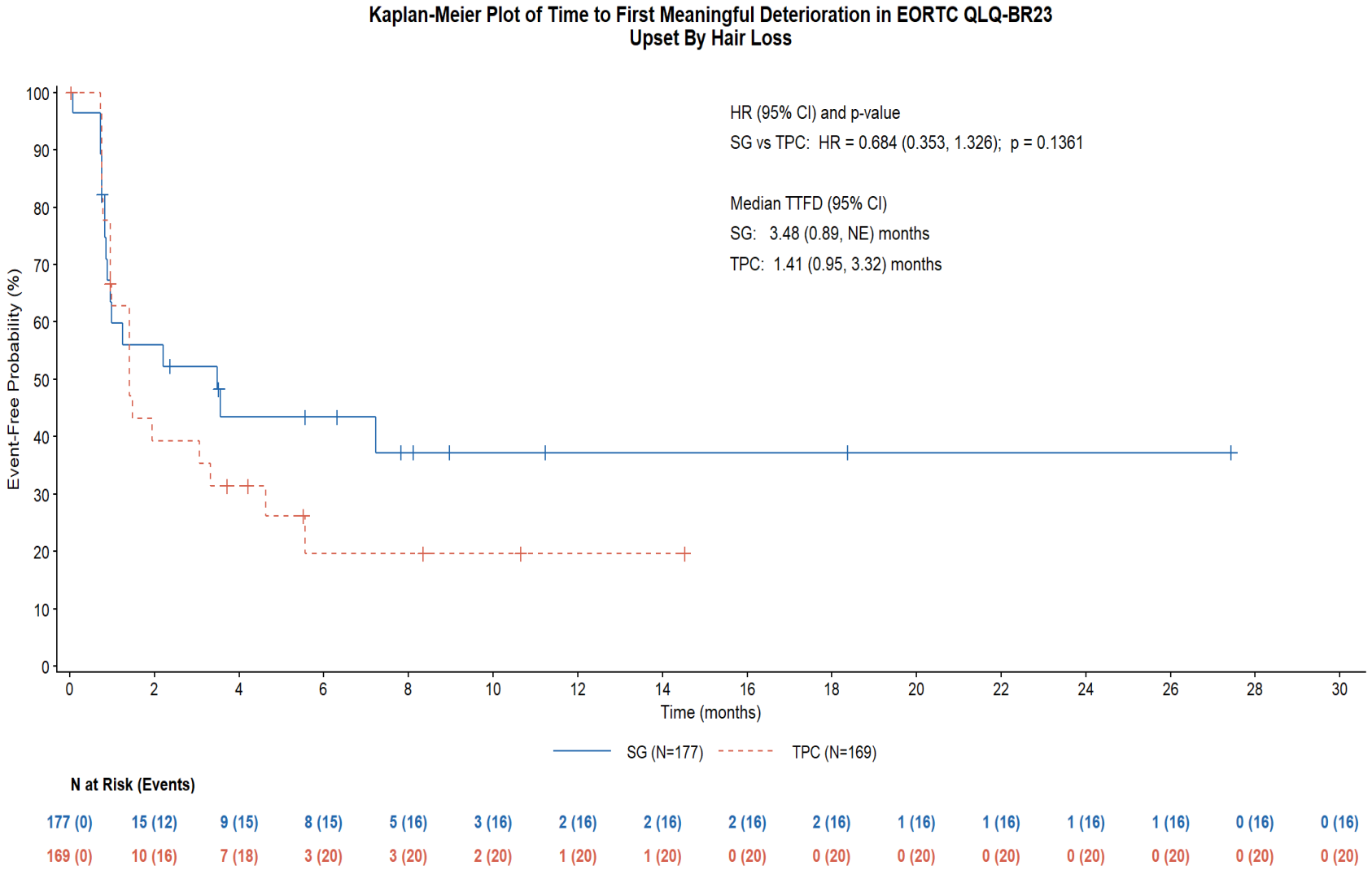
5.45. Figure 1.1.21: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 BREAST SYMPTOMS — mITT — Excluding patients preselected to receive nab-paclitaxel



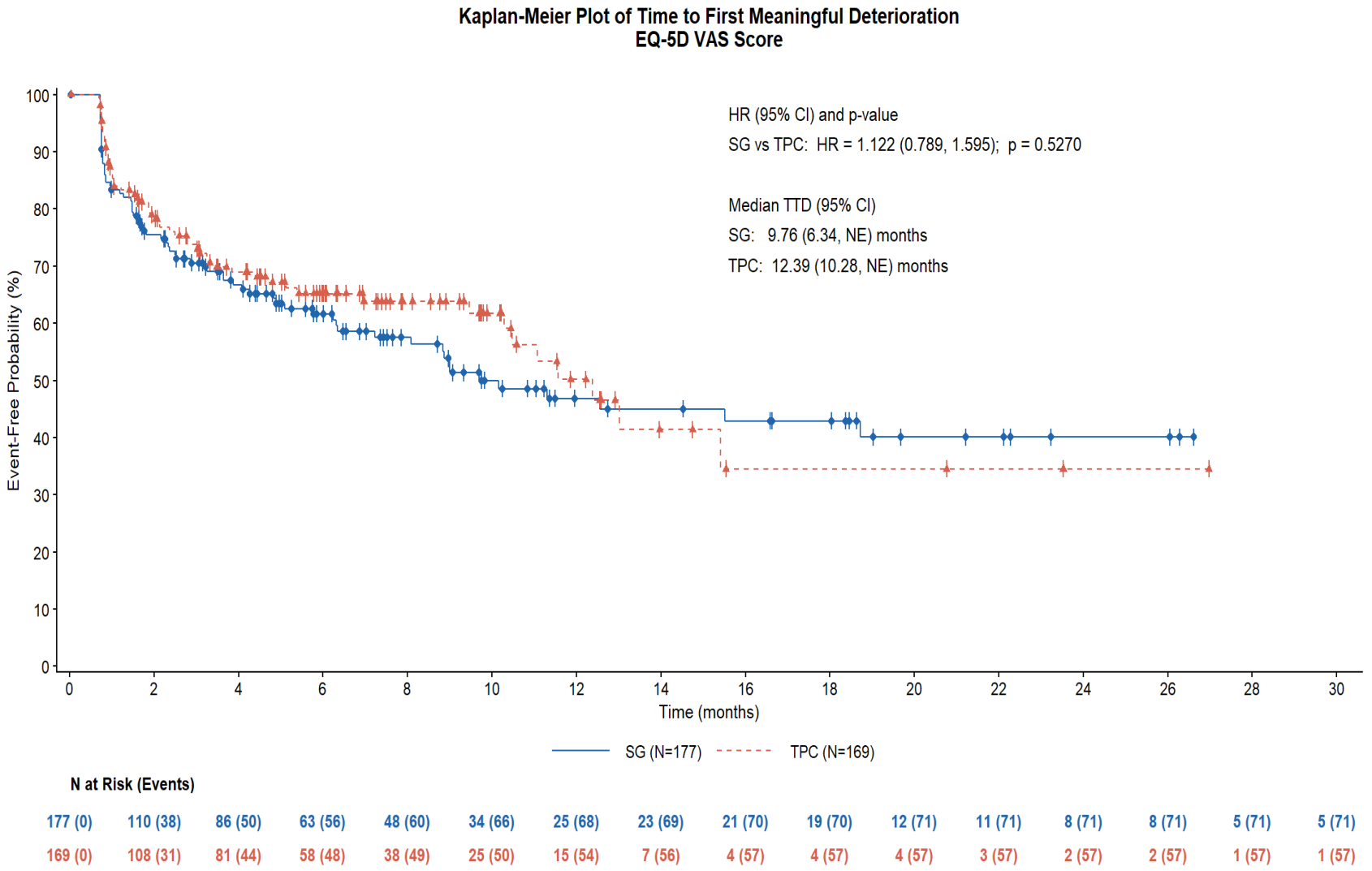
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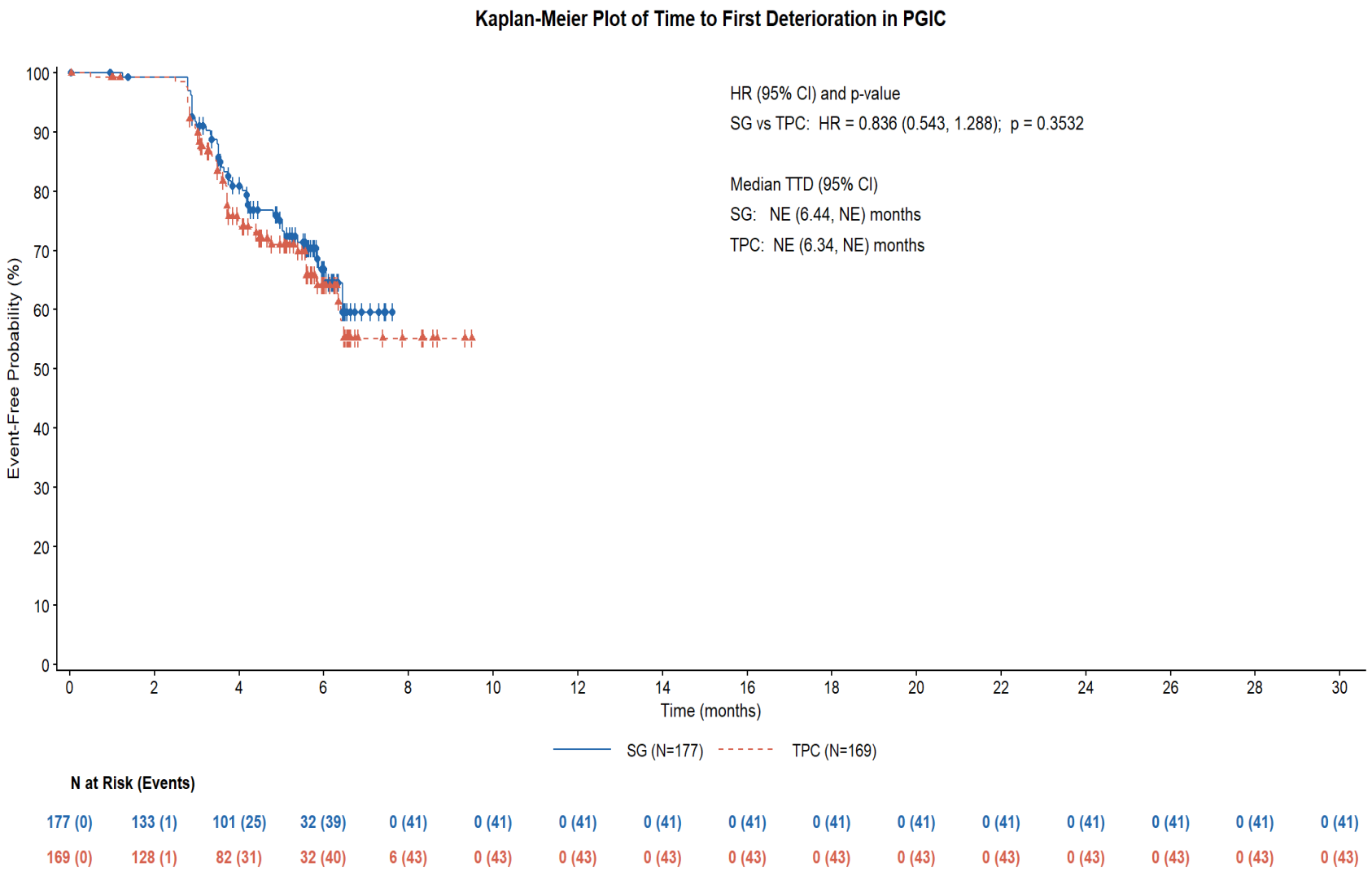
5.47. Figure 1.1.23: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION EORTC QLQ BR23 UPSET BY HAIR LOSS — mITT — Excluding patients preselected to receive nab-paclitaxel



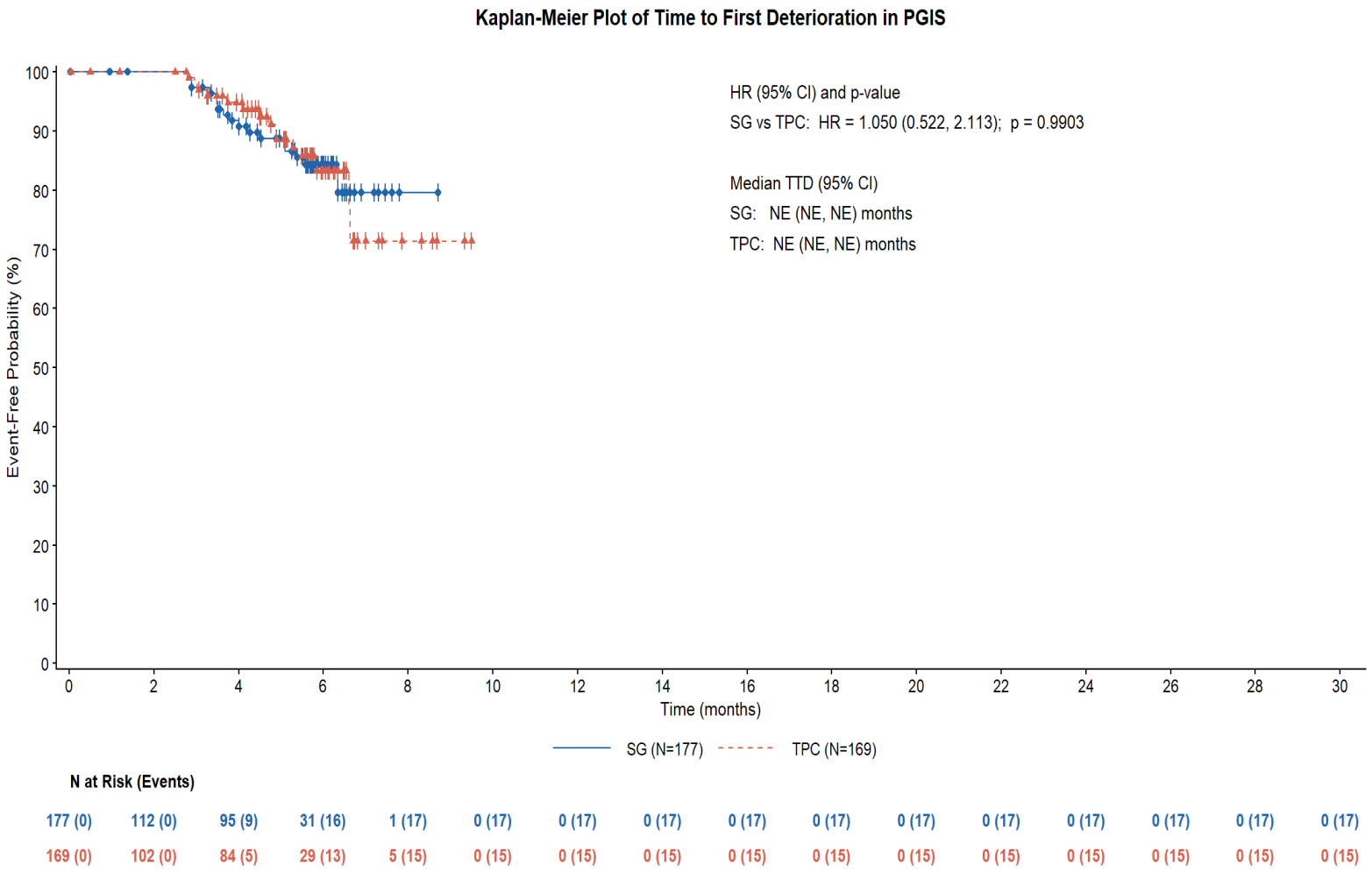
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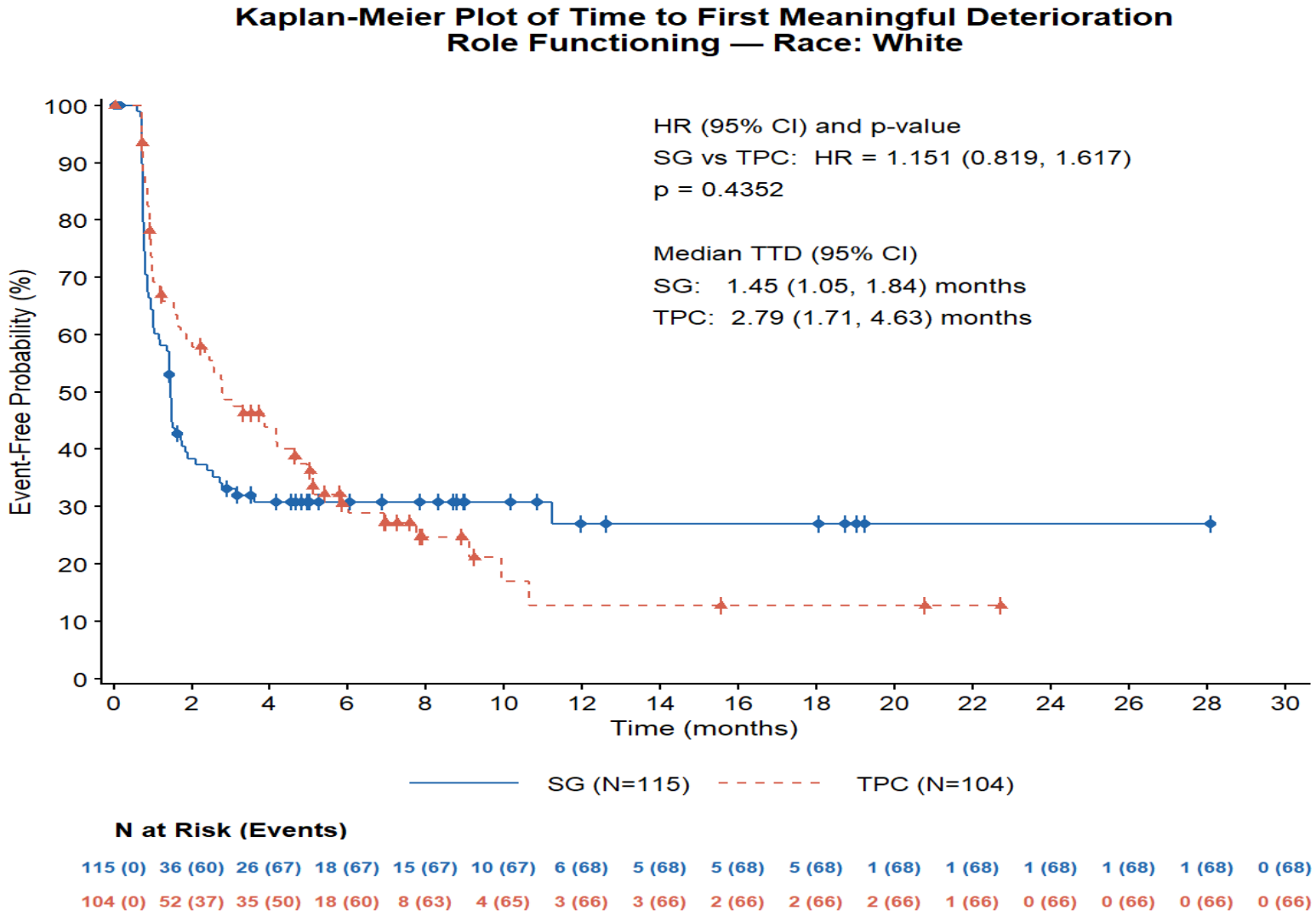
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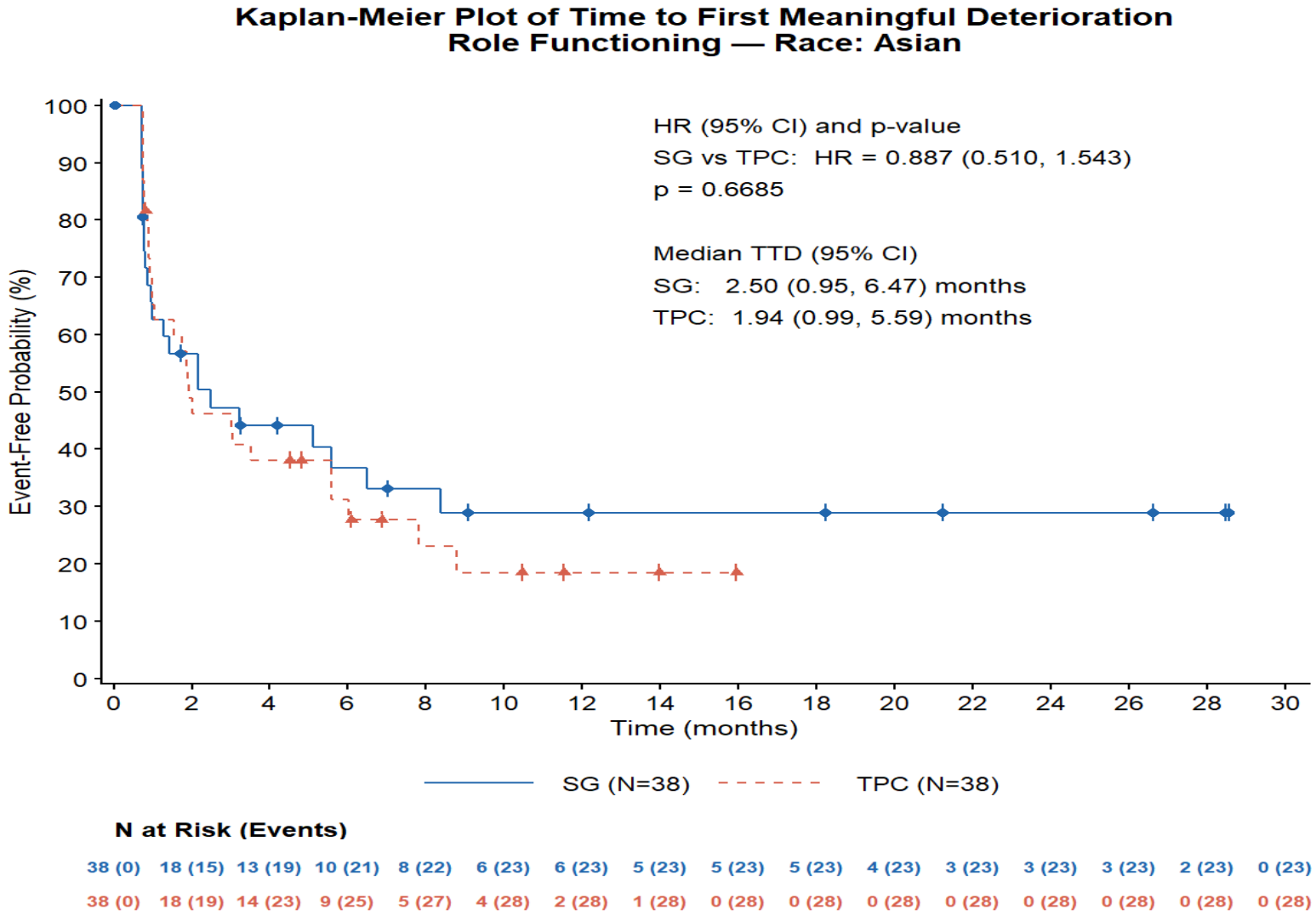
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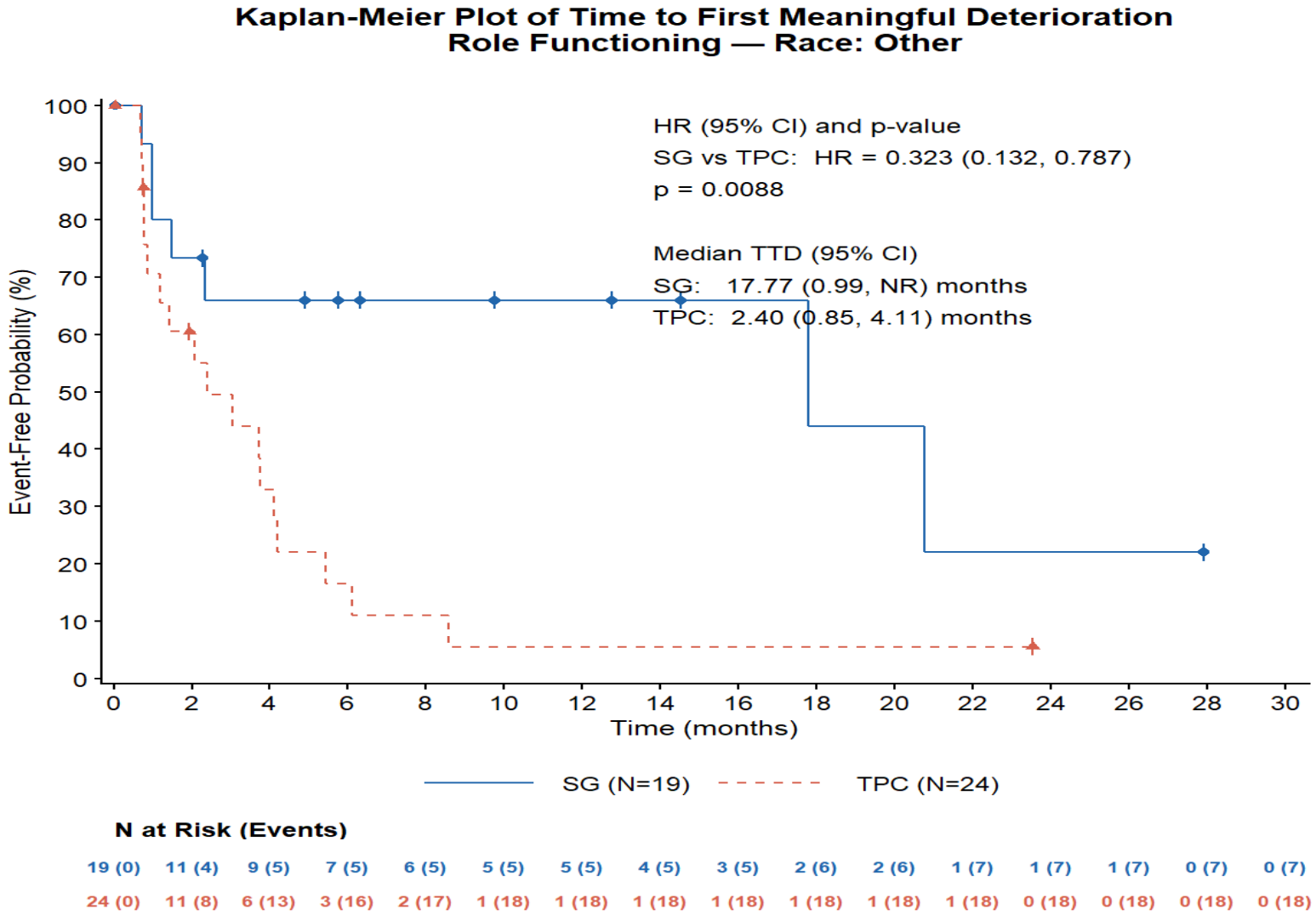
5.51. Figure 1.1.1: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Role Functioning Race White — mITT — Excluding patients preselected to receive nab-paclitaxel



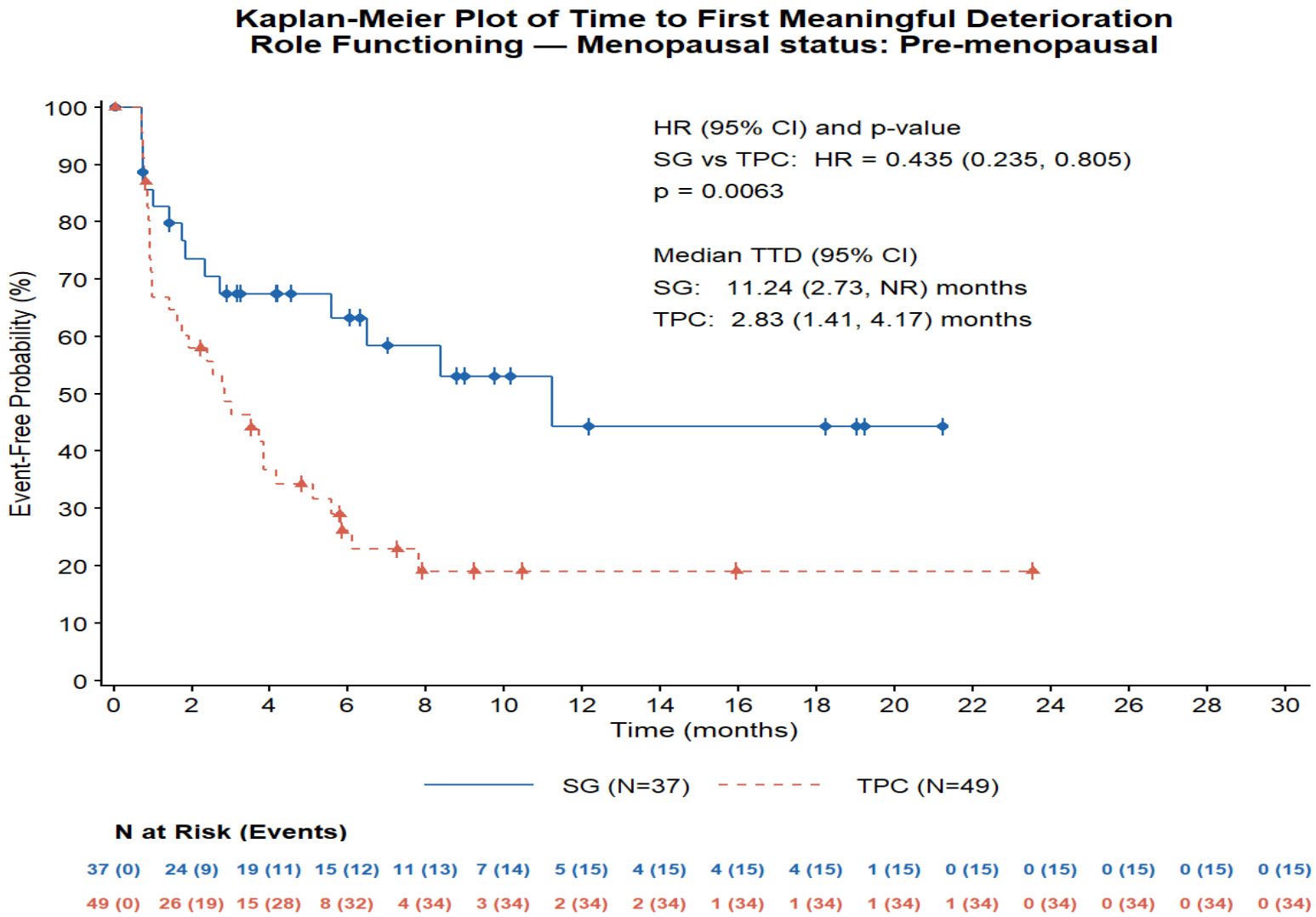
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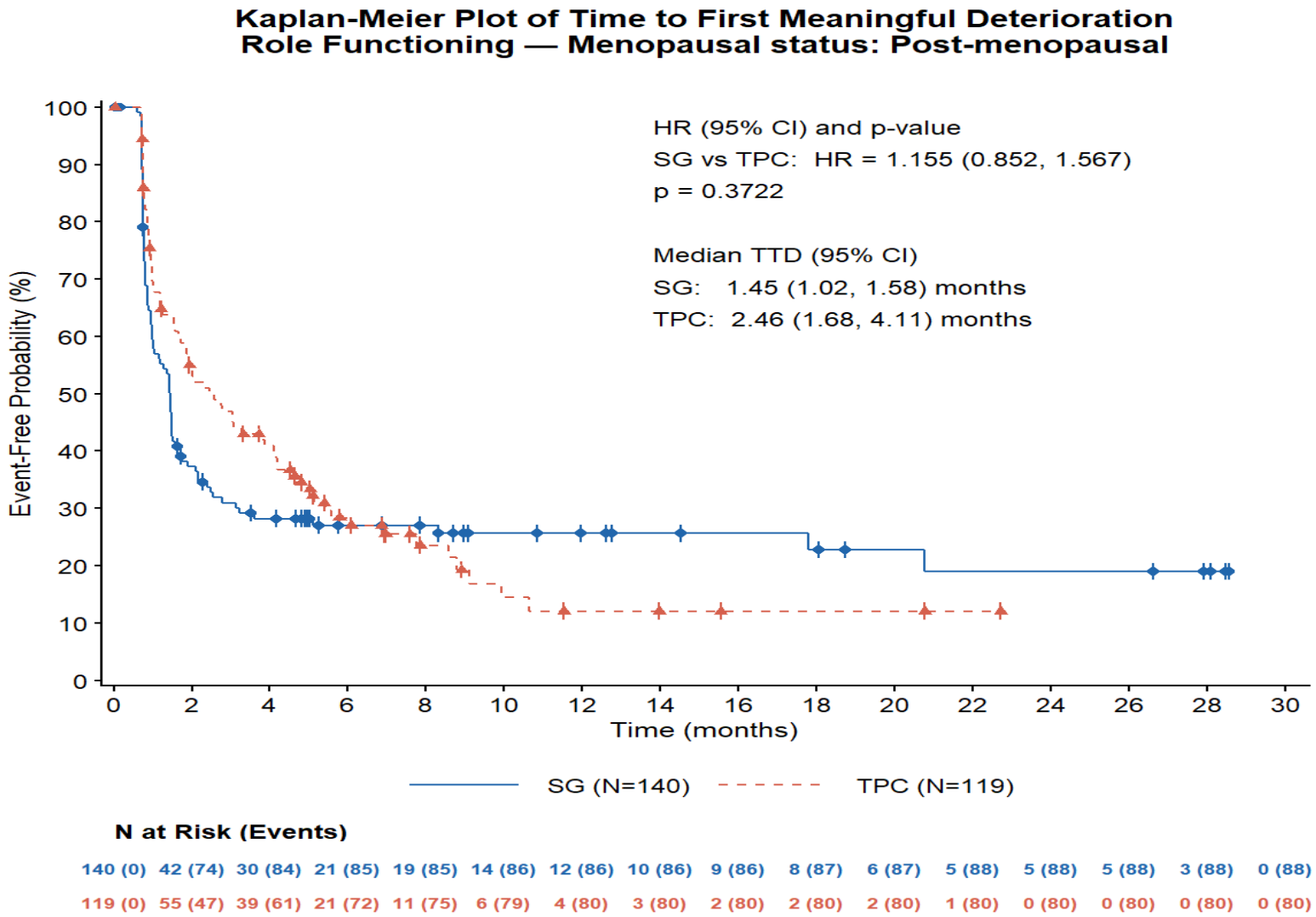
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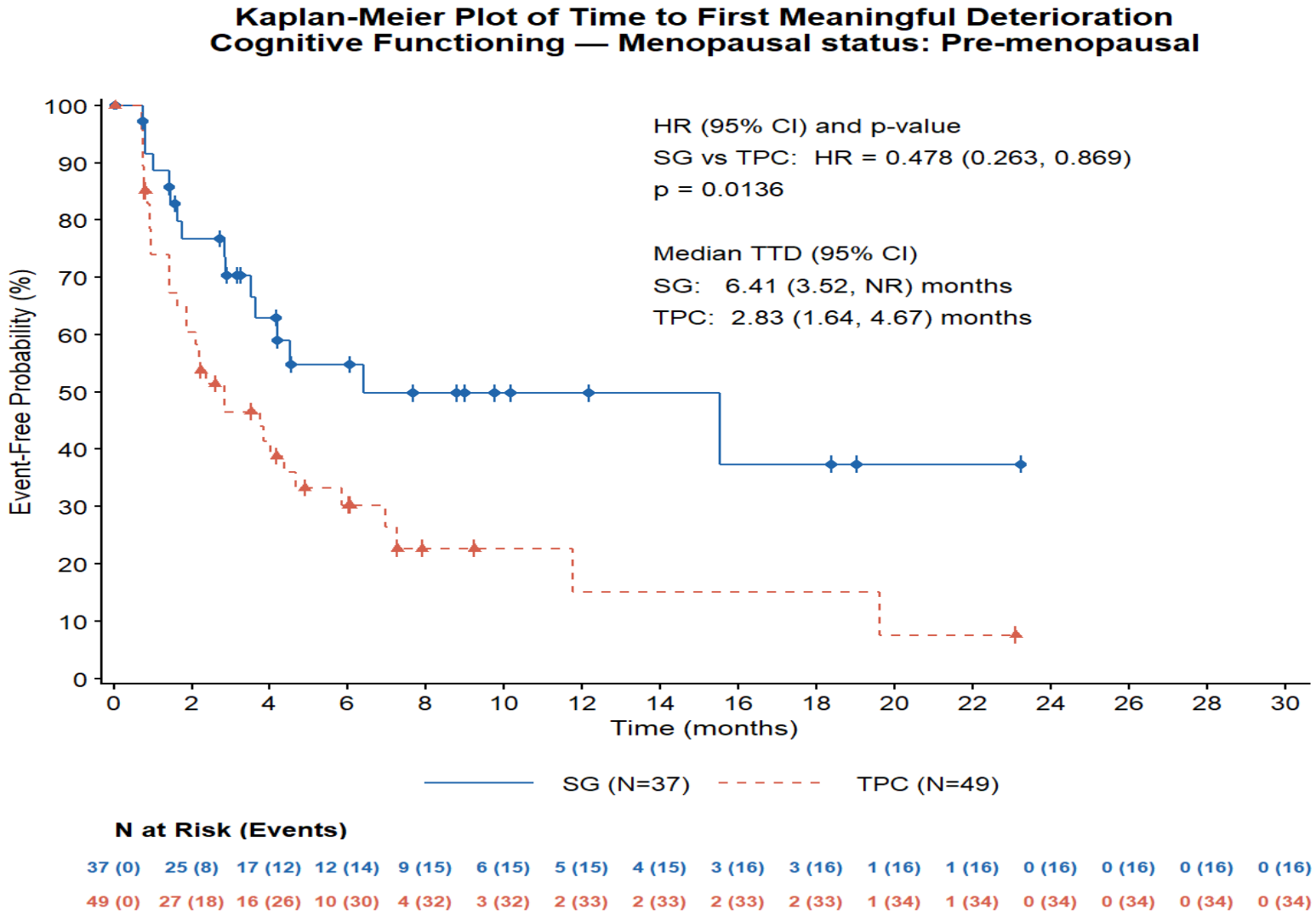
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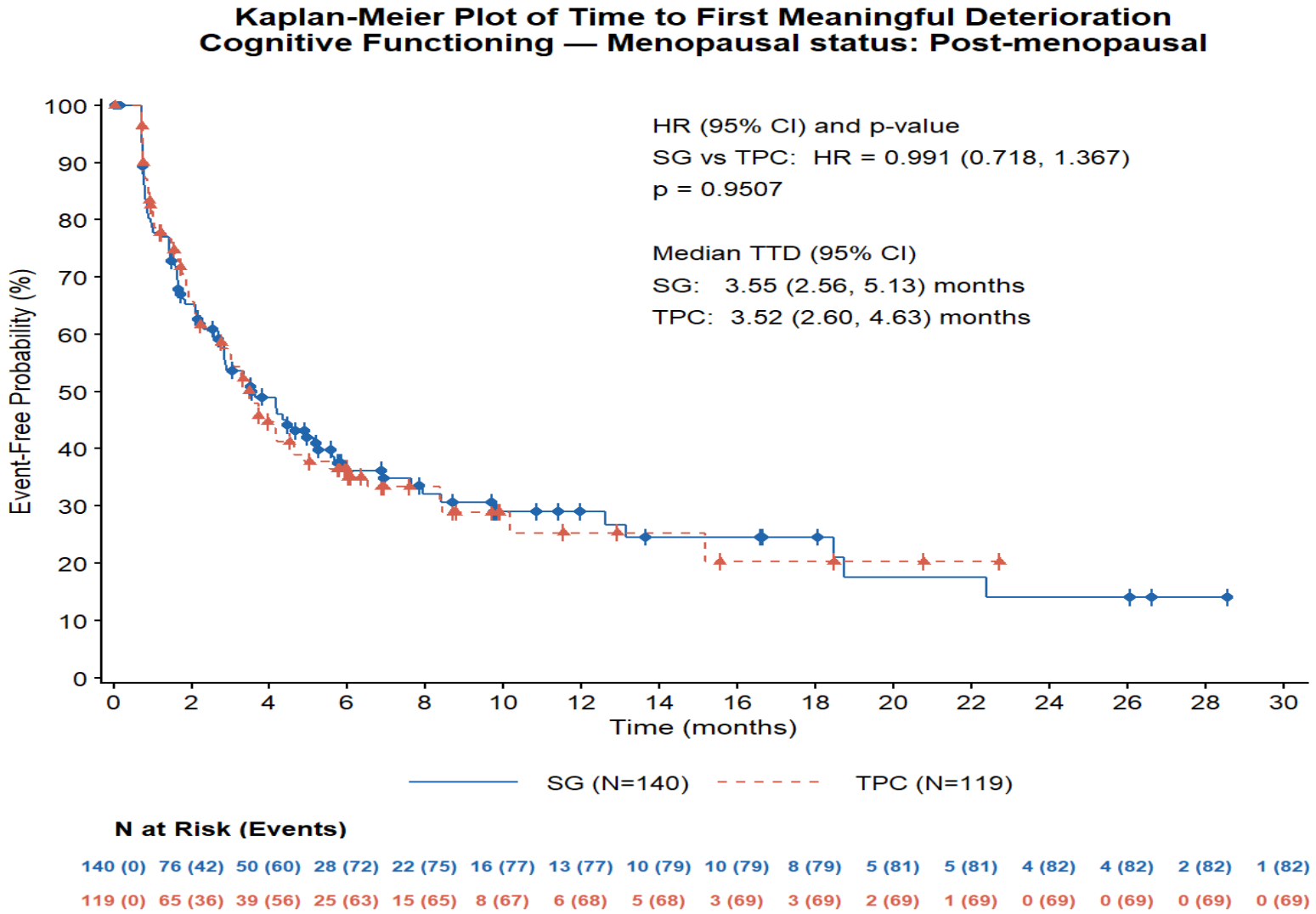
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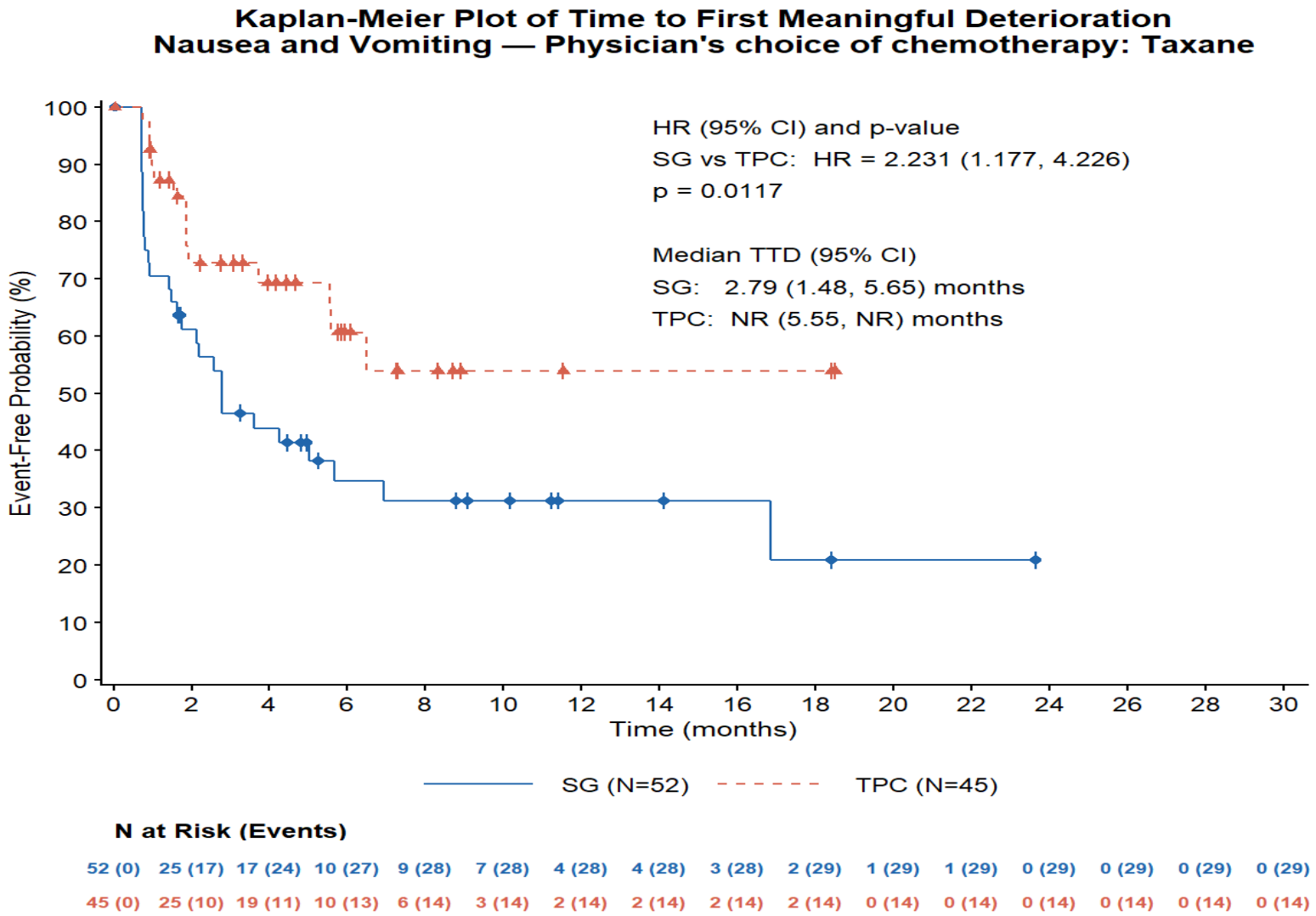
5.56. Figure 1.1.6: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Cognitive Functioning Menopausal status Pre menopausal — mITT — Excluding patients preselected to receive nab-paclitaxel



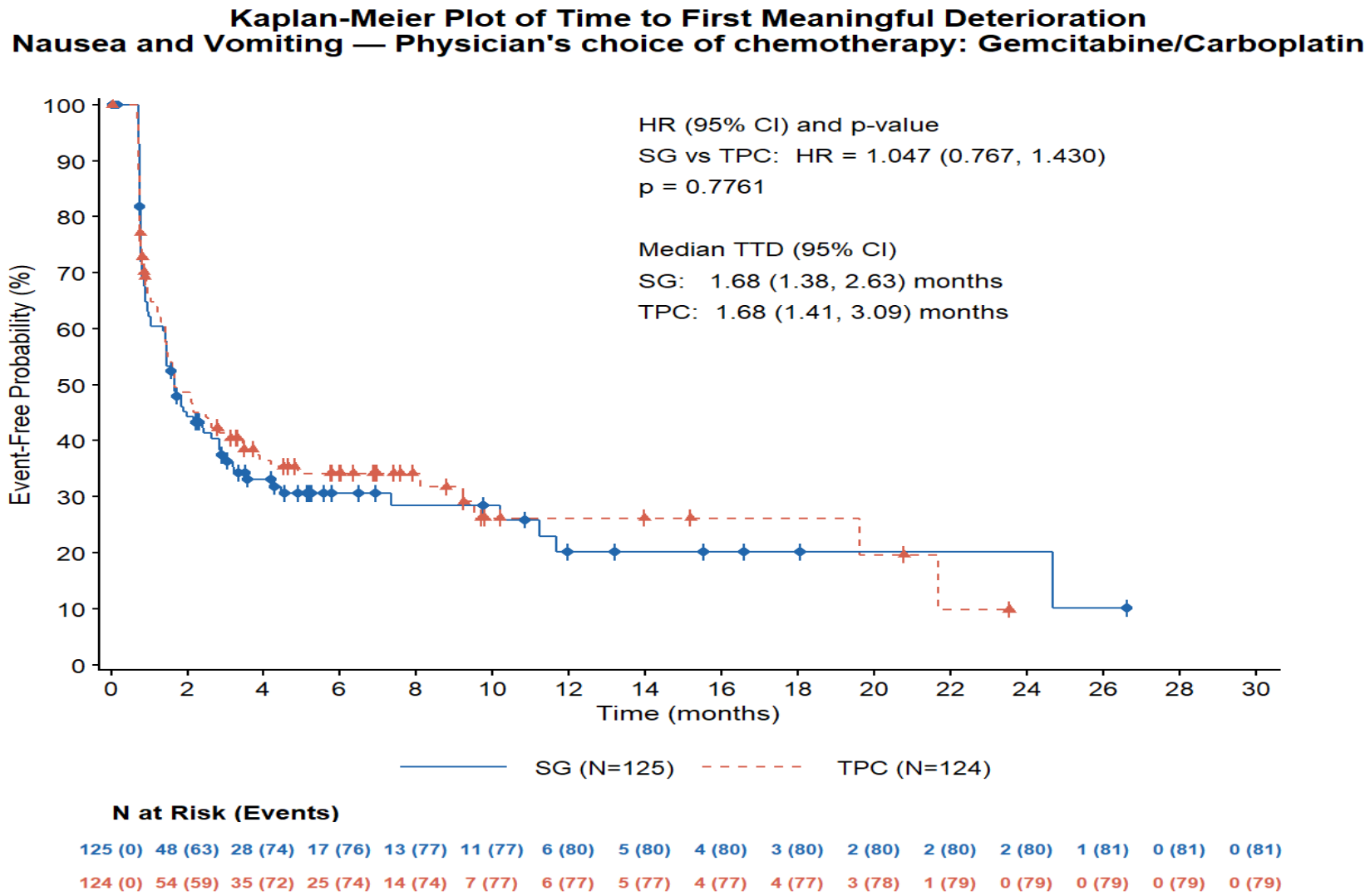
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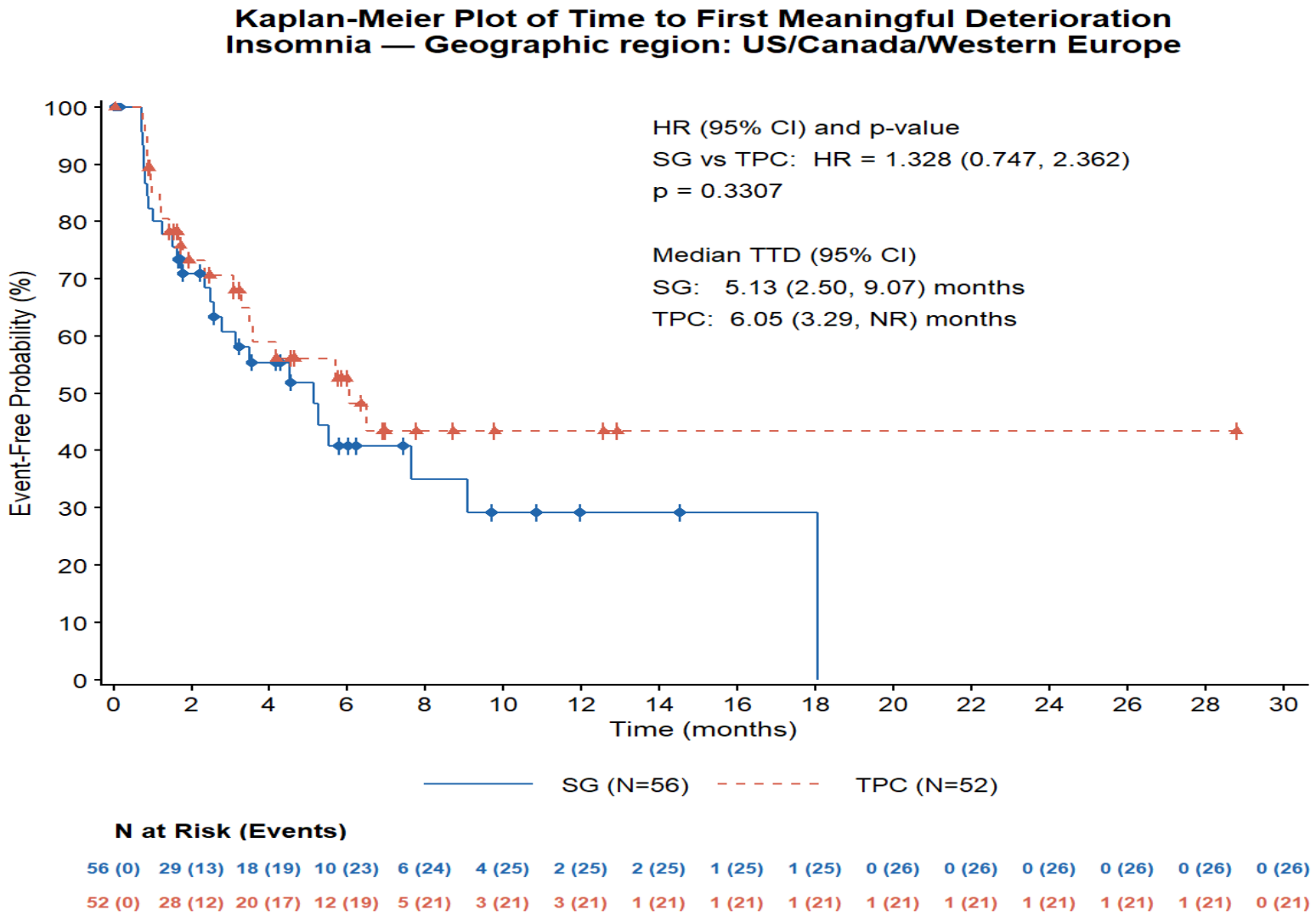
5.58. Figure 1.1.8: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Nausea and Vomiting Physician s choice of chemotherapy Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



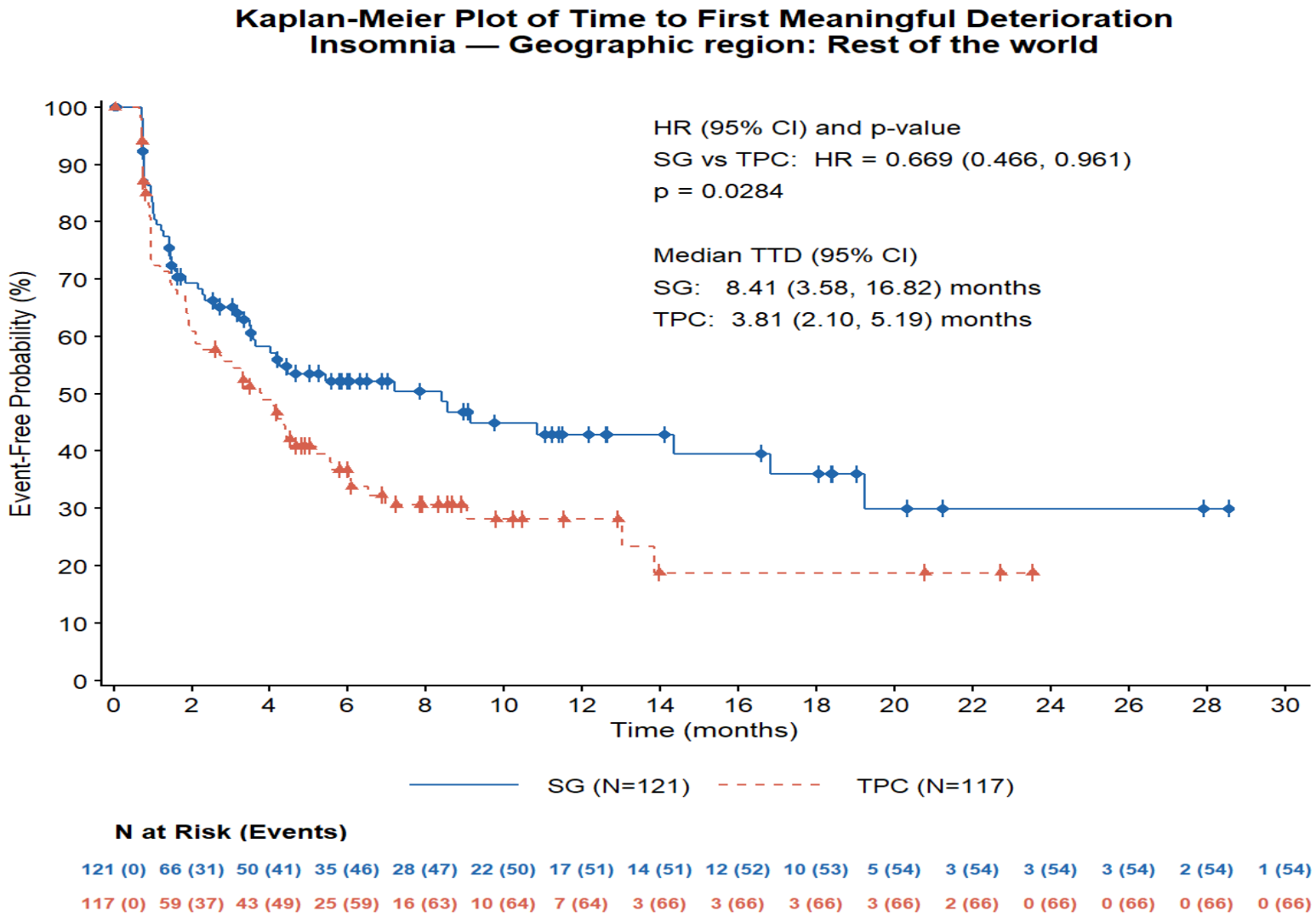
5.59. Figure 1.1.9: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Nausea and Vomiting Physician s choice of chemotherapy Gemcitabine Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



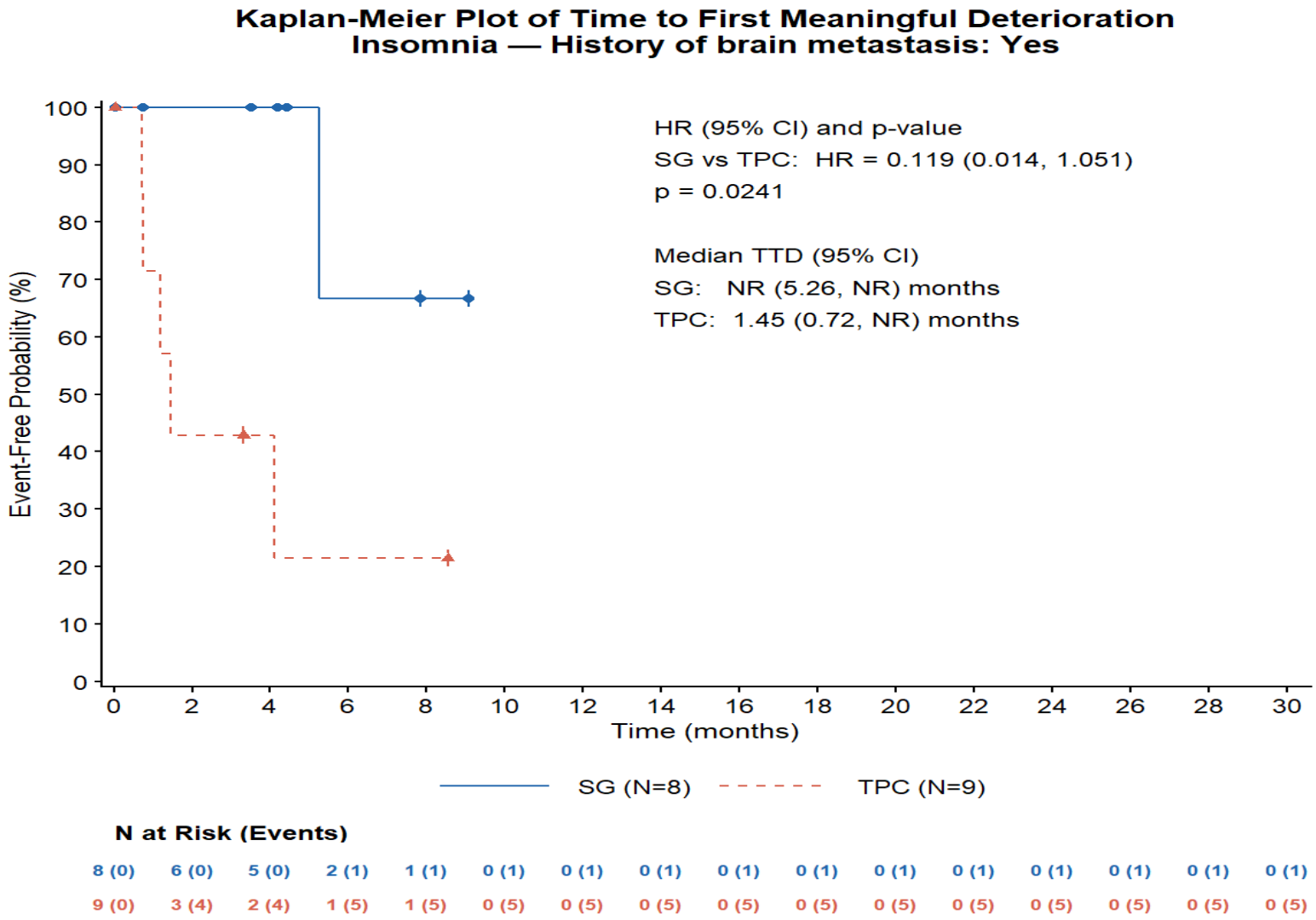
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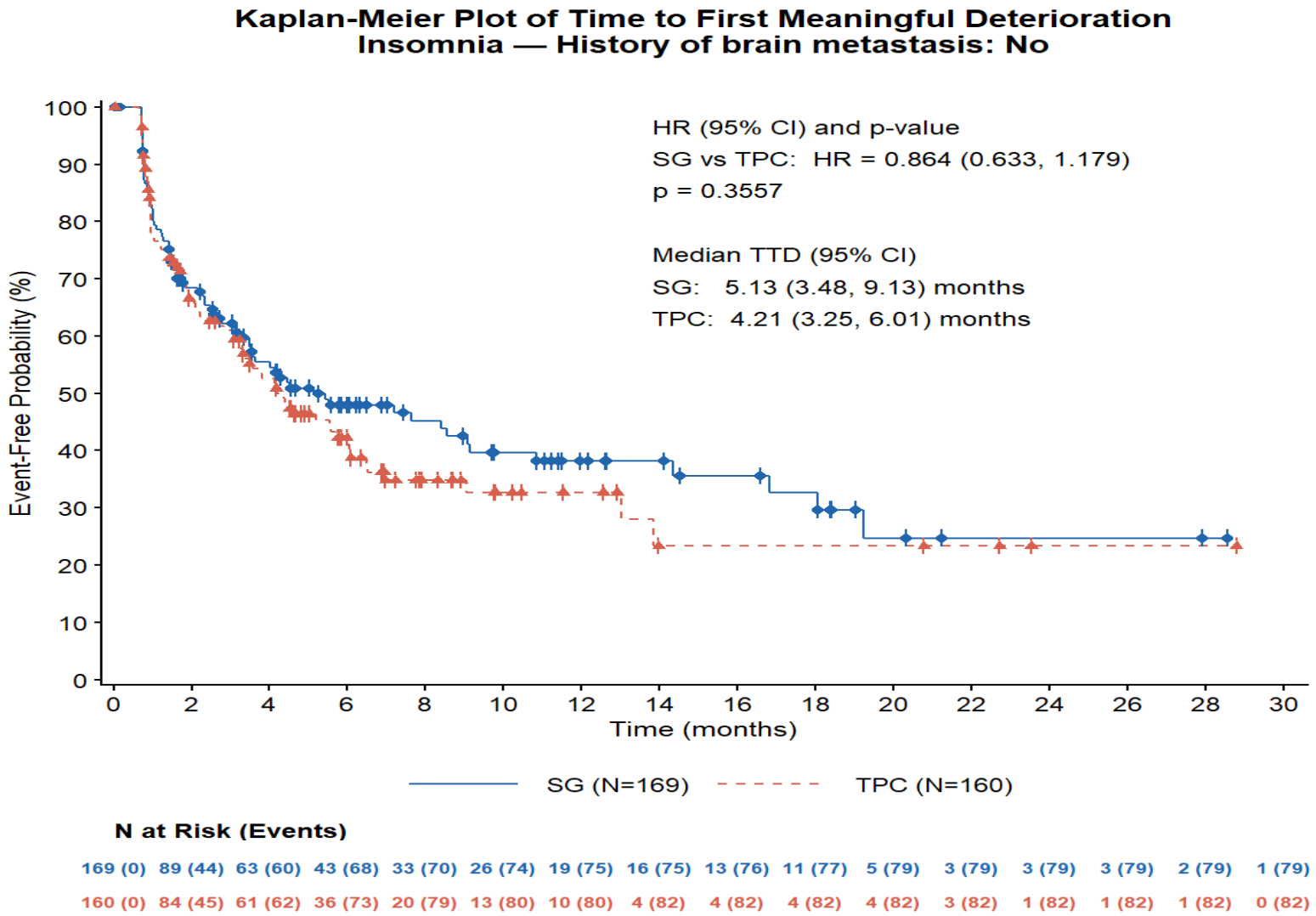
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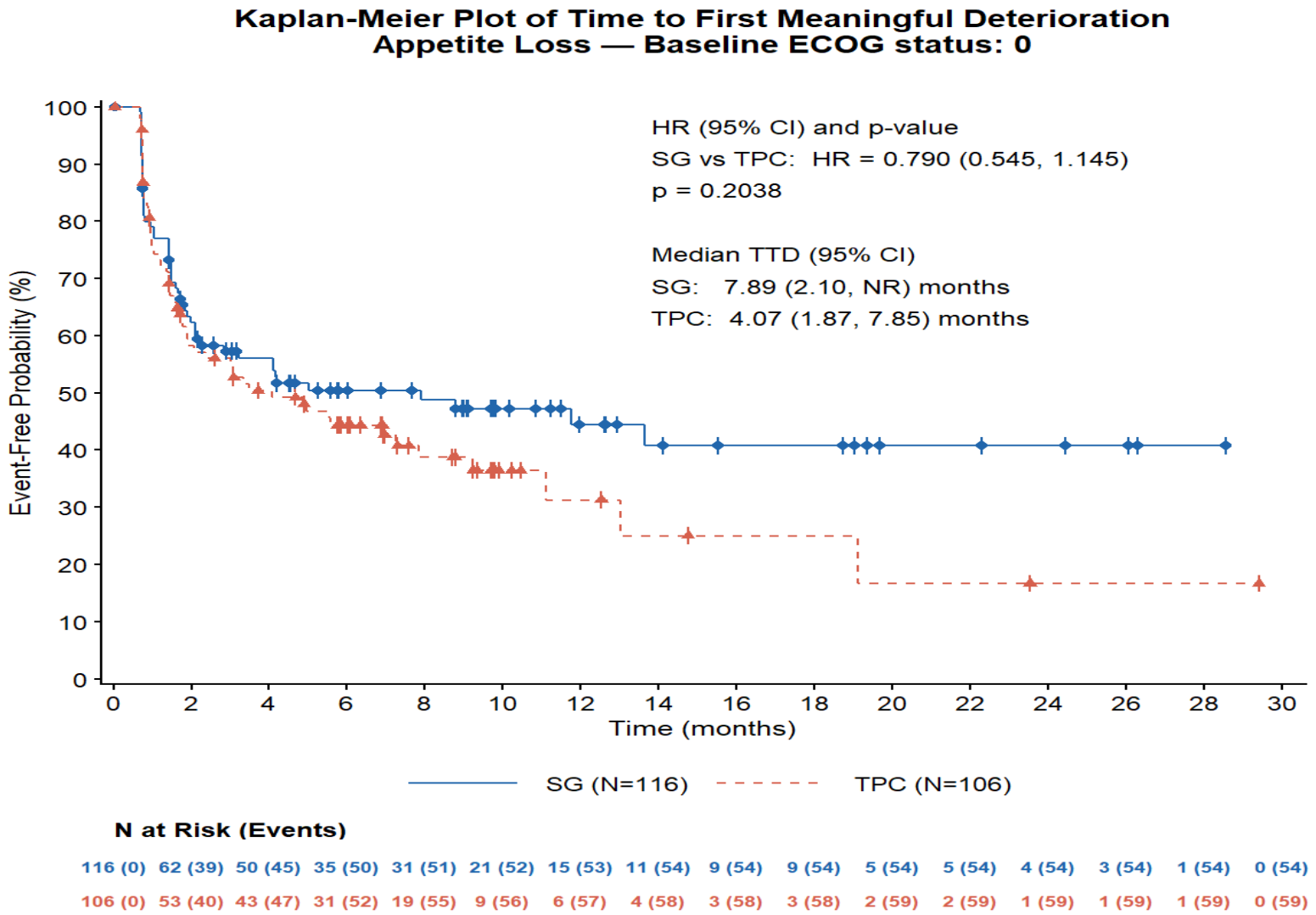
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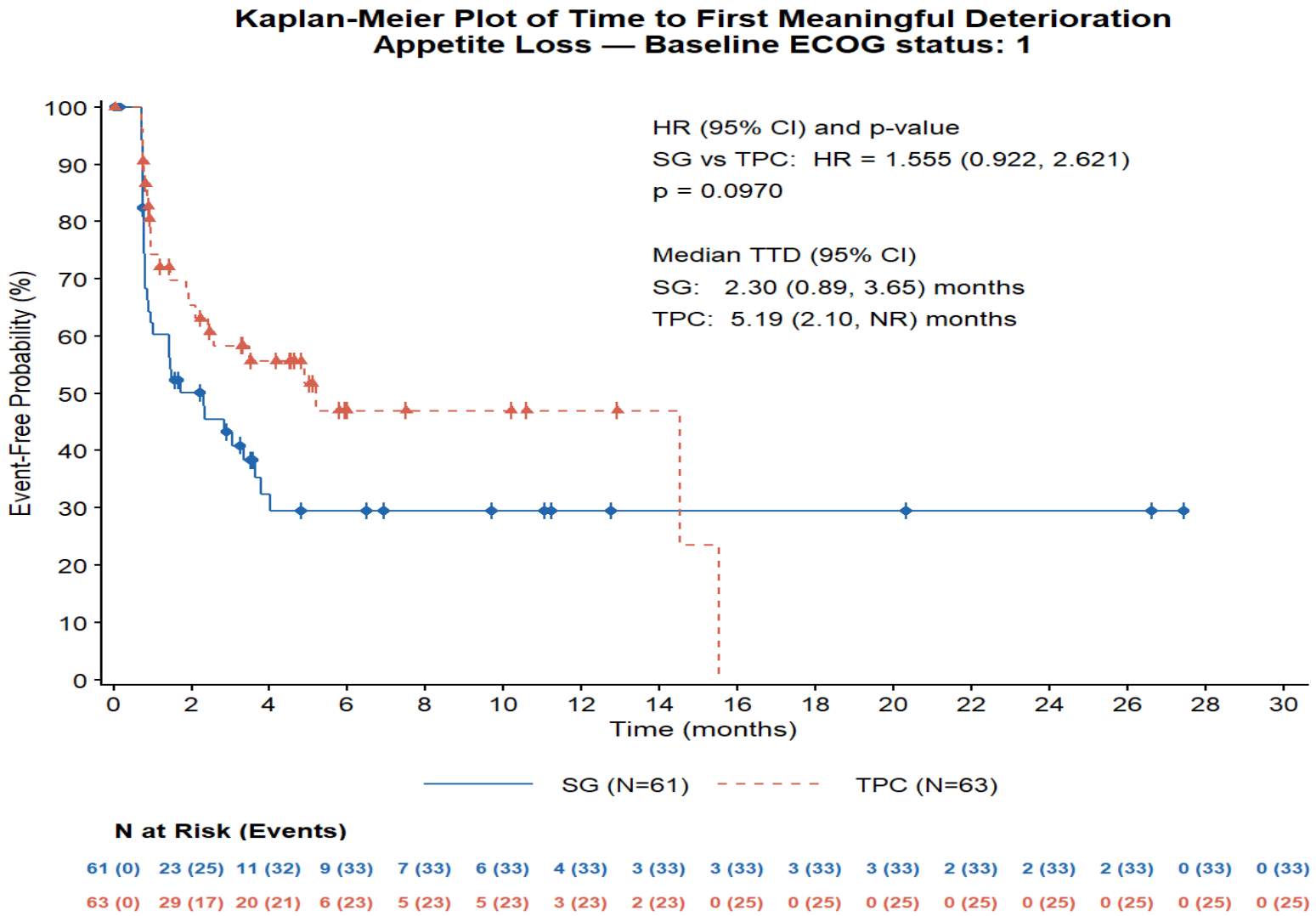
5.63. Figure 1.1.13: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Insomnia History of brain metastasis No — mITT — Excluding patients preselected to receive nab-paclitaxel



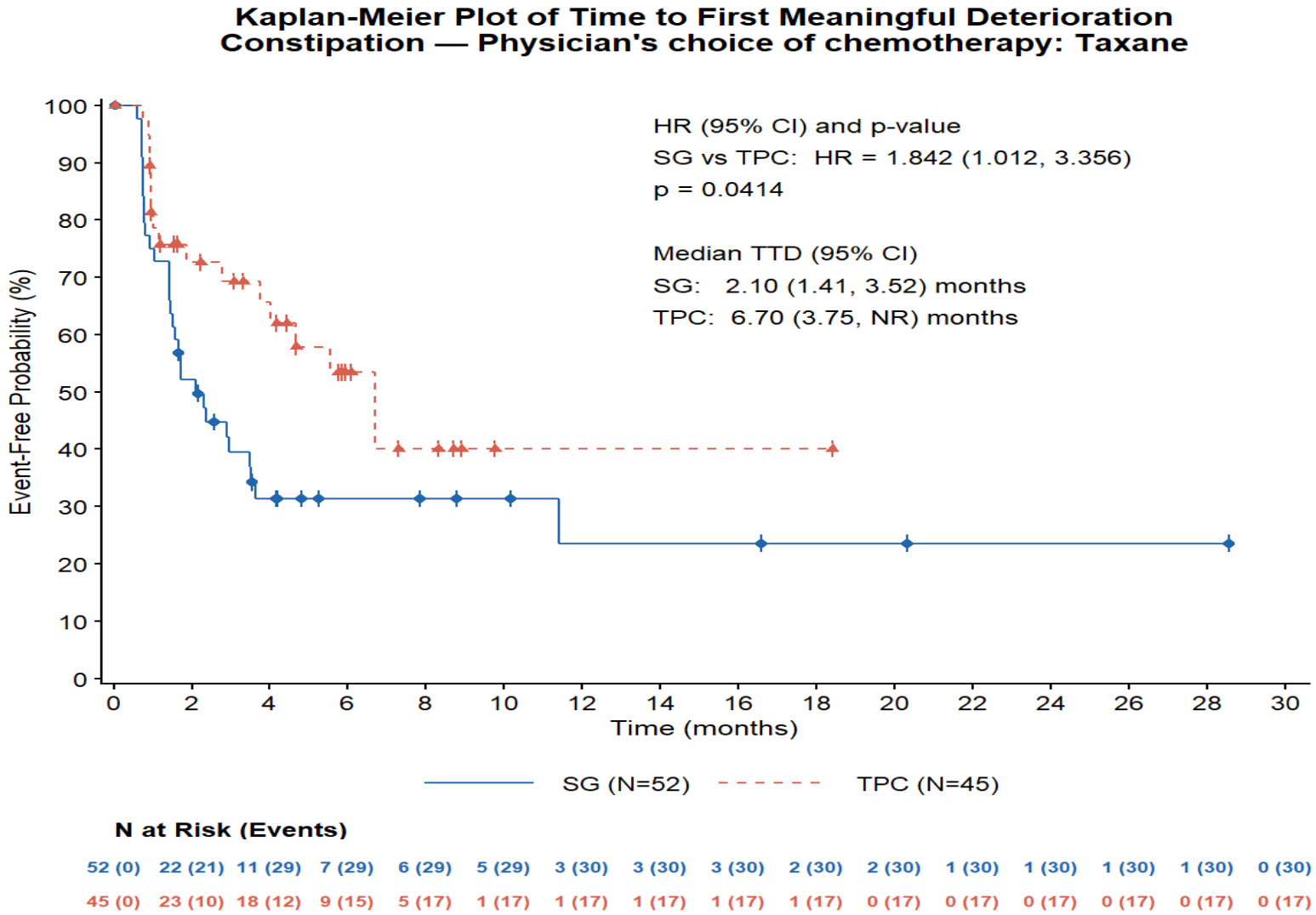
5.64. Figure 1.1.14: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Appetite Loss Baseline ECOG status 0 — mITT — Excluding patients preselected to receive nab-paclitaxel



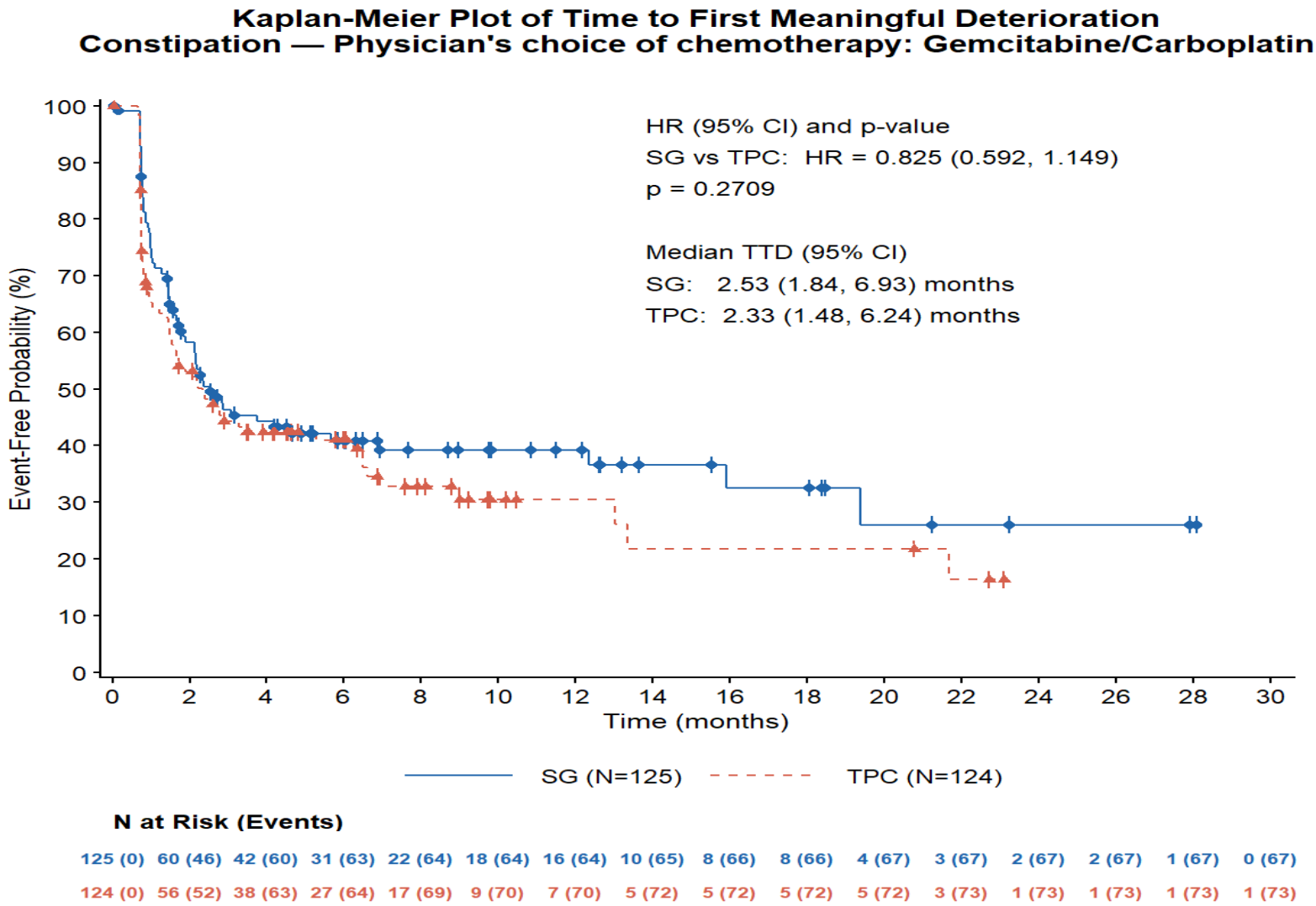
5.65. Figure 1.1.15: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Appetite Loss Baseline ECOG status 1 — mITT — Excluding patients preselected to receive nab-paclitaxel



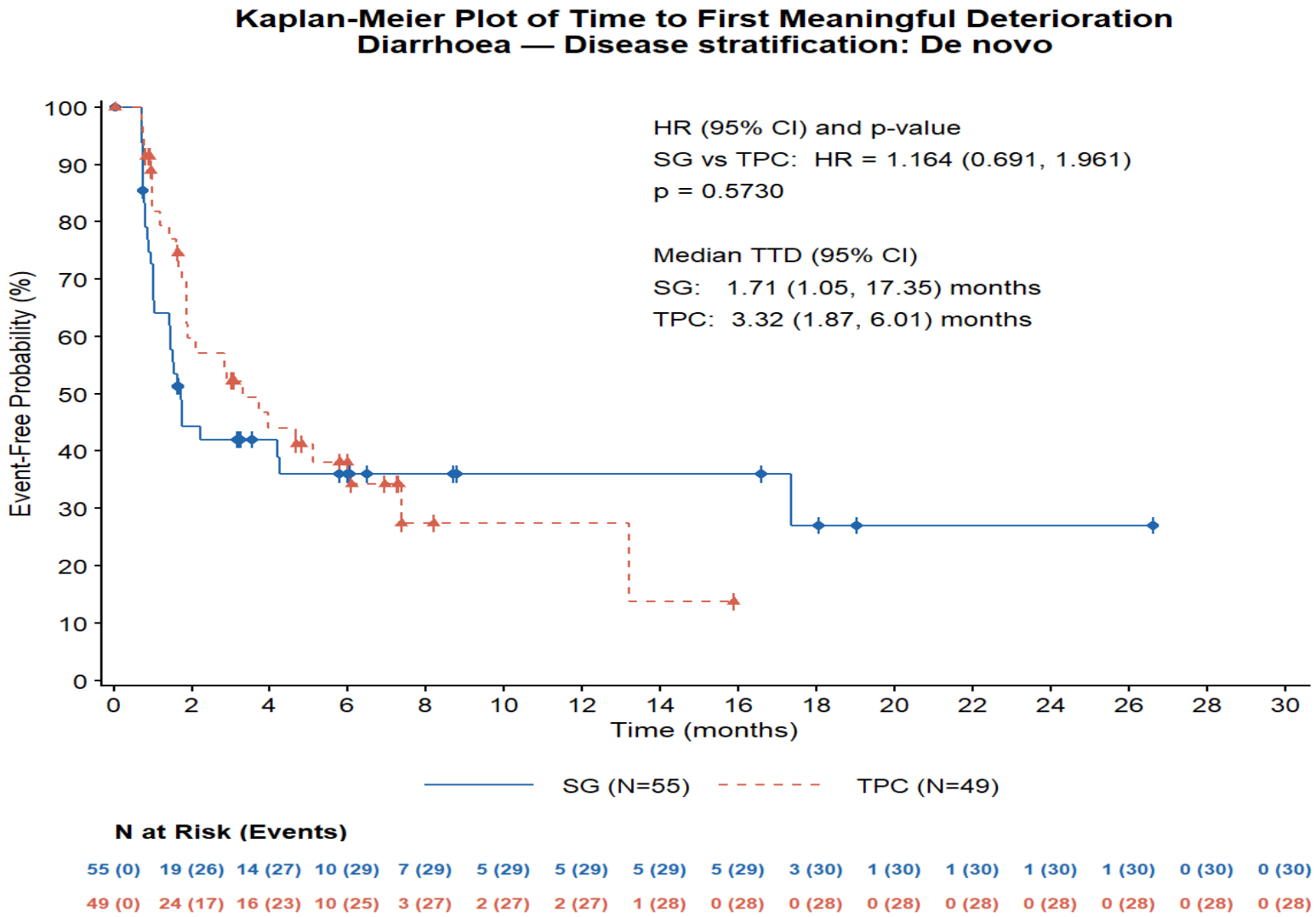
5.66. Figure 1.1.16: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Constipation Physician's choice of chemotherapy Taxane — mITT — Excluding patients preselected to receive nab-paclitaxel



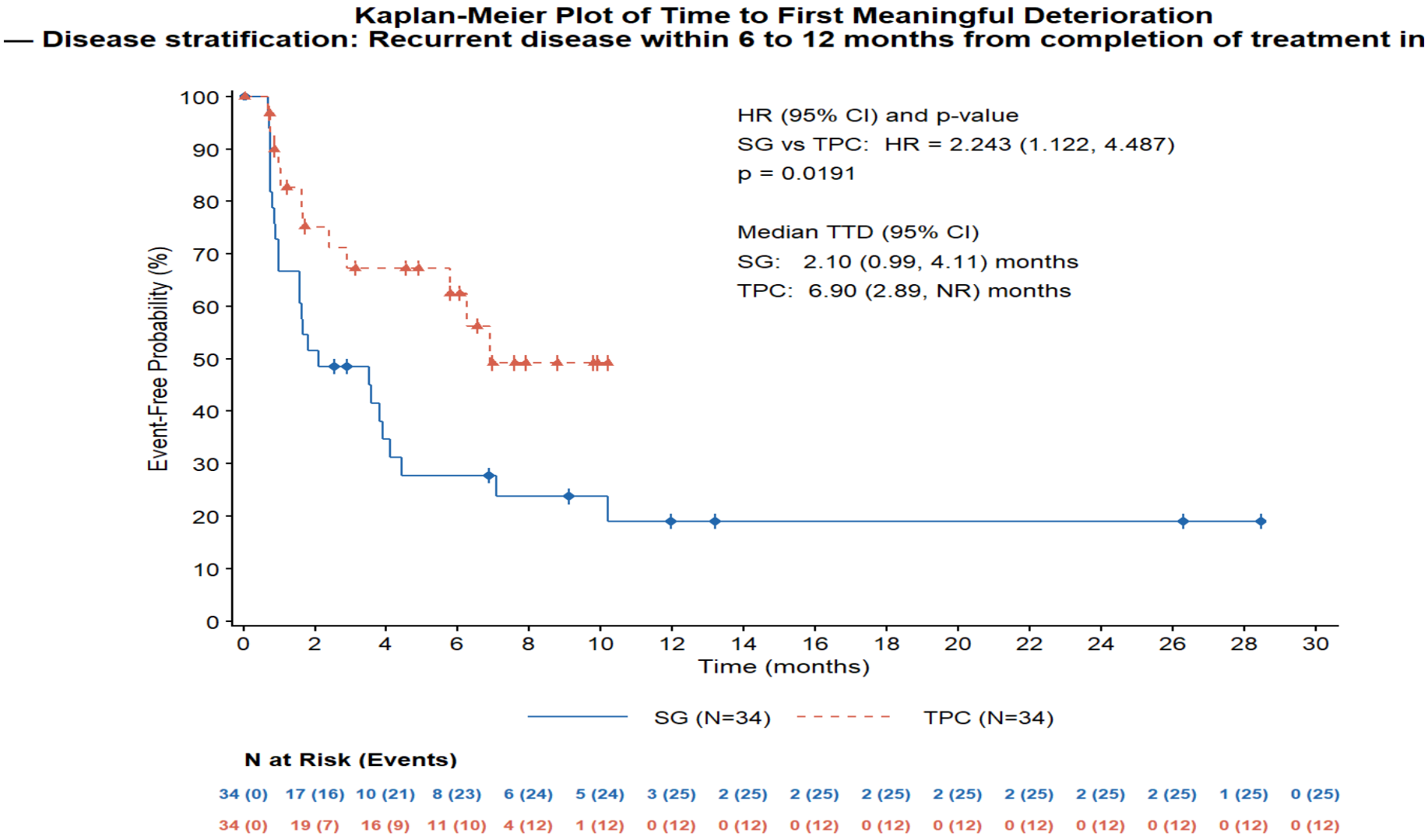
5.67. Figure 1.1.17: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Constipation Physician's choice of chemotherapy Gemcitabine Carboplatin — mITT — Excluding patients preselected to receive nab-paclitaxel



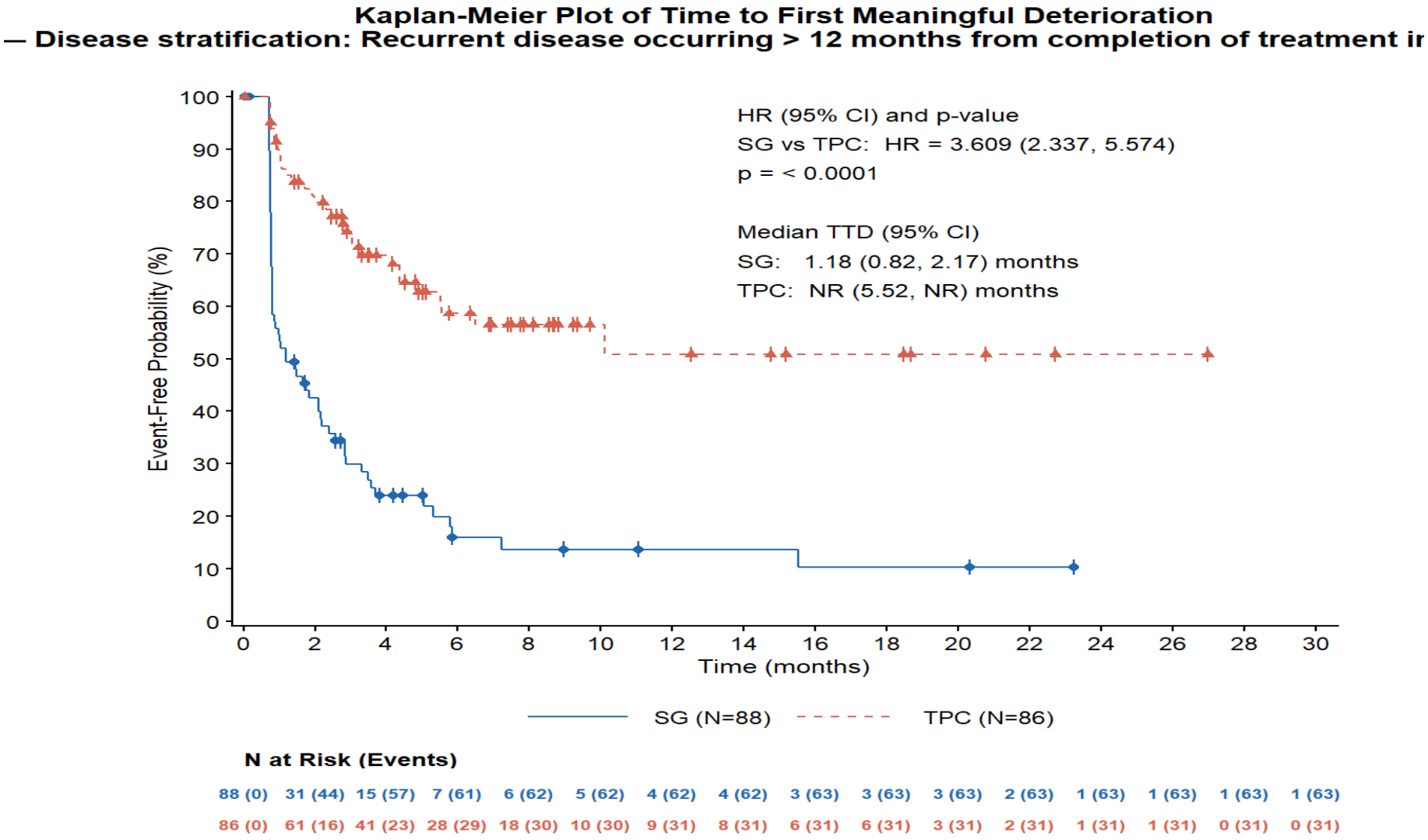
5.68. Figure 1.1.18: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Diarrhoea Disease stratification De novo — mITT — Excluding patients preselected to receive nab-paclitaxel



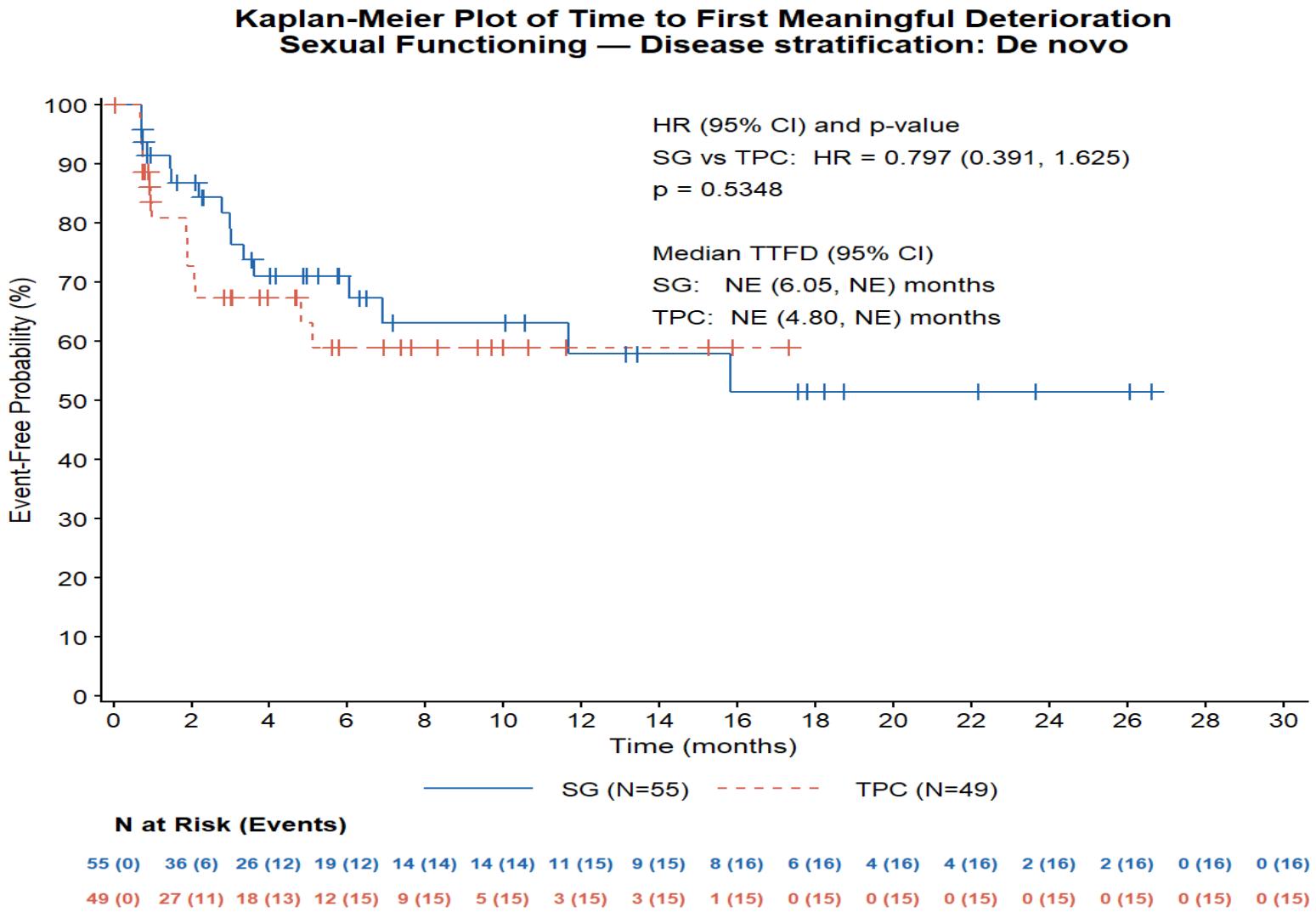
5.69. Figure 1.1.19: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Diarrhoea Disease stratification Recurrent disease within 6 to 12 months from completion of treatment in the curative setting — mITT — Excluding patients preselected to receive nab-paclitaxel



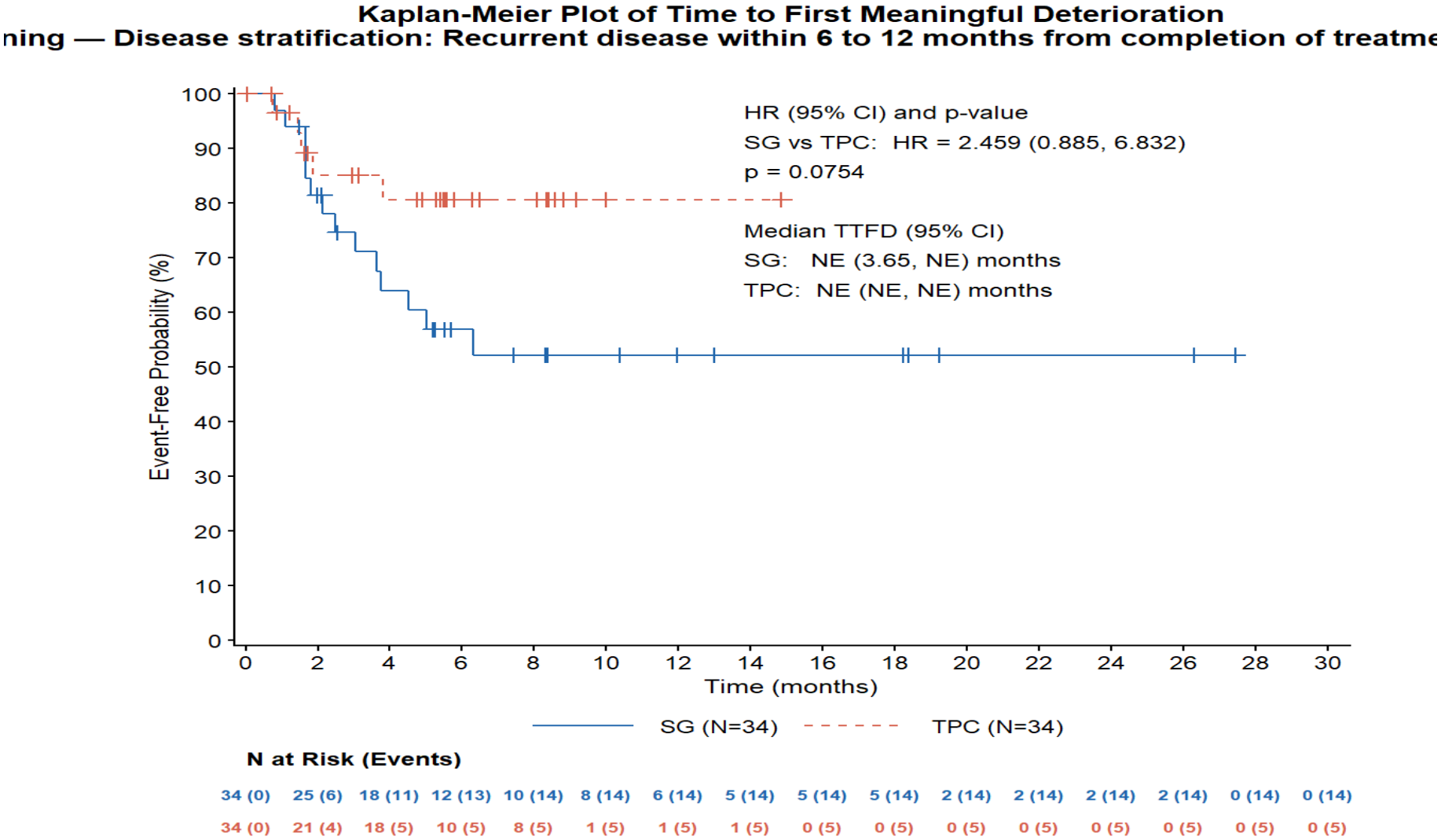
5.70. Figure 1.1.20: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION Diarrhoea Disease stratification Recurrent disease occurring 12 months from completion of treatment in the curative setting — mITT — Excluding patients preselected to receive nab-paclitaxel



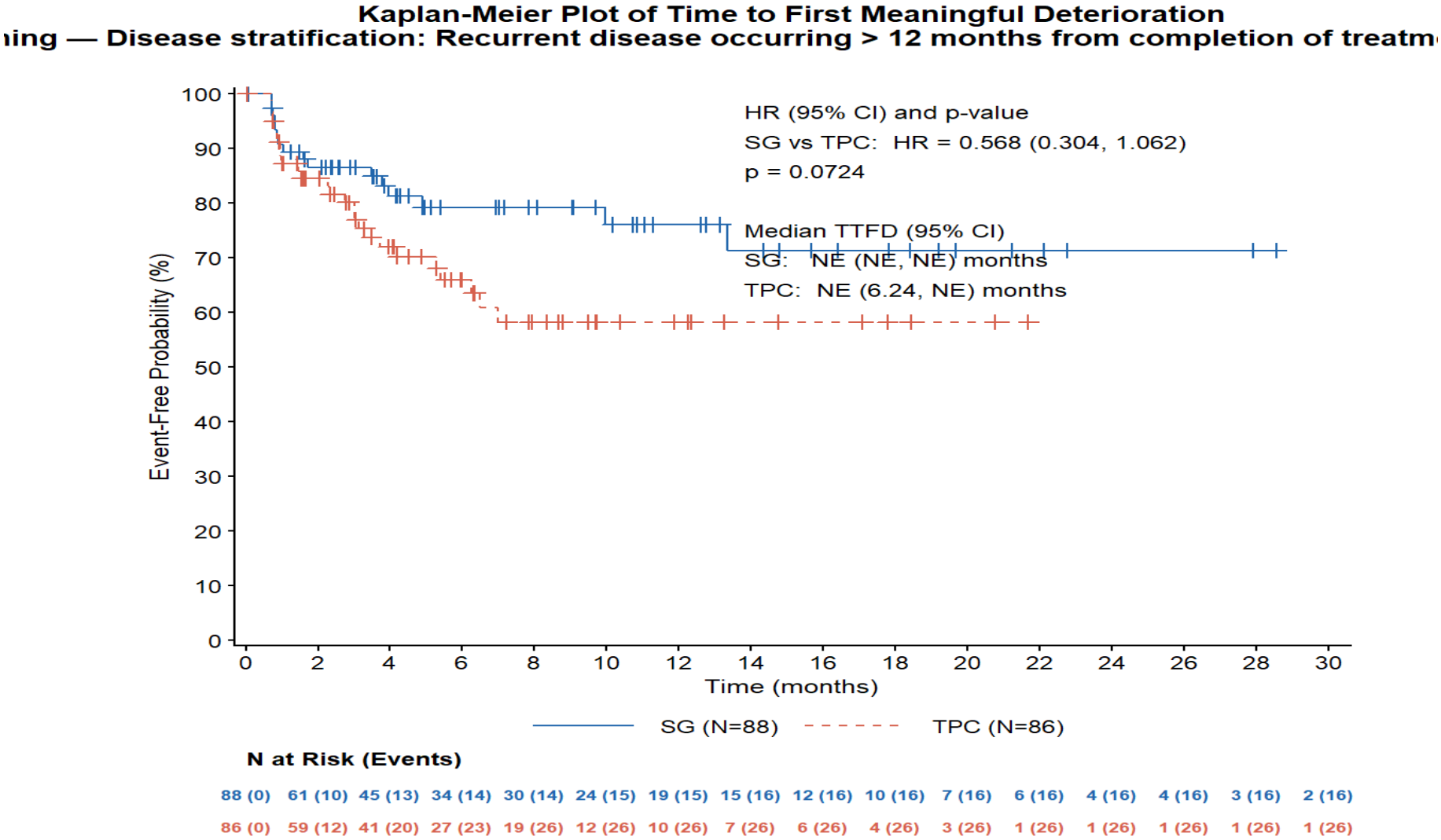
5.71. Figure 1.1.21: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION SEXUAL FUNCTIONING Disease stratification De novo — mITT — Excluding patients preselected to receive nab-paclitaxel



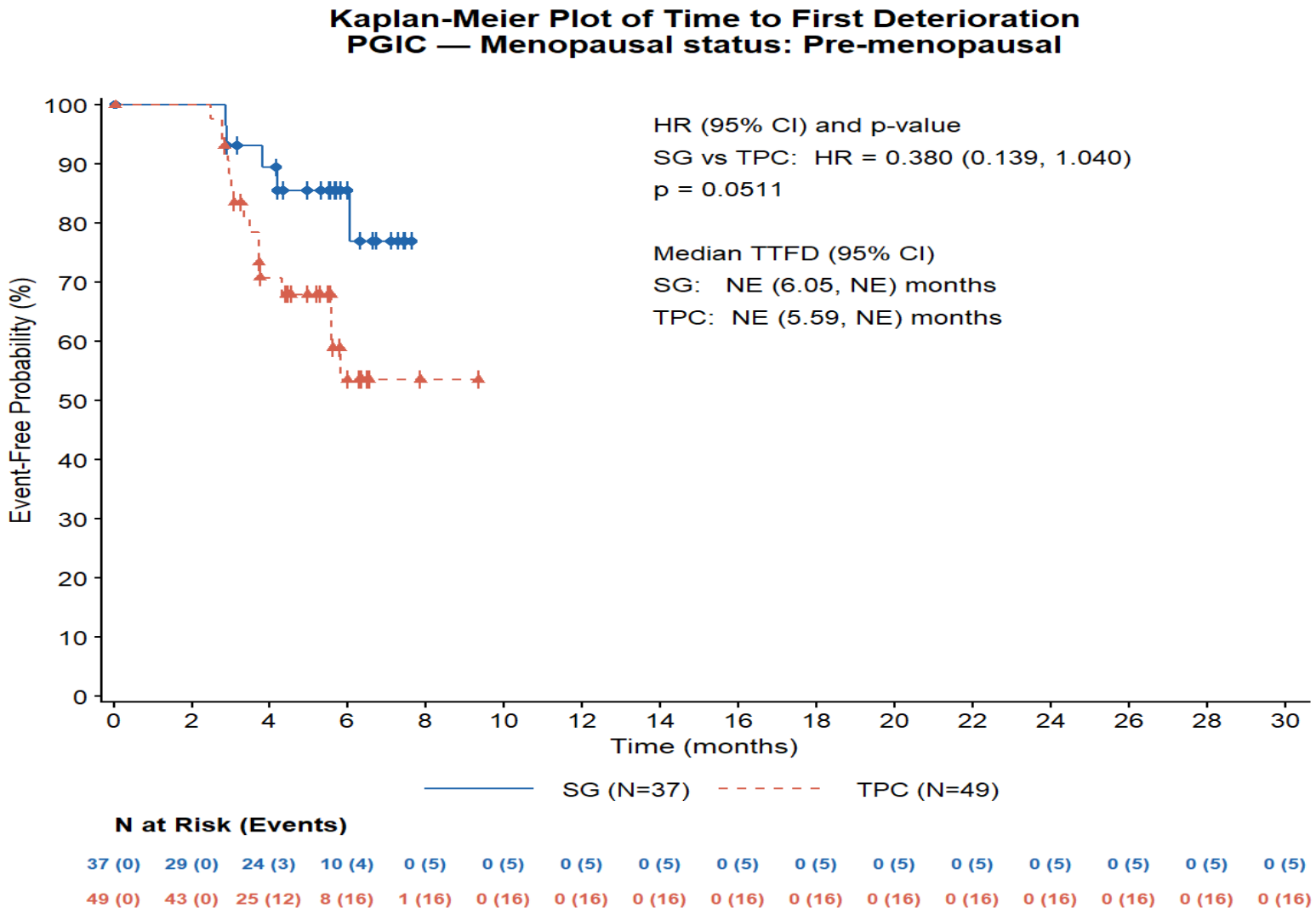
5.72. Figure 1.1.22: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION SEXUAL FUNCTIONING Disease stratification Recurrent disease within 6 to 12 months from completion of treatment in the curative setting — mITT — Excluding patients preselected to receive nab-paclitaxel



5.73. Figure 1.1.23: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION SEXUAL FUNCTIONING Disease stratification Recurrent disease occurring 12 months from completion of treatment in the curative setting — mITT — Excluding patients preselected to receive nab-paclitaxel



5.74. Figure 1.1.32: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION PGIC menon Pre menopausal — mITT — Excluding patients preselected to receive nab-paclitaxel



5.75. Figure 1.1.33: KAPLAN-MEIER PLOT OF TIME TO FIRST MEANINGFULL DETERIORATION PGIC menon Post menopausal — mITT — Excluding patients preselected to receive nab-paclitaxel

